Summer 2006
Volume 21, Number 3

ASAM News

Newsletter of The American Society of Addiction Medicine

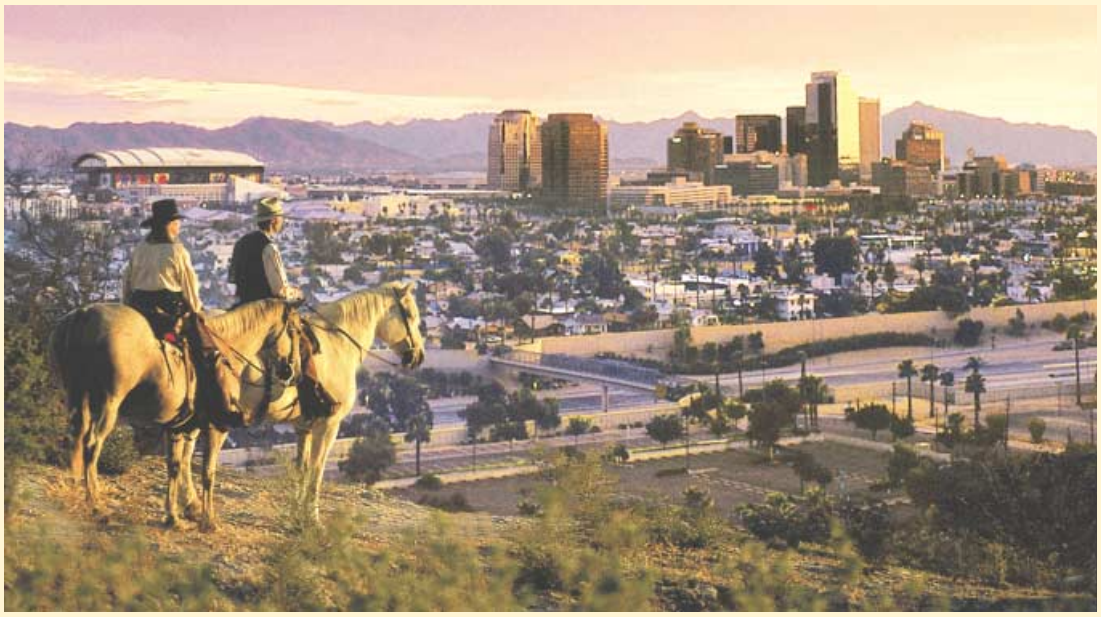
Inside

ASAM at Work for You:

Other News:

ASAM wants your opinion about future CME programs: Be sure to complete and return the Needs Assessment Survey, enclosed with this issue.

www.asam.org



New MRO Training Courses to Meet in Arizona and Washington, DC

For the first time, the ASAM's 2006 Medical Review Officer training will be offered in two different formats. A comprehensive course will be offered in at the Ritz Carlton Phoenix (Arizona) Hotel, July 21st-23rd. In addition, a new Level II training course will be offered December 8th-10th at the Marriott Metro Center Hotel in Washington, DC. The Level II MRO Training Course will go beyond the federal regulations that govern drug testing programs in transportation industries to address the ever-expanding field of drug testing for multiple purposes in the private sector. The course will be offered in tandem with a shorter and more focused Level I MRO Training Course, which is designed to help prepare registrants for the MROCC Certification Exam.

For additional information or to register for either course, visit the ASAM website at WWW.ASAM.ORG or contact ASAM's Department of Meetings and Conferences at 301/656-3920. *(See page 24 for other upcoming educational offerings.)*

ASAM Launches Online Buprenorphine Training

ASAM has partnered with Clinical Tools, Inc., to launch a new Internet-based buprenorphine training program. The online program fulfills the requirements of the Drug Addiction Treatment Act of 2000 (DATA 2000), which requires that physicians complete 8 hours of approved training and meet certain other requirements in order to obtain a waiver to prescribe buprenorphine in office-based treatment of opioid addiction. Since 2002, when the FDA approved buprenorphine for the treatment of opioid addiction, more than 7,000 U.S. physicians have obtained such waivers. Nevertheless, the demand for addiction care is such that federal authorities are asking more physicians to become qualified to use buprenorphine in office settings.

The new online training program helps to meet that need because it is available on the Internet 24 hours a day, 7 days a week. Physicians can complete the program all at once or over multiple sessions, as their individual schedules allow. The program is "browser-based," so no special software is required. Moreover, the $150 fee for the online course is much less than the typical cost of attending a face-to-face training program.

ASAM is one of seven organizations identified in DATA 2000 as eligible to offer buprenorphine training, and has been active in offering face-to-face training around the country. ASAM's partner in this venture is a physician-owned multimedia company based in Chapel Hill, North Carolina. Clinical Tools, Inc., combines expertise in health care content and development of computer applications to provide Internet-based education and information to professionals and consumers. The new training program is available on-line at www.BuprenorphineCME.com. For more information about Clinical Tools and its products, visit www.clinicaltools.com.

ASAM'S ANNUAL REPORT

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

Eileen McGrath, J.D.

In ASAM, as in most other organizations, the Executive Vice President regularly reports to the Board of Directors on the Society's accomplishments and progress toward its goals. It is through this regular flow of information that the Directors — and through them, the members — can be assured that the Society is moving in the right direction and is focused on the members' interests and needs.

As in the past, I am expanding on that tradition by providing the following summary of our accomplishments directly to you, our members. I invite you to review this report and to share with me or any of our officers your thoughts and suggestions. As always, I look forward to hearing from you!

PROGRAM DEVELOPMENT

- ASAM continues to offer buprenorphine training courses, and recently collaborated with the following organizations to offer trainings: Department of Veterans Affairs (4 trainings), American Association for the Treatment of Opioid Dependence (1 training), the California Medical Association (3 trainings), and the Caribbean Basin Addiction Technology Transfer Center (75 physicians).
- The Buprenorphine Mentoring Network, which is funded by the Center for Substance Abuse Treatment, currently involves 250 participants and 51 mentors. Mentoring activities include online resources such as a website, Clinical Guidances, a "warm line" (which refers 25 individuals per week) and daily exchanges, a 19-member organization steering committee, a one-hour course for primary care practitioners (5 presentations were completed in 2005 and 33 are planned for 2006). Articles to educate the public about the Buprenorphine Mentoring project have been published in *USA Today*, *American Medical News*, *AAFP News*, *SGIM News*, *ASAM News*, and the newsletters of 14 state medical societies.
- A series of 20 CME courses on the treatment of alcohol dependence has trained 261 physicians and 155 non-physician health professionals.
- ASAM collaborated with Clinical Tools to produce an CD-Rom buprenorphine training course.
- A CME course on "Advances in Pharmacotherapies for Alcohol Dependence" was offered at the 2006 Med.Sci. Conference.
- SAMHSA provided ASAM with a grant to integrate recovery support services into the *ASAM Patient Placement Criteria.*

PUBLICATIONS

- *Revenues:* ASAM derived $649,551 in gross revenues from its publications (excluding the Journal) in 2005. This figure includes $300,000 in grants received to support the *PPC Supplement*.
- *Principles of Addiction Medicine:* The first printing of 2,500 copies of the Third Edition of *Principles* (published in October 2003) sold out in October 2004. A second printing of 2,500 copies was completed in the same month. Sales of *Principles* in 2005 yielded gross revenues of $108,070 and estimated net revenues of $88,000.
- *ASAM Patient Placement Criteria*: 2005 sales of the *ASAM PPC-2R* outpaced projections, yielding gross revenues of $156,825 and net revenues of $127,000. (Unlike *Principles*, sales of the *PPC-2R* are not dependent on marketing campaigns; rather, they are largely driven by states' endorsement or adoption of the ASAM Criteria.)
- *ASAM News*: The newsletter lost one major advertiser in 2005 (Odyssey Pharmaceuticals, maker of Antabuse). However, that advertiser was replaced with advertising from Forest

continued on page 6

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.

Officers
President
Elizabeth F. Howell, M.D., FASAM

Immediate Past President
Lawrence S. Brown, Jr., M.D., M.P.H., FASAM

President-Elect
Michael M. Miller, M.D., FASAM, FAPA

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

Treasurer
Donald J. Kurth, M.D., FASAM

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

ASAM News
is an official publication of the American Society of Addiction Medicine. It is published six times a year. Please direct all inquiries to the Editor at ASAMNEWSLETTER@AOL.COM or phone 410/770-4866.

Chair, Publications Council
Elizabeth F. Howell, M.D., FASAM

Newsletter Review Board
LeClair Bissell, M.D.
Sheila B. Blume, M.D., FASAM
Max A. Schneider, M.D., FASAM

Founding Editor, 1985-1995
Lucy Barry Robe

Editor
Bonnie B. Wilford

Subscriptions
Free to ASAM members; $99 a year (six issues) to nonmembers. To order, phone 1-800/844-8948 or fax 301/206-9789.

Advertising
Advertising rates and schedules are available on request. Please direct inquiries to the Editor at 410/770-4866 or email ASAMNEWSLETTER@AOL.COM.

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

SAMHSA Issues Alert About Dangerous Drug Combination

The Substance Abuse and Mental Health Services Administration (SAMHSA) has issued an action alert about a new combination of drugs with a demonstrably lethal effect. The drug combines fentanyl, a powerful opioid analgesic, with heroin or cocaine. Street supplies of the drug are believed to be the cause of clusters of drug-related deaths and overdoses in East Coast and Midwest cities in recent months.

It appears that, in some cases, users believe they are purchasing extremely potent heroin or cocaine, while in other cases they are aware of the combination with fentanyl. (Another possible explanation, offered by retired DEA official John Coleman, is that addicts believe they are purchasing authentic OxyContin 80 mg tablets, which actually are counterfeits containing fentanyl. In support of his hypothesis, Mr. Coleman points to a recent issue of DEA's *Microgram* (http://www.dea.gov/programs/forensicsci/microgram/mg0406/mg0406.pdf) featuring an article on a clandestine laboratory seized in a Los Angeles suburb. There, enforcement officials found a tablet press used to make counterfeit OxyContin 80 mg tablets. On analysis, the tablets were found to contain no oxycodone, but 1.5 mg fentanyl.)

In any of these scenarios, the results can be lethal. For example, in just one week in May, 33 individuals in the Detroit area are said to have died after using the new combination drug. The same combination may have been responsible for more than 100 deaths in Chicago, Philadelphia, Camden (NJ), Harrisburg (PA), New Castle County (DE), Detroit, and Baltimore since last September.

The SAMHSA alert, issued by Dr. H. Westley Clark, Director of SAMHSA's Center for Substance Abuse Treatment, encloses a brief fact sheet about preventing and treating overdoses. "Individuals involved in the public health need to be aware of this new dangerous drug combination," Dr. Clark cautions. "They need to be prepared to alert patients, clients and others to help save lives. After all, fentanyl is 50 to 100 times more powerful than morphine." The drug acts by suppressing respiration; it also can cause irregular heartbeat.

Dr. Clark's message encourages recipients not only to advise their networks of patients and colleagues, but also to join local health authorities to bring information about the drug to first responders, emergency room personnel, street substance abuse workers, drug treatment facilities, local health care providers, the recovery community, and the public at large. It also advises local vigilance for the possible introduction of this potent drug mixture into circulation on street drug markets. *(Source: Substance Abuse and Mental Health Services Administration. For more information, contact Teddi Fine at 240/276-2130 or email SAMHSAnews@health.org.)*

Report Assesses State Readiness to Raise Alcohol Taxes

Policy analysts report that a number of states are poised to increase state alcohol excise taxes, while advocates work to have the extra funds dedicated to addiction treatment. States with active efforts to raise alcohol taxes and the proposed recipients of additional revenues are:

Arizona (earmarked for the Drug and Alcohol Treatment Fund)

Idaho (Alcoholism Treatment Account)

Kansas (Community Alcoholism and Intoxication Programs Fund)

Mississippi (Alcoholism Treatment and Rehabilitation Fund)

Montana ("treatment, rehabilitation, and prevention of alcoholism and chemical dependency")

New Jersey (Alcohol Education, Rehabilitation and Enforcement Fund)

Nevada ("increase services for prevention and treatment of alcoholism and alcohol abuse")

Oregon (Mental Health Alcoholism and Drug Services Account)

Tennessee ("To assist municipalities and counties in carrying out the provisions of the state's 1973 Comprehensive Alcohol and Drug Treatment Act)

Utah ("Programs or projects related to prevention, treatment, detection, and prosecution.)

The Center for Science in the Public Interest also is lobbying Congress to increase federal alcohol excise taxes. CSPI staff point out that beer and wine taxes have been raised only once in the past 55 years, and liquor taxes only twice. As a result of inflation, the excise tax rates and resulting revenues have dwindled dramatically, helping to keep the price of alcoholic beverages at historic lows. Such taxes typically are assessed not as a percentage of the purchase price, but as a fixed dollar amount. In fact, had beer taxes kept pace with inflation since 1951, they would be three times higher than they are today; while taxes on liquor would have increased sixfold. CSPI says that a tax increase of just five cents a drink would yield more than $20 billion in new revenue over the next five years.

Low taxes also have allowed young people to purchase relatively cheap beer and liquor, which the National Academy of Sciences (NAS) has found contributes substantially to excessive underage drinking. As a result, the NAS strongly supports increased alcohol excise taxes. Their argument is endorsed in a petition to Congress by 59 economists — including four Nobel laureates — who agree that an alcohol tax increase is both justified and overdue. *Source: Ensuring Solutions to Alcohol Problems, The George Washington University, May 2006. For more information, visit www.ensuringsolutions.org.*

DO LAWMAKERS TAKE A GENTLER APPROACH TO "CRANK" THAN "CRACK"?

When the crack epidemic hit the U.S. in the 1980s, federal lawmakers responded with draconian measures aimed at dealers and users. But as abuse of methamphetamine raises similar fears, legislators are looking to international interdiction and supply reduction strategies in lieu of tougher punishment, according to an article in the current issue of *Congressional Quarterly*.

This difference in approach betrays underlying racism, say some members of Congress interviewed for the article. For example, Congressman Elijah Cummings (D-MD) points out that whereas crack users were mostly urban and black, current users of methamphetamine tend to be rural and white. He says, "There seems to be more of an emphasis on shutting down these meth labs and trying to figure out ways to treat the addicts and then get them back into flow of society. We don't get for crack or heroin that kind of support for prevention, treatment and rehabilitation."

Others disagree. Lawmakers such as Congressman Mark Souder (R-IN) maintains that he is even less sympathetic toward methamphetamine users than to those addicted to other drugs. "When you come from areas where you see opportunities exist..., the sympathy is less than for those in urban areas where they have no jobs," Rep. Souder said. Federal officials defend the supply-reduction approach to methamphetamine by explaining that interdiction makes more sense with methamphetamine because its production involves a series of specific chemicals whose supply can be blocked.

One unavoidable similarity between crack and methamphetamine is the way in which officials describe the drugs' effects on users and communities. As was crack, methamphetamine is described as a "plague" that has emerged as the biggest problem facing police and public health authorities in rural communities. *Source: Congressional Quarterly, June 5, 2006.*

A CALL TO ACTION

Michael M. Miller, M.D., FASAM

Michael M. Miller, M.D., FASAM

An invitation to participate . . . make better use of your energies, talents and passions to move ASAM's mission forward.

As I begin the second year of my six-year term as your President-Elect, President and Immediate Past-President, I'd like to issue a Call to Action to you and other ASAM members to get involved in ASAM and your local chapter. The challenge to ASAM's officers, Board, and Chapter Presidents is to identify specific channels for your involvement — especially channels to involve those of you who are newer and younger members. We must make better use of your energies, talents and passions to move ASAM's mission forward. Our members must never be in the position of saying, "I'd like to do something, but I don't know what or how."

One of the concerns we all share is the quality of medical care. Every ASAM physician is concerned about the plight of the person with addictive disease, worries about how misunderstood and stigmatized their illness is, and laments the barriers to care faced by most of our patients or potential patients. One way to close gaps in quality and access is to become involved in the public policy arena. Through the leadership of Kevin Kunz, M.D., and ASAM consultant James F. Callahan, D.P.A., we are working toward the goal of having an active public policy committee in every State chapter to coalesce the energies of ASAM members in each State, and to advocate with State and Federal agencies and legislators on behalf of our patients and our practices.

If your state chapter hasn't yet realized this vision, perhaps you are the person who'll step up to the plate and take on the challenge. Alexis Geier-Horan in ASAM's national office; ASAM Public Policy Committee co-chairs Mark Kraus, M.D., and Petros Levounis, M.D., as well as Kevin Kunz and Jim Callahan and Legislative Advocacy Committee chair Don Kurth, M.D., and all the ASAM officers are ready to assist any ASAM member who decides to direct his or her volunteer efforts into public policy.

QUALITY IMPROVEMENT

Another way to improve the quality of care is to get involved in other quality improvement (QI) efforts in medicine, so as to bring the perspective of addiction medicine to the QI activities already under way. Therefore, the other part of my Call to Action is to invite you to participate in ASAM's Quality Improvement Council. You can learn more about this work by visiting the new QI page on the ASAM website (www.asam.org). I hope I can excite your passion for quality improvement by highlighting several points that are discussed in greater length on that new web link:

1. The Institute of Medicine's 2005 report, *Improving the Quality of Health Care for Mental and Substance-Use Conditions,* is a follow-up to their highly publicized reports of 1999 and 2001 *(Crossing the Quality Chasm).* ASAM provided formal commentary on the new report and contributed to the development of a proposed legislative agenda in response to its recommendations. Both documents are posted at www.asam.org
2. The AMA's Physician Consortium for Performance Measurement provides a conduit for ASAM to be involved in the development of performance measures that relate to the care of patients with substance use and chronic pain disorders.
3. ASAM continues to be involved with the Joint Commission on Accreditation of Healthcare Organizations, which is a key component of any efforts to improve the quality of health care.
4. ASAM is working with the National Association of Addiction Treatment Providers (NAATP) to identify performance measures for addiction treatment organizations.
5. ASAM's ongoing work in developing Practice Guidelines — led by Michael Mayo-Smith, M.D., and Richard Saitz, M.D., — has provided sound scientific underpinnings to many areas of addiction practice.
6. ASAM's continuous development and expansion of the *ASAM Patient Placement Criteria* provides the field with an independently developed, non-commercial system for matching patients' needs to treatment services.
7. ASAM has developed connections to the American College of Medical Quality — a national medical specialty society of physicians who work full-time in the quality arena.

There's not much debate over the fact that the quality of addiction care in America needs improvement. I hope you agree with me that there is no group of physicians better positioned to address these quality improvement challenges than the members of the American Society of Addiction Medicine. After all, ASAM is no more than you and me — our individual efforts focused collectively toward achieving specific goals. If individual ASAM members like you don't participate in defining what constitutes quality care, what constitutes the optimum measurement systems for defining quality in medical practice, and for influencing what major organizations like JCAHO are doing in the quality arena, then we can be assured that some other entities — be they physician organizations or agencies of government or other non-physician groups — will do this work for us and impose their expectations on us.

Please contact ASAM's Executive Vice President, Eileen McGrath, J.D., any ASAM officer, or the co-chairs of ASAM's Quality Improvement Council (Dr. David Gastfriend and Dr. David Mee-Lee) to let us know that you are ready to "answer the call" and to contribute to ASAM's activities in the quality improvement arena.

Speaking of "Poppycock"… A Reply to the Wall Street Journal

Randy Brown, M.D.

Randy Brown, M.D.

[ED: In a commentary published in the May 25th edition of The Wall Street Journal, *Theodore Dalrymple espouses ideas from his newly published book that include: "Heroin doesn't hook people; rather, people hook heroin," and "Withdrawal effects from opiates are trivial, medically speaking… [and] are largely, though not entirely, psychological in origin," and "Insofar as there is a causative relation between criminality and opiate addiction, it is more likely that a criminal tendency causes addiction than that addiction causes criminality." The following response to Mr. Dalrymple is offered by Randy Brown, M.D.]*

Editorials, in part, serve to present provocative opinion to the public for the purpose of stimulating discourse. On that score, touché Mr. Dalrymple: Your editorial provides ample fodder for discussion. However, one would hope that argument surrounding an issue as critical to individual and societal well-being as addiction, which appears in a publication as reputable as *The Wall Street Journal*, would have some basis in fact, particularly in a field where good science is widely available. Thus it is stunning Mr. Dalrymple's editorial entirely roots itself in scientifically unsupportable and biased views of subject on which he holds himself out as an expert.

I fully concede that a segment of Hollywood and the media — and indeed, of world literature — have romanticized drug use and the drug-using lifestyle. However, the statement that "[t]his romantic nonsense…has been accepted wholesale by doctors and litterateurs" transcends the ludicrous. Surely Mr. Dalrymple does not include the average practicing physician in his sweeping statement. If he were to survey primary care physicians (or read published surveys that have documented physician attitudes), he would find that most physicians regard patients with substance use disorders as decidedly "un-romantic." Physicians see the misery resulting from drug abuse and addiction with regularity and, more often than not, view the addicted patient as challenging at best and not worthy of customary compassion at worst.

If Mr. Dalrymple refers not to generalist physicians but rather to researchers, addiction specialists, and others who are more regularly involved in the care of addicted patients, he might make a more interesting argument — a flawed argument, lacking in supporting evidence, but a potentially interesting argument nonetheless. In the field of addiction medicine, the dominant paradigm views addiction as a chronic, relapsing and remitting medical disorder rather than a matter of poorly controlled volitional behavior. Some argue that this view inappropriately "medicalizes" a psychological or behavioral problem. However, the scientific literature strongly supports a model of addiction involving adaptation of the brain to the presence of a substance that produces neurochemical and microanatomic changes in the brain's reward centers. The normal function of these centers leads humans to engage in behaviors as basic to survival as seeking shelter, consuming food and water, and procreation. Alcohol- or drug-induced restructuring of this system, and of the higher cortical systems that regulate the seeking of immediate reward, is well-documented in the research literature, as are the behavioral correlates of such structural abnormalities.

These neurological alterations restructure priorities and values that a non-addicted individual generally considers when making choices about his or her behaviors. Mr. Dalrymple postulates simple choices ("heroin fix or immediate death"). But in the life of the addicted individual, choices are not so simple or obvious (e.g., "If I give up this one meal for a fix, I probably won't be the worse for wear.") It is the accumulation of such choices over time that creates the destructive force of addiction.

In a classic experiment, whose results have been widely replicated, rhesus monkeys given a choice of cocaine or food starve themselves because their brains become reprogrammed to "tell them" that cocaine is preferable to food. Mr. Dalrymple's minimization of the potential impact on individual functioning of damage to such primordial neurological systems thus is pseudo-scientific piffle.

It is equally obvious that, while Mr. Dalrymple may have "witnessed" many individuals who were (or claimed to be) experiencing drug withdrawal, he has not been a particularly acute observer of the objective signs of opioid withdrawal syndrome. While abdominal pain and muscle and joint aches are easily shammed, as he describes it, I would challenge Mr. Dalrymple to present to my office faking hypertension, elevated heart rate, profuse tearing, runny nose, vomiting, diarrhea, gooseflesh, and pupillary dilation — all well-documented objective manifestations of opioid withdrawal. (I also would challenge him to tolerate these "trivial" and "largely psychological" effects without support or complaint.) While opioid withdrawal usually is not life-threatening, it is hardly "trivial," and to label it as such exposes the author's lack of understanding of the very real and very distressing nature of the syndrome.

The author's arguments surrounding drugs and crime beg numerous questions. Does one cause the other? Does genetic vulnerability contribute to either or both? Do environmental stressors (such as childhood abuse and neglect or partner violence) influence the development of criminal activity and/or substance abuse? Or, more likely, is substance abuse, like most illnesses, the result of a combination of genetic vulnerability and environmental influences? Both associations are well-documented in the literature and ignored by Mr. Dalrymple.

Mr. Dalrymple also shoots wide of the mark when describing the natural history of addiction. Although the examples he cites (of DeQuincey and Burroughs requiring extended periods of opioid use to become addicted) typify a common phenomenon, they hardly represent the universe of experience of drug users and their progression to addiction. In fact, objective signs of opioid withdrawal have been documented after a single use.

All of us — drug users included — benefit from productive debate of the suffering caused by drug abuse and dependence, and the best methods for alleviating such suffering. However, derision of an already

continued on page 6

Speaking of "Poppycock"... *continued from page 5*

marginalized population hardly contributes to such productive debate.

So in response to Mr. Dalrympl's editorial, I say: "Should you have rational, factually supported discourse to supply, I'm all ears, as we all should be. However, if your future ideas are in a vein similar to those in your editorial, I pray you'll restrict them to your diary."

Dr. Brown is Assistant Professor at the University of Wisconsin School of Medicine and Public Health, Co-Director of the Alcohol and Other Drug Consultation Service at the University of Wisconsin Hospitals and Clinics, a staff physician with the NewStart Addiction Medicine Consultation Service at Meriter Hospital, Madison, Wisconsin, and a Ph.D. candidate in the Department of Population Health Sciences of the University of Wisconsin-Madison.

REFERENCES:

1. Dalrymple T (2006). Poppycock. *The Wall Street Journal* May 26, A-14.
2. Reid MC, Engles-Horton LL, Weber MB et al. (2002). Use of opioid medications for chronic noncancer pain syndromes in primary care. *Journal of General Internal Medicine* 17:173-179.
3. Saitz R, Friedmann PD, Sullivan LM et al. (2002). Professional satisfaction experienced when caring for substance-abusing patients: Faculty and resident physician perspectives. *Journal of General Internal Medicine* 17:373-376.
4. Rosenbaum M (1995). The demedicalization of methadone maintenance. *Journal of Psychoactive Drugs* 27:145-149.
5. Volkow ND, Fowler JS & Wang GJ (2004). The addicted human brain viewed in the light of imaging studies: Brain circuits and treatment strategies. *Neuropharmacology* 47 (Suppl)1:3-13.
6. Volkow N, Fowler J & Wang G (2003). The addicted human brain: Insights from imaging studies. *Journal of Clinical Investigation* 111:1444-1451.
7. Volkow ND & Fowler JS (2000). Addiction, a disease of compulsion and drive: Involvement of the orbitofrontal cortex. *Cerebral Cortex* 10:318-325.
8. Aigner TG & Balster RL (1978). Choice behavior in rhesus monkeys: Cocaine versus food. *Science* 201:534-535.
9. West R & Gossop M (1994). Overview: A comparison of withdrawal symptoms from different drug classes. *Addiction* 89:1483-1489.
10. Dinwiddie SH & Reich T (1993). Genetic and family studies in psychiatric illness and alcohol and drug dependence. *Journal of Addictive Diseases* 12:17-27.
11. Musher-Eizenman DR, Holub SC & Arnett M (2003). Attitude and peer influences on adolescent substance use: The moderating effect of age, sex, and substance. *Journal of Drug Education* 33:1-23.
12. Tuten M, Jones HE & Svikis DS (2003). Comparing homeless and domiciled pregnant substance dependent women on psychosocial characteristics and treatment outcomes. *Drug & Alcohol Dependence* 69:95-99.
13. Harris AC & Gewirtz JC (2005). Acute opioid dependence: Characterizing the early adaptations underlying drug withdrawal. *Psychopharmacology* 178:353-356.

ASAM'S ANNUAL REPORT *continued from page 2*

Labs for Campral and from Reckett-Benckiser for buprenorphine. 2005 advertising revenues were $48,010. Also in 2005, the newsletter mailing envelope was used to distribute announcements to members in the Southeast, the Pacific Northwest, and Hawaii, at the request of State Societies and Chapters, as well as applications for the Ruth Fox Scholarship Fund, saving ASAM and its chapters the cost of separate mailings.

- *Course Manuals and CD-Roms:* In 2005, course manuals and CD-Roms were prepared for the ASAM Medical Review Officer training courses, the Ruth Fox Course, the course on Pain & Addiction: Common Threads VI, and the State of the Art Course. Post-course sales of the manuals and CD-Roms, as well as grants to support development of the course manuals, generate continuing revenues to ASAM. Gross revenues in 2005 were $37,247 (because grants are allocated to the course budgets rather than publications, they are not reflected in this figure, which includes only revenues from post-course sales).
- *Supplement to the ASAM Patient Placement Criteria*: The ASAM Board has determined that the Society ought to produce a supplement to the Patient Placement Criteria that addresses the use of pharmacotherapies in addiction treatment, in the form of a series of handbooks. Because of the prevalence of alcohol use disorders, the first handbook in the series will focus on alcohol therapies. A review draft will be circulated in 2006. To cover development costs for this product, ASAM has obtain unrestricted educational grants from Alkermes and Forest Pharmaceuticals.
- *Commercial Publishing Agreement:* ASAM has entered into a contract with Lippincott Williams & Wilkins to publish ASAM's journal and books, beginning in 2007. This replaces the self-publishing arrangement currently in use for the textbooks, and a contract with Haworth Press to publish the journal.

WEBSITE

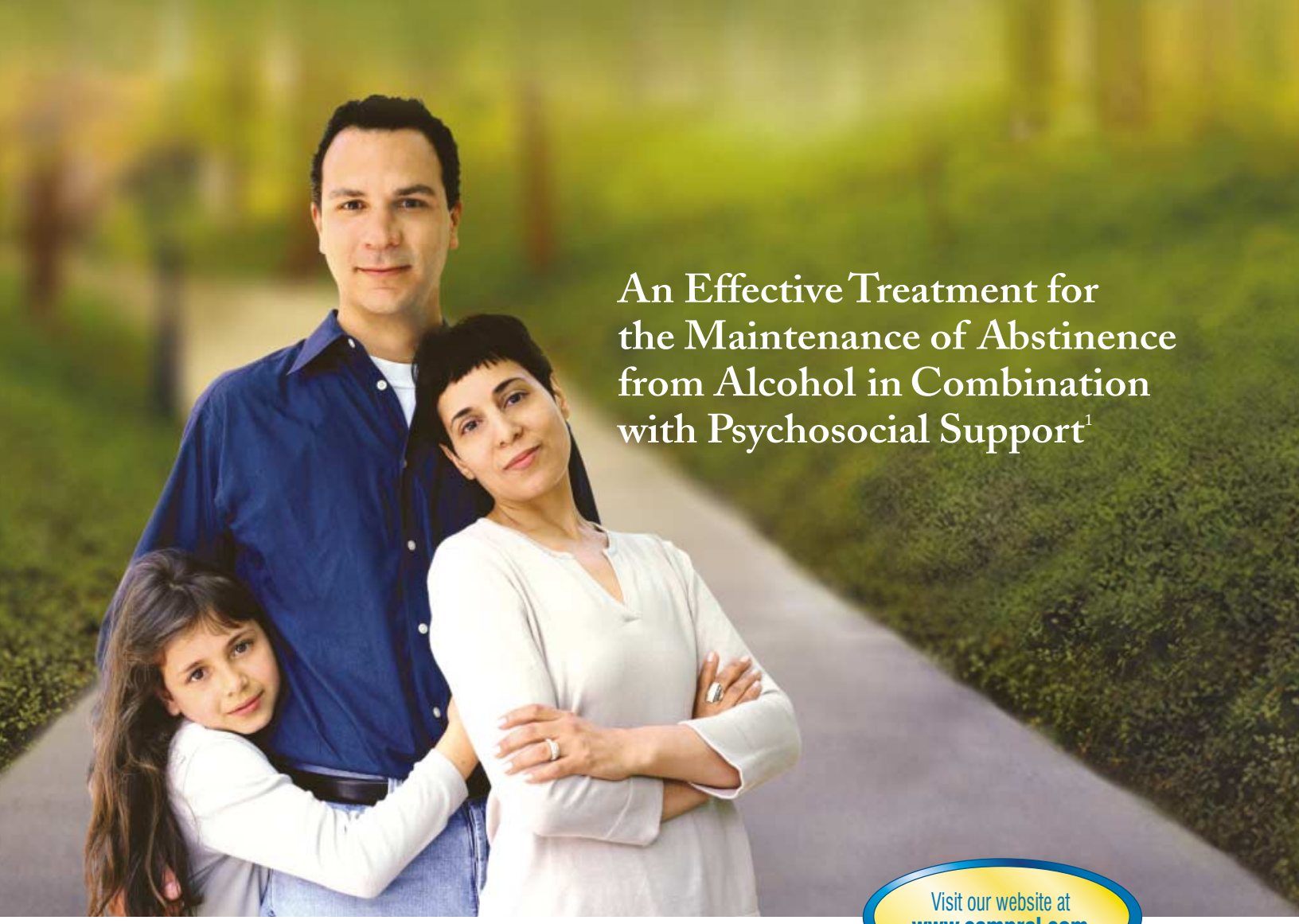
- ASAM's website (WWW.ASAM.ORG) has logged approximately 53,000 visits per month in 2006.
- Sales of course registrations and publications via the website total $57,000 in the first quarter 2006.
- The website will undergo a major redesign in 2006, to allow ASAM to add surveys, polls, new member updates, a real-time membership directory, new e-commerce, state chapter access to live rosters, and a new member center.

CONTINUING MEDICAL EDUCATION

- The ASAM Continuing Medical Education Committee held its 2nd annual retreat in March 2006 to plan the year's activities.
- In 2005, ASAM provided continuing medical education credits for 35 educational programs, including 349 hours of instruction to 2,002 physicians and 653 non-physicians. Total expenses were $969,915, with 50 percent commercial support.
- The Ruth Fox Course for Physicians celebrated its 25th anniversary during the Med-Sci Conference in San Diego.
- Attendance at Med-Sci exceeded 900, with 81 exhibitors, ASAM anticipates net revenue of $145,000 for the conference.
- ASAM received proposals for 108 workshops for the 37th Annual Conference in 2006, an increase of 60 percent over the number proposed in 2005.

CHAPTER DEVELOPMENT

- As of January 2006, ASAM had 22 active chapters. A new chapter has formed in Colorado, and others are organizing in Indiana, Minnesota and Utah. Chapters have revitalized in Tennessee and Maryland. States that have expressed interest in forming a Chapter include West Virginia, Vermont, Nebraska, Georgia, Alaska and Puerto Rico.
- The SMSS met in January 2006 to discuss ways to promote the future growth of state societies and chapters. *continued on page 9*



An Effective Treatment for the Maintenance of Abstinence from Alcohol in Combination with Psychosocial Support[1]

Visit our website at **www.campral.com**

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

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

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

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

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

Forest Pharmaceuticals, Inc.
Pharmaceuticals • Therapeutics • Healthcare • Ethicare • Managed Care • Specialty Sales

 42-126187 1/05

Campral®
(acamprosate calcium)
Delayed-Release Tablets

Strengthens the will to say no

Campral®
(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 ≤30 mL/min).

PRECAUTIONS
Use of CAMPRAL does not eliminate or diminish withdrawal symptoms. **General: Renal Impairment** Treatment with CAMPRAL in patients with moderate renal impairment (creatinine clearance of 30-50 mL/min) requires a dose reduction. Patients with severe renal impairment (creatinine clearance of ≤30 mL/min) should not be given CAMPRAL (see also CONTRAINDICATIONS). **Suicidality** In controlled clinical trials of CAMPRAL, adverse events of a suicidal nature (suicidal ideation, suicide attempts, completed suicides) were infrequent overall, but were more common in CAMPRAL-treated patients than in patients treated with placebo (1.4% vs. 0.5% in studies of 6 months or less; 2.4% vs. 0.8% in year-long studies). Completed suicides occurred in 3 of 2272 (0.13%) patients in the pooled acamprosate group from all controlled studies and 2 of 1962 patients (0.10%) in the placebo group. Adverse events coded as "depression" were reported at similar rates in CAMPRAL-treated and placebo-treated patients. Although many of these events occurred in the context of alcohol relapse, no consistent pattern of relationship between the clinical course of recovery from alcoholism and the emergence of suicidality was identified. The interrelationship between alcohol dependence, depression and suicidality is well-recognized and complex. Alcohol-dependent patients, including those patients being treated with CAMPRAL, should be monitored for the development of symptoms of depression or suicidal thinking. Families and caregivers of patients being treated with CAMPRAL should be alerted to the need to monitor patients for the emergence of symptoms of depression or suicidality, and to report such symptoms to the patient's health care provider. **Information for Patients** Physicians are advised to discuss the following issues with patients for whom they prescribe CAMPRAL. Any psychoactive drug may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that CAMPRAL therapy does not affect their ability to engage in such activities. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. Patients should be advised to notify their physician if they are breast-feeding. Patients should be advised to continue CAMPRAL therapy as directed, even in the event of relapse and should be reminded to discuss any renewed drinking with their physician. Patients should be advised that CAMPRAL has been shown to help maintain abstinence only when used as a part of a treatment program that includes counseling and support. **Drug Interactions** The concomitant intake of alcohol and CAMPRAL does not affect the pharmacokinetics of either alcohol or acamprosate. Pharmacokinetic studies indicate that administration of disulfiram or diazepam does not affect the pharmacokinetics of acamprosate. Co-administration of naltrexone with CAMPRAL produced a 25% increase in AUC and a 33% increase in the Cmax of acamprosate. No adjustment of dosage is recommended in such patients. The pharmacokinetics of naltrexone and its major metabolite 6-beta-naltrexol were unaffected following co-administration with CAMPRAL. Other concomitant therapies: In clinical trials, the safety profile in subjects treated with CAMPRAL concomitantly with anxiolytics, hypnotics and sedatives (including benzodiazepines), or non-opioid analgesics was similar to that of subjects taking placebo with these concomitant medications. Patients taking CAMPRAL concomitantly with antidepressants more commonly reported both weight gain and weight loss, compared with patients taking either medication alone. **Carcinogenicity, Mutagenicity and Impairment of Fertility** A carcinogenicity study was conducted in which Sprague-Dawley rats received acamprosate calcium in their diet at doses of 25, 100 or 400 mg/kg/day (0.2, 0.7 or 2.5-fold the maximum recommended human dose based on an AUC comparison). There was no evidence of an increased incidence of tumors in this carcinogenicity study in the rat. An adequate carcinogenicity study in the mouse has not been conducted. Acamprosate calcium was negative in all genetic toxicology studies conducted. Acamprosate calcium demonstrated no evidence of genotoxicity in an *in vitro* bacterial reverse point mutation assay (Ames assay) or an *in vitro* mammalian cell gene mutation test using Chinese Hamster Lung V79 cells. No clastogenicity was observed in an *in vitro* chromosomal aberration assay in human lymphocytes and no chromosomal damage detected in an *in vivo* mouse micronucleus assay. Acamprosate calcium had no effect on fertility after treatment for 70 days prior to mating in male rats and for 14 days prior to mating, throughout mating, gestation and lactation in female rats at doses up to 1000 mg/kg/day (approximately 4 times the maximum recommended human daily oral dose on a mg/m^2 basis). In mice, acamprosate calcium administered orally for 60 days prior to mating and throughout gestation in females at doses up to 2400 mg/kg/day (approximately 5 times the maximum recommended human daily oral dose on a mg/m^2 basis) had no effect on fertility. **Pregnancy Category C Teratogenic Effects** Acamprosate calcium has been shown to be teratogenic in rats when given in doses that are approximately equal to the human dose (on a mg/m^2 basis) and in rabbits when given in doses that are approximately 3 times the human dose (on a mg/m^2 basis). Acamprosate calcium produced a dose-related increase in the number of fetuses with malformations in rats at oral doses of 300 mg/kg/day or greater (approximately equal to the maximum recommended human daily oral dose on a mg/m^2 basis). The malformations included hydronephrosis, malformed iris, retinal dysplasia, and retroesophageal subclavian artery. No findings were observed at an oral dose of 50 mg/kg/day (approximately one-fifth the maximum recommended human daily oral dose on a mg/m^2 basis). An increased incidence of hydronephrosis was also noted in Burgundy Tawny rabbits at oral doses of 400 mg/kg/day or greater (approximately 3 times the maximum recommended human daily oral dose on a mg/m^2 basis). No developmental effects were observed in New Zealand white rabbits at oral doses up to 1000 mg/kg/day (approximately 8 times the maximum recommended human daily oral dose on a mg/m^2 basis). The findings in animals should be considered in relation to known adverse developmental effects of ethyl alcohol, which include the characteristics of fetal alcohol syndrome (craniofacial dysmorphism, intrauterine and postnatal growth retardation, retarded psychomotor and intellectual development) and milder forms of neurological and behavioral disorders in humans. There are no adequate and well controlled studies in pregnant women. CAMPRAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic Effects** A study conducted in pregnant mice that were administered acamprosate calcium by the oral route starting on Day 15 of gestation through the end of lactation on postnatal day 28 demonstrated an increased incidence of still-born fetuses at doses of 960 mg/kg/day or greater (approximately 2 times the maximum recommended human daily oral dose on a mg/m^2 basis). No effects were observed at a dose of 320 mg/kg/day (approximately one-half the maximum recommended human daily dose on a mg/m^2 basis). **Labor and Delivery** The potential for CAMPRAL to affect the duration of labor and delivery is unknown. **Nursing Mothers** In animal studies, acamprosate was excreted in the milk of lactating rats dosed orally with acamprosate calcium. The concentration of acamprosate in milk compared to blood was 1.3:1. It is not known whether acamprosate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CAMPRAL is administered to a nursing woman. **Pediatric Use** The safety and efficacy of CAMPRAL have not been established in the pediatric population. **Geriatric Use** Forty-one of the 4234 patients in double-blind, placebo-controlled, clinical trials of CAMPRAL were 65 years of age or older, while none were 75 years of age or over. There were too few patients in the ≥65 age group to evaluate any differences in safety or effectiveness for geriatric patients compared to younger patients. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (See CLINICAL PHARMACOLOGY, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS
The adverse event data described below reflect the safety experience in over 7000 patients exposed to CAMPRAL for up to one year, including over 2000 CAMPRAL-exposed patients who participated in placebo-controlled trials. **Adverse Events Leading to Discontinuation** In placebo-controlled trials of 6 months or less, 8% of CAMPRAL-treated patients discontinued treatment due to an adverse event, as compared to 6% of patients treated with placebo. In studies longer than 6 months, the discontinuation rate due to adverse events was 7% in both the placebo-treated and the CAMPRAL-treated patients. Only diarrhea was associated with the discontinuation of more than 1% of patients (2% of CAMPRAL-treated vs. 0.7% of placebo-treated patients). Other events, including nausea, depression, and anxiety, while accounting for discontinuation in less than 1% of patients, were nevertheless more commonly cited in association with discontinuation in CAMPRAL-treated patients than in placebo-treated patients. **Common Adverse Events Reported in Controlled Trials** Common, non-serious adverse events were collected spontaneously in some controlled studies and using a checklist in other studies. The overall profile of adverse events was similar using either method. Table 1 shows those events that occurred in any CAMPRAL treatment group at a rate of 3% or greater and greater than the placebo group in controlled clinical trials with spontaneously reported adverse events. The reported frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed, without regard to the causal relationship of the events to the drug.

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

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

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

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

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

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

Manufactured by: Merck Santé s.a.s.
Subsidiary of Merck KGaA, Darmstadt, Germany
37, rue Saint-Romain
69008 LYON FRANCE

Manufactured for FOREST PHARMACEUTICALS, Inc.
Subsidiary of Forest Laboratories, Inc.
St. Louis, MO 63045
07/04

Forest Pharmaceuticals, Inc.
Pharmaceuticals • Therapeutics • Healthcare • Ethicare • Managed Care • Specialty Sales

ASAM'S ANNUAL REPORT *continued from page 6*

LEGISLATIVE ADVOCACY

- ASAM sponsored its Third Annual Legislative Day in Washington, DC, in 2005. Twenty members of the Society participated in a briefing on Capitol Hill.
- The first monthly advocacy e-newsletter was distributed in September.
- The Government Relations Department assisted the Center for Substance Abuse Treatment in recruiting addiction specialists for Hurricane Katrina Medical Relief Teams.
- ASAM partnered with the American Psychiatric Association in a letter of support for Rep. Mark Souder's bill to lift the 30-patient limit on prescribing of buprenorphine, and in a letter urging that the new Medicare prescription drug plan cover medications for the treatment of opioid addiction.
- ASAM staff attended numerous advocacy coalition meetings and Capitol Hill briefings. ASAM also supported addiction-related legislation and amicus briefs, and joined other health professions organizations in efforts to oppose prosecution of drug-using pregnant women, to support the Congressional Addiction Treatment and Recovery Caucus, to urge Medicare coverage for tobacco cessation treatment, and many others.

PUBLIC POLICY

- ASAM's Public Policy Committee has proposed to develop or revise statements on "Pharmacotherapies for Alcohol and Other Drug Use," "Marijuana," "Methadone and Buprenorphine Treatment of Opioid Dependence and Withdrawal," and "Labeling and Advertising of Alcoholic Beverages."
- The Committee also submitted comments on proposed rule-making regarding the labeling and advertising of alcoholic beverages to the federal Alcohol and Tobacco Tax and Trade Bureau. This document emphasized the Society's recommendation that "nutritional" information would be inappropriate in labeling or advertising alcoholic beverages, and that all regulations should be made mandatory.

MEMBERSHIP

As of March 15, 2006, ASAM received membership renewals from 2,022 members, 118 fewer than had renewed at the same date in 2005. However, 304 new members had joined ASAM, compared to 139 at the same date in 2005. Total ASAM membership is 2,326, compared to 2,270 in 2005, for an increase of 2.4 percent. Membership revenues were approximately $3, 000 less in 2005 than in the previous year, while expenses were $85,000 more in 2005 than in 2004. Membership revenues in 2006 are forecast to be $838,663 — approximately the same amount received in 2005.

MEMBERSHIP ACTIVITIES THROUGH THE FIRST QUARTER 2006 INCLUDED:

- The Member-Get-A-Member Campaign (Oct '05 - April '06) has resulted in the recruitment of 41 new members.
- Membership packets were sent to 981 new and prospective members.
- SMSS Presidents, Membership Chairs, and Executive Directors met in October 2005 to discuss 2005-2006 membership plans.

CERTIFICATION

- Through the first quarter 2006, 401 physicians had applied to sit for the ASAM Certification Examination, compared to 406 the last time the exam was offered (2004).
- Nineteen physicians were elected Fellows of the Society.

NOMINATIONS AND AWARDS

- The Nominations & Awards Council selected candidates for ASAM officers to fill terms from 2007 through 2009, and for Director-at-Large to fill terms from 2007 through 2011. Voting will take place in October and November 2006.
- The Council is working with the Board to consider several motions related to disclosure of potential conflicts of interest by candidates for officer and Board seats.
- All of the Council's nominees for 2006 awards were approved by the Board and accepted their awards at ASAM's 2006 Med-Sci Conference. Awards went to Rudolf Moos, Ph.D. (the R. Brinkley Smithers Distinguished Scientist Award), James Smith, M.D., FASAM, Barry Stimmel, M.D., FASAM, and Larry Gentilello, M.D., FACS (the ASAM Annual Award), and Carlo DiClemente, Ph.D. (the John P. McGovern, M.D., Lecture and Award), Cindy Parks-Thomas, Ph.D. (the Med-Sci Conference Award), and Janet Soeffing, M.D. and Hannah Knudsen, M.D. (the Young Investigator Award).

FUND-RAISING AND DEVELOPMENT

- The Ruth Fox Memorial Endowment Fund achieved its goal of reaching $4 million in pledges and donations by year-end 2005.
- Contributions received for the 2006 Medical-Scientific Conference totaled $147,000, compared to $215,000 received for the 2005 conference (this is largely attributable to the fact that the Pain Course has been rescheduled for Fall 2006).
- Four Ruth Fox Scholarship recipients were selected from a pool of 21 applicants to attend the 2006 Med-Sci Conference.

FINANCES

ASAM experienced a deficit of $162,085 in 2005, compared with a budget surplus of approximately $600,000 in 2004. Two factors contributed to the difference. First, the Third Edition of ASAM's textbook, Principles of Addiction Medicine, was published in October 2003 and realized a large volume of sales in 2004. Sales projections for 2005 anticipated that a contract with a commercial publisher would by signed by mid-year, resulting in expanded marketing activities.

The second factor resulted from a problem with the indirect costs associated with the CSAT Buprenorphine Mentoring grant, which has been corrected, but resulted in a $137,000 charge against the bottom line for that activity.

As 2005 unfolded, additional grant opportunities and reductions in operating expenses mitigated the impact of these budgeting errors by 55 percent. The Board directed that up to $80,000 of the actual 2005 deficit be recouped in 2006 and the remainder in 2007. Staff have revised the 2006 forecast to incorporate a surplus of more than $100,000, although the 2006 budget will face challenges in achieving projected revenues and expenses.

Cocaine Immune Booster Shows Promise

An investigational medication designed to induce the body's natural defenses to inactivate cocaine before it reaches the brain has cleared an important human trials hurdle. Dr. Bridget Martell, Dr. Thomas Kosten, and their colleagues at Yale University tested the compound, designated TA-CD, in an open-label study involving 18 cocaine-addicted participants who took it for either 8 or 12 weeks.

No participant reported adverse effects, and all still had cocaine-specific antibodies in their bloodstream six months after the first injection. At the six-month follow-up, participants reported that exposure to cocaine produced only mild euphoric effects, even though blood tests showed waning concentrations of the antibodies. *(Source: NIDA Notes. For more information, see Biological Psychiatry 58(2):158- 164, 2005.)*

GVG Shows Promise In Early Human Trials

A potential medication for treatment of drug abuse and addiction — gamma-vinyl GABA (GVG) — has taken an important step in the medication development process. Having previously shown promise in tests with laboratory animals, it now has been shown to be safe in a small clinical trial with cocaine and methamphetamine abusers. GVG also proved effective: 16 of 18 patients in treatment for addiction to cocaine, methamphetamine, or both tested negative for the drugs throughout the last six weeks of the open-label trial. The next step involves a larger, randomized double-blind study. *(Source: NIDA Notes. For more information, see Synapse 55:122-125, 2005.)*

Nicotine Vaccine Moves Forward

A vaccine to prevent nicotine addiction demonstrated a good safety profile in a recent clinical trial with 68 healthy smokers. Dr. Dorothy Hatsukami of the University of Minnesota and colleagues found NicVAX to be safe and well tolerated, with side effects comparable to those of placebo. Overall, the reported side effects — most commonly general discomfort, headache, and muscle pain — were mild to moderate in severity.

The vaccine triggers the production of antibodies that bind nicotine in the blood and prevent it from reaching the brain. Nevertheless, healthy smokers who received the vaccine did not experience craving or withdrawal symptoms, nor did they increase the number of cigarettes smoked during a 38-week study and follow-up. *(Source: NIDA Notes. For more information, see Pharmacodynamics and Drug Action 78(5):456-467, 2005.)*

Smoke-Free Policies Don't Deter Treatment Enrollment

A New Jersey state requirement that residential addiction programs establish completely smoke-free environments and help patients stop smoking has not deterred smokers from entering treatment for other addictions, nor has it increased the number of early discharges.

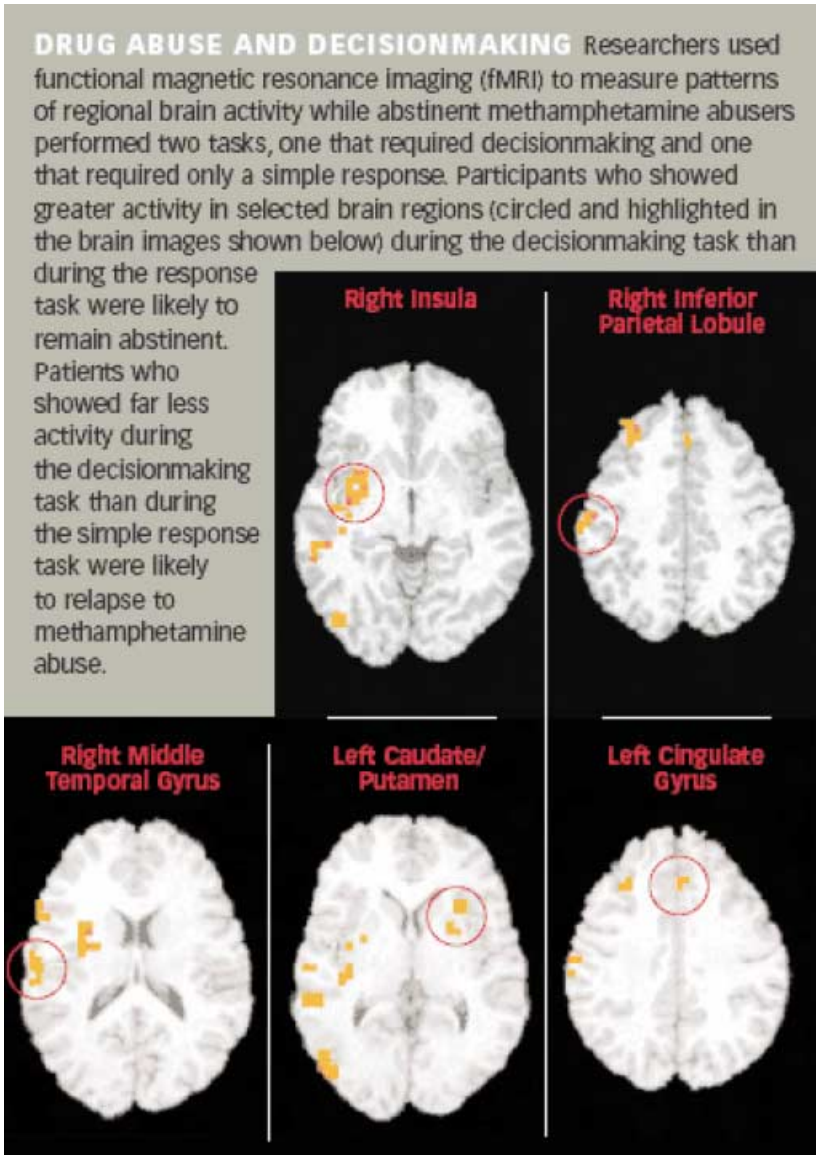
Dr. Jill Williams, Dr. Douglas Ziedonis, and their colleagues at the University of Medicine and Dentistry of New Jersey found that half of the programs had tobacco-free facilities and grounds one year after the new licensure standards went into effect. More than 90 percent of residential programs provided assessment, counseling, or education programs and materials for nicotine-dependence treatment, compared with 37 to 53 percent the preceding year.

Most patients (77 percent) smoked and most smokers (65 percent) wanted to quit or cut back. To assist patients in smoking cessation, the state funded an eight-week course of nicotine-replacement therapy and special staff training. *(Source: NIDA Notes. For more information, see the Journal of Substance Abuse Treatment 28(4):331-340, 2005.)*

BRAIN ACTIVITY PREDICTS METHAMPHETAMINE RELAPSE RISK

Investigators have shown that functional magnetic resonance imaging of the brain, combined with a psychological test, can predict with high accuracy whether an individual will relapse following treatment for methamphetamine addiction. Their study revealed a characteristic pattern of brain activity in methamphetamine-abusing men who relapsed within one to three years after completing treatment and a different pattern in men who did not.

Dr. Martin Paulus and colleagues at the University of California, San Diego, based their work on previous studies showing that poor choices made by drug abusers correlate with distinctive patterns of activity in some areas of the brain. Dr. Paulus's team hypothesized that activity patterns in those regions might also be associated with relapse to drug abuse, which involves similarly destructive decisions.



To test their hypothesis, the researchers recruited 46 men who had voluntarily entered and completed a 28-day inpatient drug treatment program after abusing methamphetamine for periods ranging from 3 to 34 years. When each man had been abstinent for about four weeks, he participated in two psychological tests. During one, he was asked to watch a computer screen and press a button every time a symbol appeared. In the other, he was asked to try to predict whether a flashing symbol would next occur on the left side or right side of the computer screen. The difference between the two tasks was that, in the first, the test-taker needed only to react to the symbol, whereas in the second, he needed to decide which side to choose. The researchers used fMRI to record the men's brain activity throughout the tests.

A year or more (360 to 967 days) after the imaging sessions, Dr. Paulus's team was able to locate and contact 40 of the 46 patients. Of the 40, 18 had relapsed to methamphetamine abuse (median time to relapse, 279 days; range, 36 to 820 days). When they compared the relapsers' fMRI results with those of the 22 non-relapsers, the researchers identified nine regions in which brain activity differed in the relapsers and non-relapsers during decisionmaking. The relapse group showed less activation of the dorsolateral, prefrontal, parietal, and temporal cortices and the insula — all regions associated with evaluation and choice among actions that may lead to either beneficial or harmful outcomes.

The patterns of brain activation predicted relapse in 17 of the 18 men who had resumed methamphetamine abuse and predicted successful abstinence in 20 of the 22 patients who had not relapsed, Dr. Paulus says. "The most striking aspect of this result is that the fMRI pattern had 90 percent accuracy in predicting outcome," Dr. Paulus adds. Other brain regions predicted the timing of relapse, he added.

The investigators note that the clinical implications of the new finding are promising, but uncertain. For example, no women were included among the participants. "It's important to confirm the findings in women, for whom social, demographic, and other factors associated with relapse may differ," Dr. Paulus points out. Nevertheless, he says that, in principle, programs treating methamphetamine abuse might use the fMRI protocol to assess patients, then assign those likelier to relapse to higher levels of care. Dr. Paulus believes such an approach might prove cost-effective, even with typical fMRI charges of up to $700 per hour in academic imaging centers. "The human and social costs of relapse are high," Dr. Paulus notes. "Using this imaging technique to precisely allocate care to the patients who need it most might well produce enough savings elsewhere to more than offset its expense. An alternative, more practical course of action might be to use these fMRI results as a benchmark for development of other assessments that are less costly, but have the same predictive strength." *(Source: Zickler P, NIDA Notes, Volume 20, Number 5, April 2006. For more information, see Paulus MP, Tapert SF & Schuckit MA (2005). Neural activation patterns of methamphetamine-dependent subjects during decision making predict relapse. Archives of General Psychiatry 62(7):761-768.)*

Highlights of ASAM's 37th Med-Sci

Physicians and other health care professionals from around the world gathered in sunny San Diego for ASAM's 37th Annual Medical-Scientific Conference to hear outstanding experts present the latest research and clinical strategies for a wide range of addiction-related topics. Chair Jeffrey Samet, M.D., M.A., M.P.H. and the Program Committee organized a diverse program that afforded multiple opportunities to interact with experts in the field.

The official opening of the conference featured an address by Rudolf H. Moos, Ph.D., Professor of Psychiatry and Behavioral Sciences at Stanford University and Senior Research Career Scientist with the Department of Veterans Affairs. Dr. Moos, who received the 2006 R. Brinkley Smithers Distinguished Scientist Award, delivered a lecture on "Common Social Factors in the Development and Remission of Alcohol Use and Other Addictive Disorders."

Other major events included special day-long symposia organized by the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the Center for Substance Abuse Treatment. A perennial favorite, the Ruth Fox Course for Physicians, marked its 25th anniversary with a very clinically focused program.

Ruth Fox Course Marks 25th Year

ONDCP Director John Walters

An address by John P. Walters, Director of the White House Office of National Drug Control Policy, was a highlight of the 25th Anniversary Ruth Fox Course for Physicians. The first Ruth Fox course was held in Seattle, Washington, in 1980. Organized by the late Maxwell N. Weisman, M.D., the course is dedicated to providing practicing physicians with cutting-edge knowledge about current trends in the field of addiction medicine.

The course, which was co-chaired by Doctors Margaret A.E. Jarvis, Louis E. Baxter, Sr., and John C. Tanner, also featured presentations by Jeffrey D. Baxter, M.D., John N. Chappel, M.D., FASAM, Lynda Hyder Ferry, M.D., David R. Gastfriend, M.D., Keith Humphreys, Ph.D., Larry M. Gentilello, M.D., FACS, Stanley E. Gitlow, M.D., FACP, FASAM, David C. Lewis, M.D., Peter A. Mansky, M.D., and James C. Montgomery, M.D.

HIV and Hep C in Drug Users

In a symposium entitled "Clinical Approaches to HIV and Hepatitis C Infections in Drug Abuse," the National Institute on Drug Abuse (NIDA) brought together an expert faculty to address clinical issues vital to addiction specialists who care for patients at risk for or diagnosed with these common infectious diseases.

Faculty members Andrea Cox, M.D., Ph.D., Brian Edlin, M.D., M.P.H., Richard Garfein, Ph.D., M.P.H., Ramesh Ganju, Ph.D., Kristy Marie Hendricks, Sc.D., Charles B. Hinkin, Ph.D., ABPP, Robert Horsburgh, M.D., Kenneth E. Sherman, M.D., Ph.D., Jack Stapleton, M.D., Ellen Tedaldi, M.D., and Terry Wright, M.D., discussed the epidemiology and pathophysiology of HIV and HCV in drug-using populations, the neuropsychiatric and psychological complications of the disorders, and promising new medications for the treatment of the addicted and infected patient. Faculty members also reviewed gaps in the knowledge base and outlined directions for future research.

The symposium was organized by Frank J. Vocci, Jr., Ph.D., and Jag H. Khalsa, Ph.D., of NIDA's Division of Medications Development. *(To order audiotapes or CD-Roms of the NIDA symposium, contact* www.dcporder.com/asam/ *and request packages 607 and 613.*

Pharmacotherapies for Alcoholism

A symposium sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) focused on "Medications Development for Alcoholism: From the Bench to the Patient." Organized by NIAAA's Mark L. Willenbring, M.D., and Raye Z. Litten, Ph.D., the symposium featured a multidisciplinary perspective on medications development, highlighting the translation of drug discoveries through preclinical testing and clinical trials to adoption in clinical practice. Specific topics included:

- The results of clinical trials of naltrexone, topiramate, ondansetron, and other promising new medications;
- New research findings on the treatment of adults and adolescents with co-occurring addictive and psychiatric disorders;
- The role of genetics in predicting treatment outcomes;
- Preclinical advances in discovering and testing novel compounds; and
- Real-world issues confronting physicians who wish to use the new medications in clinical practice.

Symposium faculty included Raymond F. Anton, M.D., Jack R. Cornelius, M.D., M.P.H., Bankole A. Johnson, M.D., Ph.D., George F. Koob, Ph.D., Henry R. Kranzler, M.D., John M. Littleton, M.D., Ph.D., Barbara J. Mason, Ph.D., and Mark L. Willenbring, M.D. *(To order audiotapes or CD-Roms of the NIAAA symposium, contact* www.dcporder.com/asam/ *and request packages 625 and 630.*

CONFEERENCE IN SAN DIEGO . . .

Treating Methamphetamine Addiction

To provide up-to-date information on methamphetamine addiction and its treatment, the Center for Substance Abuse Treatment (CSAT) brought together some of the nation's leading experts on the drug for a half-day symposium. Chaired by CSAT Director H. Westley Clark, M.D., J.D., M.P.H., FASAM, the symposium was organized by Anton C. Bizzell, M.D., Medical Director in CSAT's Division of Pharmacologic Therapies. In addition to Dr. Clark, symposium faculty included Rachel Gonzales, Ph.D., William Haning, M.D., Walter Ling, M.D., Edythe London, Ph.D., Jane C. Maxwell, Ph.D., Richard Rawson, Ph.D., and Matt Torrington, M.D. Topics addressed by the faculty included:

- The epidemiology of methamphetamine abuse;
- Methamphetamine's effects on the brain and behavior;
- Medical aspects of methamphetamine abuse;
- Methamphetamine withdrawal and its management;
- Identification and management of psychological complications;
- Psychosocial and behavioral treatments: The Matrix Model; and
- Treatment issues specific to women, adolescents, and other special populations.

A CD-Rom of materials developed for the symposium is availabe from CSAT at no charge. To request a copy, email Mimi Ghim, Ph.D., at mghim@jbsinternational.com, or telephone Dr. Ghim at 301/495-1080. (*To order audiotapes or CD-Roms of the CSAT symposium, contact* www.dcporder.com/asam/ *and request package 635.*

New CME Program a Success

A packed room greeted speakers at the debut of ASAM's new educational program on "Pharmacologic Therapies for Alcohol Dependence." Offered for the first time during the Med-Sci Conference, the program focuses on how physicians can use ASAM's *Patient Placement Criteria* to successfully integrate new pharmacologic therapies with other components of addiction care. The program was made possible by an unrestricted educational grant from Cephalon, Inc.

Faculty for the program included noted addiction researcher and educator Charles P. O'Brien, M.D., Ph.D., of the University of Pennsylvania, and Richard N. Rosenthal, M.D., director of the addiction program at New York's Roosevelt Hospital and immediate Past President of the American Academy of Addiction Psychiatry. They were joined by ASAM Criteria developers David Mee-Lee, M.D., and Gerald Shulman, M.A., FACATA. Program Chair Marc Fishman, M.D., delivered a highly interactive session. Presenters used case vignettes and an extended Q&A period to afford participants ample opportunity to interact with the faculty around real clinical concerns.

ASAM is planning to offer the program in other locations around the country. For more information or to register, visit the ASAM website at www.asam.org or contact Angela Warner at awarner@asam.org.

Abstracts to be Published

Abstracts of many of the Med-Sci presentations will be published in upcoming issues of **ASAM News**, organized by theme. Watch for the July-August issue for abstracts related to the use of buprenorphine in the treatment of opiate addiction.

Med-Sci Support Acknowledged

The following individuals and organizations graciously provided financial support and services to make possible ASAM's 2006 Medical-Scientific Conference:

- Bendiner & Schlesinger
- Bradford Health Services
- The California Society of Addiction Medicine
- The Center for Substance Abuse Treatment/SAMHSA
- Cephalon, Inc.
- COPAC, Inc.
- Dr. and Mrs. Joseph E. Dorsey
- Endo Pharmaceuticals, Inc.
- The William J. Farley Center
- Forest Pharmaceuticals, Inc.
- Hazelden & Hazelden – Springbrook
- The John P. McGovern Foundation
- Marworth Treatment Center
- Memorial Hermann Prevention & Recovery Center
- The National Institute on Alcohol Abuse and Alcoholism/NIH
- The National Institute on Drug Abuse/NIDA
- Pine Grove/Next Step
- Ridgeview Institute
- Santé Center for Healing
- Schick Shadel Hospital
- The Christopher D. Smithers Foundation
- Tyco Healthcare – Mallinckrodt, Inc.

ASAM President Elizabeth F. Howell, M.D., FASAM, presides at the Annual Awards Luncheon, where ASAM honored individuals who had made special contributions to the Medical-Scientific Conference and the field of addiction medicine.

Dr. Howell presents the John P. McGovern Award on Addiction and Society to Carlo C. DiClemente, Ph.D., Professor and Chair of the Department of Psychology at the University of Maryland. The McGovern Award honors an individual who has made "highly meritorious contributions to public policy, treatment, research, or prevention which has increased our understanding of the relationship of addiction and society."

Larry Gentilello, M.D., FACS, acknowledges receipt of the ASAM Annual Award presented to him for "expanding the frontiers of the field of Addiction Medicine and broadening our understanding of the addiction process through research and innovation." Dr. Gentilello, who is a trauma surgeon, has led the fight nationally to overturn UPPL laws and other statutory barriers to addiction care.

ASAM Past President Marc Galanter (center) congratulates Young Investigator Award winners Janet Soeffing, M.D. (left) and Hannah K. Knudson, Ph.D. (right). Dr. Soeffing and Dr. Knudson shared the 2006 award, which recognizes the best abstract submitted by an author who is within five years of receiving a doctoral degree.

Co-chairs Margaret A.E. Jarvis, M.D., Louis E. Baxter, Sr., M.D., FASAM, and John Tanner, D.O., FASAM, enjoy the success of this year's Ruth Fox Course for Physicians. The course marked its 25th anniversary in 2006.

Immediate Past President Lawrence Brown, Jr., M.D., M.P.H., FASAM (left) congratulates Peter E. Selby, M.D., FASAM, on his election as a Fellow of ASAM. Dr. Selby is one of 19 physicians elected Fellows of the Society in 2006.

Cindy Parks Thomas, Ph.D., shows off her Medical-Scientific Program Committee Award, which recognizes the submitted abstract that received the highest rating for scientific merit.

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

Barry Stimmel, M.D., FASAM, acknowledges receipt of the Annual Award for his distinguished service to ASAM, including editorship of ASAM's journal.

James W. Smith, M.D., FASAM (left) accepts the Annual Award from Dr. Howell.

Photos courtesy of ASAM Board Member and Region VI Director Thomas L. Haynes, M.D., FASAM

Treat the Condition

Opioid Dependence Is a Chronic Medical Condition

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

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

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

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

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

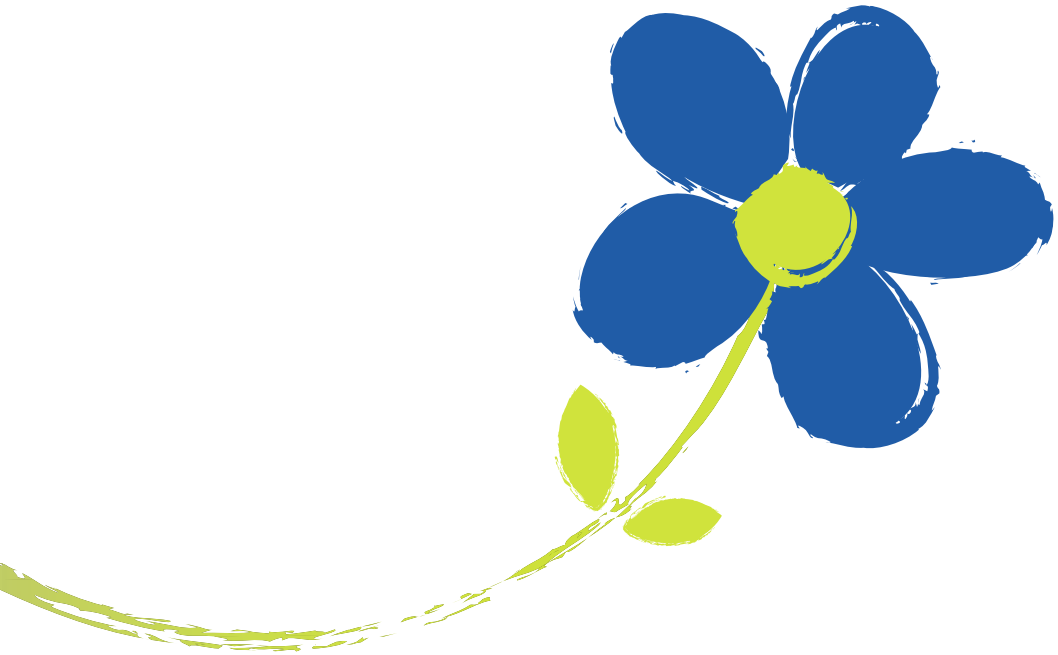
Due caution should be exercised when driving cars or operating machinery.

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

Please see adjacent Brief Summary of Prescribing Information.

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

Transform the Life



In the Privacy and Convenience of Your Office

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

Target the Biological Basis of Opioid Dependence

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

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

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

Suboxone®
(buprenorphine HCl/naloxone HCl dihydrate) C III sublingual tablets

Because Treatment Transforms Lives

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

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

WARNINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

PRECAUTIONS

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

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

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

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

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

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

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

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

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

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

Carcinogenesis, Mutagenesis and Impairment of Fertility: *Carcinogenicity.* Carcinogenicity data on SUBOXONE are not available. Carcinogenicity studies of buprenorphine were conducted in Sprague-Dawley rats and CD-1 mice. Buprenorphine was administered in the diet to rats at doses of 0.6, 5.5, and 56 mg/kg/day (estimated exposure was approximately 0.4, 3 and 35 times the recommended human daily sublingual dose of 16 mg on a mg/m^2 basis) for 27 months. Statistically significant dose-related increases in testicular interstitial (Leydig's) cell tumors occurred, according to the trend test adjusted for survival. Pair-wise comparison of the high dose against control failed to show statistical significance. In an 86-week study in CD-1 mice, buprenorphine was not carcinogenic at dietary doses up to 100 mg/kg/day (estimated exposure was approximately 30 times the recommended human daily sublingual dose of 16 mg on a mg/m^2 basis).

Mutagenicity: SUBOXONE: The 4:1 combination of buprenorphine and naloxone was not mutagenic in a bacterial mutation assay (Ames test) using four strains of *S. typhimurium* and two strains of *E. coli*. The combination was not clastogenic in an *in vitro* cytogenetic assay in human lymphocytes, or in an intravenous micronucleus test in the rat.

SUBUTEX: Buprenorphine was studied in a series of tests utilizing gene, chromosome, and DNA interactions in both prokaryotic and eukaryotic systems. Results were negative in yeast (*Saccharomyces cerevisiae*) for recombinant, gene convertant, or forward mutations; negative in *Bacillus subtilis* "rec" assay, negative for clastogenicity in CHO cells, Chinese hamster bone marrow and spermatogonia cells, and negative in the mouse lymphoma L5178Y assay. Results were equivocal in the Ames test: negative in studies in two laboratories, but positive for frame shift mutation at a high dose (5 mg/plate) in a third study. Results were positive in the Green-Tweets (*E. coli*) survival test, positive in a DNA synthesis inhibition (DSI) test with testicular tissue from mice, for both *in vivo* and *in vitro* incorporation of [^{3}H]thymidine, and positive in unscheduled DNA synthesis (UDS) test using testicular cells from mice.

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

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

Pregnancy: *Pregnancy Category C:*

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

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

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

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

Non-teratogenic effects: Dystocia was noted in pregnant rats treated *im* with buprenorphine 5 mg/kg/day (approximately 3 times the recommended human daily sublingual dose of 16 mg on a mg/m^2 basis). Both fertility and peri- and postnatal development studies with buprenorphine in rats indicated increases in neonatal mortality after oral doses of 0.8 mg/kg/day and up (approximately 0.5 times the recommended human daily sublingual dose of 16 mg on a mg/m^2 basis), after *im* doses of 0.5 mg/kg/day and up (approximately 0.3 times the recommended human daily sublingual dose of 16 mg on a mg/m^2 basis), and after *sc* doses of 0.1 mg/kg/day and up (approximately 0.06 times the recommended human daily sublingual dose of 16 mg on a mg/m^2 basis). Delays in the occurrence of righting reflex and startle response were noted in rat pups at an oral dose of 80 mg/kg/day (approximately 50 times the recommended human daily sublingual dose of 16 mg on a mg/m^2 basis).

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

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

*Sublingual solution. Doses in this table cannot necessarily be delivered in tablet form, but for comparison purposes:
"Very low" dose (1 mg solution) would be less than a tablet dose of 2 mg
"Low" dose (4 mg solution) approximates a 6 mg tablet dose
"Moderate" dose (8 mg solution) approximates a 12 mg tablet dose
"High" dose (16 mg solution) approximates a 24 mg tablet dose

OVERDOSAGE

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

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

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

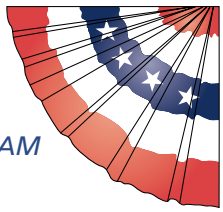
High doses of naloxone hydrochloride, 10-35 mg/70 kg may be of limited value in the management of buprenorphine overdose. Doxapram (a respiratory stimulant) also has been used.

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

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

#138274BS July 2005

Candidates Slated for ASAM Elections



Lawrence S. Brown, Jr., M.D., M.P.H., FASAM
Chair, Nominations & Awards Council

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

ASAM's Board of Directors has approved an outstanding slate of candidates for the posts of President-Elect, Secretary, Treasurer, and Director-at-Large (six to be elected). In addition, three ASAM members have submitted petitions of candidacy, as permitted by the ASAM by-laws: Donald J. Kurth, M.D., FASAM, for President-Elect; Stuart Gitlow, M.D., M.P.H., M.B.A., for Treasurer; and Lori D. Karan, M.D., FASAM, for Treasurer. (The deadline for such petitions was May 15, 2006.)

Candidates will stand for election in November 2006, for terms to begin in April 2007. The candidates are:

PRESIDENT-ELECT

Louis E. Baxter, Sr., M.D., FASAM
Richard A. Beach, M.D., FASAM
Donald J. Kurth, M.D., FASAM

SECRETARY

Peter A. Mansky, M.D.
A. Kenison Roy, III, M.D., FASAM *(incumbent)*

TREASURER

Stuart Gitlow, M.D., M.P.H., M.B.A.
Lori D. Karan, M.D., FASAM
Donald J. Kurth, M.D., FASAM *(incumbent)*
James W. Smith, M.D., FASAM

DIRECTORS-AT-LARGE (5 to be elected)

Richard A. Beach, M.D., FASAM
Stuart Gitlow, M.D., M.P.H., M.B.A. *(incumbent)*
R. Jeffrey Goldsmith, M.D. *(incumbent)*
James A. Halikas, M.D., FASAM
Merrill S. Herman, M.D.
Lori D. Karan, M.D., FACP, FASAM
Mark L. Kraus, M.D., FASAM
Donald J. Kurth, M.D., FASAM
A. Kenison Roy, III, M.D., FASAM
James W. Smith, M.D., FASAM
Penelope P. Ziegler, M.D., FASAM *(incumbent)*

OSTEOPATHIC MEDICINE DIRECTOR (1 to be elected)

Allan M. Ebert, D.O.
Scott Smolar, D.O. *(incumbent)*
John C. Tanner, D.O., FASAM

Candidates' election statements will be published in the next issue of **ASAM News.** Ballots will be mailed in October 2006 and must be returned to the ASAM office by December 1, 2006.

All ASAM members are encouraged to participate in this process, which has important implications for the future of ASAM. Any member with questions or comments about the election process should contact me through the ASAM office.

CALIFORNIA SOCIETY ISSUES RECOMMENDATIONS ON METHAMPHETAMINE

David Pating, M.D., President of the California Society of Addiction Medicine, reports that CSAM has devised a series of recommendations to help the State of California address the problem of methamphetamine abuse and addiction. The recommendations were prepared by Timmen L. Cermak, M.D., and have been reviewed and approved by CSAM's Executive Council. Dr. Pating adds that CSAM's goal in offering the recommendations is to "avoid incarceration, prolonged suffering, and the burdens on families and society caused by methamphetamine use."

Although the recommendations were written for California, Dr. Pating says they are suitable for most states. Copies of the 20-page report can be downloaded at no charge from the CSAM website at www.csam-asam.org. For more information, contact the California Society of Addiction Medicine at 575 Market Street, Suite 2125, San Francisco, CA 94105 (phone 415/927-5730 or fax 415/.927-5731). A summary of the recommendations follows:

Recommendation 1. Early Intervention

An addiction medicine — emergency medicine collaborative response is required. It should involve:

- Repeal the Uniform Accident and Sickness Policy Provision Law (UPPL) to remove insurance non-payment barriers to toxicology screening and encourage all physicians to use toxicology screening to help diagnose substance dependence.
- Require emergency physicians to order drug and alcohol screens for specific presenting problems.
- Methamphetamine-involved patients seeking emergency care should be referred to treatment.
- Clinical outreach contacts by professionals trained in brief intervention with substance abusers should be made as a follow-up to referral and should be tabulated in order to assess the aggregate level of response to clinical referrals.
- Confidentiality of test results must be guaranteed and should not prejudice insurance coverage or law enforcement action. Patterned after the public health response to infectious diseases, follow-up will offer non-punitive contact with the healthcare system while demonstrating a compassionate response to patients' suffering. *(See pages 6-7 of the full report for details of the Emergency Medicine — Addiction Medicine Collaborative Project.)*

Recommendation 2. Improve Proposition 36

- Increase funding to $209 million to account for inflation and to meet current needs.
- Increase access to opiate agonist treatment (buprenorphine and methadone maintenance).
- Stratification of courts and treatment providers by (a) introducing case outreach for no-shows and drop-outs from care; (b) introducing clinical case management of high utilizers, most especially psychotic individuals; and (c) relying on drug courts for more intensive supervision of repeat Prop 36 failures and chronic criminal recidivists, identified by UCLA as 1.6 percent of Prop 36 arrestees.
- Remove barriers to funding treatment and prescription medications for dual diagnosis participants.
- Urine toxicology testing should be directly funded by Prop 36.
- Prop 36 funds should be withdrawn from parole-based treatment. Parolees should be funded from existing Department of Corrections and parole funding sources.
- Improve central data collection and analysis. Prop 36 should fund a full-time data analyst at DADP and continuing university-based outcomes studies.

Recommendation 3. Remove Barriers to Dual Diagnosis Treatment

Current regulations restrict the use of mental health funding within substance abuse treatment programs. As a result, methamphetamine treatment programs are frequently unable to access the psychiatric services and medications required for treatment to be effective. A portion of Prop 36 funds should be earmarked to provide psychiatric assessments, management and medications to methamphetamine users in substance abuse treatment when psychosis or suicidal depression are present.

Recommendation 4. Education

Awareness and prevention campaigns directed toward high-risk populations [should address the following:]

- Physicians and other health care professionals require education about methamphetamine and the special populations involved with its use.
- Education is often the first phase of treatment, especially when substance abusers are still in denial. To be effective, public information campaigns need to be developed and delivered in ways that are meaningful to at-risk sub-populations, including women, adolescents,...men who have sex with men, [and] heterosexual males exhibiting high-risk sexual behavior.
- School-based drug education programs should be reviewed and updated with guidelines for methamphetamine-specific information geared to different grade levels.

Recommendation 5. Improve Treatment Coverage

[Insurance coverage for extended treatment should include:]

- Up to 12 months for methamphetamine users covered by CALPERS.
- Up to 12 months for adolescents covered by Medi-Cal.
- Medi-Cal should...be modified to cover residential treatment for adolescent methamphetamine users when clinically indicated.

Recommendation 6. CSAM's Blueprint for the Future: The Public Health Model

CSAM views methamphetamine as the currently popular drug that has provoked a wave of fear in the general public. Yet methamphetamine is only one of a number of drugs that present a significant public health concern. Both CSAM and the AMA view all substance dependence as a primary disease. Consistent with this view, the Little Hoover Commission 2003 Report on Addiction concludes that the best approach to reducing addiction is to provide treatment to anyone requesting treatment. CSAM is committed to advancing evidence-based treatment approaches that promote public health solutions to both the suffering of individuals and the social problems created by addictive disease. We strongly encourage all state efforts addressing substance abuse to be consistent with basic public health principles.

Texas Society Addresses Physician Health Issues

Bob Jones, M.D., President of the Texas Society of Addiction Medicine (TSAM), reports that the Texas Medical Association's House of Delegates has taken favorable action on two resolutions introduced TSAM. The first resolution called for the Texas Medical Association to study and monitor the Texas Medical Board's disciplinary actions and suggest alternatives to "overly harsh punishments for…minor and administrative violations."

The second resolution urged the Texas Medical Association to work with the Texas Medical Board to: (1) treat addiction among physicians as a disease process, (2)…resolve inequities in how the disease of addiction in physicians is treated in Texas; and (3)… develop and implement a diversion program for the treatment of addicted physicians in Texas (Res. 306).

Both resolutions were voted favorably, and were referred jointly to the TMA's Council on Scientific Affairs and Committee on Physician Health and Rehabilitation for follow-up action.

Pennsylvania Society Urges State to Eliminate Treatment Obstacles

On behalf of the Pennsylvania Society of Addiction Medicine, President-Elect Adam J. Gordon, M.D., M.P.H., has asked Pennsylvania Secretary of Health Calvin Johnson, M.D., to change the state's requirements for licensure of alcohol and drug treatment programs to facilitate the use of buprenorphine in the treatment of opioid addiction.

In a letter to Secretary Johnson, Dr. Gordon explains that existing state regulations restrict the use of buprenorphine to treatment programs that are licensed to use methadone. Even facilities that intend to treat patients only with buprenorphine must obtain such a license. Dr. Gordon explains that this requirement is contrary to the intent of the federal Drug Addiction Treatment Act of 2000 (DATA 2000), which specifically allows the use of buprenorphine by licensed and credentialed physicians in both inpatient and outpatient settings. The only restriction imposed by the federal legislation is that appropriately licensed and credentialed physicians treat no more than 30 patients at any given time.

Dr. Gordon points out that current Pennsylvania regulations — which were written in the 1960s and revised in the 1990s — circumvent that the intent of DATA 2000 and ignore scientific advances that facilitate the treatment of opioid-dependent patients. This has a particularly adverse effect on "poor and vulnerable patients," he says. For example, they require patients to consult one physician for their buprenorphine treatment and a different physician for the balance of their medical care, causing undue expense and leading to unnecessary fragmentation of care.

To correct the problem, Dr. Gordon asks that Pennsylvania regulations be revised so that physicians who are properly credentialed by the federal government under DATA 2000 are allowed to provide buprenorphine treatment in any drug and alcohol treatment facility in the Commonwealth. He concludes: "We hope this issue can be addressed expediently to solve the problem of the disparity between the need for treatment of opioid dependent patients and the ability of the Commonwealth to efficiently and adequately meet that need. We would be more than happy to meet with you or your designee personally regarding these concerns."

State Leadership Needed to Improve Addiction Care

State Governors and lawmakers need to assert leadership to ensure that addiction treatment and prevention services are effective, coordinated, accountable, and delivered by trained staff, according to experts who testified at a pair of public hearings convened by the Join Together organization, based at the Boston University School of Public Health. Government-funded programs provide most of the addiction treatment and prevention services in the U.S., and states are in the forefront of efforts to prevent and treat alcohol and drug problems. Who should lead this effort at the state level and how government entities and services can best be structured were frequent themes of testimony to the Blueprint for the States Policy Panel.

The hearings come as many states have dismantled their formerly independent alcohol and drug agencies, moving responsibility for treatment and prevention into mental health, public health, or even child welfare departments. Suzanne Gelber, Ph.D., of the Avisa Group, co-author of a recent report on state alcohol and drug agencies, testified that many state agencies "tend to be stepchildren in reorganizations." She noted that just four states — Connecticut, New York, Ohio, and South Carolina — have a cabinet-level agency devoted specifically to addiction prevention and treatment. Her report concluded that the "need for interagency collaboration is greater for substance abuse agencies than for almost any other health or human services agency, because virtually every government agency has clients with overt or hidden substance abuse disorders that complicate their lives and hence affect the other services' use, costs and effectiveness."

Dr. Gelber added that state agencies also need the support — and ear — of the Governor and/or legislature. "Without it, the agency drowns," she said, regardless of where the agency is housed. Florida drug czar Jim McDonough agreed, explaining: "Location is a big part of authority.... I sit 50 feet from the governor. I don't see him very often, but people think I do."

Some testifiers, such as Kathryn Jett, Director of the California Department of Alcohol and Drug Programs, said that a single state agency (SSA) for substance use disorders is essential to coordinate services and programs. But Dave Wanser of the Texas Commission on Alcohol and Drug Abuse (once independent but now merged with the state health and mental health departments), disagreed, saying that the merger of his agency had given the State a "true public health viewpoint" on addiction that it previously lacked. Pamela Hyde, secretary of the New Mexico Human Services Department, supported that point of view. Ms. Hyde, who oversees an interagency Behavioral Health Collaborative that involves leaders inside and outside government in developing alcohol and other drug policy, said: "All agencies have to work together. We need a single *state* response, not a single state *agency* response."

Ironically, these changes come at the same time that States and providers face increased calls for accountability — notably from the Federal government, the single largest funder of addiction treatment and prevention services. Witnesses repeatedly endorsed the concept of using permanent advisory groups, policy-review committees, and other methods to fuel cross-agency collaboration. *Source: Adapted from Bob Curley, "State Leadership Needed to Improve Addiction Treatment, Prevention," JoinTogether Online, February 24, 2006.*

AMA HOUSE ACTS ON PATIENT PRIVACY, OTHER ISSUES

Stuart Gitlow, M.D.
ASAM Representative to the AMA House of Delegates

Over the course of recent meetings, members of the American Medical Association's House of Delegates have concluded that privacy and confidentiality of personal health information are gradually being eroded, helped along by HIPAA and other legislation thought by many to be protective but actually responsible for reductions in true privacy. In the addiction field, our patients have been protected by stringent federal law (e.g., CFR 42), but those protections often are overlooked, particularly by those who treat addictive disorders part-time and those who incorrectly believe that HIPAA's weaker privacy clauses apply to the treatment of patients with addictive disorders.

From recent developments, it is clear that all physicians are about to feel tremendous pressure from government and third party payers to move to electronic medical records. You will be told that your office will become more efficient, that you will be able to spend less time on charting and more time on patient care, and that your billable hours will increase. However, the true gains associated with electronic medical records will go to third party payers, which will be able to collate key data elements from each patient's electronic medical record and use it for a variety of commercial applications. Clearly, there is potential value here from a public health perspective, but there also are many commercial uses of such heretofore private data, including carve-out recommendations, marketing campaigns, and data storage.

Several states are beginning to make recommendations to their physicians as to electronic medical record vendors, but such recommendations often are influenced by groups that represent third party payers rather than physicians in private practice. (My personal perspective on this issue is somewhat complex, as I have long been an advocate for better use of technology in medicine. However, I also have become quite wary of the potential pitfalls in such technologies, as well as the relative preponderance of problems over benefits for individuals patients.)

Prodded by the House of Delegates, the AMA is beginning to explore its role in this arena. While it is somewhat late to enter the field, the organization has been fortunate to miss the jumbled inventory of organizations and faux-organizations that have been raising their voices about electronic patient data collection. That field has now started to coalesce and needs leadership from organized medicine. Accordingly, the AMA has been asked to explore the development of a claims data warehouse for physicians, as well as to develop principles to guide data collection, warehousing, and use of electronic medical record information and claims data by third parties. As a result, over the coming years, the AMA will be defining members' needs related to adoption of health information technology, identifying its role in the field, conducting focus groups with physicians, and participating in discussions with vendors to determine their ability to protect the integrity and safety of patient data. This is an area we need to closely monitor, especially in view of the special vulnerabilities and needs of our patients with addictive disorders.

OTHER ISSUES AT AMA MEETINGS

In addition to patient privacy, the AMA's House of Delegates has enacted a number of policies of interest to ASAM members:

- The House of Delegates has approved a policy that federal, state, and local tax rates on alcohol should be based on the grams of ethanol present, rather than on the fluid volume of beer, wine, or distilled spirits.
- The AMA will support a public awareness campaign devised by the National Council on Alcoholism and Drug Disorders (NCADD) to overcome public misperceptions concerning the origins and treatment of substance use disorders.
- The AMA will actively support legislation to ban smoking in all workplaces.
- The AMA will work to end the exclusion of benzodiazepines from Medicare reimbursement. (This arbitrary policy has its origins in the personal beliefs of a Congressional staffer and never has been supported by any scientific evidence.)
- The AMA will initiate discussions with the Motion Picture Association of America of data showing a correlation between smoking in the movies and increasing rates of teen smoking.
- The AMA will encourage the government of Guam to support age 21 as the minimum drinking age and the imposition of comprehensive smoke-free public places within the territory.

Obviously, the majority of these policies are supportive rather than directive. In recent years, the AMA's focus has been on issues such as tort reform, privacy, and violence. Often, issues related to addictive disease have garnered general support but few of the dollars necessary to drive legislative implementation. Fortunately, ASAM has increased its own visibility on Capitol Hill, where our delegation has focused increasingly on building AMA support for ASAM policies. This allows us, when walking the Hill, to speak of ASAM's own policies and the broad support they have obtained from the rest of the house of medicine.

Thanks go to Drs. Lloyd Gordon, Michael Miller, and Brian Hurley for their hard work on behalf of ASAM at the AMA's semiannual meetings. The next meeting of the House of Delegates is scheduled for November 2006 in Las Vegas. ASAM members who are in the area are welcome to lend a hand. Your input is crucial to assisting your delegation as it pursues ASAM's policy interests within the AMA. Please contact me at drgitlow@aol.com with any suggestions, questions, or comments. We also are interested in adding medical students, residents/fellows, and young physicians (those under 40 or in their first five years of practice) to our delegation.

ADDICTION TREATMENT: Pharmacotherapies At Last

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

Historically, addiction treatment has been primarily "talk therapy" between a concerned other (spouse to spouse), a sponsor to a newcomer, or a therapist engaged in one-to-one counseling. Over the years, such therapy has evolved to include structured individual and group therapy, found originally in therapeutic communities, then refined and redefined in residential facilities, and finally adapted for outpatient care in individual and group sessions. Such talk therapy has been augmented with psychosocial and psychological approaches, leading to the development of more elaborate and scientifically tested modalities such as cognitive behavioral therapy (CBT) and motivational enhancement therapy (MET). Evidence-based studies of these newer psychotherapeutic modalities consistently show efficacy over the older versions of "talk therapy." But many patients were unable to gain or maintain recovery from their illnesses. As a result, practitioners in other medical specialties have regarded addiction treatment and its practitioners as somewhat suspect (even though rates of recovery for many disorders are in the same range as those for addiction treatment!).

But with the advent of pharmacotherapies for addiction, all that has changed. As a result of research supported by the National Institute of Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and other public and private funders, we now understand the neurologic, metabolic and physiologic aspects of addiction in ways that allow the development of new and efficacious medications. In rigorous testing, such pharmacotherapies have been shown to improve the treatment outcomes of patients suffering from addictive disease. Even more refined medications are being developed and await FDA approval, which should considerably increase the arsenal so that particular agents can be matched to specific patient's needs. (ASAM is contributing to this advance through the work now under way to develop a series of supplements on pharmacotherapies to the ASAM Patient Placement Criteria.)

Another key development is our current understanding of the effects of co-occurring psychiatric and medical disorders. At one time, hardly anyone considered the effects of such co-occurring disorders on patient outcomes, or understood the necessity of simultaneous recognition and treatment of all identified disorders. Even when attempts were made to treat the psychiatric disorders with the medications that were available at the time, the results were sometimes disastrous. In fact, in early addiction treatment, the use of any psychoactive substance was frowned upon, as total abstinence was the prescription for any and every problem that was related to substance use. It is now clear in hindsight why the outcomes were not very good.

Today, addiction medicine and addiction treatment are at the edge of a new and exciting plateau. Thanks to advances in scientific knowledge, and the attending development of sophisticated pharmacotherapies, the specialty of addiction medicine is finally taking its place alongside other medical specialties that have a defined body of scientific knowledge and evidence-based treatments for specific medical conditions. This is an exciting time to practice addiction medicine, indeed!

Dr. Madras Appointed to ONDCP Post

Dr. Bertha Madras

President Bush has appointed Bertha Madras, Ph.D., to the post of Deputy Director for Demand Reduction in the Office of National Drug Control Policy (ONDCP). There, Dr. Madras oversees the implementation of the President's prevention and treatment policies and programs, including Access to Recovery (ATR), student drug testing, and screening, brief intervention, referral and treatment (SBIRT).

In announcing the appointment, John P. Walters, Director of National Drug Control Policy, said, "Dr. Madras brings a wealth of knowledge to ONDCP through her extensive work as a researcher and professor. Her commitment to studying the disease of drug addiction and substance abuse will be a great help to our work at ONDCP. I am eager for Dr. Madras to join the Administration's anti-drug efforts, where we can make use of her expertise to enhance and aid the work of prevention and treatment efforts throughout the country."

Prior to her appointment, Dr. Madras was a Professor of Psychobiology in the Department of Psychiatry at Harvard Medical School and chair of the Division of Neurochemistry at the New England Primate Research Center. In addition, Dr. Madras has served on several important advisory boards, including the Molecular Neuropharmacology and Signaling Review Committee of the National Institutes of Health and the Medications Development Scientific Advisory Board of the National Institute of Drug Abuse. She is widely known as a lecturer on how drugs affect the brain. Her research portfolio includes work on cocaine, Ecstasy, and cannabinoids.

Dr. Fleming Named to IOM Committee

Dr. Michael Fleming

Addiction expert Michael F. Fleming, M.D., M.P.H., has been elected to membership in the Institute of Medicine of the National Academy of Sciences. He thus joins 1,460 experts in every field of medicine to be so honored by the IOM, which serves as a national resource for independent analysis and recommendations on issues related to medicine, biomedical sciences, and health.

IOM members make a commitment to involve themselves in the work of the Institute, which conducts studies and other activities addressing a wide range of issues in medical science, health services, public health, and health policy. Current IOM studies include an evaluation of the nation's system for ensuring the safety of prescription drugs after they have reached the market, and an assessment of contributions of the behavioral and social sciences toward preventing and reducing motor vehicle crashes involving youth.

The election recognizes Dr. Fleming's many professional achievements. For example, as Professor of Family Medicine at the University of Wisconsin Medical School, Dr. Fleming has developed a highly productive research program focused on the prevention and treatment of alcohol and drug use disorders. He also is Director of an NIH-funded postdoctoral research fellowship in the Department of Family Medicine, is a primary mentor for a number of faculty and fellows, and directs the pain consultation service and the inpatient addiction medicine consultation service at the University of Wisconsin Hospital.

Dr. Fleming has been a principal investigator on 13 NIH grants, and currently serves as PI on an NIH-funded study to test the efficacy of methylphenidate for the treatment of ADHD in children who also meet criteria for fetal alcohol spectrum disorder (FASD). The long-term goal of this research is to increase the ability of children with FASD to learn and succeed as independent adults. In addition to his teaching and research responsibilities, Dr. Fleming has published a number of seminal articles on primary care treatment of alcohol use disorders, with a special focus on the treatment of alcohol problems in women and older adults.

DR. GOLD RECEIVES NAATP AWARD

Dr. Mark Gold

ASAM member Mark S. Gold, M.D., has received the 2006 Nelson J. Bradley Lifetime Achievement Award from the National Association of Addiction Treatment Providers (NAATP). The award, which recognizes Dr. Gold's 30-year career as a researcher and educator, was presented in May during NAATP's annual meeting by John Schwarzlose, President and CEO of the Betty Ford Center in Rancho Mirage, California.

Dr. Gold is Distinguished Professor of Psychiatry, Neuroscience, and Community Health & Family Medicine at the University of Florida College of Medicine, where he also is affiliated with the McKnight Brain Institute. In addition, he is Chief of the Addiction Medicine Division in the Department of Psychiatry and holds the department's Associate Chair for Education.

Although he is a prominent researcher, Dr. Gold's first interest is training addiction professionals. At the University of Florida, he teaches functional neuroanatomy in the first year neuroscience course for medical students, and has an active role in the internal medicine, family medicine and psychiatry modules. Also under Dr. Gold's leadership, all medical students at the University of Florida are required to complete a two-week mandatory rotation in the clinical addiction medicine program.

Dr. H. Westley Clark

PROFILE OF CSAT DIRECTOR H. WESTLEY CLARK, M.D.

A recent press report profiled ASAM member H. Westley Clark, M.D., J.D., M.P.H., FASAM, who directs the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration. The article, which highlights Dr. Clark´s views on why youth turn to alcohol and drugs and what adults and the community can do to help them, is reprinted here by permission of *The Washington Post.*

Adults Must Stop Backing Up When Teens Need Them Most

Courtland Milloy

H. Westley Clark is a doctor and a lawyer — no small accomplishment for a black guy who grew up poor in Detroit. He could have gone on to make plenty of money, no doubt, and never looked back. But he couldn't forget where he came from or ignore the devastated lives of those left behind.

Clark, 59, is director of the Center for Substance Abuse Treatment at the U.S. Department of Health and Human Services. That position gives him a unique perspective on one of the most serious problems ever to plague black America.

"From the ages of 18 to 25, our kids go from being below the national average when it comes to crime and substance abuse to being above the national average," Clark said during a recent interview at his office in Rockville. "There are certain things in our community that seem to be working until that kid reaches 16 or 17. Then all of a sudden, their involvement in crime and substance abuse shoots up. So what happens? What in our community suddenly disappears?"

To put it bluntly: Us. Confronted by teenagers eager to be grown-ups — big kids with "ants in their pants," as Clark calls them — parents, teachers and community leaders alike begin to back away, often out of fear, and then expect them to become responsible adults all by themselves. And when some of them fall short and turn to drugs to ease the pain of failure, those same adults profess to be shocked at their behavior and ashamed of them.

Of course, African-Americans are not the only group affected by substance abuse. The scourge of rural white America, for instance, is methamphetamine. And the abuse of prescription drugs continues to rise among the affluent of all races. But African-Americans are uniquely at risk, with alcohol and drugs fueling rates of AIDS, homicide and incarceration that are the highest in the country. In the District, for instance, one in 20 residents is infected with HIV, the virus that causes AIDS. About one in 10 — an estimated 60,000 men, women and teenagers — is addicted to alcohol or drugs. "Substance abuse undermines the future and potential of all kinds of people," Clark said. "But let's face it: We are losing a generation of African-Americans."

Clark could easily have been lost to the streets. But his parents, neither of whom finished elementary school, made sure that he and his three brothers understood the importance of education. All went to college and paid their own way. Clark graduated from the University of Michigan Medical School and Harvard Law School. He spent three years as a health policy expert on Capitol Hill and then worked 12 years as an addiction psychiatrist at a community health clinic in San Francisco. He came to DHHS in 1998.

"People say poverty keeps us from doing the right thing, but we must be careful with the rationalizations. That's the message of the snake oil salesmen," Clark said. "People are trying to achieve a modicum of comfort through illegal drugs, when some things they'd be able to endure through faith, recreational activities and a change in world view, which would allow them to amass the resources necessary to get out of poverty."

Clark's office oversees millions of dollars in block grants that go to health agencies and community groups across the country. A variety of approaches to treatment get support; no "one size fits all." But government aid alone is not the answer, he said. Responsibility for recovery lies not just with the addict or treatment center but with the entire community. "Who in the environment is telling the kid that it's not okay to get high?" he asked. "Who is sending the message that says, 'You can count on me not to give you a beer or marijuana?' The community has to reinforce abstinence. Everybody's got to be responsible."

He added: "My days are numbered; I'll be 60 soon. So you have to think: Who are you going to pass the baton to? You don't just pass the baton to your immediate family. You pass it to the community, and if the community embraces the concepts of education, training, skill development and safety, then everybody benefits, and the future is assured."

As Clark sees it, denial and neglect must give way to integrity and courage. That prescription might strike some as a bitter pill to swallow. Or it might be sweet salvation, especially considering the alternative. *Source: Milloy C (2006). Adults must stop backing up when teens need them most. The Washington Post, March 15, page B-1.*

Ruth Fox Memorial Endowment Fund

Dr. Ruth Fox

Dear Colleague:

The 2006 Ruth Fox Donor Reception, held during ASAM's Medical-Scientific Conference in San Diego, honored the generosity of those who have made donations to the Fund. As in years past, the cost of the reception was underwritten by a generous gift from ASAM member Joseph E. Dorsey, M.D., and Mrs. Dorsey.

The Reception also afforded an opportunity to recognize the accomplishments of this year's recipients of the Ruth Fox Scholarships, given to an outstanding group of physicians -in-training. The scholarships cover travel, hotel and registration expenses for recipients to attend the Med-Sci Conference and Ruth Fox Course, as well as one year's free membership in ASAM. The four scholarship recipients for 2006 are Kathleen Ang-Lee, M.D. (Seattle, Washington), Katrina Ball, D.O. (Loma Linda, California), Norana Irene Caivano, M.D. (West Hollywood, California), and Mark Hrymoc, M.D. (Harbor UCLA Medical Center, Los Angeles). All told, 24 such scholarships have been awarded.

The Ruth Fox Memorial Endowment Fund was established to assure ASAM's continued ability to provide ongoing leadership in newly emerging areas affecting the field of addiction medicine, to continue its commitment to educating physicians, to increasing access to care and to improving the quality of care. With the professional and financial support of ASAM's members and friends, the Fund will achieve its mission.

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

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

Claire Osman
Director of Development

Florida physician and philanthropist Joseph E. Dorsey, M.D., FASAM, welcomes guests to the Ruth Fox Memorial Endowment Fund Reception. A traditional highlight of Med-Sci, the reception honors donors to the Fund. As in years past, Dr. and Mrs. Dorsey underwrote the cost of the reception.

ASAM President-Elect Michael M. Miller, M.D., FASAM (center), and President Elizabeth F. Howell, M.D., FASAM (right) congratulate Dr. Joseph E. Dorsey (left) on the success of this year's Ruth Fox Memorial Endowment Fund reception.

ASAM's Director of Development Claire Osman and Ruth Fox Fund Chair Max A. Schneider, M.D., FASAM, take a moment to enjoy the reception.

Photos courtesy of ASAM Board Member and Region VI Director Thomas L. Haynes, M.D., FASAM

ASAM Staff & Consultants

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

Berit Boegli
Conferences &
Meetings Consultant
BBOEG@ASAM.ORG

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

Janet Brownell
Program Development Manager
JBROWNELL@ASAM.ORG

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

Valerie Foote
Data Entry Operator
VFOOT@ASAM.ORG

Joanne Gartenmann
Consultant
JGART@ASAM.ORG

Tracy Gartenmann
Director of PCSS &
Buprenorphine Training
TGART@ASAM.ORG

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

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

Gionne Graetz
Program Development Manager
GGRAETZ@ASAM.ORG

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

Lynda Jones
Director of Finance
LJONE@ASAM.ORG

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

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

Noushin Shariate
Accounts Payable
NSHAR@ASAM.ORG

Angela Warner
Program Development
Manager
AWARNER@ASAM.ORG

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

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

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

Hoag Memorial Hospital Presbyterian
Chemical Dependency Services

Immediate Opening:
Medical Director, Chemical Dependency Services

One of a kind opportunity affiliated with Hoag Memorial Hospital Presbyterian
Providing world-class medical care

Located on the bayside bluffs overlooking the beautiful Newport Beach harbor, Hoag Hospital is a 511-bed, not-for-profit acute care hospital that remains one of the most respected healthcare providers in Southern California. Fully accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and designated as a Magnet hospital by the American Nurses Credentialing Center (ANCC), Hoag offers a comprehensive mix of healthcare services, including Centers of Excellence in cancer, heart and vascular, neuroscience, orthopedics and women's health services.

Hoag is the preferred workplace of Orange County's most skilled medical team because it offers unparalleled teamwork, compassionate care and a progressive environment where the latest advances in medicine are constantly being introduced.

Hoag Hospital Chemical Dependency Services is looking for a Medical Director who is a Board Certified Physician with at least 5 years experience in Addiction Medicine and ASAM Certification.

For consideration submit your cover letter and CV to Linda May, Director, Physician Support Services
Email: Linda.May@HoagHospital.org, Fax: 949/764-5933

For more information on Hoag Hospital, visit www.HoagHospital.org

HOAG® HOSPITAL
NEWPORT BEACH • CA

ASAM Conference Calendar

ASAM

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

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

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

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

OTHER EVENTS OF NOTE

July 6-8, 2006
European Association of Addiction Therapy
Second Annual Conference
Central Hall Westminster
London, England
To register, visit: www.eaat.org

July 9-12, 2006
Forging Our Future — Meeting the Challenges of Leadership:
First SAAS National Conference for Executives and Senior Managers in Addiction Services
Sponsored by the State Associations of Addiction Services (SAAS)
Westin Michigan Avenue Hotel,
Chicago, Illinois
To register, visit: www.saasnet.org

July 12-14, 2006
National Conference on Women, Addiction and Recovery:
News You Can Use
Sponsored by the Center for Substance Abuse Treatment, in partnership with NIDA and NIAAA
Anaheim, California

[Note: There is no registration fee for this conference. Space is limited and registrations will be accepted on a first-come, first-serve basis.]
To register, visit: http://conferences.jbs.biz/womensconference

November 2-4, 2006
Association for Medical Education and Research in Substance Abuse
30th Annual National Conference
Washington, DC

[Note: NIAAA has funded 20 scholarships for individuals who would be attending an AMERSA conference for the first time. Applicants must be health professional educators or researchers who are conducted alcohol-related research or are interested in the field. They must be providing training or research to underserved populations such as Latinos, African-Americans, or women. For more information, email Isabel@amersa.org or phone 401/349-0000.]

BUPRENORPHINE TRAINING

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

August 2, 2006
Minneapolis, MN
Sponsored by ASAM.

September 7, 2006
San Francisco, CA
Sponsored by ASAM &
the California Medical Association

September 7, 2006
San Francisco, CA
Sponsored by ASAM &
the California Medical Association

October 27, 2006
New York, NY
Sponsored by ASAM

December 3, 2006
Anaheim, CA
Sponsored by ASAM

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

EDITOR-IN-CHIEF
Journal of Addiction Medicine

A nationwide search is under way to identify the founding Senior Editor-in-Chief for the new ***Journal of Addiction Medicine (JAM).*** The new journal, which is to be the official medical-scientific publication of the American Society of Addiction Medicine, will be published by Lippincott, Williams & Wilkins, a Wolters Kluwer subsidiary.

JAM will be the new voice of addiction medicine, with a distinctive look and feel. It will be dedicated to the dissemination of scientific, clinical, and policy advances worldwide. The following assets will establish a leadership role for *JAM* in the scientific and medical literature:

- ★ *JAM* will be the official journal of the world's largest addiction medicine society.
- ★ *JAM* will have a base subscribership of more than 3,000 ASAM members — the largest reader base of any journal of addiction medicine.
- ★ *JAM* will be distributed to a readership that includes the largest group of researchers, educators and master clinicians in addiction medicine.
- ★ *JAM's* readership includes international thought leaders, governmental policymakers and field decisionmakers.
- ★ *JAM* will have ongoing relationships with a large cohort of internationally renowned scientists who participate annually in ASAM's conferences.
- ★ *JAM* will have a steady stream of presentation material from the symposia, plenary sesions, workshops and syllabi of ASAM's many scientific and educational conferences.
- ★ *JAM* will have access to the management and marketing resources of one of the world's leading medical publishers.
- ★ *JAM* will have editorial independence. While operating under the oversight of ASAM's Board of Directors, it will be independent of direct operational involvement in editorial decisions.
- ★ *JAM* will have an opportunity to highlight major papers from the ***Journal*** in ASAM's widely-distributed newsletter, ***ASAM New.***
- ★ *JAM* will have an opportunity to innovate in the realm of electronic media and multi-publication integration with the Society's other leading products, including the widely used ***ASAM Patient Placement Criteria*** and the comprehensive text, ***Principles of Addiction Medicine.***
- ★ *JAM* will have access to the new electronic information services operated by Wolters Kluwer, including the widely-used OVID bibliographic retrieval service.

Leaders in the field of addiction medicine are invited to submit their candidacy for this position. Letters expressing interested should be addressed to Eileen McGrath, J.D., ASAM Executive Vice President/CEO, and submitted by July 31, 2006. Letters may be submitted by email (emcgrath@asam.org; subject line: Journal), fax (301-656-3815; Attn: Journal), or mail (ASAM, 4601 No. Park Ave., Suite 101 Upper Arcade, Chevy Chase, MD 20815). Letters of interest will be treated as confidential.