Year-End Double Issue 2006/2007
Volume 21, Number 6 & Volume 22, Number 1

ASAM News

Newsletter of The American Society of Addiction Medicine

Inside

See pages 5-9 for profiles of ASAM's newly elected Officers and Board members!

WWW.ASAM.ORG

Election Results in This Issue!

ASAM's 38th Med-Sci Conference to Convene in Miami

Addiction medicine practitioners, educators and researchers will gather in Miami, Florida, April 27-29th for ASAM's 38th Annual Medical-Scientific Conference. The conference welcomes ASAM members as well as non-member physicians, nurses, psychologists, counselors, students and residents. It features three full days of clinical and scientific offerings, as well as ASAM's annual Business Meeting on Friday morning, April 27th.

The Med-Sci Conference is preceded by the Ruth Fox Course for Physicians and ASAM's course on Pain and Addiction — Common Threads VIII, both scheduled for Thursday, April 26th. Educational activities conclude on Sunday, April 29th with a Buprenorphine Training Course. All the events take place at Miami's Marriott Doral Resort and Spa.

For additional information or to register, visit the ASAM website at **WWW.ASAM.ORG** or contact ASAM's Department of Meetings and Conferences at 301/656-3920. *(See pages 14-15 and 32 for more education and training opportunities.)*

ASAM Board to Consider Avenues to Specialty Status

ASAM's Board of Directors has appointed a Medical Specialty Action Group to "develop a knowledge base and recommend actions to the ASAM Board regarding recognition of Addiction Medicine as a physician specialty by the American Board of Medical Specialties (ABMS)." The Action Group, co-chaired by ASAM President-Elect Michael M. Miller, M.D., FASAM, FAPA, and Chapters Council Chair Kevin Kunz, M.D., M.P.H., FASAM, held its inaugural meeting December 1-2, 2006, at the Hazelden Foundation, Center City, Minnesota. Dr. Miller and Dr. Kunz report that the Board's action is prompted by members' growing concern that too few physicians are appropriately trained to diagnose and treat patients with alcohol, nicotine and other substance use disorders. Moreover, surveys show that most patients and their families are uncertain as to how to identify a physician who can help them with such a disorder.

ASAM has offered a certifying examination in Addiction Medicine for more than 20 years and, through that process, has certified more than 3,800 physicians. However, this certification process is not currently recognized by the ABMS.

The Action Group will review the ABMS requirements for recognition of certifying boards, as well as the requirements of the Accreditation Council for Graduate Medical Education (ACGME) for accrediting programs to provide advanced training. Their findings will be summarized in a report that is to be submitted to the ASAM Board at its April 2007 meeting. In the report, the Action Group is expected to outline the requirements for achieving recognition of Addiction Medicine and to describe the specific steps and costs ASAM must undertake if it decides to pursue formal recognition by ABMS. *(For more information, see page 4 of this issue, as well as the March-April* **ASAM News**.)

Eileen McGrath, J.D.

ASAM, PCSS Project Support New Buprenorphine Cap

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

The Physician Clinical Support System (PCSS), an ASAM-coordinated mentoring network for physicians who use buprenorphine in office-based treatment of opioid dependence, is a valuable resource for physicians who plan to treat more than 30 patients under the newly expanded buprenorphine treatment limits *(see the related news report on page 3).* Funded by the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration, the PCSS is operated by ASAM and a consortium of cosponsoring organizations.

A key resource is the PCSS "warm line" (877/630-8812), which provides a national system of telephone triage by registering participating physicians and matching them with an appropriate mentor within 48 hours. The warm line fields approximately 25 inquiries a week from physicians who seek general information about buprenorphine. It also provides an important referral service by engaging physicians in the PCSS mentoring network and directing them to the SAMHSA buprenorphine website and information service. Other resources provided through the PCSS include clinical guidances on the following topics:

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

The guidances are available free of charge through the PCSS website (WWW.PCSSMENTOR.ORG), as is the PCSS listserv, which allows users to share information about clinical best practices.

Outcomes data on the PCSS, which now serves more than 1,400 physicians in all 50 states and Puerto Rico through 70 training mentors, show that the system is having a positive impact on access to buprenorphine treatment by helping physicians incorporate such treatment into their practices. As a result, the PCSS project was cited favorably during a Capitol Hill press conference hosted by Senator Carl Levin (D-MI) to mark the anniversary of the DATA 2000 Act, which reversed many years of legal limitations by allowing physicians to treat opioid addiction in office-based settings.

To access the PCSS, to find or become a mentor, or for additional information, phone 877/630-8812, email PCSSPROJECT@ASAM.ORG, or visit WWW.PCSSMENTOR.ORG.

JOIN THE PCSS!

The Physician Clinical Support System (PCSS), a national mentoring network offered free of charge to physicians treating opioid dependence, is a service supported by SAMHSA and coordinated by ASAM to help physicians implement buprenorphine in their practices. To learn more, visit WWW.PCSSMENTOR.ORG or call 1-877/630-8812.

ASAM Dues Structure to Change

ASAM's Membership Department has announced that national membership dues will change in 2007 for members in the following categories:

- Regular membership will be $300 (was $290)
- Resident membership will be $35 (was $70)
- Medical student membership will be $0 (was $20)

A renewal notice will be mailed to all members in October 2006, and dues are payable by January 1, 2007.

For more information, contact the ASAM Membership Department at 301/656-3920.

American Society of Addiction Medicine
4601 North Park Ave., Suite 101
Chevy Chase, MD 20815

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

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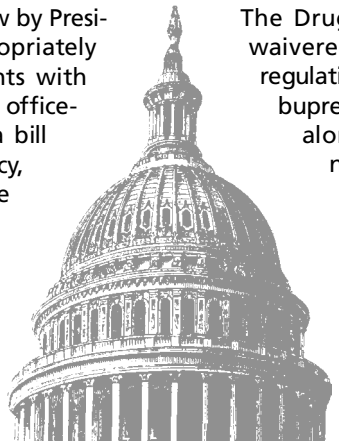
Advertising
Advertising rates and schedules are available on request. Please direct inquiries to the Editor at 410/770-4866 or email ASAMNEWSLETTER@AOL.COM.

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).

CONGRESS RAISES CAP ON BUPRENORPHINE TREATMENT



Legislation passed by Congress and signed into law by President Bush in December 2006 will allow appropriately credentialed physicians to treat up to 100 patients with buprenorphine and buprenorphine with naloxone in office-based settings. The measure, which was part of a bill reauthorizing the Office of National Drug Control Policy, more than triples the previous limit of 30 patients. (The original 30-patient limit, which applied to both individual physicians and practice groups, was set by the Drug Addiction Treatment Act of 2000. The Congress changed the limit to 30 patients per certified physician in July 2006.)

Specifically, the new law amends the federal Controlled Substances Act to allow qualified physicians to treat up to 100 patients for opioid addiction with drugs in CSA Schedules III, IV or V that are specifically approved for this indication by the U.S. Food and Drug Administration. At present, buprenorphine (Subutex®) and buprenorphine with naloxone (Suboxone®) are the only drugs that have received such approval.

To prescribe buprenorphine in the office-based treatment of addiction, physicians must be federally ***certified*** and hold a waiver from the Drug Enforcement Administration. To obtain a waiver, the physician must notify the Center for Substance Abuse Treatment (CSAT, a component of the Substance Abuse and Mental Health Services Administration) of his or her intent before beginning to prescribe or dispense buprenorphine. The Notice of Intent must contain information on the physician's qualifying credentials, as defined in the law, and additional certifications, including evidence that the physician has the capacity to refer buprenorphine patients for appropriate counseling and other non-pharmacologic therapies.

The Drug Enforcement Administration (DEA) assigns each waivered physician a special identification number. DEA regulations require that this ID number be included on all buprenorphine prescriptions for opioid addiction therapy, along with the physician's regular DEA registration number.

Under the new law, one year after the date on which the physician initially submitted a Notice of Intent, he or she will be able to submit a second Notice of Intent to treat up to 100 patients.

ASAM and other medical and addiction field organizations waged a vigorous campaign to lift the 30-patient limit. Explaining their motivation, ASAM member and Review Course co-chair Edwin A. Salsitz, M.D., explained: "Of the estimated six million people in the United States who are dependent on opioids, many have been forced to wait for the medical treatment they so desperately need simply because of a mandated 30-patient 'cap' on how many patients a doctor may treat." Dr. Salsitz, of Beth Israel Medical Center in New York City, added: "Enactment of the legislation will begin to address this inequality."

SAMSHA has created a special form for physicians to use in filing a Notice of Intent to begin treating up to 100 patients. The form can be downloaded from the SAMHSA buprenorphine website (WWW.BUPRENORPHINE.SAMHSA.GOV) and, when completed, faxed to SAMHSA at 240/276-1630, or mailed to SAMSHA's Division of Pharmacologic Therapies, Attn: Opioid Treatment Waiver Program, One Choke Cherry Road, Rm. 2-1063, Rockville, MD 20857. For further information, visit SAMHSA's general website (WWW.SAMHSA.GOV) and click on "What's New" or call the SAMSHA Help/Info line at 866/287-2728.

Kennedy, Ramstad Launch New Campaign for Parity

Congressmen Patrick Kennedy (D-RI) and James Ramstad (R-MN) are hosting a series of public hearings on insurance coverage for addiction and mental health services and say they plan to reintroduce legislation to require insurers to cover those conditions at parity with care of other medical disorders.

The two lawmakers, who co-chair the bipartisan Congressional caucus on Addiction, Treatment and Recovery, recently traveled to Kennedy's home state of Rhode Island to hold the first public hearing, which included testimony from the leaders of the three largest health insurers in the state, as well as members of the public, employers, mental health and addiction advocates, and health care professionals. James Purcell, the CEO of Blue Cross Blue Shield of Rhode Island, testified that his company now supports parity and that restrictions on the number of office visits for mental health problems were a mistake.

Kennedy and Ramstad said they will reintroduce the Paul Wellstone Mental Health and Addiction Equity Act, which would bar health plans with 50 or more members from setting different reimbursement, co-payments, deductibles or limits for mental health or addiction care than for other disorders *(For more on parity, see page 21).*

HBO Announces Addiction Education Project

The Home Box Office cable channel (HBO) has announced a multimedia campaign to increase public understanding that addiction is a treatable disorder. Developed in partnership with the Robert Wood Johnson Foundation, the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the project launch is tied to a documentary entitled "Addiction," which premiers on HBO March 15th from 9:00-10:30 p.m. in the Eastern and Pacific time zones.

The project also encompasses a 30-city nationwide community outreach campaign, funded by the Robert Wood Johnson Foundation and coordinated by Join Together, Faces and Voices of Recovery, and CADCA.

The centerpiece documentary is a 14-part film series that provides guidance in navigating the often confusing world of addiction treatment and recovery. The filmmakers promise a candid depiction of the emotional, psychological, social, and political toll of addiction, as well as a focus on the fact that addiction is treatable and that there are millions of Americans in long-term recovery. Topics covered include the nature of addiction, addiction in the workplace, and the protracted insurance battles waged by families, as well as the difficulty of finding and affording specialized treatment. The film series also is said to highlight medical advances in addiction treatment, such as breakthroughs in brain imaging.

All the films will initially be offered during a free HBO preview weekend from Thursday, March 15th through Sunday, March 18th in participating cable systems.

Medical Specialty Action Group Examines Options for Specialty Recognition of Addiction Medicine

Michael M. Miller, M.D., FASAM, FAPA and Kevin Kunz, M.D., M.P.H., FASAM, Co-Chairs

Addiction is a major public health problem in America, and Addiction Medicine is a specialized area of medical practice designed to address it. Although Addiction Medicine has been recognized by the American Medical Association and many state and federal agencies, there are no Departments of Addiction Medicine within accredited medical schools in the United States and no primary residencies in Addiction Medicine. (There are some fellowships, most of which are approved by the Accreditation Council on Graduate Medical Education, or ACGME, and sponsored by academic departments of Psychiatry. Multidisciplinary fellowships, in which board-certified internists, pediatricians, family physicians and others receive training in Addiction Medicine, are not certified by the ACGME.)

To fill this void, ASAM has offered a national certification process for physicians who wish to be credentialed as specialists in Addiction Medicine. Like other medical specialties, ASAM turned to the National Board of Medical Examiners (NBME) to develop the examination. Through this process, more than 3,800 physicians have become ASAM-certified in Addiction Medicine over the past 20 years. However, these physicians cannot inform patients and others that they are "board-certified" because the American Board of Medical Specialties (ABMS) has not recognized Addiction Medicine as a primary medical specialty.

The current situation has a number of aspects that are adverse both to Addiction Medicine practitioners and to their patients and the general public:

- Many patients and families do not know how to find a physician who has the specialized skills and knowledge needed to evaluate and/or manage a substance use disorder.
- Some insurers and managed care organizations have set reimbursement schedules that do not adequately reflect the special skills and knowledge Addiction Medicine practitioners possess.
- Hospital medical staffs and academic medical centers do not have official departments of Addiction Medicine and thus lack a formal basis for offering training in the specialty.
- ASAM-certified Addiction Medicine specialists sometimes are unable to secure positions on hospital medical staffs or managed care panels.

Indeed, there is something seriously wrong with the American health care delivery system when physicians who are qualified to treat a disorder that afflicts 10 percent of the population cannot win appropriate recognition of their professional knowledge and skills!

ASAM members and other leaders in the field have proposed that ABMS recognition of the specialty of Addiction Medicine would address many of these problems. In fact, ASAM's mission statement and strategic plan both call for efforts to win recognition of Addiction Medicine as a primary medical specialty. Therefore, ASAM's Board has approved a deliberative process to close the gap. The Board created the Medical Specialty Action Group (MSAG) and charged it to "develop a knowledge base and recommend actions to the ASAM Board regarding the recognition of Addiction Medicine as a physician specialty by the American Board of Medical Specialties."

At its inaugural meeting at the Hazelden Foundation in December 2006, members of the Action Group identified two alternate pathways to specialty recognition:

1. Establish an independent American Board of Addiction Medicine (ABAM) now, with the goal of having it recognized by the ABMS as a primary specialty Board, or
2. Establish an independent American Board of Addiction Medicine (ABAM) now, but focus first on creating conjoint subspecialities of Addiction Medicine with existing ABMS primary specialties, and later seek to establish Addiction Medicine as an ABMS-recognized primary medical specialty.

The Action Group determined that research was warranted to identify the pros and cons of both approaches, so that the ASAM Board can be presented with a realistic set of options (including the attendant costs) from which to choose. To execute the multiple activities required, the Action Group formed itself into four committees:

Process and Structure Committee: This group is charged with gathering data on the requirements, process, costs and other issues that would need to be addressed if ASAM decides to pursue recognition of Addiction Medicine by the ABMS.

Training Committee: This committee is to gather data on the steps involved in creating Addiction Medicine training programs that meet ACGME and ABMS guidelines; the content of the training to be offered; whether training programs currently exist that meet those guidelines, and what it would cost to create and sustain such training programs.

Finance Committee: This committee is to gather data and develop sound estimates of the income and expenses required to execute each of the two options for recognition of Addiction Medicine as a medical specialty, including the potential income and costs to ASAM, and the estimated costs to finance the work of the Action Group until ABMS recognition is achieved. The Finance Committee also has been charged with identifying potential financial arrangements that might be used to create and sustain the proposed American Board of Addiction Medicine and to develop ACGME-approved training programs.

Steering Committee: This group is to coordinate the work of all the Committees, communicate progress to ASAM's Board and membership, and oversee preparation of the report to ASAM's Board in April 2007.

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Members of ASAM's Medical Specialty Action Group gathered at Hazelden's headquarters in Center City, Minnesota, in December 2006 to kick off the Group's activities to formulate a strategy to win formal recognition of Addiction Medicine as a medical specialty.

ASAM Members Elect New Officers, Board Members

The following Officers and Directors at Large will be installed at the Annual Business Meeting, Friday, April 27th, during ASAM's 38th Annual Medical-Scientific Conference in Miami, Florida. At that time, Michael M. Miller, M.D., FASAM, FAPA, will assume the Presidency of ASAM and Elizabeth F. Howell, M.D., FASAM, will become Immediate Past President. ASAM officers serve a two-year term (2007-2009), while Board members serve a four-year term (2007-2011).

President-Elect

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

PRINCETON, NEW JERSEY

Dr. Louis Baxter is Executive Medical Director of the Professional Assistance Program of New Jersey — a post he assumed two years ago, after serving for seven years as Executive Medical Director of the former Physicians' Health Program of the Medical Society of New Jersey. Dr. Baxter also is Medical Director of the Division of Addiction Services of the New Jersey Department of Health, and an Associate Clinical Professor of Medicine at the medical school of the University of Medicine and Dentistry of New Jersey. In addition, he has been a faculty member in Medicine at Temple University, Rutgers University, and Thomas Jefferson Medical College. For 10 years, he was Medical Director of Addiction Services at the Geisinger Medical Center in Danville, Pennsylvania.

A 1973 graduate of the University of Pennsylvania with a dual major in Biology and American Civilization, Dr. Baxter received his medical degree from Temple University School of Medicine and completed an Internship and Residency in Internal Medicine at the University of Medicine and Dentistry of New Jersey in 1981. He completed training in Addiction Medicine and became a member of ASAM in 1988.

As a consultant and national expert on various topics related to addiction and addiction treatment, Dr. Baxter has lent his expertise to assignments for the Center for Substance Abuse Treatment, the U.S. Food and Drug Administration, the Drug Testing Advisory Board of the Substance Abuse Mental Health Services Administration, and the National Football League. He says, "I brought the name and mission of ASAM into state and federal policymaking when I served as Chairman of the Ambulatory Detoxification Committee of the Pennsylvania Department of Health, as a consultant to the New Jersey Department of Health, Alcohol Division, and currently as a member of the National Advisory Council of the Center for Substance Abuse Treatment. In these endeavors, I have always sought to promote and advance ASAM and the field of Addiction Medicine."

Dr. Baxter has written, reviewed, and published many articles and textbook chapters. For example, he has contributed to ASAM's *Principles of Addiction Medicine, Third Edition*, and is a chapter co-author in *Legal Medicine, 7th Edition.* He also has contributed to numerous CSAT publications and is a contributor to the National Strategic Plan for Interdisciplinary Faculty Development that made the recommendation that addiction education become part of the core curriculum of all allied health educational programs in the nation. Dr. Baxter also has served on many ASAM committees, including the Membership, Physicians' Health, Forensic Medicine, and Nomination and Awards Committees, and has chaired the Cross-Cultural Clinical Concerns Committee. He is co-director of the Ruth Fox Program Committee, and has presented regularly at ASAM conferences and meetings since 1992.

He explains, "My dedication and absolute commitment to ASAM and its mission, as evidenced by my professional activities and accomplishments, is my greatest contribution to ASAM and the field of Addiction Medicine. At every opportunity, I have advanced and promoted the mission, goals, and policies of ASAM, as represented in our Strategic Plan, as well as in the local, state, and federal policymaking, medical education, and addiction treatment arenas in which I have been involved. I recognize the value and worth of every ASAM member and I intend to make ASAM membership a true value, with real and meaningful career opportunities for its members. Concisely put: I am dedicated to ASAM."

Dr. Baxter is certified in addiction medicine and is a Fellow of ASAM. He also was named a Fellow of the American College of Legal Medicine in 2004 and is certified as a Medical Review Officer by the Medical Review Officer Coordinating Council.

Asked how he sees his new role, Dr. Baxter says: "My election as President-Elect will allow me to continue to advocate for the ideals and mission of ASAM. I will work to promote ASAM's recognition as *the* specialty society for Addiction Medicine, and of its members as experts in all matters concerning addictive disorders, their prevention and treatment. I believe that my relationships with the aforementioned agencies, my experience as a treatment provider, and my ability to execute ASAM mandates at the local, state and federal levels will allow me to foster ASAM's growth and development and to help the society win even greater acceptance in mainstream medicine."

SECRETARY

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

METAIRIE, LOUISIANA

Dr. Ken Roy graduated from the Tulane University School of Medicine and, in 1994, completed a residency in psychiatry at that institution. He went on to become board certified in psychiatry by the American Board of Psychiatry and Neurology. Today, Dr. Roy holds the academic rank of Clinical Assistant Professor at Tulane University's School of Medicine. He admits patients to two New Orleans area hospitals, maintains a private psychiatric practice, teaches psychiatry residents and medical students, and works with organized medicine in Louisiana.

As a general practitioner in recovery, Dr. Roy became interested in Addiction Medicine. He has worked to develop addiction treatment programs at several New Orleans area hospitals, as well as outpatient and residential programs for Addiction Recovery Resources of New Orleans, a private non-profit agency that provides ambulatory detoxification, intensive outpatient and residential addiction, dual diagnosis, and chronic pain management services. Dr. Roy also is an expert on the care of impaired physicians, having served on the Impaired Physicians Committee of the Louisiana State Medical Society and as a consultant on impairment issues to multiple organizations.

A member of ASAM since 1984, Dr. Roy won ASAM certification in 1986. He was first elected to the ASAM Board of Directors in 1988 and was re-elected in 1992, 1998 and 2002. He has served on the ASAM Review Course Committee and has been chair of the Membership Committee. He also been active in ASAM's State Medical Specialty Society (SMSS) program — now the Chapters Council — and heads the Parity Action Group. Dr. Roy was elected a Fellow of ASAM in 1997 and a Distinguished Fellow of the American Psychiatric Association in 2005.

In his work within ASAM, Dr. Roy says he has helped to maintain a focus on the development of criteria-based, medically-directed treatment models across multiple levels of care. He also has helped to develop the implications of addiction as a primary disease and a brain disease. Dr. Roy says that parity in insurance coverage is essential to the adequate treatment of addictive disease, attraction of physicians to the field, development of training for physicians. and the development of an active Addiction Medicine specialty in medicine. As ASAM Secretary, he says, "I will continue attention to these issues at a high level of leadership and apply the benefits of elected office to advance the work of the Parity Action Group."

Installation of Officers

ASAM's new officers and members of the Board of Directors will be installed during the Annual Business Meeting at 7:30 a.m. Friday, April 27th, during the Medical-Scientific Conference in Miami, Florida.

TREASURER

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

WOONSOCKET, RHODE ISLAND

Dr. Stuart Gitlow is board certified in Psychiatry, with CAQs in Addiction and Forensic Psychiatry. His clinical practice represents a mixture of those areas: he is medical director of a community mental health center and maintains a private practice in Addiction Medicine. He also works as a medical expert in Addiction Medicine for the Social Security Administration, providing forensic testimony on addiction disability cases throughout the New England and Mid-Atlantic regions. In addition, Dr. Gitlow holds a faculty appointment at the Mount Sinai School of Medicine and serves as an impartial medical examiner for the State of Rhode Island, a consultant for Rhode Island and Massachusetts Disability Determination Services, and a peer reviewer for MCMC, MES, and Reed Reviews.

As Chief of the Annenberg Training Program in Addictive Disease, Dr. Gitlow has raised a $12 million endowment to allow hundreds of medical students to spend one or two months immersed in the addiction rehabilitation process. Each student receives an ASAM membership and travel expenses to allow him or her to attending ASAM's annual meeting. The purpose is to interest students in Addiction Medicine and to follow them longitudinally to determine the most effective methods to keep them involved and active in the field.

Dr. Gitlow enjoys writing and has had a regular column in *Counselor* magazine for five years. The second edition of his textbook, *Substance Use Disorders: A Practical Guide*, was published earlier this year. Designed primarily for an in-training audience, the text encourages active participation in ASAM and provides an overview of the Society's public policies and placement criteria. A new book, *Avoiding Common Psychiatric Errors* — featuring an extensive section on addiction-related issues — will be published in 2007.

Dr. Gitlow explains that this combination of activities keeps him involved in medical education, research, and clinical activities, while allowing him to maintain a firm understanding of the necessities of managing a medical practice. His MPH studies focused on addiction epidemiologic issues and his MBA studies, completed in 2006, included extensive coursework on the marketing and management of nonprofit organizations — knowledge he already has found useful within ASAM and the AMA, where he represented ASAM in the Young Physician Section (which he chaired). He currently represents ASAM in the AMA's House of Delegates, where he chairs the Action Team on Alcohol and Health.

Dr. Gitlow says, "ASAM has achieved much over the past decades, but it is our task to define, educate, and pursue the goal of continued acceptance of Addiction Medicine. As a psychiatrist, I recognize that we need to differentiate Addiction Medicine from Addiction Psychiatry. Many wonder about how the two possible pathways and career options overlap; it is up to ASAM to present a central pathway for all physicians. I feel that true Board certification remains a critically important goal."

DIRECTOR AT LARGE

R. Jeffrey Goldsmith, M.D.

CINCINNATI, OHIO

Dr. Jeffrey Goldsmith has been a faculty member in the Department of Psychiatry at the University of Cincinnati College of Medicine since 1981. He also is Professor of Clinical Psychiatry, Director of Addiction Fellowships, and staff psychiatrist at the Cincinnati VAMC Dual Diagnosis Clinic. He has been with the VAMC since 1983 and recently completed 11 years with the Cincinnati Addiction Research Center, which is part of NIDA's Clinical Trials Network, Medication Development Research Unit, and Clinical Trials Organization. He has been a co-investigator and principal investigator for a number of clinical trials, including the buprenorphine/naloxone study, which was the pivotal study for FDA approval of buprenorphine as a treatment for opioid addiction. He has published more than 50 chapters and papers on his research, and developed an ACGME-accredited Addiction Psychiatry fellowship and a VA-funded Addiction Medicine Fellowship.

Dr. Goldsmith is board-certified in Psychiatry and holds a CAQ in Addiction Psychiatry. He was certified by ASAM in 1986. Within ASAM, he has chaired the Continuing Medical Education Committee for the past six years and has helped the Society successfully undergo two site visits by ACCME. He currently chairs the Training Committee and serves on the Steering Committee of ASAM's Medical Specialty Action Group. Dr. Goldsmith served as program chair for the last two Nicotine Dependence Conferences and has served on the Med-Sci Program Committee for the past four years. He currently serves on the Publications Task Force and recently was appointed to the Editorial Board of the *Journal of Addictive Diseases.* He is a founding member of the American Academy of Addiction Psychiatry and a member of the board of the Cincinnati Psychoanalytic Institute.

Dr. Goldsmith says that his greatest contribution to Addiction Medicine has been his 25 years of service as a medical educator. During that time, he has mentored medical students, psychiatry residents, Addiction Psychiatry fellows, and Addiction Medicine fellows. He has designed summer internships for students, a PGYI rotation for psychiatry residents, advanced psychotherapy series for outpatient psychiatry residents, and an ACGME-accredited fellowship in Addiction Psychiatry. He also has supervised and lectured medical students and physicians in all aspects of their training, from medical school to ASAM. He says this experience has allowed him to learn the basics of Addiction Medicine, as well as the vulnerabilities that addiction specialists encounter in working in the field and what they need to sustain a lifelong passion in the face of cultural disinterest and stigma. Using this experience, Dr. Goldsmith says his goal is to "keep ASAM vital through my leadership in offering new continuing medical education products — products that bring us up to date and appeal to the newer generation of physicians, through the ethical incorporation of pharmaceutical companies' financial support of these products, and through my understanding of what Addiction Doctors need to grow and sustain their enthusiasm."

DIRECTOR AT LARGE

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

SAN FRANCISCO, CALIFORNIA

As a member of the Drug Dependence Research Center team at the University of California, San Francisco, Dr. Lori Karan participates in pharmacokinetic and safety investigations for new addiction medications before those drugs are tested for efficacy in larger-scale clinical trials. She also is involved in mechanistic studies looking at the role of various neurosteroids in alcoholism, chronic stress, aging, and eating.

Dr. Karan began her career providing medical leadership to a detoxification and treatment center that emphasized recovery through the Twelve Steps. Her clinical activities have since included directing a tertiary care addictions unit, providing addictions inpatient consultation, caring for perinatal addicted women, serving on the board of directors of an HIV prevention outreach team, providing methadone maintenance, and caring for patients with pain and addiction.

In 1993, Dr. Karan guest-edited a seminal issue of the *Journal of Substance Abuse Treatment* entitled "Towards a Broader View of Recovery: Integrating Nicotine Addiction and Chemical Dependency Treatments." She subsequently received a Scientist Development Award from the National Institute on Drug Abuse and retrained in clinical pharmacology, neuroscience, and research methodology.

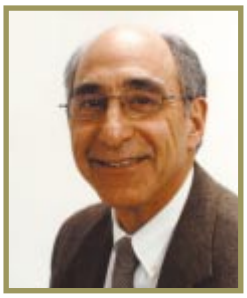
Dr. Karan is an internist who was elected to Fellowship in the American College of Physicians in 1994 and became a Fellow of ASAM in 1996. Active in the leadership of ASAM and the California Society of Addiction Medicine, Dr. Karan has co-chaired the second and third National AIDS and Chemical Dependency Forums (1988, 1989), nine Nicotine Research Roundtables (1991-1999), the ASAM Nicotine Conference (1998) and the CSAM State of the Art Conference (2001). She also served as co-editor of the pharmacology section of ASAM's textbook, *Principles of Addiction Medicine*, and authored two of its chapters. In addition, she has designed workshops for the ASAM Med-Sci conferences on how to critically review the scientific literature, and spearheaded a supplementary track within CSAM's Review Course to help physicians prepare for ASAM's 2006 Certification Examination in Addiction Medicine. She notes that, having spent 13 years of her life in ASAM on the East Coast and 8 years on the West Coast, she is uniquely qualified to understand the regional differences within the Society.

Asked about her goals as an ASAM Board member, Dr. Karan says: "ASAM is a vibrant organization with a rich history, a dedicated mission, and quality products. We now need to focus on achievable goals, including attaining specialty or subspecialty status, improving reimbursement for our services, fostering our publications, reviving our clinical heart, and bettering our communications and governance. Our most important priorities are achieving specialty status within ABMS and improving reimbursement for addiction treatment. Doing this will attrace new physicians to our field, improve access to treatment, enhance quality of care, and further our ability to advocate for our patients."

DIRECTOR AT LARGE

Mark L. Kraus, M.D., FASAM

WATERBURY, CONNECTICUT



Dr. Mark Kraus is a general internist and a partner in Westside Medical Group of Waterbury, Connecticut. He holds an appointment as Assistant Clinical Professor of Medicine at the Yale University School of Medicine, where he helped to create and implement an Addiction Medicine rotation in the Yale Primary Care General Internal Medicine Residency Program. Dr. Kraus also serves as Chief Medical Officer of Connecticut Counseling Centers in Danbury, Connecticut.

Dr. Kraus was certified in Addiction Medicine in 1988 and elected a Fellow of ASAM in 1997.

Within ASAM, he has served as an Associate Mentor in the PCSS Program, as an Alternate Regional Director for the New England Region, and as chair of the Development Committee of ASAM's Strategic Planning Task Force. He currently co-chairs ASAM's Public Policy Committee and serves as a member of ASAM's Legislative, Membership, Medical Education/CME Committees.

At the state level, Dr. Kraus co-chaired Governor Rowland's Blue Ribbon Task Force on Addiction Services, which created a blueprint for public policy on addiction treatment that has had a "ripple effect" in other states. He is a member of the Connecticut Alcohol and Drug Policy Council and the Connecticut Mental Health Policy Council. He also has been active in the Connecticut State Medical Society, chairing the Committee on Alcohol and Other Drug Dependencies and helping to win that society's recognition of Addiction Medicine as a subspecialty.

Dr. Kraus is a founding member and the first President of the Connecticut Society of Addiction Medicine, for which he also serves on the Executive Committee, chairs the Public Policy/Legislative Committee, and represented CtSAM to the Subspecialty Committee of the Connecticut State Medical Society.

In other activities, Dr. Kraus has co-chaired the Physicians' Task Force on Addiction Medicine for the Association for Medical Education and Research in Substance Abuse (AMERSA).

He has served as a reviewer and consensus panelist for the Center for Substance Abuse Treatment; as a member of the Physicians' Work Group for the National Institute on Drug Abuse; and as an organizer and expert panelist for the National Leadership Conferences on Medical Education in Substance Abuse, sponsored by the Office of National Drug Control Policy. One of his goals is to promote collaboration among the principal addiction societies: ASAM, AMERSA, AAAP, and AOAAM.

Dr. Kraus says, "As an Addiction Medicine educator, clinical researcher, clinical administrator, public policymaker, and a practitioner with 30 years' experience, I am acutely aware of the outside pressures, clinical barriers, and financial problems we face daily. As a member of the Board, I will represent the views of our membership and advocate for our patients so that we can continue to deliver high quality care."

DIRECTOR AT LARGE

Donald J. Kurth, M.D., FASAM

RANCHO CUCAMONGA, CALIFORNIA

Dr. Donald Kurth was born in New England, raised in New Jersey, and attended Columbia University in New York City, where he graduated Phi Beta Kappa and received a scholarship to study at England's Oxford University. He earned his medical degree at Columbia University's College of Physicians and Surgeons, then trained at Johns Hopkins and UCLA. He became board certified in Emergency Medicine in 1987.

Dr. Kurth began his career as medical director of a busy southern California emergency department. He helped to develop the Trauma Center System in Los Angeles and opened his own urgent care center, with more than 50 employees and an annual budget of several million dollars. Later, he founded and developed his own IPA for managed care contracting purposes. For his work, he received the Small Business Person of the Year Award in 1993 from the U.S. Small Business Administration. During that time, Dr. Kurth also served as a physician volunteer for the Flying Samaritans (who provide free medical care in impoverished areas in Baja, Mexico) and founded the Free Pediatric Immunization Clinic in his hometown.

Today, Dr. Kurth is Associate Professor of Psychiatry and Chief of Addiction Medicine at Loma Linda University. For the past 10 years, he also has served as Medical Director of the inpatient Chemical Dependency Unit and of a large outpatient program at Loma Linda's Behavioral Medicine Center.

Dr. Kurth also has served as a member of the City Council of Rancho Cucamonga, California, a municipality of 150,000 citizens and a combined annual budget of almost $100 million. He has brought the expertise gained through that experience to his service as ASAM Treasurer, where he led efforts to ensure the Society's financial stability through innovations designed to increase checks and balances, enhance reserve fund development, and improve investment policies.

Dr. Kurth's accomplishments have been recognized by a Robert Wood Johnson Fellowship in Developing Leadership in Reducing Substance Abuse, which he credits with helping him sharpen his leadership skills and learning how to develop those leadership skills in others.

Dr. Kurth joined ASAM in 1995 and, in 1997, was certified in Addiction Medicine. As President of the California Society of Addiction Medicine, Dr. Kurth helped to spearhead Proposition 36, repeal of the state's UPPL law, and led the effort to achieve parity for addiction treatment. Based on his experiences in California, he helped to found the ASAM Legislative Advocacy Committee, ASAM's Legislative Day, and the ASAM Legislative Advocacy Newsletter. He also has co-chaired ASAM's Parity Action Group, fighting to ensure fair reimbursement for all physicians. He says, "My first love is advancing our specialty and developing public policies to improve access to addiction treatment for our patients. Board certification for Addiction Medicine must be our next goal."

DIRECTOR AT LARGE

Penelope P. Ziegler, M.D., FASAM

WILLIAMSBURG, VIRGINIA

Dr. Penelope Ziegler has practiced Addiction Medicine full-time since 1985. She is board-certified in Psychiatry and Addiction Psychiatry. In 1986, Dr. Ziegler became Medical Director of Williamsburg Place and the William J. Farley Center in Williamsburg, Virginia, providing ambulatory detoxification, short-term partial hospitalization primary addiction treatment, dual diagnosis treatment, and an extended treatment program for health care and other professionals at the Farley Center. Since moving into Emeritus status in June 2006, Dr. Ziegler has been lecturing nationally, writing and continuing to teach and consult at the Farley Center.

Dr. Ziegler holds an appointment as Associate Clinical Professor in the Department of Psychiatry at the Medical College of Virginia. Of her approach to medical education, Dr. Ziegler observes that "Some of my patients are addicted to alcohol, some to opioids, sedatives or stimulants. But in addition, many have complicated, comorbid illnesses — problems ranging from untreated mood disorders to chronic pain syndromes, to sexual trauma and PTSD, to personality disorders — which put them at high risk for being either unable to maintain abstinence or for being able to stay abstinent, but to remain at high risk for suicide, divorce, stress-related illness and disruptive behavior. My experience has taught me to look more deeply, to treat the whole person, and I have tried to teach this to addiction medicine specialists and other professionals in the addiction field."

Although primarily engaged in clinical practice, Dr. Ziegler also has been involved in research projects related to addicted physicians and other health care professionals. She also has developed treatment protocols for chemically dependent patients with chronic pain, utilizing acupuncture, neurofeedback, and other complementary approaches.

Dr. Ziegler joined ASAM in 1986, was certified in Addiction Medicine in 1987, and was named a Fellow of ASAM in 2000. She has been an active member of the ASAM Infectious Disease Committee, planning annual symposia, workshops and one-day forums, and helping to develop the *ASAM Guidelines for HIV Infection and AIDS in Addiction Treatment.* She also has served on the Publications Council, the Fellowship Committee, and several task forces.

At the state level, Dr. Ziegler helped to organize the Pennsylvania Society of Addiction Medicine and served on its first Board of Directors. Since moving to Virginia, she has been involved with the Virginia Chapter and is an organizer of the Tidewater ASAM group.

Dr. Ziegler says: "It has been my privilege to serve on the ASAM Board of Directors for the past four years. The Board has worked hard to develop a Strategic Plan and has had training designed to help us implement this plan. Now comes the fun part — putting the plan into action and bringing these new ideas to fruition. I want to be involved in making this happen, in making ASAM the pivotal health care organization treating addicted patients and advocating for the rights and needs of persons with addictive disease, their families, and all who are touched by this devastating illness."

DIRECTOR REPRESENTING OSTEOPATHIC MEDICINE

Scott Smolar, D.O.

GREENBRAE, CALIFORNIA

Dr. Scott Smolar is the Medical Director of Marin County Community Mental Health Services in Greenbrae, California. He also holds an appointment as Assistant Clinical Professor at the University of California, San Francisco.

Dr. Smolar took his undergraduate degree *cum laude* from Hobart and William Smith Colleges in 1985. There, he completed an individual major, explaining how systems of healing and human consciousness vary among civilizations and the implications for the achievement of peaceful societies. He earned a degree in Osteopathic Medicine (D.O.) from the University of New England and went on to complete residencies in adult and child/adolescent psychiatry at the Oregon Health Sciences University. Elective rotations and a senior project consulting to an adolescent homeless shelter led to his interest in how psychiatric disorders interface with addictive disease.

Dr. Smolar completed a two-year clinical and research fellowship at the University of California, San Francisco, where he worked on clinical trials of buprenorphine and research on cue-induced craving. He also worked at the Richmond Area Multiservice Center as a child psychiatrist. Upon completion of his residency and fellowship training, Dr. Smolar became medical director and an attending psychiatrist at the San Francisco General Hospital in the Opiate Treatment Program, where he provided treatment to opiate-dependent and polysubstance-dependent individuals who had multiple medical disorders. He also participated in research into the treatment of stimulant abuse.

Following his work at San Francisco General Hospital, Dr. Smolar went on to work for Marin County Mental Health as a child and adolescent psychiatrist. He also served as medical director of the opiate treatment program at the San Francisco Veterans Administration Medical Center.

Dr. Smolar is board-certified in General Psychiatry and board-eligible in Child and Adolescent Psychiatry. He won ASAM certification in Addiction Medicine in 2000. In addition to his service on ASAM's Board of Directors, Dr. Smolar has been an active member of the California Society of Addiction Medicine, helping to plan CSAM conferences and serving as a speaker at CSAM educational courses. Through these activities, he has helped to educate medical students, residents, and family physicians about the identification, diagnosis and treatment of addictive disease. In addition to ASAM, Dr. Smolar also is a member of the American Osteopathic Association and the American College of Osteopathic Neurologists and Psychiatrists.

Dr. Smolar says: "From the beginning of my psychiatric training, I have had an interest in and dedication to understanding the interrelationship of addiction medicine and addiction psychiatry. I have come to understand that the human brain's reward system is strongly related to the ability both to create and to destroy; hence, our understanding of addiction is vital to the survival of humankind."

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.

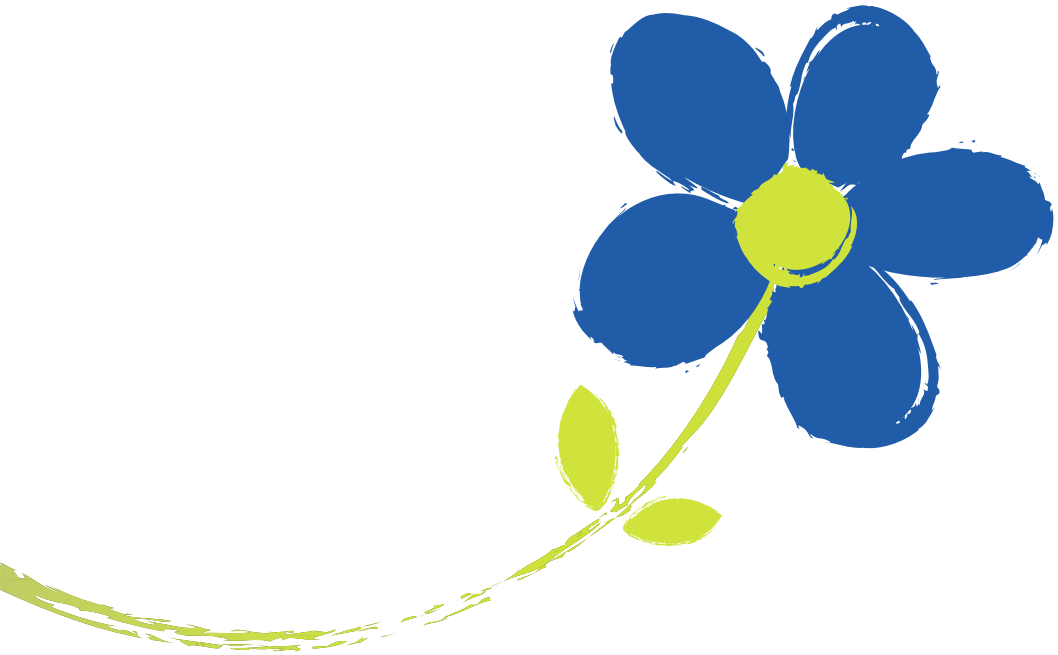
Due caution should be exercised when driving cars or operating machinery.

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

✔ ALERT: Error in CSAT TIP 43

The federal Center for Substance Abuse Treatment has issued an alert concerning an error in its Treatment Improvement Protocol (TIP) 43, titled "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs." The notice clarifies a typographical error and some confusing wording in the original (2005) edition of the TIP, which could lead to inappropriate treatment of neonatal abstinence syndrome. Specifically:

- ✔ On page 219, in column 1, at the 9th line from the bottom, the text reads: "0.4 mg/kg/**dose.**" It should read "0.4 mg/kg/**day**."
- ✔ On the same page, in column 1, at the 6th line from the bottom, the text reads "**0.4** mg/kg/dose." It should read "**0.04** mg/kg/dose."

In subsequent printings of TIP 43, the copy has been changed to read as follows: "If pharmacological management is indicated, several methods have been found useful. The American Academy of Pediatrics Committee on Drugs policy statement on Neonatal Drug Withdrawal (1998) describes several agents for the treatment of NAS including methadone, tincture of opium, paregoric, and morphine. One method (J. Greenspan, Thomas Jefferson University Hospital, Philadelphia, personal communication, October 2006) uses neonatal opium solution (0.4 mg/mL morphine-equivalent; starting dosage, **0.4 mg/kg/day** orally in six to eight divided doses [timed with the feeding schedule]). Dosage is increased by **0.04 mg/kg/dose** until control is achieved or a maximum of 2.0 mg/kg/day is reached. If Neonatal Abstinence Scores stay high but daily dosage nears maximum, symptoms are reassessed and concurrent phenobarbital therapy considered. When control is achieved, the dosage is continued for 72 hours before pharmacological weaning, in which dosages are decreased 10 percent daily or as tolerated. When 0.2 mg/kg/day is reached, medication may be stopped. Decisions about dosage decrease during pharmacological weaning are based on Neonatal Abstinence Scores, weight, and physical exams."

CSAT officials have asked users of TIP 43 to make these corrections in the 2005 edition. They advise that the problem has been corrected in all subsequent editions.

MSAG GROUP REPORT *continued from page 4*

The Action Group also established the following overall schedule for its work:

- **Phase I** (2003 – November 2006): ASAM reaches consensus on ADM specialty status and the MSAG Steering Committee begins its work.
- **Phase II** (December 2006 – April 2007): The Action Group develops a knowledge base, formulates a plan, and submits the plan to the Board of Directors for approval.
- **Phase III** (April 2007 – completion): With approval of the ASAM Board, the American Board of Addiction Medicine is created as the organizing nucleus to pursue ABMS recognition of Addiction Medicine as a primary or secondary specialty.

The Action Group is committed to keeping ASAM members and other interested parties fully informed of its progress. Watch **ASAM News** to follow the group's work and to read its report to the Board of Directors.

National Leaders Call for Changes in Medical Education, Licensure, Accreditation

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

I was pleased to represent ASAM at a December 2006 National Leadership Conference on Medical Education in Substance Abuse, sponsored by the Office of National Drug Control Policy (ONDCP). That invitational gathering brought together 60 key officials of Federal agencies, organized medicine, medical training institutions, licensure and certification bodies, and insurance experts to discuss ways to enhance the training of physicians in the prevention, diagnosis and management of substance use disorders, including prescription drug abuse. commitment to mutual goals.

Dr. Lawrence S. Brown

Dr. Bertha K. Madras

The event was a follow-up to a 2004 meeting hosted by ONDCP, at which I also represented ASAM. Considerable progress has been made in the ensuing two years, but the goals for enhanced physician training about the addictions have not yet been fully achieved. Therefore, ONDCP hosted a second conference to assess progress, refine strategies, and reaffirm commitment to mutual goals.

In her opening remarks, Conference Chair Bertha K. Madras, Ph.D., who is ONDCP's Deputy Director for Demand Reduction, made the mission clear: "We enlist your expertise in developing strategies to promote medical education curricula on drug- and alcohol-related disorders, the improvement of medical education after graduation, implementation of screening and brief intervention in mainstream medical care, obtaining appropriate physician reimbursement for these services, and preventing the nonmedical use of prescription medications.…We ask you, as leaders in health care, to collaborate with us in forging these strategies and implementing practical solutions within your spheres of influence."

ONDCP Director John P. Walters pledged that his office and other Federal agencies will continue to support scientific research and clinical education that help to reduce the illness and deaths associated with substance use disorders. He also promised support for research that helps bring the medical community better tools to identify, prevent, and treat those who are at risk for or experiencing such disorders, including problems with prescription drugs.

Meeting in a series of Working Groups, conferees developed targeted strategies and action plans in seven areas of medical education and practice:

Undergraduate Medical Education. For example, one of the recommendations from the Working Group on Undergraduate Medical Education is to identify "champions" in each medical school to help identify specific curricular needs related to teaching about substance use disorders. To achieve this goal, the group suggested that the Association of American Medical Colleges and the American Association of Colleges of Osteopathic Medicine create a network of such faculty through a Listserv. The group saw such communication as affording an opportunity to nurture faculty in how to mentor students and foster their interest in teaching about substance use disorders. This Working Group also developed strategies related to faculty development, best practices, and the creation of Centers of Excellence to compile information and disseminate program models and related knowledge.

Graduate Medical Education. The Working Group on Graduate Medical Education offered a variety of strategies. One that I find particularly interesting is a proposal to bring together representatives of the institutions of medicine to develop minimum standards for training all medical students and residents in the recognition of substance use disorders. Participants would include the Accreditation Council on Graduate Medical Education (ACGME), the relevant boards of the American Board of Medical Specialties, the chairs of the relevant Residency Review Committees, the National Board of Medical Examiners (NBME) and the National Board of Osteopathic Medical Examiners (NBOME), and others who create and maintain the requirements for core content in each of the targeted specialties.

Such a gathering would lay the groundwork for an approach to the American Board of Medical Specialties and the various specialty societies and boards with a request for stronger requirements for the content of specialty board examinations related to substance use disorders.

Continuing Medical Education. The Working Group on Continuing Medical Education focused on ways to motivate physicians to seek, learn, and implement available evidence-based practices for screening and brief intervention. For example, the group recommended steps to enhance practicing physicians' access to high-quality CME programs, such as creating an accessible Web portal where physicians could readily identify and/or link to high-quality CME courses relevant to their practices.

The group also endorsed the concept of collaborating with organizations that can effectively reach the target audiences, such as the Accreditation Council on Continuing Medical Education (ACCME) and Physicians and Lawyers for National Drug Control Policy (PLNDP).

Licensure, Accreditation, Certification and Standards. This Working Group considered ways to use the systems that regulate medical practice and health care delivery — such as licensure, accreditation, and certification — to create incentives for change in physicians' ability to identify and treat substance use disorders and to prescribe medications with abuse potential so as to meet patients' medical needs without contributing to prescription drug abuse.

Recommended strategies include creating a joint committee composed of ASAM, the American Osteopathic Academy of Addiction Medicine (AOAAM), the American Academy of Addiction Psychiatry (AAAP), the Association for Medical Education and Reseach in Substance Abuse (AMERSA), and other stakeholders to develop a pool of academically-vetted question items at various levels of difficulty, normed across all levels of training (student, resident, etc.), that could be offered to the National Board of Medical Examiners, the National Board of Osteopathic Medical Examiners, ABMS specialty boards, medical schools, and other sponsors of certification or specialty examinations. Such a group also could work with the National Board of Medical Examiners to develop a pool of self-assessment questions for use in CME courses that prepare physicians for certification and specialty board examinations.

This Working Group also endorsed collaboration with the Federation of State Medical Boards (FSMB) to encourage state boards of medicine to place a renewed emphasis on physician competence in screening and brief intervention for SUDs and proper prescribing of controlled substances.

Similarly, the group proposed collaborative activities with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to enhance the effectiveness of the existing JCAHO standard on screening for substance use disorders (for example, by focusing on this requirement in surveyor training sessions). Group members also raised the possibility of incorporating a specific item on screening and referral as a "provision of care performance element" in accreditation surveys of hospitals, long-term care, and ambulatory care centers.

Recognizing that appropriately credentialed addiction experts play an essential role as resources for training, consultation and referral, the Working Group called for the development of a credentialing system that recognizes such expertise—whether through subspecialties in psychiatry, family medicine, pediatrics, et al., or through recognition of Addiction Medicine as a primary medical specialty, as advocated by ASAM.

Funders and Payers of Services. Given the relationship between health plans' reimbursement policies and patients' access to care, this Working Group focused on ways to identify and overcome specific financing and reimbursement practices that are barriers to care. Their recommendations were designed to support reimbursement policies that encourage physicians' acquisition of knowledge and skills and their employment of clinical best practices with regard to screening and intervention for substance use disorders, as well as optimal prescribing of drugs with abuse potential.

For example, the group called for widespread efforts to activate the new HCPCS codes and to educate providers about their use. The new Healthcare Common Procedure Coding System (HCPCS) Level II codes, to be used by Medicaid for reimbursement of screening and brief intervention (SBI) services after January 2007, are not automatically activated in the State Medicaid programs, so a key strategy is to encourage State Medicaid Directors to activate these codes within their States so that providers can use them for reimbursement purposes. Participants suggested that ONDCP, national medical associations and their State affiliates, and the Center for Medicaid and Medicare Services (CMS) should work collaboratively with Medicaid Directors to accomplish this task in each State. The group also suggested strategies to educate physicians about the new HCPCS codes and how to use them to get paid.

Members of the group agreed that even the small increase in Medicaid reimbursements under the new CMS "pay-for-performance" measures has proved a significant incentive for change. Therefore, they proposed adding a performance measure for screening and brief intervention to the 10 voluntary performance measures for emergency departments and trauma centers that are currently in place.

As a complement to the new HCPCS coding, the Working Group endorsed current efforts to add screening and brief intervention to the American Medical Association's Current Procedural Terminology (CPT) codes, so as to clear the way for reimbursement for these services by private insurers and Medicare. A parallel strategy would involve bringing together the major commercial insurers to secure their agreement to pay for services based on the CPT codes.

The group also addressed the problem of UPPL and the ways in which these archaic laws discourage staff in emergency departments and other health care settings from conducting screening and brief intervention. While praising the efforts by ASAM members and other advocates to remove UPPL laws at the State level, members of the Working Group recommended that ONDCP work with the national medical organizations to support model Federal legislation that would eliminate UPPL laws nationwide, rather than continuing the current State-by-State effort.

Prescriber Education and the Prevention of Prescription Drug Abuse. Members of this Working Group addressed the fact that most practitioners are not aware that prescribing a controlled drug is a significant diagnostic event and that nonmedical use is a substantial risk with all controlled substances. The group's recommendations for change focused on "mainstreaming" prescriber education, so that sound prescribing practices and steps to prevent prescription drug abuse are taught in the same way as other areas of clinical knowledge and skills. (For example, current research shows that multiple focused interventions are required to induce physicians to change their practice behaviors; in fact, this principal underlies pharmaceutical manufacturers' product detailing.) Members of the Working Group also felt that providing "toolkits" and other practical resources would facilitate physicians' willingness to conduct screening and history-taking, support appropriate prescribing decisions, and foster careful follow-up monitoring.

The group also endorsed a proposal to incorporate language that reflects competence in prescribing controlled drugs into licensure standards and certification/recertification programs. Some group members proposed that, at the time of re-registration with DEA, physicians should be required to provide evidence of CME credits and/or focused self-assessment in this area.

Next Steps. In acknowledging the reports from the Working Groups, Dr. Madras said: "These are wonderful recommendations from very thoughtful, very enlightened groups. A number of these suggestions will be carved into a working document that we can work together to implement…. Like you, we are cognizant of the challenges that we face in implementation. But above all, we are

continued on page 16

Family Practice Work Group is Active in Education Activities

Norman Wetterau, M.D., FAAFP, FASAM, Chair

Much has been happening at the nexus of Addiction Medicine and Family Practice. First, our specialty was well-represented at a National Leadership Conference on Medical Education in Substance Abuse, sponsored by the Office of National Drug Control Policy in December 2006 *(see the conference report on page 14).* I was pleased to serve on the planning committee. At the conference, family practice also was represented by Amy McGaha, M.D., of the Division of Medical Education at the American Academy of Family Physicians (AAFP), Joseph Gravel, M.D., a member of the board of the Association of Family Medicine Residency Directors (AFMRD), and Paul Seale M.D., who directs a program at Mercer University School of Medicine that trains residents in how to conduct screening and brief intervention for substance use disorders.

I submitted information on activities in Family Medicine for the conference papers, and Dr. McGaha and Dr. Gravel agreed to take some of the conferees' recommendations back to their respective organizations. We have hope for real advances arising from this conference.

NIDA/Family Medicine Links. Another development is a new program sponsored by the National Institute on Drug Abuse, titled "NIDA Goes to the Doctor," through which the agency plans to disseminate the latest information on substance use disorders to practicing physicians. Plans include submission of articles by NIDA to the *Family Practice* newsletter and establishment of a special website for use by primary care physicians. To market the initiative, we are working to bring NIDA Director Nora Volkow, M.D., to the next AAFP annual meeting to address a plenary session.

"Adopt a Residency" Program. ASAM has agreed to work with AFMR to develop a program through which members of ASAM would be serve as volunteer faculty in Family Medicine residency programs. Programs that are open to such assistance would be identified through an AFMR needs survey.

The ASAM Board of Directors has agreed to provide two or more ASAM members who are family physicians and a staff person to work with AFMR staff, and also to try to find funding support. (A program that simply provides curriculum ideas and names of potential faculty may not require funding, but some level of funding could lead to an enhanced program.)

Focus on Adolescents. Family physicians see many adolescent patients, but how many physicians know how to screen for substance use disorders and how to respond to evidence of risk or actual involvement? To address this issue, the New York State Academy of Family Physicians (NYSAFP) is collaborating with the federal Center for Substance Abuse Prevention (CSAP) in a pilot program through which CSAP materials have been distributed to all NYSAFP members. The materials include physician guidelines on how to discuss substance use with adolescents, as well as educational materials for adolescents and their parents.

As a result of the initial distribution, at least 50 NYSAFP members ordered additional copies of the CSAP materials. A follow-up survey found that many of the family physicians personally gave the educational materials to adolescent patients and their parents, rather than merely placing the materials on display in a waiting room. Survey respondents also reported that a number of parents or teens commented favorably about the materials. Most physicians said that having the materials available made them more likely to ask about alcohol and drug use, and that they felt more comfortable in doing so. The pilot study continues, with more results to be reported as we gain experience.

The NYSAFP group also is discussing whether it would be helpful to develop a website for adolescent patients (e.g., FAMILYDOCTORTEEN.ORG). Such a site could become a trusted resource for information on various behavioral and health needs of adolescents.

Med-Sci Sessions. The program for ASAM's Annual Medical-Scientific Conference features numerous sessions of interest to primary care physicians. For example, on Thursday evening, April 26th, ASAM's Family Practice Work Group plans to offer a component session from 8:00 to 10:00 p.m. Speakers will address methods and resources for teaching primary care residents about substance use disorders.

Also, a symposium on "Promising Early Interventions in Adolescent Substance Abuse" is scheduled for Friday, April 27th, from 2:00 to 4:00 p.m. Symposium faculty will describe Internet-based interventions for adolescents who smoke, what works in reducing binge drinking by college students, and programs designed for use in primary care office settings that enhance the identification of and intervention with adolescents with mental health and substance use disorders.

You can help to "spread the word" about these educational opportunities by encouraging primary care colleagues, whether or not they are ASAM members, to attend the Med-Sci conference.

NATIONAL LEADERS CALL FOR CHANGES *continued from page 15*

determined — absolutely determined — and dedicated to making the most positive changes in this preventable and profoundly important public health problem….

Dr. Madras called on the conferees "to do your best to disseminate what you've heard, to implement what you can through your organization or agency, and to help us at ONDCP with the implementation of these recommendations." She added, "I am profoundly optimistic that this conference will result in fundamental public health improvements in our nation."

I share that optimism, and have assured Dr. Madras that ASAM and its members are ready to provide the energy and enthusiasm required to achieve our mutual goals.

Lawrence S. Brown, Jr., M.D., M.P.H., FASAM, is ASAM's Immediate Past President and Senior Vice President of Addiction Research and Treatment Corporation, Brooklyn, New York. Dr. Brown also holds a teaching appointment at Weill Medical College of Cornell University.

NIDA Launches Centers of Excellence

NIDA Director Nora D. Volkow, M.D.

The National Institute on Drug Abuse (NIDA) recently announced the establishment of four Centers of Excellence for Physician Information, which are to be developed in collaboration with the American Medical Association's Research Education Consortium. The Centers are to serve as national models to support the advancement of addiction awareness, prevention, and treatment in primary medical practices. They will specifically target physicians in training, including medical students and resident physicians in primary care specialties such as internal medicine, family practice, and pediatrics.

In its announcement, NIDA described the goals of the Centers of Excellence as "to raise awareness among primary care physicians of drug addiction as a health issue and to further facilitate the dissemination of knowledge as to how best to prevent, diagnose, and treat patients struggling with abuse of and addiction to prescription and illicit drugs." Activities to be conducted include identifying drug addiction knowledge gaps, developing educational materials and resources for physicians in training to address those gaps, and determining the most effective means of delivering the information.

The initial Center sites identified in the announcement are at Creighton University School of Medicine; the University of Pennsylvania School of Medicine (in collaboration with Drexel University College of Medicine), the University of North Dakota School of Medicine and Health Sciences, and the Massachusetts Consortium of Medical Schools (including the University of Massachusetts Medical School, Tufts University School of Medicine, Boston University School of Medicine, and Harvard Medical School/Cambridge Health Alliance).

"These new Centers of Excellence are just one step in a broad cooperative effort to increase awareness among primary care physicians and other health professionals, as well as patients, about drug addiction as a major public health issue," said NIH Director Elias A. Zerhouni, M.D. "This AMA-NIDA collaboration is part of NIDA's ongoing activities to provide physicians and other medical professionals with the tools and skills needed to incorporate NIDA-funded research findings into their clinical practice," added NIDA Director Nora D. Volkow, M.D.

SAMHSA Advises Caution on Lab Tests for Alcohol Abuse

SAMHSA has issued an Advisory that cautions licensure bodies, other monitoring organizations, and staff in criminal justice settings that a widely used test for alcohol consumption is "scientifically unsupportable" as the sole basis for legal or disciplinary action.

According to the advisory, the EtG (ethyl glucuronide) urine test, often used to detect alcohol use among individuals legally prohibited from drinking because of their professional, employment or parole status, is "inappropriate" as the sole basis for a definitive, life-altering decision.

The advisory, titled *"The Role of Biomarkers in the Treatment of Alcohol Use Disorders,"* calls the EtG urine test "one of an evolving group of highly sensitive tests for the ingestion of alcohol." It says that the EtG test and other similar highly sensitive tests are not able to distinguish between alcohol absorbed into the body from exposure to many common commercial and household products containing alcohol as opposed to the actual consumption of beverage alcohol. Therefore, calling such a test "positive" for consumption or relapse, especially at low concentrations, could have devastating consequences for someone who signs an alcohol abstinence contract or is required to be abstinent by law.

"This advisory is a clarification," says addiction psychiatrist Kenneth Hoffman, M.D., M.P.H., medical officer with the Division of Pharmacologic Therapies in SAMHSA's Center for Substance Abuse Treatment. Dr. Hoffman added that CSAT issued the advisory to alert medical review officers and other officials to know that the EtG test is appropriate for use in clinical settings, but should not be used as a stand-alone test in a forensic situation or professional licensure situation.

The problem is that the EtG test is highly sensitive, Dr. Hoffman said, adding: "For example, there's a popular hand-sanitizer that's about 64-percent ethanol. The alcohol in that product can be absorbed through the skin and metabolized to EtG and EtS (ethyl sulfate). With tests highly sensitive to detecting EtG or EtS, that might cause a positive result, even though no alcohol was consumed. A positive EtG or other similar highly sensitive test alone may have nothing to do with relapse or inappropriate use of alcohol."

For more information on the advisory or to view the full text in PDF format, visit WWW.KAP.SAMHSA.GOV/PRODUCTS/MANUALS/ADVISORY.

WEBSITE OFFERS RESOURCES FOR CAREGIVERS, PATIENTS, FAMILIES

A website titled "*Silent Treatment: Addiction in America*" offers a range of resources and links to access research on addiction and treatment and personal stories of daily struggles and victories on the road to recovery, including a comprehensive five-part *newspaper series* that was distributed nationwide by the *McClatchy-Tribune News Service.*

Physicians, patients and family members can use the site (HTTP://WWW.SILENTTREATMENT.INFO/INDEX.HTML) to find tools and links to connect with others interested in finding and improving addiction treatment. For example, advocates will find a host of resources, including logos, public service announcements, and *"Breaking the Silence: An Action Guide,"* which contains suggestions and resources for working with the media. For those engaged in professional and public education, a set of PowerPoints can be downloaded, as can copies of interviews with leading scientists and policymakers. For teens, there is a self-assesment instrument. For patients and families, there is information on how to find a treatment program and how to pay for care.

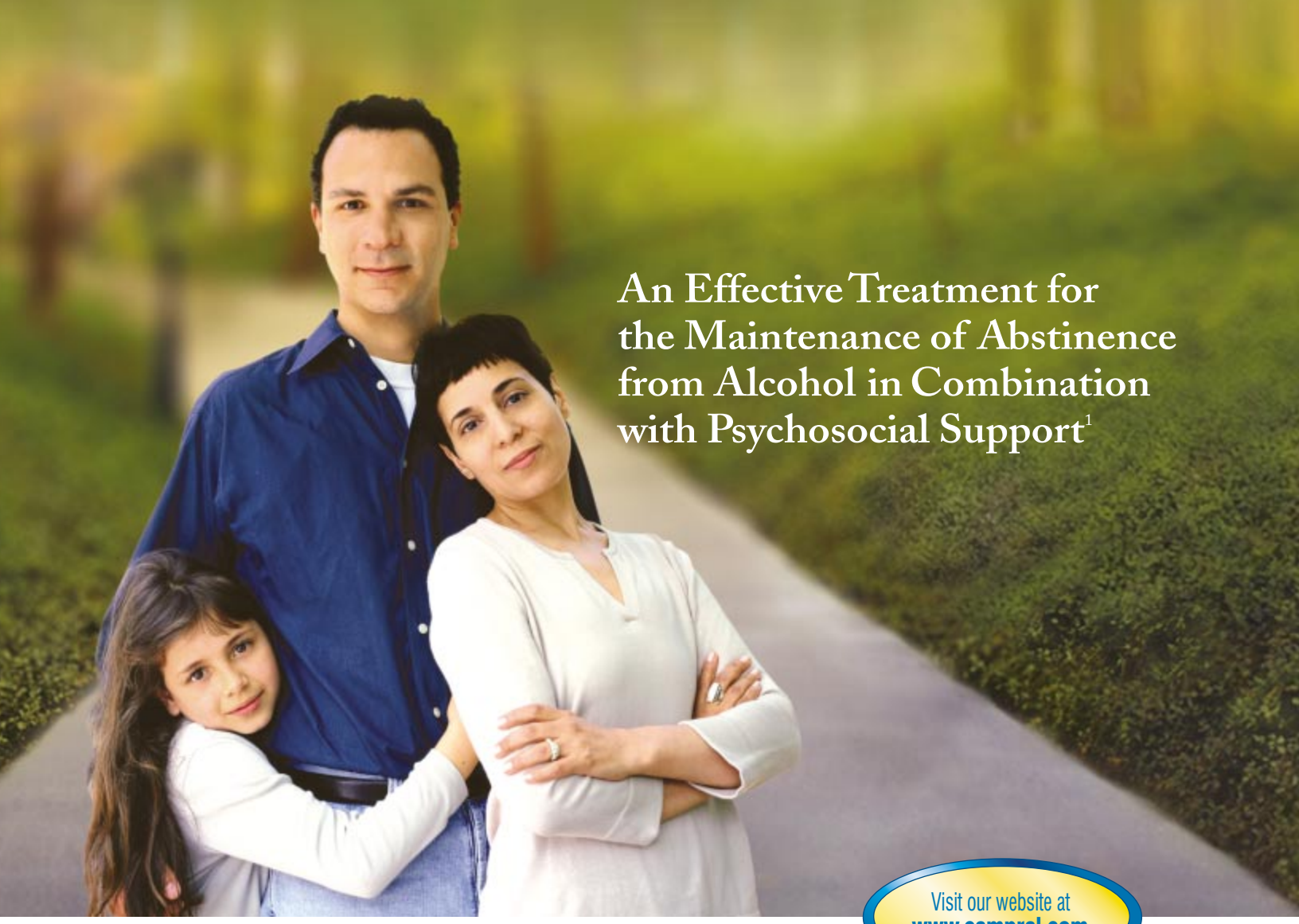
The strength of the site, produced by *Public Access Journalism LLC* with the support of the *Robert Wood Johnson Foundation,* is that it brings together many resources in a single, easy-to-navigate location.

National Alcohol Screening Day

National Alcohol Screening Day is set for April 5, 2007. For those interested in marking the day with community screenings for alcohol problems, screening kits are availble for $50. They include 50 AUDIT screening forms; publicity templates (news releases, PSAs etc.); posters; videos; educational materials and giveaways.

For $150, local organizers can obtain web-based materials, including screening instruments for unlimited community use. Sponsoring organizations can customize their welcome page and referral message, and generate reports and graphs of screening results, community demographics, and utilization.

The kits can be ordered and additional information obtained from program coordinator Liz Sisto at National Alcohol Screening Day, One Washington Street, Suite 304, Wellesley, MA 02481, by phone at 781/239-0071 x 108, or by email at ESISTO@MENTALHEALTHSCREENING.ORG.



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

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

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 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.

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With New Congress, New Hope for Parity

With control of the House and Senate now in Democratic hands, Congressmen Patrick Kennedy (D-RI) and James Ramstad (D-MN) have announced that they will reintroduce the Paul Wellstone Mental Health and Addiction Equity Act, which would bar health plans with 50 or more members from setting different reimbursement schedules, co-payments, deductibles or benefit limits for mental illness or addiction than for other medical disorders.

In past Congresses, the Wellstone legislation garnered enough support for passage in both the House and Senate, but a vote on the measure was repeatedly blocked by the former Republican leadership in the House. Kennedy said he has received assurances from the new Democratic House leaders that the measure will be allowed to come to the floor for a vote once it works its way through the committee process.

"The American people should not be forced to wait any longer for Congress to knock down the barriers to treatment for mental illness and chemical addiction," said Rep. Ramstad, who chided the former Republican leadership for letting ideology triumph over science.

In calling for parity, Congressman Ramstad frequently offers details of his own recovery from addiction. President Bush, who has admitted his own past struggles with alcohol abuse, indicated in 2002 that he would sign a parity bill into law, although he has not announced a position on the Wellstone Act.

At press time, hearings on the parity bill were scheduled for January 22nd in Minneapolis, January 29 in Rockville, Maryland, February 10th in Los Angeles and February 17th in Vancouver, Washington. Congressman Kennedy said the goal of the hearings is to "compile testimony from Americans across the country in an effort to pass the most responsible and comprehensive federal equity bill possible." Local members of Congress who have signed onto the parity measure will coordinate the regional hearings.

OREGON PARITY LAW TAKES EFFECT

Oregon's parity law — one of the strongest in the Nation — went into effect January 1, 2007. The law covers group health plans that collectively insure more than one million (or one in every three) Oregonians. It does not apply to federal employees or Medicare or Medicaid beneficiaries (who already have parity coverage under an Executive Order issued during the Clinton administration). Nor does it cover individual health insurance policies or employees in so-called "self-insured plans," in which the employer actually pays the health benefits but hires an insurance company to handle paperwork and record-keeping. Many large businesses are self-insured. Another group unaffected by the law is the estimated 600,000 Oregonians with no health insurance.

Nevertheless, even those who acknowledge the limitations of the new law say it represents a significant step forward. "It's harder and harder now to argue that mental health is completely different from physical health," said Joel Ario, head of the Oregon Division of Insurance. "The theory of parity is: We don't tell a heart patient, 'You've capped out. No more doctor visits.' "

During debate on the parity bill in 2005, the Associated Oregon Industries and the National Federation of Independent Business warned that passage would cause small businesses to drop all coverage for employees rather than face additional costs associated with the new mental health and addiction benefits. However, proponents of the measure pointed to state data showing that parity for Oregon state employees, in effect since 2003, had raised costs less than 1 percent in its first year.

A key step in implementing the law was to define "mental illness." In crafting a definition, state officials relied heavily on recommendations from an advisory council representing business, insurance and medical specialists and advocacy groups. State officials decided to define "mental or nervous conditions" to be consistent with the definitions in the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association The definition of "chemical dependency" follows the *DSM* criteria, although it includes both alcohol and drugs but excludes tobacco. Even so, the broad definition of mental illness, plus inclusion of alcohol and drug addiction, make Oregon's parity law one of the strongest in the U.S. However, the rules allow insurers to determine "medical necessity" (that is, which treatments to cover for a given illness) and parity advocates expect that to be a crucial battleground as the new parity law takes effect.

Oregon's expansive law and the rules to enforce it "came out right," with compromises by all sides, says Mike Becker, public policy director for Blue Cross and Blue Shield of Oregon, which did not endorse or oppose the statute but supported a move toward parity. "The importance of this," he says, "is the recognition of equal treatment between behavioral health care benefits and medical benefits."

SURVEY: 3 of 4 Support Addiction Parity

The National Alliance on Mental Illness (NAMI) and Mental Health America (formerly the National Mental Health Association) recently released results of a national survey showing that 89 percent of Americans support parity in coverage for mental illness and 74 percent support parity for addiction treatment. Support for parity was strong among both Democrats and Republicans, as well as among employers and employees, according to researchers.

In releasing the results, Mental Health America CEO David Shern noted: "For too long, insurance companies have offered limited or negligible mental health and substance abuse coverage. The myth propelling mental-health inequity in insurance coverage — that improving coverage would bear too much cost to businesses — instead robs U.S. businesses and governments of millions of dollars each year and costs our society productive citizens and healthy families. This survey demonstrates that Americans agree — regardless of political affiliations — that equitable mental health care is long overdue."

The survey findings represent the third in a series of results from the *"Mental Heath America Attitudinal Survey."*
For previous findings, visit HTTP://WWW.MENTALHEALTHAMERICA.NET/.

Varenicline Effective in Smoking Cessation, Study Says

A Cochrane Review conducted by researchers from England's Oxford University concluded that smokers who take the anti-smoking drug varenicline (Chantix®) are three times more likely to quit smoking than those who try to quit without the aid of medication. The U.S. Food and Drug Administration approved the drug in 2006 for use in the treatment of nicotine addiction. It appears to have a dual mechanism of action, blocking nicotine receptors in the brain and preventing withdrawal. The twice-daily pill, taken over 12 weeks, is the only smoking cessation agent other than bupropion (Zyban®) that does not itself contain nicotine.

The research reported in the Cochrane Review involved six studies sponsored by drug-maker Pfizer, including studies that compared the drug to placebo and to bupropion, which is widely used for smoking prevention. Investigators found that one-year abstinence rates were three times higher among the varenicline users than the placebo group and 1.6 times higher than the abstinence rate among the group treated with bupropion. A total of 4,924 smokers took part in the six studies examined in the review.

Thomas Glynn of the American Cancer Society commented that while varenicline is "not going to be a revolution, it's going to be a substantial step forward."

Source: Cahill K, Stead LF & Lancaster T (2007). Nicotine receptor partial agonists for smoking cessation. Cochrane Database of Systematic Reviews, *Issue 1, Art. No. CD006103.*

New CSAT Publications Address Outpatient Treatment

Two new Treatment Improvement Protocols (TIPs) from the federal Center for Substance Abuse Treatment provide guidance to clinicians and administrators who work in outpatient treatment programs. TIP 46 is titled S*ubstance Abuse: Administrative Issues in Outpatient Treatment.* The companion text, TIP 47, is titled *Substance Abuse: Clinical Issues in Intensive Outpatient Treatment.* The TIPs update the subject matter of CSAT's TIP 8, *Intensive Outpatient Treatment for Alcohol and Other Drug Abuse,* published in 1994.

Since TIP 8 was published, substantial changes have occurred in almost every aspect of the way treatment services are conceptualized and delivered. Outpatient programs are now widely used for clients of all ages with a moderate range of problems. As intensive outpatient treatment (IOT) programs have grown in popularity, clinicians have had to keep abreast of new treatment approaches and services provided beyond their own programs. Also, given that IOPs are serving a broader patient population than ever before — including adolescents, homeless persons, and patients with co-occurring mental disorders — program administrators face an array of challenges, including high turnover in the administrative and clinical ranks.

Most of the concepts in TIP 46 address these administrative challenges. The TIP thus provides basic information about operating an outpatient treatment program, including policies and procedures, staffing, and budgets. It also offers strategies for program survival and growth, including guidance on developing structural elements of a successful program, including strategic planning and partnerships, bylaws, and program policy. TIP 46 also provides recommendations and an annotated list of resources to assist programs in cultural competence education, assessment, and training.

In contrast, TIP 47 is designed for clinical staff of outpatient programs, including IOPs, day treatment and partial hospitalization programs. It reviews available treatment options as well as the clinical skills required, synthesizes recent developments in treatment research and practice, and offers 14 guiding principles for outpatient treatment (involving individualized assessment and care, patient monitoring, and ongoing care).

The TIP describes the core services that outpatient programs should be able to provide, as well as the enhanced services that often are delivered onsite or through established links with community-based providers, such as adult education and parenting classes.

To order free copies of TIP 46 and 47, phone the National Clearinghouse for Alcohol and Drug Information at 1-800/729-6686 (English and Spanish) or 1-800/487-4889 (TDD). Request NCADI number BKD545 for TIP 46 or NCADI number BKD551 for TIP 47. Or download TIP 46 from the SAMHSA website at WWW.KAP.SAMHSA.GOV/PRODUCTS/MANUALS/TIPS/NUMERICAL.HTM. (TIP 47 will be available online and in print soon.)

Almost Half of Treatment Programs Offer Specialized Services for Women

A new report from the Substance Abuse and Mental Health Services Administration shows that almost half of all addiction treatment programs offer some sort of specialized women's services. The data come from the National Survey of Substance Abuse Treatment Services (N-SSATS).

Among the 13,371 treatment facilities that responded to the N-SSATS survey in 2005, 13 percent did not accept women as clients. Of the 11,578 facilities that did accept women, 41 percent offer at least one special program or group for female patients: 24 percent offered special programs or groups for adult women only and 3 percent for pregnant or postpartum women only, while another 14 percent offered special programs or groups for both.

Larger facilities were more likely than smaller facilities to offer specialized programs for women. Only 30 percent of the smallest facilities (those with 14 or fewer patients on the survey reference date in 2005) had special programs or groups for women, compared with 59 percent of the largest facilities (those with 120 or more patients).

Facilities offering special programs or groups for women were less likely than facilities without such programs to be operated by private for-profit organizations (24 vs. 32 percent) but more likely to be operated by private non-profit organizations (61 vs. 53 percent). For all other types of facility operation (i.e., State, Local, Tribal and Federal government), the distribution of facilities offering special programs or groups for women was similar to the distribution of facilities not offering such programs.

For a copy of the full survey report, visit SAMHSA's website at HTTP://WWW.OAS.SAMHSA.GOV/2K6/WOMENTX/WOMENTX.HTM.

FDA Issues Methadone Warning

Overdoses of methadone (Dolophine®) can lead to respiratory and cardiac problems and cause death, according to a warning letter issued by the U.S. Food and Drug Administration. FDA says it acted in response to reports of death and life-threatening side-effects in patients taking methadone. These have occurred in patients who recently started methadone for pain control and in patients who have been switched to methadone after being treated for pain with other potent analgesics, according to the agency.

Methadone may accumulate to toxic levels if the drug is taken too often or if the amount taken is too high. Problems also can occur if methadone is used in combination with certain other medications (such as benzodiazepines) that intensify methadone's CNS depressant effect, or with supplements that slow metabolism of the drug. In such cases, methadone can cause slow or shallow breathing, as well as dangerous changes in heartbeat that may not be felt by the patient Because methadone's analgesic effects last up to 8 hours but the drug can remain in the system for more than 50 hours, patients who escalate their doses to relieve re-emergent pain may unwittingly ingest toxic amounts.

Noting that "Prescribing methadone is complex," the warning urges physicians to be cautious in prescribing methadone and to monitor their patients carefully. It also offers the following advice:

- **"Patients should take methadone exactly as prescribed.** Taking more methadone than prescribed can cause breathing to slow or stop and can cause death. A patient who does not experience good pain relief with the prescribed dose of methadone should talk to his or her doctor.
- **"Patients taking methadone should not start or stop taking other medicines or dietary supplements without talking to their health care provider.** Taking other medicines or dietary supplements may cause less pain relief. They may also cause a toxic buildup of methadone in the body, leading to dangerous changes in breathing or heartbeat that may cause death.
- **"Health care professionals and patients should be aware of the signs of methadone overdose.** Signs of methadone overdose include trouble breathing or shallow breathing; extreme tiredness or sleepiness; blurred vision; inability to think, talk or walk normally; and feeling faint, dizzy or confused. If these signs occur, patients should get medical attention right away."

FDA urged physicians who prescribe methadone to read and carefully follow the methadone prescribing information at WWW.FDA.GOV/CDER/FOI/LABEL/2006/006134S028LBL.PDF. FDA recently approved new prescribing information for methadone products approved for pain control, based on its review of the scientific literature. A Medication Guide for patients also is planned.

More than 2 million prescriptions for methadone were issued in 2003 and use of the drug continues to increase because of its effectiveness and relatively low cost. However, adverse events have increased in tandem with the greater exposure. As a result, an estimated 2,452 overdose deaths were linked to methadone in 2003, compared to 623 deaths in 1999.

Binge Drinking, Gender, and Clinical Depression

Although previous research has shown that alcohol consumption and depression frequently are related, such findings have not been consistent. A new study may offer an explanation by suggesting that *how* researchers measure both alcohol consumption and depression is a key issue in interpreting findings on the relationship between alcohol and depression, as is the role of gender. The study was published in the December 2006 issue of *Alcoholism: Clinical & Experimental Research*.

"Not all studies have found a significant relationship between drinking and depression," said Dr. Kathryn Graham, senior scientist at the Centre for Addiction and Mental Health and a member of the research team, "and some have found a relationship for one gender but not the other. In our study, we included two quite different types of measures of depression. We also used four clearly different types of alcohol consumption measures that examined both drinking pattern as well as overall consumption."

The researchers conducted a general population telephone survey of 6,009 males and 8,054 females aged 18 to 76 years. The population surveyed included four types of alcohol measures for both the past year and the week prior to the survey (frequency of drinking, usual and maximum quantity per drinking occasion, overall volume consumed, and frequency of heavy episodic drinking), as well as two depression measures (meeting criteria for a clinical diagnosis of major depression and recent depressed feelings).

> ***"Systematic consideration of the types of measures for alcohol consumption and depression and gender may lead to clearer, more consistent findings."***

Results suggest that the measurement used and the subjects' gender are key issues in interpreting the relationship between alcohol and depression. Specifically, depression is primarily related to drinking larger quantities per occasion and unrelated to drinking frequency. Second, the overall relationship between depression and alcohol consumption is stronger for women than for men, but only when depression is measured as meeting a clinical diagnosis of major depression. Conversely, there is no gender difference when depression is measured as *recent* depressed feelings.

"These findings provide critical clarification of the relationship between alcohol consumption and depression that will be essential for future research intended on identifying causal directions and mechanisms," said Dr. Graham. "For example, in the past, longitudinal research has been conducted that attempted to disentangle the alcohol-depression relationship in order to identify whether alcohol consumption leads to depression, depression leads to alcohol consumption, or some third factor associated with both alcohol consumption and depression accounts for the relationship. No clear pattern has emerged from these studies. Systematic consideration of the *types of measures* for alcohol consumption and *depression and gender* may lead to clearer, more consistent findings," he concluded.

Future research also might attempt to specify how the social context of drinking affects the links between depression and drinking. For example, the association of clinical depression with episodes of heavy drinking may be stronger for women who have heavy-drinking partners and/or who have more social opportunities to drink.

Sources: Massak A, Demers A & Rehm J (2006). Does the association between alcohol consumption and depression depend on how they are measured? Alcoholism: Clinical & Experimental Research *30(12), and the Addiction Technology Transfer Center National Office.*

Gene Is Linked to Craving for Alcohol

A new study has found that individuals carrying a G allele of the A118G polymorphism of the mu opioid receptor gene (OPRM1) crave alcohol more than do individuals who have the more common A allele.

The findings are published in the January issue of *Alcoholism: Clinical & Experimental Research*. "The more sensitive mu-opioid receptor in individuals carrying a G allele of the A118G polymorphism may lead to different behavioral responses due to a different physiological functioning of the receptor," explained Dr. Esther van den Wildenberg, a researcher at the University of Maastricht and corresponding author for the study. "Beta-endorphins are released upon alcohol or drug intake. Different receptor functioning could affect functions such as drug-induced euphoria and analgesia which might influence the subjective experience of the drug and subsequent use."

Dr. Van den Wildenberg added that "We were interested whether heavy drinking individuals — in other words, not yet alcohol dependent — carrying a copy of the G allele would respond differently than 'standard' genotype individuals when exposed to alcohol cues. If the G allele affects subjective experience such as craving for alcohol after exposure, this could also have an influence on subsequent drinking behavior. It turns out that G allele carriers *do* crave significantly more for alcohol after alcohol exposure, compared with the A allele individuals."

The study involved 108 male, heavy drinkers. Participants were either homozygous for the A allele (n=84) or carrying at least one copy of the G allele (n=24). All participated in a cue-reactivity test in which they were exposed to water and beer in three-minute trials. Dependent variables included subjective craving for alcohol, subjective arousal, and saliva production. "By looking at cue-elicited craving in heavy drinkers, we look more specifically into a so-called 'endophenotype,'" Dr. van den Wildenberg explained. An endophenotype, she said, is something of an intermediate phenotype. It lies "between" the genotype (referring to genes) and the phenotype (which refers to the disorder) and thus reflects a biological mechanism that *underlies* the disorder. "Not only did G allele carriers report even significantly more craving for alcohol than the A allele individuals," said Dr. van den Wildenberg, "but G allele carriers reported more life-time drug use compared with the 'standard' genotype participants."

Reviewers noted that study's primary finding is important because it demonstrates that persons who have the G allele may have more difficulty with cue-induced craving than persons who do not have the G allele, and thus be more prone to relapse in a high-risk situation.

Source: Wiers RW. Dessers J, Janssen R. Lambrichs E et al. (2006). A functional polymorphism of the mu-opioid receptor gene (OPRM1) influences cue-induced craving for alcohol in male heavy drinkers. Alcoholism: Clinical & Experimental Research *30(12).*

Spot in Brain May Control Craving

Damage to a silver dollar-sized area of the brain seems to eliminate the urge to smoke, investigators have reported in the January 26th issue of the journal Science. The surprising discovery may shed important new light on craving, a key feature of addiction. The research was inspired by a stroke survivor who claimed he simply forgot his two-pack-a-day addiction to tobacco, even without a conscious desire to quit. "The quitting is like a light switch that went off," said Dr. Antoine Bechara of the University of Southern California, who with colleagues scanned the brains of 69 smokers and ex-smokers to pinpoint the region involved. "This is very striking."

The finding points scientists toward new approaches to smoking cessation that target the little-known brain region called the insula. And it sparked excitement among addiction researchers. "It's a fantastic paper, it's a fantastic finding," said Nora Volkow, M.D., Director of the National Institute on Drug Abuse and a longtime investigator of the brain's addiction pathways. "What this study shows unequivocally is the insula is a key structure in the brain for perceiving the urges to take the drug," Dr. Volkow added.

Some 44 million Americans smoke, and the government says more than 400,000 persons die of smoking-related illnesses each year. Declines in smoking have slowed in recent years, making it unlikely that the nation will reach a public health goal of reducing the rate to 12 percent by 2010. Part of the reason is that nicotine is one of the most addictive substances known, and many smokers suffer repeated relapses when they try to quit.

Thus, Dr. Bechara was surprised when a patient reported that his body "forgot the urge to smoke" following a stroke. At the time, Dr. Bechara was at the University of Iowa studying the effects of certain types of brain damage after strokes or other injuries. While the patient (code-named Nathan) was hospitalized, stroke specialists sent his information to that brain registry. Nathan was 38, had smoked from the age of 14, and said he enjoyed smoking and had had no intention to quit. But following his stroke, he surprised his wife by not even asking for a cigarette while in the hospital.

This suggests what Dr. Bechara calls a "disruption of smoking addiction." To learn more about the phenomenon, Dr. Bechara and colleagues culled their brain-damage registry and found 69 patients who had smoked regularly before their injuries. Nineteen, including Nathan, incurred damage to the insula. Of those, 13 had quit smoking, 12 of them with surprising ease, within a day of the brain injury, and without experiencing any craving since they stopped. Of the remaining 50 patients with damage to other regions of the brain, 19 stopped smoking post-injury, but only four met the broken-addiction criteria. If Dr. Bechara's findings are validated in subsequent studies, they suggest that developing drugs that target the insula might help smokers quit. The insula contains nicotine receptors, so it should be possible to create a nicotine-specific drug, although the quest may take years.

More immediately, NIDA Director Volkow called for a different experiment, in which scientists would temporarily alter the function of certain brain regions with pulses of magnetic energy, or "transcranial magnetic stimulation." Focusing such magnetic pulses on the insula can clarify its role, she said.

Other neurologic functions — such as the reward pathways — currently are under study for their role in addiction. The insula discovery doesn't contradict that work, but adds another layer to the knowledge of the brain's role in addiction, Dr. Bechara added.

Source: Naqvi NH, Rudrauf D, Damasio H & Bechara A (2007). Damage to the insula disrupts addiction to cigarette smoking. Science *315(5811):531-534.*

New Alcohol Guidelines to Be Sent to ASAM Members

Your next issue of ASAM News will arrive in an unfamiliar envelope, because it will be accompanied by a copy of the newly updated *"Helping Patients Who Drink Too Much — A Clinician's Guide."* Produced by the National Institute on Alcohol Abuse and Alcoholism, the 40-page Guide contains practical tools for implementing alcohol screening and is accompanied by online teaching resources. For your personal use, or as a resource for teaching students or colleagues, you'll find the Guide and all the accompanying details in the March-April **ASAM News!**

REPORT PROVIDES COMPREHENSIVE PICTURE OF RX DRUG ABUSE

A new report from the Gulf Coast Addiction Technology Transfer Center (ATTC) synthesizes information from multiple federal datasets to provide a comprehennsive picture of prescription drug abuse.

Prepared by noted epidemiologist Jane C. Maxwell, Ph.D., the report describes a particularly acute problem with the illicit sale and non-medical use of prescription opioids. In fact, the report points to federal data showing that persons aged 19-25 have the highest rates of lifetime nonmedical use. For example, rhe use of OxyContin® by 12th graders and young adults had increased significantly since 2002 At the same time, fewer adolescents surveyed thought there was great risk in nonmedical use of these drugs in 2005 than in 2004. Prescription drugs are described by teens as "easy to obtain, especially from family or friends,…less shameful to use, and safer than illegal drugs."

According to the report, abuse of prescription opioids often is combined with other prescription drugs and alcohol, usually "to get high." Adverse events — such as emergency department visits and drug-related deaths – usually involve multiple drugs and alcohol.

Treatment admissions related to prescription opioids are increasing. The patients who are admitted for problems with prescirption opioids differ in many sociodemographic characteristics from users of heroin and other illicit drugs. For example, the prescription drug users typically began their use at a later age, are more likely to be first admissions to treatment, and generally do not use their drug on a daily basis. They also are more likely to come to treatment because of a referral from another health care provider.

The full report, titled "*Trends in the Abuse of Prescription Drugs,"* can be accessed at the Gulf Coast ATTC website (WWW.UTATTC.NET). The national network of ATTCs is supported by the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration.

Percent of Population Reporting Lifetime Nonmedical Use of Selected Prescription Drugs, 2002-2005

	2002	2003	2004	2005
Vicodin,Lortab, Lorcet	5.6 **	6.6	6.9	7.2
OxyContin	0.8 **	1.2	1.3	1.4
Methadone	0.4	0.5	0.5	0.7
Xanax, Alprazolam, Ativan, or Lorazepam	3.5 **	4.0	3.9	4.2
Clonazepam	1.0 *	1.2	1.1	1.0
Diazepam	6.1	6.2	6.1	6.1
Soma	1.0	1.1	1.1	1.0

**Difference between 2002 and 2003 estimate, p<0.05*
***Difference between 2002 and 2003 estimate, p<0.01*

Source: Office of Applied Studies (2006). National Survey on Drug Use and Health. Rockville, MD: Substance Abuse and Mental Health Services Administration (HTTP://WWW.OAS.SAMHSA.GOV/NSDUH.HTM).

Emergency Department Visits Involving Nonmedical Use of Selected Pharmaceuticals, 2004

	Number	%
Opiates/opioids	**158,281**	**31.9**
Hydroodone/combinations	42,491	
Oxyodone/combinations	36,559	
Methadone	31,874	
Benzodiazepines	**144,385**	**29.1**
Alprazolam	49,842	
Clonazepam	26,238	
Muscle relaxants	**28,338**	**5.7**
Carisoprodol	17,366	
Cyclobenzaprine	5,932	
All ED visits involving nonmedical use of pharmaceuticals	**495,732**	**100**

Source: Office of Applied Studies (2006). Drug Abuse Warning Network. Rockville, MD: Substance Abuse and Mental Health Services Administration (HTTP://DAWNINFO.SAMHSA.GOV/PUBS/SHORTREPORTS/DEFAULT.ASP)

Age of Injection Drug Users Is Increasing, CDC Study Finds

The age of injection drug users increased substantially between 1979 and 2002, according to a study by CDC investigators, which appears in the January 22nd issue of *Archives of Internal Medicine*. In the 200-2002 surveys, 1.5 percent of persons born between the late 1940s and early 1960s reported ever engaging in injection drug use (yielding a weighted estimate of 3.4 million persons). This is the highest prevalence of injection drug use ever seen in older adults.

Study author Gregory L. Amstrong, M.D., found that, from 1979 through 2002, the mean age of participants reporting injection drug use within the past year increased from 21 to 36 years; and the age of participants who had ever engaged in injection use increased from 26 to 42 years. These findings have obvious implications for identifying patients at risk for bloodborne infections such as hepatitis and HIV, as well as for populations that may be expected to seek addiction treatment.

At 3.1 percent, the overall rate of injection drug use was highest among persons 35 to 49 years; higher in men (2.0 percent) than in women (1.0 percent), and higher in Whites (1.7 percent) than in African-Americans (0.8 percent). The prevalence of injection drug use decreased as the subjects' annual income and educational level increased.

Ten years earlier (1990-1992), 1.6 percent of the survey population reported ever engaging in injection drug use, and the prevalence did not differ by race. *Source: Armstrong GL (2007). Injection Drug Users in the United States, 1979-2002*. Archives of Internal Medicine *167(2):166-173.*

Metropolitan Areas Data Available from SAMHSA

Treatment planners and researchers will find data for specific metropolitan areas (as well as state and substate regions) at the website of the Office of Applied Studies of the Substance Abuse and Mental Health Administration (HTTP://OAS.SAMHSA.GOV/METRO.HTM). Data are current through 2004 and can be accessed for state-designated treatment planning areas.

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ASAM'S CHAPTERS COUNCIL TO MEET

ASAM's Chapters Council will meet February 2-3, 2007, in Washington, DC, in connection with ASAM's Legislative Day. The Legislative Day program allows ASAM members to visit Capitol Hill to educate members of Congress and their staffs about the value of Addiction Medicine in treating substance use disorders and ASAM's mission to expand access to treatment.

Items for discussion by the Chapters Council include membership reports and news of efforts to attain recognition by state medical societies and representation in the state Houses of Delegates, activities related to parity, and educational initiatives.

Council Chair Kevin Kunz, M.D., FASAM, will brief Council members on activities of ASAM's newly created Medical Specialty Action Group, which he co-chairs with ASAM President-Elect Michael M. Miller, M.D. *(see the related article on page 4)*. Watch for a full report of the Council meeting in the March-April **ASAM News**!

ASAM's Board of Directors and members of the Chapters Council gathered in Bethesda, Maryland, October 26, 2006. Present were (from the left):

FRONT ROW: ***Nancy Brighindi, M.B.A., CAE; Martha J. Wunsch, M.D., FASAM; James F. Callahan, D.P.A.; Kevin B. Kunz, M.D., M.P.H., FASAM; Brian Hurley, M.D.; Michael M. Miller, M.D., FASAM; Elizabeth F. Howell, M.D., FASAM; Donald J. Kurth, M.D., FASAM; Ken Roy, M.D., FASAM; Jack Whites, M.D.; Marc Galanter, M.D., FASAM.***

SECOND ROW: ***Helen Huff, M.A., M.S.; Caroline M. Gellrick, M.D., FASAM; Raju Hajela, M.D., M.P.H., FASAM; John Verdon, M.D., FASAM; Penelope P. Ziegler, M.D., FASAM; Marcia R. Flugsrud-Breckenridg, M.D., Ph.D.; Howard C. Wetsman, M.D.; Hermese Bryant; Merrill S. Herman, M.D.; Berton J. Toews, M.D., FASAM; Richard Soper, M.D., J.D., M.S.; J. Ramsay Farah, M.D., M.P.H.***

THIRD ROW: ***Jeffrey Kamlet, M.D., FASAM; Daniel J. McCullough, M.D.; Brad Hall, M.D.; Louis E. Baxter, Sr., M.D., FASAM; Robert N. Jones, M.D.; Allan Michael Ebert, D.O., FASAM; C. Chapman Sledge, M.D., FASAM; Stephen A. Wyatt, D.O.; George L. Carlson, M.D.; George D. Hall, M.D., FAAFP; Thomas L. Haynes, M.D., FASAM; Ronald J. Schwerzler, M.D.; Marvin D. Seppala, M.D.; Amy J. Hotaling.*** *(Photographer: John P. Femino, M.D., FASAM)*

CtSAM Targets Physicians in Training

Ken Freedman, M.D., M.B.A., FASAM, President of the Connecticut Society of Addiction Medicine, reports that the recent membership initiative was very initiative, resulting in a total membership in excess of 50, and that future member recruitment efforts will target physicians in training. For example, CME Chair Sam Silverman, M.D. and his committee are organizing a series of dinner meetings with residents and fellows. These sessions, to be cosponsored by the Connecticut State Medical Society and ASAM, will be funded by educational grants from pharmaceutical companies. Dr. Silverman says the goal of the dinners is to introduce young physicians to Addiction Medicine. They will feature ASAM members in all specialties discussing practice opportunities and recent advances in Addiction Medicine.

Dr. Silverman also reports that CtSAM is working with the Rushford Center to sponsor an educational program on underage drinking — an issue that is of interest to policymakers and physicians alike. CtSAM is exploring the possibility of working with ASAM and Connecticut Department of Mental Health and Addiction Services to organize this event.

On the policy front, CtSAM has partnered with the state medical society and professional organizations representing dentristy, nursing, et al., to develop a unified model identification and treatment program for impaired professionals. The authorizing legislation was tabled during the last legislative session, but is once again under consideration.

CtSAM also worked with the state medical society to achieve repeal of the state UPPL. To pass the bill, CtSAM agreed that it would address only alcohol. However, the societies now are working to add other drugs. (For more information on CtSAM activities, contact Dr. Freedman at KENNETH.FREEDMAN@PO.STATE.CT.US or phone Executive Director Elisa Daues at 860/964-0618.)

VASAM Seeks Recognition by State Medical Society

President Carol Currier, M.D., reports that the Virginia Society of Addiction Medicine (VASAM) is mounting a campaign to be admitted to the Medical Society of Virginia (MSV) House of Delegates. The chapter meets all the criteria for admission except the requirement that 60 percent of VASAM members must also be members of MSV. Therefore, the VASAM Board members are urging all chapter members to join the MSV.

(For more information, contact Dr. Currier at CCURRIER@LMGDOCTORS.COM.)

Massachusetts Society is Growing

President Wayne Pasanen, M.D., reports that the Massachusetts Society of Addiction Medicine (MASAM) had a very successful year in 2006. While the membership held steady at 73, the level of activity of the chapter increased.

Education Committee chair Jeffrey Baxter, M.D., organized several interesting programs, two of which were held in conjunction with AAAP. MASAM also partnered with the other New England chapters to host the Cape Cod Symposium, a major national substance abuse meeting. The highlight of the Cape Cod meeting was the presence of both former Governor and Presidential candidate Michael Dukakis and his wife Kitty. Those in attendance found Mrs. Dukakis' remarks about her own battle with depression and alcoholism inspirational.

The chapter contracted with the Massachusetts Medical Society for administrative support services, which should enhance chapter development and growth, and also allows MASAM to hold its educational programs at the State Society's splendid headquarters.

Four Massachusetts physicians — Drs. Jeffrey Baxter, Dan McCullough, Stephen Ryzewicz and David Gastfriend — attended the meeting of ASAM's new Medical Specialty Action Group to investigate the possibilities for specialty recognition of Addiction Medicine. Dr. McCullough also has been named co-chair of a national membership recruitment effort.

On a more mundane note, MASAM resolved all of its legal and administrative issues with appropriate filings to the Federal and State government. Moreover, the chapter is fiscally solvent, with a surplus in its bank account.

In terms of future programming, Dr. Pasanen says: "We need to develop an active Public Policy committee and become more involved in pressing the issues of accessibility, parity and quality. A specific area of concern for the chapter should include examination of issues surrounding diversion of prescription medications, particularly opiates." He adds: "The future appears bright. The goals include further educational programs for both the membership and other physicians and health care professionals.... We continue to be blessed in Massachusetts by the presence and involvement of Jim Callahan, a consistent catalyst for ASAM and MASAM activity. We are the beneficiaries of his commitment and compassion." (For more information, contact Amy Ruzsa at ARUZSA@MMS.ORG or phone 781/434-7314.)

WEST VIRGINIA CHAPTER IS ORGANIZING

Brad Hall, M.D., reports that membership in the new West Virginia chapter has reached 13, and that WVSAM will be represented at the Spring Conference of the Academy of Family Physicians, March 30-April 1 in South Charleston. Leaders hope that the opportunity to interact with more than 400 Family Physicians will help the chapter's recruitment effort.

The AFP Spring Conference program features two different presentations on Addiction Medicine. WVSAM organizers hope to participate in a similar conference in the Fall of 2007.

(For more information, contact Brad Hall, M.D., at PBH2006@CITYNET.NET.)

Advocacy Efforts at the State Level

Alexis Geier-Horan, ASAM's Director of Government Relations, reports the following developments:

Louisiana: State Representative Sydnie Mae Durand has agreed to put a parity bill forward in the Louisiana House of Representatives. Dr. Ken Roy is calling on other Louisiana members to help with planning and grassroots recruitment and coalition-building in support of this effort. Contact Alice Vaccaro at ALICEVACCARO@BELLSOUTH.NET for more information and to volunteer.

New Jersey: A committee of the New Jersey State Senate passed a bill in December 2006 that would provide for full parity for addiction services in health care coverage. S.807 was approved by a 29-9 vote. Whether the measure reaches the desk of Governor John Corzine for signature depends on whether it wins approval of the full Assembly.

Tennessee: Through the efforts of President Richard Soper, M.D., and TNSAM members, the Tennessee Medical Association has added a resolution to its 2007 legislative package urging the state's Comptroller to complete a review of Tennessee alcohol and drug abuse statutes.

Florida Society Sets Date for Annual Conference

FSAM will hold its Annual Conference March 1-4, 2007, at the McKnight Brain Institute of the University of Florida College of Medicine. Thanks go to Mark Gold, M.D., and the University's Division of Addiction Medicine for hosting the event. *Visit the FSAM website* (WWW.FSAMONLINE.ORG) *for the conference program and to register online.*

Ruth Fox Memorial Endowment Fund

Dr. Ruth Fox

Dear Colleague:

As you make your plans to attend ASAM's 38th Annual Medical-Scientific Conference in Miami, remember to mark your calendars for the annual Ruth Fox Reception, which is scheduled for Friday evening, April 27th. The reception, which is a by-invitation-only event, honors those who have supported the Ruth Fox Memorial Endowment Fund over the years. We would be pleased to add your name to that honor roll of philanthropists.

In the next issue of ASAM News, we'll report on the physicians-in-training who have been chosen to receive the 2007 Ruth Fox Scholarships. The scholarships are an important component of ASAM's educational mission. Each year, they allow an outstanding group of physicians-in-training to attend the Medical-Scientific Conference and the Ruth Fox Course for Physicians. The scholarships cover travel, hotel and registration expenses, as well as one year's membership in ASAM. The four scholarship recipients selected in 2006 were 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 scholarships are but one example of the work supported by the Ruth Fox Memorial Endowment Fund, which was established to assure ASAM's continued ability to provide ongoing leadership in newly emerging areas of addiction medicine, to continue its commitment to educating physicians, to increasing access to care and to improving the quality of care.

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

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38th Annual Medical-Scientific Conference

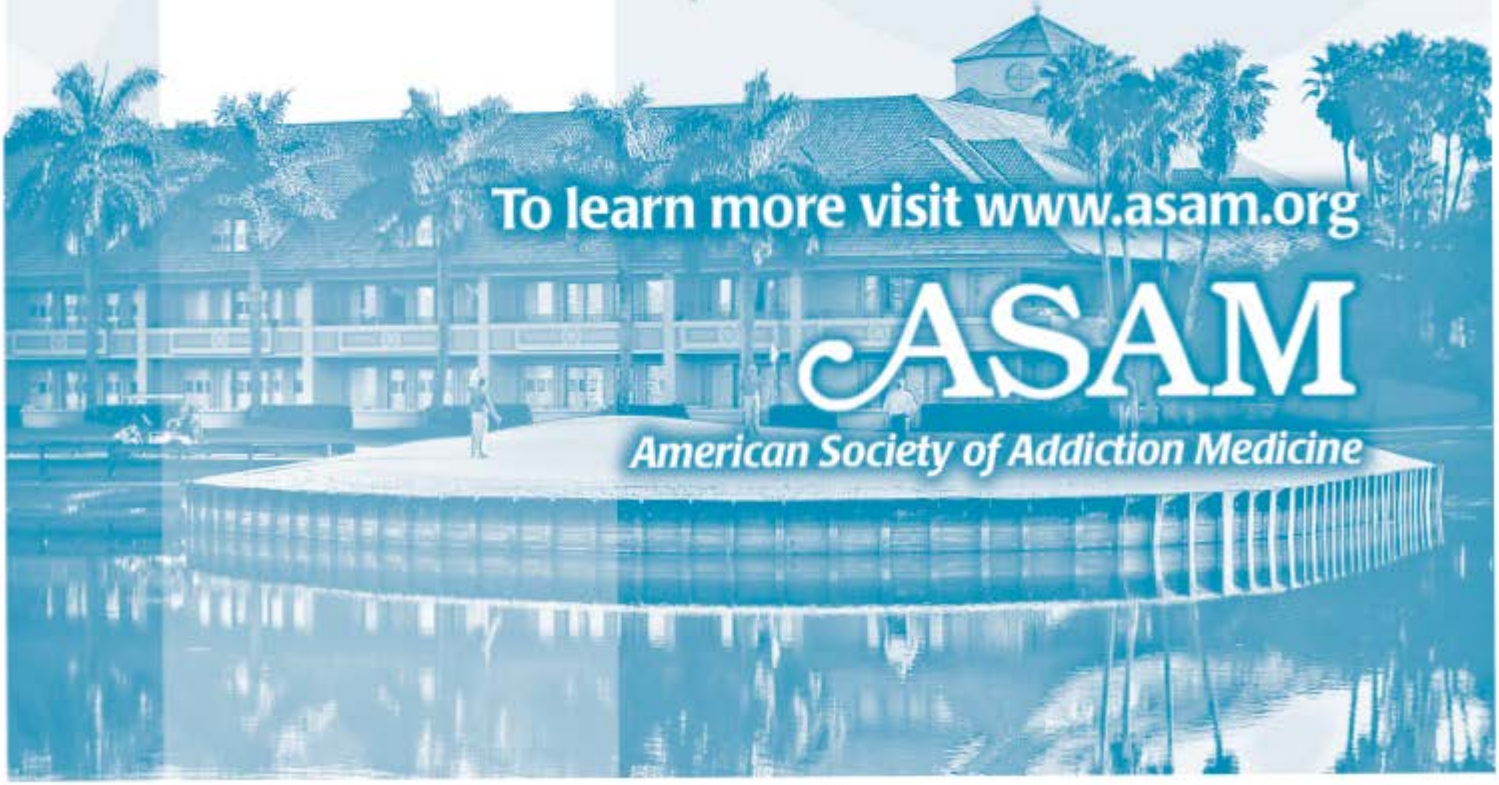
MIAMI 2007

April 27-29, 2007
The Marriott Doral Resort and Spa
Miami, Florida USA

The Ruth Fox Course for Physicians
April 26, 2007

Pain and Addiction: Common Threads VIII
April 26, 2007

Buprenorphine and Office Based
Treatment of Opioid Dependence Training
April 29, 2007



ASAM Conference Calendar

ASAM

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

April 26, 2007
Pain and Addiction:
Common Threads VIII —
Buprenorphine for
Addiction and Pain
Management
Marriott Doral Resort & Spa
Miami, Florida
[8 Category 1 CME Credits]

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

April 29, 2007
Buprenorphine and
Office-Based Treatment
of Opioid Addiction
Marriott Doral Resort & Spa
Miami, Florida
[8 Category 1 CME Credits]

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

October 28, 2007
Buprenorphine and
Office-Based Treatment
of Opioid Addiction
Hyatt Regency Capitol Hill
Washington, DC
[8 Category 1 CME Credits]

OTHER EVENTS OF NOTE

March 5-6, 2007
National Conference on Pain,
Opioids and Addiction
(Sponsored by the National Institute
on Drug Abuse and the American
Medical Association)
Natcher Center, NIH Campus
Bethesda, Maryland
For more information, visit
HTTP://CONFERENCES.MASIMAX.COM/OPIOID

May 21-22, 2007
14th Annual Nicotine Dependence
Conference
Siebens Bldg., The Mayo Clinic
Rochester, Minnesota
[14 Category 1 CME Credits]
For more information, contact
Mayo Nicotine Dependence Program
at 507/266-1093 or
MULHOLLAND.MICHELLE@MAYO.EDU

June 21-24, 2007
7th International Conference on
Pain and Chemical Dependency
Sheraton New York Hotel
New York City
[20 Category 1 CME Credits]
For more information or to register,
visit WWW.IAPCD.COM

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

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