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PSYCHIATRIC NEWS

inside

VA to Keep Using *DSM* To Diagnose PTSD in Vets

A government-requested report says there is no need to change *DSM-IV* criteria for diagnosing posttraumatic stress disorder when evaluating veterans for the disorder.

BY AARON LEVIN

DSM-IV criteria for posttraumatic stress disorder (PTSD) are well-founded and should remain the standard for diagnosis, the Institute of Medicine (IOM) reported in June. The report had been requested by the Department of Veterans Affairs in response to concern about increasing numbers of veterans applying for PTSD disability compensation.

Diagnosis should be carried out by experienced clinicians familiar with *DSM-IV* standards, added the IOM group, chaired by Richard Mayeux, M.D., M.S., a professor of neurology, psychiatry, and epidemiology at the College of Physicians and Surgeons at Columbia University.

"The committee strongly concludes that the best way to determine whether a person is suffering from PTSD is with a thorough, face-to-face interview by a health professional trained in diagnosing psychiatric disorders," Mayeux said.

"In asking the IOM to evaluate and confirm the *DSM-IV* criteria, the VA was not seeking to challenge the criteria but to provide validation of those criteria to those who did challenge them," said Ira Katz, M.D., Ph.D., deputy chief patient care services officer for mental health at the VA. "The goals were very well met."

Acceptance of the *DSM-IV* criteria meant that new, idiosyncratic standards need not be created and verified, a major concern for Darrel Regier, M.D., M.P.H., executive director of the American Psychiatric Institute for Research and Education and director of APA's Division of Research.

"Frankly, I'm surprised that things went so smoothly," Regier told *Psychiatric News*. "A panel of experts agreed that the present criteria were evidence based and that there were plenty of assessment instruments to use."

Separating diagnosis from treatment and disability was a good choice because the latter two issues probably lay more at the heart of the VA's concerns, said Regier.

The IOM committee will also review evidence for PTSD treatment and prognosis and for determining standards of disability related to the disorder. Those two reports are expected by the end of the year.

Although the primary diagnostic tool for PTSD is the knowledge and experience of the clinician, the report also suggested that use of structured or semistructured interviews such as the Clinician-Administered PTSD Scale (CAPS), the Structured Clinical Interview for *DSM-IV* (SCID), the PTSD Symptom Scale—Interview

Please see ***VA*** *on page 42*

U.S. Unique in Approach To Funding Prescription Plans

Comparisons of U.S. and foreign publicly funded drug benefits have been described by experts as a trade-off between more choices on one hand and more affordability on the other, with the costs to taxpayers mixed.

BY RICH DALY

In the midst of high-profile efforts to change the recently instituted Medicare drug benefit, the policies of other industrialized nations may provide previews of the impact that changes could produce.

Approaches to publicly subsidized prescription drugs in other countries differ in important ways from those in the United States—most allow access to fewer drugs but cover more people than the approach used by the United States, according to health policy experts from Europe, Canada, and Australia who provided a briefing to congressional staff on the issue in June.

Among the major differences between the U.S. approach, which subsidizes drug coverage for about 43 million elderly and disabled, and those of other industrialized countries is that most other nations consider the comparative effectiveness of medicines sold in those markets when deciding what to include in their formularies.

"Without rigorous evaluation [by a third party] the drug industry inevitably will be dominated by marketing," said Steven Morgan, an assistant professor in the Department of Health Care and Epidemiology at the University of British Columbia.

He pointed out that 13 percent annual growth in per-capita drug expenditures by Americans since 1995 coincided with huge increases in direct-to-consumer advertising. Such advertising increased from less than $500 million in 1995 to more than $4 billion in 2005.

Drug spending per capita in Canada, which bans such marketing, has increased much more slowly than it has in the U.S. market since the mid-1990s.

The leading U.S. drug-assessment initia-

Please see ***Funding*** *on page 42*

At this year's APA Institute on Psychiatric Services, the bright lights and endless attractions of New York will compete for attention with a rich scientific program. Many of the sessions will focus on community-psychiatry issues and on the theme "Trauma and Violence in Our Communities." Institute coverage begins on page 28, and the preliminary program begins on page 31.

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Who Can Call Themselves Physicians: Law Would Draw the Line

Consumer surveys consistently report a demand by the public for federal legislation to help them understand the qualifications of their health care professionals. New legislation seeks to respond to that demand.

BY RICH DALY

The Healthcare Truth and Transparency Act aims to bar practitioners who have not graduated from medical school from misrepresenting themselves as physicians through advertising. Under the legislation, sponsored by Rep. John Sullivan (R-Okla.), nonphysician health professionals who continue to misrepresent themselves would face investigation and fines by the Federal Trade Commission.

The legislation is backed by APA as a member of the Coalition for Health Care Accountability, Responsibility, and Transparency (CHART), a physicians' advocacy group. The legislation is needed to help patients avoid "substandard—and perhaps even dangerous—care" through misleading claims, said APA President-elect Carolyn Robinowitz, M.D., in a written statement.

"Information is power—the power to make better choices, to protect you and your family's safety, and to keep costs in check by getting you the care you need the first time," she said.

The legislation aims to eliminate practices such as those of Louisiana psychologists, who in recent years won the right to prescribe psychoactive medications and to refer to themselves as "medical psychologists." That title is misleading, APA maintains, because the law that gave Louisiana psychologists prescribing privileges placed their oversight with the nonphysician Louisiana State Board of Examiners of Psychologists rather than with a state medical board.

"The term 'medical psychologist' encourages a patient to believe he or she is being seen by a medical doctor, when they're really being seen by someone without a medical degree. To me, that is deceptive," Robinowitz said.

Sullivan said that the increasingly complex health care system has created a need to help consumers understand the differences in the kind of care they are offered.

The vast majority of Americans (90 percent) appear to be concerned about the qualifications of the professionals who provide their health care, according to a recent CHART survey. It found 86 percent support federal legislation that would make it easier for them to understand the qualifications of the health care professionals who treat them and their families.

The measure comes as changes in state laws in recent years related to practitioners' scope of practice have blurred the line between physicians, other clinicians who have some degree of medical training, and nonmedically trained practitioners. Adding to the confusion are nonphysician clinicians who use "physician" inaccurately or employ misleading uses of "doctor."

"While non-M.D. practitioners have an important role in the health care system, in fairness to the patients, the line must be clear as to the qualifications of the providers treating them," Sullivan said. "As we focus on improving the delivery of health care in America, we must start by insisting on a level of transparency and truth in advertising that will empower patients to make an informed decision when it comes to their health care."

In addition to APA, CHART members include the American Academy of Ophthalmology, American Academy of Otolaryngology–Head and Neck Surgery, American College of Surgeons, American Medical Association, and American Society of Anesthesiologists.

The text of the Healthcare Truth and Transparency Act is posted at <http://thomas.loc.gov/cgi-bin/query/z?c109:H.R.5688:>. ■

APA Invites Nominations for MIT Position

The APA Nominating Committee continues to accept recommendations for candidates for the member-in-training trustee-elect (MITTE) position for APA's 2007 election.

The resident elected in the 2007 election will serve as MITTE (without vote) from May 2007 to May 2008, and as MITT (member-in-training trustee, with vote) from May 2008 to May 2009.

Residents must have been accepted as APA members in both APA and their district branch, be in their PGY-2 or PGY-3 year in the summer of 2006, and have written permission from their training directors to fulfill the two-year commitment as MITTE and MITT as a part of their training.

Information about the MITTE/MITT positions, eligibility criteria, and submission forms are posted on APA's Web site at <www.psych.org/edu/res_fellows/rf/mitte.cfm>.

All materials must be received by August 4.

More information on the MITTE nominating process is available by contacting Carol Lewis by e-mail at clewis@psych.org or by phone at (703) 907-8527. ■

APA RESOURCES

- **APA and the APA Answer Center:** (888) 35-PSYCH in the U.S. and Canada; in other countries: (703) 907-3700. The Answer Center is open Monday through Friday, 8:30 a.m. to 6 p.m. Eastern time. All APA departments and staff may be reached through the Answer Center.
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Psychiatrists Address Needs Of Older Americans

BY PEDRO RUIZ, M.D.

Spurred by my attendance at the annual meeting of the American Association for Geriatric Psychiatry (AAGP) in Puerto Rico last March, I decided to devote this column to the mental health needs of older adults.

Interest in this population is burgeoning as evidenced by the excellent turnout at the AAGP meeting—about 1,200 people. Leading geriatric psychiatry into the future is AAGP's impressive and committed leadership: Dr. Dan G. Blazer II as past president, Dr. Christopher C. Colenda as president, and Dr. Gary Moak as president-elect, as well as Christine de Vries, AAGP's executive director.

Several facts help explain the rising interest in America's older citizens. According to the AAGP, about 32 million Americans are now aged 65 and over. While they make up 13 percent of the U.S. population, they account for 19 percent of all suicides—the highest suicide rate of any age group. By the year 2010, there will be about 40 million older adults in this country, and it is estimated that more than 8 million (or 20 percent) will experience mental health problems. That number will only increase as successive waves of baby boomers reach the traditional retirement age.

A major barrier to access to care for the elderly is inadequate reimbursement for psychiatric services under Medicaid and Medicare, and serious workforce shortages only add to the problem. There are only 2,700 board-certified geriatric psychiatrists and 500 to 700 geropsychologists. Other factors that prevent older Americans from getting the care they need are denial of their conditions, reluctance to seek care due to stigma and insensitivity among some sectors of society, failure of clinicians to detect and diagnose mental conditions among older adults, insufficient funding for mental health programs directed to older adults, and lack of "medigap" insurance coverage.

These factors present a formidable challenge since currently about 20 percent of persons over age 55 suffer from mental problems unrelated to age. The most common of these conditions are anxiety disorders, cognitive disorders, and mood disorders. Schizophrenia and personality disorders are less common among older adults. Moreover, declining health, loss of loved ones, and chronic conditions put older adults at higher risk for mental health problems.

APA and AAGP continue to fight for parity for mental health benefits under Medicare, but for now we are saddled with a system in which the copay for most mental health services is much higher (50 percent) than for most other medical services (20 percent). The discrepancy is nothing less than tragic: 70 percent of older adults who commit suicide see their primary care professionals within one month of committing suicide. It is not an overstatement to say that many of these suicides could be prevented if seniors were given the same coverage for mental health services as they have for other medical services.

Substance abuse is another common condition among older adults, and yet substance abuse treatment is not covered by most medical insurance plans for this population. About 45 percent of older adults over age 55 drink alcohol—that is, 36 million persons. In 2000, about 1.7 million older adults were in need of substance abuse treatment; in 2020, this number is estimated to be about 4.4 million.

The most common substances used or abused by older adults are marijuana, prescription drugs, and cocaine. Comorbid conditions are very common, frequently leading to poor outcomes; decreased quality of life; and increased health care utilization, disabilities and impairment, caregiver stress, mortality, and suicide.

In March Dr. Blazer warned a congressional subcommittee about "the impending public health crisis caused by an unprecedented increase in the burden of mental illness among aging persons, especially among the baby-boom generation." He presented a list of recommendations to stem the crisis, including increased funding for research on aging and for the Mental Health Outreach and Treatment for the Elderly program and funding restored to Fiscal 2005 levels for the geriatric health professions program under the Public Health Service Act.

APA and the AAGP have a long history of working together on mental health issues that affect the elderly and will continue to address ways to overcome the many barriers to care our seniors encounter. To be as effective as possible in this quest, we also need to collaborate with patient-oriented groups.

Older Americans are among the most vulnerable people in this country to inhumane care. Let's secure for them access to the full range of acute and long-term psychiatric services that will help them maintain a satisfying quality of life and remain in the community for as long as possible. These services must include home-based care, crisis-intervention services, respite care and other services for caregivers, and programs geared to special populations, such as racial and ethnic minorities. Let us not stop our efforts until we fulfill our professional responsibility to our seniors. ■

Bober Named

Daniel I. Bober, D.O., has been selected as the 2007 Jeanne Spurlock Congressional Fellow. Bober is a fifth-year child and adolescent psychiatry resident at the Yale Child Study Center in New Haven, Conn. He plans to enter a forensic psychiatry fellowship at the University of Massachusetts Medical School before beginning the congressional fellowship. Bober will begin his fellowship on Capitol Hill in July 2007 and will end in December 2007. ■

Rural Counties Suffer From Child Psychiatry Shortage

Child and adolescent psychiatrists remain in short supply, especially in underserved counties, while attempts to increase numbers have progressed only slowly.

BY AARON LEVIN

The number of child and adolescent psychiatrists per capita rose from 1990 to 2001, but still fell short of the need, a shortage compounded by an unequal distribution of practitioners, according to a recent report by Christopher Thomas, M.D., and Charles Holzer III, Ph.D., of the Department of Psychiatry and Behavioral Sciences at the University of Texas Medical Branch at Galveston.

Rural counties and those with high poverty rates, regardless of population, had few or no child psychiatrists.

"Wealthier counties have not reached saturation in service, and incentives for practice in underserved areas are insufficient," wrote Thomas and Holzer. The study was published online in the *American Journal of Child and Adolescent Psychiatry* on May 17 and will appear in the September print edition.

Thomas and Holzer tracked the number and distribution of child and adolescent psychiatrists from a list compiled by the Department of Health and Human Services, comparing data from 1990, 1995, 2000, and 2001. The total of 6,256 child psychiatrists is probably an overestimate, said Thompson in an interview, because not all are in active, full-time practice. Some are retired, while others are administrators, teachers, or researchers.

Data were broken down by state and county and showed a slight general increase from 1990 to 2001 in proportion to the number of young people. There was an average of 6.73 child and adolescent psychiatrists per 100,000 youth in the United States in 1990 and 8.67 in 2001. However, other studies have estimated that 14.38 child and adolescent psychiatrists would be needed per 100,000 youth in ideal circumstances, and only six states (Connecticut, Hawaii, Maryland, Massachusetts, New York, and Rhode Island) met that standard in 2001.

Often any increase in the number of child psychiatrists was outpaced by added numbers of young people. Maryland, for instance, had 64 more clinicians in 2001 than in 1990, but because there were more youngsters, the rate per 100,000 children remained nearly the same: 18.0 in 2001 versus 18.6 in 1990.

In 2001 the rate of child psychiatrists per 100,000 youth varied from 3.1 in Alaska to 21.3 in Massachusetts. Rates were also especially low in rural counties and in counties with higher percentages of youth living in poverty. Even that distribution wasn't uniform, wrote Thomas and Holzer.

"Although metropolitan counties were more likely to have child and adolescent psychiatrists than rural counties, almost half the metropolitan counties did not have even one child and adolescent psychiatrist," they said.

Many psychiatrists in urban areas do not accept third-party reimbursement, which limits the number of psychiatrists available to provide services through managed care organizations.

Several factors may account for the slow growth in the numbers of child and adolescent psychiatrists, said Thomas in an interview. Child psychiatry is a subspecialty and requires three years of general psychiatry residency plus two years of child psychiatry.

Medical school debt, the bane of most new physicians, exerts its influence in their choice of specialty. Half of first-year residents who say they are interested in child psychiatry stay in adult psychiatry so they can begin earning income a year sooner, said Thomas Anders, M.D., of the Department of Psychiatry at the University of California, Davis, and the president of the American Academy of Child and Adolescent Psychiatry (AACAP).

Medical students may also have too little exposure to child psychiatry and thus fail to consider it as a career option, said Anders. Stigma plays a role, too, he said. "To go into child psychiatry takes courage and exposure."

About 10 percent of child psychiatry residency slots go unfilled each year, so AACAP (in cooperation with APA) is trying to raise the visibility of the subspecialty among medical students and PGY-1 and PGY-2 psychiatry residents, said Anders. Increasing residency slots is difficult because it takes funding, approval from the institution and accrediting bodies, supervision, and additional patients who can afford such care or have insurance that covers it.

The organization has seen success with a triple-board program, developed jointly by AACAP, APA, the American Academy of Pediatrics, the American Board of Psychiatry and Neurology, and the American Board of Pediatrics, that now takes in 21 new residents each year at 10 institutions, said Anders. These residencies require two years of pediatrics, followed by three years of an integrated adult and child psychiatry curriculum *(Psychiatric News*, March 3).

AACAP has also proposed a pilot project allowing board certified/eligible family physicians or pediatricians to enter the last three years of such programs and expects a decision from the Residency Review Committee in Psychiatry in October. A "radical" faction has even suggested making child psychiatry its own specialty (as opposed to the current designation as a subspecialty) to reduce the residency time spent on general psychiatry below certification levels, but that is a minority view, said Anders. "The predominant thinking is that you need adult psychiatry and that we are still a subspecialty."

Both AACAP and APA are working on a policy level, too. Anders noted that bills have been introduced into Congress—although not yet passed—that would extend loan forgiveness programs for all mental health professions, remove the 50 percent cap on Medicare-funded training slots in hospitals for all subspecialties, and designate child psychiatry a shortage subspecialty. (Child psychiatry is already recognized as a shortage specialty by the federal Department of Health and Human Services Bureau of Health Professions and the Accreditation Council on Graduate Medical Education.)

please see ***Child Psychiatry*** *on page 41*

Demand Outstrips Supply

Below are the number of accredited child and adolescent psychiatry residency training programs in the United States and the number of residency positions filled by academic year. Numbers exclude combined programs.

Academic Year	No. of residency programs	No. of residency positions filled
July 2000 thru June 2001	115	702
July 2001 thru June 2002	115	655
July 2002 thru June 2003	116	681
July 2003 thru June 2004	115	707
July 2004 thru June 2005	115	715
July 2005 thru June 2006	114	739
July 2006 thru June 2007	113	725

Source: Accreditation Council on Graduate Medical Education

When Idealism, Reality Collide

No one has to tell Adam Bowman, M.D., about a shortage of child psychiatrists.

His days at Delaware Guidance Services in Lewes, Del., are crammed with brief med checks, hemmed in by insurers' rules, and pressed by the needs of children from the coast and farmlands of Sussex County. Like all child psychiatrists, he has to deal with the educational and social problems that many of his patients experience. To top it off, the local hospital has no inpatient psychiatric ward.

Bowman is just two years out of residency, but reality has begun to temper the idealism that drew him to the field.

"I went into child psychiatry because I thought if I started working with children and their families early, I could change the outcomes in their lives," he said. "I still feel that way, but now I'm more skeptical. I see the effects of poverty, school problems, lack of insurance, poor coordination among social agencies, and a disjointed medical-records system."

Most children he sees are covered by Medicaid or by Delaware's child mental health services program, which provides mental health and substance abuse treatment to children without health insurance, or children with Medicaid who require services more intensive than the basic 30 hours of outpatient treatment can provide.

Following Medicaid's rules, children who come to Delaware Guidance Services are initially evaluated by a psychologist or social worker, and if appropriate, are then referred to Bowman or his colleague, Ruben Portnoy, M.D.

Bowman does his own evaluation but will only be paid for one hour, even if he feels that a longer time would be preferable. After that, the child may see the therapist once a week and Bowman once a month to monitor medications. Ideally, Bowman would like to hold some sessions with the patient and others with the patient and the family, but rarely has that luxury, he said.

This split therapy is complicated even more by the absurdities of insurers, he said. "Some companies won't reimburse a psychiatrist and a psychologist or social worker if they see the patient on the same day. That's ludicrous when patients live an hour away."

If split therapy is not easy for the children, it's not easy for Bowman, either. He was trained in psychotherapy in his residency at Jefferson Medical College in Philadelphia, preparation for a more intensive approach to patients, but that's hard to do in a 15-minute med check.

Overall, the county's children need more support for mental health services from many sources, not just psychiatrists.

"There's also a shortage of good therapists to work with, and there's a real shortage of insurance or government funding to pay for these services," he said.

Shortage Affects Entire Country

Data from the year 2000 indicate that metropolitan counties were more likely to have child and adolescent psychiatrists than rural counties, but almost half of the metropolitan counties did not have even one child and adolescent psychiatrist.

	Counties	Child Psychiatrists: Mean no. per county	Child Psychiatrists: Mean no. per 100,000 youth
Metropolitan areas of more than 1 million people	413	9.9	6.9
Metropolitan areas of 250,000 to 1 million people	325	3.6	5.6
Metropolitan areas of fewer than 250,000 people	351	1.3	5.4
Urban population of more than 20,000 people, adjacent to a metropolitan area	218	0.3	2.1
Urban population of more than 20,000 people, not adjacent to a metropolitan area	105	0.7	4.4
Urban population of 2,500 to 19,999 people, adjacent to a metropolitan area	609	0.1	1.2
Urban population of 2,500 to 19,999 people, not adjacent to a metropolitan area	450	0.1	1.7
Rural population of fewer than 2,500 people, adjacent to a metropolitan area	235	0.0	0.3
Rural population of fewer than 2,500 people, not adjacent to a metropolitan area	435	0.0	0.3

Source: Christopher Thomas, M.D., and Charles Holzer III, Ph.D., *Journal of the American Academy of Child and Adolescent Psychiatry*, September 2006

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IMPORTANT SAFETY INFORMATION

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  Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of nine antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking and behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials

- **To reduce the risk of hypertensive crisis, which is potentially life-threatening, foods and beverages high in tyramine must be avoided while on EMSAM 9 mg/24 hr or 12 mg/24 hr, and for 2 weeks following discontinuation of EMSAM at these doses or reducing the dose to EMSAM 6 mg/24 hr**
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- After stopping treatment with SSRIs, SNRIs, TCAs, MAOIs, mirtazapine, bupropion; meperidine and analgesics such as: tramadol, methadone, and propoxyphene; dextromethorphan; St. John's wort; and buspirone, approximately 1 week (5 weeks for fluoxetine) should elapse before starting therapy with EMSAM. At least 2 weeks should elapse after stopping EMSAM before starting therapy with buspirone or a drug that is contraindicated with EMSAM
- **Carbamazepine** and **oxcarbazepine** are contraindicated in patients taking MAO inhibitors, including EMSAM
- The use of EMSAM is contraindicated for use with **sympathomimetic amines**, including amphetamines as well as cold products and weight-reducing preparations that contain vasoconstrictors (eg, pseudoephedrine, phenylephrine, phenylpropanolamine, and ephedrine)
- Patients taking EMSAM should not undergo **elective surgery requiring general anesthesia** or be given **local anesthesia** containing sympathomimetic vasoconstrictors
- EMSAM should not be used in the presence of **pheochromocytoma** since such tumors secrete pressor substances
- **Adults** with MDD or co-morbid depression in the setting of other psychiatric illness **being treated with antidepressants** should be observed for **clinical worsening and suicidality**, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases
- Risk of **bipolar disorder** should be ruled out prior to initiating antidepressant therapy. EMSAM is not approved for the treatment of bipolar depression
- Due to the potential for elevated blood pressure, the use of EMSAM with **buspirone** is not recommended
- As with other MAOIs, **postural hypotension** can occur with EMSAM therapy. Dose increases in the **elderly** should be made with caution and patients should be observed closely for postural changes in blood pressure throughout treatment
- EMSAM should be used with caution in patients with certain concomitant systemic illnesses that can produce **altered metabolism or hemodynamic responses**
- As with other psychoactive drugs, EMSAM may have the potential to **impair judgment, thinking, or motor skills**. Patients should not drive or operate hazardous machinery until they are certain EMSAM does not impair their ability to engage in such activities
- The use of **alcohol** is not recommended while taking EMSAM
- EMSAM should not be used in combination with **tyramine-containing nutritional supplements**
- EMSAM should be used in **pregnancy** only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when administering EMSAM to a nursing mother
- EMSAM is contraindicated in patients with known **hypersensitivity** to selegiline or to any component of the transdermal system
- **Treatment-emergent adverse events** in short-term clinical trials that occurred at a ≥2% incidence with EMSAM and for which the incidence was greater than placebo include: application site reaction (24% vs 12%), headache (18% vs 17%), insomnia (12% vs 7%), diarrhea (9% vs 7%), dry mouth (8% vs 6%), dyspepsia (4% vs 3%), rash (4% vs 2%), pharyngitis (3% vs 2%), and sinusitis (3% vs 1%)

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The first and only transdermal MAOI— no dietary modifications at the starting and target dose of 6 mg/24 hr

Significant relief— proven short-term efficacy with longer time to relapse

Demonstrated tolerability— reported sexual dysfunction similar to placebo; minimal weight change

INDICATION

EMSAM is indicated for the treatment of Major Depressive Disorder (MDD).

Dose-Dependent Dietary Modifications:

To reduce the risk of hypertensive crisis, which is potentially life-threatening, foods and beverages high in tyramine must be avoided while on EMSAM® 9 mg/24 hr and 12 mg/24 hr, and for 2 weeks following discontinuation of EMSAM at these doses, or reducing the dose to EMSAM 6 mg/24 hr.

- Estimates of the incidence of sexual dysfunction cited in product labeling may underestimate actual incidence

EMSAM® 6 mg/24 hr
(selegiline transdermal system)

Unique Delivery. Proven Results.

EM-K0006 05/06 Printed in USA

EMSAM® (SELEGILINE TRANSDERMAL SYSTEM) Rx only

CONTINUOUS DELIVERY FOR ONCE-DAILY APPLICATION

Brief Summary of Prescribing Information. For complete prescribing information please consult official package circular.

Suicidality in Children and Adolescents

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of EMSAM or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised for the need for close observation and communication with the prescriber. EMSAM is not approved for use in pediatric patients. (See WARNINGS and PRECAUTIONS, Pediatric Use.)

Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of nine antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

INDICATIONS AND USAGE

EMSAM is indicated for the treatment of major depressive disorder.

The efficacy of **EMSAM** in the treatment of major depressive disorder was established in 6- and 8-week placebo-controlled trials of outpatients with diagnoses of DSM-IV category of major depressive disorder (see **Clinical Efficacy Trials** in Full Prescribing Information).

A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, and suicide attempt or suicidal ideation.

The benefit of maintaining patients with major depressive disorder on therapy with **EMSAM** after achieving a responder status for an average duration of about 25 days was demonstrated in a controlled trial (see **Clinical Efficacy Trials** under **CLINICAL PHARMACOLOGY** in Full Prescribing Information). The physician who elects to use **EMSAM** for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient (see **DOSAGE AND ADMINISTRATION**).

The antidepressant action of **EMSAM** in hospitalized depressed patients has not been studied.

CONTRAINDICATIONS

EMSAM is contraindicated in patients with known hypersensitivity to selegiline or to any component of the transdermal system.

EMSAM is contraindicated with selective serotonin reuptake inhibitors (SSRIs, e.g., fluoxetine, sertraline, and paroxetine), dual serotonin and norepinephrine reuptake inhibitors (SNRIs, e.g., venlafaxine and duloxetine), tricyclic antidepressants (TCAs, e.g., imipramine and amitriptyline), bupropion hydrochloride; meperidine and analgesic agents such as tramadol, methadone and propoxyphene; the antitussive agent dextromethorphan; St. John's wort; mirtazapine; and cyclobenzaprine. **EMSAM** should not be used with oral selegiline or other MAO inhibitors (MAOIs e.g., isocarboxazid, phenelzine, and tranylcypromine) (see **WARNINGS**).

Carbamazepine and oxcarbazepine are contraindicated in patients taking selegiline (see **PRECAUTIONS, Drug Interactions**).

As with other MAOIs, **EMSAM** is contraindicated for use with sympathomimetic amines, including amphetamines as well as cold products and weight-reducing preparations that contain vasoconstrictors (e.g., pseudoephedrine, phenylephrine, phenylpropanolamine, and ephedrine).

As with other MAOIs, patients taking **EMSAM** should not undergo elective surgery requiring general anesthesia. Also, they should not be given cocaine or local anesthesia containing sympathomimetic vasoconstrictors. **EMSAM** should be discontinued at least 10 days prior to elective surgery. If surgery is necessary sooner, benzodiazepines, mivacurium, rapacuronium, fentanyl, morphine, and codeine may be used cautiously.

As with other MAOIs, **EMSAM** is contraindicated for use in patients with pheochromocytoma.

EMSAM is an irreversible MAO inhibitor. As a class, these compounds have been associated with hypertensive crises caused by the ingestion of foods containing high amounts of tyramine. In its entirety, the data for **EMSAM** 6 mg/24 hours support the recommendation that a modified diet is not required at this dose. Due to the more limited data available for **EMSAM** 9 mg/24 hours and 12 mg/24 hours, patients receiving these doses should follow **Dietary Modifications Required for Patients Taking EMSAM 9 mg/24 hours and 12 mg/24 hours.** (See **WARNINGS** and **PRECAUTIONS, Drug Interactions**, *Tyramine*.)

WARNINGS

Clinical Worsening and Suicide Risk

Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders.

Pooled analyses of short-term placebo-controlled trials of nine antidepressant drugs (SSRIs and others) in children and adolescents with MDD, OCD, or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal behavior or thinking (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. There was considerable variation in risk among drugs, but a tendency toward an increase for almost all drugs studied. The risk of suicidality was most consistently observed in the MDD trials, but there were signals of risk arising from trials in other psychiatric indications (obsessive compulsive disorder and social anxiety disorder) as well. **No suicides occurred in these trials.** It is unknown whether the suicidality risk in pediatric patients extends to longer-term use, i.e., beyond several months. It is also unknown whether the suicidality risk extends to adults.

All pediatric patients being treated with antidepressants for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Such observation would generally include at least weekly face-to-face contact with patients or their family members or caregivers during the first 4 weeks of treatment, then every other week visits for the next 4 weeks, then at 12 weeks, and as clinically indicated beyond 12 weeks. Additional contact by telephone may be appropriate between face-to-face visits.

Adults with MDD or co-morbid depression in the setting of other psychiatric illness being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms.

Families and caregivers of pediatric patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for **EMSAM** (selegiline transdermal system) should be written for the smallest quantity consistent with good patient management, in order to reduce the risk of overdose. Families and caregivers of adults being treated for depression should be similarly advised.

Screening Patients for Bipolar Disorder

A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that **EMSAM** is not approved for use in treating bipolar depression.

Hypertensive Crisis

EMSAM is an irreversible MAO inhibitor. MAO is important in the catabolism of dietary amines (e.g., tyramine). In this regard, significant inhibition of intestinal MAO-A activity can impose a cardiovascular safety risk following the ingestion of tyramine-rich foods. As a class, MAOIs have been associated with hypertensive crises caused by the ingestion of foods with a high concentration of tyramine. Hypertensive crises, which in some cases may be fatal, are characterized by some or all of the following symptoms: occipital headache which may radiate frontally, palpitation, neck stiffness or soreness, nausea, vomiting, sweating (sometimes with fever and sometimes with cold, clammy skin), dilated pupils, and photophobia. Either tachycardia or bradycardia may be present and can be associated with constricting chest pain. Intracranial bleeding has been reported in association with the increase in blood pressure. Patients should be instructed as to the signs and symptoms of severe hypertension and advised to seek immediate medical attention if these signs or symptoms are present.

In 6 of the 7 clinical studies conducted with **EMSAM** at doses of 6 mg/24 hours–12 mg/24 hours, patients were not limited to a modified diet typically associated with this class of compounds. Although no hypertensive crises were reported as part of the safety assessment, the likelihood of developing this reaction cannot be fully determined since the amount of tyramine typically consumed during the course of treatment is not known and blood pressure was not continuously monitored.

To further define the likelihood of hypertensive crises with use of **EMSAM**, several Phase I tyramine challenge studies were conducted both with and without food (see **PRECAUTIONS, Drug Interactions**, *Tyramine*). In its entirety, the data for **EMSAM** 6 mg/24 hours support the recommendation that a modified diet is not required at this dose. Due to the more limited data available for **EMSAM** 9 mg/24 hours, and the results from the Phase I tyramine challenge study in fed volunteers administered **EMSAM** 12 mg/24 hours (see **PRECAUTIONS, Drug Interactions**, *Tyramine*), patients receiving these doses should follow **Dietary Modifications Required for Patients Taking EMSAM 9 mg/24 hours and 12 mg/24 hours.**

If a hypertensive crisis occurs, **EMSAM** should be discontinued immediately and therapy to lower blood pressure should be instituted immediately. Phentolamine 5 mg or labetalol 20 mg administered slowly intravenously is recommended therapy to control hypertension. Alternately, nitroprusside delivered by continuous intravenous infusion may be used. Fever should be managed by means of external cooling. Patients must be closely monitored until symptoms have stabilized.

Dietary Modifications Required for Patients Taking EMSAM 9 mg/24 hours and 12 mg/24 hours

The following foods and beverages should be avoided beginning on the first day of **EMSAM** 9 mg/24 hours or 12 mg/24 hours treatment and should continue to be avoided for two weeks after a dose reduction to **EMSAM** 6 mg/24 hours or following the discontinuation of **EMSAM** 9 mg/24 hours or 12 mg/24 hours.

Food and beverages to avoid and those which are acceptable[1]:

Class of Food and Beverage	Tyramine-Rich Foods and Beverages to Avoid	Acceptable Foods, Containing No or Little Tyramine
Meat, Poultry and Fish	Air dried, aged and fermented meats, sausages and salamis (including cacciatore, hard salami and mortadella); pickled herring; and any spoiled or improperly stored meat, poultry and fish (e.g., foods that have undergone changes in coloration, odor, or become moldy); spoiled or improperly stored animal livers	Fresh meat, poultry and fish, including fresh processed meats (e.g., lunch meats, hot dogs, breakfast sausage, and cooked sliced ham)
Vegetables	Broad bean pods (fava bean pods)	All other vegetables
Dairy	Aged cheeses	Processed cheeses, mozzarella, ricotta cheese, cottage cheese and yogurt
Beverages	All varieties of tap beer, and beers that have not been pasteurized so as to allow for ongoing fermentation	As with other antidepressants, concomitant use of alcohol with **EMSAM** is not recommended. (Bottled and canned beers and wines contain little or no tyramine.)
Miscellaneous	Concentrated yeast extract (e.g., Marmite), sauerkraut, most soybean products (including soy sauce and tofu), OTC supplements containing tyramine	Brewer's yeast, baker's yeast, soy milk, commercial chain-restaurant pizzas prepared with cheeses low in tyramine

[1] Adapted from K. I. Shulman, S. E. Walker. *Psychiatric Annals.* 2001; 31:378-384.

Use With Other Drugs Affecting Monoamine Activity

Serious, sometimes fatal, central nervous system (CNS) toxicity referred to as the "serotonin syndrome" has been reported with the combination of non-selective MAOIs with certain other drugs, including tricyclic or selective serotonin reuptake inhibitor antidepressants, amphetamines, meperidine, or pentazocine. Serotonin syndrome is characterized by signs and symptoms that may include hyperthermia, rigidity, myoclonus, autonomic instability with rapid fluctuations of the vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. Similar less severe syndromes have been reported in a few patients receiving a combination of oral selegiline with one of these agents.

Therefore, **EMSAM** should not be used in combination with selective serotonin reuptake inhibitors (SSRIs, e.g., fluoxetine, sertraline, paroxetine); dual serotonin and norepinephrine reuptake inhibitors (SNRIs, e.g., venlafaxine and duloxetine); tricyclic antidepressants (TCAs, e.g., imipramine and amitriptyline); oral selegiline or other MAOIs (e.g., isocarboxazid, phenelzine, and tranylcypromine), mirtazapine; bupropion hydrochloride; meperidine and analgesic agents such as tramadol, methadone, and propoxyphene; the antitussive agent dextromethorphan, or St. John's wort because of the risk of life-threatening adverse reactions. Also, **EMSAM** should not be used with sympathomimetic amines, including amphetamines as well as cold

products and weight-reducing preparations that contain vasoconstrictors (e.g., pseudoephedrine, phenylephrine, phenylpropanolamine, and ephedrine). (See **CONTRAINDICATIONS**.)

Concomitant use of **EMSAM** (selegiline transdermal system) with buspirone hydrochloride is not advised since several cases of elevated blood pressure have been reported in patients taking MAOIs who were then given buspirone HCl.

After stopping treatment with SSRIs; SNRIs; TCAs; MAOIs; meperidine and analgesics such as tramadol, methadone, and propoxyphene; dextromethorphan; St. John's wort; mirtazapine; bupropion HCl; or buspirone HCl, a time period equal to 4-5 half-lives (approximately 1 week) of the drug or any active metabolite should elapse before starting therapy with **EMSAM**. Because of the long half-life of fluoxetine and its active metabolite, at least five weeks should elapse between discontinuation of fluoxetine and initiation of treatment with **EMSAM**. At least two weeks should elapse after stopping **EMSAM** before starting therapy with buspirone HCl or a drug that is contraindicated with **EMSAM**.

PRECAUTIONS

General

Hypotension

As with other MAOIs, postural hypotension, sometimes with orthostatic symptoms, can occur with **EMSAM** therapy. In short-term, placebo-controlled depression studies, the incidence of orthostatic hypotension (i.e., a decrease of 10 mmHg or greater in mean blood pressure when changing position from supine or sitting to standing) was 9.8% in **EMSAM**-treated patients and 6.7% in placebo-treated patients. It is recommended that elderly patients treated with **EMSAM** be closely observed for postural changes in blood pressure throughout treatment. Dose increases should be made cautiously in patients with pre-existing orthostasis. Postural hypotension may be relieved by having the patient recline until the symptoms have abated. Patients should be cautioned to change positions gradually. Patients displaying orthostatic symptoms should have appropriate dosage adjustments as warranted.

Activation of Mania/Hypomania

During Phase III trials, a manic reaction occurred in 8/2036 (0.4%) patients treated with **EMSAM**. Activation of mania/hypomania can occur in a small proportion of patients with major affective disorder treated with other marketed antidepressants. As with all antidepressants, **EMSAM** should be used cautiously in patients with a history of mania.

Use in Patients With Concomitant Illness

Clinical experience with **EMSAM** in patients with certain concomitant systemic illnesses is limited. Caution is advised when using **EMSAM** in patients with disorders or conditions that can produce altered metabolism or hemodynamic responses.

EMSAM has not been systematically evaluated in patients with a history of recent myocardial infarction or unstable heart disease. Such patients were generally excluded from clinical studies during the product's premarketing testing.

No ECG abnormalities attributable to **EMSAM** were observed in clinical trials.

Although studies of phenylpropanolamine and pseudoephedrine did not reveal pharmacokinetic drug interactions with **EMSAM**, it is prudent to avoid the concomitant use of sympathomimetic agents, such as some decongestants.

Information for Patients

Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with **EMSAM** and should counsel them in its appropriate use. A patient **Medication Guide About Using Antidepressants in Children and Teenagers** is available for **EMSAM**. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. The complete text of the Medication Guide is reprinted at the end of this document.

Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking **EMSAM**.

Clinical Worsening and Suicide Risk

Patients, their families and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment or when the dose is adjusted up or down. Families and caregivers of patients should be advised to observe for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly change in the medication.

General

Patients should be advised not to use oral selegiline while on **EMSAM** therapy.

Patients should be advised not to use carbamazepine or oxcarbazepine while on **EMSAM** therapy.

Patients should be advised not to use meperidine and analgesic agents such as tramadol, methadone, and propoxyphene.

Patients should be advised not to use sympathomimetic agents while on **EMSAM** therapy.

Patients should be advised not to use selective serotonin reuptake inhibitors (SSRIs, e.g., fluoxetine, sertraline, paroxetine, and St. John's wort), dual serotonin and norepinephrine reuptake inhibitors (SNRIs, e.g., venlafaxine and duloxetine), tricyclic antidepressants (TCAs, e.g., imipramine and amitriptyline), mirtazapine, oral selegiline or other MAOIs (e.g., isocarboxazid, phenelzine, and tranylcypromine), bupropion hydrochloride or buspirone hydrochloride while on **EMSAM** therapy.

EMSAM has not been shown to impair psychomotor performance; however, any psychoactive drug may potentially impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that **EMSAM** therapy does not impair their ability to engage in such activities.

Patients should be told that, although **EMSAM** has not been shown to increase the impairment of mental and motor skills caused by alcohol, the concomitant use of **EMSAM** and alcohol in depressed patients is not recommended.

Patients should be advised to notify their physician if they are taking, or plan to take, any prescription or over-the-counter drugs, including herbals, because of the potential for drug interactions. Patients should also be advised to avoid tyramine-containing nutritional supplements and any cough medicine containing dextromethorphan.

Patients should be advised to use **EMSAM** exactly as prescribed. The need for dietary modifications at higher doses should be explained, and a brief description of hypertensive crisis provided. Rare hypertensive reactions with oral selegiline at doses recommended for Parkinson's disease and associated with dietary influences have been reported. The clinical relevance to **EMSAM** is unknown.

Patients should be advised that certain tyramine-rich foods and beverages should be avoided while on **EMSAM** 9 mg/24 hours or **EMSAM** 12 mg/24 hours, and for two weeks following discontinuation of **EMSAM** at these doses (see **CONTRAINDICATIONS** and **WARNINGS**).

Patients should be instructed to immediately report the occurrence of the following acute symptoms: severe headache, neck stiffness, heart racing or palpitations, or other sudden or unusual symptoms.

Patients should be advised to avoid exposing the **EMSAM** application site to external sources of direct heat, such as heating pads or electric blankets, heat lamps, saunas, hot tubs, heated water beds, and prolonged direct sunlight since heat may result in an increase in the amount of selegiline absorbed from the **EMSAM** patch and produce elevated serum levels of selegiline.

Patients should be advised to change position gradually if lightheaded, faint, or dizzy while on **EMSAM** therapy.

Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during **EMSAM** therapy.

Patients should be advised to notify their physician if they are breast-feeding an infant.

While patients may notice improvement with **EMSAM** (selegiline transdermal system) therapy in one to several weeks, they should be advised of the importance of continuing drug treatment as directed.

Patients should be advised not to cut the **EMSAM** system into smaller portions.

For instructions on how to use **EMSAM**, see **DOSAGE AND ADMINISTRATION, How to Use EMSAM**.

Drug Interactions

The potential for drug interactions between **EMSAM** and a variety of drugs was examined in several human studies. Drug interaction studies described below were conducted with **EMSAM** 6 mg/24 hours. Although no differences are expected, drug interaction studies have not been conducted at higher doses (see In vitro *Metabolism* in Full Prescribing Information). In all of the studies described below, no drug-related adverse events were noted that required discontinuation of any subjects. Further, the incidence and nature of the adverse events were consistent with those known for selegiline or the test agent.

Alcohol

The pharmacokinetics and pharmacodynamics of alcohol (0.75 mg/kg) alone or in combination with **EMSAM** 6 mg/24 hours for 7 days of treatment was examined in 16 healthy volunteers. No clinically significant differences were observed in the pharmacokinetics or pharmacodynamics of alcohol or the pharmacokinetics of selegiline during co-administration. Although **EMSAM** has not been shown to increase the impairment of mental and motor skills caused by alcohol (0.75 mg/kg) and failed to alter the pharmacokinetic properties of alcohol, patients should be advised that the use of alcohol is not recommended while taking **EMSAM**.

Alprazolam

In subjects who had received **EMSAM** 6 mg/24 hours for 7 days, co-administration with alprazolam (15 mg/day), a CYP3A4/5 substrate, did not affect the pharmacokinetics of either selegiline or alprazolam.

Carbamazepine

Carbamazepine is an enzyme inducer and typically causes decreases in drug exposure, however, slightly increased levels of selegiline and its metabolites were seen after single application of **EMSAM** 6 mg/24 hours in subjects who had received carbamazepine (400 mg/day) for 14 days. Changes in plasma selegiline concentrations were nearly two-fold, and variable across the subject population. The clinical relevance of these observations is unknown. Carbamazepine is contraindicated with MAOIs, including selegiline (see **CONTRAINDICATIONS**).

Ibuprofen

In subjects who had received **EMSAM** 6 mg/24 hours for 11 days, combined administration with the CYP2C9 substrate ibuprofen (800 mg single dose) did not affect the pharmacokinetics of either selegiline or ibuprofen.

Ketoconazole

Seven-day treatment with ketoconazole (200 mg/day), a potent inhibitor of CYP3A4, did not affect the steady-state pharmacokinetics of selegiline in subjects who received **EMSAM** 6 mg/24 hours for seven days and no differences in the pharmacokinetics of ketoconazole were observed.

Levothyroxine

In healthy subjects who had received **EMSAM** 6 mg/24 hours for 10 days, single dose administration with levothyroxine (150 µg) did not alter the pharmacokinetics of either selegiline or levothyroxine (as judged by T_3 and T_4 plasma levels).

Olanzapine

In subjects who had received **EMSAM** 6 mg/24 hours for 10 days, co-administration with olanzapine, a substrate for CYP1A2, CYP2D6, and possibly CYP2A6, did not affect the pharmacokinetics of either selegiline or olanzapine.

Phenylpropanolamine (PPA)

In subjects who had received **EMSAM** 6 mg/24 hours for 9 days, co-administration with PPA (25 mg every 4 hours for 24 hours) did not affect the pharmacokinetics of PPA. There was a higher incidence of significant blood pressure elevations with the co-administration of **EMSAM** and PPA than with PPA alone, suggesting a possible pharmacodynamic interaction. It is prudent to avoid the concomitant use of sympathomimetic agents with **EMSAM**.

Pseudoephedrine

EMSAM 6 mg/24 hours for 10 days, co-administered with pseudoephedrine (60 mg three times a day) did not affect the pharmacokinetics of pseudoephedrine. The effect of pseudoephedrine on **EMSAM** was not examined. There were no clinically significant changes in blood pressure during pseudoephedrine administration alone, or in combination with **EMSAM**. Nonetheless, it is prudent to avoid the concomitant use of sympathomimetic agents with **EMSAM**.

Risperidone

In subjects who had received **EMSAM** 6 mg/24 hours for 10 days, co-administration with risperidone (2 mg per day for 7 days), a substrate for CYP2D6, did not affect the pharmacokinetics of either selegiline or risperidone.

Tyramine

Selegiline (the drug substance of **EMSAM**) is an irreversible inhibitor of monoamine oxidase (MAO), a ubiquitous intracellular enzyme. MAO exists as two isoenzymes, referred to as MAO-A and MAO-B. Selegiline shows greater affinity for MAO-B; however, as selegiline concentration increases, this selectivity is lost with resulting dose-related inhibition of MAO-A. Intestinal MAO is predominantly type A, while in the brain both isoenzymes exist.

MAO plays a vital physiological role in terminating the biological activity of both endogenous and exogenous amines. In addition to their role in the catabolism of monoamines in the CNS, MAOs are also important in the catabolism of exogenous amines found in a variety of foods and drugs. MAO in the gastrointestinal tract (primarily type A) provides protection from exogenous amines with vasopressor actions, such as tyramine, which if absorbed intact can cause a hypertensive crisis, the so-called "cheese reaction." If a large amount of tyramine is absorbed systemically, it is taken up by adrenergic neurons and causes norepinephrine release from neuronal storage sites with resultant elevation of blood pressure. While most foods contain negligible amounts or no tyramine, a few food products (see **WARNINGS**) may contain large amounts of tyramine that represent a potential risk for patients with significant inhibition of intestinal MAO-A resulting from administration of MAOIs. Tyramine-containing nutritional supplements should be avoided by patients taking **EMSAM**.

Animal studies have indicated the transdermal administration of selegiline via **EMSAM** 6 mg/24 hours allows for critical levels of MAO inhibition to be achieved in the brain while avoiding levels of gastrointestinal inhibition. To further define the risk of hypertensive crises with use of **EMSAM**, several Phase I tyramine challenge studies were conducted both with and without food.

Fourteen tyramine challenge studies including 214 healthy subjects (age range 18-65; 31 subjects >50 years of age) were conducted to determine the pressor effects of oral tyramine with concurrent **EMSAM** treatment (6 mg/24 hours–12 mg/24 hours), measured as the dose of tyramine required to raise systolic blood pressure by 30 mmHg (TYR30). Studies were conducted with and without concomitant administration of food. Studies conducted with food are most relevant to clinical practice since tyramine typically will be consumed in food. A high-tyramine meal is considered to contain up to 40 mg of tyramine.

One study using a crossover design in 13 subjects investigated tyramine pressor doses (TYR30) after administration of **EMSAM** 6 mg/24 hours and oral selegiline (5 mg twice daily) for 9 days. Mean pressor doses (TYR30) of tyramine capsules administered without food were 338 mg and 385 mg in subjects treated with **EMSAM** and oral selegiline, respectively.

Another study using a crossover design in 10 subjects investigated tyramine pressor doses after administration of **EMSAM** 6 mg/24 hours or tranylcypromine 30 mg/day for 10 days. Mean pressor doses (TYR30) of tyramine capsules administered without food were 270 mg in subjects treated with **EMSAM** 6 mg/24 hours and 10 mg in subjects treated with tranylcypromine.

In a third crossover study, tyramine without food was administered to 12 subjects. The mean tyramine pressor doses (TYR30) after administration of **EMSAM** 6 mg/24 hours for 9 and 33 days were 292 mg and

204 mg, respectively. The lowest pressor dose was 50 mg in one subject in the 33-day group.

Tyramine pressor doses were also studied in 11 subjects after extended treatment with **EMSAM** (selegiline transdermal system) 12 mg/24 hours. At 30, 60, and 90 days, the mean pressor doses (TYR30) of tyramine administered without food were 95 mg, 72 mg, and 88 mg, respectively. The lowest pressor dose without food was 25 mg in 3 subjects at day 30 while on **EMSAM** 12 mg/24 hours. Eight subjects from this study, with a mean tyramine pressor dose of 64 mg at 90 days, were subsequently administered tyramine with food, resulting in a mean pressor dose of 172 mg (2.7 times the mean pressor dose observed without food, $p < 0.003$).

With the exception of one study (N=153), the phase III clinical development program was conducted without requiring a modified diet (N=2553, 1606 at 6 mg/24 hours, and 947 at 9 mg/24 hours or 12 mg/24 hours). No hypertensive crises were reported in any patient receiving **EMSAM**.

In its entirety, the data for **EMSAM** 6 mg/24 hours support the recommendation that a modified diet is not required at this dose. Due to the more limited data available for **EMSAM** 9 mg/24 hours and 12 mg/24 hours, patients receiving these doses should follow **Dietary Modifications Required for Patients Taking EMSAM 9 mg/24 hours and 12 mg/24 hours**. (See **WARNINGS**.)

Warfarin

Warfarin is a substrate for CYP2C9 and CYP3A4 metabolism pathways. In healthy volunteers titrated with Coumadin® (warfarin sodium) to clinical levels of anticoagulation (INR of 1.5 to 2), co-administration with **EMSAM** 6 mg/24 hours for 7 days did not affect the pharmacokinetics of the individual warfarin enantiomers. **EMSAM** did not alter the clinical pharmacodynamic effects of warfarin as measured by INR, Factor VII or Factor X levels.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In an oral carcinogenicity study in rats, selegiline given in the diet for 104 weeks was not carcinogenic up to the highest evaluable dose tested (3.5 mg/kg/day, which is 3 times the oral maximum recommended human dose on a mg/m^2 basis).

Carcinogenicity studies have not been conducted with transdermal administration of selegiline.

Mutagenesis

Selegiline induced mutations and chromosomal damage when tested in the *in vitro* mouse lymphoma assay with and without metabolic activation. Selegiline was negative in the Ames assay, the *in vitro* mammalian chromosome aberration assay in human lymphocytes, and the *in vivo* oral mouse micronucleus assay.

Impairment of Fertility

A mating and fertility study was conducted in male and female rats at transdermal doses of 10, 30, and 75 mg/kg/day of selegiline (8, 24 and 60 times the maximum recommended human dose of **EMSAM** [12 mg/ 24 hours] on a mg/m^2 basis). Slight decreases in sperm concentration and total sperm count were observed at the high dose; however, no significant adverse effects on fertility or reproductive performance were observed.

Teratogenic Effects - Pregnancy Category C

In an embryofetal development study in rats, dams were treated with transdermal selegiline during the period of organogenesis at doses of 10, 30, and 75 mg/kg/day (8, 24, and 60 times the maximum recommended human dose [MRHD] of **EMSAM** [12 mg/24 hours] on a mg/m^2 basis). At the highest dose there was a decrease in fetal weight and slight increases in malformations, delayed ossification (also seen at the mid dose), and embryofetal post-implantation lethality. Concentrations of selegiline and its metabolites in fetal plasma were generally similar to those in maternal plasma. In an *oral* embryofetal development study in rats, a decrease in fetal weight occurred at the highest dose tested (36 mg/kg; no-effect dose 12 mg/kg); no increase in malformations was seen.

In an embryofetal development study in rabbits, dams were treated with transdermal selegiline during the period of organogenesis at doses of 2.5, 10, and 40 mg/kg/day (4, 16, and 64 times the MRHD on a mg/m^2 basis). A slight increase in visceral malformations was seen at the high dose. In an *oral* embryofetal development study in rabbits, increases in total resorptions and post-implantation loss, and a decrease in the number of live fetuses per dam, occurred at the highest dose tested (50 mg/kg; no-effect dose 25 mg/kg).

In a prenatal and postnatal development study in rats, dams were treated with transdermal selegiline at doses of 10, 30, and 75 mg/kg/day (8, 24, and 60 times the MRHD on a mg/m^2 basis) on days 6-21 of gestation and days 1-21 of the lactation period. An increase in post-implantation loss was seen at the mid and high doses, and an increase in stillborn pups was seen at the high dose. Decreases in pup weight (throughout lactation and post-weaning periods) and survival (throughout lactation period), retarded pup physical development, and pup epididymal and testicular hypoplasia, were seen at the mid and high doses. Retarded neurobehavioral and sexual development was seen at all doses. Adverse effects on pup reproductive performance, as evidenced by decreases in implantations and litter size, were seen at the high dose. These findings suggest persistent effects on the offspring of treated dams. A no-effect dose was not established for developmental toxicity. In this study concentrations of selegiline and its metabolites in milk were ~ 15 and 5 times, respectively, the concentrations in plasma, indicating that the pups were directly dosed during the lactation period.

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

Labor and Delivery

The effect of **EMSAM** on labor and delivery in humans is unknown.

Nursing Mothers

In a prenatal and postnatal study of transdermal selegiline in rats, selegiline and metabolites were excreted into the milk of lactating rats. The levels of selegiline and metabolites in milk were approximately 15 and 5 times, respectively, steady-state levels of selegiline and metabolites in maternal plasma. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised administering **EMSAM** to a nursing mother.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established (see **BOX WARNING** and **WARNINGS, Clinical Worsening and Suicide Risk**).

Anyone considering the use of **EMSAM** in a child or adolescent must balance the potential risks with the clinical need.

Geriatric Use

One hundred ninety-eight (198) elderly (≥65 years of age) patients participated in clinical studies with **EMSAM** 6 mg/24 hours to 12 mg/24 hours. There were no overall differences in effectiveness between elderly and younger patients. In short-term, placebo-controlled depression trials, patients age 50 and older appeared to be at higher risk for rash (4.4% **EMSAM** versus 0% placebo) than younger patients (3.4% **EMSAM** versus 2.4% placebo).

ADVERSE REACTIONS

The premarketing development program for **EMSAM** included selegiline exposures in patients and/or normal subjects from two different groups of studies: 702 healthy subjects in clinical pharmacology/pharmacokinetics studies and 2036 exposures from patients in controlled and uncontrolled major depressive disorder clinical trials. The conditions and duration of treatment with **EMSAM** varied and included double-blind, open-label, fixed-dose, and dose titration studies of short-term and longer-term exposures. Safety was assessed by monitoring adverse events, physical examinations, vital signs, body weights, laboratory analyses, and ECGs.

Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators. In the tables and tabulations that follow, standard COSTART terminology has been used to classify reported adverse events. The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation.

Adverse Findings Observed in Short-Term, Placebo-Controlled Trials

Adverse Events Associated with Discontinuation of Treatment

Among 817 depressed patients who received **EMSAM** (selegiline transdermal system) at doses of either 3 mg/24 hours (151 patients), 6 mg/24 hours (550 patients) or 6 mg/24 hours, 9 mg/24 hours, and 12 mg/24 hours (116 patients) in placebo-controlled trials of up to 8 weeks in duration, 7.1% discontinued treatment due to an adverse event as compared with 3.6% of 668 patients receiving placebo. The only adverse event associated with discontinuation, in at least 1% of **EMSAM**-treated patients at a rate at least twice that of placebo, was application site reaction (2% **EMSAM** vs. 0% placebo).

*Adverse Events Occurring at an Incidence of 2% or More Among **EMSAM**-Treated Patients*

Table 1 enumerates adverse events that occurred at an incidence of 2% or more (rounded to the nearest percent) among 817 depressed patients who received **EMSAM** in doses ranging from 3 to 12 mg/24 hours in placebo-controlled trials of up to 8 weeks in duration. Events included are those occurring in 2% or more of patients treated with **EMSAM** and for which the incidence in patients treated with **EMSAM** was greater than the incidence in placebo-treated patients.

Only one adverse event was associated with a reporting of at least 5% in the **EMSAM** group, and a rate at least twice that in the placebo group, in the pool of short-term, placebo-controlled studies: application site reactions (see *Application Site Reactions*, below). In one such study which utilized higher mean doses of **EMSAM** than that in the entire study pool, the following events met these criteria: application site reactions, insomnia, diarrhea, and pharyngitis.

These figures cannot be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physicians with some basis for estimating the relative contribution of drug and non-drug factors to the adverse event incidence rate in the population studied.

Table 1. Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Major Depressive Disorder with EMSAM[1]

Body System/Preferred Term	EMSAM (N=817)	Placebo (N=668)
	(% of Patients Reporting Event)	
Body as a Whole		
Headache	18	17
Digestive		
Diarrhea	9	7
Dyspepsia	4	3
Nervous		
Insomnia	12	7
Dry Mouth	8	6
Respiratory		
Pharyngitis	3	2
Sinusitis	3	1
Skin		
Application Site Reaction	24	12
Rash	4	2

[1] Events reported by at least 2% of patients treated with **EMSAM** are included, except the following events which had an incidence on placebo treatment ≥ to **EMSAM**: infection, nausea, dizziness, pain, abdominal pain, nervousness, back pain, asthenia, anxiety, flu syndrome, accidental injury, somnolence, rhinitis, and palpitations.

Application Site Reactions

In the pool of short-term, placebo-controlled major depressive disorder studies, application site reactions (ASRs) were reported in 24% of **EMSAM**-treated patients and 12% of placebo-treated patients. Most ASRs were mild or moderate in severity. None were considered serious. ASRs led to dropout in 2% of **EMSAM**-treated patients and no placebo-treated patients.

In one such study which utilized higher mean doses of **EMSAM**, ASRs were reported in 40% of **EMSAM**-treated patients and 20% of placebo-treated patients. Most of the ASRs in this study were described as erythema and most resolved spontaneously, requiring no treatment. When treatment was administered, it most commonly consisted of dermatological preparations of corticosteroids.

Male and Female Sexual Dysfunction with MAO-Inhibitors

Although changes in sexual desire, sexual performance and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment.

Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. Table 2 shows that the incidence rates of sexual side effects in patients with major depressive disorder are comparable to the placebo rates in placebo-controlled trials.

Table 2. Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials with EMSAM

Adverse Event	EMSAM	Placebo
	IN MALES ONLY	
	(N=304)	(N=256)
Abnormal Ejaculation	1.0%	0.0%
Decreased Libido	0.7%	0.0%
Impotence	0.7%	0.4%
Anorgasmia	0.2%	0.0%
	IN FEMALES ONLY	
	(N=513)	(N=412)
Decreased Libido	0.0%	0.2%

There are no adequately designed studies examining sexual dysfunction with **EMSAM** treatment.

Vital Sign Changes

EMSAM and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. In the pool of short-term, placebo-controlled major depressive disorder studies, 3.0% of **EMSAM**-treated patients and 1.5% of placebo-treated patients experienced a low systolic blood pressure, defined as a reading less than or equal to 90 mmHg with a change from baseline of at least 20 mmHg. In one study which utilized higher mean doses of **EMSAM**, 6.2% of **EMSAM**-treated patients and no placebo-treated patients experienced a low standing systolic blood pressure by these criteria.

In the pool of short-term major depressive disorder trials, 9.8% of **EMSAM**-treated patients and 6.7% of placebo-treated patients experienced a notable orthostatic change in blood pressure, defined as a decrease of at least 10 mmHg in mean blood pressure with postural change.

Does Being a Psychiatrist Affect Response to Cancer?

Psychiatrists who have been diagnosed with cancer note that their medical training can be both a help and a hindrance as they struggle through treatment toward an uncertain future.

BY EVE BENDER

Though hardly surprising, psychiatrists are no different from other people when it comes to coping with the reality of being diagnosed with cancer, according to panelists at APA's 2006 annual meeting in May in Toronto.

"Denial is alive and well and working in psychiatrists," said Madelaine Wohlreich, M.D., who spoke from personal experience.

Wohlreich, a medical advisor at Eli Lilly and Co., found a lump in her breast in January 2005. For six months prior to her discovery, she had experienced pain that she attributed to a bra not fitting well.

She found her denial "particularly striking" given the fact that her mother had breast cancer and had a mastectomy when Wohlreich was 11. In fact, she decided to become a physician in part because of the stressful medical problems experienced by her mother and other family members, she said.

As an adult, Wohlreich was diagnosed with breast cancer soon after finding the lump and experienced "terror, an absolute sense of the world collapsing, as anyone would," she noted.

Waiting to receive her diagnosis was perhaps the most difficult time for her. "Foremost, I had fear that I was facing my own death," during this time.

Eve Bender

Madelaine Wohlreich, M.D., a psychiatrist who was diagnosed with breast cancer in 2005, found that her status as a physician had its benefits as far as her treatment was concerned.

Wohlreich noted that being a physician as well as a patient can be a double-edged sword. Her work in the pharmaceutical industry ensured that she had good health benefits, and her career as a psychiatrist helped her sift through medical literature with more ease than someone without a medical degree.

During the first few days after the diagnosis, Wohlreich spent much of her time in front of the computer searching for information on breast cancer treatment and prognosis. However, she said, "the disadvantage of being a physician and facing this diagnosis is that you are more aware than others about the potential for negative outcomes. I've seen patients dying of cancer and knew too much about what I might be facing in the future."

Another disadvantage of her status as a physician was that she could not "assign magical powers to my treatment team as many other patients with cancer do," she said, being aware that luck would play a role in the course of her illness—not just the medical skills of her treatment team.

"Describing yourself as a physician to members or your treatment team does grant some privileges and respect," Wohlreich said, "but sometimes I felt the need to say, 'please talk to me now as a patient and not a physician because I'm feeling overwhelmed.' "

She found many positive ways to cope with the diagnosis and treatment that she endured by becoming involved with real-life and Internet breast cancer support groups, through which she found women with whom she had much in common.

She gained a number of close friends in the process but noted, "I'm well aware that some of them with less-positive prognoses will likely succumb to this illness."

She also took a course titled "Look Good. . .Feel Better," offered to women undergoing cancer treatment through the American Cancer Society in conjunction with several cosmetology organizations.

Her professional status enabled her proactively to seek out a highly skilled team of physicians to perform an elective bilateral mastectomy with reconstruction.

Wohlreich noted that reflecting upon her experience has helped her "deepen my knowledge of myself, my beliefs, and the meaning of life." In addition, she has found it "extremely important and meaningful" to share her experience with others.

Abigail Schlesinger, M.D., was a fellow in child and adolescent psychiatry at the University of Pittsburgh Medical Center's Western Psychiatric Institute and Clinic last year when she began experiencing flu-like symptoms and developed enlarged right supraclavicar nodes.

She hadn't seen a physician in several years, but concerned family members urged her to

please see ***Cancer*** *on page 41*

25 Years of AIDS Epidemic: A Psychiatrist Learns to Heal

It has been 25 years since the first AIDS cases were identified. To mark that grim anniversary, a psychiatrist who has long fought against the disease's ravages was asked by *Psychiatric News* to look back on how treatment and he have changed.

BY MARSHALL FORSTEIN, M.D.

"No one has touched me for six months. Even my own mother won't come near me." After introducing myself as a psychiatry resident in 1982, these were the first words spoken through a cascade of tears by a 35-year-old gay man when I asked how he was doing.

Only a few months before, I had been reading as much as I could about "GRID" (gay-related immune deficiency syndrome), which had been recently reported in Los Angeles, New York City, and San Francisco.

After completing my internship in San Francisco in 1980, my partner and I moved to Boston for my residency at Massachusetts General Hospital. Little did I know how quickly I would be caught up in the medical care, social activism, and politics of what we came to know as HIV disease.

The epidemiology suggested that whatever was causing the collapse of gay men's immune systems (soon followed by the cases of AIDS in other populations) was sexually transmitted. A decade of sexual liberation appeared to be the wave on which this disease was riding, a wave that turned into fear and anxiety that permeated the gay community.

As I became more immersed in the clinical care of people with AIDS, some colleagues and supervisors warned me about becoming too identified professionally with this stigmatizing disease.

At the same time I was seeing more patients with AIDS in the medical setting, we began the unrelenting experience of losing patients, friends, and colleagues to the epidemic. The Era of Unremitting Grief had begun. We visited the AIDS quilt that spent days laid out on the vast expanse of the Mall in Washington, D.C. Amid thousands, in eerie silence broken only by sobbing, and sometimes wailing, we discovered panel after panel marking the passing of people we had known. I remember wondering if any of us would survive the disease or the overwhelming loss. The image of thousands of gay men, their lovers, friends, and families grieving together on the Mall between the Washington Monument and the Capitol is forever etched in my mind. In retrospect, becoming involved clinically, academically, and politically served as a mechanism to contain my personal fear and anxiety about the epidemic that was exploding around me.

courtesy of Marshall Forstein, M.D.

Marshall Forstein, M.D.: "Colleagues and supervisors warned me about becoming too identified professionally with this stigmatizing disease."

After leaving residency, I served as medical director of the Boston Gay and Lesbian Counseling Service. After the discovery of HIV as the causative agent, I was asked to help develop a counseling and testing protocol for the ELISA antibody test that Massachusetts's state laboratory was developing. "To test or not to test" became the dilemma for a generation of gay men and then for injecting drug users at a time when there was no treatment to offer for the underlying HIV infection that was almost always fatal.

At that time, testing was encouraged as a way to inform people who believed they had been at high risk for contracting HIV to change their sexual and injecting drug-use behaviors. In the absence of a definitive treatment for HIV infection, only prophylaxis for opportunistic infections was available, and many gay men believed that testing for antibodies would only further stigmatize and isolate already marginalized people. Later, the reticence I had in promoting testing turned to advising testing once we had ammunition against the virus.

As the epidemic grew in nongay populations, community-based organizations had to find ways to treat people whose only commonality was being HIV infected. Increasing numbers of psychiatric patients, intravenous drug users, women of childbearing age, and children began to constitute what became known as the "changing face of AIDS." These individuals often found support in agencies that had evolved in the gay community. While people with AIDS were quite diverse, HIV infection helped to create political and social coalitions in the interest of pushing for more AIDS funding for research and treatment.

In 1985, in addition to seeing AIDS patients at Cambridge Hospital, I had a half-time private practice that had become about 70 percent people with AIDS. Few psychiatrists, even in the rich psychiatric mecca of Boston, were willing to involve

Please see ***AIDS*** *on page 41*

Marshall Forstein, M.D., is an associate professor of psychiatry at Harvard Medical School and director of adult psychiatry residency training at Cambridge Health Alliance. He chaired the APA Commission on AIDS from 1992 to 2004.

APA Responds to HIV/AIDS

1983

Committee on Gay, Lesbian, and Bisexual Issues recommends that APA establish a special component on AIDS

APA presents the first workshop on AIDS at the annual meeting

First APPI journal publication, "Psychiatric Aspects of HIV," in *Psychosomatics*

1984

APA establishes the Subcommittee on Psychiatric Aspects of AIDS

First *AJP* article publication: "Psychopathology Complicating Acquired Immune Deficiency Syndrome," *American Journal of Psychiatry*

1985

American Psychiatric Press releases its first AIDS monograph, "Psychiatric Implications of Acquired Immunodeficiency Syndrome"

1986

APA issues its first two AIDS policy statements addressing practice implications and patient discrimination

APA awards its first government contract to provide training to mental health care providers on the psychiatric dimensions of HIV/AIDS

1987

APA establishes the Committee on the Psychiatric Aspects of AIDS

APA adopts AIDS-related policies on confidentiality and disclosure, and on inpatient/outpatient psychiatric units

1988

APA establishes Commission on AIDS, allowing its members to report directly to the Board of Trustees

Commission on AIDS releases its recommendations for a full response to the AIDS epidemic

APA releases the *AIDS Primer* for psychiatrists and residents, its first comprehensive training manual

APA takes active posture with state licensing boards regarding the importance of treatment and rehabilitation of psychiatrically impaired physicians without threat of license loss

1989

APA and AMA cosponsor an international HIV conference

APA adopts policies on name reporting of HIV-seropositive individuals

APA makes first formal request to outside organizations and committees to increase HIV content in residency curriculum and examinations

1990

APA adopts policies on occupational exposure to HIV and psychiatrists who are HIV infected

APA releases its first videotape addressing HIV-related psychiatric problems and patient stigma

1991

APA establishes the Office of HIV Psychiatry

1992

APA sponsors its first Pan American conference on AIDS

1993

APA collaborates with NAMI to produce HIV videotape addressing the needs of people living with HIV and mentall illness

APA adopts policies on psychiatric hospitalization of children and adolescents with HIV/AIDS

1996

APA adopts policies on vertical transmission of HIV from mother to child

APA awarded contract to establish a searchable database for tracking and maintaining AIDS resources

1997

APA adopts policies on HIV-related neuropsychiatric findings and associated impairments and on needle exchange

1998

APA adopts policies on HIV antibody testing and management of HIV-related neuropsychiatric conditions

1999

APA releases its first HIV residency training curriculum, distributed nationwide

APA announces the availability of online AIDS resource center

2000

APA awarded subcontract to develop the first HIV neuropsychiatric curriculum for nonphysicians

APA releases "Practice Guidelines for the Treatment of Patients with HIV/AIDS"

2001

APA offers online HIV CME course

2003

APA offers first medical student senior elective in HIV psychiatry

APA offers its first HIV training using distant-learning technology

APA awarded subcontract to train minority community-based organizations

2004

APA awarded sixth contract to conduct HIV/AIDS trainings and develop clinical resources

APA adopts policy on hepatitis C coinfection

2005

APA presents to the Presidents Advisory Council on HIV/AIDS and testifies at Senate hearings

2006

APA awarded funding to train primary care clinicians as HIV trainers

To date APA has trained nearly 30,000 psychiatrists, residents, and mental health clinicians in HIV/AIDS

Primary Care Treating More Serious Mental Illness

A greater number of people with serious mental illness are seeking help from primary care clinicians, while psychiatrists increasingly treat less serious conditions.

BY RICH DALY

General practitioners treat most of the people who have mental illness, according to a recent study. And there is an increasing likelihood that their patients include those with major mental health problems.

A comparison of two nationally representative household surveys that screened for mental disorders 10 years apart found that the use of only general practitioners when seeking mental health treatment was the fastest growing and most popular approach among the survey respondents. The study, published in the July *American Journal of Psychiatry*, found that respondents treated by only a general physician for any mental illness grew from 2.6 percent in a previous survey to 6.5 percent in the most recent study.

The researchers attributed that finding to the increasing role of general physicians as insurance plan "gatekeepers," increased access to mental health screening tools, the growing popularity and safety of psychotropic medications, and the increasing use of psychotherapies by general practitioners.

One of the study authors, Harold Pincus, M.D., vice chair of strategic initiatives in the Department of Psychiatry at Columbia University, said the most troubling finding was that patients with serious disorders expanded their exclusive use of general practitioners to treat their mental illness.

The increased utilization of mental health care among those with moderate mental illness—such as mild to moderate depression—bodes well for the health of the population, said the authors, because research has found that, overall, psychotherapy and medication have equivalent effectiveness. However, the increased reliance on general physicians for mental health care is more worrisome among patients with more serious illnesses in light of the increasing evidence that such illnesses respond best to combined psychotherapy and pharmacotherapy, which general practitioners are unlikely to provide.

"There is a question of whether the right people are being cared for by the right professionals," Pincus told *Psychiatric News*.

The findings were based on comparisons of the assessments of mental disorders among the 5,388 respondents in the 1990 to 1992 National Comorbidity Survey (NCS) and the 4,319 respondents in the NCS Replication conducted from 2001 to 2003.

The study highlighted the need for more information about what is provided within "the black box of care" —that is, what specific treatments are used and their effectiveness in improving mental health, Pincus said. More studies need to investigate whether people are getting the quality of mental health care that they need for a given condition, he said. The results concerned Pincus in light of his previous research that found an increase in the prescribing of psychotropic medications by general practitioners, who are unlikely to have training in psychotherapy.

"People are making choices for medications and are maybe less interested in psychotherapy," he said.

Continuing stigma over treatment from a psychiatrist or mental health professional may drive some of the use of general practitioners alone for serious illnesses, he said.

The study showed that more comprehensive mental health care training is needed for primary care physicians, Pincus said. It also highlighted the need for psychiatrists to communicate better with general practice physicians and establish closer referral relationships with them so they are more aware of the types of conditions that require specialty care, he said.

"General medical care without specialty use may result in lower treatment intensity and adequacy than in specialty care," the researchers said.

Psychiatrists were the second most common source of mental health care among the more recent survey respondents, which saw their use rise from 2.4 percent to 5.2 percent of respondents. The researchers credited this to diminished stigma, greater recognition that mental illness requires treatment, and greater demand for and availability of pharmacotherapies.

People with serious mental illness remained a minority of those who sought care from psychiatrists. The proportion of serious to less-serious cases remained the same as the overall number seeking care rose, so psychiatrists likely saw increases in both types of patients, according to the study authors.

> **"There is a question of whether the right people are being cared for by the right professionals."**

Although patients' use of nonpsychiatric mental health clinicians, without first consulting with their primary care physician, grew from 3.6 percent of respondents to 4.3 percent, the authors had expected more substantial growth in this area.

"Given the fact that there has been a growth in the supply of nonphysician mental health providers, we might have expected to see more of that," Pincus said.

Major decreases in the use of psychotherapy alone to treat mental illness continued in the most recent survey, a situation the authors attributed to both tighter insurance coverage and the growing popularity of psychotropic medications.

"Changing Profiles of Service Sectors Used for Mental Health Care in the United States" is posted at <http://ajp.psychiatryonline.org/cgi/content/full/163/7/1187>. ■

Antipsychotics Prone to Prescribing Errors

Prescribing errors are not rare in psychiatric practice or in other areas of medicine. Fortunately, only a small portion of errors have a potential for serious harm, according to a British study.

BY JIM ROSACK

Medication errors are a major cause of patient morbidity and mortality in nearly all medical specialties. More than 7,000 deaths each year in the United States are attributed to medication errors, according to a recent Institute of Medicine report, and researchers have estimated that nearly 60 percent of all adverse events are the result of medication errors. Nonetheless, few studies have examined medication errors in psychiatry.

Medication errors can result either from a prescribing error or a dispensing error or a combination of both. A new study by a group of British pharmacists suggests that in psychiatry, prescribing errors are fairly common.

David Taylor, Pharm.D., the chief pharmacist at Maudsely Hospital in London, teamed with pharmacists at other U.K. National Health Service mental health centers to evaluate all prescriptions written in a one-week (five working days) period in June 2004. Their report appears in the July *Journal of Psychopharmacology*. The study was funded by the United Kingdom Psychiatric Pharmacy Group.

A total of 22,036 prescriptions were reviewed from eight outpatient acute mental health centers and one inpatient psychiatric hospital to identify errors in the writing of the prescription that could result in "an unintentional significant reduction in the probability of treatment being timely and effective, or an increase in the risk of harm when compared with general accepted practice."

Prescribing errors were categorized by pharmacists at the nine sites as grade 1, an error or omission of doubtful or negligible importance; grade 2, an error or omission likely to result in minor adverse effects or worsening of condition; grade 3, an error or omission likely to result in serious effects or relapse; or grade 4, an error or omission likely to result in fatality. A panel of five "expert psychopharmacologists" reviewed all grade 3 and grade 4 errors and assigned a consensus rating.

Of the more than 22,000 prescriptions checked, 11,668 (52.9 percent) were for psychotropic medications. Prescribing errors meeting the study definition were detected in 523 (2.4 percent) prescriptions. More errors occurred with prescriptions for antipsychotics (17 percent) than for any other category. Hypnotics and anxiolytic medications were involved in the second highest proportion of prescription errors (13.2 percent).

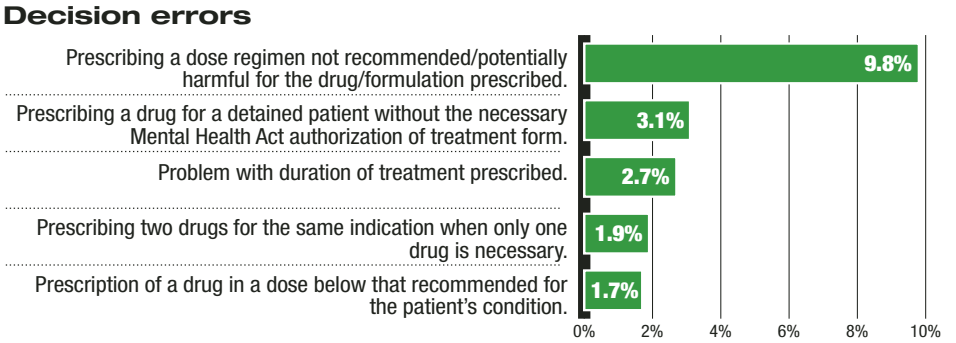
Taylor and his colleagues found that "prescription-writing errors" were far more common (77.4 percent) than "decision-making errors" (22.6 percent). Errors categorized as involving the writing of the prescription most frequently involved writing an incomplete prescription (27.5 percent of total prescribing errors), such as not specifying a start date or failing to completely specify dosage, dosage route, or frequency of administration. In 13 percent of prescriptions, the prescriber neglected to sign the prescription. The problem with 1.5 percent of the prescriptions was illegible handwriting that could not be accurately transcribed by a pharmacist. Other prescription-writing errors involved writ-

please see ***Prescribing*** *on page 41*

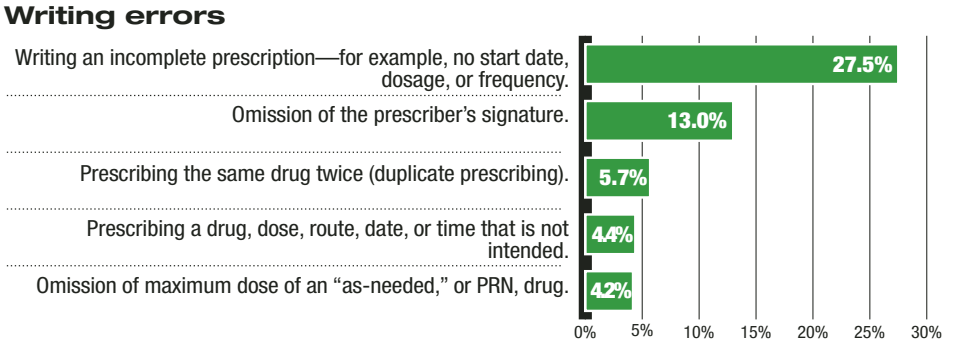
What Are the Most Common Prescribing Errors?

Researchers in the United Kingdom looked at all prescriptions written in one week (five working days) in June 2004 from eight outpatient mental health centers and one psychiatric hospital to determine whether prescribing errors had occurred. Below are the 10 most common errors shown in the two categories that the researchers identified: decision-making errors and errors in the prescription-writing process.

Decision errors



Writing errors



Source: Jean Stubbs, Camilla Haw, and David Taylor, *Journal of Psychopharmacology,* July 2006

At the first sign of moderate Alzheimer's disease

Treat today with NAMENDA

- Unique mechanism for treating Alzheimer's disease
  - –NAMENDA targets a different pathway–glutamate[1]
- Clinical evidence confirms cognitive, functional, behavioral, and global benefits in moderate and severe Alzheimer's disease[2,3]
- Effective as first-line treatment or in combination with an acetylcholinesterase inhibitor[2,3]

Preferred status on the majority of health plan and Medicare Part D formularies[4]

NAMENDA® (memantine HCl) is contraindicated in patients with known hypersensitivity to memantine HCl or any excipients used in the formulation. The most common adverse events reported with **NAMENDA** vs placebo (≥5% and higher than placebo) were dizziness, confusion, headache, and constipation. In patients with severe renal impairment, the dosage should be reduced.

References: 1. NAMENDA® (memantine HCl) Prescribing Information. Forest Pharmaceuticals, Inc., St Louis, Mo. **2.** Reisberg B, Doody R, Stöffler A, Schmitt F, Ferris S, Möbius HJ, for the Memantine Study Group. Memantine in moderate-to-severe Alzheimer's disease. *N Engl J Med*. 2003;348:1333-1341. **3.** Tariot PN, Farlow MR, Grossberg GT, Graham SM, McDonald S, Gergel I, for the Memantine Study Group. Memantine treatment in patients with moderate to severe Alzheimer disease already receiving donepezil: a randomized controlled trial. *JAMA*. 2004;291:317-324. **4.** Data on file. Forest Laboratories, Inc.

For more details, visit **www.namenda.com**

Forest Pharmaceuticals, Inc.

Please see brief summary of Prescribing Information on the adjacent page.

Namenda
memantine HCl

Extending memory and function

62-1008558 04/06

Namenda
memantine HCl

Rx Only

Brief Summary of Prescribing Information.

For complete details, please see full Prescribing Information for Namenda.

INDICATIONS AND USAGE
Namenda (memantine hydrochloride) is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

CONTRAINDICATIONS
Namenda (memantine hydrochloride) is contraindicated in patients with known hypersensitivity to memantine hydrochloride or to any excipients used in the formulation.

PRECAUTIONS
Information for Patients and Caregivers: Caregivers should be instructed in the recommended administration (twice per day for doses above 5 mg) and dose escalation (minimum interval of one week between dose increases).

Neurological Conditions
Seizures: Namenda has not been systematically evaluated in patients with a seizure disorder. In clinical trials of Namenda, seizures occurred in 0.2% of patients treated with Namenda and 0.5% of patients treated with placebo.

Genitourinary Conditions
Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine.

Special Populations
Hepatic Impairment
Namenda undergoes partial hepatic metabolism, with about 48% of administered dose excreted in urine as unchanged drug or as the sum of parent drug and the N-glucuronide conjugate (74%). The pharmacokinetics of memantine in patients with hepatic impairment have not been investigated, but would be expected to be only modestly affected.

Renal Impairment
No dosage adjustment is needed in patients with mild or moderate renal impairment. A dosage reduction is recommended in patients with severe renal impairment.

Drug-Drug Interactions
N-methyl-D-aspartate (NMDA) antagonists: The combined use of Namenda with other NMDA antagonists (amantadine, ketamine, and dextromethorphan) has not been systematically evaluated and such use should be approached with caution.

Effects of Namenda *on substrates of microsomal enzymes: In vitro* studies conducted with marker substrates of CYP450 enzymes (CYP1A2, -2A6, -2C9, -2D6, -2E1, -3A4) showed minimal inhibition of these enzymes by memantine. In addition, *in vitro* studies indicate that at concentrations exceeding those associated with efficacy, memantine does not induce the cytochrome P450 isoenzymes CYP1A2, CYP2C9, CYP2E1, and CYP3A4/5. No pharmacokinetic interactions with drugs metabolized by these enzymes are expected.

Effects of inhibitors and/or substrates of microsomal enzymes on Namenda: Memantine is predominantly renally eliminated, and drugs that are substrates and/or inhibitors of the CYP450 system are not expected to alter the metabolism of memantine.

Acetylcholinesterase (AChE) inhibitors: Coadministration of Namenda with the AChE inhibitor donepezil HCl did not affect the pharmacokinetics of either compound. In a 24-week controlled clinical study in patients with moderate to severe Alzheimer's disease, the adverse event profile observed with a combination of memantine and donepezil was similar to that of donepezil alone.

Drugs eliminated via renal mechanisms: Because memantine is eliminated in part by tubular secretion, coadministration of drugs that use the same renal cationic system, including hydrochlorothiazide (HCTZ), triamterene (TA), metformin, cimetidine, ranitidine, quinidine, and nicotine, could potentially result in altered plasma levels of both agents. However, coadministration of Namenda and HCTZ/TA did not affect the bioavailability of either memantine or TA, and the bioavailability of HCTZ decreased by 20%. In addition, coadministration of memantine with the antihyperglycemic drug Glucovance® (glyburide and metformin HCl) did not affect the pharmacokinetics of memantine, metformin and glyburide. Furthermore, memantine did not modify the serum glucose lowering effect of Glucovance®.

Drugs that make the urine alkaline: The clearance of memantine was reduced by about 80% under alkaline urine conditions at pH 8. Therefore, alterations of urine pH towards the alkaline condition may lead to an accumulation of the drug with a possible increase in adverse effects. Urine pH is altered by diet, drugs (e.g. carbonic anhydrase inhibitors, sodium bicarbonate) and clinical state of the patient (e.g. renal tubular acidosis or severe infections of the urinary tract). Hence, memantine should be used with caution under these conditions.

Carcinogenesis, Mutagenesis and Impairment of Fertility
There was no evidence of carcinogenicity in a 113-week oral study in mice at doses up to 40 mg/kg/day (10 times the maximum recommended human dose [MRHD] on a mg/m² basis). There was also no evidence of carcinogenicity in rats orally dosed at up to 40 mg/kg/day for 71 weeks followed by 20 mg/kg/day (20 and 10 times the MRHD on a mg/m² basis, respectively) through 128 weeks.

Memantine produced no evidence of genotoxic potential when evaluated in the *in vitro S. typhimurium* or *E. coli* reverse mutation assay, an *in vitro* chromosomal aberration test in human lymphocytes, an *in vivo* cytogenetics assay for chromosome damage in rats, and the *in vivo* mouse micronucleus assay. The results were equivocal in an *in vitro* gene mutation assay using Chinese hamster V79 cells.

No impairment of fertility or reproductive performance was seen in rats administered up to 18 mg/kg/day (9 times the MRHD on a mg/m² basis) orally from 14 days prior to mating through gestation and lactation in females, or for 60 days prior to mating in males.

Pregnancy
Pregnancy Category B: Memantine given orally to pregnant rats and pregnant rabbits during the period of organogenesis was not teratogenic up to the highest doses tested (18 mg/kg/day in rats and 30 mg/kg/day in rabbits, which are 9 and 30 times, respectively, the maximum recommended human dose [MRHD] on a mg/m² basis).

Slight maternal toxicity, decreased pup weights and an increased incidence of non-ossified cervical vertebrae were seen at an oral dose of 18 mg/kg/day in a study in which rats were given oral memantine beginning pre-mating and continuing through the postpartum period. Slight maternal toxicity and decreased pup weights were also seen at this dose in a study in which rats were treated from day 15 of gestation through the post-partum period. The no-effect dose for these effects was 6 mg/kg, which is 3 times the MRHD on a mg/m² basis.

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

Nursing Mothers
It is not known whether memantine is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when memantine is administered to a nursing mother.

Pediatric Use
There are no adequate and well-controlled trials documenting the safety and efficacy of memantine in any illness occurring in children.

ADVERSE REACTIONS
The experience described in this section derives from studies in patients with Alzheimer's disease and vascular dementia.

Adverse Events Leading to Discontinuation: In placebo-controlled trials in which dementia patients received doses of Namenda up to 20 mg/day, the likelihood of discontinuation because of an adverse event was the same in the Namenda group as in the placebo group. No individual adverse event was associated with the discontinuation of treatment in 1% or more of Namenda-treated patients and at a rate greater than placebo.

Adverse Events Reported in Controlled Trials: The reported adverse events in Namenda (memantine hydrochloride) trials reflect experience gained under closely monitored conditions in a highly selected patient population. In actual practice or in other clinical trials, these frequency estimates may not apply, as the conditions of use, reporting behavior and the types of patients treated may differ. Table 1 lists treatment-emergent signs and symptoms that were reported in at least 2% of patients in placebo-controlled dementia trials and for which the rate of occurrence was greater for patients treated with Namenda than for those treated with placebo. No adverse event occurred at a frequency of at least 5% and twice the placebo rate.

Table 1: Adverse Events Reported in Controlled Clinical Trials in at Least 2% of Patients Receiving Namenda and at a Higher Frequency than Placebo-treated Patients.

Body System Adverse Event	Placebo (N = 922) %	Namenda (N = 940) %
Body as a Whole		
Fatigue	1	2
Pain	1	3
Cardiovascular System		
Hypertension	2	4
Central and Peripheral Nervous System		
Dizziness	5	7
Headache	3	6
Gastrointestinal System		
Constipation	3	5
Vomiting	2	3
Musculoskeletal System		
Back pain	2	3
Psychiatric Disorders		
Confusion	5	6
Somnolence	2	3
Hallucination	2	3
Respiratory System		
Coughing	3	4
Dyspnea	1	2

Other adverse events occurring with an incidence of at least 2% in Namenda-treated patients but at a greater or equal rate on placebo were agitation, fall, inflicted injury, urinary incontinence, diarrhea, bronchitis, insomnia, urinary tract infection, influenza-like symptoms, abnormal gait, depression, upper respiratory tract infection, anxiety, peripheral edema, nausea, anorexia, and arthralgia.

The overall profile of adverse events and the incidence rates for individual adverse events in the subpopulation of patients with moderate to severe Alzheimer's disease were not different from the profile and incidence rates described above for the overall dementia population.

Vital Sign Changes: Namenda and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, diastolic blood pressure, and weight) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. There were no clinically important changes in vital signs in patients treated with Namenda. A comparison of supine and standing vital sign measures for Namenda and placebo in elderly normal subjects indicated that Namenda treatment is not associated with orthostatic changes.

Laboratory Changes: Namenda and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Namenda treatment.

ECG Changes: Namenda and placebo groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in ECG parameters associated with Namenda treatment.

Other Adverse Events Observed During Clinical Trials
Namenda has been administered to approximately 1350 patients with dementia, of whom more than 1200 received the maximum recommended dose of 20 mg/day. Patients received Namenda treatment for periods of up to 884 days, with 862 patients receiving at least 24 weeks of treatment and 387 patients receiving 48 weeks or more of treatment.

Treatment emergent signs and symptoms that occurred during 8 controlled clinical trials and 4 open-label trials were recorded as adverse events by the clinical investigators using terminology of their own choosing. To provide an overall estimate of the proportion of individuals having similar types of events, the events were grouped into a smaller number of standardized categories using WHO terminology, and event frequencies were calculated across all studies.

All adverse events occurring in at least two patients are included, except for those already listed in Table 1, WHO terms too general to be informative, minor symptoms or events unlikely to be drug-caused, e.g., because they are common in the study population. Events are classified by body system and listed using the following definitions: frequent adverse events - those occurring in at least 1/100 patients; infrequent adverse events - those occurring in 1/100 to 1/1000 patients. These adverse events are not necessarily related to Namenda treatment and in most cases were observed at a similar frequency in placebo-treated patients in the controlled studies.

Body as a Whole: *Frequent:* syncope. *Infrequent:* hypothermia, allergic reaction.

Cardiovascular System: *Frequent:* cardiac failure. *Infrequent:* angina pectoris, bradycardia, myocardial infarction, thrombophlebitis, atrial fibrillation, hypotension, cardiac arrest, postural hypotension, pulmonary embolism, pulmonary edema.

Central and Peripheral Nervous System: *Frequent:* transient ischemic attack, cerebrovascular accident, vertigo, ataxia, hypokinesia. *Infrequent:* paresthesia, convulsions, extrapyramidal disorder, hypertonia, tremor, aphasia, hypoesthesia, abnormal coordination, hemiplegia, hyperkinesia, involuntary muscle contractions, stupor, cerebral hemorrhage, neuralgia, ptosis, neuropathy.

Gastrointestinal System: *Infrequent:* gastroenteritis, diverticulitis, gastrointestinal hemorrhage, melena, esophageal ulceration.

Hemic and Lymphatic Disorders: *Frequent:* anemia. *Infrequent:* leukopenia.

Metabolic and Nutritional Disorders: *Frequent:* increased alkaline phosphatase, decreased weight. *Infrequent:* dehydration, hyponatremia, aggravated diabetes mellitus.

Psychiatric Disorders: *Frequent:* aggressive reaction. *Infrequent:* delusion, personality disorder, emotional lability, nervousness, sleep disorder, libido increased, psychosis, amnesia, apathy, paranoid reaction, thinking abnormal, crying abnormal, appetite increased, paroniria, delirium, depersonalization, neurosis, suicide attempt.

Respiratory System: *Frequent:* pneumonia. *Infrequent:* apnea, asthma, hemoptysis.

Skin and Appendages: *Frequent:* rash. *Infrequent:* skin ulceration, pruritus, cellulitis, eczema, dermatitis, erythematous rash, alopecia, urticaria.

Special Senses: *Frequent:* cataract, conjunctivitis. *Infrequent:* macula lutea degeneration, decreased visual acuity, decreased hearing, tinnitus, blepharitis, blurred vision, corneal opacity, glaucoma, conjunctival hemorrhage, eye pain, retinal hemorrhage, xerophthalmia, diplopia, abnormal lacrimation, myopia, retinal detachment.

Urinary System: *Frequent:* frequent micturition. *Infrequent:* dysuria, hematuria, urinary retention.

Events Reported Subsequent to the Marketing of Namenda, both US and Ex-US
Although no causal relationship to memantine treatment has been found, the following adverse events have been reported to be temporally associated with memantine treatment and are not described elsewhere in labeling: atrioventricular block, bone fracture, carpal tunnel syndrome, cerebral infarction, chest pain, claudication, colitis, dyskinesia, dysphagia, gastritis, gastroesophageal reflux, grand mal convulsions, intracranial hemorrhage, hepatic failure, hyperlipidemia, hypoglycemia, ileus, impotence, malaise, neuroleptic malignant syndrome, acute pancreatitis, aspiration pneumonia, acute renal failure, prolonged QT interval, restlessness, Stevens-Johnson syndrome, sudden death, supraventricular tachycardia, tachycardia, tardive dyskinesia, and thrombocytopenia.

ANIMAL TOXICOLOGY
Memantine induced neuronal lesions (vacuolation and necrosis) in the multipolar and pyramidal cells in cortical layers III and IV of the posterior cingulate and retrosplenial neocortices in rats, similar to those which are known to occur in rodents administered other NMDA receptor antagonists. Lesions were seen after a single dose of memantine. In a study in which rats were given daily oral doses of memantine for 14 days, the no-effect dose for neuronal necrosis was 6 times the maximum recommended human dose on a mg/m² basis. The potential for induction of central neuronal vacuolation and necrosis by NMDA receptor antagonists in humans is unknown.

DRUG ABUSE AND DEPENDENCE
Controlled Substance Class: Memantine HCl is not a controlled substance.

Physical and Psychological Dependence: Memantine HCl is a low to moderate affinity uncompetitive NMDA antagonist that did not produce any evidence of drug-seeking behavior or withdrawal symptoms upon discontinuation in 2,504 patients who participated in clinical trials at therapeutic doses. Post marketing data, outside the U.S., retrospectively collected, has provided no evidence of drug abuse or dependence.

OVERDOSAGE
Because strategies for the management of overdose are continually evolving, it is advisable to contact a poison control center to determine the latest recommendations for the management of an overdose of any drug. As in any cases of overdose, general supportive measures should be utilized, and treatment should be symptomatic. Elimination of memantine can be enhanced by acidification of urine. In a documented case of an overdosage with up to 400 mg of memantine, the patient experienced restlessness, psychosis, visual hallucinations, somnolence, stupor and loss of consciousness. The patient recovered without permanent sequelae.

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Rev. 07/05

Military Broadens Online MH Screening

After the early success of its online mental health tool, the military expands the use of anonymous health screenings to include a phone version and an alcohol-dependence test.

BY RICH DALY

The U.S. military's online mental health screening tool, developed to address rising stress levels in troops at home and abroad, has proven more effective than the Department of Defense's (DoD) traditional screening programs in gathering candid responses on possible mental health problems.

The new Web site, which allows anonymous self-screenings for signs of depression, bipolar disorder, generalized anxiety disorder, posttraumatic stress disorder (PTSD), and alcohol abuse, had elicited more openness than the four in-person assessments the military uses, according to preliminary findings of ongoing research on the program.

"People tend to be more candid when using an online or telephone-based screening than in person, and we can speculate that it is because there is more privacy or they are more comfortable," said Air Force Col. Joyce Adkins, a psychologist in the Pentagon's Office of Health Affairs and program manager of the Mental Health Self-Assessment Program.

"People tend to be more candid when using an online or telephone-based screening than in person."

The program, which went online in January and has been widely publicized to members of the military and their families, assesses answers to questions about recent behavior and mood swings. If the responses indicate possible problems, the site refers participants to a central locator office that provides contact information for local clinicians.

The initial findings answer the criticisms of some veterans leaders who described the online surveys as inadequate substitutes for face-to-face encounters with psychiatrists or mental health professionals. The findings of higher degrees of candor among online respondents in the DoD program are similar to the findings reported by other researchers of online mental health screening tools.

A study titled "Psychology of the Internet" published in 1999 by Cambridge University Press found that people tend to disclose more information about themselves to computers than in face-to-face contact. A 2004 study in the *Journal of Clinical Psychology* found that computer-based assessment can gather information of greater quantity and higher quality than clinician-administered assessment.

In addition, a 2003 study in the *Journal of Medical Internet Research* found that a Web-based depression and anxiety test was reliable for identifying patients with and without major depressive disorder and several anxiety disorders—panic disorder with and without agoraphobia, social phobia/social anxiety disorder, obsessive-compulsive disorder, and PTSD.

"I don't know that people are being dishonest otherwise, but they are more candid across the board" with the online approach, Adkins maintained.

Michele Ybarra, Ph.D., who has researched online mental health tools, said studies of this emerging area of care indicate that those who use online screening tools are then more likely to seek in-person care from mental health clinicians than people who fail to take advantage of them.

"The concern was that people would use these tools to say, 'Oh, I'm not that bad off so I don't need any help,' but we have found they do just the opposite of that," said Ybarra, president of Internet Solutions for Kids Inc, a not-for-profit research company.

The military's standard screening tools for mental illness among troops are included as part of its mandatory health assessments that occur immediately before and after deployment and then three to six months after return.

A recent study found that a third of service members returning from Iraq who completed the postdeployment survey received counseling (*Psychiatric News*, June 16).

A fourth screening tool, the Periodic Health Assessment (PHA), is given to all members of the military and their families annually.

"The PHA is designed for everybody, every year, to do a global health assessment," Adkins said.

The new screening tool and the military's more traditional mental health screening programs ask similar questions, and both require more research to better assess their effectiveness, said Capt. Thomas Grieger, M.C., an associate professor of psychiatry at the Uniformed Services University of the Health Sciences. Both a Government Accountability Office study and a DoD National Quality Management Program study questioned whether adequate referrals followed the use of such screening tools.

"You would know if you might have a problem, but it would not definitively tell you that your problem is significant, nor would it be able to tell you that it isn't," said Grieger, who represents the Society of Uniformed Services Psychiatrists in the APA Assembly. "It just says that you have some symptoms."

Adkins emphasized that the online program is designed to supplement—not replace—the more formal programs. The online program, Adkins said, helps to fill a void when face-to-face screening and counseling are not immediately available to a service member or relative. It is also described as primarily an educational tool for those under stress and those who know someone under stress.

Other measures of the site's success include its level of use. While Adkins declined to specify the overall number of users, she said its use has steadily increased since its launch to the point that "thousands" use it each week.

Following the success of the online mental-assessment program, the military now plans to add an anonymous phone-based version for those without Internet access. It is scheduled to be launched by the end of the year.

Also planned is an early intervention, cognitive-behavioral psychoeducational program to provide preemptive education in depression, PTSD, and generalized anxiety disorder to those whose screenings did not indicate that they may need treatment.

The DoD also is developing a Web-based psychoeducation program on alcohol abuse that is in the pilot stage.

Military clinicians knew that a key component of the online program's success would be its ability to be "relevant, convenient, targeted, and trusted." To meet the last goal, the DoD chose the nonprofit company Screening for Mental Health Inc., which created the National Depression Screening Day program, to design the online tool.

Paul Davidson, executive director of the nonprofit National Gulf War Resource Center, said the reluctance of members of the military to seek mental health assistance is affected by fears that just asking for help will impact their status within their unit and the military careers. He praised the online tool as providing a place where they can feel comfortable to answer honestly and find out if they need professional help.

"For some this may be their only way to find out if they should seek help," he told *Psychiatric News*.

The online screening tool is posted at <www.militarymentalhealth.org/welcome.asp>. ■

Pentagon Does About Face On Classifying Homosexuality

The military quickly retreats after media reports and protests from APA and others condemn its classification of homosexuality as a mental disorder decades after it was deleted from the *DSM*.

BY KEN HAUSMAN

Buried for years in the Pentagon's list of conditions it classifies as mental disorders is one that more than three decades ago psychiatrists stated is not a disorder at all.

It turns out that while APA acted to remove homosexuality from its compendium of psychiatric illnesses in 1973—a decision backed by all major medical and mental health organizations—the military chose until last month to maintain its labeling of homosexuality as a mental disorder.

The list that included homosexuality was contained in a section of "Department of Defense Instruction Number 1332.38," delineating "Conditions Not Constituting a Physical Disability" and a subsection titled "Developmental Defects and Other Specific Conditions." The Department of Defense (DoD) document was last issued in 2003 and is current DoD policy.

Immediately after the Pentagon's policy came to light last month, APA Medical Director James Scully Jr., M.D., sent a letter to William Winkenwerder Jr., M.D., assistant secretary for health affairs at DoD, asking him to "update" the document listing the disorders, which the DoD calls an "instruction," to eliminate homosexuality from the list. Scully emphasized that, "based on scientific and medical evidence, APA declassified homosexuality as a mental disorder in 1973—a position shared by all other major health and mental health organizations based on their own reviews of the science."

American Psychological Association Executive Director Gwendolyn Keita, Ph.D., also sent Winkenwerder a letter citing APA's removal of homosexuality from the *DSM* in 1973, urging a need to remove "the stigma of mental illness that has long been associated with homosexual orientation."

Protests also quickly made their way from Capitol Hill to the Pentagon. Eight members of Congress joined Rep. Martin Meehan (D-Mass.), a member of the House Armed Services Committee, in a letter to Defense Secretary Donald Rumsfeld stating that it is "disappointing" that the Pentagon continues to label homosexuality a mental disorder "more than 30 years after the mental health community recognized that such a classification was a mistake. There is no scientific basis for such a classification, which leads me to believe that the classification is motivated by something more sinister."

Meehan's letter also calls on Rumsfeld to bring all medical policies and regulations in line with current professional thinking to "meet the mental health care needs of all of our servicemen and women, including the estimated 65,000 lesbian, gay, and bisexual services members serving in our armed forces today."

All of the protests along with considerable media coverage apparently led the DoD to act in an uncharacteristically rapid manner. On June 28, less than two weeks after the list of disorders became public, Pentagon officials deleted homosexuality from the list. The department issued a statement saying, "Homosexuality should not have been characterized as a mental disorder." It said that a "clarification" would soon be issued that acknowledges and corrects the policy.

"I am glad that the Pentagon agreed—23 years too late—to bring its list of disorders up to date when the error was brought to its attention" said Serena Yuan Volpp, M.D., chair of the APA Committee on Gay, Lesbian, and Bisexual Issues. "I hope Pentagon officials continue to work on making the culture of the military less discriminatory toward gay and lesbian service members."

The change will have no effect on any policies at the DoD, including its discharge of any service member whose homosexuality becomes known—the "don't ask, don't tell" policy. The Pentagon affirmed this by noting that while it will remove homosexuality from the disorders list, doing so "will have no practical impact" since it was just a list of conditions. ■

Most Inmates Would Benefit From Community-Based Care

Prerelease planning, including psychoeducation and vocational training, could help ensure the success of inmates with mental illness after they are released from jail or prison.

BY EVE BENDER

A large proportion of people in jails and prisons are in need of acute psychiatric treatment and should be receiving mental health services in the community, according to information presented at APA's annual meeting in Toronto in May.

According to Henry Weinstein, M.D., chair of APA's Corresponding Committee on Jails and Prisons, people with mental illness fell under the auspices of the criminal justice system as state psychiatric hospitals emptied in the 1970s and 1980s and began to fill prisons and jails.

"In addition to being inhumane, it is also very costly to incarcerate people with serious mental illness," said Weinstein, a clinical professor of psychiatry at New York University and director of the Program in Psychiatry and the Law at New York University Medical Center and Bellevue Hospital.

Though deinstitutionalization was originally driven by state budget concerns, incarcerating people with mental illness is costly due to a number of factors. For instance, "these inmates are usually incarcerated for longer periods of time" than are people without mental illness, Weinstein said.

APA committee members have studied the costs of incarcerating people with serious mental illness and have urged legislators to shift adequate funds into corrections to treat them, he said.

"It's in the interest of state legislatures and corrections for these patients to receive treatment in the community rather than behind bars," he said.

Weinstein and his co-presenters emphasized the importance of mental health courts as one way to divert offenders from incarceration to treatment.

"The resources of the mental health system need to be greatly expanded, with priority given to treating those who are in danger of becoming mentally ill offenders," said H. Richard Lamb, M.D., one of the workshop's presenters.

Lamb, a professor of psychiatry and director of the Division of Psychiatry, Law, and Public Policy at the University of Southern California, conducted a study of the characteristics of 104 randomly sampled men confined to the Los Angeles County Jail.

The inmates had been identified by jail personnel as having mental illness and housed on a 1,500-bed unit designed for offenders with mental illness.

Based on his findings, Lamb determined that 80 percent of the sample had a serious mental illness, including schizophrenia, schizoaffective disorder, bipolar disorder, or major depressive disorder.

Lamb and his colleagues determined that 73 percent of the sample was more appropriate for community mental health treatment, while 27 percent were appropriately placed in the criminal justice system because of "lengthy criminal histories of drug possessions and sales and serious property and weapons charges."

Offenders with mental illness can present unique problems for treatment in or out of the criminal justice system, Lamb noted, due to behavioral problems and treatment noncompliance.

Over 90 percent of the sample had a history of being noncompliant with psychotropic medications, 94 percent had prior arrests, and 79 percent had been arrested for violent crimes.

David Hathcox

Erik Roskes, M.D., said that some prisoners experience "gate fever," in which they have trouble adjusting to life outside of prison. This may be especially true for ex-inmates with mental illness.

Tom Hamilton, Ph.D., the past president of the National Alliance on Mental Illness (NAMI)-Texas and NAMI liaison to APA's Corresponding Committee on Jails and Prisons, was involved in research on Texas inmates, which showed that incarcerating people with mental illness was far more expensive than treating them.

Hamilton highlighted findings from a government study of 100 inmates entering state prisons and county jails in Texas, which found that 1 in 4 inmates had serious mental illness based on matching jail and mental health records.

Those with mental illness had twice the number of jail episodes and three times the number of jail days per episode as the average offender, Hamilton pointed out.

In addition, inmates with mental illness were charged with more infractions per offense than the average nonmentally ill offender.

Hamilton noted that a 2004 cost analysis of inmates in Harris County, Texas, showed that by diverting offenders with mental illness to the community for treatment instead of incarcerating them, there is a potential 40 percent savings per consumer.

Under a program run by the Mental Health and Mental Retardation Author-

*Please see **Inmates** on page 41*

ADHD: It's bigger than just

CONCENTRATION

Attention Deficit Hyperactivity Disorder affects as many as 4 million children in the United States,[1] and each patient comes to the physician with a unique set of symptoms and circumstances, resulting in an individual response to any given therapy.

In order for physicians to better manage the needs of each individual patient, research needs to bring more treatment options to clinical practice. When physicians are able to tailor therapy to individual needs and responses, they may manage the array of symptoms associated with ADHD more effectively. This helps more patients achieve better outcomes.

ADHD is a widespread and complex disorder. At Cephalon, we're concentrating on helping physicians meet individual patient needs.

Reference: 1. Dey AN, Bloom B. Summary health statistics for U.S. children: National Health Interview Survey, 2003. Centers for Disease Control and Prevention, National Center for Health Statistics. 2005. *Vital Health Stat 10.* (223):4.

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Medication Costs Continue To Outpace Inflation

Antipsychotics had the highest average percentage change in price in the first quarter of 2006 of any specific therapeutic category of brand-name drugs, with an increase of 6.6 percent.

BY MARK MORAN

Manufacturer prices for brand-name drugs rose 6.2 percent in the 12 months ending with the first quarter of 2006, more than one-and-a-half times the 3.5 percent rate of general inflation, according to an annual drug price survey by AARP (formerly the American Association of Retired Persons).

Moreover, in the first three months of 2006, the average price increase of 3.9 percent marked the steepest rate of increase for any three-month period since AARP began doing the survey more than six years ago.

The analysis is based on a sample of 197 brand-name drugs that are among the 200 most widely dispensed drugs or the 200 with the highest sales levels among retail and mail-order prescriptions filled by the AARP Pharmacy Service for 2003.

The seven brand-name drug products with the highest price increase during the first three months of 2006 had increases ranging from 8 percent to 13.3 percent. One of those was Seroquel (25 mg), which ranked seventh, with a price increase of 8 percent.

The drugs with the greatest increase in price during the first quarter of 2006 were Ambien 5 mg (13.3 percent); Combivent 120-20 mcg/act (12 percent); Atrovent inhaler 18 mcg/act (12 percent); Ambien 10 mg (9.9 percent); Proscar 5 mg (8.9 percent); and Lexapro 10 mg (8 percent).

When the data were grouped by therapeutic category, antipsychotics had the highest average three-month percentage change in price during the first quarter of 2006 of any specific category, with an increase of 6.6 percent in price. Antidementia drugs followed, with an increase of 6 percent. (Those two therapeutic categories were exceeded only by the nonspecific category of "other therapeutic agents," which increased by 7.1 percent.)

Among the 25 top-selling brand-name prescription drugs, Aricept (an antidementia drug ranking 15th in sales) had a price increase of 6 percent during the first quarter of 2006.

The AARP survey is prepared by the AARP Public Policy Institute and the PRIME Institute at the University of Minnesota.

"Through the end of the first quarter of 2006, annual increases in manufacturer prices charged to wholesalers for widely used brand-name prescription drugs, on average, continued to substantially exceed the rate of general inflation," according to the report. "In fact, the first-quarter average-price increase (3.9 percent) was the highest ever for a first quarter during the more than six-year period of analysis in AARP's study of drugs widely used by older Americans."

The report noted that with the enactment of the Medicare Modernization Act (MMA), which established the Medicare Part D prescription program, AARP challenged manufacturers to keep the rate of price increase to the rate of general inflation.

Clifford Binder of the AARP Public Policy Institute told *Psychiatric News* that it could not be determined if the initiation of the new prescription-drug program in January played a role in pushing up the prices of drugs. "We are continuing to monitor the effect of the MMA on drug prices," he said.

"While the rate of increase did slow down beginning in mid-2004, the first-quarter 2006 results represent a disturbing reversal of that trend," according to the report. "It remains to be seen whether this is a one-time change or the beginning of a pattern of an increasing rate of price increase."

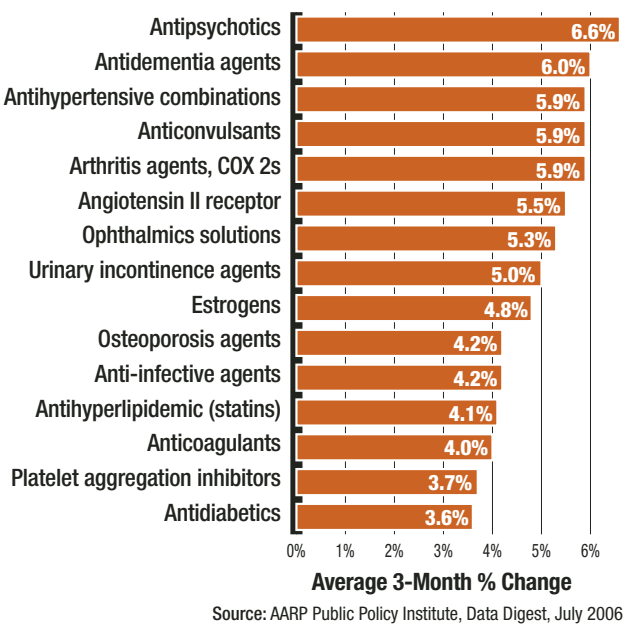
The manufacturer price increases translate also into increases in the cost of therapy for patients. The average annual increase in cost of therapy for 187 widely used brand-name drugs used to treat chronic conditions was $59.57 for the 12 months ending with the first quarter of 2006, compared with $47.43 in 2005 (*Psychiatric News*, November 4, 2005).

According to the report, a typical older American (who takes four prescription drugs a day) is likely to have experienced an annual increase on average in the cost of therapy of $238.28 for the first 12 months ending with the first quarter of 2006, assuming the drugs are brand-name products and the full price increase was passed along to the consumer.

"Trends in Manufacturer Prices of Prescription Drugs Used by Older Americans" is posted at <www.aarp.org/research/health/drugs/aresearch-import-869-2004-06--IB69.html>. ■

Up, Up, Up. . .

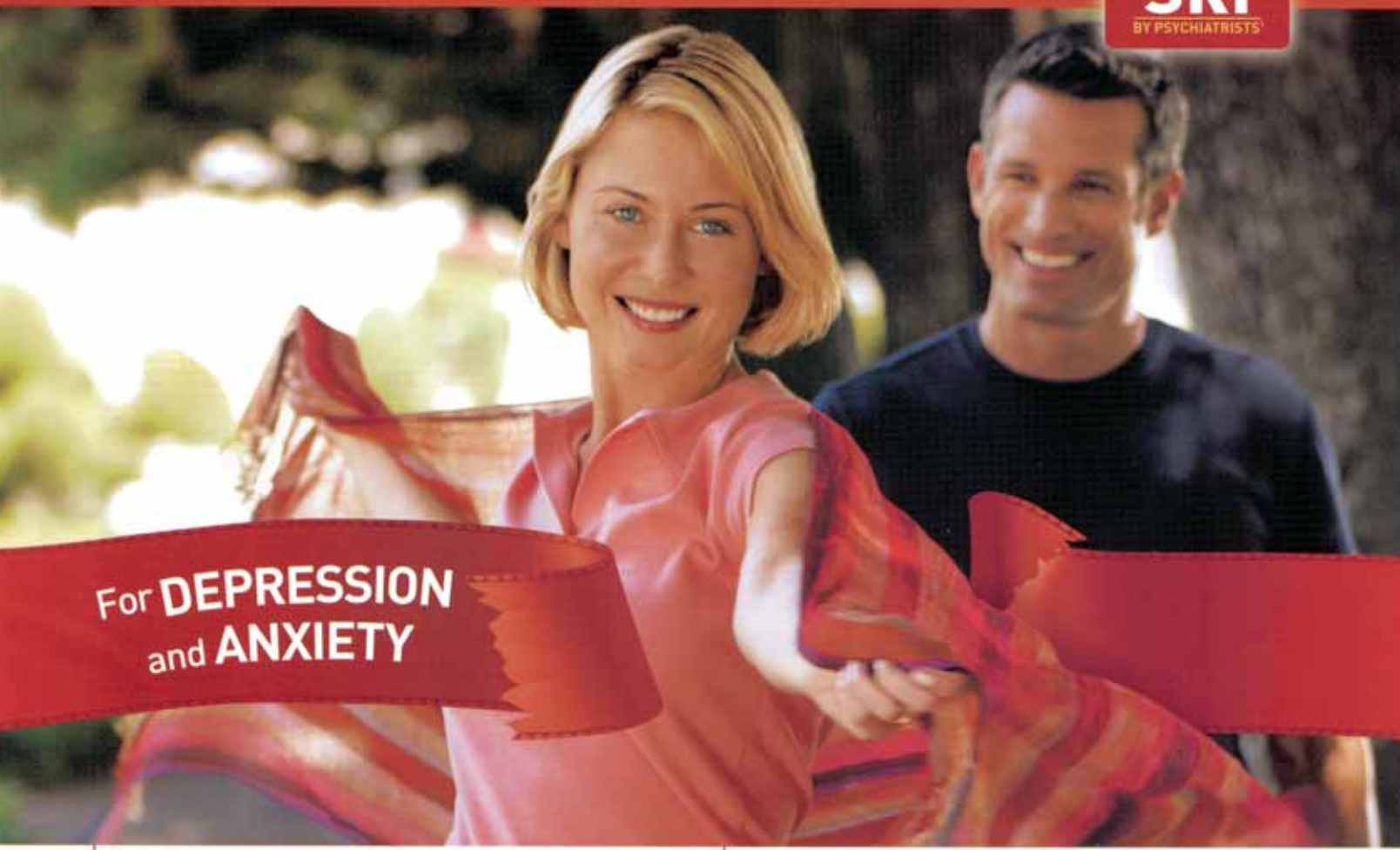
The percentages below represent the average three-month percentage change in manufacturers' prices for brand-name prescription drugs by therapeutic category for the first quarter of 2006. Prices have been adjusted for inflation.



Source: AARP Public Policy Institute, Data Digest, July 2006

A POWERFUL SSRI that's well tolerated

#1 PRESCRIBED SRI BY PSYCHIATRISTS[1]



UP TO 90% of depressed patients present with symptoms of anxiety[2]

PROVEN EFFICACY for Major Depressive Disorder and Generalized Anxiety Disorder[3]

Lexapro escitalopram oxalate

POWER TO ENJOY LIFE™

IMPORTANT SAFETY INFORMATION – Depression is a serious condition that can lead to suicidal thoughts and behavior. Antidepressants increased the risk of suicidal thinking and behavior (2% to 4%) in short-term studies of 9 antidepressant drugs in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. Patients started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior, especially at the beginning of therapy or at the time of dose changes. This risk may persist until significant remission occurs. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients.

Lexapro is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs), pimozide (see DRUG INTERACTIONS – Pimozide and Celexa), or in patients with hypersensitivity to escitalopram oxalate. As with other SSRIs, caution is indicated in the coadministration of tricyclic antidepressants (TCAs) with Lexapro. As with other psychotropic drugs that interfere with serotonin reuptake, patients should be cautioned regarding the risk of bleeding associated with the concomitant use of Lexapro with NSAIDs, aspirin, or other drugs that affect coagulation. The most common adverse events with Lexapro versus placebo (approximately 5% or greater and approximately 2x placebo) were nausea, insomnia, ejaculation disorder, somnolence, increased sweating, fatigue, decreased libido, and anorgasmia.

References: 1. IMS National Prescription Audit. May 2005. **2.** Sadock BJ, Sadock VA. *Kaplan and Sadock's Synopsis of Psychiatry: Behavioral Sciences/Clinical Psychiatry.* 9th ed. Philadelphia, Pa: Lippincott Williams & Wilkins;2003:552. **3.** LEXAPRO (package insert). St Louis, Mo: Forest Pharmaceuticals, Inc.; 2005.

Please see brief summary of prescribing information for LEXAPRO on following page.

Visit the LEXAPRO website at www.lexapro.com

LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION

Brief Summary: For complete details, please see full prescribing information for Lexapro.

Suicidality in Children and Adolescents Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Lexapro or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

CONTRAINDICATIONS Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated (see **WARNINGS**). Concomitant use in patients taking pimozide is contraindicated (see **Drug Interactions** – Pimozide and Celexa). Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Lexapro. **WARNINGS-Clinical Worsening and Suicide Risk Clinical Worsening and Suicide Risk** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. A causal role for antidepressants in inducing suicidality has been established in pediatric patients. Pooled analyses of short-term placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with MDD, OCD, or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal behavior or thinking (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. There was considerable variation in risk among drugs, but a tendency toward an increase for almost all drugs studied. The risk of suicidality was most consistently observed in the MDD trials, but there were signals of risk arising from some trials in other psychiatric indications (obsessive compulsive disorder and social anxiety disorder) as well. **No suicides occurred in any of these trials.** It is unknown whether the suicidality risk in pediatric patients extends to longer-term use, i.e., beyond several months. It is also unknown whether the suicidality risk extends to adults. **All pediatric patients being treated with antidepressants for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Such observation would generally include at least weekly face-to-face contact with patients or their family members or caregivers during the first 4 weeks of treatment, then every other week visits for the next 4 weeks, then at 12 weeks, and as clinically indicated beyond 12 weeks. Additional contact by telephone may be appropriate between face-to-face visits. Adults with MDD or co-morbid depression in the setting of other psychiatric illness being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.** The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. **Families and caregivers of pediatric patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers.** Prescriptions for Lexapro should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. Families and caregivers of adults being treated for depression should be similarly advised. **Screening Patients for Bipolar Disorder:** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Lexapro is not approved for use in treating bipolar depression. **Potential for Interaction with Monoamine Oxidase Inhibitors In patients receiving serotonin reuptake inhibitor drugs in combination with a monoamine oxidase inhibitor (MAOI), there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Furthermore, limited animal data on the effects of combined use of SSRIs and MAOIs suggest that these drugs may act synergistically to elevate blood pressure and evoke behavioral excitation. Therefore, it is recommended that Lexapro should not be used in combination with an MAOI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days should be allowed after stopping Lexapro before starting an MAOI. Serotonin syndrome has been reported in two patients who were concomitantly receiving linezolid, an antibiotic which is a reversible non-selective MAOI. PRECAUTIONS General** Discontinuation of Treatment with Lexapro During marketing of Lexapro and other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with Lexapro. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (see **DOSAGE AND ADMINISTRATION** in full prescribing information). Abnormal Bleeding Published case reports have documented the occurrence of bleeding episodes in patients treated with psychotropic drugs that interfere with serotonin reuptake. Subsequent epidemiological studies, both of the case-control and cohort design, have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding. In two studies, concurrent use of a non-steroidal anti-inflammatory drug (NSAID) or aspirin potentiated the risk of bleeding (see **Drug Interactions**). Although these studies focused on upper gastrointestinal bleeding, there is reason to believe that bleeding at other sites may be similarly potentiated. Patients should be cautioned regarding the risk of bleeding associated with the concomitant use of Lexapro with NSAIDs, aspirin, or other drugs that affect coagulation. Hyponatremia Cases of hyponatremia and SIADH (syndrome of inappropriate antidiuretic hormone secretion) have been reported in association with Lexapro treatment. All patients with these events have recovered with discontinuation of escitalopram and/or medical intervention. Hyponatremia and SIADH have also been reported in association with other marketed drugs effective in the treatment of major depressive disorder. Activation of Mania/Hypomania In placebo-controlled trials of Lexapro in major depressive disorder, activation of mania/hypomania was reported in one (0.1%) of 715 patients treated with Lexapro and in none of the 592 patients treated with placebo. One additional case of hypomania has been reported in association with Lexapro treatment. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorders treated with racemic citalopram and other marketed drugs effective in the treatment of major depressive disorder. As with all drugs effective in the treatment of major depressive disorder, Lexapro should be used cautiously in patients with a history of mania. Seizures Although anticonvulsant effects of racemic citalopram have been observed in animal studies, Lexapro has not been systematically evaluated in patients with a seizure disorder. These patients were excluded from clinical studies during the product's premarketing testing. In clinical trials of Lexapro, cases of convulsion have been reported in association with Lexapro treatment. Like other drugs effective in the treatment of major depressive disorder, Lexapro should be introduced with care in patients with a history of seizure disorder. Interference with Cognitive and Motor Performance In a study in normal volunteers, Lexapro 10 mg/day did not produce impairment of intellectual function or psychomotor performance. Because any psychoactive drug may impair judgment, thinking, or motor skills, however, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro therapy does not affect their ability to engage in such activities. Use in Patients with Concomitant Illness Clinical experience with Lexapro in patients with certain concomitant systemic illnesses is limited. Caution is advisable in using Lexapro in patients with diseases or conditions that produce altered metabolism or hemodynamic responses. Lexapro has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were generally excluded from clinical studies during the product's premarketing testing. In subjects with hepatic impairment, clearance of racemic citalopram was decreased and plasma concentrations were increased. The recommended dose of Lexapro in hepatically impaired patients is 10 mg/day (see **DOSAGE AND ADMINISTRATION** in full prescribing information). Because escitalopram is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Until adequate numbers of patients with severe renal impairment have been evaluated during chronic treatment with Lexapro, however, it should be used with caution in such patients (see **DOSAGE AND ADMINISTRATION** in full prescribing information). **Drug Interactions** CNS Drugs - Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs. Alcohol - Although Lexapro did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by patients taking Lexapro is not recommended. Monoamine Oxidase Inhibitors (MAOIs) - See **CONTRAINDICATIONS** and **WARNINGS. Drugs That Interfere With Hemostasis (NSAIDs, Aspirin, Warfarin, etc.)** Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of the case-control and cohort design that have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding have also shown that concurrent use of an NSAID or aspirin potentiated the risk of bleeding. Thus, patients should be cautioned about the use of such drugs concurrently with Lexapro. Cimetidine - In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of 400 mg/day cimetidine for 8 days resulted in an increase in citalopram AUC and C_{max} of 43% and 39%, respectively. The clinical significance of these findings is unknown. Digoxin - In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of citalopram and digoxin (single dose of 1 mg) did not significantly affect the pharmacokinetics of either citalopram or digoxin. Lithium - Coadministration of racemic citalopram (40 mg/day for 10 days) and lithium (30 mmol/day for 5 days) had no significant effect on the pharmacokinetics of citalopram or lithium. Nevertheless, plasma lithium levels should be monitored with appropriate adjustment to the lithium dose in accordance with standard clinical practice. Because lithium may enhance the serotonergic effects of escitalopram, caution should be exercised when Lexapro and lithium are coadministered. Pimozide and Celexa - In a controlled study, a single dose of pimozide 2 mg co-administered with racemic citalopram 40 mg given once daily for 11 days was associated with a mean increase in QTc values of approximately 10 msec compared to pimozide given alone. Racemic citalopram did not alter the mean AUC or C_{max} of pimozide. The mechanism of this pharmacodynamic interaction is not known. Sumatriptan - There have been rare postmarketing reports describing patients with weakness, hyperreflexia, and incoordination following the use of an SSRI and sumatriptan. If concomitant treatment with sumatriptan and an SSRI (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram) is clinically warranted, appropriate observation of the patient is advised. Theophylline - Combined administration of racemic citalopram (40 mg/day for 21 days) and the CYP1A2 substrate theophylline (single dose of 300 mg) did not affect the pharmacokinetics of theophylline. The effect of theophylline on the pharmacokinetics of citalopram was not evaluated. Warfarin - Administration of 40 mg/day racemic citalopram for 21 days did not affect the pharmacokinetics of warfarin, a CYP3A4 substrate. Prothrombin time was increased by 5%, the clinical significance of which is unknown. Carbamazepine - Combined administration of racemic citalopram (40 mg/day for 14 days) and carbamazepine (titrated to 400 mg/day for 35 days) did not significantly affect the pharmacokinetics of carbamazepine, a CYP3A4 substrate. Although trough citalopram plasma levels were unaffected, given the enzyme-inducing properties of carbamazepine, the possibility that carbamazepine might increase the clearance of escitalopram should be considered if the two drugs are coadministered. Triazolam - Combined administration of racemic citalopram (titrated to 40 mg/day for 28 days) and the CYP3A4 substrate triazolam (single dose of 0.25 mg) did not significantly affect the pharmacokinetics of either citalopram or triazolam. Ketoconazole - Combined administration of racemic citalopram (40 mg) and ketoconazole (200 mg), a potent CYP3A4 inhibitor, decreased the C_{max} and AUC of ketoconazole by 21% and 10%, respectively, and did not significantly affect the pharmacokinetics of citalopram. Ritonavir - Combined administration of a single dose of ritonavir (600 mg), both a CYP3A4 substrate and a potent inhibitor of CYP3A4, and escitalopram (20 mg) did not affect the pharmacokinetics of either ritonavir or escitalopram. CYP3A4 and -2C19 Inhibitors - *In vitro* studies indicated that CYP3A4 and -2C19 are the primary enzymes involved in the metabolism of escitalopram. However, coadministration of escitalopram (20 mg) and ritonavir (600 mg), a potent inhibitor of CYP3A4, did not significantly affect the pharmacokinetics of escitalopram. Because escitalopram is metabolized by multiple enzyme systems, inhibition of a single enzyme may not appreciably decrease escitalopram clearance. Drugs Metabolized by Cytochrome P4502D6 - *In vitro* studies did not reveal an inhibitory effect of escitalopram on CYP2D6. In addition, steady state levels of racemic citalopram were not significantly different in poor metabolizers and extensive CYP2D6 metabolizers after multiple-dose administration of citalopram, suggesting that coadministration, with escitalopram, of a drug that inhibits CYP2D6, is unlikely to have clinically significant effects on escitalopram metabolism. However, there are limited *in vivo* data suggesting a modest CYP2D6 inhibitory effect for escitalopram, i.e., coadministration of escitalopram (20 mg/day for 21 days) with the tricyclic antidepressant desipramine (single dose of 50 mg), a substrate for CYP2D6, resulted in a 40% increase in C_{max} and a 100% increase in AUC of desipramine. The clinical significance of this finding is unknown. Nevertheless, caution is indicated in the coadministration of escitalopram and drugs metabolized by CYP2D6. Metoprolol- Administration of 20 mg/day Lexapro for 21 days in healthy volunteers resulted in a 50% increase in C_{max} and 82% increase in AUC of the beta-adrenergic blocker metoprolol (given in a single dose of 100 mg). Increased metoprolol plasma levels have been associated with decreased cardioselectivity. Coadministration of Lexapro and metoprolol had no clinically significant effects on blood pressure or heart rate. Electroconvulsive Therapy (ECT) - There are no clinical studies of the combined use of ECT and escitalopram. **Carcinogenesis, Mutagenesis, Impairment of Fertility** Carcinogenesis Racemic citalopram was administered in the diet to NMRI/BOM strain mice and COBS WI strain rats for 18 and 24 months, respectively. There was no evidence for carcinogenicity of racemic citalopram in mice receiving up to 240 mg/kg/day. There was an increased incidence of small intestine carcinoma in rats receiving 8 or 24 mg/kg/day racemic citalopram. A no-effect dose for this finding was not established. The relevance of these findings to humans is unknown. Mutagenesis Racemic citalopram was mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) in 2 of 5 bacterial strains (Salmonella TA98 and TA1537) in the absence of metabolic activation. It was clastogenic in the *in vitro* Chinese hamster lung cell assay for chromosomal aberrations in the presence and absence of metabolic activation. Racemic citalopram was not mutagenic in the *in vitro* mammalian forward gene mutation assay (HPRT) in mouse lymphoma cells or in a coupled *in vitro/in vivo* unscheduled DNA synthesis (UDS) assay in rat liver. It was not clastogenic in the *in vitro* chromosomal aberration assay in human lymphocytes or in two *in vivo* mouse micronucleus assays. Impairment of Fertility When racemic citalopram was administered orally to 16 male and 24 female rats prior to and throughout mating and gestation at doses of 32, 48, and 72 mg/kg/day, mating was decreased at all doses, and fertility was decreased at doses ≥ 32 mg/kg/day. Gestation duration was increased at 48 mg/kg/day. **Pregnancy-Nonteratogenic Effects** Neonates exposed to Lexapro and other SSRIs or SNRIs, late in the third trimester, have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome (see **WARNINGS**). When treating a pregnant woman with Lexapro during the third trimester, the physician should carefully consider the potential risks and benefits of treatment (see **DOSAGE AND ADMINISTRATION** in full prescribing information). **Labor and Delivery** The effect of Lexapro on labor and delivery in humans is unknown. **Nursing Mothers** Racemic citalopram, like many other drugs, is excreted in human breast milk. There have been two reports of infants experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of citalopram by its mother and, in the second case, no follow-up information was available. The decision whether to continue or discontinue either nursing or Lexapro therapy should take into account the risks of citalopram exposure for the infant and the benefits of Lexapro treatment for the mother. **Pediatric Use** Safety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS-Clinical Worsening and Suicide Risk). **Geriatric Use** Approximately 6% of the 1144 patients receiving escitalopram in controlled trials of Lexapro in major depressive disorder and GAD were 60 years of age or older; elderly patients in these trials received daily doses of Lexapro between 10 and 20 mg. The number of elderly patients in these trials was insufficient to adequately assess for possible differential efficacy and safety measures on the basis of age. Nevertheless, greater sensitivity of some elderly individuals to effects of Lexapro cannot be ruled out. In two pharmacokinetic studies, escitalopram half-life was increased by approximately 50% in elderly subjects as compared to young subjects and C_{max} was unchanged (see **CLINICAL PHARMACOLOGY**). 10 mg/day is the recommended dose for elderly patients (see **DOSAGE AND ADMINISTRATION** in full prescribing information). Of 4422 patients in clinical studies of racemic citalopram, 1357 were 60 and over, 1034 were 65 and over, and 457 were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but again, greater sensitivity of some elderly individuals cannot be ruled out. **ADVERSE REACTIONS** Adverse event information for Lexapro was collected from 715 patients with major depressive disorder who were exposed to escitalopram and from 592 patients who were exposed to placebo in double-blind, placebo-controlled trials. An additional 284 patients with major depressive disorder were newly exposed to escitalopram in open-label trials. The adverse event information for Lexapro in patients with GAD was collected from 429 patients exposed to escitalopram and from 427 patients exposed to placebo in double-blind, placebo-controlled trials. Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tables and tabulations that follow, standard World Health Organization (WHO) terminology has been used to classify reported adverse events. The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. **Adverse Events Associated with Discontinuation of Treatment Major Depressive Disorder** Among the 715 depressed patients who received Lexapro in placebo-controlled trials, 6% discontinued treatment due to an adverse event, as compared to 2% of 592 patients receiving placebo. In two fixed-dose studies, the rate of discontinuation for adverse events in patients receiving 10 mg/day Lexapro was not significantly different from the rate of discontinuation for adverse events in patients receiving placebo. The rate of discontinuation for adverse events in patients assigned to a fixed dose of 20 mg/day Lexapro was 10%, which was significantly different from the rate of discontinuation for adverse events in patients receiving 10 mg/day Lexapro (4%) and placebo (3%). Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice that of placebo, were nausea (2%) and ejaculation disorder (2% of male patients). **Generalized Anxiety Disorder** Among the 429 GAD patients who received Lexapro 10-20 mg/day in placebo-controlled trials, 8% discontinued treatment due to an adverse event, as compared to 4% of 427 patients receiving placebo. Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice the placebo rate, were nausea (2%), insomnia (1%), and fatigue (1%). **Incidence of Adverse Events in Placebo-Controlled Clinical Trials Major Depressive Disorder** Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred among 715 depressed patients who received Lexapro at doses ranging from 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The prescriber should be aware that these figures can not be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and non-drug factors to the adverse event incidence rate in the population studied. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were insomnia, ejaculation disorder (primarily ejaculatory delay), nausea, sweating increased, fatigue, and somnolence (see TABLE 1). **TABLE 1: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Major Depressive Disorder* [Lexapro (N=715) and Placebo (N=592)]: Autonomic Nervous System Disorders:** Dry Mouth (6% and 5%); Sweating Increased (5% and 2%). **Central & Peripheral Nervous System Disorders:** Dizziness (5% and 3%). **Gastrointestinal Disorders:** Nausea (15% and 7%); Diarrhea (8% and 5%); Constipation (3% and 1%); Indigestion (3% and 1%); Abdominal Pain (2% and 1%). **General:** Influenza-like Symptoms (5% and 4%); Fatigue (5% and 2%). **Psychiatric Disorders:** Insomnia (9% and 4%); Somnolence (6% and 2%); Appetite Decreased (3% and 1 %); Libido Decreased (3% and 1%). **Respiratory System Disorders:** Rhinitis (5% and 4%); Sinusitis (3% and 2%). **Urogenital:** Ejaculation Disorder[1,2] (9% and <1%); Impotence[2] (3% and <1%); Anorgasmia[3] (2% and <1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: headache, upper respiratory tract infection, back pain, pharyngitis, inflicted injury, anxiety. [1]Primarily ejaculatory delay. [2]Denominator used was for males only (N=225 Lexapro; N=188 placebo). [3]Denominator used was for females only (N=490 Lexapro; N=404 placebo). **Generalized Anxiety Disorder** Table 2 enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia (see **TABLE 2**). **TABLE 2: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Generalized Anxiety Disorder* [Lexapro (N=429) and Placebo (N=427)]: Autonomic Nervous System Disorders:** Dry Mouth (9% and 5%); Sweating Increased (4% and 1%). **Central & Peripheral Nervous System Disorders:** Headache (24% and 17%); Paresthesia (2% and 1%). **Gastrointestinal Disorders:** Nausea (18% and 8%); Diarrhea (8% and 6%); Constipation (5% and 4%); Indigestion (3% and 2%); Vomiting (3% and 1%); Abdominal Pain (2% and 1%); Flatulence (2% and 1%); Toothache (2% and 0%). **General:** Fatigue (8% and 2%); Influenza-like symptoms (5% and 4%). **Musculoskeletal:** Neck/Shoulder Pain (3% and 1%). **Psychiatric Disorders:** Somnolence (13% and 7%); Insomnia (12% and 6%); Libido Decreased (7% and 2%); Dreaming Abnormal (3% and 2%); Appetite Decreased (3% and 1 %); Lethargy (3% and 1%); Yawning (2% and 1 %). **Urogenital:** Ejaculation Disorder[1,2] (14% and 2%); Anorgasmia[3] (6% and <1%); Menstrual Disorder (2% and 1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: inflicted injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. [1]Primarily ejaculatory delay. [2]Denominator used was for males only (N=182 Lexapro; N=195 placebo). [3]Denominator used was for females only (N=247 Lexapro; N=232 placebo). **Dose Dependency of Adverse Events** The potential dose dependency of common adverse events (defined as an incidence rate of ≥5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). Table 3 shows common adverse events that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group. **TABLE 3: Incidence of Common Adverse Events* in Patients with Major Depressive Disorder Receiving Placebo (N=311), 10 mg/day Lexapro (N=310), 20 mg/day Lexapro (N=125)]: Insomnia** (4%, 7%, 14%); **Diarrhea** (5%, 6%, 14%); **Dry Mouth** (3%, 4%, 9%); **Somnolence** (1%, 4%, 9%); **Dizziness** (2%, 4%, 7%); **Sweating Increased** (<1%, 3%, 8%); **Constipation** (1%, 3%, 6%); **Fatigue** (2%, 2%, 6%); **Indigestion** (1%, 2%, 6%). *Adverse events with an incidence rate of at least 5% in either of the Lexapro groups and with an incidence rate in the 20 mg/day Lexapro group that was approximately twice that of the 10 mg/day Lexapro group and the placebo group. **Male and Female Sexual Dysfunction with SSRIs** Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. Table 4 shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-controlled trials. **TABLE 4: Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials [In Males Only: Lexapro (N=407) and Placebo (N=383)]: Ejaculation Disorder** (primarily ejaculatory delay) (12% and 1%); **Libido Decreased** (6% and 2%); **Impotence** (2% and <1%). **[In Females Only: Lexapro (N=737) and Placebo (N=636)]: Libido Decreased** (3% and 1%); **Anorgasmia** (3% and <1%) There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Priapism has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes** Patients treated with Lexapro in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes** Electrocardiograms from Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to an increase of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Events Observed During the Premarketing Evaluation of Lexapro** Following is a list of WHO terms that reflect treatment-emergent adverse events, as defined in the introduction to the **ADVERSE REACTIONS** section, reported by the 1428 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. All reported events are included except those already listed in Tables 1 & 2, those occurring in only one patient, event terms that are so general as to be uninformative, and those that are unlikely to be drug related. It is important to emphasize that, although the events reported occurred during treatment with Lexapro, they were not necessarily caused by it. 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 on one or more occasions in at least 1/100 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1000 patients. Cardiovascular - *Frequent:* palpitation, hypertension. *Infrequent:* bradycardia, tachycardia, ECG abnormal, flushing, varicose vein. Central and Peripheral Nervous System Disorders - *Frequent:* light-headed feeling, migraine. *Infrequent:* tremor, vertigo, restless legs, shaking, twitching, dysequilibrium, tics, carpal tunnel syndrome, muscle contractions involuntary, sluggishness, coordination abnormal, faintness, hyperreflexia, muscular tone increased. Gastrointestinal Disorders - *Frequent:* heartburn, abdominal cramp, gastroenteritis. *Infrequent:* gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult. General - *Frequent:* allergy, pain in limb, fever, hot flushes, chest pain. *Infrequent:* edema of extremities, chills, tightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. Hemic and Lymphatic Disorders - *Infrequent:* bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical. Metabolic and Nutritional Disorders - *Frequent:* increased weight. *Infrequent:* decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. Musculoskeletal System Disorders - *Frequent:* arthralgia, myalgia. *Infrequent:* jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness. Psychiatric Disorders - *Frequent:* appetite increased, lethargy, irritability, concentration impaired. *Infrequent:* jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, amnesia, anxiety attack, bruxism, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. Reproductive Disorders/Female* - *Frequent:* menstrual cramps, menstrual disorder. *Infrequent:* menorrhagia, breast neoplasm, pelvic inflammation, premenstrual syndrome, spotting between menses. *% based on female subjects only: N= 905 Respiratory System Disorders - *Frequent:* bronchitis, sinus congestion, coughing, nasal congestion, sinus headache *Infrequent:* asthma, breath shortness, laryngitis, pneumonia, tracheitis. Skin and Appendages Disorders - *Frequent:* rash. *Infrequent:* pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodule. Special Senses - *Frequent:* vision blurred, tinnitus. *Infrequent:* taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste. Urinary System Disorders - *Frequent:* urinary frequency, urinary tract infection. *Infrequent:* urinary urgency, kidney stone, dysuria, blood in urine. **Events Reported Subsequent to the Marketing of Escitalopram** Although no causal relationship to escitalopram treatment has been found, the following adverse events have been reported to have occurred in patients and to be temporally associated with escitalopram treatment during postmarketing experience and were not observed during the premarketing evaluation of escitalopram: abnormal gait, acute renal failure, aggression, angioedema, atrial fibrillation, diplopia, dystonia, extrapyramidal disorders, gastrointestinal hemorrhage, grand mal seizures (or convulsions), hepatitis, hypotension, myocardial infarction, neuroleptic malignant syndrome, orthostatic hypotension, pancreatitis, pulmonary embolism, QT prolongation, rhabdomyolysis, seizures, serotonin syndrome, SIADH, thrombocytopenia, torsades de pointes, toxic epidermal necrolysis, ventricular tachycardia and visual hallucinations. **Events Reported Subsequent to the Marketing of Racemic Citalopram** Although no causal relationship to racemic citalopram treatment has been found, the following adverse events have been reported to have occurred in patients and to be temporally associated with racemic citalopram treatment and were not observed during the premarketing evaluation of citalopram: acute renal failure, akathisia, allergic reaction, anaphylaxis, angioedema, choreoathetosis, delirium, dyskinesia, ecchymosis, erythema multiforme, gastrointestinal hemorrhage, grand mal seizures (or convulsions), hemolytic anemia, hepatic necrosis, myoclonus, neuroleptic malignant syndrome, nystagmus, pancreatitis, priapism, prolactinemia, prothrombin decreased, QT prolongation, rhabdomyolysis, serotonin syndrome, spontaneous abortion, thrombocytopenia, thrombosis, torsades de pointes, toxic epidermal necrolysis and ventricular arrhythmia.

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Katrina Response Can Learn From Urban-Renewal Disaster

When the cementing relationships of "weak" social ties are disrupted, the emergence of tribal hostility and factionalism after displacement should not be a surprise.

BY MARK MORAN

The aftermath of 25 years of "urban renewal" in American cities testifies to the enormous power of place in individual and social stability, and to the profound psychosocial implications of displacement.

So said psychiatrist Mindy Thompson Fullilove, M.D., in a lecture at APA's 2006 annual meeting in Toronto.

The American experiment in urban renewal and the displacement of entire neighborhoods in cities across the country carries profound lessons for how to respond to the destruction of the Gulf region by Hurricane Katrina, she said.

"There is much to be done in the management of displacement, and psychiatrists have a very fundamental role in the process," Fullilove said. "For the suffering person who comes to us and needs our care, it is essential to place the life story of this person who has suffered from displacement in the larger context of where the person came from, why the person was forced to move, and where the person might possibly go.

"Whatever symptoms [such people] present with may literally be the symptoms of this rupture in their life pattern, and the most important thing you can do is to reorient them to the task of living."

Regarding the reconstruction of the Gulf region in the aftermath of Hurricane Katrina, Fullilove said psychiatrists can also play a part in helping to generate political will to commit adequate resources—a commitment that she said needs to be comparable in scale to the Marshall Plan to rebuild Europe after the destruction of World War II.

"The failure to have a reasonable plan after Katrina is at the heart of illness and destruction that are going to affect generations of people," she said.

Fullilove is a research psychiatrist at the New York State Psychiatric Institute and a professor of clinical psychiatry and public health at Columbia University. She has conducted research on AIDS and other epidemics in poor communities, with a special interest in the relationship between the collapse of communities and decline in health.

She has published widely and has written two books, *Root Shock: How Tearing Up City Neighborhoods Hurts America and What We Can Do About It* (One World/Ballantine Publishers, 2004) and *The House of Joshua: Meditations on Family and Place* (University of Nebraska Press, 1992 and 2002).

Urban Renewal Can Be Ethnic Cleansing

Fullilove's observations were drawn from her study of the aftereffects of urban renewal, the effort from 1949 to 1973 to rebuild America's inner cities by uprooting long-established, largely poor, predominantly African-American communities. This effort was and is still widely regarded as "progress," but Fullilove said it could more properly be described as a form of ethnic cleansing.

During that period, 2,532 urban renewal projects were undertaken, two-thirds of which were directed toward African-American neighborhoods at a time when blacks were just 12 percent of the U.S. population; in this way, African Americans had five times the risk of being affected by displacement than should have been expected on the basis of population, she said.

"There was a great desire to get African Americans away from downtown areas," Fullilove said. In the place of their indigenous, organic neighborhoods were built office buildings, tourist attractions, cultural institutions, and sports arenas.

As an example, she showed before and after photographs of the Hill District, an African-American neighborhood in Pittsburgh that was uprooted to make room for, among other buildings, the Mellon Arena, home to the Pittsburgh Penguins hockey team.

"There is a real clash of who wants the land for what," she said. "This is a fundamental clash in all episodes of displacement. Whoever has the power to write the history of displacement will say that whoever used to have the land used it badly and that they will use it well. There is no narrative of displacement that does not contain this story line."

Communal Relationships Destroyed

Yet these same neighborhoods were home to a rich culture and a crucial web of family and communal relationships that have been irrevocably lost. Fullilove illustrated her remarks with photographs taken by Charles "Teenie" Harris, an African-American photographer who left behind a remarkable photographic record of everyday life in the Hill District: dances, parades, checkers games, customers in a barbershop, and casual neighborhood gatherings on sidewalk stoops.

It was in African-American neighborhoods like the Hill District that jazz music also flourished. This distinctively American music was nearly lost along with the rest of the cultural heritage of uprooted neighborhoods, only to be preserved by aficionados in Japan and Europe. "In this way it became a very cerebral music, divorced from the folk culture of the ghetto," Fullilove said. "It became a different kind of music, not the music of the community, but the music of music lovers."

She likened the psychological devastation of losing one's home in this way to "root shock," the trauma suffered by plants that are uprooted from the soil that nurtures them.

"If your home was here," she said, "you can never go home again. There are people from the Hill District whose homes were in what is now the middle of the ice at Mellon Arena. They have a feeling about where their home is, but they can never go there."

Beyond the losses—financial and psychological—of the displaced populations, Fullilove emphasized that the uprooting of communal relationships has a profound impact on the larger society.

She drew on the work of sociologist Mark Granovetter's 1973 article "The Strength of Weak Ties" to illustrate how individuals are typically bound by both "strong ties"—those of race, religion, or tribe—and "weak ties," relationships with individuals forged in the day-to-day course of living: the barber, the waitress at the coffeeshop, the cashier at the grocery story.

She noted that when people lose the web of relationships that comprise their weak ties, they fall back on the strong—and potentially socially divisive—ties of race, religion, and tribe.

"It was precisely these weak ties that were severed in the uprooting of neighborhoods," Fullilove said. "Those weak ties are the relationships that get people jobs and that link them to the political system. They spread across ethnic groups, and when those cementing relationships are broken, the emergence of tribal hostility and factionalism after displacement is absolutely to be expected."

She also cited the work of social psychiatrist Alexander Leighton, M.D., to stress that as social bonds are ruptured, the overall social organization changes. It was Leighton who posited two theoretical extremes—the model supportive community and the loose collection of individuals—and said that as a society moved along the continuum away from the model toward the loose collection, it could expect to see more and more mental illness.

As the weak ties that bind individuals to one another have been ruptured, Fullilove said, American society has moved more and more toward the extreme of the loose collection of individuals. She added that Leighton pointed out 50 years ago that status and wealth do not protect individuals in a society that is moving toward a mere collection of individuals.

"The well-to-do in a collection have worse health than the poor do in a model supportive community," she said.

Fullilove noted that recent research appears to bear out this dismal predic-

Please see ***Urban Renewal*** *on page 42*

David Hathcox

Mindy Thompson Fullilove, M.D.: "The failure to have a reasonable plan after Katrina is at the heart of illness and destruction that are going to affect generations of people."

Endowment Honors MH Advocates

When David Satcher, M.D., was U.S. Surgeon General from 1998 to 2002, he crusaded tirelessly to focus the federal government and the rest of the nation on the unmet need for mental health care among minorities and children.

In landmark reports such as "Mental Health: A Report of the Surgeon General," "Action Agenda for Children's Mental Health," "Mental Health: Culture, Race, and Ethnicity," and "Call to Action to Prevent Suicide," Satcher tried to awaken his country to the wide-ranging causes and consequences of mental illness, the effective treatments for it, and the barriers that keep so many from taking advantage of those treatments.

Now, a very well-known American couple who has long admired his efforts have announced a fitting tribute to Satcher.

Comedian and activist Bill Cosby and his wife, Camille, have endowed the Poussaint-Satcher-Cosby Chair in Mental Health at Morehouse School of Medicine in Atlanta. The "Poussaint" in the title honors psychiatrist Alvin Poussaint, M.D., who is a professor of psychiatry at Harvard and served as an advisor on "The Cosby Show."

The chair, which the Cosbys endowed at a June 5 ceremony with a $3 million gift for mental health research, is to be part of the Satcher Health Leadership Institute at Morehouse. The institute's mission is to spotlight issues and research in "mental health, sexual health, the health of the black family, and related issues impacting the community," according to a press release announcing the endowment.

Satcher, who is a former director of the Centers for Disease Control and Prevention, received his undergraduate degree from Morehouse and before becoming surgeon general chaired its Department of Community Medicine and Family Practice. Also at the June 5 ceremony, Satcher was named president of Morehouse School of Medicine.

In 2002 APA acknowledged Satcher's efforts with its Patient Advocacy Award.

Greater CBT Use May Aid Insomnia Treatment

CBT-based interventions for insomnia are not widely available in clinical practice, and future research should focus on implementing low-threshold treatment options for insomnia in primary care settings, say researchers.

BY MARK MORAN

Cognitive-behavioral therapy (CBT) has been found to be more effective than the drug zopiclone (Imovane) in short- and long-term management of insomnia in older adults.

On average, patients who received CBT improved their "sleep efficiency"—a ratio of total time spent asleep to actual time spent in bed, multiplied by 100—by 9 percent, compared with a decline of 1 percent in the group receiving zopiclone. These statistically and clinically significant improvements in the CBT group were maintained at six-month follow-up, according to a report in the June 28 *Journal of the American Medical Association*.

"Given the increasing amount of evidence of the lasting clinical effects of CBT and lack of evidence of long-term efficacy of hypnotics, clinicians should consider prescribing hypnotics only for acute insomnia," wrote lead author Berge Svertsen, Psy.D., and colleagues. "At present, CBT-based interventions for insomnia are not widely available in clinical practice, and future research should focus on implementing low-threshold treatment options for insomnia in primary care settings. . . . Future research should seek to identify which single factors in the CBT regimen produce the best results and to what extent booster sessions at one to two years after initial treatment may be necessary to maintain improvements."

Svertsen and colleagues are with the University of Bergen in Norway.

In the study, 46 adults with an average age of 60.8 years were randomly assigned to either CBT (18), a medication regimen of 7.5 mg. zopiclone nightly (16), or placebo medication (12).

Five learning modules were included in the CBT condition: sleep-hygiene education, sleep restriction, stimulus control, cognitive therapy, and progressive relaxation technique.

In the sleep-hygiene education module, the patient learns about the impact of lifestyle habits such as exercise, diet, and alcohol use and the influence of environmental factors such as light, noise, and temperature. The sleep-restriction module involves a strict schedule of bedtimes and rising times with the aim of increasing "sleepdrive" through partial sleep deprivation.

> "This study demonstrated superior benefits of CBT over zopiclone for treatment of chronic insomnia in older adults at six-week and six-month follow-up."

In the stimulus-control module, the aim is to break associations between the sleep environment and wakefulness by teaching the participant not to engage in bedroom activities incompatible with sleep and to stay in the bedroom only when asleep or sleepy. The cognitive-therapy module aims to identify, challenge, and replace beliefs and fears regarding sleep or the loss of sleep with realistic expectations regarding sleep and daytime function.

Finally, the progressive relaxation technique teaches the patient to recognize and control muscular tension through the use of exercise instructions on audiotape or compact disc, and to practice the technique at home on a daily basis.

Ambulant clinical polysomnographic (PSG) data and sleep diaries were used in the assessment of four outcome measures: total wake time, total sleep time, sleep efficiency, and slow-wave sleep (time spent in sleep stages 3 and 4).

At six weeks, the total wake time for the CBT group improved significantly more than for both the placebo group and the zopiclone group; zopiclone was not significantly better than placebo. And the amount of PSG-recorded slow-wave sleep improved significantly in the CBT group compared with the placebo and zopiclone groups.

At six month follow-up, total wake time, sleep efficiency, and slow-wave sleep were all significantly better in the CBT group than in the zopiclone group. Similar to PSG, the sleep diaries showed an increase in total sleep time in the CBT group at six months compared with six-week follow-up.

"This study demonstrated superior benefits of CBT over zopiclone for treatment of chronic insomnia in older adults at six-week and six-month follow-up," the authors wrote. "Future research should require effects in slow-wave sleep and define effects on daytime sleepiness."

The study was funded by grants from the University of Bergen, Meltzer Fund, and Norwegian Foundation for Health and Rehabilitation.

An abstract of "Cognitive-Behavioral Therapy vs. Zopiclone for Treatment of Chronic Primary Insomnia in Older Adults" is posted at <http://jama.ama-assn.org/cgi/content/abstract/295/24/2851>. ■

KNOWTHEFACTS

41% of all patients had the metabolic syndrome at baseline in the landmark CATIE schizophrenia study.[1]

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Reference: 1. McEvoy JP, Meyer JM, Goff DC, et al. Prevalence of the metabolic syndrome in patients with schizophrenia: baseline results from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) schizophrenia trial and comparison with national estimates from NHANES III. *Schizophr Res.* 2005;80:19-32.

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Off-Label Psychotropic Use Reveals Complex Patterns

Off-label prescribing of psychotropic medications to Georgia Medicaid recipients in 2001 was highly prevalent, mostly predictable, and unexpectedly rational, a new report says.

BY JIM ROSACK

It is certainly no surprise to learn that the majority of antidepressant, anticonvulsant, and antipsychotic medications dispensed to Georgia Medicaid enrollees in 2001 were for "off-label" indications. However, some patterns of off-label prescribing revealed in a new study are at once intriguing and reassuring, while others may be unexpected.

"We had expected that the prevalence of off-label use of psychotropic medications would be high before we started doing the analysis," Hua Chen, Ph.D., told *Psychiatric News*. Chen, an assistant professor of pharmacy at the University of Houston College of Pharmacy, and her colleagues examined patterns of prescribing for antidepressant, anticonvulsant, and antipsychotic medications among patients enrolled in the Georgia Medicaid program in 2001. Their report appeared in the June *Journal of Clinical Psychiatry*. As part of Chen's doctoral dissertation, the study had no external sources of funding.

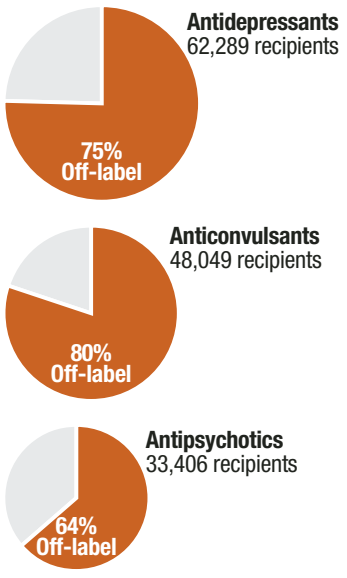
Chen reviewed the computerized Georgia Medicaid administrative claims files containing pharmacy, physician, hospital, and nursing home claims to identify Medicaid enrollees who were at least 18 years old as of January 1, 2001, and filled a prescription for any drug in the three classes in 2001. For an enrollee's prescription to be included in the analysis, the patient had to be continuously eligible for Medicaid for 24 consecutive months from January 1, 2000, through December 31, 2001. Chen's team imposed this requirement to allow the inclusion of diagnoses that preceded the prescription use in determining the on- or off-label status of each prescription.

To define off-label prescribing, Chen started with the definition outlined in U.S. Food and Drug Administration (FDA) standards. According to the FDA, off-label prescribing is "the use of a prescription drug for an indication, dosage form, dose regimen, population, or other use not mentioned in the approved labeling." Due to limitations in the state Medicaid claims database, however, the team did not consider off-label use related to dosage limits, duration of time, or route of administration. In addition, prescribing an antidepressant, anticonvulsant, or antipsychotic for monotherapy, although it is solely labeled for adjunct therapy, was also not considered as off-label use.

To determine whether a prescription was given for an on- or off-label use, diagnostic codes from the *International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM)* were identified for each indication approved for each antidepressant, anticonvulsant, and antipsychotic medication prescribed. Any prescription for a medication filled during 2001 was categorized as off-label if none of the *ICD-9-CM* codes listed for the patient during the 24-month study window could be matched with an approved indication for the drug the patient had been prescribed. The overwhelming majority of prescriptions for antidepressants, anticonvulsants, and antipsychotics were dispensed for off-label indications, according to Chen (see chart below).

More off Than on

In 2001 Georgia Medicaid patients filled prescriptions for medications in these three classes of psychotropics more often for off-label use than for approved indications.



Source: Hua Chen, M.D., Ph.D., et al., *Journal of Clinical Psychiatry,* June 2006

Antidepressants were the most commonly prescribed psychotropic medication, and 75 percent of those prescriptions were for off-label uses, according to the study. Sertraline (Zoloft) was the most commonly prescribed overall; it was prescribed off-label nearly 67 percent of the time. Amitriptyline, the second most common antidepressant prescribed for this population, had the highest level of off-label prescriptions, 81 percent.

Off-label use of antidepressants was strongly associated with being elderly, with those aged 65 and older being 5.1 times more likely to get an off-label prescription for an antidepressant than those under age 65. Males were 1.5 times more likely than females to get an off-label prescription for an antidepressant. Interestingly, patients with renal failure were 1.4 times more likely than those with no renal problems to use an antidepressant off-label—a finding that was true of all three drug categories. Chen and her team were surprised to find that renal failure was the only common factor that increased patients' odds for off-label prescribing of antidepressants, anticonvulsants, and antipsychotics.

Anticonvulsants, although second of the three drug classes in terms of total prescriptions filled, had the highest percentage of off-label use (80.12 percent). That, Chen told *Psychiatric News*, was partly driven by the finding that an exceedingly high percentage of prescriptions (98.04 percent) for gabapentin (Neurontin) were filled for off-label uses. While the researchers would have expected a majority of gabapentin prescriptions to be off-label (the drug is approved for use only in patients who have epilepsy with partial seizures or who have postherpetic neuralgia), Chen said her group was surprised by the finding that nearly all gabapentin prescriptions were off-label.

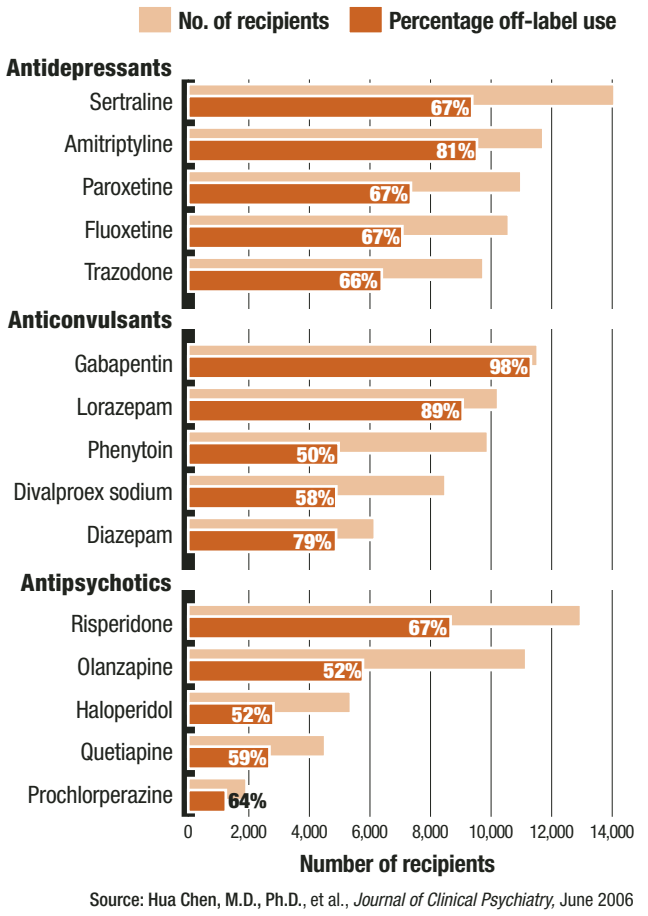
In general, factors associated with increased odds of being prescribed an off-label anticonvulsant again included being aged 65 or older (odds ratio 4.5), along with being white (odds ratio 1.7) and having a prescription for a newer generation anticonvulsant versus an older drug (odds ratio 7.6). Off-label use of anticonvulsants was also associated with several nonseizure disorders, including schizophrenia (odds ratio 1.7), connective tissue disorders (odds ratio 1.5), major depressive disorder (odds ratio 1.4), liver disease (odds ratio 1.4), and diabetes (odds ratio 1.2).

Chen noted that she and her colleagues were also surprised by the relatively high percentage of antipsychotics—specifically "the expensive

please see ***Patterns*** *on page 42*

Most Popular Off-Label Drugs

The top five most frequently dispensed antidepressants, anticonvulsants, and antipsychotics to Georgia Medicaid enrollees in 2001 also tended to have the highest levels of off-label use.



Source: Hua Chen, M.D., Ph.D., et al., *Journal of Clinical Psychiatry,* June 2006

SAD Patients Appear to Come In Two Varieties

Although most seasonal affective disorder patients have delayed biological clocks, a few may have advanced ones. Thus, the former may respond to light therapy in the morning and the latter in the evening.

BY JOAN AREHART-TREICHEL

A few years ago, researchers thought that seasonal affective disorder (SAD) was simply due to the shorter days of winter. Then they realized that SAD probably has a circadian (24-hour) rhythm component as well. In other words, bright-light therapy is known to shift people's biological clocks, and also known to counter SAD depression. So it seemed plausible that people with SAD become depressed in winter because the later dawn shifts their biological clocks later with respect to real time and their sleep/wake cycles.

But now it looks as though not all people with SAD have tardy biological clocks, a new study suggests. In fact, it may be that a few have biological clocks that tick too fast.

The investigation was headed by Alfred Lewy, M.D., Ph.D., vice chair of psychiatry at Oregon Health and Science University. Results were published in the May 9 *Proceedings of the National Academy of Sciences.*

Lewy and his colleagues selected 68 individuals diagnosed with SAD to participate in their double-blind, placebo-controlled, three-week winter trial. The subjects were randomly placed in one of three groups. A group of 22 subjects were given low-dose melatonin capsules each afternoon for three weeks to advance their biological clocks because giving a small dose of exogenous melatonin in the afternoon, when the body does not normally produce melatonin, is known to advance the clock. In fact, the afternoon melatonin served as a proxy for morning light therapy since the latter is difficult to study in double-blind, placebo-controlled trials.

Another group of 22 subjects were given low-dose melatonin capsules each morning for three weeks to delay their biological clocks. In short, the morning melatonin served as a proxy for evening light therapy.

The remaining 24 of the 68 subjects served as controls. Each day they received capsules of a placebo, instead of melatonin, during the three weeks of observation.

All subjects were assessed for levels of depression at both the start and end of the study. The scientists then compared depression outcomes for the three groups.

Seventeen of the subjects—11 from the first group and six from the second—experienced a substantially greater reduction in depression than the placebo group did (34 percent versus 14 percent). However, the remaining 27 subjects in the two active groups did not. Why the 17 subjects showed a substantial reduction in depression while the 27 subjects did not was because the improved group had received the correct treatment for their body clocks (afternoon melatonin for the prototypical phase-delayed subjects and morning melatonin for the atypical phase-advanced sub-

please see ***SAD Patients*** *on page 23*

PARTIAL COMPLIANCE

A hidden danger in schizophrenia

Look for the following risk factors:

- A history of relapse and rehospitalization[1–3]
- Poor insight[1,4,5]
- Disorganized thinking[4,5]
- Cognitive impairment[4,5]
- Delusional ideas or beliefs, such as thinking that medication is poison[4]
- A history of drug or alcohol abuse[4–7]
- A tendency to discontinue medication when feeling better[4]

Any one of these may mean your patient is at risk for partial compliance.

Partial compliance can lead to serious consequences.[2,5,8]

Don't wait to take action!

References: 1. Ayuso-Gutiérrez JL, del Río Vega JM. Factors influencing relapse in the long-term course of schizophrenia. *Schizophr Res.* 1997;28:199–206. **2.** Csernansky JG, Schuchart EK. Relapse and rehospitalisation rates in patients with schizophrenia: effects of second generation antipsychotics. *CNS Drugs.* 2002;16:473–484. **3.** Lam YWF, Velligan D, Ereshefsky L, et al. Intra-individual variability in plasma concentrations as an indicator of adherence in schizophrenia. Poster presented at: 42nd Annual New Clinical Drug Evaluation Unit (NCDEU) Meeting: June 10–13, 2002; Boca Raton, Fla. **4.** Lacro JP, Dunn LB, Dolder CR, Leckband SG, Jeste DV. Prevalence of and risk factors for medication nonadherence in patients with schizophrenia: a comprehensive review of recent literature. *J Clin Psychiatry.* 2002;63:892–909. **5.** Weiden PJ, Zygmunt A. The road back: working with the severely mentally ill. Medication noncompliance in schizophrenia: part 1. Assessment. *J Pract Psychiatry Behav Health.* March 1997:106–110. **6.** Gilmer TP, Dolder CR, Lacro JP, et al. Adherence to treatment with antipsychotic medication and health care costs among Medicaid beneficiaries with schizophrenia. *Am J Psychiatry.* 2004;161:692–699. **7.** Hunt GE, Bergen J, Bashir M. Medication compliance and comorbid substance abuse in schizophrenia: impact on community survival 4 years after a relapse. *Schizophr Res.* 2002;54:253–264. **8.** Weiden PJ, Kozma C, Grogg A, Locklear J. Partial compliance and risk of rehospitalization among California Medicaid patients with schizophrenia. *Psychiatr Serv.* 2004;55:886–891.

Janssen L.P.

Experts Seek Best Way To Treat Trauma Reactions

The timing and nature of early interventions following traumatic events may help reduce the incidence or severity of PTSD symptoms.

BY AARON LEVIN

Early diagnosis and intervention—either psychotherapeutic or pharmacological—following trauma may some day reduce symptoms of posttraumatic stress disorder (PTSD), said two researchers with different perspectives on the issue.

"Many people suffer PTSD symptoms immediately after an exposure to trauma, but most of them recover within the next three months without formal health intervention," said Richard Bryant, Ph.D., the Scientia Professor in the School of Psychology at Australia's University of New South Wales. "The real question is how to identify shortly after an event people who will be at high risk for PTSD later, as opposed to those having transient stress reactions."

Bryant spoke at a conference on early psychological intervention following mass trauma sponsored by the Department of Psychiatry and Behavioral Sciences and the School of Public Health at the New York Medical College in Valhalla, N.Y. He argued for improved diagnostic approaches and for innovative ways of treating the large number of patients to be expected following major disasters like hurricanes or terror attacks.

At the same meeting, Matthew Friedman, M.D., Ph.D., executive director of the Department of Veterans Affairs' National Center for Post-Traumatic Stress Disorder in White River Junction, Vt., reported on promising avenues of research involving the action of neurotransmitters in specific areas of the brain.

The term "acute stress disorder" (ASD) was introduced in 1994 as a kind of precursor to PTSD, recalled Bryant. *DSM-IV* says that ASD could be diagnosed two days after trauma, but this assumed a momentary event, said Bryant. Long-lasting trauma like Hurricane Katrina or service in Iraq might continue for extended periods, so the "end" of traumatic exposure had to be reckoned not by the calendar but by the patient's experience and the context of the event. Also, remission frequently occurred in the first week following trauma, so two days was too early to make a diagnosis, he said in disagreement with the *DSM-IV* standards.

Much of the thinking about PTSD has depended on an early diagnosis of ASD, but there are two problems with that, said Bryant. Since 1994, a dozen prospective studies have examined the hypothesized links between ASD and PTSD. These studies showed, however, that while a high percentage of those who have ASD after trauma go on to develop PTSD, a much lower percentage of those with PTSD were ever diagnosed with ASD. Much has also made of dissociation in response to trauma as a critical part of ASD and a source of ongoing mental disorder, he said, but dissociation was a misleading diagnostic term.

"Dissociation is not the key," said Bryant. "If you include it, then you will miss a lot of PTSD cases. The stress of the event is the best predictor of PTSD."

Cognitive models—how the victim understands and appraises the stressful experience—are influential, and cognitive style also helps predict the occurrence of PTSD. Furthermore, cognitive-behavioral therapy (CBT) appears to work in response, especially when compared with supportive counseling, his own research has shown.

"Can we apply this knowledge to make a difference in mass trauma events?" asked Bryant. "The limitations are daunting."

Thousands of people may need help, but mobilizing enough mental health professionals to do formal early interventions is nearly impossible. CBT works, but new ways have to be devised to deliver it to large numbers of people, he suggested.

"Ninety percent of CBT is self-help, done outside the office, so let's put it on the Web," said Bryant. Web-based therapy could take a modular approach, he said. People could take a self-test, then be shifted to other pages for instruction in CBT. Whether this would work is not known, he said.

"We must set up a trial in a controlled way," he said. "We need to develop strategies to assist those who can benefit from CBT strategies and find creative means of delivery—but these need to be tested empirically."

Research has been leading to better understanding of how PTSD manifests itself in the brain and may provide targets for intervention right after trauma, said Friedman.

PTSD is a disorder of reactivity, he said. Control is carried out by neurotransmitters that serve to prime the stress system when it is needed for protection, but it has negative consequences when it overreacts.

For instance, norepinephrine is normally effective in mobilizing fear, the flight response, and sympathetic activation and consolidating memory. Too much norepinephrine, however, induces hypervigilance, autonomic arousal, flashbacks, and intrusive memories. In acute response to trauma, serotonin promotes self-defense, rage, and attenuation of fear, but too little serotonin results in aggression, violence, impulsivity, depression, and anxiety.

"The problem in PTSD is that the 'on' switch is stuck on 'on,' " said Friedman. The body needs to mobilize just enough but no more.

A possible pharmacological intervention to treat acute stress, a "morning-after pill," would focus on upstream mechanisms and reduce corticotropin releasing factor activity, normalize hypothalamic-pituitary-adrenal axis function, reduce locus ceruleus/norepinephrine activation, and normalize immunologic function.

Such an acute intervention, given shortly after trauma, might simultaneously reduce excessive stress responses, enhance inadequate stress responses, and promote rapid recovery of normal functioning. It might thus shorten the recovery time following a traumatic event.

Several compounds have been suggested as candidates: beta-blockers, hydrocortisone, tricyclic antidepressants, risperidone, and benzodiazepines. Corticotropin releasing factor antagonists have been tried in animals but are not yet ready for humans. Another important area in neuroscience research is the rapid neurotransmitters, like gamma-aminobutyric acid (GABA, an inhibitory neurotransmitter) and glutamate (a major excitatory neurotransmitter), he said.

Friedman went a step further in suggesting that it might someday be possible to identify children at risk and "inoculate" them against PTSD by teaching about stress and how to cope with it in the schools, much like sex education is taught today. Also, since most people get over stressful events, there has been a reluctance to use medications for fear of pathologizing the incident. "There are no such reservations about pandemic flu, however," he said. "So we need a cultural shift." ■

Opiate Addiction Made Easier By Plethora of Web Sites

What's your pleasure—OxyContin, opium poppies, coca leaves, or peyote? These and other controlled substances are being peddled by Web sites located not only in other countries, but also in the United States.

BY JOAN AREHART-TREICHEL

New Year's Day 2003 stands out sharply in the memory of Robert Forman, Ph.D., a clinical scientist affiliated with the University of Pennsylvania's Center for Studies of Addiction and Treatment Research Institute.

Forman learned that an acquaintance was addicted to opioid medications and obtaining them via the Internet. Forman started perusing the Internet for Web sites offering to sell such medications without a prescription. "I was amazed by what I found," he told *Psychiatric News*.

He was so dumbfounded by the plethora of such sites that he had located that he and some colleagues decided to launch an explorative study to get a better idea of their prevalence and content.

Between March 3, 2003, and September 7, 2004, they conducted 47 Internet searches for such sites. The searches were intended to replicate what Internet users would undertake if they conducted the searches themselves using terms such as, "codeine," "Vicodin," "OxyContin," "no prescription codeine," "no prescription Vicodin," and "no prescription OxyContin." Each search was limited to the first 100 sites listed because any Internet search usually presents the results that are most relevant to the search term first.

The searches yielded 302 Web sites offering to sell opioid medications without a prescription, the team reported in the July *American Journal of Psychiatry*. The harvest of such Web sites was especially rich when they prefaced their searches with the words "no prescription." Although both Google and Yahoo provided access to such Web sites, Yahoo generated significantly more sites than Google did.

"The whole phenomenon was absolutely jaw-dropping at first—and still is," Forman said.

George Woody, M.D., a professor of psychiatry at the University of Pennsylvania and one of the study investigators, told *Psychiatric News* that he was both surprised and troubled "by the breadth and depth of offers to sell prescription opioid medications on the Web without any meaningful medical evaluation showing that the person requesting the medication had a problem that required it."

How much Internet users, especially young people, are tapping these Web sites for opioid medications is not known, the study investigators stated in their study report. However, three national drug-use monitoring studies have cited marked increases in prescription opioid use, especially by youth, during the past five years. These increases could well be due to young people's easy access to opioid medications via the Internet, suspected the researchers.

And that leads to the question: Why are such Web sites allowed to exist? One reason, the researchers explained in their study report, is because many are located in countries that do not require prescriptions for opioid medications or do not enforce prescription regulations that are in effect in the United States. For example, of the 302 Web sites that were found to be selling opioid medications without a prescription, 189 (65 percent) were registered in 44 countries outside the United States. That leaves, of course, the remaining 113 (35 percent) that were registered in the United States. The U.S. Drug Enforcement Administration is taking action against some of these sites, Forman said, but unfortunately many still abound.

Indeed, during their searches for Web sites selling opioid medications without a prescription, the researchers came across Web sites selling numerous other controlled substances as well. These included sedatives, stimulants, steroids, marijuana, opium poppies, coca leaves, nitrous oxide, psilocybin, and peyote. Only cocaine, ecstasy, heroin, and LSD seemed to be missing.

All things considered, Wood advised, psychiatrists "should be aware of the possibility that their patients may be purchasing opioid medications [or other controlled substances] on the Web and should ask them about it, especially if their patients are suspected or shown to have a substance use disorder."

The study was funded by the National Institute on Drug Abuse Clinical Trials Network.

"The Availability of Web Sites Offering to Sell Opioid Medications Without Prescriptions" is posted at <http://ajp.psychiatryonline.org/cgi/content/full/163/7/1233>. ■

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Reference: 1. Goff DC, Sullivan LM, McEvoy JP, et al. A comparison of ten-year cardiac risk estimates in schizophrenia patients from the CATIE study and matched controls. *Schizophr Res.* 2005;80:45-53.

GZ274981T

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Workplace Bullying Overlooked As Cause of Severe Stress

Workplace bullying is far from rare and can take a grim toll on people's mental and physical health, contributing to anxiety, depression, sleep difficulties, sexual impairment, and other deleterious effects.

BY JOAN AREHART-TREICHEL

It may start off as a snicker, a dirty look, or a belittling comment and then mushroom slowly, but inexorably, into put downs in front of colleagues, nasty comments behind a person's back, or the withholding of information a person needs to do his or her job.

It is called "workplace bullying," and it is far from uncommon and can have a devastating impact on people's mental and physical health, authorities on the subject revealed at an APA annual meeting symposium in Toronto in May.

Virtually all employees have experienced, at some point, unkind words or behaviors from coworkers or superiors. But to qualify as workplace bullying, such verbal and behavioral abuse must be persistent, unwanted by the person at whom it is directed, and harmful to that individual, Loraleigh Keashly, Ph.D., a researcher at Wayne State University, reported.

David Hathcox

Loraleigh Keashly, Ph.D.: The targets of workplace bullying are often overachievers or submissive individuals.

Many American workers appear to be, or have been at some point, the targets of workplace bullying. In their U.S. Department of Veterans Affairs investigation, which included some 8,600 subjects, Keashly and her coworkers found that 94 percent had been bullied at least periodically, and 36 percent frequently. The National Institute for Occupational Safety and Health surveyed employees in more than 500 organizations to find out how many had been the victims of workplace bullying, Keashly also pointed out. Twenty-five percent reported that they had.

Workplace bullying is "a particularly noxious form of occupational stress," Liza Gold, M.D., a clinical associate professor of psychiatry at Georgetown University, explained. Thus, it should come as no surprise that it can have a pernicious impact on people's mental and physical health.

Ten years ago, Renato Gilioli, M.D., a University of Milan psychiatrist, and colleagues established the first center in Italy to help victims of workplace stress and harassment. Since then, they have examined 3,279 individuals for workplace-related psychiatric disorders and found that 1,919 subjects (58.5 percent) were related to bullying. They then studied these 1,919 subjects to learn more about workplace bullying and its psychological consequences.

As Gilioli reported at the symposium, 68 percent met the criteria for an adjustment disorder, 18 percent met criteria for mood disorders, 10 percent had symptoms suggestive of posttraumatic stress disorder, and 4 percent showed signs suggesting other anxiety disorders.

Further, the victims of workplace bullying often have difficulty falling asleep, experience nightmares regarding their workplace situation, wake up feeling exhausted, and incur sexual impairment, Gilioli added, on the basis of research that he and his group have conducted in Scandinavia.

In fact, people who are bullied in the workplace may use alcohol or other substances to cope with bullying's injurious effects, Judith Richman, Ph.D., a professor of psychiatry at the University of Illinois at Chicago, reported. She and her colleagues found that this was the case in a study of some 2,500 university employees. One of the victims who met this particular profile was a female psychiatric resident. First a surgery resident derided her intellectual abilities, then a male psychiatric supervisor did. She started using alcohol to combat her distress, Richman explained, giving an example of the link between the substance abuse and bullying.

Alcohol, of course, is no solution to being bullied in the workplace. Yet there are no easy answers on how to deal with it, symposium speakers concurred. Nonetheless, some approaches appear to be more effective than others.

Confronting the bully or retaliating can be risky tactics, Keashly warned. The reason is that, by confronting the bully, the organization may view the complaining employee, and not the bully, as the problem employee.

Sometimes going to one's boss and discussing the problem can be helpful, Keashly said. So can talking with other coworkers about it and finding out whether they, too, are being bullied, and if so, perhaps forming an alliance with them. For example, Keashly said that she consulted on a case in Detroit in which one teacher bullied other teachers until one of the victims decided to not take it anymore. She talked various colleagues into joining her in reporting the bully to the principal.

But looking for a position in another organization is often the best solution, Gold advised, because if bullying is tolerated in the person's workplace, then "there is a culture there that supports it," and it is highly unlikely that such a culture can be detoxified. ■

Quitting Often No Solution

Suppose victims of workplace bullying decide that the only way to escape it is by quitting their job. But what are their options if they cannot find a position in another organization.

Not very good from a financial or legal viewpoint, David Yamada, J.D., reported at an annual meeting symposium on the consequences of workplace bullying (see article at left). Yamada is a professor of law at Suffolk University in Boston. Victims might quit their jobs, but they then will likely lose employer-sponsored health insurance, and the costs of paying for continued coverage under the COBRA law may be prohibitive.

They might quit their jobs and file for unemployment benefits, but such benefits may be contested by employers who claim that the workers quit voluntarily.

They might seek workers' compensation for incapacity due to work-induced depression, but such claims are often denied.

They might apply for Social Security disability payments on the basis that they are mentally ill because of workplace bullying, but then they must demonstrate that they are fundamentally impaired in performing a variety of normal life activities.

Or they can resort to a lawsuit against the individuals who bully them, but "most workplace bullies fall through the cracks of the legal system," Yamada explained. Thus, the chances of receiving financial compensation from them are slim.

In short, the financial and legal safety net for people bullied in the American workplace is virtually nonexistent, Yamada concluded, which is not the case in Australia, Canada, and European countries.

So Yamada is in the process of developing the New Workplace Institute, a nonprofit research and education center whose goal is to promote healthy, productive, socially responsible workplaces. One of its first initiatives will be the Safety Net Project, which will provide information and, eventually, direct advice to bullied workers about employee benefits such as health insurance, workers' compensation, unemployment insurance, and disability payments.

Yamada has also drafted model antibullying legislation, dubbed the Healthy Workplace Bill, that would provide compensation to targets of severe workplace bullying who can demonstrate physical or psychological harm.

Since 2003 variations of the Healthy Workplace Bill have been introduced—but not yet enacted—in six states, and efforts on behalf of the bill are under way in several other states as well.

Psychopathology in Bereaved Kids Less Complicated Than Expected

When a parent dies, children may have symptoms of psychopathology, but they are less severe than in children with major depression.

BY AARON LEVIN

The death of a mother or father would seem to present a great risk of psychopathology for a child, yet a recent study indicates that being depressed is worse than being bereaved.

"Bereavement negatively affect[s] children but to a lesser degree than does clinical depression," wrote Julia Cerel, Ph.D., of the College of Social Work at the University of Kentucky, and four colleagues. Family socioeconomic status and the surviving parent's level of depression also influenced the child's risk of psychopathology.

Little is known from rigorous studies about how children fare after the death of a parent, wrote Cerel and her colleagues in the June *Journal of the American Academy of Child and Adolescent Psychiatry*. Many earlier studies have looked retrospectively at the histories of bereaved children and adults who later sought psychiatric treatment, while others had methodological problems such as small sample sizes, narrowly selected populations, or interviews conducted with parents or teachers rather than the affected child.

"We still have far to go to understand childhood bereavement," agreed Cynthia Pfeffer, M.D., a professor of psychiatry and head of the Childhood Bereavement Program at Weill Medical College of Cornell University in New York City. "There are meager amounts of empirical research in the field, and this paper is a good start in answering many questions about bereaved children."

Cerel and colleagues recruited 360 bereaved children by scanning obituaries and contacting funeral homes within a 50-mile radius of Columbus, Ohio. These children were between the ages of 6 and 17, had never experienced the death of a sibling, and had lost one parent. Of these, 191 "simple bereaved" children had no significant stressor other than parental death, while the rest faced additional stresses such as another death or serious illness in the extended family, parental unemployment, parental death by homicide or suicide, or a mental health contact in the immediate family in the previous two years. These "complex bereaved" children had an average of 1.7 additional stressors per child.

The researchers also recruited two comparison groups: 128 community controls—children of similar ages but who had not experienced the death of an immediate family member—and 110 children diagnosed with depression. The bereaved children were interviewed about two months after the parent's death and again at six, 13, and 25 months after the death. The two control groups were interviewed initially and at six, 13, and 25 months later. Data were

please see ***Children*** *on page 23*

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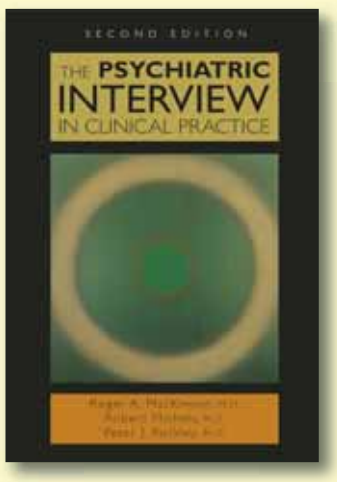

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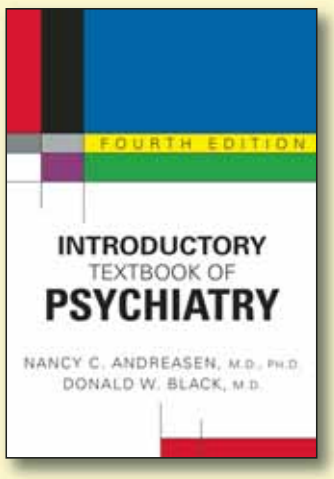

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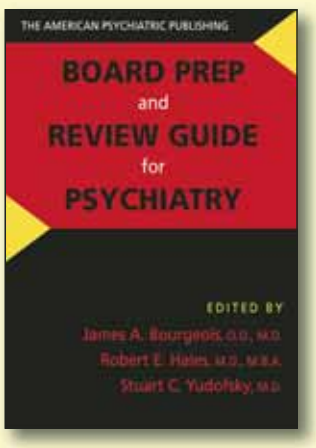

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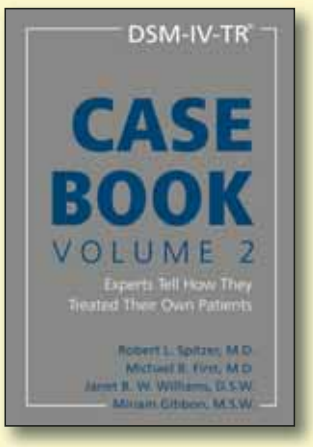

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Compound Improves Cognition In Schizophrenia Patients

An agonist of the alpha-7 nicotinic acetylcholine receptor is found to improve the mental performance of subjects with schizophrenia.

BY JOAN AREHART-TREICHEL

For over a decade, scientists have attempted to find new drugs for affective disorders by targeting specific nerve receptors known to be involved in those conditions. Now investigators are starting to use a similar tack to find valuable new drugs for treating schizophrenia (*Psychiatric News*, May 19).

One of the more provocative dramas unfolding in this domain concerns the alpha-7 nicotinic acetylcholine receptor. Faulty alpha-7 receptors appear to be responsible for some of the neurocognitive deficits in schizophrenia, notably difficulty in paying attention. Moreover, nicotine has been found to enhance the action of the alpha-7 receptors and to lead to a modest improvement in neurocognition function, especially in concentration, in individuals with schizophrenia. Indeed, the reason why persons with schizophrenia often smoke heavily may be because nicotine helps them pay attention better and think more clearly.

Robert Freedman, M.D., chair of psychiatry at the University of Colorado Health Science Center, Ann Olincy, M.D., associate professor of psychiatry there, and colleagues decided to search for an alpha-7 receptor agonist that is better than nicotine at enhancing the mental performance of individuals with schizophrenia. Freedman is also editor in chief of the *American Journal of Psychiatry*.

The search led them to a compound derived from a marine worm and dubbed DMXB-A. After DMXB-A showed positive neurocognitive effects in both experimental animals and in healthy human volunteers, the researchers decided to conduct a small "proof-of-concept" study to see whether DMXB-A might also show promise as a mental enhancer in individuals with schizophrenia.

Eleven persons with schizophrenia participated in the trial. Although none of them smoked, all were taking antipsychotic medications. On one day, they received DMXB-A, and immediately afterward their neurocognitive performances were measured with the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS). The RBANS measures attention, immediate memory, delayed memory, language proficiency, and visuospatial ability. On another day, the subjects received a placebo, and the RBANS was used to measure their neurocognitive performances right after. The mental performances of the subjects under the two conditions were then compared.

DMXB-A led to significantly better mental performances than the placebo did, the researchers reported in the June *Archives of General Psychiatry*. And these superior performances were also greater than those produced by nicotine in another small study of schizophrenia subjects conducted by the same group. Thus DMXB-A might indeed enhance the neurocognition of individuals with schizophrenia and perhaps better than nicotine does, the group concluded.

Moreover, "we were surprised by the marked effects that some of the patients experienced in terms of the clearing of their cognition and the decrease in their symptoms," Freedman added in an interview with *Psychiatric News*. "We did not expect that much effect after a single-day administration [of DMXB-A]. Improvement in schizophrenia, even for a brief period, is always a heartening finding, because it suggests the possibility that the patients' disability can improve."

These results, however preliminary, are "very important," William Carpenter Jr., M.D., told *Psychiatric News*. Carpenter is director of the Maryland Psychiatric Research Center and a schizophrenia authority. "Impaired cognition and primary negative symptoms are the critical unmet therapeutic needs for schizophrenia." And even if DMXB-A per se does not pan out as a schizophrenia medication, it still adds to the growing body of evidence that "the alpha-7 nicotinic acetycholine receptor is the best molecular target for new drug discovery in schizophrenia."

Freedman and his colleagues are now conducting a phase 2 trial with DMXB-A, and 30 subjects are enrolled. "We expect results late this year," he said.

The proof-of-concept trial was funded by the Veterans Affairs Medical Research Service, the National Institutes of Health, the National Alliance for Research on Schizophrenia and Depression, the Stanley Medical Research Institute, and the Institute for Children's Mental Disorders.

An abstract of "Proof-of-Concept Trial of an Alpha 7 Nicotinic Agonist in Schizophrenia" is posted at <http://archpsyc.ama-assn.org/cgi/content/abstract/63/6/630>. ■

Children

continued from page 20

gathered from 1989 to 1996 and assessed using *DSM-III-R* criteria. Significantly more bereaved families (34 percent) and those of depressed children (37 percent) dropped out of the study by 25 months compared with those of community controls (8 percent). Lower socioeconomic status correlated closely with withdrawing from the study. The researchers will address retention in another paper.

The primary outcome measure was a scale summing symptoms of behavioral, anxiety, mood, and other disorders (BAMO), developed by Cerel and coauthor Mary Fristad, Ph.D., of Ohio State University.

Bereaved children exhibited greater psychopathology than did community controls but less than depressed children. On the combined BAMO scale, the average difference between the depressed and control group was twice that between the bereaved and control group.

There was one difference between the simple and complex bereaved children. BAMO scores were similar at the initial interview, but the simple bereaved group's scores declined by the six-month interview, while the complex bereaved group's score declined the most between six and 13 months.

Two other covariates were associated with worse functioning by the children: lower socioeconomic status and parental depression. Loss of the deceased parent's income is important in itself, but also affects the surviving family's ability to cope during a stressful time.

"The surviving parent is also bereft," said Pfeffer. "The child has lost one parent and has one distraught parent with his or her own psychological problems and can't parent well."

The study results may indicate that bereaved children are not as depressed as is commonly believed or that they have symptoms of disorders other than depression, said Pfeffer. Her own studies of children who lost a parent in the September 11 attacks have revealed a greater incidence of anxiety disorders than that found in controls, for instance.

The researchers found no difference between a death long anticipated by the family and a sudden death. "Although a sudden death is shocking, living with a dying parent for weeks, months, or years is also difficult for a child and puts stress on the entire family," they said.

Anticipation of a parent's death requires further prospective study, said Pfeffer. Children may develop symptoms during the course of the parent's illness, and some may find that death brings a sense of relief. "It would help to know how children feel before and after a parent's death," she said, to learn which symptoms appear at which time.

Thus, when a child's parent dies, clinicians should be aware of risk factors like depressive symptoms in the surviving parent, other stressful family events, and lower socioeconomic status, wrote Cerel and her team. Such children, they concluded, "will warrant more careful monitoring, and support for their grieving parents will be an important part of their own recovery."

Future research will go beyond symptoms of psychopathology and look at grief emotions in these children, risk behaviors, and behavior in school, said Cerel.

An abstract of "Childhood Bereavement: Psychopathology in the 2 Years Postparental Death" is posted at <www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list--uids=16721318&itool=iconabstr&query--hl=5&itool=pubmed—docsum>. ■

SAD Patients

continued from page 16

jects), according to the researchers.

So there seem to be two types of SAD patients, Lewy and his team concluded. The biological clocks of most shift later in winter, so they will respond to morning light treatment. A minority, however, may have biological clocks that shift earlier in winter, so they will respond to evening light treatment.

"The old thinking was that [the cause of SAD] was the shorter day," said Lewy in an interview. "The new thinking is that it is either the later dawn or the earlier dusk."

These findings also have a practical implication, Lewy pointed out. A test to determine which SAD patients have slow clocks, and thus would respond to morning light therapy, and which SAD patients have fast clocks, and thus would respond to evening light therapy, is available only for research purposes. However, it may become clinically available in a year or two.

Now that SAD seems to show a strong biological-clock component, it is time to see whether there might also be a circadian-misalignment component to nonseasonal depression, Lewy asserted. Its role may be minor, he said, but "even if the role is small, it is so easy to treat. You can give light to just about anybody. It is extremely safe."

The study was funded by the Public Health Service and the National Alliance for Research on Schizophrenia and Depression.

An abstract of "The Circadian Basis of Winter Depression" is posted at <www.pnas.org/cgi/content/abstract/103/19/7414>. ■

NAMI Honors Psychiatrists For Disaster Relief

The National Alliance on Mental Illness (NAMI) honored 16 physicians with Exemplary Psychiatrists Awards during APA's 2006 annual meeting in Toronto in May. The 2006 awards focus on psychiatrists who have made substantial contributions to state or local NAMI activities and demonstrate exemplary commitment and expertise in the area of disaster psychiatry. The annual award program is supported by Eli Lilly and Co.

The following received the awards:

Gregory Binus, M.D.
Linda Carpenter, M.D.
Mary Diamond, D.O.
Avrim Fishkind, M.D.
Elizabeth Henderson, M.D.
Mary Mandell, M.D.
Andrew Morris, M.D.
James Nininger, M.D.
Carol North, M.D.
Anand Pandya, M.D.
Ilisse Perlmutter, M.D.
David Post, M.D.
Robert Rosenheck, M.D.
John Sargent, M.D.
Jeffrey Taxman, M.D.
Bryan P. Warren, M.D. ■

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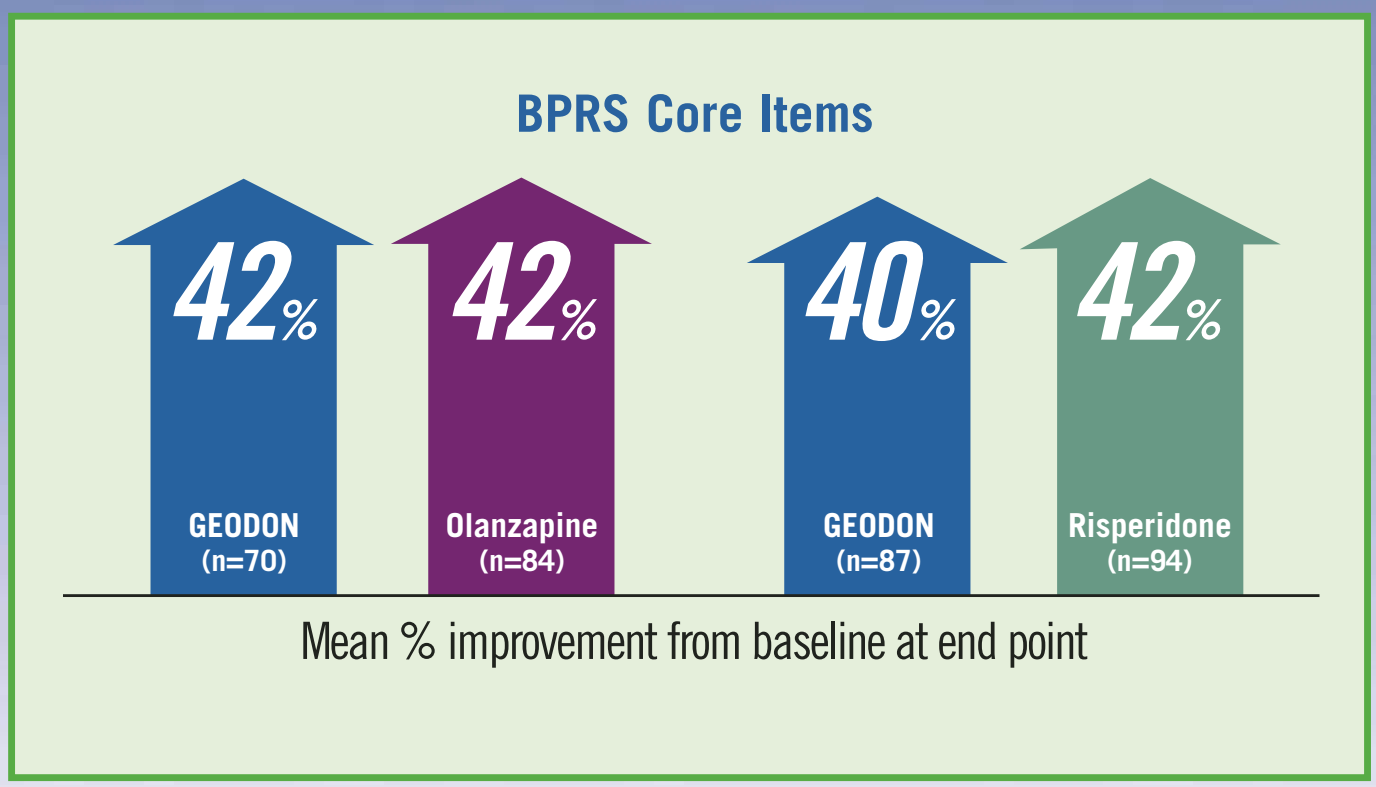

A 6-week, double-blind, randomized study of GEODON vs olanzapine and an 8-week, double-blind, randomized study of GEODON vs risperidone.

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  —up to 6 months vs olanzapine[4]

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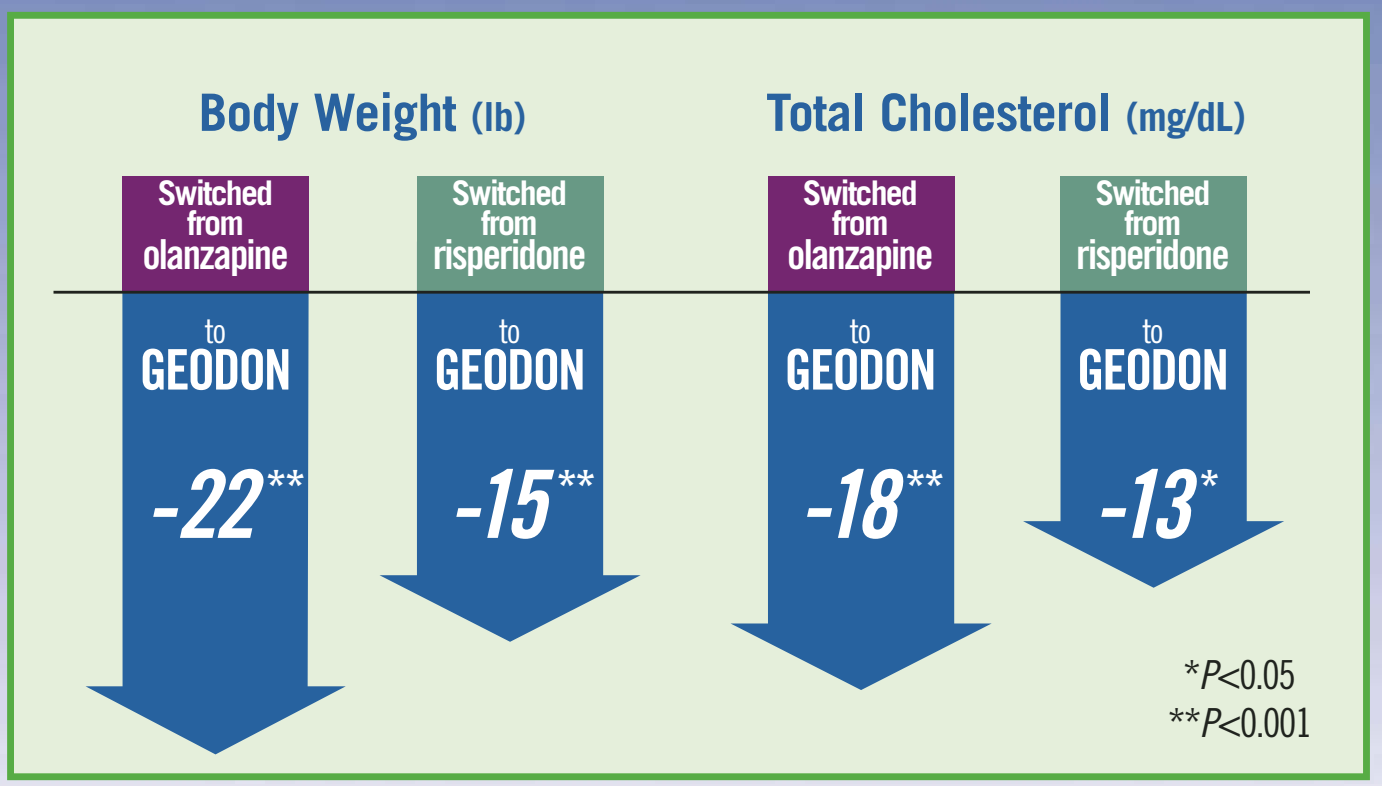

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- Patients switching to GEODON from olanzapine and risperidone also experienced reductions in triglycerides[5]

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Hawaii Psychiatrist Honored For Advocacy Efforts

March 8 was named Dr. Krishna Kumar Day by County of Kauai Mayor Bryan Baptiste.

BY MARK MORAN

Legislators and politicians of every stripe in Hawaii who know something about psychiatry and mental health most likely know about Krishna Kumar, M.D.

For more than two decades Kumar has been a force in the state's battles over insurance coverage of mental illness, affordable access to the antipsychotic clozapine, psychologist prescribing privileges, stigma, and other issues. In that time, he has garnered honors and commendations from political leaders in the Aloha State at every level; and this year, Bryan Baptiste, mayor of the County of Kauai, Hawaii, named March 8 "Dr. Krishna Kumar Day."

"Dr. Kumar's 35-year journey as a psychiatrist has always been about his dedication to our community and especially our children," Baptiste said. "He is able to provide treatment and care to many psychiatric patients and their families, collaborating with various health care professionals for comprehensive care of the patient, and removing the stigma of mental illness by improving awareness."

The honor caps a career devoted to working in the public arena to improve treatment of mental illness and to raise the status of psychiatry. Kumar (who became an APA distinguished life fellow during the convocation at APA's 2006 annual meeting in Toronto) has served as president of the Hawaii Psychiatric Medical Association (HPMA) and for seven years as the chair of its Public Affairs Committee. In those capacities and as a clinician and private citizen, he has worked with the Hawaii Medical Association, American Medical Association, advocacy groups, legislators, employers, and insurance leaders in the state.

David Hathcox

Krishna Kumar, M.D.

Among the efforts in which he has been involved, Kumar cites the HPMA's work to improve health insurance coverage for mental illness as among the most gratifying.

"In 1975, the first outpatient visit to obtain treatment from a psychiatrist was not covered by the insurance companies in Hawaii, and there was an annual cap of $500 for all outpatient psychiatric treatment," he said. "Today six psychiatric disorders have unlimited insurance coverage, and other psychiatric disorders have 24 outpatient visits a year for each family member. There is a provision for exchanging two outpatient visits for each hospital day of coverage."

As chair of the district branch's Public Affairs Committee, Kumar led a candlelight ceremony for two consecutive years at the Hawaii statehouse to raise public awareness about mental illness and to combat stigma. The ceremony attracted more than 3,000 people each time, he said.

In 1995 Kumar received an Exemplary Psychiatrist Award from the National Alliance on Mental Illness "for exemplifying the kind of professional treatment and personal caring we strive to make available to all people who have severe mental illnesses." ■

Human Rights Award

APA members are asked to submit nominations for APA's 2007 Human Rights Award. The award, conferred yearly on an individual and/or an organization, recognizes efforts that exemplify the capacity of human beings to act courageously and effectively to prevent human rights violations, to protect others from human rights violations and their psychiatric consequences, and to help victims recover from human rights abuses.

Nomination letters should succinctly describe the contributions that are the basis for the nomination and be accompanied by the individual's curriculum vitae or the organization's mission statement.

Recipients will receive a plaque, to be presented at the Convocation of Fellows at APA's 2007 annual meeting in May.

The deadline for receipt of nominations is August 15. Materials should be submitted by mail to Office of International Activities, APA, 1000 Wilson Boulevard, Suite 1825, Arlington, Va. 22209; fax to (703) 907-1087; or e-mail to edalder@psych.org. ■

Whatever Your Passion, Indulge It in New York

Give your regards to Broadway and other favorite Big Apple sites while you are in town for APA's fall meeting.

BY SPENCER ETH, M.D.

There could be no better time to visit New York City than October 5 to 8 to attend APA's 58th Institute on Psychiatric Services (IPS) at the Marriott Marquis Hotel in Times Square. Early fall in the northeast is always glorious, with its seasonally mild temperatures and colorful foiliage. A major election is being held this autumn, and the city will be abuzz with campaigns for governor and the U.S. Senate and House of Representatives. Whether the hometown baseball teams, the Yankees and Mets, will be in the playoffs remains to be seen, but as the saying goes, "You gotta believe."

Your base at the Marriott Marquis, site of all IPS sessions, is in the center of the Broadway theater district. Although it is never too early to purchase advance tickets for the hottest shows, rest assured that there will be an opportunity to buy discount tickets on the day of the performance (and remember that Wednesday and Saturday are matinee days). You might also consider the Off and Off-Off Broadway productions. Several ticket services can be accessed through an Internet search of the term "Broadway theater tickets."

The city also abounds with world-class opera, ballet, dance, and live music concerts of every imaginable variety. These productions can be found at many locations throughout the city, including Lincoln Center and Carnegie Hall.

No trip to New York is complete without a visit to at least one of the city's famous museums. Even if you have toured the Metropolitan Museum of Art (the Met), don't miss a chance to view the renovated Museum of Modern Art, Guggenheim Museum, Whitney Museum of American Art, or one of the smaller gems, such as the Frick Collection. And there are the Madison Avenue art galleries waiting to be seen.

For visitors and locals alike, much of the special pleasure of Manhattan is found by simply walking through the many distinctive neighborhoods. Armed with a street-by-street guidebook (I suggest *Eyewitness New York*), you can stroll north from the Theater District to the 843 acres of Central Park. Be sure to stop by the Strawberry Fields memorial to John Lennon, the Angel of the Waters statue at Bethesda Fountain, and the zoo.

Bordering the park is Central Park West, home to the American Museum of Natural History and the Planetarium (don't forget the kids), and the magnificent Dakota and San Remo apartment buildings.

Heading south from Times Square on the West Side are Chelsea and the Garment District, which blends into Greenwich Village, home to universities, coffeehouses, and music clubs. The far west end of Greenwich Village is now called the Meat Packing District, where some of the newer, trendier attractions are found.

Below Greenwich Village are SoHo (South of Houston Street), TriBeCa (Triangle Below Canal Street), Little Italy, and Chinatown. At the bottom of Manhattan Island are the former site of the World Trade Center, Wall Street, and the Staten Island ferry station, the start of an inexpensive boat trip and great view of the Statue of Liberty. On the East Side of Manhattan are famous landmarks, including the United Nations and Empire State buildings, Fifth Avenue, and St. Patrick's Cathedral.

Walking around the city, or even riding the subways, can stimulate an appetite-not to worry, as Manhattan boasts a seeming unlimited number of restaurants catering to every style and taste. A pleasant surprise is the quality and quantity of lower-priced establishments. But, be sure to review restaurant guides, such as Zagat and Michelin, and make reservations for your favorites.

General information about New York City is readily available. Closer to October you may also want to scan the weekly periodicals (*New Yorker*, *New York*, *Time Out New York*, and *Village Voice*) and newspapers (*New York Times*, *Post*, and *Daily News*, all available online). I'm looking forward to seeing you in the Big Apple in October! ■

Spencer Eth, M.D., is the local arrangements consultant to the IPS Scientific Program Committee.

How to Register

- Register online for the 2006 Institute on Psychiatric Services at <www.psych.org/edu/ann_mtgs/ips/06/index.cfm>.
- Or use the registration form found in the preliminary program booklet and mail or fax the completed form to APA. The booklet can be obtained by calling (888) 357-7924.

Register before **September 7** and save on fees. A discounted fee is available for residents; medical students attend free.

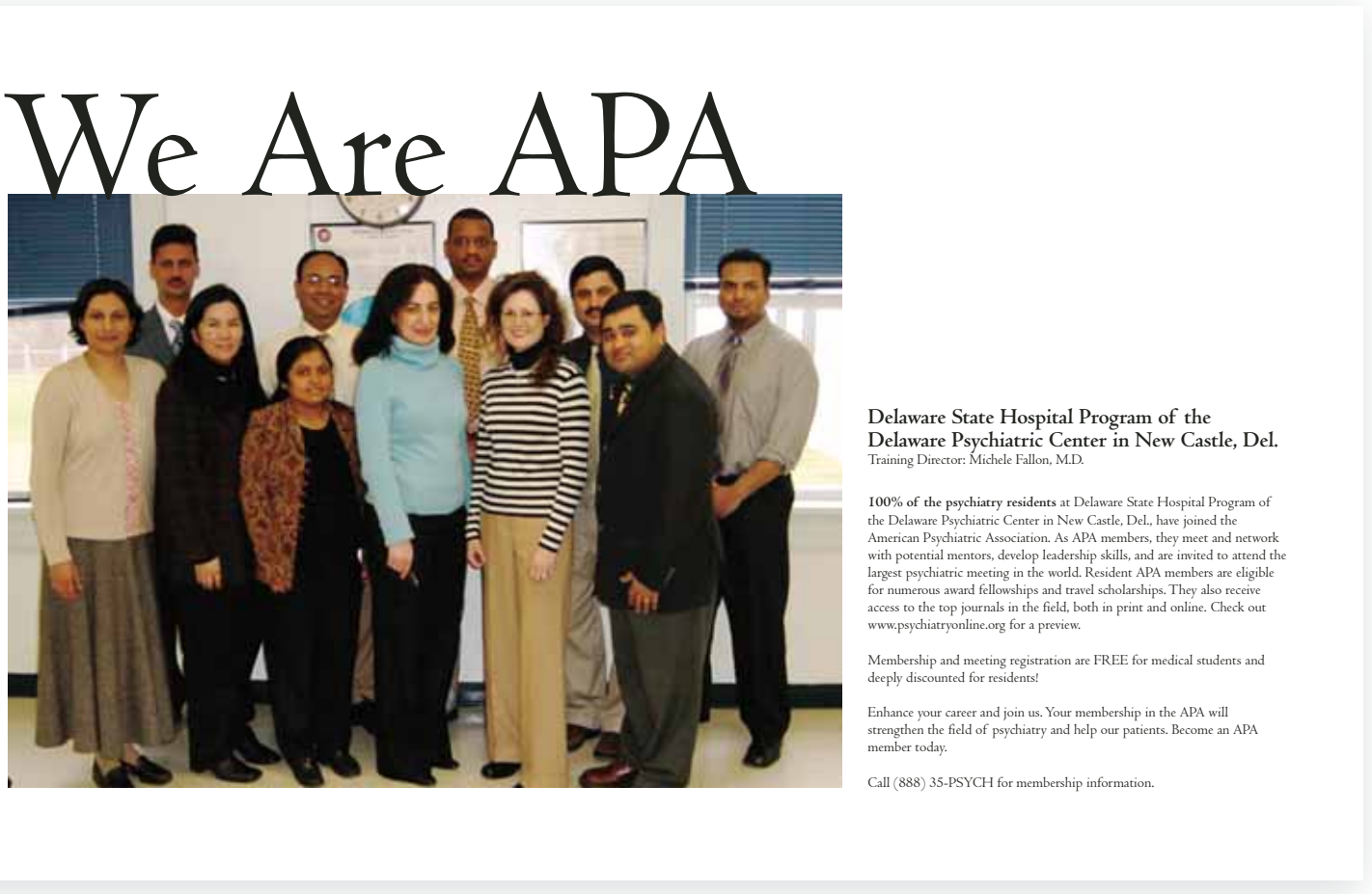
Another Residency Program Joins APA's 100% Club

The psychiatry residency training program at the Delaware State Hospital Program of the Delaware Psychiatric Center in New Castle, Del., is the latest residency program to have all of its psychiatry residents become members of APA.

It joins the ranks of an exclusive organization within APA: the 100% Club. This club was established to encourage residents throughout the United States and Canada to join APA and to do so with other trainees in their programs, according to Deborah Hales, M.D., director of APA's Division of Education and Career Development.

A photo of each program that joins the 100% Club will be turned into a poster and mailed to every medical school in the United States and Canada to encourage medical students to join APA. In addition, programs in the 100% Club receive a major textbook from American Psychiatric Publishing Inc. and a free online subscription to *Focus: The Journal of Lifelong Learning* for each year that all of their residents are APA members.

"We are delighted to all be members of APA and look forward to enjoying the benefits of the 100% Club," said Michele Fallon, M.D., the program's residency training director.



Back row from left: Jagwinder Sandhu, M.D., Sachidanand Kamtam, M.D., Izzeldeen Elhage, M.D., Ajay Sharma, M.D., Arshad Siddiqui, M.D. Front row from left; Yadvinder Sandhu, M.D., Rhodora Tolentino, M.D., Anasuya Salem, M.D., Nana Berikashvili, Michele Fallon, M.D. (residency training director), and Khaled Mirza, M.D.

More information about the 100% Club is available from Nancy Delanoche of APA's Division of Education and Career Development at (703) 907-8635. Programs that are interested in signing up all their residents should also contact Delanoche. ■

Special Lectures to Explore Key Issues Facing Psychiatry

The lectures at the Institute on Psychiatric Services will be presented by an impressive list of psychiatric clinicians, researchers, and policymakers.

BY CHARLES W. HUFFINE JR., M.D.

Thanks to the wonderful resources available in and near New York City and the breadth of interests represented on the Scientific Program Committee of APA's Institute on Psychiatric Services (IPS), we have a remarkably diverse plate of lectures awaiting you this fall.

Here are just some of the lectures you can attend: Paula Panzer, M.D., will discuss a community agency's focus on trauma, which speaks directly to the theme of the conference, "Trauma and Violence in Our Communities"; Mark Olfson, M.D., will discuss antidepressant medication and suicidality; Jeffrey Lieberman, M.D., will summarize the CATIE study's findings on antipsychotic drugs; Saun Eack, M.S.W., will present a lecture for Gerard Hogarty, who died after he had accepted the invitation to discuss the evolution of psychosocial treatment; and Kenneth Kendler, M.D., will give an overview of 'psychiatric genetics.

Several lecturers will discuss social issues that impact the world of community practice: Ellen Haller, M.D., and Susan Vaughn, M.D., will discuss lesbian and gay families; Franklin Kameny and Barbara Gittings will discuss gay pride and its relationship to health; Annelle Primm, M.D., will present research findings on disparities in mental health; Ned Cassem, M.D., will discuss psychiatry and spirituality at the end of life; Paul Appelbaum, M.D., will discuss behavioral genetics and its impact on preventing crime and punishing offenders; Laurie Flynn, former executive director of NAMI, will discuss the "anti-screening" movement; and my friend Sanho Tree will discuss toxic illnesses, deforestation, homelessness, and other collateral damage of the war on drugs.

Leon Eisenberg, M.D., will treat us to a history lecture on Benjamin Rush and the yellow fever epidemic, while others will talk about the future of psychiatry, including Charles Nemeroff, M.D., on psychiatry in the next millennium; Herbert Pardes, M.D., on prospects for psychiatric care in the future; and Bernard Aarons, M.D., on services and science—"shall the twain ever meet?"

Others will grapple with daunting policy issues in psychiatry, including Thomas Wise, M.D., who will discuss whether the subspecialty of psychosomatic psychiatry is needed; Neal Cohen, M.D., on the public health challenge for psychiatry; and Lloyd Sederer, M.D., on meeting the mental health needs of New York City.

Two other lecturers will anticipate the fabulous Celebration Recovery on Saturday night by addressing the pressing policy issue of bringing the mental health field in line with federal policies regarding the recovery movement in mental health and transforming the mental health system. The talk by Mark Raggins, M.D., will provide an articulate first-person narrative on becoming a recovery-oriented psychiatrist, and Katherine Power, director of the Center for Mental Health Services in SAMHSA, will address the issues of recovery and trauma, thus returning to the IPS theme chosen by APA President Pedro Ruiz, M.D.

Please do look over the lectures and partake of this treasure trove of good ideas and thoughtful discussions. We are very fortunate to attract such a prominent group of leaders in mental health and related fields who are willing to give of their time and come to New York at their own expense to share their expertise.

Charles Huffine, M.D., is chair of the IPS Scientific Program Chair,

IPS Program Change

The recipient of the 2006 Alexander Gralnick Award for Research in Schizophrenia, Prof. Gerry Hogarty of the Western Psychiatric Institute and Clinic in Pittsburgh, recently passed away. Hogarty was to receive the Gralnick Award and present the Gralnick Lecture at APA's 2006 Institute on Psychiatric Services, which is being held October 5 to 8 in New York City. In his place, Shaun Eack, M.S.W., of the University of Pittsburgh will present Hogarty's work. The session will be held October 7 at 10 a.m. Thomas McGlashan, M.D., chair of the award committee, will offer perspectives on Hogarty's life and work.

Erratum

Douglas Robert Luther, M.D., was incorrectly listed as deceased in the "In Memoriam" list published in the June 2 issue. It was his father, Robert Luther, M.D., who died. APA apologizes for this error. ■

From N.Y. Lunatic Asylum to New York Hospital's Westchester Division

BY LUZY OZARIN, M.D., M.P.H.

Psychiatric services delivered in general hospitals may appear to be a 20th-century innovation, but the practice began in 1752, when the Pennsylvania Hospital in Philadelphia provided for mental patients. In New York City, the New York Hospital, which received a royal charter in 1771, also admitted mental patients when it opened in 1792. Curable patients were preferred, and public patients, whose care was paid for by their townships, were admitted along with private patients.

The demand for admission led to construction of an adjacent building in 1808 known as the New York Lunatic Asylum. The state legislature provided an annuity to the hospital (1816-1849) to help defray the costs for public patients. (The first state mental hospital in New York opened in 1843 in Utica.)

Thomas Eddy, a Quaker member of the Hospital Board of Governors of New York Hospital, had corresponded with Samuel Tuke of the Quaker York Retreat in England, where a new approach to treating mentally ill people, known as moral treatment, had been instituted. It consisted of kindly treatment, occupational and recreational activities, minimal or no restraint, and medication as needed. Eddy successfully pressed the Board of Governors to use the moral treatment approach at the New York Lunatic Asylum.

In 1816 the need for a larger asylum led to the purchase of land around 120th Street, and in 1821 the Bloomingdale Asylum was opened. Administration of the asylum was under a lay superintendent or warden, and visiting physicians provided medical services. The Asylum and Inspection committees of the Board of Governors provided supervision.

In 1825 James McDonald, M.D., was appointed "resident physician" and in 1831 was sent to study mental hospitals in Europe. McDonald was dissatisfied with his limited authority and urged the Board of Governors to give the resident physician more authority over patient treatment. Gradually this was accomplished, and after mid-century the resident physician became superintendent, while a warden oversaw tasks not related to patient care.

The asylum had been named Bloomingdale after the main road alongside the property, and this name maintained until well into the 20th century.

The press for admission continued as the city's population increased, and in 1868 the Board of Governors bought farm land north of the city in White Plains, Westchester County. In 1894 a large hospital was opened with the name of Society of the New York Hospital, Bloomingdale, White Plains. In the early 1900s Payne Whitney, a member of the Board of Governors, left a fund to New York Hospital for "neurologic and psychiatric work." To provide these services, a building known as the Payne Whitney Clinic was constructed at the New York Hospital site. In 1936 the name Bloomingdale disappeared, and the psychiatric hospital is now named Payne Whitney Westchester.

Three histories of Bloomingdale have been written. In 1848 Pliny Earle, M.D., a founding father of the predecessor of the American Psychiatric Association and super-

please see ***History Notes*** *on page 30*

letters to the editor

Readers are invited to submit letters not more than 500 words long for possible publication. *Psychiatric News* reserves the right to edit letters and to publish them in all editions, print, electronic, or other media. Receipt of letters is not acknowledged. Letters should be sent by mail to *Psychiatric News*, APA, Suite 1825, 1000 Wilson Boulevard, Arlington, Va. 22209 or by e-mail to pnews@psych.org. Clinical opinions are not peer reviewed and thus should be independently verified.

Black-Box Warnings

The March 3 issue ran an article on an FDA panel's unexpected recommendation of a black-box warning for stimulants, despite minimal evidence of a direct link to serious or fatal outcomes and a level of risk (even accepting such a link) far, far below that involved in many nonpsychiatric medications.

While one would have thought that the FDA had learned by now—given the fiasco of the antidepressant black-box warning—that its actions can have serious consequences and must therefore be well considered, cautious, and scientifically based, that is not what we see. This latest recommendation is even more clearly based in a new role the FDA is assuming, that of a moral watchdog whose purpose is to make sure the rest of us "do the right thing." The underlying assumption is that we don't read the literature and don't pay any attention to the *PDR* and related databases and instead prescribe what the drug companies tell us to prescribe with the only other motive to get rich off a gullible public. Or perhaps it is that the FDA believes that we have no understanding or concern for the wider issues of prescriptive practice and are incompetent to guide overall prescribing patterns.

Whatever the rationale, the FDA and its advisory panels have a disturbing new face of moral rectitude these days. Behind that façade, one easily senses politics, prejudice, and power hunger. The fact is that there was no excuse for putting a black box on antidepressants, and it did great harm, which the FDA is not tracking. The good data in the black box are part of every medical student's training and contained in every psychiatric textbook and *PDR* entry.

The black-box recommendation for stimulants (hopefully it is stimulants—imagine the comic horror of a black box on "ADHD drugs") is even more openly a departure from science. It is based on the panel's vague concerns about overprescribing and the legitimacy of psychiatric diagnosis.

Dr. Steven Nissen, and FDA consultant, wants my hand to tremble when I prescribe stimulants. Does his tremble when he prescribes digoxin or any one of the other toxic and potentially lethal drugs he prescribes routinely as a cardiologist? I want it to, because I regularly have to clean up the psychiatric mess created when nonpsychiatrists prescribe drugs with psychiatric side effects they never check for and wouldn't admit to seeing.

And then, of course, when the press gets hold of news about black-box warnings, reporters write uninformed articles, confirming every stigma and prejudice our culture has and encouraging witch hunts all around.

ROGER HENSLEY, M.D.
South Bend, Ind.

I read with interest the article in the March 17 issue reporting that physicians are not attending to the black-box warnings in the way in which they were intended. I have noted that in the past two years antidepressants (concerning suicide risk in children and adolescents as well as adults) and second-generation antipsychotics (concerning cerebrovascular events in dementia patients) now have black-box warnings. Moreover, stimulants are also under consideration for a black-box warning for cerebrovascular events.

One would expect that a black-box warning would be used only for severe and well-proven risks. After reviewing the data on these warnings, I cannot say this appears obvious. In the September 2005 *Journal of Clinical Psychiatry*, Rosa Liperoti and colleagues reported that there is no apparent link between second-generation antipsychotics (SGAs) and cerebrovascular events in individuals with dementia. The study was sponsored by NIH. This would appear to be the most definitive research on the issue, yet I hear no discussion about withdrawing the black box from the labeling of SGAs.

It appears to me that the FDA has lowered the threshold for adding black-box warnings and is reluctant to withdraw them even in the face of contradictory data. It is therefore difficult to attend the warnings with the same vigor as I have in the past. One hears echoes of the little boy who cried wolf.

GREG UNFRIED, M.D.
Evansville, Ind.

history notes

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intendent of the hospital, published *A History, Description, and Statistics of the Bloomingdale Hospital for the Insane*. In 1921 the Society of the New York Hospital produced *A Psychiatric Milestone* to mark the hospital's centenary. In 1945 William L. Russell, M.D., superintendent of Bloomingdale from 1911-1936 published the *New York Hospital, A History of the Psychiatric Service, 1721-1936*. Preserved hospital records provide a treasure trove of information about 19th- and early 20th-century psychiatry.

The history of Bloomingdale also portrays its contributions to American psychiatry. Seven APA presidents have been superintendent or on the staff of the hospital: Charles Nichols, M.D. (1873-74), Pliny Earle, M.D. (1884-85), William Russell, M.D. (1931-32), Clarence Cheney, M.D. (1935-36), Macfie Campbell, M.D. (1936-37), Karl Bowman, M.D. (1941-46), and Samuel Hamilton, M.D. (1946-47). ■

NYC

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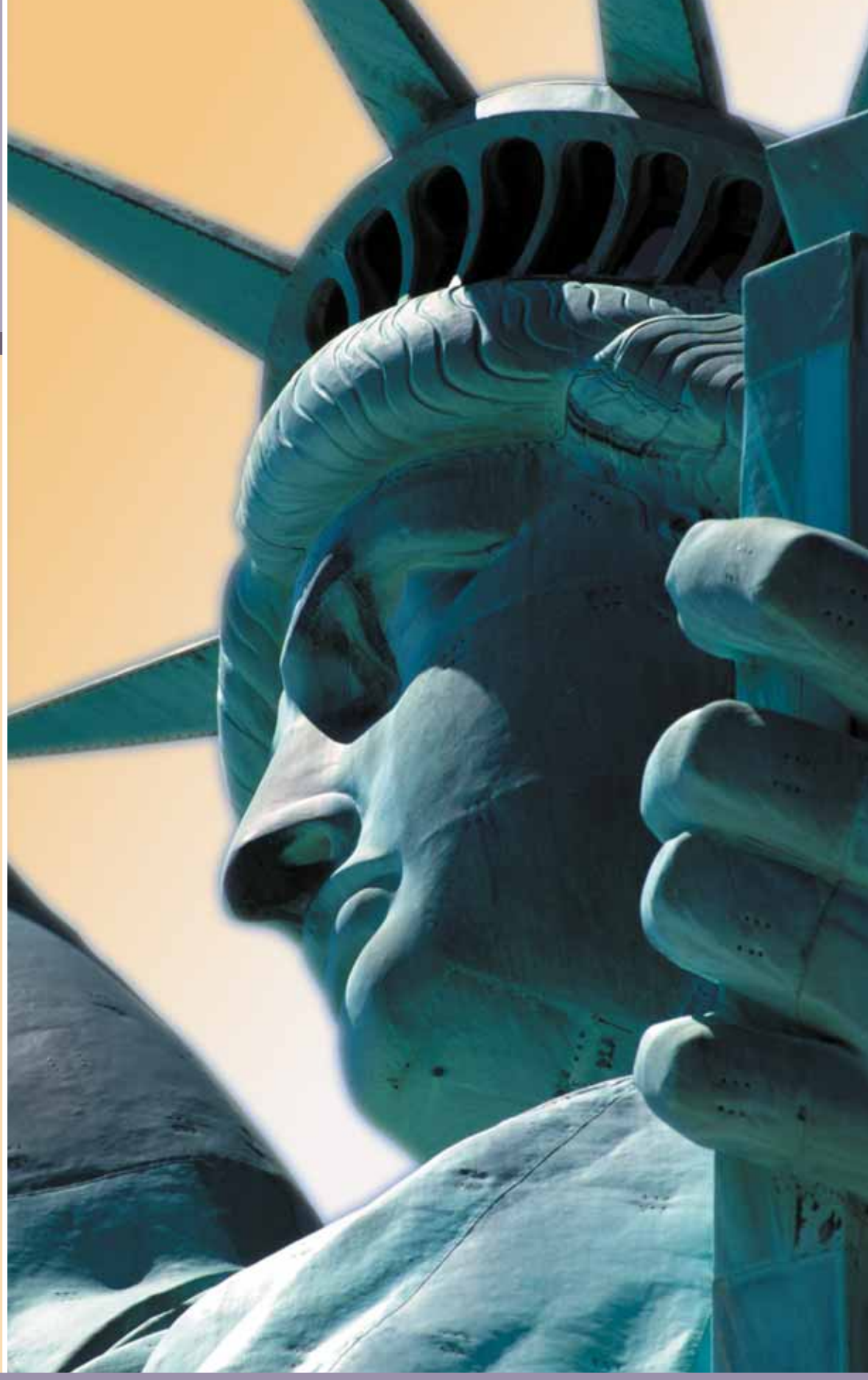
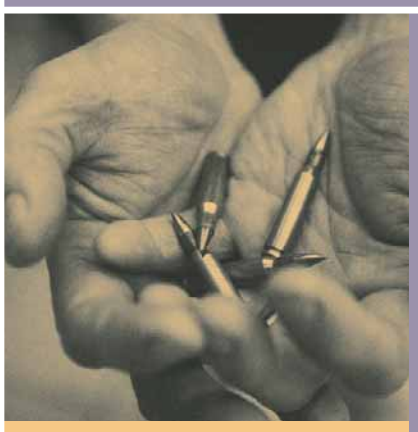


Conference Highlights and Advance Registration

Trauma and Violence in Our Communities



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Treating patients with mental illness requires a continuum of specialized training and support to meet the needs of these individuals. The APA Institute on Psychiatric Services (IPS) focuses on clinical and service programs, especially those that provide a complex array of services and clinical innovations to meet the needs of those suffering from mental illness in social and community contexts. The clinical focus of the IPS is on innovations and adaptations of proven therapies and serves as a forum for discussing systems of care, quality management, government policy, and social and economic factors.

Mental health professionals in community practice and/or those that serve in the public sector including, but not limited to, state, community, and Veterans Affairs hospitals, community clinics, jails or other agencies, will find this comprehensive, educational, and networking event indispensable in their professional development.

Opening Session and Awards Ceremony

Thursday, October 5, 2006
12 noon–1:30 p.m.

Kick-off the Conference with the APA President. Don't miss this opportunity to hear the APA President, and guest lecturer, Suzanne Vogel-Scibilia, M.D., President, National Alliance on Mental Illness, and congratulate your colleagues at the awards ceremony.

Educational Sessions

Attend over 300 timely, information-packed presentations led by industry experts. Session topics include: Trauma and Violence; Recovery Issues; Social and Community Psychiatry; Psychopharmacology; Resident and Medical Student Concerns; Substance Abuse; Child and Adolescent Issues; AIDS, Cross-Cultural and Minority Issues; Psychiatric Administration and Services; Treatment Techniques and Outcome Studies; Health Services Research; and much more…

For a complete list and more detailed information on educational sessions at the 58th Institute on Psychiatric Services, please visit www.psych.org/IPS2006.

Who We Are

The American Psychiatric Association is a national medical specialty society, founded in 1844, whose 35,000 physician members specialize in the diagnosis, treatment, and prevention of mental illnesses including substance abuse disorders. For more information, visit the APA Web site at www.psych.org.

Preliminary Schedule of Events

October 5–8, 2006

Thursday, October 5, 2006

8:00 a.m.–5:00 p.m.	Educational Sessions
10:00 a.m.–11:30 a.m.	Lecture by Paul S. Appelbaum, M.D., on Behavioral Genetics and the Prevention and Punishment of Crime
12 noon–1:30 p.m.	Opening Session and Awards Ceremony featuring Pedro Ruiz, M.D., and Suzanne Vogel-Scibilia, M.D.
1:30 p.m.–3:00 p.m.	Lecture by Bernard Arons, M.D., on Services and Science: Shall the Twain Ever Meet?
1:30 p.m.–5:45 p.m.	Exhibit Hall hours
4:00 p.m.–5:45 p.m.	Exhibit Hall reception and prize drawings
6:00 p.m.–9:00 p.m.	Industry-Supported Dinner Symposium

Friday, October 6, 2006

8:00 a.m.–5:00 p.m.	Educational Sessions
8:30 a.m.–5:00 p.m.	HIV Symposium, featuring Francine Cournos, M.D., and Marshall Forstein, M.D.
10:00 a.m.–11:30 a.m.	Plenary Session, entitled "Hurricane Katrina: Leadership Lessons Learned," by Cheryll Bowers-Stephens, M.D.
9:30 a.m.–12 noon and 3:00 p.m.–5:45 p.m.	Exhibit Hall Hours with beverages, snacks, and prize drawings
12 noon–1:30 p.m.	Meet the Experts Luncheon for Residents, ECP's and Medical Students
	Industry-Supported Luncheon Symposia
1:30 p.m.–3:00 p.m.	Lecture by SAMHSA's, A. Kathryn Power, M.Ed., on Trauma and Recovery
3:30 p.m.–5:00 p.m.	Local Chairs' Forum on The Role of Academic Departments and Faculty in Forging the Future of Psychiatry
5:00 p.m.–6:00 p.m.	Reception for Residents, ECP's, and Medical Students
6:00 p.m.–9:00 p.m.	Industry-Supported Dinner Symposium
6:00 p.m.–9:00 p.m.	AACP Forum and Reception for all attendees

Saturday, October 7, 2006

7:30 a.m.–8:30 a.m.	Health Services Research Breakfast
8:00 a.m.–5:00 p.m.	Educational Sessions
8:30 a.m.–5:00 p.m.	AGLP Day featuring the John E. Fryer, M.D. Award Lecture
8:30 a.m.–11:30 a.m.	American Orthopsychiatric Association's Symposium on Prevention of Aggression in Children and Young Adults
9:30 a.m.–12 noon	Exhibit Hall Hours with beverages, snacks, and prize drawings
10:00 a.m.–11:30 a.m.	APF's Alexander Gralnick Award Lecture on The Evolution of Psychosocial Treatment for Schzophrenia
12 noon–1:30 p.m.	Industry-Supported Luncheon Symposia
1:30 p.m.–3:00 p.m.	Lecture by Herbert Pardes, M.D., on Prospects for Psychiatric Care in the Future
3:30 p.m.–5:00 p.m.	APA's Oskar Pfister Award Lecture, by Ned H. Cassem, M.D.
4:00 p.m.–7:00 p.m.	Celebration Recovery with music, food, and entertainment
7:00 p.m.–10:00 p.m.	Industry-Supported Dinner Symposium

Sunday, October 8, 2006

8:00 a.m.–12 noon	Educational Sessions
8:30 a.m.–3:30 p.m.	Full-Day Seminar on Treating Homeless People Who Have Mental Illnesses
9:00 a.m.–5:00 p.m.	AGLP Fall Business Meeting
10:00 a.m.–11:30 a.m.	APA's Judd Marmor Award Lecture by Kenneth Kendler, M.D., on Psychiatric Genetics

Lectures and Plenary Sessions

Thursday, October 5, 10:00 a.m.–11:30 a.m.

Behavioral Genetics and the Prevention and Punishment of Crime, by Paul S. Appelbaum, M.D.

Dr. Appelbaum will discuss the recent advances in behavioral genetics that relate to antisocial behavior, and their potential implications for adjudication of criminal behavior and preventive interventions.

Paul S. Appelbaum, M.D., is Professor and Director, Division of Psychiatry, Law and Ethics, Department of Psychiatry, Columbia University. He was previously the A.F. Zeleznik Distinguished Professor; Chair, Department of Psychiatry; and Director, Law and Psychiatry Program, University of Massachusetts Medical School. Dr. Appelbaum is Past President of the American Psychiatric Association (APA) and the American Academy of Psychiatry and Law, and serves as Chair of APA's Council on Psychiatry and Law. He received APA's Isaac Ray Award for "outstanding contributions to forensic psychiatry and the psychiatric aspects of jurisprudence," and was elected to the Institute of Medicine of the National Academy of Sciences.

Thursday, October 5, 12 noon–1:30 p.m.

Reflections on Recovery

Suzanne E. Vogel-Scibilia, M.D., is currently the President, National Alliance for the Mentally Ill (NAMI), and Medical Director, Beaver County Psychiatric Services. She has had Bipolar Disorder since the age of 15. She is the mother of five children, two of whom have been diagnosed with mental illnesses. She is a psychiatrist with board certification in general psychiatry, addiction psychiatry, and geriatric psychiatry, and has additional board certification from the American Board of Adolescent Psychiatry. She also has a thriving practice in Beaver, Pennsylvania. Dr. Vogel-Scibilia stays very active leading local peer education and support groups, and acts in an advisory capacity for national organizations. She is a consumer, family member, and provider, and she represents the broad perspective that NAMI brings to the important advocacy movement.

Thursday, October 5, 1:30 p.m.–3:00 p.m.

Services and Science: Shall the Twain Ever Meet?, featuring Bernard S. Arons, M.D.

Dr. Arons will address the successes of generative interaction of science and services. He will identify the significant barriers to enhanced interaction of science and services, and tell about three or more immediate actions that would leap over the barriers.

Dr. Arons is the Executive Director and CEO of the National Development and Research Institutes, Inc. (NDRI). The NDRI advances scientific knowledge in the areas of substance abuse, mental health, HIV/AIDS, and other related social and health concerns in order to contribute to the prevention and solution of these social problems. Previously, Dr. Arons was the Director of the Center for Mental Health Services, SAMHSA, U.S. Department of Health and Human Services.

Thursday, October 5, 1:30 p.m.–3:00 p.m.

APA's Benjamin Rush Award Lecture, entitled Furor Therapeutics: Benjamin Rush and the Yellow Fever Epidemic, by Leon Eisenberg, M.D.

Dr. Eisenberg is the Presley Professor of Social Medicine and Professor of Psychiatry Emeritus, Harvard Medical School, where he also chaired the Department of Social Medicine and Health. As consultant to the World Health Organization's Division of Mental Health, he chaired three international scientific work groups and served on several others. He has been a recognized leader in child psychiatry for over 40 years through his work in pharmacological trials, research, teaching and social policy and for his theories of autism and social medicine. He has received prestigious awards from the American Academy of Pediatrics, the American Psychiatric Association, and the American Orthopsychiatric Association, to name but a few. His publications include more than 250 peer-reviewed journal articles, 130 book chapters, and nine edited books, including most recently "Bridging Disciplines in the Brain, Behavioral, and Clinical Sciences" (National Academy Press, 2000).

Friday, October 6, 10:00 a.m.–11:30 a.m.

Cheryll Bowers-Stephens, M.D., M.B.A., on Hurricane Katrina: Leadership Lessons Learned

Cheryll Bowers-Stephens, M.D., M.B.A., is the former Assistant Secretary for the Office of Mental Health in the Louisiana Department of Health and Hospitals. She is a graduate of Spellman University, with an undergraduate degree in psychology and computer science. She also holds an M.B.A. from the University of New Orleans and an M.D. from Louisiana State University in New Orleans. Her general psychiatry residency was at the Ochsner Medical Foundation, followed by a child and adolescent fellowship at Tulane University. Her clinical area of expertise is treatment of youth with co-occurring mental illness and developmental disabilities. She has served for the past ten years in program administration and program development. In this role, she has emphasized the importance of infant mental health, services to at-risk youth ages 0–5 and their families, and collaboration at the community level. Dr. Bowers-Stephens has been engaged in Project Legacy, an effort to transform mental health for the State of Louisiana. Currently, she is the Chief Executive Officer for the The Schopenhauser Group, LLC.

Friday, October 6, 1:30 p.m.–3:00 p.m.

Trauma and Recovery; Learning and Doing, by A. Kathryn Power, M.Ed., Director, Center for Mental Health Services, SAMHSA, U.S. Department of Health and Human Services

In this lecture the importance of violence, trauma, and abuse in women's lives will be highlighted. Violence and trauma is far more prevalent than commonly understood, and there is a disconnect between the prevalence of trauma and its recognition in the health, mental health, and substance abuse provider communities. The relationship between trauma and mental health and substance abuse problems is a critical one for providers to identify and treat, and many new individual and community models for integrated trauma counseling have been developed that have been demonstrated to facilitate recovery. The essential features in trauma integrated counseling will be featured in terms of their support for the process of recovery in women's lives.

Friday, October 6, 1:30 p.m.–3:00 p.m.

Comparative Effectiveness of Antipsychotic Drugs: Results of the NIMH-CATIE Study, by Jeffrey A. Lieberman, M.D.

Dr. Lieberman is currently the Chair, Department of Psychiatry, College of Physicians and Surgeons, Columbia University; Director, New York State Psychiatric Institute; and Director, Lieber Center for Schizophrenia Research. Dr. Lieberman earned his medical degree from George Washington University. He has held research leadership positions in New York City at Mt. Sinai School of Medicine, Albert Einstein College of Medicine, and at the State University of New York School of Medicine. He was recruited to the University of North Carolina School of Medicine in 1996. With research focused on neurobiology, pharmacology, and the treatment of schizophrenia and related psychotic disorders, Dr. Lieberman has authored more than 300 scientific papers.

Saturday, October 7, 8:00 a.m.–9:30 a.m.

Do We Really Need Another Subspecialty? Psychosomatic Medicine: What Is It and What About the Name?, by Thomas N. Wise, M.D.

Dr. Wise graduated from Duke University School of Medicine. He is currently the Chair, Department of Psychiatry, at Inova Fairfax Hospital. He is also the Director of Behavioral Services at Inova Health Systems, and is Professor of Psychiatry and Behavioral Sciences, at Johns Hopkins University School of Medicine. Dr. Wise is Editor-in-Chief of the Journal of Psychosomatics, is President of the Board, American Psychiatric Publishing, Inc., and is active on many other journals as an editorial board member reviewer.

Saturday, October 7, 1:30 p.m.–3:00 p.m.

Prospects for Psychiatric Care in the Future, by Herbert Pardes, M.D., President and Chief Executive Officer, New York-Presbyterian Hospital

This lecture will focus on the implications of government support versus how psychopharmacological care will fare with tougher scrutiny and reservations regarding the numbers of people who genuinely benefit from pharmacological care; develop an understanding of what the current political perspective will mean for the care of the chronically mentally ill; and elaborate how the prevailing culture will impact the nature of mental health manpower and education of psychiatrists.

Sunday, October 8, 10:00 a.m.–11:30 a.m.

APA's Judd Marmor Award Lecture featuring Kenneth S. Kendler, M.D., on Psychiatric Genetics: A Current Perspective

Dr. Kendler is the Banks Distinguished Professor of Psychiatry, Professor of Human Genetics, and Director, Virginia Institute for Psychiatric and Behavioral Genetics. He received his medical degree from the Stanford University School of Medicine. His research interests include psychiatric genetics, epidemiology, schizophrenia, and the genetics of psychiatric and drug abuse disorders.

Health Services Research Track

The American Psychiatric Association is pleased to offer, for the first time at the 2006 Institute on Psychiatric Services, a special Health Services Research program track. This track, is designed to highlight the implications of current health services research for psychiatric practice, introduce psychiatric residents to the field of health services research, and update clinicians on innovative and practical approaches for improving mental health care. This track will benefit public sector psychiatrists and those working in systems of care. Among the offerings are the following activities:

Symposium

Thursday, October 5, 8:30 a.m.–11:30 a.m.

Monitoring Depression Severity: Clinical Applications in Psychiatry

This symposium will update clinicians on the systematic management of depression using the nine item Patient Health Questionnaire (PHQ-9). A simple quantitative instrument, the PHQ-9 holds significant promise for improving the treatment of depression by equipping physicians with a standardized tool for monitoring the severity of depression.

Lecture

Friday, October 6, 10:00 a.m.–11:30 a.m.

Anti-Depressant Medication and Suicidality

Mark Olfson, M.D., M.P.H., Clinical Professor of Psychiatry at Columbia University, will provide a clinical update on the use of antidepressant medication and suicidality.

Friday, October 6, 12 noon–1:30 p.m.

"Meet the Experts" Luncheon

This luncheon, for Residents only, includes a senior health services researcher on the panel of presenting experts.

Saturday, October 7, 7:30 a.m.–8:30 a.m.

Health Services Research Breakfast

This breakfast is designed to provide psychiatric residents and young investigators the opportunity to interact with senior investigators in the health services research field. The recipients of the Health Services Research Early Career Award and Senior Scholar Award are recognized at the breakfast and will share their health services research experiences.

Symposium

Saturday, October 7, 8:30 a.m.–11:30 a.m.

National Institute of Mental Health (NIMH) Health Services Research

The Division of Services and Intervention Research, NIMH, presents a symposium on several current clinical trials it is currently supporting and their implications for psychiatric practice.

Lecture

Sunday, October 8, 8:00 a.m.–9:30 a.m.

Disparities in Mental Health Care: What Does Research Tell Us?

Annelle Primm, M.D., M.P.H., Director of APA's Office of Minority/National Affairs, will provide an overview and an update on disparities in mental health care and treatment for minority populations.

Association of Gay and Lesbian Psychiatrists Track

Over the past year, the Association of Gay and Lesbian Psychiatrists (AGLP), LGBT psychiatrists, and the APA have raised $50,000 to endow the John E. Fryer, M.D., award, for a public figure who has made significant contributions to LGBT mental health. Dr. Fryer was known as Dr. Anonymous when he gave a courageous speech at the 1972 APA Annual Meeting, which led to the declassification of homosexuality as a mental illness. Barbara Gittings and Franklin Kameny, Ph.D., who were on the same panel as Dr. Fryer in 1972, will both be recipients of the first award. To honor the new award, the Institute on Psychiatric Services (IPS) will feature a day of programming on LGBT mental health. AGLP will also hold its Fall Business Meeting and sponsor two receptions during the IPS. For full details see www.aglp.org. To register for the IPS see www.psych.org/IPS2006.

Friday, October 6, 5:00 p.m.–5:30 p.m.

APA LGBT Caucus and AGLP Meeting

Evening Reception
(details to be announced)

Lecture

Saturday, October 7, 8:00 a.m.–9:30 a.m.

Lesbian and Gay Families

Ellen Haller, M.D., Adjunct Professor of Psychiatry, University of California at San Francisco, and Susan Vaughn, M.D., Assistant Professor of Clinical Psychiatry, Columbia University

Ellen Haller, M.D.

Susan Vaughn, M.D.

Workshop

Saturday, October 7, 10:00 a.m.–11:30 a.m.

Sex and Sexuality and Special Populations Among Gay, Lesbian and Bisexual People

Robert P. Cabaj, M.D., will lead this workshop that will focus on understanding the complex role that sexuality plays in the lives of lesbians and gay men and describe how it influences their mental health. Presenters include Robert Kertzner, M.D., Ronald Hellman, M.D., and Samantha Kelleher, M.D.

Saturday, October 7, 11:30 a.m.–1:30 p.m.

Lunch
(details to be announced)

Saturday, October 7, 1:30 p.m.–3:00 p.m.

John E. Fryer, M.D. Award Lecture, entitled Gay, Proud, and Healthy: From Heresy to Humdrum

Franklin E. Kameny, Ph.D., and Barbara Gittings, Gay Rights Activists

Barbara Gittings

Franklin E. Kameny, Ph.D.

Workshop

Saturday, October 7, 3:30 p.m.–5:00 p.m.

Demons, Satan, Science, and Homosexuality: A Film Analysis

David L. Scasta, M.D., Co-Chair, AGLP Film Task Force, will lead this workshop that will help participants gain familiarity with religious precepts, which make the coming out process difficult for Lesbian, Gay, Bisexual, and Transgendered people and compel efforts to effect sexual orientation change. This workshop will also feature the AGLP produced film entitled, "Can I Change," focusing on the harms of conversion or "reparative" therapy. Presenters include Alicia Salzer, M.D., Mary Barber, M.D., and Reverend Larry Waltz

Early evening reception for the John E. Fryer, M.D. Award Winners
(details to be announced)

Sunday, October 8, 9:00 a.m.–5:00 p.m.

AGLP Fall Business Meeting

Medical Updates

The following Medical Updates will be presented during the IPS.

Kenneth Prager, M.D. Columbia University	***Pulmonary Disease***	Thursday, October 5, 2006 8:00 a.m.–9:30 a.m.
Joseph Lux, M.D. Bellevue Hospital and New York University	***HIV/AIDS***	Thursday, October 5, 2006 10:00 a.m.–11:30 a.m.
James Tsai, M.D. Columbia University	***Ophthalmology***	Thursday, October 5, 2006 3:30 p.m.–5:00 p.m.
Russell Kellogg, M.D. St. Vincent's Hospital and New York Medical College	***Preventive Health Care***	Friday, October 6, 2006 10:00 a.m.–11:30 a.m.

Local Chairs' Forum

Friday, October 6, 3:30 p.m.–5:00 p.m.

The Role of Academic Departments and Faculty in Forging the Future of Psychiatry

This forum will include the following chairs of psychiatry from the local medical schools.

Jonathan D. Brodie, M.D., Ph.D.	New York University
Joseph T. English, M.D.	St. Vincent's Hospital
Javier Escobar, M.D.	University of Medicine and Dentistry of New Jersey
Stephen M. Goldfinger, M.D.	State University of New York, Downstate Medical Center
T. Byram Karasu, M.D.	Albert Einstein College of Medicine
Charles H. Kellner, M.D.	University of Medicine and Dentistry of New Jersey
Jeffrey A. Lieberman, M.D.	College of Physicians and Surgeons, Columbia University
Mark J. Sedler, M.D.	Stony Brook University School of Medicine

During this forum, attendees will have a unique opportunity to address this very relevant topic for the profession and field of psychiatry at large. This forum will provide a wonderful opportunity for medical students and residents to share their opinions and ideas on how best to delineate the future of academic psychiatry in this country. It will also provide an opportunity to assess the positive and negative aspects of this profession, from an academic point of view. Hopefully, as a result of this forum, a better future outlook will be envisaged for the future generations of psychiatrists, both in this country and abroad.

APPI Bookstore

Stop by your on-site source for the latest publications, training materials, and journals. You'll find new, best-selling titles, and classical references on every area of psychiatry. APA members can take advantage of 15% member discounts and APA Members-in-Training receive a 25% discount on all purchases.

Continuing Medical Education

Accreditation/Designation: The American Psychiatric Association (APA) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The APA designates this educational activity for a maximum of 40 category 1 credits towards the AMA Physician's Recognition Award and for the CME requirement of the APA. Each physician should claim only those credits that he/she actually spent in the educational activity. CME credit is earned on an hour-for-hour basis for most sessions on the scientific program.

Exhibits

The exhibits are an integral part of the educational program and you are encouraged to schedule daily visits to the Exhibit Hall to enjoy refreshments, win prizes, and speak with the exhibitors who offer computer software, books, pharmaceutical information, psychiatric programs, employment opportunities, medical instruments, financial services, insurance programs, lab testing, management services, and much more.

Requests for the *Exhibitor Prospectus* or inquires regarding commercial or educational exhibits should be directed to: Kevin Klipsch, Exhibits Manager, Phone: (314) 994-9640, Fax: (314) 994-9650, E-mail: kklipsch@expomanage.net.

Trainee Session

Clinical Approaches to Working With People Who Are Homeless and Have Mental Illnesses: Challenges and Rewards

Sunday, October 8, 8:30 a.m.–3:30 p.m.

Astor Ballroom, Seventh Floor, New York Marriott Marquis

Sponsored by the Center for Mental Health Services, Substance Abuse and Mental Health Services Administration; and the Department of Psychiatry, State University of New York, Downstate Medical Center

Chp.: Stephen M. Goldfinger, M.D.
Participants: Carol L.M. Caton, Ph.D., Alan D. Felix, M.D., Hunter L. McQuistion, M.D., Fred C. Osher, M.D., Ezra Susser, M.D., M.P.H., Suzanne Wagner, M.S., L.M.S.W., Andrea White, M.S.W., Van Yu, M.D.

Goals of the Session:

This training session will bring together many of the national leaders who provide mental health services to individuals who are homeless and have serious mental illnesses. The goal is to encourage more mental health professionals to work with people who are homeless with serious mental illnesses and with the organizations that provide services and support to this population. The format will include a combination of formal presentations, clinical consultations, and interactive panels; clinicians, academics, consumers, residents, and policymakers. Participants will also have the opportunity to discuss strategies with their colleagues across disciplines and gain a deeper understanding of diverse approaches to dealing with people who are homeless and have mental illnesses.

Who Should Attend?

This session focuses on orienting psychiatrists, psychiatric residents, and other human service professionals to work with individuals who are homeless with mental illnesses.

Registration:

Pre-registration is required; the registration fee is $40 before September 7, and $50 thereafter. Attendance is limited to the first 250 registrants. Non-trainees will be admitted depending on space availability. The registration fee includes continental breakfast and lunch. To register for this session, please use the registration form included in this booklet or register online at www.psych.org/IPS2006.

If you have questions, please contact Jill L. Gruber CMP, Associate Director, IPS at (703) 907-7815 or by e-mail at jgruber@psych.org.

58th Institute on Psychiatric Services

APA's Leading Educational Conference on Public and Community Psychiatry

October 5–8, 2006
New York, NY

1-888-35-PSYCH or (703) 907-7300
Advance Registration Deadline is September 7, 2006.
Register today at www.psych.org/IPS2006!

The mission of the IPS is to train and support psychiatrists to provide quality care and leadership through the study of an array of clinical innovations and services necessary to meet the needs of individuals who suffer from mental illness, substance abuse, or other assaults to their mental health due to trauma or adverse social circumstances, in order to assure optimal care and hope of recovery.

Future APA Annual Meetings

Institutes on Psychiatric Services

2007
New Orleans Marriott
New Orleans, LA
October 11–14

If you are interested in preparing a submission for the 2007 Institute on Psychiatric Services, please fill out your submission online at www.psych.org/IPS2007, beginning on September 1, 2006.

2008
Palmer House Hilton
Chicago, IL
October 2–5

Annual Meetings

2007
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May 19–24

2008
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May 3–8

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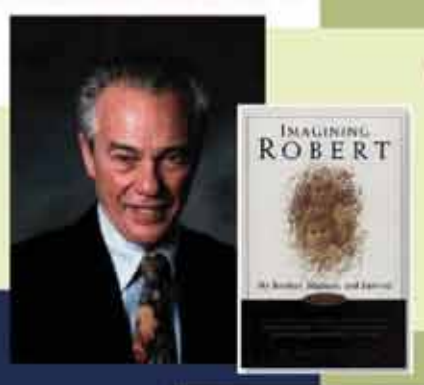


Guest Speakers including:

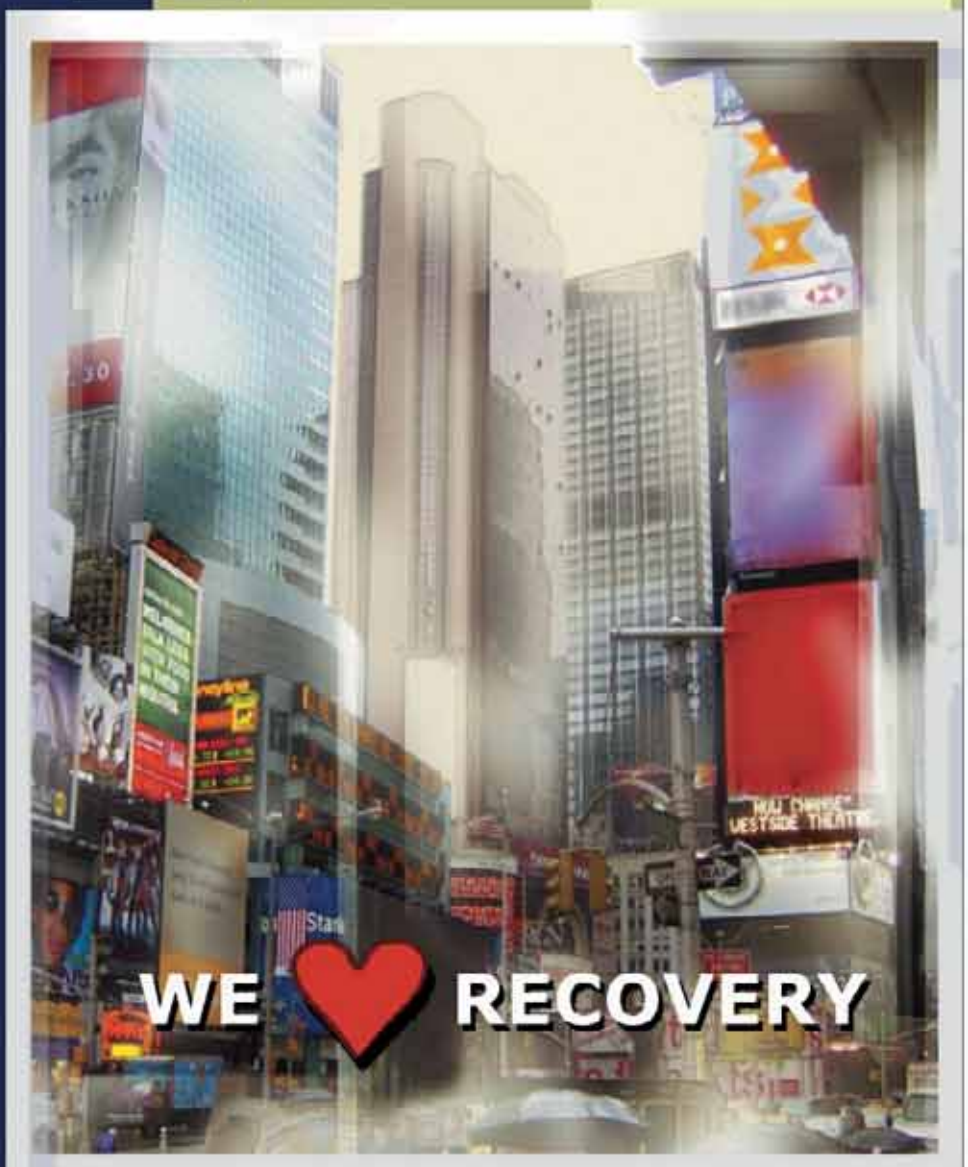
Jay Neugeboren, author of:
"Imagining Robert: My Brother, Madness, and Survival: A Memoir" & "Transforming Madness: New Lives for People Living with Mental Illness"

Presented by:

The Irwin Foundation

In collaboration with the

American Psychiatric Association's
58th Institute on Psychiatric Services
October 5-8, 2006 ■ New York, NY



What is Celebration Recovery?

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- *An opportunity to learn more about recovery from mental illness*

About The Irwin Foundation -

- *A nonprofit organization committed to education, advocacy, training, and research initiatives to advance the Recovery Vision*
- *A forum for consumers, patients, family members, advocates, psychiatrists, mental health professionals, and community stakeholders to share ideas, recognize consumer achievements, eliminate stigma, and inspire hope*

Why you should attend -

- *To support and learn about recovery, expand networks, and build coalitions*

For more information, contact: info@irwinfoundation.org
Visit our web sites at: www.irwinfoundation.org
www.celebrationrecovery.org

The Irwin Foundation receives sponsorship from a wide array of private, public, and voluntary entities.

For hotel, air travel, registration, and general information about the 58th Institute on Psychiatric Services, please call: 1-888-357-7924 or visit APA's web site: www.psych.org/IPS2006

Registration Information

Take Advantage of Advance Registration and Save

The full-time registration fee covers admission to the exhibits, including prize drawings, beverages and receptions in the exhibit hall; all scientific sessions, including Industry-Supported lunch and dinner Symposia; and other special events. The registration fee also includes the *Program Book* and *Syllabus* (for most registration categories), as well as the latest issue of the journal *Psychiatric Services*. The deadline for advance registration is September 7, 2006. After September 7, you may still register online until October 4, 2006, 11:59 p.m., eastern standard time, but the on-site fees will apply.

Three Easy Ways To Register:

***Internet:** www.psych.org/IPS2006	***Fax:** (703) 907-1097	**Mail:** Send completed registration form and payment, payable to American Psychiatric Association, to: APA Registrar, 1000 Wilson Boulevard, Suite 1825, Arlington, VA 22209-3901

*Registration by credit card only. Available 24 hours a day. Please do not mail your form afterward.

Guest Registration: Only one guest is allowed to register with each full-time registrant and cannot be an APA member. The guest must reside in the same household and be able to receive mail at the same mailing address. The "Guest" category is intended for a spouse/significant other.

Confirmation: If you do not receive registration confirmation within four weeks of mailing or faxing your form, please call the Registrar toll free at 1-888-357-7924, or 703-907-7810. You may also e-mail the Registrar at hball@psych.org.

Registration Fee Exemption Policy: IPS registration fees are waived only for:
- APA Honorary Fellows
- Medical Students (with valid I.D.)
- District Branch Executive Staff (who are not APA members)

Registration Fee Reduction Policy: If you qualify in one of the categories listed below, you cannot register online, since verification is required.

Nonmember Medical Students: Proper identification, such as a copy of your valid medical student I.D. card or letter from an instructor, must be received with your registration form to qualify for the fee exemption.

Nonmember Psychiatric Residents: A letter from an instructor or director of training, verifying your status as a psychiatric resident, must be enclosed to quality for the reduced registration fee.

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On-Site Registration: Attendees may register in the Foyer, Fifth Floor, New York Marriott Marquis, beginning on:

Thursday, October 5	7:30 a.m.–5:45 p.m.
Friday, October 6	7:30 a.m.–5:45 p.m.
Saturday, October 7	7:30 a.m.–5:45 p.m.
Sunday, October 8	7:30 a.m.–10:30 a.m.

Registration Refunds: Requests for registration refunds must be made in writing by September 21, 2006, and sent to:

APA Registrar, American Psychiatric Association,
1000 Wilson Boulevard, Suite 1825, Arlington, VA 22209-3901,
(703) 907-1097; fax: (703) 907-1097; e-mail: hball@psych.org.

Note: After September 21, 2006, no changes in registration or refunds will be granted. Written requests, postmarked by September 21, 2006, will be honored, less a $20 processing fee. Refunds for no-shows are not permitted. There will be no exceptions to the refund policy.

Travel Information

MACNAIR TRAVEL MANAGEMENT DESTINATION: EXCELLENCE

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MacNair Travel Management/American Express and the American Psychiatric Association have arranged for airfare discounts on United Airlines for those attending the 58th Institute on Psychiatric Services, October 5–8, 2006, in New York, NY.

United – 2% off some United, United Express, United code share flights (operated by US Airways, US Airways Express, or Air Canada) published fares; (7% discount if ticketed at least 30 days prior to travel), 5% off some unrestricted coach fares (10% if ticketed at least 30 days prior to travel); 10% discount is offered on full, unrestricted coach, business and first class fares, (15% if ticketed at least 30 days prior to travel). Area pricing is also offered; price is determined by your geographical location.

United Airlines 1-800-521-4041 Meeting ID Code: 550TZ

US Airways Shuttle: For attendees traveling to NYC from either Boston or Washington, DC, MacNair Travel is offering a specially discounted fare (up to 50% savings) on the US Airways Shuttle. Please check with a MacNair consultant for details.

Call MacNair Travel Management to make your travel arrangements: 1-888-662-2624 (toll free) in the U.S. or Canada.
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E-mail requests can be sent to apa@macnairtravel.com.

Be sure to identify yourself as an APA Institute on Psychiatric Services or APA IPS attendee.

Registration Form

Advance Registration Deadline: September 7, 2006

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1) Personal Information

APA Member? ☐ Yes, member # (if known) ☐☐☐☐☐☐ ☐ No

First Name ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Middle Initial ☐

Last Name ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Degree ☐☐☐☐

Address ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Address ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

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Zip Code ☐☐☐☐☐ – ☐☐☐☐ Country (if outside U.S.) ☐☐☐☐☐☐☐

Day Phone ☐☐☐ – ☐☐☐ – ☐☐☐☐ Fax ☐☐☐ – ☐☐☐ – ☐☐☐☐

E-mail _____

Nonmember Only: Are you a psychiatrist? ☐ Yes ☐ No

If you are disabled or require special services, please indicate your needs or requirements:

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Guest Registration (Only if registering for meeting; cannot be an APA member; I.D. required on-site.)

First Name ☐☐☐☐☐☐☐☐☐☐☐☐ Middle Initial ☐ Last Name ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

2) Registration Fees (*Includes Syllabus)

APA Member:	**Before 9/7/2006**	**On-site**	**Amount**
Full-Time Registration	$175	$225	$
Members-in-Training (Member Class MT)*	$60	$75	$
Daily Registration, per day (All member Categories except Medical Students)	$100	$150	$
Daily Registration – Sunday, October 8, Only	$75	$100	$
Medical Student*	$ FEE EXEMPT	$ FEE EXEMPT	$
APA Honorary Fellow*	$ FEE EXEMPT	$ FEE EXEMPT	$
Nonmember:			
Full-Time Registration*	$340	$390	$
Psychiatric Resident, Student, Public Agency Clinical Staff (Masters Level or Less), Mental Health Chaplain, or Advocacy Group Member*	$85	$100	$
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Medical Student*	$ FEE EXEMPT	$ FEE EXEMPT	$
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Full-Time Registration (APA Members and Nonmembers)*	$155	$205	$
Daily Registration, per day	$95	$155	$
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Full-Time Registration	$125	$175	$
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Trainee Session: Sunday, October 8 (see page 7 for details)	$40	$50	$

3) Payment Information

☐ Check Enclosed ☐ Visa ☐ MasterCard ☐ American Express (no other cards accepted)

Account Number ☐☐☐☐ – ☐☐☐☐ – ☐☐☐☐ – ☐☐☐☐ Expires ☐☐ (Mo.) – ☐☐ (Yr.)

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Special APA group rates will be given to Institute on Psychiatric Services attendees if reservations are made by **September 5, 2006**, by either making your reservations on the Internet, or by calling the number listed below. Upon checkout, you will be charged with ALL room nights confirmed on your reservation. If you need to cancel your reservation, you must do so 72 hours PRIOR to your reservation date. If the cancellation is received less than 72 hours prior to the reservation date, the New York Marriott Marquis will charge you for ONE night's lodging and tax. If you change your arrival date within 72 hours of your reservation, the New York Marriott Marquis reserves the right to charge you for ALL NIGHTS on your original reservation on which you will not stay in the hotel. If you fail to arrive on your confirmed arrival date, your reservation will be cancelled for ALL NIGHTS, and you will be charged for ONE night's room and tax.

All reservations are made on a space-available basis. After the cut-off date of September 5, 2006, discounted rates may not be available. The New York Marriott Marquis reserves the right to discontinue the group rate after September 5, 2006, or if the room block fills prior to this date.

Check-in is at 3:00 p.m. and check-out is at 12 noon.

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Internet Reservations: www.nymarriottmarquis.com

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Directions:

From Laguardia: Follow the Grand Central Parkway toward Manhattan/Triborough Bridge. After paying the toll stay on the left and follow signs to FDR Drive South. Exit onto 42nd Street/United Nations. Follow 42nd Street to 8th Avenue. Turn right and go to 46th Street. Turn right and the hotel will be on the right at the end of the block.

From JFK: Take the Van Wyck Expressway to Grand Central Parkway to the L.I.E. to the Midtown Tunnel. Stay right, and turn left onto East 37th Street. Turn right onto 3rd Avenue. Turn left onto 42nd Street. Follow 42nd Street to 8th Avenue. Turn right and go to 46th Street. Turn right and the hotel will be on the right at the end of the block.

From Newark: Take the New Jersey Turnpike North to the Lincoln Tunnel. Follow signs to 42nd Street. Take a left onto 8th Avenue. Turn right onto 46th Street. Hotel will be on the right at the end of the block.

AIDS

continued from page 6

themselves in the care of patients with this devastating disease.

I ministered to a patient population of young, previously healthy, productive gay men and their partners who had been blindsided by the disease without even knowing what was coming.

Within six months, about half my patients had died, leaving me bereft, financially diminished, and trying to sort out how one could tolerate doing this work with no end in sight.

I began to teach and find ways to contribute without just filling up my patient hours with people who would die. I learned from my patients and their survivors how to face a premature demise, and it has not escaped me that my partner and I soon adopted our first child in the midst of it all.

I began to make lists. One was of close friends in San Francisco, New York, Vermont, Boston, and elsewhere who had died. One was of patients I had already lost, and one was of the people we knew who were infected and might all too soon move from one list to another.

In retrospect, the first of these lists might have been titled "Dear friends for whom I have not yet had time to grieve." How many funerals should a man of my age expect to attend? How do I answer patients wanting to know if I would come to their funeral?

Were it not for patients and friends who taught me how to live in the face of death, I might have abandoned what had become a major focus of my professional life.

The words of a patient return to me as I try to capture what it felt like: "It was like standing in a beautiful field with my friends and lovers when the shooting began. All around me lay the dead, and yet I remained standing, wondering how in the midst of all this horror I had been spared. It makes no sense."

We spent a good amount of time together in psychotherapy trying to "make sense" of the insensible. Together we bore witness to preserve the memory of legions of gay men, and later all people, who had succumbed to this virus.

Today many of my patients are living longer, healthy lives. Remarkable advances in our ability to treat persons living with HIV infection have occurred in the past 25 years. Where I was once at the bedside of patients suffering from tuberculosis, pneumocystis carinii pneumonia, and candidal esophagitis and managing issues of distress and dying, I now take adavantage of the availability of viral-load monitoring and a larger palette of antiretroviral medications and see a decrease in incidence of AIDS and death from it.

But these trends are also powerful reminders for psychiatrists to continue to broaden their scope of assessment and intervention. Opportunistic infections, CNS malignancies, metabolic and electrolyte disorders, and new medications can all cause significant CNS disease and dysfunction.

However, the ominous sense of foreboding never abates, and people who became infected in recent years face more complex psychological and social issues than did the generation that preceded them. And people are still dying of AIDS, though at a slower rate.

My patients sometimes still wait, unsure about how to go forward with their lives in the face of the infection still within, though it may be shackled for the moment.

In reflection, this epidemic has brought forth the best and worst in human beings. The challenges ahead are unparalleled, with ever-new generations of young people at risk for HIV, often the most vulnerable and marginalized in our society.

In developing nations, armies of children born to parents they lose to AIDS remain unschooled, unfed, unparented, and often armed. No existing social structures can provide for the needs of these youngsters, who are left to the kindness of others or to fend for themselves.

As the 25th year of this pandemic passes, I experience the fragility of life in every moment, committing myself to doing what I can, working through those lists, believing that one might indeed heal the soul, if not the heart. ■

Inmates

continued from page 10

ity of Harris County called New Start, offenders with mental illness are mandated to receive outpatient treatment once released from jail.

In 2004, the recidivism rate for offenders who received treatment through the program was 5 percent, according to Hamilton.

"The most unsafe thing you can do is to place [people] with mental illness in prison and not treat them, and then release them to the community without linking them to treatment," he said.

Prerelease mental health services for inmates are crucial to ensure their success in the community, said Erik Roskes, M.D., director of forensic treatment at Springfield Hospital Center in Sykesville, Md., and a member of APA's Task Force on Forensic Outpatient Services.

"It's important that we realize that transition in this context is extremely difficult for many inmates and especially those with mental illness," Roskes said. However, postrelease treatment planning can also pose unique challenges, Roskes noted.

For instance, since jail inmates are usually not detained for a lengthy period and may have little notice before their release, it can be difficult to arrange community mental health services for them.

Although prison sentences are longer, and prison staff may have more time to make arrangements for postrelease mental health services, prisons are often located several hours from inmates' homes, which can present problems regarding treatment planning and access to services.

Treatment planning may include psychoeducation regarding medications, addiction, and mental illness, as well as relapse prevention, life-skills education, assertiveness training, and vocational preparation and job placement, Roskes said.

In addition, the days and weeks preceding release can provoke anxiety about being accepted back in the community, he noted. Parole officers and clinicians should be aware that although stress levels may level off after release, they may increase again after "a few months, once they realize it's not so easy being on the outside."

It is vital that forensic psychiatrists "honestly believe that [offenders with mental illness] can and do recover and change their lives, and we can help them do that," Roskes emphasized.

Cassandra Newkirk, M.D., noted that it is also important for corrections staff and case managers in particular to note that after spending 30 days in jail or prison, Medicare and Medicaid benefits stop. This can be especially problematic for people who bounce in and out of jail for short periods of time.

Newkirk is director of mental health services for GeoCare Inc., a Boca Raton, Fla., company that provides mental health services to people in jails and prisons, and a member of APA's Committee on Jails and Prisons.

"We must advocate for court diversion so that people with serious mental illness never get into the correctional system to begin with," she stated. ■

Child Psychiatry

continued from page 4

Preliminary congressional budget proposals for Fiscal 2007 have slightly increased funding by $3 million to $300 million for the Children's Hospital Graduate Medical Education payment program, which pays for child and adolescent psychiatrists to train in hospitals. The Child Health Care Crisis Relief Act has been languishing in the House and Senate for several years. It proposes a loan-forgiveness program for child psychiatrists and mental health professionals who agree to work with seriously ill patients, are from racial or ethnic minority groups, or live in underserved areas. It is unlikely to pass soon, according to APA's Department of Government Relations.

In the meantime, AACAP is seeking to ease the shortage of child and adolescent psychiatrists by using telepsychiatry to reach rural areas, integrating services with psychologists and social workers, and increasing cooperation with pediatricians and other primary care physicians. AACAP will hold a four-day institute on child psychiatry for pediatricians at its annual meeting in San Diego in October, said Anders.

"We have to reconsider child mental health services overall," said Thomas. "It will take time to increase our workforce, but we still have an obligation to provide the best services to our patients."

"The Continuing Shortage of Child and Adolescent Psychiatrists" can be accessed at <www.jaacap.com> by clicking on "Online Advance Publication" and then the title of the study. ■

Prescribing

continued from page 8

ing milligrams when the drug strength should have been written as micrograms or misspelling a drug name.

"Decision-making errors" most frequently involved the "prescribing of a dose regimen that is not recommended for the drug/formulation prescribed" (9.8 percent of all prescriptions). Other errors were categorized as involving prescribing a drug for a longer period than recommended or approved (2.7 percent) or prescribing two drugs for the same indication (1.9 percent). Dosages below the recommended effective dose range for a patient's condition were somewhat less common (1.7 percent), as was the failure by the prescriber to consider a potentially significant drug interaction (1.1 percent).

The majority of patients receiving a prescription containing an error were inpatients (83.4 percent) and were between the ages of 18 and 64 (69.2 percent). In 280 of the 523 errors (53.5 percent of prescription errors), the medication was administered to the patient before the error was identified.

Fortunately, the majority of the errors identified in the study were grade 1 (47.8 percent) or grade 2 (45.9 percent). Only 17 errors (3.3 percent) were classified as grade 3 or grade 4. Most of these 17 errors involved the prescribing of high doses of single drugs or of multiple drugs that when taken together could result in serious central nervous system depression, potentially precipitating respiratory failure.

Overall, Taylor and his colleagues concluded, "pharmacy staff detected on average one prescribing error for every 42 prescriptions checked." Over three-fourths of the errors amounted to "slips of the pen," that is, were a prescription writing error. Thankfully, they noted, "most errors were of doubtful or minor importance, but "1 in 33 errors was deemed likely to result in serious effects or death."

"Prescription Error in Psychiatry: A Multi-Center Study" is posted online at <http://jop.sagepub.com/cgi/content/abstract/20/4/553>. ■

Cancer

continued from page 5

seek immediate care. Within days of seeing a primary care doctor, she saw a surgeon and was scheduled for a CT scan and biopsy.

"I felt as if I got Cadillac care because I was a doctor," Schlesinger said.

As it was with Wohlreich, waiting for the biopsy results was the most difficult time for Schlesinger. "Once I heard from the surgeon that I had cancer, I was scared. I associated it with death," she said.

She noted that "blame is unavoidable" when presented with a diagnosis of cancer.

"I blamed myself," she said. Perhaps she had burned one too many food items, or there was something else in her environment that caused her cancer, she remembered thinking.

"To this day I still wonder, 'Did I do something that resulted in me having cancer?' " Schlesinger said.

When she found out that she had lymphoma, she was relieved because she knew someone who had survived the disease, and she had read favorable statistics associated with lymphoma. "Not all cancer equals death," she noted.

Schlesinger also benefited from strong support. "My family accompanied me to a lot of my treatments," she said.

On the job, she spent time with her supervisor discussing her limitations. "Did I think I could work with suicidal patients? Did I have enough energy to complete all of my work?" she asked.

But in addition to facing her limitations, Schlesinger also noted that her diagnosis and treatment gave her a profound awareness of her strengths. "I knew what I could do no matter how I was feeling," she stated. ■

Funding

continued from page 1

tive, the Drug Effectiveness Review Project (DERP), conducts regular systematic reviews of evidence of the comparative performance of drugs within leading therapeutic classes. DERP is sponsored by a group of 15 state governments and two private health care groups; it evaluates competing drugs but does not make recommendations for drug coverage. Such reviews could be more effective, Morgan said, if their results were incorporated into the drug-appraisal process and the coverage policies of major private and public prescription plans.

Transparency Missing in U.S.

At the heart of such reviews in other countries is an attempt to create transparency in the price-setting process. Critics of the U.S. drug market in general, and Part D in particular, say there is little publicly available information to explain why particular drugs are sold at particular prices by their manufacturers.

In a response to the international experts, Mark Hayes, Republican health policy director for the Senate Finance Committee, pointed out that several transparency provisions were in the Senate-passed version of the legislation that created the drug benefit but were stripped out after opposition from the House.

"There is tremendous amount of opposition to this from the drug industry," said Cybele Bjorklund, Democratic staff director of the House Ways and Means Committee.

National Formularies Weighed

Although Australia and New Zealand use national formularies, the approach varies in other industrialized nations. England uses a negative formulary of drugs that the government drug program will not cover, while Canada has many local drug formularies.

National prescription-drug plans in much of Europe have added so-called demand-side efforts in recent years to encourage physicians and pharmacists to help control prices through measures such as increased use of generic drugs. Such efforts have had limited success because Europeans have been reluctant to adopt them, said Panos Kanavos, Ph.D., a research fellow at the London School of Economics and Political Science.

Proponents of a national drug formulary created by the federal government cite data that U.S. drug costs are among the world's highest, but those claims were questioned by several researchers. Such price comparisons, Kanavos said, usually omit a range of discounts that manufacturers offer to U.S. insurers that purchase in large volume.

"The United States has done a better job of keeping a discount in the system," Kanavos said.

Critics of the Part D program have urged that the national formulary used by the Department of Veterans Affairs (VA) be applied to Medicare. A Families USA review compared Part D drug prices with prices negotiated by the VA and found that every drug compared was less expensive in the VA system, with a median price difference of 46 percent.

The Families USA report, said Hayes, does not account for the fact that the VA system achieves lower prices by mandating a mail-order system, while Part D participants can use local pharmacies. In addition, drugs not covered under the VA plan are simply unavailable, whereas Part D recipients can switch to a plan that will cover a drug they need.

A recent proposal by congressional Democrats would change the Medicare Part D program so that one drug-plan option would be administered by the federal government. That change would allow the government to negotiate drug prices on behalf of Medicare recipients. Democrats argue that such an approach would allow the government to get better prices because it could buy on a massive scale.

Such a change would mimic, in part, the drug systems of Australia and New Zealand, where the government plans fund virtually all medicines and give the governments "significant buying power. . . to negotiate acceptable pricing with suppliers," Morgan said.

The U.S. drug benefit depends on market forces to drive down prices through the competition of a large number of insurers to gather the most Medicare beneficiaries into their plans.

More information on international efforts to provide drug benefits is posted at <www.allhealth.org/event_062306.asp>. ■

VA

continued from page 1

Version (PSS-I), can complement clinical interviews.

While some of these interviews might take time to administer, they can provide indications of presence and severity of symptoms.

Time Shouldn't Be Concern

"If you're making judgments with major treatment and compensation implications, time shouldn't be an issue," said Regier.

Self-report instruments of war-related stress may help the clinician elicit greater detail about trauma exposure than an initial interview would, said the report, but "they should not substitute for a comprehensive diagnostic interview."

The VA uses the same four-question screening test for PTSD as the Department of Defense. It also uses a number of other instruments to evaluate symptoms and treatment response but has no system-wide convention for choosing them.

No biomarkers currently have sufficient sensitivity and specificity to be useful for diagnosing PTSD, noted the IOM committee, in response to a question from the VA. Neuropsychiatric tests might help validate subjective reports, but they were less useful diagnostically because results might characterize other psychiatric disorders as well.

The IOM also noted that PTSD was a true disorder because it met standards for validity, having distinct clinical features that had been consistently documented in a variety of settings and cultures, longitudinal stability, and some evidence that genetic factors accounted for about one-third of PTSD symptoms.

Disability Claims Questioned

At committee hearings in February, several speakers suggested that many veterans applying for disability compensation for PTSD through the VA were not suffering from the disorder, but looking for a government pension. Clinicians should be aware of the potential for malingering and should consider discrepancies in the patient's reports, lack of cooperation in evaluation or treatment, and evidence of antisocial personality disorder in their evaluation, said the committee, echoing APA recommendations.

"Part of the reason for asking that clinically well-trained people evaluate patients is to avoid overdiagnosing people faking PTSD," said Regier. Several psychometric tests, like the MMPI-2 or the Impact of Event Scale–Revised, do a good job of detecting fakery, he added. Other speakers at the February hearings presented evidence that there were few instances of malingering among Vietnam War veterans studied. Although the impetus for the IOM report arose from concern about veterans of earlier wars, Katz said that about 30 percent of returning veterans of Iraq and Afghanistan come to the VA for medical care. Of those, 33 percent have mental health concerns, and 15 percent of that group have at least some symptoms of PTSD.

Nothing specific in the report should cause the VA to change its approach to diagnosing PTSD, but the department is continually seeking to improve its services, said Katz. "The issue isn't business as usual, but enhancement as usual," he said. "The VA views the best diagnosis as an evolving process, guided by empirical-research evidence and accumulating evidence."

The IOM report also did not presage any developments for PTSD criteria that might appear in *DSM-V*, said Regier. Research over the next several years may generate new information that could confirm present standards or guide new ones, he said.

"Posttraumatic Stress Disorder: Diagnosis and Assessment" is posted at <www.nap.edu/catalog/11674.html#toc>. ■

clinical & research news

Patterns

continued from page 16

atypicals"—that were prescribed off-label. Just over 50 percent of prescriptions were for olanzapine (Zyprexa) (the most expensive psychotropic medication during 2001) were off-label, while over 65 percent of prescriptions for risperidone (Risperdal) were off-label (see chart on page 16). Chen and her colleagues were surprised to find that those aged 65 and older were 5.2 times more likely to be dispensed an off-label antipsychotic prescription than those under the age of 65. Other factors associated with off-label prescribing of antipsychotics included being white (odds ratio 1.9). Several nonpsychotic disorders were associated with increased odds of being prescribed an off-label antipsychotic, including cyclothymic disorders (odds ratio 3.9), mental retardation (odds ratio 2.5), major depressive disorder (odds ratio 2.1), Alzheimer's disease (odds ratio 2.1), and paralysis (odds ratio 2.2).

"We aren't really able to say whether the off-label uses documented in our study were appropriate or not," Chen said. "Off-label scripts are commonly written to control certain symptoms, for example, using antipsychotics or anticonvulsants to manage aggressiveness," Chen explained. *ICD-9-CM* coding, however, "was designed mainly for identifying diseases, rather than symptoms, and most symptoms may not be coded for billing purposes."

Some generalizations can be made, Chen said. It would be generally inappropriate, she said, to use a mood stabilizer as monotherapy for a patient with schizophrenia or an atypical antidepressant as monotherapy for a patient with nonpsychotic depression. Yet many of the trends noted appear to be plausibly appropriate, such as using anticonvulsants for patients with pain disorders or using antipsychotics for youth with more severe behavioral disorders such as attention-deficity/hyperactivity disorder with conduct disorder or intermittent explosive disorder.

Chen told *Psychiatric News* that the study findings "can be generalized to almost all Medicaid populations. Although there are minor differences in benefit designs across Medicaid plans, they all have relatively comprehensive coverage on psychotropic medications, and pharmacy benefit management tools have not been extensively used to control psychotropic drug costs in Medicaid, according to a recent study published on *Health Affairs*.

But the findings are not generalizable to the general population, she noted. "The prevalence of off-label prescribing estimated from our study is slightly higher than the estimates derived from the general population because Medicaid plans tend to have a more generous coverage than commercial insurance on psychotropic medications, especially on antipsychotic drugs, and Medicaid covers a majority patients with severe mental disorders."

"Off-Label Use of Antidepressant, Anticonvulsant, and Antipsychotic Medications Among Georgia Medicaid Enrollees in 2001" is posted at <www.psychiatrist.com/abstracts/200606/060615.htm>. ■

community news

Urban Renewal

continued from page 13

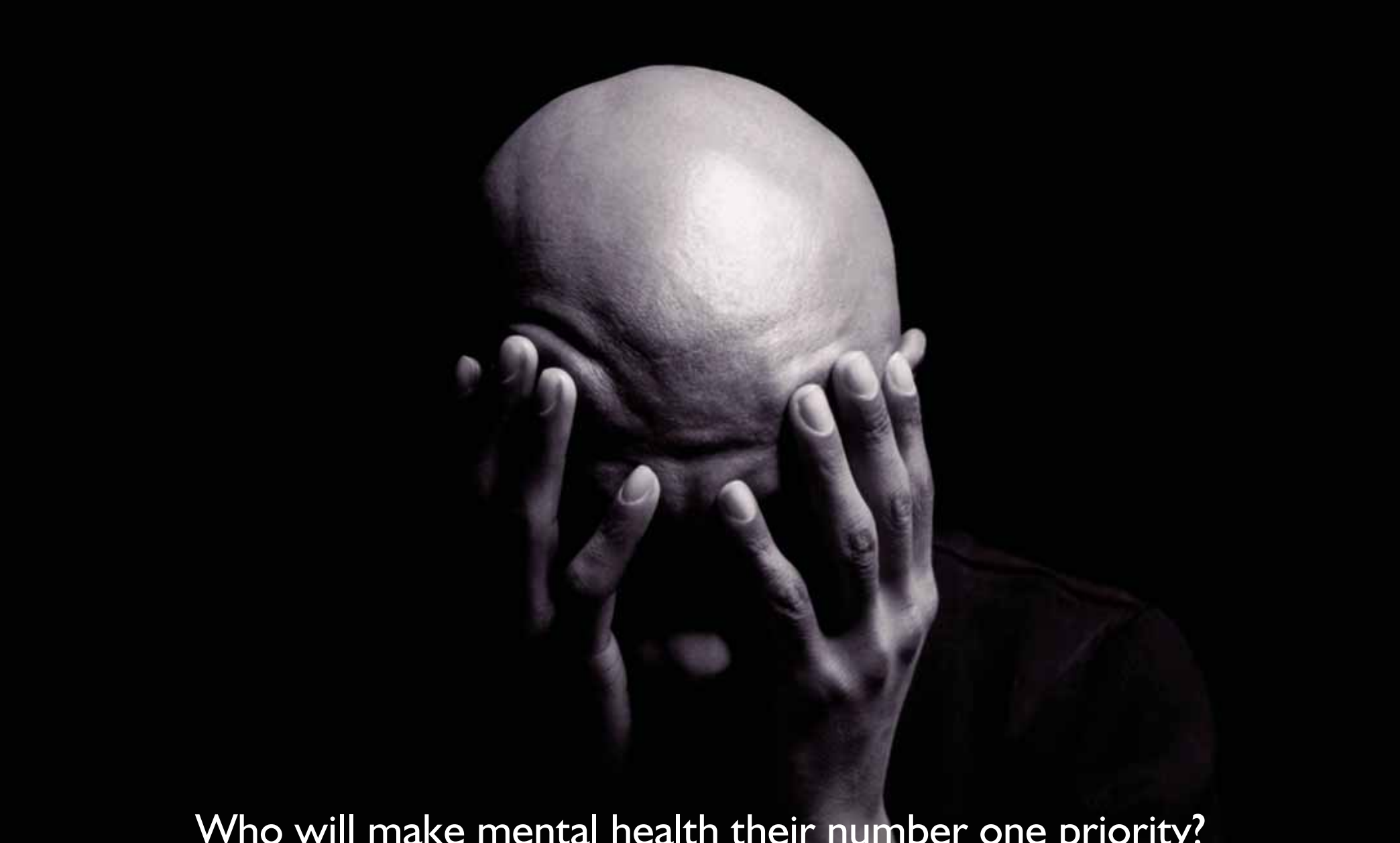
tion, citing a report in the May 3 *Journal of the American Medical Association (JAMA)* showing that middle-aged white people in America have worse health overall than white people of the same age in England, despite much higher health care spending here.

In the categories of diabetes, blood pressure, and cancer, England's poorest citizens—those in the lowest one-third of income levels—did better than the richest one-third of Americans.

Importantly, as the state of social organization changes, individuals within the society adopt new, more aggressive behaviors to fend for themselves. She cited Geoffrey Canada's 1996 book *Fist, Stick, Knife, Gun*, which showed the downward spiral of urban violence from fistfighting to guns.

"The change in the state of organization has made the gun not optional," she said. "In a state where everyone has a gun, everyone has to have a gun. The tragic part of this decline in social relationships is that it takes much more aggressive behavior to take care of yourself. In a well-organized community, there are established ways of sharing. In a disintegrated community, you have to fight with someone else."

An abstract of "Disease and Disadvantage in the United States and England" is posted at <http://jama.ama-assn.org/cgi/content/abstract/295/17/2037>. ■



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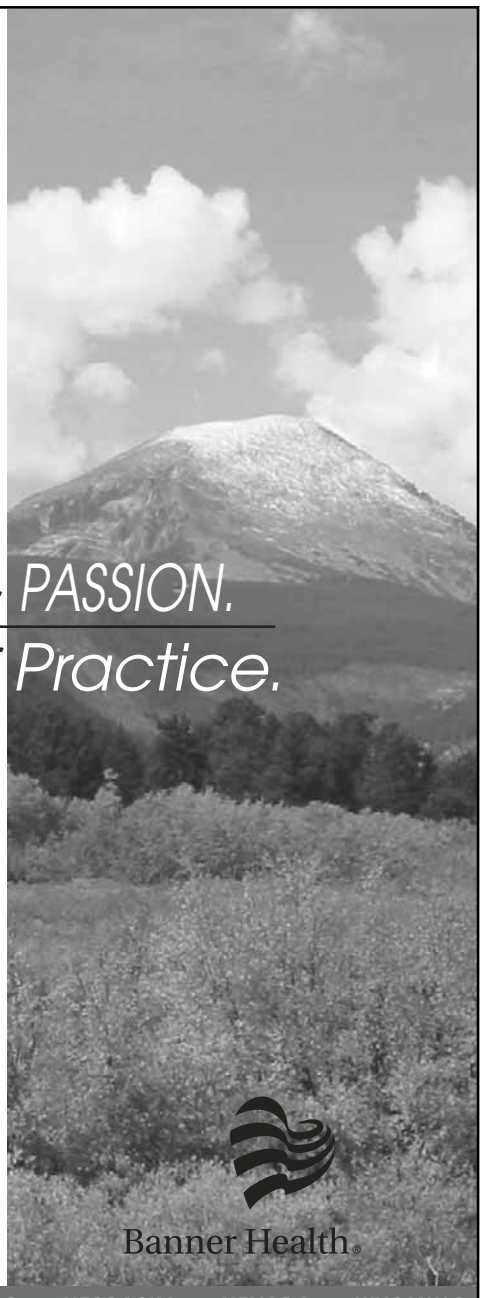

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Please contact:
Phone: 303-344-7838
E-Mail: eileen.t.jones-charlett@kp.org
Fax: 303-344-7818

ADULT/FAMILY BILINGUAL PSYCHIATRIST - DENVER

Come to the Mile High City, where you can wake up to the golden sun glistening lightly on the snow-capped Rockies. Where the city life offers the convenience of the arts, shopping, and sports. Be a part of our progressive community mental health center with a comprehensive array of services.

The Mental Health Center of Denver is seeking a bilingual Spanish/English Psychiatrist to work in our El Centro de las Familias center to provide culturally competent psychiatric services to adults, children, and families who are mono-lingual Spanish speakers. This team is located in W. Denver, in the heart of Denver's Hispanic community and close to the mountains. Work on a team of all bilingual staff: social workers, case managers, psychiatrists, admin., and nurse to provide well coordinated care plans. This position may be part-time or full-time - 20-40 hours depending on candidate. Candidates interested in full-time would work half-time at El Centro and half-time on our geriatrics team. For more information contact:

Erich WonSavage, (303) 504-6517
Human Resources, MHCD
www.mhcd.org - Fax: (303) 758-5793
Email: resumes@mhcd.org

MHCD
Enriching Lives and Minds

CONNECTICUT

Full time position in Dual Diagnosis

Department of Psychiatry, Yale School of Medicine, is recruiting a Staff Psychiatrist for Yale-New Haven Psychiatric Hospital (Y-NHPH), Yale-New Haven Hospital (Y-NHH). Will work primarily in a dual diagnosis inpatient unit, and secondarily assuming psychiatric liaison duties in a primary care clinic as well as consultation/liaison duties. MD degree and fellowship training in consultation/liaison psychiatry and addiction psychiatry are required. Well developed clinical skills in general, consultation-liaison, and addiction psychiatry are essential. Demonstrated clinical teaching skills required as well. A clinical research background is desired. Must be board eligible in general psychiatry and psychosomatic medicine. Position carries academic appointment as Assistant Professor of Psychiatry. Please send CV and 3 letters of recommendation no later than July 1, 2006 to: William H. Sledge, MD, George D and Esther S. Gross Professor of Psychiatry, 184 Liberty St, New Haven, CT 06519. Yale University is an equal opportunity, affirmative action employer. Applications from women and minority group members are invited.

LEDYARD: Southeast CT - General or Child Psychiatrist - clinical care to patients in acute, residential & partial setting. Salary & benefits. Position offers opportunity for administrative title & responsibilities for interested/qualified candidates. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

Associate Medical Director
New England Area

Nationally known as one of the MOST BEAUTIFUL residential communities in America! Located in the picturesque northwest corner of Connecticut. An **Associate Medical Director** is needed for a 12-Bed Geriatric inpatient psychiatric program. Behavioral health program is part of state-of-the-art 78-bed Medical Center serving CT, MA, and NY. The best that modern medicine has to offer with a 92 year history of community service. Lucrative private practice potential. Exceptional prep schools, parks, and recreation. Enjoy all the charms of New England! Contact Mark Blakeney, Horizon Health, 800-935-0099, email CV to mark.blakeney@horizonhealth.com, fax: 972-420-8233. EOE

GENERAL PSYCHIATRY—
CENTRAL CONNECTICUT

Opportunity for BC/BE psychiatrist to join well established two-person successful adult psychiatric private practice. Practice is affiliated with Bristol Hospital, a leading community hospital offering a comprehensive mental health continuum, including both inpatient and outpatient settings. Our central Connecticut location offers a wide range of upscale suburban living options, including first-rate schools, many desirable cultural activities, and easy accessibility to NY and Boston. We offer a benefits package and salary. To learn more about this opportunity, call toll-free, Christine Bourbeau in the recruitment office at 800-892-3846 or fax your CV to 860-585-3086. EOE. Email address: **cbourbeau@brishosp.chime.org**

DELAWARE

NEWARK/WILMINGTON: General Psychiatrist. Fulltime position for inpatient & partial hospital program. Willing to consider part-time if M-F schedule. Salary & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

DISTRICT OF COLUMBIA

The Department of Psychiatry and Behavioral Sciences at the GWU Medical Faculty Associates, an independent non-profit clinical practice affiliated with the George Washington University, is seeking a psychiatrist for a full-time academic appointment. This position will include: 1) oversight of an acute admissions team with psychiatry residents and medical students on the psychiatric unit in the GWU Hospital; 2) outpatient clinical work; and, 3) opportunities for additional medical student and resident education and clinical research. The applicant must be license eligible in the District of Columbia and Board Certified or Board Eligible in General Psychiatry. Academic rank and salary will be commensurate with qualifications. Review of applications begins on August 21, 2006 and will continue until the position is filled. Please send letter of interest and CV to Jeffrey S. Akman, MD, Chair, Department of Psychiatry and Behavioral Sciences, 2150 Pennsylvania Avenue, NW, Washington, DC 20037. Tel. 202-741-2880; fax 202-741-2891. The GWU Medical Faculty Associates is an Equal Opportunity/Affirmative Action Employer.

FLORIDA

Kick back and relax in the Florida sunshine! Sandy white beaches and tropical drinks! Premier psychiatric group practice has 2 exceptional needs! 1) Child and Adolescent Need - 100% OUTPATIENT 2) Adult Need - 100% OUTPATIENT with C/L opportunity to make over **$200,000/year!** For more info, contact Carrley Ward at 800-735-8261 x 219, fax your CV to 703-995-0647 or email: cward@medsourceconsultants.com

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Boca Raton Prestigious/Upscale Psychiatric Group in sunny seaside resort town seeks psychiatrist. Outpatient Practice. Partnership track in a friendly and collegial work environment. Must have Fl. license prior to hire. Fax Resume to 561 392 9170 or e-mail brpg7284@lycos.com

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Located along South Florida's east coast just minutes from the Atlantic Ocean, CARF accredited community mental health center is seeking a part-time/full-time inpatient and outpatient psychiatrists to provide comprehensive psychiatric care to children and adults. Must be Board Certified (or eligible). Excellent salary and benefits package, great staff and a lovely coastal community. Seeking applications directly from candidates. (No recruitment firms please!) Send/Fax CV: HR, New Horizons, 4500 W. Midway Rd., Ft. Pierce, FL 34981 FAX (772) 468-5606 EOE/ADA/DFWP www.nhtcinc.org

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FT. MYERS/MERBOURNE/ORLANDO/DAYTONA/MIAMI/FORT LAUDERDALE/OCALA/GAINESVILLE - Psychiatrists needed for rapidly expanding Nursing Home Service. Great support. No call. Average Salary 210K + benefits. Part-time available. Some travel required. Must have FL Medicare & FL Medicaid provider #s. Call Mike at 866-936-5250.

PANAMA CITY - Adult board certified or board eligible psychiatrist to join staff of comprehensive community mental health center. Salary range is: $176,000 - $183,000. Beautiful area of the country. Apply through our website www.lifemanagementcenter.org or send CV to: **Peter Hampton, Ph.D., Executive Director, Life Management Center of Northwest Florida, 525 E. 15th St., Panama City FL 32405**, EOE/DFWP. Pre-hire drug screen required.

The University of South Florida, Department of Psychiatry & Behavioral Medicine seeks an Associate Professor. This position will serve as Medical Director of USF Psychiatric Services at Tampa General Hospital, being responsible for the management of the Consultation Liaison Psychiatry program. Applicants should possess a Doctorate of Medicine. **Florida license and Board Certification in General Psychiatry is required. Additional subspecialty Board Certification in Psychosomatic Medicine is preferred**. For consideration at the rank of Associate Professor the candidate must have five years of experience at the Assistant Professor rank or equivalent. Interested individuals should forward a current CV and five letters of recommendation to: Jack Zak, M.D. Chair, Search Committee, 3515 E. Fletcher Avenue, Tampa, Florida 33613. Inquiries may be made by phone: (813)974-4657 Fax: (813)974-2478 or email: mtavrell@hsc.usf.edu. This position is open until filled and application review begins September, 2006.

USF Health is committed to increasing its diversity and will give individual consideration to qualified applicants for this position with experience in ethnically diverse settings, who possess varied language skills, or who have a record of providing medical care to underserved or economically challenged communities. The University of South Florida is an EO/EA/AA Employer. For disability accommodations, contact Maureen Tavrell at (813)974-4657 a minimum of five working days in advance. According to FL law, applications and meetings regarding them are open to the public.

Miami: FL LICENSED PSYCHIATRIST; active private practice; affluent area; hosp, office, snf settings; excellent incentive plan incl salary & benefits. Dr. Carter, S. FL Psychiatric Assoc. 305-935-6060. FAX CV to 305-935-1717 or EMAIL: aventuraoffices@bellsouth.net.

GEORGIA

HORIZON HEALTH
Medical Director Needed
1 hour south of MACON, GA

Horizon Health seeks outstanding Medical Director for a 15-bed adult behavioral health program located within 99-bed hospital. Enjoy all the benefits of beautiful Georgia, a state rich in history, charm and southern hospitality. Excellent practice opportunity with solid support from hospital and staff. Stipend or Employment available. Please contact Diane Odom for more information 800-935-0099 or e-mail diane.odom@horizonhealth.com EOE

WellStar Health System is seeking a Clinical Liaison Adult Psychiatrist to join an established and growing practice located in Marietta, GA. This position would consist of both inpatient and outpatient psychiatry/liaison work. WellStar offers a competitive compensation and benefits package. Please send CV to provider. positions@wellstar.org or fax to 770-792-1738. EOE.

BE/BC General Psychiatrist to join an expanding out-patient practice in St. Marys, GA, home of the Kings Bay Naval Base, a suburb of Jacksonville, FL, and listed in US News and World Report as one of the ten best retirement communities in the U.S.

Interested parties should send their CV to Bryan Warren, M.D., 235 Cardinal Circle West, St. Marys, GA, 31558.

ATLANTA: Medical Director - administrative & direct clinical care duties. Psychiatric, addiction, & dual diagnoses programs for adolescents & adults. Salary & benefits offered. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

ILLINOIS

PSYCHIATRIST NEEDED!

A well established and very busy private practice, located in the Chicago area is looking to hire a full time or part time psychiatrist. Work includes hospitals, outpatients and nursing homes. Compensation package is very attractive and negotiable. For more information please call Kathy at our office between 8am and 4pm 1-312-565-2251.

Greater Chicagoland area! Local group practice is looking for dedicated **Child & Adult** psychiatrists to work mostly **OUTPATIENT!** Highly lucrative opportunity with *competitive salary, full benefits, loan repayment, & possible sign on & relocation packages!* Partnership opportunities available as well! For more info, contact Ariana Sanjabi @ 800-735-8261 x 214, fax your CV to 703-995-0647 or email: asanjabi@medsourceconsultants.com

INDIANA

Join hospital staff in culturally-rich university town voted by *USA Today* as one of the eight most desirable places to live in the US, based on economy, climate, housing, safety and leisure activities. Enjoy a very strong salary with full benefits. Contact Jim Ault at St. John Associates, 1-800-737-2001 or **jault@stjohnjobs.com**. Visit our website at **www.stjohnjobs.com**

IOWA

The North Central Iowa Mental Health Center is accepting applications for a General Psychiatrist. The Center is located on the grounds of Trinity Regional Medical Center. The doctor will treat patients on the inpatient and partial hospitalization units at Trinity Regional as well as providing out patient services. The Center also has an Assertive Community Treatment team. The Center serves an area of 120,000 people and treats about 3500 patients per year. Compensation is based on salary plus productivity bonus. Will consider applicants with J-1 Visas. Please send cover letter, CV and references to:

Jim Burr, CEO
North Central Iowa Mental Health Center
720 Kenyon Road
Fort Dodge, IA 50501
jimburr4759@hotmail.com

KANSAS

Osawatomie State Hospital (OSH) is seeking a full time board certified/board eligible **Psychiatrist** to join its in-patient staff. OSH is a JCAHO accredited 176 bed psychiatric facility which serves the adult population. Programs consist of a crisis stabilization unit, acute care units, and a continuing care unit. The hospital is adjacent to a major highway, which combines a friendly rural setting and easy access to a large metropolitan area. Generous benefits package include paid malpractice insurance, paid holidays, vacation and sick leave, medical and dental insurance, retirement plan, opportunities for CME. For more information, contact M. Gustilo, M.D. at 913-755-7083, e-mail to Merma@osh.ks.gov or send CV to Osawatomie State Hospital, Attn: Dr. Gustilo, P.O. Box 500, Osawatomie, KS 66064. SRS is an Equal Opportunity Employer committed to a diverse workforce; women, minorities and persons with disabilities are urged to apply. Paid for by Osawatomie State Hospital.

Spanish Speaking (bilingual) Child, Adolescent, and Adult Psychiatrist

Johnson County Mental Health Center (located in a suburb of Kansas City) is seeking a full-time/part-time Child, Adolescent, and Adult Psychiatrist who is fluent in Spanish. Requires a medical degree; (M.D. or D.O.); successful completion of an ACGME accredited Child and Adolescent Psychiatry Residency Program & must be eligible for licensure to practice in KS. Must have board eligibility or certification through ABPN; compensation commensurate with experience. Interested applicants should contact: Dr. Jane Lauchland, Johnson County Mental Health Center, 6000 Lamar, Suite 130, Mission, KS 66202; 913-831-2550; FAX to 913-826-1594; Jane.Lauchland@jocogov.org. EOE M/F/D.

LOUISIANA

PSYCHIATRIST
MEDICAL DIRECTOR

Central Louisiana State Hospital, Pineville, LA, seeks Medical Director for 132 patient psychiatric hospital. Campus housing available. Community of approximately 50,000 including two colleges, music and arts, good schools, sports. Full medical benefits, retirement, generous sick and vacation leave, and tax-sheltered savings plan. Salary depends on experience and credentials. EOE. For other information call Ann Hall, HR Manager 318-484-6321; fax 318-484-6345; ahall@dhh.la.gov.

Two psychiatrists
Public Health Psychiatry

Outstanding opportunities for psychiatrists to be integral to the renewal and growth of adult mental health service delivery and research in New Orleans and South Louisiana at the LSU Health Sciences Center New Orleans Department of Psychiatry. Successful applicants will direct and implement new community -based programs and will be actively encouraged to design and supervise related clinical research. The positions carry a full-time academic appointment with rank appropriate to the individual's academic background, and also offer major opportunities for teaching and as well as best-practice research in undergraduate and post-graduate instruction. Position responsibilities will vary according to skills and interests of the individual. Salary is competitive and negotiable depending on qualifications and experience. LSUHSC is an equal opportunity, affirmative-action employer. Contact: Howard J. Osofsky, M.D., Ph.D., Head, Department of Psychiatry, LSU Health Sciences Center in New Orleans, PO Box 1287, Metairie, LA 70004-1287, (504) 568-6004.

Medical Directorship role for an Adult/Geri Psychiatrist! J1-Visa Sponsor! Clinical role is for mostly inpatient w/light call. Great program-building initiatives. Bonus plan + private practice OK. Salary to $170k + bene. Call Dave Featherston @ 800-575-2880 x 314 dfeatherston@medsourceconsultants.com

2 CHILD PSYCHIATRISTS

Outstanding opportunities for child psychiatrists to be integral to the renewal and growth of mental health service delivery and research in New Orleans and South Louisiana at the LSU Health Sciences Center Department of Psychiatry. Successful candidates will help lead the expansion of clinical, teaching and research programs. A successful applicant will need Board Certification with a Certificate of Added Qualifications in Child Psychiatry. A demonstrated record of academic productivity, teaching, clinical and administrative experience is desirable. Salary and rank are commensurate with experience. The positions involve direct clinical responsibilities and local travel. All positions can be tailored to individual interests for either clinical-track or tenure-track appointments. Relocation expenses and University benefits are supplied. New Orleans remains one of the most exotic cities in the United States providing stimulating work and cultural advantages. Send CV and reference to: Martin Drell, M.D. Child Psychiatry Division, Department of Psychiatry, LSU School of Medicine, P.O. Box 1287, Metairie, LA. 70004-1287, (504) 568-6004.

Southwest Louisiana area seeks BE/BC psychiatrist for community mental health centers located in Allen and Beauregard Parishes. Generous compensation and benefits package. Please send your CV and supporting documents to the following address:

Lake Charles Mental Health Center
Attn: Laura Lyles
4105 Kirkman Street
Lake Charles, LA 70607
Telephone: (337) 475-8725
Fax: (337) 475-8054
E-mail: lalyles@dhh.la.gov

MAINE

Dartmouth Faculty Psychiatrists

Dartmouth Medical School, Department of Psychiatry, in collaboration with the State of Maine Department of Health and Human Services, seeks faculty psychiatrists for the Riverview Psychiatric Center in Augusta, Maine. The Center is the flagship inpatient hospital serving central and southern Maine's system of public mental health care. A 92-bed, state of the art, replacement hospital opened in the Spring of 2004. Preference will be given to candidates with forensic training and/or experience. Maine licensure required. These are full-time Dartmouth faculty appointments with salary and rank commensurate with experience and academic accomplishments. Protected time for scholarly activities. Central and southern Maine offers exceptional opportunities to enhance your quality of life. We have safe communities, with very low crime, good schools and unparalleled four season recreational activities. Augusta is less than one hour from the Maine coast and closer to numerous crystal clear lakes and mountains. It is no wonder Maine is called "vacationland." Please send CV and three letters of reference to: **Alan I. Green, MD, Professor and Chair of Psychiatry, Dartmouth Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756**. Dartmouth Medical School is an EOE/AA Employer and encourages applications from women and members of minority groups.

Maine's First Magnet Hospital and the World's First Free-Standing Psychiatric Magnet Hospital Seeking Adult and Child/Adolescent Psychiatrists

We are seeking BC/BE psychiatrists for both our adult and child/adolescent inpatient and outpatient programs. Acadia Hospital is a thriving, non-profit, private community-based hospital offering acute psychiatric care for adults and children, as well as chemical dependency programs. One of the only two private psychiatric hospitals in Maine. The Acadia Hospital offers physicians clinical practice in a highly collaborative, multi-disciplinary setting. Competitive salary and benefit package. Send resume to: Vice President of Medical Affairs, The Acadia Hospital, P.O. Box 422, Bangor ME 04402-0422.
www.acadiahospital.org

SOUTHERN MAINE

How would you like to be valued as part of a professional team for one of Southern Maine's largest mental health and community service based agencies where there is a strong commitment to staff, clients, and their agency mission?

Counseling Services, Inc. is a comprehensive and integrated community mental health center serving adults and children with serious mental health and substance abuse problems. Our programs include Complementary Therapies, Child and Family Primary Care Services, Adult and Family Primary Care Services, Primary Care Support Services, Psychiatric Services, Assessment Referral and Treatment, and Crisis Response Services.

We are currently recruiting for full-time, part-time, or contracted adult and child psychiatrists. The positions will involve direct patient care at our community mental health centers in Southern Maine. The physician will work with a multidisciplinary team providing outpatient services to a variety of programs.

We offer a generous time-off program, a comprehensive medical, dental and life insurance benefit, and other attractive incentives.

If you are aware of a qualified individual who would want to explore these exciting opportunities, please contact the Human Resources Department at 207-294-7104. A resume and cover letter may be sent to: Counseling Services, Inc., P.O. Box 1010, Saco, Maine 04072 or human.resources@csimaine.com. We are an equal opportunity employer.

MARYLAND

Medical Director Eastern Shore, MD

Nationally known as one of the MOST BEAUTIFUL areas in America! Located on the picturesque Eastern Shore of Maryland. A **Medical Director** is needed for a 57-Bed **Child and Adolescent** Residential Treatment Center in **Cambridge, MD**. Included in the services is a 15-bed acute inpatient unit. Exceptional salary with full benefits including health insurance, dental and vision coverage, 401K, Long/Short term disability, Paid Time off, and more. Contact Mark Blakeney, Horizon Health, 800-935-0099, email CV to mark.blakeney@horizonhealth.com, fax: 972-420-8285. EOE

Faculty Position Assistant Professor (Tenure Track) Department of Psychiatry

The Department of Psychiatry at the Uniformed Services University of the Health Sciences, Bethesda, MD is seeking to fill an Assistant Professor, tenure-track, teaching and research position with particular emphasis on biological psychiatry. The Department is comprised of twenty full-time faculty and has active research interests in the neurobiology and behavior of stress, PTSD, anxiety, depression, and substance abuse. The successful candidate will be responsible for developing a funded research program and will participate in medical student and resident education and clinical care. Individuals who hold an M.D., have completed an approved psychiatric residency and are board eligible/certified are invited to apply. Send curriculum vitae, description of current and anticipated research interests and the names and addresses of four references to: Robert J. Ursano, M.D., Chairman, Department of Psychiatry, Uniformed Services University, 4301 Jones Bridge Road, Bethesda, MD 20814 (rursano@usuhs.mil). Review of applications is ongoing. The University is an affirmative action/equal opportunity employer.

Baltimore! Be in the center of it all; right outside our nation's capitol! Large teaching hospital has an opportunity for an adult psychiatrist. 40 HOUR WORK WEEK, LIGHT CALL! Salaried position with full benefits with bonus incentives! For more info, contact Sarah McGlinnen at 800-735-8261 x 216, fax your CV to 703-995-0647, or e-mail: smcglinnen@medsourceconsultants.com.

Psychiatrist

Springfield Hospital Center - a 405 bed psychiatric in patient facility, operated by The Maryland State Mental Hygiene Administration seeks Maryland licensed Psychiatrists. Our rural 400 acre campus is located 22 miles west of Baltimore and convenient to Washington, DC. via routes 70 & 29. We offer full time and part time positions with comprehensive benefits, which include 27 days of paid leave, medical coverage and access to Maryland State Employees Pension at retirement. Additionally, Contractual day/night positions available. Both Board & Non-Board Certified physicians will be considered. Salary for these positions is negotiable. Please send CV to: Jonathan Book, M.D., Clinical Dir, SHC, 6655 Sykesville Rd. Sykesville, Maryland 21784. For questions call 410-970-7006 or email Jbook@dhmh.state.md.us. EOE

PSYCHIATRIST PT for fast-paced growing Geriatric Behavioral Health Practice to provide consultation services in LTC setting in Maryland. Background in medical/neurological basis for psychiatric symptoms desirable. Fax cover letter and resume to CGS, 410-832-5783, Attn.: Dr. Fitting.

Clifton T. Perkins Hospital Center, a JCAHO-accredited institution and Maryland's only maximum security forensic hospital, is seeking candidates for the position of staff psychiatrist. Candidates with forensic interest or experience would be especially well-suited. Responsibilities include the provision of high quality psychiatric care on an inpatient unit in a state-of-the-art forensic facility. Additional opportunities include evaluations of dangerousness, competency to stand trial, and criminal responsibility.

Join a vibrant medical staff with expertise in care of the seriously mentally ill within a forensic setting. Faculty appointments are available at University of Maryland and Johns Hopkins, if eligible. The hospital is centrally located 20 minutes from Baltimore, 35 minutes from DC, and 20 minutes from Annapolis. Competitive salary with excellent benefits, flexible working hours, and the opportunity for paid overnight call.

Interested candidates should contact C. Dennis Barton, Jr., MD, MBA, at 410-724-3078 or P.O. Box 1000, 8450 Dorsey Run Road, Jessup, MD 20794 (BartonD@dhmh.state.md.us.)

BALTIMORE - The Walter P. Carter Center, a 51 bed adult inpatient facility on the downtown campus of the University of Maryland, is seeking a BC/BE psychiatrist. This is a full-time faculty position in the Department of Psychiatry at the U. of Md. School of Medicine, and involves direct patient care, the teaching and supervision of residents and medical students, and opportunities for research. Please contact Louis Cohen, M.D., Clinical Director at 410-209-6101; or e-mail at LCohen@psych.umaryland.edu.

Inpatient psychiatry position on the bucolic Eastern Shore of Maryland. Close proximity to DC, Baltimore, and the Atlantic Coast beaches. Full-time and part-time options are available. Work on a general psychiatry inpatient unit with a team approach to patient care. For more information contact Allan Anderson, MD at 410-228-5511 ext. 2107, or e-mail at: aanderson@shorehealth.org.

MASSACHUSETTS

Psychiatrist - Southbridge/Sturbridge area. Part time adult psychiatrist needed for G.B. Wells Center, a large, friendly community mental health center and part of Harrington Memorial Hospital. Excellent working conditions, very flexible. For more information, write/call: Zamir Nestelbaum, M.D., @ G.B. Wells Center, 29 Pine St., Southbridge, MA, 01550. 508-765-9167. An AA/EOE/ADA Employer.

ON call psychiatrist - Southbridge, MA. Harrington memorial Hospital has on call opportunities. Salaried position, 1 in 7 rotation, weekend rounds, very flexible. Excellent working conditions. For more information, write/call: Zamir Nestelbaum, M.D., @ G.B. Wells Center, 29 Pine St., Southbridge, MA, 01550. 508-765-9167. An AA/EOE/ADA Employer.

PSYCHIATRIST

The Department of Psychiatry at St. Elizabeth's Medical Center of Boston is actively recruiting a psychiatrist for a 350-bed tertiary care hospital of a six-hospital network. The Medical Center is a major teaching affiliate of Tufts University School of Medicine, with 4 residency and 3 fellowship programs. Excellent starting salary and benefits package provided. Physician would be eligible to participate in a bonus incentive program. Contact: Deborah Santoro at 617-562-5478.

DEPARTMENT OF PSYCHIATRY - MASSACHUSETTS GENERAL HOSPITAL - HARVARD MEDICAL SCHOOL — The Massachusetts General Hospital Department of Psychiatry, rated #1 psychiatry department by US News and World Report for the past decade, is committed to excellence in clinical care, teaching and research. The department is comprised of a staff of approximately 600 professional appointees who work in a variety of settings including consultation/liaison; emergency psychiatry; medical-psychiatric inpatient service; and outpatient services responsible for approximately 100,000 outpatient visits annually with specialty programs including Anxiety and Traumatic Stress; Addictions; Bipolar; Child & Adolescent Psychiatry; Depression; Eating Disorders; Obsessive Compulsive and Related Disorders; Schizophrenia, and Women's Perinatal and Mental Health. Continued growth throughout the department creates open positions for psychiatrists, psychologists and PhD level researchers. Interested individuals should apply directly to: **Jerrold F. Rosenbaum, MD, Psychiatrist-in-Chief, Department of Psychiatry, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114**. The Massachusetts General Hospital is an affirmative action/equal opportunity employer. Minorities and Women are strongly urged to apply.

BOSTON MEDICAL CENTER — Boston University School of Medicine

Boston University School of Medicine / Boston Medical Center, Department of Psychiatry, is seeking board-certified psychiatrists for the following positions:

Adult Psychiatrist to provide direct patient care our consultation/ liaison and outpatient adult psychiatry services Position includes teaching and supervision of medical students and residents.

Child/Adolescent Psychiatrist to provide direct patient care in our outpatient/urgent care and consultation/liaison child/adolescent psychiatry services. Special interest and experience in neuropsychological conditions preferred. This position involves program leadership, direct patient care and supervision of medical students and residents.

Academic/Clinical specialties of the Department of Psychiatry include psychological trauma, medical psychiatry, consultation-liaison, emergency psychiatry and community mental health.

Boston Medical Center, a teaching hospital for the Boston University School of Medicine, is a busy community hospital in Boston which serves a diverse, multicultural patient population.

Academic appointment commensurate with experience. Competitive salary base with incentive and full benefits. All interested applicants should send CV and cover letter to Marice Nichols, 85 East Newton Street, Suite 802, Boston, MA 02118 or fax to (617) 414-1975. Boston University School of Medicine/ Boston Medical Center is an equal opportunity/affirmative action employer.

Worcester - The University of Massachusetts Medical School (UMMS) seeks a psychiatrist board-certified in Forensic Psychiatry to join its nationally known Law and Psychiatry Program to be Director of Forensic Services at Worcester State Hospital in the Central Massachusetts Area, located by the campus of the medical school. Duties include administering the inpatient forensic service; conducting court-ordered forensic evaluations; supervising forensic fellows and assisting the Director of Forensic Psychiatry Training in coordination of training experiences, seminars, and ACGME-accreditation activities for the Fellowship in Forensic Psychiatry; teaching post-doctoral fellows in Forensic Psychology, psychiatric residents and medical students; and conducting research. Some flexibility related to duties, faculty rank and academic opportunities commensurate with individual's experience and interests. Letters of interest and *curriculum vitae* should be sent to Jeffrey Geller, M.D., M.P.H., Director, Public Sector Psychiatry, UMMS, 55 Lake Avenue North, Worcester, MA 01655, email Jeffrey.Geller @umassmed.edu, or fax 508-856-3270. UMMS is an affirmative action, equal opportunity employer.

CAMBRIDGE: Child & Adolescent Psychiatry

Outpatient Child & Adolescent Psychiatrist - half time position available at Cambridge Health Alliance, Division of Child and Adolescent Psychiatry, Harvard Medical School. An innovative and growing multidisciplinary team at the Center for Child and Adolescent Development seeks a half-time child psychiatrist. Must have special interest/expertise in psychopharmacology and in autism, bipolar disorder, and childhood psychosis. Opportunity to work closely with other team members including neuropsychology, pediatric neurology, social workers, psychologists and other prescribers. A half time position is available providing outpatient psychopharmacology services in a dynamic community based clinic. Position includes supervision of child psychiatry fellows, general psychiatry residents, medical students, and other trainees. Program development and research opportunities for candidate with appropriate experience.

The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School with excellent residencies in adult and child psychiatry. Academic appointment up to the rank of Associate Professor, as determined by the criteria of Harvard Medical School, is anticipated. We seek candidates with demonstrated excellence in academic teaching of complex clinical assessment, child and adolescent psychopharmacology, family assessment and treatment, particular interest and experience in working with ethnic and minority populations and the underserved, and enthusiasm for the public health mission of CHA.

Qualifications: Board Certified, demonstrated knowledge of clinical and research child and adolescent psychiatry, commitment to public sector populations, excellent clinical and teaching skills, leadership and management skills, team oriented, problem solver. Bilingual and/or bicultural abilities are desirable. Competitive compensation, excellent benefit package. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. **Send CV & letter to: Jean A. Frazier, MD, Dept. of Psychiatry, Cambridge Health Alliance-Station Landing, 1493 Cambridge Street, Cambridge, MA 02139. Fax: 781-306-8644. jfrazier@challiance.org (email preferred)**

CORRECTIONAL & FORENSIC PSYCHIATRY

The University of Massachusetts Medical School seeks psychiatrists for its innovative and multidisciplinary correctional mental health program, which provides services at several locations throughout the state. We offer generous, newly enhanced salaries, excellent benefits, regular hours without call responsibilities, and a faculty appointment with the University of Massachusetts Medical School. Send letter of interest and curriculum vitae to: Kenneth Appelbaum, MD, University of Massachusetts Medical School, Health & Criminal Justice Programs, 1 Research Drive, Suite 120C, Westborough, MA 01581; Kenneth.Appelbaum@umassmed.edu; Phone: 508-475-3236; Fax: 508-475-3258. UMMS is an equal opportunity employer.

Lynn BayRidge Hospital, a non-profit psychiatric facility on Boston's North Shore, a teaching site for Boston University Medical School, has a position for an inpatient and/or partial hospitalization program psychiatrist, or for the appropriate candidate, as unit Medical Director. Experience with dually diagnosed patients is a plus. The Medical Director position includes substantial direct service; candidates for Medical Director must be board-certified, and have demonstrated skill in leadership. No required night call, but participation in a lucrative call system is optional. Full benefit package includes generous time off as well as reimbursement for malpractice insurance and CME expenses. Contact Barry Ginsberg, M.D., Medical Director, 60 Granite Street, Lynn MA 01904. Phone (781) 477-6964, Fax (781) 477-6967, email bginsber@nhs-healthlink.org.

BOSTON AREA

Attleboro - Medical Director. Administrative & direct clinical care duties. General & specialty programs for children - adults. No weekend call. **Pembroke - Geriatric Psychiatrist** for specialty inpatient unit. **Brookline: General Psychiatrist** - adult inpatient and partial services. No call. Salary, benefits and bonus offered. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Psychiatrists Only
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Over 400 Locum Tenens and Permanent Placement Opportunities
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MINNESOTA

PRAIRIE ST. JOHN'S

Offering Hope and Healing to Those Suffering from Psychiatric Conditions and Addictions

Child and Adolescent Psychiatrist

Prairie St. John's, a Catholic Healthcare Organization, is looking for enthusiastic and dynamic Psychiatrists dedicated to helping others improve the quality of their lives. We are expanding services in the Mpls-St. Paul area and need Psychiatrists to provide care at Child_Adolescent PHP and Clinic.

The Prairie St. John's organization started in Fargo, ND and provides services in a continuum of care that includes inpatient, partial hospital, intensive outpatient and clinic services to adults, adolescents and children. Starting salary up to $210,000 dependent on qualifications, plus potential productivity compensation. Excellent benefits. Full or Part-time available. View us online at www.prairie-stjohns.com.

Send CV and letter of interest to: Karen Frigen, Development Specialist, Prairie St. John's, 510 4th St. S., Fargo, ND 58103 or e-mail to kfrigen@prairie-stjohns.com.

MISSISSIPPI

HORIZON HEATH
Associate Medical Director

The Gateway city of Northern Mississippi, Corinth, has an opportunity for an Associate Medical Director for a 19-bed Adult psych unit. Location provides an excellent opportunity to establish your own practice with the benefit of a stipend, income guarantee and call coverage. Contact Diane Odom Horizon Health for more details, Email CV to diane.odom@horizonhealth.com, Fax: 972-420-8233. 800-935-0099. EOE

MISSOURI

KANSAS CITY: Major metro, family community. 100% OUTPATIENT, NO CALL. Full or part time for practicing Adult Psych. Salary plus keep 60% of billings after base is covered. Non-profit MH center, full range services. Susan Springer @ 800.575.2880 ext 315 sspringer@medsourceconsultants.com

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Ozark Center
Freeman Health System
Behavioral Health Division

Adult and Child/Adolescent Psychiatrists

- Join the Behavioral Health Division for FHS which is the largest & fastest growing health system in the area.
- Eight psychiatrists working together as a group in a shared call situation
- At FHS enjoy the security and growth potential of a fully integrated delivery system with the completion of a large expansion of facilities opening in 2007.
- Join freedom and autonomy of working within a physician-driven system with 170+ employed physicians covering all specialties providing an excellent local and regional referral base for your services

EXCELLENT SALARY AND BENEFITS
JOPLIN, MISSOURI -Service Area of 450,000 + Lakes, fishing, hunting; excellent public & private schools; mild climate-four seasons; one of the lowest costs of living in the nation. Call Nancy at 800-353-6812, Fax CV to 417-347-9320.

We want to hear from you!!
njpaul@freemanhealth.com/
www.freemanhealth.com

ST. LOUIS, MISSOURI - CHRISTIAN HOSPITAL: Seeking a BC/BE Psychiatrist for Inpatient adult and geriatric practice at Christian Hospital in St. Louis County. Collegial work environment. Shared call. No commuting with both inpatient units located side by side. Be your own boss in this contract position! St. Louis is a large city with a small town feel. **To learn more, contact Michelle Kraft at 800-678-7858, x63705; fax 314-726-0026; e-mail mkraft@cejkasearch.com.** ID#26770PY. *For more opportunities, visit www.cejkasearch.com.*

MONTANA

PSYCHIATRIST-Seeking full-time board certified psychiatrist to fill staff position in VA Montana Healthcare System. Certifications or experience in addiction psychiatry and or pain management a plus. Responsibilities include adult outpatient treatment with urgent care/walk-in service and inpatient consultation service in a facility where state-of-the-art medicine is practiced. Fort Harrison Hospital is located in Helena, the State Capital. In beautiful western Montana, Helena has downhill and cross-country skiing, awesome fly-fishing, camping, hunting, and numerous other outdoor activities nearby. The availability of cultural activities, including concerts, annual jazz and bluegrass festivals as well as those events associated with Carroll College, a high quality educational system, is a notable asset of the community. This is also a rapidly growing community with excellent school system. It is a wonderful place to raise children. Competitive salary, benefits and liability included. Fax curriculum vitae to 406-447-7978 or call Human Resources at 406-447-7933.

INTERMOUNTAIN WEST - MONTANA. Free standing facility. Primarily outpatient psychiatry with some consultation-liaison. Full complement of community support services. Excellent income potential. Located in Kalispell in the Rocky Mountains' Flathead Valley near Glacier National Park. Breathtaking vistas with pristine mountain lakes, wilderness areas, blue ribbon trout streams, world-class hunting, fishing, snowmobiling, and skiing. **Contact Michelle Kraft at 800-678-7858, x63705; fax 314-726-0026; e-mail mkraft@cejkasearch.com.** ID#27255PY. *For more opportunities, visitwww.cejkasearch.com.*

BIG OPPORTUNITY UNDER THE BIG SKY

BE/BC PSYCHIATRIST, MONTANA - You've earned it. Things are different here. The Great Falls Clinic seeks a BE/BC Psychiatrist to join the Neurosciences Department of a rapidly expanding 125-physician multi-specialty group. Successful candidates will have strong skills in both adult and geriatric psychiatry as well as a medical management approach to patient care.

Great Falls is a warm and safe community perfect for a physician interested in making a home for themselves and/or their family. Access to world-class recreational venues, outdoor activities, scenic vistas and regional culture are right outside your practice door. This opportunity does not qualify as a J-1 waiver site. For more information about this wonderful opportunity, contact Kate Bogue, Physician Recruitment Coordinator at (406) 771-3332 or kate.bogue@gfclinic.com. You may also visit our website at www.gfclinic.com

NEVADA

The University of Nevada School of Medicine, Department of Family Medicine, is seeking candidates for two full-time, administrative faculty positions as physicians/psychiatrists at the Mojave Adult, Child and Family Services (MACFS) mental health clinic in Las Vegas. Excellent benefits package available. For complete position description and requirements, contact: Search Chair/Coordinator, (Jim Parcells, C.O.O., 702-968-5000/Pam Soucy, PHR, 702-968-5071) or view at http://jobs.unr.edu (reference posting #60025).

NEW JERSEY

PSYCHIATRISTS
On Call
Evenings, Nights & Weekends

Carrier Clinic, a regionally prominent, private, not-for-profit psychiatric facility in suburban/rural Somerset County in central New Jersey, offers challenging career opportunities for board eligible Psychiatrists in the inpatient hospital serving adolescents, adults and older adults.

As a member of our medical staff, you will provide comprehensive psychiatric and mental status assessments and medical screening on all new admissions. Will also cover house for medical emergencies.

Carrier has an excellent salary and benefits, including relocation assistance if required. Interested candidates are invited to submit a CV to:

CARRIER CLINIC
Donna Mozet, Director of Human Resources
252 Route 601
Belle Mead, NJ 08502
E-mail (preferred): dmozet@carrierclinic.com
Fax: 908-281-1666
Visit us on the web at: www.carrier.org
EOE

GENERAL ADULT/ADDICTIONS PSYCHIATRIST
Full Time

Carrier Clinic, a regionally prominent, private, not-for-profit psychiatric facility in suburban/rural Somerset County in central New Jersey, offers a challenging career opportunity for a board certified General Adult Psychiatrist with experience in addictions.

Carrier offers members of the medical staff an excellent salary and benefits package, including generous CME, both on-site and time to attend off campus programs. Central New Jersey offers lovely communities, excellent school systems and a close proximity to Princeton, New York and Philadelphia. Interested candidates are invited to submit a CV to:

CARRIER CLINIC
Donna Mozet, Director of Human Resources
252 Route 601
Belle Mead, NJ 08502
E-mail (preferred): dmozet@carrierclinic.com
Fax: 908-281-1666
Visit us on the web at: www.carrier.org
EOE

CHILD/ADOLESCENT PSYCHIATRIST
Full Time

Carrier Clinic, a regionally prominent, private, not-for-profit psychiatric facility in suburban/rural Somerset County in central New Jersey, offers a challenging career opportunity for a board certified Child/Adolescent Psychiatrist for our inpatient Adolescent Unit. This is a Full-Time position, created as a result of the expansion of our adolescent services.

Carrier offers members of the medical staff an excellent salary and benefits package, including generous CME, both on-site and time to attend off campus programs. Central New Jersey offers lovely communities, excellent school systems and a close proximity to Princeton, New York and Philadelphia. Interested candidates are invited to submit a CV to:

CARRIER CLINIC
Donna Mozet, Director of Human Resources
252 Route 601
Belle Mead, NJ 08502
E-mail (preferred): dmozet@carrierclinic.com
Fax: 908-281-1666
Visit us on the web at: www.carrier.org
EOE

The Garden State!
Respected free standing psychiatric hospital has 2 needs. 1) MEDICAL DIRECTOR - addictions experience or interest is a plus 2) C&A psychiatrist- 100% OUTPATIENT. **Rewarding opportunity** with competitive base salary & full benefits package! For more info, contact Lindsay McCartney at 800-735-8261 x 213, fax your CV to 703-995-0647 or email: lmccartney@medsourceconsultants.com

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SOUTH JERSEY: General Psychiatrist. Full-time position -general psych & dual diagnoses inpatient treatment for adults. Salary & benefits offered. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Psychiatrist - well established, for profit outpatient mental health practice located in south jersey, has immediate opening for experienced adult, adolescent and/or child psychiatrist. Fee for service cliental, private practice model within comprehensive multi-disciplinary group of highly qualified clinicians. Fax CV to (856) 985-8148 or call (856) 983-3866 ext. 3018.

NEW MEXICO

Presbyterian Medical Services is a non-profit integrated healthcare network with JCHO accreditation providing medical, dental, behavioral health, children's services and supportive living services to the multi-cultural people of New Mexico. We are seeking a **Psychiatrist** who will see clients of all ages to work in our Farmington clinic. Excellent benefits. Sign-on bonus offered. For more information contact Diane Kramer at (800) 477-7633; fax (505) 954-4414; diane_kramer@pmsnet.org; P.O. Box 2267, Santa Fe, NM 87504. EOE.

Medical Director of Child & Adolescent Division

The Department of Psychiatry at the University of New Mexico, School of Medicine is seeking an outstanding Child & Adolescent Psychiatrist for the position of Director of Child & Adolescent Psychiatry. This person also serves as Medical Director of Child and Adolescent Inpatient and Outpatient services. This Division encompasses a variety of activities including a fellowship in Child & Adolescent Psychiatry; an internship in Clinical Psychology; Telemedicine/Rural Psychiatry, juvenile corrections, and inpatient and outpatient services. The Director collaborates and participates in strategic planning and program development with University Hospital as well as multiple local, state and national agencies. Teaching duties include supervision of medical students, residents, psychology interns and trainees of multiple disciplines. We are eager to put together the right package to assure that we recruit the best person for this position. Minimum qualifications include Doctorate Degree, licensable in New Mexico, board certified in Child & Adolescent Psychiatry, proven clinical experience, and United States citizenship or permanent residence. Desirable qualifications: leadership experience in academic administration, research experience, teaching and curriculum development experience. This position may be subject to criminal records screening in accordance with New Mexico law. For best consideration, interested parties should send Curriculum Vitae, a brief signed letter indicating interests, and the names of three current references to the attention of Renu Prinja, Medical Department Personnel Representative, University of New Mexico, School of Medicine, Department of Psychiatry, 2400 Tucker NE MSC 09 5030, Albuquerque, NM 87131. The position will remain open until filled. For preliminary inquiries contact, Samuel J. Keith M.D. Milton Rosenbaum Professor, Chairman, Department of Psychiatry, University of New Mexico, 2400 Tucker NE, MSC 095030 Albuquerque, NM 87131. The University of New Mexico is an Affirmative Action / Equal Opportunity employer and educator.

NEW YORK CITY & AREA

ALBERT EINSTEIN
COLLEGE OF MEDICINE
Of Yeshiva University
Department of Psychiatry and Behavioral Science

The Sound View Throgs Neck Community Mental Health Center

PSYCHIATRIST - Full-time. Continuing Day Treatment and MICA Program. PSYCHIATRISTS - Part-Time Child/Adolescent and Adult Outpatient Programs. These Programs seek psychiatrists experienced in diagnostic evaluation and psychopharmacology, to provide clinical care, supervise a team and teach medical students, psychiatry residents and clinical fellows. New York State License, Board Certified/Board Eligible in Psychiatry. DEA Registration. These positions carry a faculty appointment. Knowledge of Spanish a plus.

In return for your expertise, we offer a competitive salary, outstanding benefits package and a professional work environment offering career growth potential. For consideration, please submit your CV with salary history to: **Thomas F. Betzler, MD., Executive Director, Sound View Throgs Neck Community Mental Health Center, 2527 Glebe Avenue, Room 304, Bronx, NY 10461; Fax: (718) 931-7307; Email: tbetzler@aecom.yu.edu . Equal Opportunity Employer.**

Psychiatrists
Full time positions available at Kirby Forensic Psychiatric Center, a New York State Office of Mental Health facility specializing in the treatment of a wide range of patients with forensic concerns. The psychiatrist leads a multi disciplinary team, with opportunities to utilize clinical, administrative, and teaching skills. Prior forensic training is not expected, but opportunities exist to develop forensic skills. Kirby is affiliated with the NYU residency and forensic fellowship programs. We are conveniently located near the Triboro Bridge.

Please fax or mail resume to:
Kirby Forensic Psychiatric Center
Wards Island Complex
Wards Island, NY 10035
James Hicks, M.D.,
Associate Clinical Director
Fax 646-672-6893
Kirby Forensic Psychiatric Center is an equal opportunity employer

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Psychiatrists

Child/Adolescent & Adult

YAI/Premier Healthcare is a nationally recognized, well-established NYC diagnostic & treatment center for people with disabilities and their families. We are currently seeking part time and Fee for Service psychiatrists.
- Bronx Adult Group Homes - FFS
- Brooklyn - Child & Adult - PT
- Bronx - 3 month - TEMP - Child - 1 day per week

This is an opportunity to work with a professional team of doctors and nurses in a multi-cultural, team environment. Send CV to: Karen Meyers, Clinical Recruiter, Premier HealthCare, 460 West 34 Street, N.Y., N.Y. 10001 Fax 212-563-4836 Email: kmeyers@yai.org

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NYC Borough-Be part of well-organized, well-run mobile team. Work 3 or 4 days/wk on award winning ACT program, then spend one day on a residential program. Transportation provided or reimbursed. **NO CALL!** Hourly or salaried w/ benefits! Call **Karen @ 800-575-2880 x307**. E-mail to **KBrennan@MedSourceConsultants.com**

NEW YORK STATE

Saint Francis Hospital and Health Centers

Psychiatrist

Saint Francis Hospital Department of Psychiatry, a respected leader providing mental health care, has an opening for a fulltime inpatient Unit Chief. This position requires NYS license and BC/BE in psychiatry. Will consider new graduates. The Hospital offers a competitive salary and benefit package and opportunity for additional income.

Saint Francis Hospital is located in Poughkeepsie, New York in the scenic Hudson Valley, with easy access to New York City. The Hudson Valley offers an excellent lifestyle with affordable housing and surprising sophistication. Dutchess County is a rapidly growing "up and coming" community and is a great place to live, raise a family, work and build a career.

Send CV and letter of interest to Human Resources @ Saint Francis Hospital, 241 North Road, Poughkeepsie, New York 12601 or e-mail to jobs@sfhhc.org

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P/T CHILD/ADOLESCENT PSYCHIATRIST WANTED. Outpatient position with leading LI Children and Family Mental Health Agency. Fax Resume: HR-(516)626-8403.

GREATER BINGHAMTON HEALTH CENTER
ADULT PSYCHIATRIST
And
CHILD/ADOLESCENT PSYCHIATRISTS

GBHC, (JCAHO-Accredited New York State Office of Mental Health facility) is seeking full time, board certified/board eligible **ADULT PSYCHIATRISTS** for its 140 bed adult inpatient facility and **CHILD/ADOLESCENT PSYCHIATRISTS** for its Child/Adolescent unit. Abundant on-site CME. Salaried, permanent positions with excellent New York State benefits.

Submit CV to: Personnel Office, Greater Binghamton Health Center, 425 Robinson St., Binghamton, NY 13904. Fax: (607) 773-4117. EOE/AAE.

Inpatient/ Outpatient Psychiatrists
Ellis Hospital
Schenectady, NY 12308

The Ellis Hospital Department of Psychiatry, a respected leader in mental health in the Capital Region of New York State, has openings for full-time NYS licensed, BC/BE inpatient and outpatient psychiatrists. The hospital offers a generous salary and benefit package, opportunities for continuing education, and a stimulating work environment.

Ellis Hospital is located in Schenectady, NY, in the Mohawk Valley at the foothills of the Adirondack Mountains. The area is well-known for its beautiful lakes, including scenic Lake George, numerous parks, ski resorts, golf courses, and the famous Saratoga Raceway, all within an hour's drive. Major cities within a three-hour drive include New York and Boston.

For further information, contact Anthony Yacona, M.D., Chairman, Department of Psychiatry, Ellis Hospital, 1101 Nott St., Schenectady, NY 12308 at (518)-243-4154 or e-mail yaconaa@ellishospital.org.

Assistant/Associate Professor (2 Positions)

Stony Brook University has two faculty positions for Assistant/Associate Professors of Mental Health Services Research/Psychiatric Epidemiology available immediately. *Required:* Ph.D., D.P.H., or M.D. or equivalent. Doctoral degree from accredited institution. Demonstrated research experience in Mental Health Services, Psychiatric Epidemiology, or Mental Health Policy. *Preferred:* Track record of funded research in this area. Salary commensurate with experience; full benefits. Send resume to: Mark J. Sedler, M.D., MPH, Chairman, Department of Psychiatry and Behavioral Science, Health Science Center, T10-020, Stony Brook University, Stony Brook, NY 11794-8101, or fax: (631) 444-1560. Equal Opportunity/Affirmative Action Employer. Visit *www.stonybrook/cjo* for further information.

Northern New York!
Psychiatrist

A **Psychiatrist** is needed for a 28-bed adult inpatient unit located in a 159-bed community hospital and regional referral center. Positioned on the US/Canadian border, the city offers the opportunity to explore the cultures of neighboring Canada. Charming city located along the southern shore of the beautiful **St. Lawrence River**. Salaried position. **J-1 Waiver Available**. Please contact Mark Blakeney, Horizon Health, for more details. Office 800-935-0099, e-mail mark.blakeney@horizonhealth.com, fax 972-420-8233. EOE

NORTH CAROLINA

EXPANDING SUBSTANCE ABUSE SERVICES

John Umstead Hospital, a state psychiatric hospital located in Butner, NC seeks psychiatrist for the Alcohol & Drug Abuse Treatment unit. Convenient to Raleigh/Durham/Chapel Hill and has close ties with duke University and UNC-Chapel Hill. Competitive salary and benefit package. Requires graduation from an accredited medical school, completion of an accredited psychiatric residency, and board certification or eligibility. Send state application (PD-107) and/or vitae to JUH; Human Resources Office; 1003 12th St.; Butner, NC 27509 or contact Dr. Lou Ann Crume, Clinical Director at 919-575-7233. Fax 919-575-7550. EEO/AA Emp.

FORENSIC PSYCHIATRISTS
The Federal Medical Center located in Butner, North Carolina, is seeking BC/BE staff psychiatrists. Board certification or an interest in Forensic Psychiatry is ideal. The 310 bed all male Mental Health Component is part of a 989 bed JCAHO accredited facility located north of Raleigh and the Research Triangle Park. Applicants are required to possess a license to practice medicine in any of the 50 states and full U.S. citizenship. Staff psychiatrists are part of a multi-disciplinary team with a primary focus in performing court ordered forensic evaluations. Care of the chronically mentally ill is a part of the job responsibilities. FMC Butner is a site for community rotations for psychiatry residents from the nearby Duke University Medical Center and a site for the Forensic Psychiatry Fellowship sponsored by the University of North Carolina at Chapel Hill. Interested candidates should contact Mona Hill, Medical Recruiter, at (919) 575-3900, ext. 6040, or J. Zula, M.D., Chief of Psychiatry, at ext. 5475. **FMC Butner is an Equal Opportunity Employer committed to a policy of nondiscrimination on the basis of race, gender, religion, color, national origin, disability, marital status, and status as a covered veteran.** EEO/AA Employer

NORTH DAKOTA

MeritCare Health System of Fargo, ND is seeking an Adult Psychiatrist to join its 32-member multi-disciplinary Psychiatry Department. Faculty appointment and teaching of psychiatry residents is available through University of North Dakota School of Medicine. MeritCare is an integrated 384-physician multi-specialty group practice, 583-bed Level II tertiary/trauma hospital with 26 primary care clinic sites in two states. Sister cities, Fargo, ND and Moorhead, MN are a tri-college community of 200,000 located near the heart of Minnesota's lake country. Fargo-Moorhead offers excellent educational systems, recreation and sporting activities as well as a variety of entertainment and cultural events. This is an excellent opportunity with a competitive compensation and benefits package being offered. Drug-free workplace. AA/EOE. This is not a designated HPSA site.

To apply send CV to:

Jill Gilleshammer, Physician Recruiter
MeritCare Health System
P O Box MC
Fargo, North Dakota 58122
Phone: (800) 437-4010, ext. 280-4851
Email: Jill.Gilleshammer@meritcare.com

PSYCHIATRIST

The **North Dakota State Hospital** located in Jamestown, ND is seeking a **Staff Psychiatrist** to join our 19 member clinical staff, Monday-Friday, 8-5. NDSH is a JCAHO accredited and Medicare certified facility with an average daily census of 129 adult and adolescent psychiatric and chemically dependent patients. Requires ND licensure. Board Certification must be completed within 3 years. 160K+ salary DOE with additional dollars or paid leave for limited on-call. Excellent benefit package including health insurance premium paid at 100%; paid pension equal to 9% of salary; relocation expenses. We are a HPSA site and will consider J-1 Visa candidates. Contact Lyle A. Grove, SPHR, Human Resource Dept. (701) 253-3015; Fax (701) 253-3000 or e-mail grovel@state.nd.us. EOE

OHIO

Medical Director/Staff position at one of the largest CMHC in Ohio. Clinically the positions will be a mix of in and outpatient work. Call is shared equally and they are employed positions. Staff $160K-$170K Med Dir $170K-$180K Contact Matt Brewster 800 575-2880 x 311

PSYCHIATRISTS
Greater Cleveland Area

Horizon Health seeks psychiatrists for hospital-based psychiatric services in greater Cleveland, OH. Opportunities exist for: Child/Adolescent, General Adult, Geriatric, and Eating Disorders Specialists. **Salaried positions with exceptional benefits. J-1 waiver applicants welcome**. Contact: Mark Blakeney, Horizon Health, 800-935-0099, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. Visit our web site: www.horizonhealth.com. EOE.

SEEKING Executive Director for Summit County, Ohio Alcohol, Drug Addiction and Mental Health Services Board. Professional with extensive administrative experience in operating large governmental agency or nonprofit with understanding of mental health and addiction recovery and prevention services. Leadership, communication skills, fiscal, government funding and managed care knowledge required. Successful experience with voted local levy support preferred. Equal employment opportunity. Respond in writing with resume, references and salary requirements by August 31, 2006 to ADM Search Committee, c/o Greg Kavinsky, Co-Chair, 2558 Arbor Court, Uniontown, OH 44685-7814.

OREGON

Oregon State Hospital

Oregon State Hospital is currently recruiting for Psychiatrists with interest and/or experience in adult and forensic programs. A strong benefits package complements salary. Opportunities for additional on-call work can increase your income substantially.

Oregon State Hospital provides specialized mental health services, including general adult, geriatric, and forensic treatment programs with campuses in Salem and Portland. Oregon State Hospital currently employs approximately 1,200 staff, including 30 Psychiatrists.

Located in the beautiful Willamette Valley, the area offers a great diversity of recreational activities. Within an hour's drive one finds the Cascades, the Coastal Range, and the Pacific Ocean. Oregon is justifiably famous for its world-class fishing, hunting, skiing, golfing, windsurfing, white water rafting, camping, and mountaineering opportunities.

Contact:
Becky Hawkins, Office of Human Resources
Oregon State Hospital
2600 Center Street NE
Salem, OR 97301-2682

Phone: (503) 945-2822
Fax: (503) 945-9910
E-Mail: Becky.Hawkins@state.or.us

PENNSYLVANIA

UNIQUE CAREER OPPORTUNITY
FOR ADULT PSYCHIATRIST

This is a superb opportunity for a BC/BE psychiatrist interested in a combination of emergency psychiatry and inpatient care. Establish a close working relationship with our psychiatric emergency service and our inpatient behavioral science unit. You will work with a large salaried hospital-based group who practice at LVH, an 800-bed academic community hospital where opportunities exist to teach medical students and residents and pursue career advancement. The successful candidate will also be eligible for faculty appointment at Penn State/Hershey. We are offering an excellent call schedule and a favorable lifestyle so that you can enjoy the beautiful Lehigh Valley where more than 700,000 people appreciate safe neighborhoods, good schools and easy access to major metropolitan areas. Philadelphia is 1 hour south and NYC is 1.5 hours east. For more information, call 610-969-0213. Email CV to Pamela.Adams@LVH.com or fax to (610) 969-0214.

Psychiatrist

Fairmount Behavioral Health System, a leading provider of Psychiatric Services, has opportunities available for full time board certified or board eligible psychiatrists to provide clinical care on our Adult Services Units. Join our dynamic multi disciplinary team and find city convenience on a wooded 27 acre campus. Our services include Inpatient Psych Services for Children, Adolescents & Adults, Partial Hospitalization Program for Adolescents & Adults, Inpatient Dual Diagnosis for Adults and Drug and Alcohol Rehabilitation for Adults. Interested candidates should email c.v. to: Dr. Sureshkumar, CMO at Thambipillai.Sureshkumar@uhsinc.com or fax to 215-483-8187.

PSYCHIATRIST
Salary Plus Benefits

Horizon Health managed inpatient psychiatric program seeks psychiatrist 45 minutes north of **Pittsburgh. Salaried position with benefits**. Join a successful, thriving, well established group practice in the area as well as service a 20-bed Geropsych program or a 20-bed Chemical Dependency program. Contact: Mark Blakeney, Horizon Health, 800-935-0099 x7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. Visit our web site: www.horizonhealth.com. EOE.

Child/Adolescent Psychiatry
The best of both worlds - flexible scheduling and high-end care!

Geisinger Health System's Division of Psychiatry in Danville, PA, is seeking a child/adolescent psychiatrist. This position offers an excellent quality of life and an opportunity to work part-time or full-time depending on the needs of the candidate.

This position offers:
- A flexible schedule - start/end times are negotiable.
- A collaborative team of psychiatrists/psychologists with experience and expertise in a variety of psychiatric specialties.
- The support of multiple PAs, a nurse specialist and masters-level therapists.
- An excellent call schedule (1 in 7).
- The opportunity to work in a comprehensive academic practice that sees a wide variety of clinical activity from pediatric to geriatric patients and diagnostic types (including ECT).
- Research opportunities through the Weis Center for Research and the Center for Health Research and Rural Advocacy (both located on the campus of Geisinger Medical Center). Current research projects include studies on genomic schizophrenia, adolescent depression and improving the delivery of adult depression through primary care.
- An accredited Clinical Psychiatry Internship and the opportunity to teach pediatric and emergency medicine residents.
- An established referral base through Geisinger Health System's 40 community medical groups, 3 hospitals, local/community physicians and broad-base of third party contracts.

Pediatric specialty services include:
- A comprehensive program dedicated to treating kids with bedwetting problems
- Disruptive behavior
- Asperger's Group
- Adolescent treatment
- In-school services
- Community psychiatry
- Neuro-psych services

Last year, more than 100 physicians joined Geisinger Health System. And it's no wonder. While many healthcare organizations are struggling, Geisinger and the Division of Psychiatry is experiencing unprecedented growth. In the past two years they have added a 10-bed Adolescent Inpatient Unit at Geisinger South Wilkes-Barre, the neuro-psychiatry practice has doubled and added 2 post-doctoral fellows and Pediatric Psychiatry has experienced significant growth. At Geisinger, you'll experience the support, camaraderie and professional challenges of a leading practice while discovering the charms of Pennsylvania living...all while having the time and flexibility to enjoy your new quality of life.

To discuss this opportunity, contact:
Kathy Kardisco, Recruiter
Geisinger Department of Professional Staffing,
100 North Academy Avenue, Danville, PA 17822-2428
Phone: 1-800-845-7112 o
Fax: 1-800-622-2515
e-mail: kkardisco@geisinger.edu

STATE COLLEGE area: Child and/or General Psychiatrist. Inpatient & outpatient.
CLARION: General or Child Psychiatrist - inpatient & partial programs. Admin/clinical position.
Salary, bonus, & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Outpatient Child/Adolescent and Adult Psychiatrists: Positions available in the scenic Laurel Highlands of Southwestern Pennsylvania (60 minutes SE of Pittsburgh/3 hours NW of to D.C.). Join team of seven psychiatrists in a progressive community-based behavioral health program. Full-time and part-time positions available in a comprehensive outpatient service. Treatment provided in concert with a team of professional counselors and certified psychiatric nurses. Crisis Intervention team provides 24/7 on-call coverage. Competitive salary and excellent benefit package. **J-1/H-1 positions available**. Please forward CV to: Brian Eberts, M.D., Medical Director, Chestnut Ridge Counseling Services, Inc., 100 New Salem Road, Uniontown, PA 15401 FAX: 724 437-6415 EMAIL: beberts@crcsi.org

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Pennhurst Medical Group, P.C. Various Pennsylvania locations BC/BE, Excellent Salary, Benefits, Full Time, No Billing, Part Time and Locums Positions. Send CV to bp@pennhurstmedical.com or by fax 610-524-0952. Feel free to call Bob Plunkett at 610-524-2400 x 160 with any questions or for more information.

RHODE ISLAND

Rhode Island Hospital

Psychiatrist, Adult Outpatient and Mood Disorders

The Department of Psychiatry, Rhode Island Hospital, a Lifespan partner and Brown University affiliated program, is seeking a psychiatrist with interests in adult outpatient responsibilities within an established fulltime hospital-based group. The outpatient component involves assessment and treatment of patients as a member of a specialized multidisciplinary team. Interest and expertise in mood disorders is desirable. We offer an opportunity for both teaching as well as clinical research involvement to complement clinical practice. The candidate must be Board Certified or eligible, and may be eligible for a clinical appointment at Brown University School of Medicine. Salary and benefits commensurate with level of training. Please send CV's along with a letter of interest to Richard J. Goldberg, M.D., Psychiatrist-in-Chief, APC-9, Rhode Island Hospital, 593 Eddy St, Providence, RI 02903 and/or e-mail to rjgoldberg@lifespan.org.

SOUTH CAROLINA

AIKEN - minutes from Augusta GA - General Psychiatrist - inpatient & outpatient combination practice. **BENNETTSVILLE - East Carolina**. Medical Director for 8 bed adult-geriatric unit. Some call, ER consults & staff supervision. Salary, benefits and bonus offered. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

TENNESSEE

100% outpatient work located at the entrance of the Smokey Mountains. It's Tenn.'s most picturesque area to live and work. Knoxville Area Hospital seeks psychiatrist for adult or Child work. Limited call and No travel. Call Ken Pruchnicki @ 800-575-2880 x 319.
kpruchnicki@medsourceconsultants.com

HORIZON HEALTH
Medical Director

Horizon Health seeks an outstanding Medical Director for the 22-bed adult psychiatric program in northwest Tennessee. State-of-the-art 142-bed hospital provides high quality patient care. Conveniently located less than two hours from Memphis and Nashville, TN. Located near Kentucky Lake where outdoor activities are plentiful. Excellent practice opportunity with solid support from hospital and staff. Competitive stipend, practice guarantee, and relocation package. **Horizon Health also seeks** a Psychiatrist for a 10-bed geriatric psych program in south central TN, 1 hour from Chattanooga, TN. Please contact Diane Odom for more information 800-935-0099 or e-mail diane.odom@horizonhealth.com EOE

TEXAS

AMARILLO: Private Practice group seeking associate/partner. Inpatient & outpatient. Community need & great income potential. **SAN ANGELO:** General /Geriatric and Child Psychiatrist. Join an established private practice - will offer employment, benefits & program directorship. **MCALLEN:** Child Psychiatrist - inpatient/outpatient private practice. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

Well-established Private Practice - Seeking Psychiatrist for successful, established private practice in San Antonio, Texas. Physician has the option to become associate/partner. Practice has been providing Psychiatric services for 12 years. Options available - Locum Tenems - rent the practice by August 1, 2006; form a partnership with option to buy later or sell out. This position will require a minimum effort of 40 hours per week. Exclusively outpatient, dedicated to mood disorders to life span of 8 years to 100 years. No inpatient work, no on call, with annual salary potential over $200,000. Physician has option to work Saturdays and work inpatient if desired. Practice attends many up scaled patients from Mexico. Very well controlled Practice can see up to 90 patients per week. Qualifications include: Board Certified or Board Eligible in Psychiatry, Texas Medical License, DEA number, and bilingual in Spanish a plus. Submit inquiries and CV to: Isaac Ayala & Associates, 10000 IH Ten West, Suite 450, and San Antonio, Texas 78230. Call 210 697-8155, Fax 210 697-8850 or e-mail ayalai@aol.com.

BLUEBONNET TRAILS MHMR
Has openings for the following positions :

2 FULL TIME STAFF PSYCHIATRISTS to serve our adult and child population in the following counties: GUADALUPE (Seguin, TX), CALDWELL (Luling, TX), and GONZALES (Gonzales, TX). Willing to negotiate contract/part time inquiries.
PART TIME (2 days per week) CHILD AND ADOLESCENT PSYCHIATRIST available in BASTROP and BURNET counties.

Counties are beautifully located in central Texas, close to Austin and San Antonio. Please send CV to Vicky Hall, Mental Health Director, at Vicky.hall@bluebonnetmhmr.org, fax (512) 244-8401, or for additional information, visit our website at www.bluebonnetmhmr.org

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San Antonio State Hospital is a 203 bed JCAHO accredited psychiatric hospital located within 10 minutes from the downtown Riverwalk in beautiful San Antonio, Texas. We are seeking a board certified or board-eligible full-time Adult Psychiatrist and one full-time Child/Adolescent Psychiatrist. The Child/Adolescent Psychiatrist will join our two board certified child psychiatrists and an experienced multi-disciplinary treatment team on our Adolescent Unit. The Adult Psychiatrist will join the multi-disciplinary treatment teams on our adult units. Advantages include no state income tax, paid sick leave, paid vacation, paid time off for CME, 12-14 paid holidays, retirement plan, availability of additional 401 or 457 plan, possibility of clinical faculty appointment with the University of Texas Health Science Center at San Antonio; on-call not required but option to do so for additional pay, 40 hour work week, congenial colleagues and co-workers, San Antonio, Texas has excellent schools, a myriad of cultural, educational opportunities and nationally recognized medical center and wonderful climate.

Contact: Terresa Stallworth, M.D., Clinical Director for more information
Phone (210) 531-7715 or 7716
Fax (210) 531-7876
Email Address:
terresa.stallworth@dshs.state.tx.us
San Antonio State Hospital
6711 S. New Braunfels, Suite 100
San Antonio, Texas 78223-3006
San Antonio State Hospital is an equal opportunity/drug free workplace

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HOUSTON - Baylor College of Medicine is seeking board-certified or board-eligible psychiatrists to fill clinical openings at Ben Taub General Hospital, a major teaching, service, and research hospital of the College. Positions are available in emergency psychiatry and outpatient psychiatry, including work in community clinic settings. Bilingual English/Spanish providers are encouraged to apply. Please send a confidential CV and any additional information which might be of use to the search committee to Britta Ostermeyer, MD, Baylor College of Medicine, Department of Psychiatry, One Baylor Plaza, BCM350, Houston, TX 77030 or email brittao@bcm.edu Baylor College of Medicine is an Equal Opportunity, Affirmative Action and Equal Access employer.

Texas Forest Country - The Burke Center, a multi-site, JCAHO accredited community mental health center, has an immediate opening for either a **general psychiatrist or child psychiatrist** willing to treat some adults. The position is outpatient only, primarily located in Livingston, although there may be some work in other locations or by telemedicine. Enjoy an excellent lifestyle with a 40-hour work week, no call, competitive salary, and fantastic benefits. Physician Assistants and Advanced Nurse Practitioners will be considered as well. Recreational opportunities abound in national forests nearby. Houston is less than 2 hours away; Dallas 3 hours; major state university nearby. Please send CV to Mark Janes, M.D., Medical Director, Burke Center, 4101 S. Medford Drive, Lufkin, TX 75901. Fax: (936)634-8601. Email: markj@burke-center.org. Check out the details on our website: *www.burke-center.org*.

Psychiatrists needed in Houston, Texas. Full-time employee, very competitive salary and benefits package. Seeking two (2) psychiatrists: Position 1 is for provision of physician services to psychiatric patients in an inpatient setting. Position 2 is for provision of physician services to psychiatric patients primarily in an outpatient setting, with some inpatient and possible psychiatric research services. Must have current Texas Medical License. Current Medicare number preferred. **Please email resume and references to: dgafford@dapaprograms.com**

North Texas State Hospital

North Texas State Hospital is a preeminent psychiatric facility located in North Central Texas with campuses in Vernon and Wichita Falls. Psychiatrist in our organization have the opportunity for a professionally stimulating practice that genuinely makes a difference in these patients' lives, while at the same time affording themselves a rich quality of life in an area with a comparatively low cost of living. The Vernon Campus serves as the only adult Maximum Security facility and adolescent forensic program in the Texas Department of State Health Services and the Wichita Falls campus is a multi-faceted general psychiatric facility serving north central and west Texas. Populations served include: forensic, substance abuse, adult, child, adolescent, geriatric, and developmentally disabled. If you are looking for a challenging and rewarding position with an excellent salary, employment security, outstanding benefits* and opportunities for professional growth, we invite you to visit our progressive, modern facility at North Texas State Hospital. **No state income tax, paid sick leave, paid vacation, paid time off for CME, 12-14 paid holidays per year, retirement plan, additional pay available if on call is provided, and much more.*

Contact **Thomas R. Mareth, M.D.**
for more information.
Phone: (940) 552-4150
Fax: (940) 553-2530
thomas.mareth@dshs.state.tx.us
North Texas State Hospital-P.O. Box 2231-Vernon, Texas 76385
North Texas State Hospital is an Equal Opportunity/Drug Free Workplace
Not a Healthcare Shortage Opportunity

Assistant Professor

The Department of Psychiatry and Behavioral Sciences at the University of Texas Medical Branch in Galveston is seeking an Assistant Professor.

Responsibilities include inpatient care, outpatient clinics, resident supervision and teaching. Research opportunities are available. Successful candidates must be board certified/board eligible in Psychiatry.

Candidates with interest and skills in this area should send a curriculum vitae and cover letter to: **Robert M.A. Hirschfeld, M.D., The University of Texas Medical Branch, Department of Psychiatry and Behavioral Sciences, 301 University Boulevard, Galveston, TX 77555-0188**.

The University of Texas Medical Branch is an equal opportunity, affirmative action institution which proudly values diversity. Candidates of all backgrounds are encouraged to apply.

Lubbock Regional Mental Health Mental Retardation Center (LRMHMRC) is recruiting for a board certified or board eligible inpatient psychiatrist for Sunrise Canyon Hospital, a JCAHO accredited, 30 bed adult psychiatric community hospital. Primary responsibilities will include direct patient care and supervision of mid-level professionals.

LRMHMRC offers a competitive salary and compensation package, including 96 hours of paid vacation, 12 paid sick days and eleven paid holidays the first year. Other benefits include a company-sponsored retirement plan, fully paid professional liability insurance and one week of CME with up to $1,000 allowance annually.

LRMHMRC is one of the largest comprehensive behavioral healthcare providers in West Texas. LRMHMRC has been in operation for over 40 years, has a budget of over $24 million and serves over 6,000 people per year. The Sunrise Canyon Hospital's milieu includes a multidisciplinary treatment team approach, including collaboration among psychologists, social workers, an occupational therapist, chemical dependency counselors and crisis intervention staff.

Sunrise Canyon Hospital is located in Lubbock, Texas (population 200,000) which is home to Texas Tech University, a top-tier research institute. Lubbock offers citizens a home-town feel, with big city luxuries. The largest medical community from Dallas to Los Angeles, the city boasts more physicians per capital than Dallas, Phoenix or Denver, but has an average commute of only 17 minutes and a comparatively low cost of living. On average, Lubbock enjoys 227 days of sunshine per year. Visit www.lubbocktexas.com

For more information contact Mary Gerlach, Hospital Administrator at 806-790-5330 or by email: mgerlach@lubbockmhmr.org

LRMHMRC is an equal opportunity and Affirmative Action Employer.

UTAH

CHAIR, DEPARTMENT OF PSYCHIATRY
UNIVERSITY OF UTAH SCHOOL OF MEDICINE

The University of Utah School of Medicine is embarking on a national search for the position of Chair of the Department of Psychiatry. Visionary candidates with a distinguished record of clinical, educational, and investigative accomplishments are invited to apply. Past administrative experience of substance is expected. The Department of Psychiatry at the University of Utah School of Medicine is comprised of 55 full-time physicians, and 129 adjunct faculty members, as well as a very successful training program in adult, pediatric, and triple board programs.

The Department of Psychiatry has exceptional opportunities, including its own inpatient hospital, the newly created University Brain Institute, and a Vanguard site for the National Children's Study.

Interested applicants should submit an electronic curriculum vitae, list of references, and a brief statement describing academic interests and professional goals to:

Jennifer L. Allie
Director, Faculty Administration
University of Utah School of Medicine
30 North 1900 East Room 1C047 SOM
Salt Lake City, UT 84132
PH: (801) 581-5705
FAX: (801) 581-3338
Email: jennifer.allie@hsc.utah.edu

UNIVERSITY OF UTAH IS AN EEO/AA EMPLOYER AND ENCOURAGES APPLICATIONS FROM WOMEN AND MINORITIES

Chief, Psychiatry - VA Salt Lake City Health Care System, Salt Lake City, Utah.
VASLCHCS is affiliated with the Univ. of Utah School of Medicine, and seeks a full-time, tenured or tenure track assoc. or full professor to head Psychiatry Service. VISN 19 is a recent recipient of a Mental Illness Research, Education, and Clinical Center (MIRECC) award centered on suicide prevention, with a portion of the program at the VASLCHCS, under the direction of, Chief Psychiatry. An affiliation is available to the VASLCHCS GRECC and the newly formed Brain Institute at the School of Medicine. The VASLCHCS has 8 psychiatry residents and is a major medical student training site. You must be U.S. Citizen. Relocation expenses are authorized. Closes August 31, 2006. Send CV and three references to VASLCHCS (05C), 500 Foothill Dr., SLC, Utah 84148, announcement #C06-137. For additional information contact Tonya Mackintosh at 801-584-1284, x 2267 or Kellie Roe, x2205. Equal Opportunity Employer.

VA Salt Lake City Health Care System (VASLCHCS), SLC, Utah, seeks a full-time Staff Physician, Psychiatry Service, to serve on a multidisciplinary inpatient general psychiatry team. Applicants must qualify for academic appointment at Univ. of Utah School of Medicine. Must be U.S. Citizen. Relocation expenses are authorized. Closes August 30, 2006. Send CV and three references to VASLCHCS (05C), 500 Foothill Dr., SLC, Utah 84148, Announcement #C06-095A. For additional information contact Tonya Mackintosh at 801-584-1284, x 2267 or Kellie Roe, x2205. Equal Opportunity Employer.

VERMONT

Central Vermont

Washington County Mental Health Services, a CMHC located in Montpelier, is seeking a full time psychiatrist to join its high quality, dedicated psychiatric staff. Opportunities exist for outpatient work with geriatic and adult patients suffering from a wide range of mental illnesses, developmental disorders, and mental retardation. Particularly needed is a psychiatrist for a newly developing, innovative, recovery oriented and trauma informed, highly staffed, ten bed, residential program providing a level of services not previously available outside of a hospital setting in Vermont. Competitive salary and benefits; EOE. Applicant must be BE/BC. Please send cover letter and CV to: Stuart Graves, MD, 9 Heaton Street, Montpelier, VT, 05602, or e-mail to Stuartg@wcmhs.org.

VIRGINIA

GEROPSYCHIATRIST: Virginia Commonwealth University, Department of Psychiatry recruiting Virginia licensable BE/BC psychiatrist in to provide clinical care, training of fellows, residents and medical students, and research activities at Piedmont Geriatric Hospital (80%) and the University campus (20%). Teaching, research experience and geropsychiatry fellowship preferred. J-1 AVAILABLE. PGH is specialty geriatric state hospital located in Burkeville, VA, 35 minutes from Richmond. VCU is a large urban university with robust health science campus and 750-bed university hospital. The Department of Psychiatry employs over 80 fulltime faculty and has well-funded research in women's mental health, genetics, addictions, child mental health and psychopharmacology. Richmond, the State Capital, has moderate climate and rich mix of history with modern facilities, excellent suburban housing, public/private schools. Internet provides comparative cost of living. Send CV to Search Committee, c/o Mary Swartz, VCU, Box 980710, Richmond VA 23298. Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Women, minorities, and persons with disabilities are encouraged to apply.

HORIZON HEALTH
INTERIM Medical Director
Southern Virginia

Horizon Health seeks a Psychiatrist to work on an INTERIM basis from September 4-October 4. State-of-the-art medical center provides high quality patient care. Located in South Hill, Virginia the Psychiatrist will be responsible for the 15-bed adult psychiatric program. Physician will spend 2-3 hours on the inpatient program a day and will share call coverage with local physician. South Hill is located about an hour equal distance from Richmond, VA and Raleigh, NC. Horizon Health will pay physician a daily rate. Interim position could lead into permanent opportunity with full time Medical Director. Please contact Diane Odom for more information 800-935-0099 or e-mail diane.odom@horizonhealth.com, EOE

Norfolk Community Services Board seeks a part-time Child and Adolescent Psychiatrist for newly developed Family Development Center. Must be licensed to practice Medicine in Virginia. Board Certification in General Psychiatry with additional sub-specialty certification in Child and Adolescent Psychiatry preferred. Ideal candidate will have relevant experience working with the seriously emotionally disturbed. Excellent benefits package; salary commensurate with experience. Apply to Norfolk Community Services Board, 248 W. Bute Street, Norfolk VA 23510 or call (757) 441-5300 if you require special assistance. On-line application at www.norfolkcsb.org. EOE M/F/D/V. Background check required.

Christiansburg, VA - General Adult Psychiatrist needed in Virginia's New River Valley region for state-of-the-art inpatient facility with office suite contiguous to the inpatient unit. Position provides for a combination of inpatient/outpatient psychiatry, including administering ECT; on-call an average of 6-7 days/month, including 1-2 weekend days. Virginia's New River Valley region comprises the localities of Blacksburg, home of Virginia Tech, and Radford, home of Radford University, plus the town of Christiansburg and surrounding communities, a population of 175k. Carilion Health System is a nonprofit regional healthcare system comprised of several acute-care hospitals including teaching/tertiary referral center nearby, medical education programs, and 70+ multispecialty clinics. Base salary with bonus incentive plan based on quality outcome and scorecard measures. Requirements: Minimum of 3 years experience post-residency, and/or other professional experience prior to completing residency; ABMS-BC ideal, or BE acceptable with plan in place to receive certification in 2 years; excellent interpersonal and communication skills. Positions available immediately. To apply, submit CV with references and cover letter to:

Rhonda B. Creger, Physician Recruiter
Carilion Health System
POB 40032
Roanoke, VA 24022-0032
Office 540-224-5189
FAX 540-985-5329
Email: rhondac@carilion.com
Website: www.carilion.com

WASHINGTON

PSYCHIATRIST, SEATTLE SUBERB

Seeking a full-time BC/BE psychiatrist to join our multidisciplinary group practice.

Ours is a collegial and professionally stimulating practice environment. Established practice base and referral source. Set our own hours, 1-6 call. We offer a one-year salary guarantee with benefits. This area is consistently rated as one of the best places to live and work. Just minutes from downtown Seattle and the shores of Puget Sound. For more information please email CV to gmumma@Highlinemedical.org or Fax to 206-242-4625.

Emergency Psychiatry Clinical Faculty Position
University of Washington, Seattle, WA

Harborview Medical Center, Department of Psychiatry and Behavioral Sciences is seeking a psychiatrist in the Psychiatric Emergency Services (PES). The coverage is shared among several psychiatrists who work under the supervision of the PES Medical Director. The position will receive a UW clinical faculty appointment. The PES attending psychiatrists provide direct evaluation, triage and acute treatment to patients, and overall supervision of the clinical team, including residents. Pay scale is highly competitive due to shift work and off-hours schedule. University of Washington faculty engage in teaching, research and service. HMC has a nationally recognized psychiatric emergency service and strives to deliver state of the art care in an academic medical setting. Please forward your letter and CV to: Peter Roy-Byrne, MD, Box 359911 Psychiatry HMC 325 9th Avenue, Seattle 98104. The UW is building a culturally diverse faculty and strongly encourages applications from females and minority candidates. The UW is and EOE/AA employer.

The University of Washington and Harborview Medical Center (HMC) in Seattle, WA is accepting applications for a psychiatrist at the rank of Assistant or Associate Professor. This position is 1.0 FTE and will work on the inpatient and outpatient services. The position will also be responsible for teaching residents and medical students. University of Washington faculty engage in teaching, research and service. Please send application and CV to Peter Roy-Byrne MD, Chief Psychiatry, Harborview Medical Center 325 9th Ave. Box 359911, Seattle, WA 98104. The UW is building a culturally diverse faculty and strongly encourages applications from females and minority candidates. The UW is and EOE/AA employer.

BE/BC PSYCHIATRIST
Seeking BE/BC psychiatrist with an interest in geriatrics (fellowship training a plus) to join a collaborative practice affiliated with a comprehensive medical center. Mostly outpatient with some inpatient. One-year salary guarantee and practice startup support. Located just 20 minutes from downtown Seattle and the shores of Puget Sound. This area is consistently rated as one of the best places to live.
For more information send CV to gmumma @HighlineMedical.org or Fax to 206-242-4625

WEST VIRGINIA

PSYCHIATRISTS - William R. Sharpe, Jr. Hospital, a 150-bed, JCAHO-accredited, state psychiatric hospital and winner of APA Award for state/university collaboration, is searching for BE/BC psychiatrists. The facility is unique in the region for the range of psychiatric services offered and quality of care provided. The hospital is one of the largest training sites for various clinical disciplines including psychiatric residents, medical students as well as psychology, social work and nursing trainees. These are full time faculty positions with regionally competitive salaries and excellent benefits. There is no call duty. The area has an abundance of outdoor activities, four-season climate, and one of the lowest crime rates in the country. There are several metropolitan areas within easy driving distance. West Virginia University is an affirmative action/equal opportunity employer. Women and minority candidates are encouraged to apply. Positions will be open until filled. Contact Abe Adel, MD, Clinical Director, William R. Sharpe, Jr. Hospital, WVU Department of Behavioral Medicine & Psychiatry 936 William Sharpe Road, Weston, WV 26452. 304-269-1210. bettygumfoster@wvdhhr.org

WISCONSIN

Outstanding private practice opportunity. One of our 3 psychiatrists is retiring. Walk in and take over his 26-year practice. No investment required. Furniture, office staff, billing system all in place. Hospital affiliation available but not required. Lakefront community of 90,000 midway between Chicago & Milwaukee. Kenosha Psychiatric Associates. Fax (262) 652-4450. Email kenoshapsych@sbcglobal.net

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Madison, WI - noted as "U.S. Best City", two years, seeks a BC/BE child psychiatrist. *Capitol Associates*, well-recognized for more than 20 years, is Madison's largest, independent, licensed mental health clinic and is dedicated to comprehensive inpatient/outpatient care. CA boasts 14 mental health professionals, including 2 psychiatrists. A university town surrounded by many lakes, Madison has abundant recreational activities, high educational standards and support for the arts. Please consider joining our caring, energetic team. Capitol Associates, LLC, Attention: Johna Gerasch, PhD (Managing Partner), 440 Science Dr., Suite 200, Madison, WI 53711. (608) 238-5176, ext. 314.

SPECTACULAR OPPORTUNITY
FOR INPATIENT MEDICAL DIRECTOR

Gundersen Lutheran, a multidisciplinary 400 member group practice in La Crosse, WI, is seeking an experienced BC/BE Psychiatrist to perform the functions of the Medical Director of an existing Inpatient Unit and to develop a day hospital program.

This candidate will join 9 general and 4 child psychiatrists, 7 psychologists and more than 40 therapists in providing outpatient/inpatient care for a broad range of clinical disorders.

Psychiatric outpatient care is offered on our main campus and at several sites in the Gundersen Lutheran healthcare system. Inpatient care is provided in a 27-bed unit, which is adjacent to the medical center. Call will be 1:12.

Located in a city of 52,000 with a metropolitan area of 120,000 and a service delivery area of more than 500,000, Gundersen Lutheran provides the opportunity to practice metropolitan-scale medicine in a context of small town character and comforts. Nationally recognized schools, three universities, safe neighborhoods, affordable housing and extensive recreational and cultural activities make La Crosse, on the Mississippi River, an outstanding place to live and work. Our compensation package, pension plan and continuing education opportunities are exceptional.

Interested candidates are invited to call Gale Kreibich, Medical Staff Development, Gundersen Lutheran, at 1-800-362-9567, ext. 56863, 1900 South Ave., La Crosse, WI, 54601, or e-mail grkreibi@gundluth.org

We support a safe, healthy and drug-free work environment through background checks and controlled substance screening.
EOE/AA

MEDICAL DIRECTOR
Wausau, WI

Horizon Health seeks a **Medical Director** for a 12-bed adult inpatient psychiatric program at our client hospital in **Wausau, WI**. Attractive **salary** with full benefits in addition to administrative **stipend** paid for Medical Director's duties. Contact: Mark Blakeney, Horizon Health, 800-935-0099 x7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. Visit our web site: www.horizonhealth.com. EOE.

PSYCHIATRIST - Full-time position for outpatient psychiatrist with no on-call responsibilities to work in our Wauwatosa, WI counseling office. Individual must be licensable in the State of Wisconsin. Salary range $134,000 - $200,000 and excellent benefit package. Preferably adheres to evangelical Christian belief. Send CV to Mary Schoultz, HRM, Wisconsin Lutheran Child & Family Service, PO Box 245039, Milwaukee, WI 53224-9539, or for additional information, contact Dr. R.P. Ascano, Provider Service Director, (218)643-3867, rascano@wlcfs.org.

WYOMING

CASPER: General or Child Psychiatrist - combination outpatient, partial & inpatient services. Multidisciplinary treatment team support. Compensation plan offers salary, benefits & bonus potential. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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The Allure of the West!

- Ranked #1 in the U.S. by "Kiplinger's" for the lowest taxes paid per household
- Ideal to raise a family, possesses great schools, and retains its western charm although only 90 minutes from Denver
- United Medical Center is a 206-bed hospital that serves Wyoming, Northern Colorado, and Western Nebraska
- 16-bed Behavioral Health Unit (12 adult and 4 adolescent) and active outpatient clinic

Adult Psychiatrists
Opportunities for both inpatient and outpatient treatment of adults. Skills and experience in treating geriatrics a plus.

Addiction Specialist
Unique opportunity to spearhead and champion the expansion of a hospital-based, outpatient addiction treatment program. Specialization in addiction treatment is required.

Both candidates must be team players with excellent communication skills. Program development a plus. Board-Certified (or-eligible). Wyoming license (or-eligible).

Contact: Lauren Maines, Physician Recruiter, 214 E. 23rd St. Cheyenne, Wyoming 82001, Office: (307) 432-2649, Fax: (307) 432-3181, LMaines@umcwy.org.

International

MAKE A DIFFERENCE! Outstanding opportunity in cross-cultural psychiatry. Work as a psychiatrist in the W Pacific with all ages and diverse settings. Competitive salary with excellent tax benefits. Also eligible for NHSC loan repayment. Contact Dr Shearer docrobin@pticom.com, or: www.dphsaipan.com & www.saipanhospitaldocs.org

Fellowships

Geropsychiatry Fellowship, Portland, Oregon. Recruiting for 07/01/07 ACGME-accredited PGY5 level, at Oregon Health & Science Univ and Portland VA Med Center. Flexible program with either research or clinical emphasis. Training sites include inpatient, outpatient, nursing home and community. Research and clinical strengths in end-of-life/palliative care, ethics, mood disorders, dementias, Parkinson's disease, and substance abuse. Contact Dr. Linda Ganzini, Dir, Geriatric Psychiatry Training, Mental Health Div, P3MHDC, PO Box 1034, Portland, OR 97207; (503) 220-8262, Ext. 56492; or at Linda.Ganzini@va.gov. EOE.

Positions Wanted

Psychiatrist with several years of clinical and biological research experience and leadership roles in the field of schizophrenia research, looking for a full-time position to mentor young academicians and aid the development of psychiatric research in an academic, industrial, government or private foundation setting. Currently based in NYC, but willing to relocate depending on the position. Expertise includes brain imaging and genetics. Please respond to Box P-727, Psychiatric News Classifieds, American Psychiatric Publishing, Inc., 1000 Wilson Blvd. Suite 1825, Arlington, VA 22209.

CYMBALTA®

(duloxetine hydrochloride) Delayed-release Capsules

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

WARNING

Suicidality in Children and Adolescents—Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Cymbalta or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Cymbalta is not approved for use in pediatric patients. (*See* WARNINGS *and* PRECAUTIONS, Pediatric Use.)

Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

INDICATIONS AND USAGE: Cymbalta is indicated for the treatment of major depressive disorder (MDD). Cymbalta is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN).

CONTRAINDICATIONS: ***Hypersensitivity***—Known hypersensitivity to duloxetine or any of the inactive ingredients. ***Monoamine Oxidase Inhibitors (MAOIs)***—Concomitant use with Cymbalta is contraindicated (*see* WARNINGS). ***Uncontrolled Narrow-Angle Glaucoma***—In clinical trials, Cymbalta use was associated with an increased risk of mydriasis; therefore, its use is not recommended in patients with uncontrolled narrow-angle glaucoma.

WARNINGS: Clinical Worsening and Suicide Risk—Patients with MDD, both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with MDD and other psychiatric disorders.

Pooled analyses of short-term placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with MDD, OCD, or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal behavior or thinking (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. There was considerable variation in risk among drugs, but a tendency toward an increase for almost all drugs studied. The risk of suicidality was most consistently observed in the MDD trials, but there were signals of risk arising from some trials in other psychiatric indications (obsessive compulsive disorder and social anxiety disorder) as well. **No suicides occurred in any of these trials.** It is unknown whether the suicidality risk in pediatric patients extends to longer-term use, ie, beyond several months. It is also unknown whether the suicidality risk extends to adults.

All pediatric patients being treated with antidepressants for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Such observation would generally include at least weekly face-to-face contact with patients or their family members or caregivers during the first 4 weeks of treatment, then every other week visits for the next 4 weeks, then at 12 weeks, and as clinically indicated beyond 12 weeks. Additional contact by telephone may be appropriate between face-to-face visits.

Adults with MDD or co-morbid depression in the setting of other psychiatric illness being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for MDD as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (*see* PRECAUTIONS, Discontinuation of Treatment with Cymbalta).

Families and caregivers of pediatric patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for Cymbalta should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose. Families and caregivers of adults being treated for depression should be similarly advised.

Screening Patients for Bipolar Disorder—A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Cymbalta is not approved for use in treating bipolar depression.

MAOIs—In patients receiving a serotonin reuptake inhibitor (SSRI) in combination with an MAOI, there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRIs and are then started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. The effects of combined use of Cymbalta and MAOIs have not been evaluated in humans or animals. Therefore, because Cymbalta is an inhibitor of both serotonin and norepinephrine reuptake, it is recommended that Cymbalta not be used in combination with an MAOI, or within at least 14 days of discontinuing treatment with an MAOI. Based on the half-life of Cymbalta, at least 5 days should be allowed after stopping Cymbalta before starting an MAOI.

PRECAUTIONS: ***General***—Hepatotoxicity—Cymbalta increases the risk of elevation of serum transaminase levels. Liver transaminase elevations resulted in the discontinuation of 0.4% (31/8454) of Cymbalta-treated patients. In these patients, the median time to detection of the transaminase elevation was about two months. In controlled trials in MDD, elevations of alanine transaminase (ALT) to >3 times the upper limit of normal occurred in 0.9% (8/930) of Cymbalta-treated patients and in 0.3% (2/652) of placebo-treated patients. In controlled trials in DPN, elevations of ALT to >3 times the upper limit of normal occurred in 1.68% (8/477) of Cymbalta-treated patients and in 0% (0/187) of placebo-treated patients. In the full cohort of placebo-controlled trials in any indication, 1% (39/3732) of Cymbalta-treated patients had a >3 times the upper limit of normal elevation of ALT compared to 0.2% (6/2568) of placebo-treated patients. In placebo-controlled studies using a fixed-dose design, there was evidence of a dose-response relationship for ALT and AST elevation of >3 times the upper limit of normal and >5 times the upper limit of normal, respectively Postmarketing reports have described cases of hepatitis with abdominal pain, hepatomegaly and elevation of transaminase levels to more than twenty times the upper limit of normal with or without jaundice, reflecting a mixed or hepatocellular pattern of liver injury. Cases of cholestatic jaundice with minimal elevation of transaminase levels have also been reported.

The combination of transaminase elevations and elevated bilirubin, without evidence of obstruction, is generally recognized as an important predictor of severe liver injury. In clinical trials, three Cymbalta patients had elevations of transaminases and bilirubin, but also had elevation of alkaline phosphatase, suggesting an obstructive process; in these patients, there was evidence of heavy alcohol use and this may have contributed to the abnormalities seen. Two placebo-treated patients also had transaminase elevations with elevated bilirubin. Postmarketing reports indicate that elevated transaminases, bilirubin and alkaline phosphatase have occurred in patients with chronic liver disease or cirrhosis. Because it is possible that duloxetine and alcohol may interact to cause liver injury or that duloxetine may aggravate pre-existing liver disease, Cymbalta should ordinarily not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease. Effect on Blood Pressure—In MDD clinical trials, Cymbalta treatment was associated with mean increases in blood pressure, averaging 2 mm Hg systolic and 0.5 mm Hg diastolic and an increase in the incidence of at least one measurement of systolic blood pressure over 140 mm Hg compared to placebo. Blood pressure should be measured prior to initiating treatment and periodically measured throughout treatment (*see* ADVERSE REACTIONS, Vital Sign Changes). Activation of Mania/Hypomania—In placebo-controlled trials in patients with MDD, activation of mania or hypomania was reported in 0.1% (1/1139) of Cymbalta-treated patients and 0.1% (1/777) of placebo-treated patients. Activation of mania/hypomania has been reported in a small proportion of patients with mood disorders who were treated with other marketed drugs effective in the treatment of MDD. As with these other agents, Cymbalta should be used cautiously in patients with a history of mania. Seizures—Cymbalta has not been systematically evaluated in patients with a seizure disorder, and such patients were excluded from clinical studies. In placebo-controlled clinical trials in patients with MDD, seizures occurred in 0.1% (1/1139) of Cymbalta-treated patients and 0% (0/777) of placebo treated patients. In placebo-controlled clinical trials in patients with diabetic peripheral neuropathy, seizures did not occur in any patients treated with either Cymbalta or placebo. Cymbalta should be prescribed with care in patients with a history of a seizure disorder. Controlled Narrow-Angle Glaucoma—In clinical trials, Cymbalta was associated with an increased risk of mydriasis; therefore, it should be used cautiously in patients with controlled narrow-angle glaucoma (*see* CONTRAINDICATIONS, Uncontrolled Narrow-Angle Glaucoma). Discontinuation of Treatment with Cymbalta—Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in MDD placebo-controlled clinical trials of up to 9 weeks duration, the following symptoms occurred at a rate greater than or equal to 2% and at a significantly higher rate in Cymbalta-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; and nightmare.

During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (eg, paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Use in Patients with Concomitant Illness—Clinical experience with Cymbalta in patients with concomitant systemic illnesses is limited. There is no information on the effect that alterations in gastric motility may have on the stability of Cymbalta's enteric coating. As duloxetine is rapidly hydrolyzed in acidic media to naphthol, caution is advised in using Cymbalta in patients with conditions that may slow gastric emptying (eg, some diabetics). Cymbalta has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable coronary artery disease. Patients with these diagnoses were generally excluded from clinical studies during the product's premarketing testing. However, the electrocardiograms of 321 patients who received Cymbalta in MDD placebo-controlled clinical trials and had qualitatively normal ECGs at baseline were evaluated; Cymbalta was not associated with the development of clinically significant ECG abnormalities (*see* ADVERSE REACTIONS, Electrocardiogram Changes). In DPN placebo-controlled clinical trials, Cymbalta-treated patients did not develop abnormal ECGs at a rate different from that in placebo-treated patients (*see* ADVERSE REACTIONS, Electrocardiogram Changes). In three clinical trials of Cymbalta for the management of neuropathic pain associated with diabetic peripheral neuropathy, the mean duration of diabetes was approximately 12 years, the mean baseline fasting blood glucose was 176 mg/dL, and the mean baseline hemoglobin A_{1c} (HbA_{1c}) was 7.8%. In the 12-week acute treatment phase of these studies, small increases in fasting blood glucose were observed in Cymbalta-treated patients. HbA_{1c} was stable in both Cymbalta-treated and placebo-treated patients. In the extension phase of these studies, which lasted up to 52 weeks, there was an increase in HbA_{1c} in both the Cymbalta and the routine care groups, but the mean increase was 0.3% greater in the Cymbalta-treated group. There was also a small increase in fasting blood glucose in the Cymbalta-treated group. Total cholesterol was increased in Cymbalta-treated patients (2 mg/dL) and decreased in the routine care group (6 mg/dL). Increased plasma concentrations of duloxetine, and especially of its metabolites, occur in patients with end-stage renal disease (requiring dialysis). For this reason, Cymbalta is not recommended for patients with end-stage renal disease or severe renal impairment (creatinine clearance <30 mL/min). Markedly increased exposure to duloxetine occurs in patients with hepatic insufficiency and Cymbalta should not be administered to these patients.

Laboratory Tests—No specific laboratory tests are recommended.

Drug Interactions—*Potential for Other Drugs to Affect Cymbalta*—Both CYP1A2 and CYP2D6 are responsible for duloxetine metabolism. Inhibitors of CYP1A2—Concomitant use of duloxetine with fluvoxamine, an inhibitor of CYP1A2, results in approximately a 6-fold increase in AUC and about a 2.5-fold increase in C_{max} of duloxetine. Some quinolone antibiotics would be expected to have similar effects and these combinations should be avoided. Inhibitors of CYP2D6—Because CYP2D6 is involved in duloxetine metabolism, concomitant use of duloxetine with potent inhibitors of CYP2D6 may result in higher concentrations of duloxetine. Paroxetine (20 mg QD) increased the concentration of duloxetine (40 mg QD) by about 60%, and greater degrees of inhibition are expected with higher doses of paroxetine. Similar effects would be expected with other potent CYP2D6 inhibitors (eg, fluoxetine, quinidine). *Potential for Duloxetine to Affect Other Drugs*—Drugs Metabolized by CYP1A2—*In vitro* drug interaction studies demonstrate that duloxetine does not induce CYP1A2 activity, and it is unlikely to have a clinically significant effect on the metabolism of CYP1A2 substrates. Drugs Metabolized by CYP2D6—Cymbalta is a moderate inhibitor of CYP2D6. When duloxetine was administered (at a dose of 60 mg BID) in conjunction with a single 50-mg dose of desipramine, a CYP2D6 substrate, the AUC of desipramine increased 3-fold. Therefore, co-administration of Cymbalta with other drugs that are extensively metabolized by this isozyme and which have a narrow therapeutic index, including certain antidepressants (tricyclic antidepressants [TCAs], such as nortriptyline, amitriptyline, and imipramine), phenothiazines and Type 1C antiarrhythmics (eg, propafenone, flecainide), should be approached with caution. Plasma TCA concentrations may need to be monitored and the dose of the TCA may need to be reduced if a TCA is co-administered with Cymbalta. Because of the risk of serious ventricular arrhythmias and sudden death potentially associated with elevated plasma levels of thioridazine, Cymbalta and thioridazine should not be co-administered.

Drugs Metabolized by CYP3A—Results of *in vitro* studies demonstrate that duloxetine does not inhibit or induce CYP3A activity. *Cymbalta May Have a Clinically Important Interaction with the Following Other Drugs*—Alcohol—When Cymbalta and ethanol were administered several hours apart so that peak concentrations of each would coincide, Cymbalta did not increase the impairment of mental and motor skills caused by alcohol. In the Cymbalta clinical trials database, three Cymbalta-treated patients had liver injury as manifested by ALT and total bilirubin elevations, with evidence of obstruction. Substantial intercurrent ethanol use was present in each of these cases, and this may have contributed to the abnormalities seen (*see* PRECAUTIONS, Hepatotoxicity). CNS-Acting Drugs—Given the primary CNS effects of Cymbalta, it should be used with caution when it is taken in combination with or substituted for other centrally acting drugs, including those with a similar mechanism of action. Potential for Interaction with Drugs that Affect Gastric Acidity—Cymbalta has an enteric coating that resists dissolution until reaching a segment of the gastrointestinal tract where the pH exceeds 5.5. In extremely acidic conditions, Cymbalta, unprotected by the enteric coating, may undergo hydrolysis to form naphthol. Caution is advised in using Cymbalta in patients with conditions that may slow gastric emptying (eg, some diabetics). Drugs that raise the gastrointestinal pH may lead to an earlier release of duloxetine. However, co-administration of Cymbalta with aluminum- and magnesium-containing antacids (51 mEq) or Cymbalta with famotidine, had no significant effect on the rate or extent of duloxetine absorption after administration of a 40-mg oral dose. It is unknown whether the concomitant administration of proton pump inhibitors affects duloxetine absorption.

Monoamine Oxidase Inhibitors—*See* CONTRAINDICATIONS *and* WARNINGS.

Carcinogenesis, Mutagenesis, Impairment of Fertility—Carcinogenesis—Duloxetine was administered in the diet to mice and rats for 2 years. In female mice receiving duloxetine at 140 mg/kg/day (11 times the maximum recommended human dose [MRHD, 60 mg/day] and 6 times the human dose of 120 mg/day on a mg/m^2 basis), there was an increased incidence of hepatocellular adenomas and carcinomas. The no-effect dose was 50 mg/kg/day (4 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis). Tumor incidence was not increased in male mice receiving duloxetine at doses up to 100 mg/kg/day (8 times the MRHD and 4 times the human dose of 120 mg/day on a mg/m^2 basis). In rats, dietary doses of duloxetine up to 27 mg/kg/day in females (4 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis) and up to 36 mg/kg/day in males (6 times the MRHD and 3 times the human dose of 120 mg/day on a mg/m^2 basis) did not increase the incidence of tumors. Mutagenesis—Duloxetine was not mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) and was not clastogenic in an *in vivo* chromosomal aberration test in mouse bone marrow cells. Additionally, duloxetine was not genotoxic in an *in vitro* mammalian forward gene mutation assay in mouse lymphoma cells or in an *in vitro* unscheduled DNA synthesis (UDS) assay in primary rat hepatocytes, and did not induce sister chromatid exchange in Chinese hamster bone marrow *in vivo*. Impairment of Fertility—Duloxetine administered orally to either male or female rats prior to and throughout mating at daily doses up to 45 mg/kg/day (7 times the maximum recommended human dose of 60 mg/day and 4 times the human dose of 120 mg/day on a mg/m^2 basis) did not alter mating or fertility.

Pregnancy—Pregnancy Category C—In animal reproduction studies, duloxetine has been shown to have adverse effects on embryo/fetal and postnatal development. When duloxetine was administered orally to pregnant rats and rabbits during the period of organogenesis, there was no evidence of teratogenicity at doses up to 45 mg/kg/day (7 times the maximum recommended human dose [MRHD, 60 mg/day] and 4 times the human dose of 120 mg/day on a mg/m^2 basis, in rats; 15 times the MRHD and 7 times the human dose of 120 mg/day on a mg/m^2 basis in rabbits). However, fetal weights were decreased at this dose, with a no-effect dose of 10 mg/kg/day (2 times the MRHD and =1 times the human dose of 120 mg/day on a mg/m^2 basis in rats; 3 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis in rabbits). When duloxetine was administered orally to pregnant rats throughout gestation and lactation, the survival of pups to 1 day postpartum and pup body weights at birth and during the lactation period were decreased at a dose of 30 mg/kg/day (5 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis) ; the no-effect dose was 10 mg/kg/day. Furthermore, behaviors consistent with increased reactivity, such as increased startle response to noise and decreased habituation of locomotor activity, were observed in pups following maternal exposure to 30 mg/kg/day. Post-weaning growth and reproductive performance of the progeny were not affected adversely by maternal duloxetine treatment.

There are no adequate and well-controlled studies in pregnant women; therefore, duloxetine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects—Neonates exposed to SSRIs or serotonin and norepinephrine reuptake inhibitors (SNRIs), late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome (*see* WARNINGS, Monoamine Oxidase Inhibitors). When treating a pregnant woman with Cymbalta during the third trimester, the physician should carefully consider the potential risks and benefits of treatment.

Labor and Delivery—The effect of duloxetine on labor and delivery in humans is unknown. Duloxetine should be used during labor and delivery only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Duloxetine is excreted into the milk of lactating women. The estimated daily infant dose on a mg/kg basis is approximately 0.14% of the maternal dose. Because the safety of duloxetine in infants is not known, nursing while on Cymbalta is not recommended. However, if the physician determines that the benefit of duloxetine therapy for the mother outweighs any potential risk to the infant, no dosage adjustment is required as lactation did not influence duloxetine pharmacokinetics.

Pediatric Use—Safety and effectiveness in the pediatric population have not been established (*see* BOX WARNING *and* WARNINGS, Clinical Worsening and Suicide Risk). Anyone considering the use of Cymbalta in a child or adolescent must balance the potential risks with the clinical need.

Geriatric Use—Of the 2418 patients in clinical studies of Cymbalta for MDD, 5.9% (143) were 65 years of age or over. Of the 1074 patients in the DPN studies, 33% (357) were 65 years of age or over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS: Cymbalta has been evaluated for safety in 2418 patients diagnosed with MDD who participated in multiple-dose premarketing trials, representing 1099 patient-years of exposure. Among these 2418 Cymbalta-treated patients, 1139 patients participated in eight 8 or 9 week, placebo-controlled trials at doses ranging from 40 to 120 mg/day, while the remaining 1279 patients were followed for up to 1 year in an open-label safety study using flexible doses from 80 to 120 mg/day. Two placebo-controlled studies with doses of 80 and 120 mg/day had 6-month maintenance extensions. Of these 2418 patients, 993 Cymbalta-treated patients were exposed for at least 180 days and 445 Cymbalta-treated patients were exposed for at least 1 year. Cymbalta has also been evaluated for safety in 1074 patients with diabetic peripheral neuropathy representing 472 patient-years of exposure. Among these 1074 Cymbalta-treated patients, 568 patients participated in two 12 to 13 week, placebo-controlled trials at doses ranging from 20 to 120 mg/day. An additional 449 patients were enrolled in an open-label safety study using 120 mg/day for a duration of 6 months. Another 57 patients, originally treated with placebo, were exposed to Cymbalta for up to 12 months at 60 mg twice daily in an extension phase. Among these 1074 patients, 484 had 6 months of exposure to Cymbalta, and 220 had 12 months of exposure. For both MDD and DPN clinical trials, adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs.

Clinical investigators recorded adverse events using descriptive terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals experiencing adverse events, grouping similar types of events into a smaller number of standardized event categories is necessary. MedDRA terminology was used to classify reported adverse events.

The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. Events reported during the studies were not necessarily caused by the therapy, and the frequencies do not reflect investigator impression (assessment) of causality.

Adverse Events Reported as Reasons for Discontinuation of Treatment in Placebo-Controlled Trials—Major Depressive Disorder—Approximately 10% of the 1139 patients who received Cymbalta in the MDD placebo-controlled trials discontinued treatment due to an adverse event, compared with 4% of the 777 patients receiving placebo. Nausea (Cymbalta 1.4%, placebo 0.1%) was the only common adverse event reported as reason for discontinuation and considered to be drug-related (ie, discontinuation occurring in at least 1% of the Cymbalta-treated patients and at a rate of at least twice that of placebo). Diabetic Peripheral Neuropathic Pain—Approximately 14% of the 568 patients who received Cymbalta in the DPN placebo-controlled trials discontinued treatment due to an adverse event, compared with 7% of the 223 patients receiving placebo. Nausea (Cymbalta 3.5%, placebo 0.4%), dizziness (Cymbalta 1.6%, placebo 0.4%), somnolence (Cymbalta 1.6%, placebo 0%) and fatigue (Cymbalta 1.1%, placebo 0%) were the common adverse events reported as reasons for discontinuation and considered to be drug-related (ie, discontinuation occurring in at least 1% of the Cymbalta-treated patients and at a rate of at least twice that of placebo).

Adverse Events Occurring at an Incidence of 2% or More Among Cymbalta-Treated Patients in Placebo-Controlled Trials—Major Depressive Disorder—Treatment-emergent adverse events that occurred in 2% or more of patients treated with Cymbalta in the premarketing acute phase of MDD placebo-controlled trials (N=1139 Cymbalta; N=777 placebo) with an incidence greater than placebo were: Gastrointestinal Disorders—nausea, dry mouth, constipation, diarrhea, vomiting; Metabolism and Nutrition Disorders—appetite decreased (includes anorexia); Investigations—weight decreased; General Disorders and Administration Site Conditions—fatigue; Nervous System Disorders—dizziness, somnolence, tremors; Skin and Subcutaneous Tissue Disorders—sweating increased; Vascular Disorders—hot flushes; Eye Disorders—vision blurred; Psychiatric Disorders—insomnia (includes middle insomnia), anxiety, libido decreased, orgasm abnormal (includes anorgasmia); Reproductive System and Breast Disorders—males only: erectile dysfunction, ejaculation delayed, ejaculatory dysfunction (includes ejaculation disorder and ejaculation failure).

The following events were reported by at least 2% of patients treated with Cymbalta for MDD and had an incidence ≤ placebo: upper abdominal pain, palpitations, dyspepsia, back pain, arthralgia, headache, pharyngitis, cough, nasopharyngitis, and upper respiratory tract infection.

The most commonly observed adverse events in Cymbalta-treated MDD patients (incidence ≥5% and at least twice the incidence in placebo patients) were: nausea; dry mouth; constipation; decreased appetite; fatigue; somnolence; and increased sweating.

Diabetic Peripheral Neuropathic Pain—Treatment emergent adverse events that occurred in 2% or more of patients treated with Cymbalta in the premarketing acute phase of DPN placebo-controlled trials (N=225 Cymbalta 60 mg BID; N=228 Cymbalta 60 mg QD; N=115 Cymbalta 20 mg QD; N=223 placebo) with an incidence greater than placebo were: Gastrointestinal Disorders—nausea, constipation, diarrhea, dry mouth, vomiting, dyspepsia, loose stools; General Disorders and Administration Site Conditions—fatigue, asthenia, pyrexia; Infections and Infestations—nasopharyngitis; Metabolism and Nutrition Disorders—decreased appetite, anorexia; Musculoskeletal and Connective Tissue Disorders—muscle cramp, myalgia; Nervous System Disorders—somnolence, headache, dizziness, tremor; Psychiatric Disorders—insomnia; Renal and Urinary Disorders—pollakiuria; Reproductive System and Breast Disorders—erectile dysfunction; Respiratory, Thoracic and Mediastinal Disorders—cough, pharyngolaryngeal pain; Skin and Subcutaneous Tissue Disorders—hyperhidrosis.

The following events were reported by at least 2% of patients treated with Cymbalta for DPN and had an incidence ≤ placebo: edema peripheral, influenza, upper respiratory tract infection, back pain, arthralgia, pain in extremity, and pruritus.

The most commonly observed adverse events in Cymbalta-treated DPN patients (incidence ≥5% and at least twice the incidence in placebo patients) were: nausea; somnolence; dizziness; constipation; dry mouth; hyperhidrosis; decreased appetite; and asthenia.

Adverse events seen in men and women were generally similar except for effects on sexual function (described below). Clinical studies of Cymbalta did not suggest a difference in adverse event rates in people over or under 65 years of age. There were too few non-Caucasian patients studied to determine if these patients responded differently from Caucasian patients.

Effects on Male and Female Sexual Function—Although changes in sexual desire, sexual performance and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. Sexual side effects spontaneously reported by at least 2% of either male or female patients taking Cymbalta in MDD placebo-controlled trials were: Males (N=378 Cymbalta; N=247 placebo): orgasm abnormal (includes anorgasmia), ejaculatory dysfunction (includes ejaculation disorder and ejaculation failure), libido decreased, erectile dysfunction, ejaculation delayed. Females (N=761 Cymbalta; N=530 placebo): orgasm abnormal, libido decreased.

Because adverse sexual events are presumed to be voluntarily underreported, the Arizona Sexual Experience Scale (ASEX), a validated measure designed to identify sexual side effects, was used prospectively in 4 MDD placebo-controlled trials. In these trials, patients treated with Cymbalta experienced significantly more sexual dysfunction, as measured by the total score on the ASEX, than did patients treated with placebo. Gender analysis showed that this difference occurred only in males. Males treated with Cymbalta experienced more difficulty with ability to reach orgasm (ASEX Item 4) than males treated with placebo. Females did not experience more sexual dysfunction on Cymbalta than on placebo as measured by ASEX total score. These studies did not, however, include an active control drug with known effects on female sexual dysfunction, so that there is no evidence that its effects differ from other antidepressants. Physicians should routinely inquire about possible sexual side effects. See Table 4 in full PI for specific ASEX results.

Urinary Hesitation—Cymbalta is in a class of drugs known to affect urethral resistance. If symptoms of urinary hesitation develop during treatment with Cymbalta, consideration should be given to the possibility that they might be drug-related. ***Laboratory Changes***—Cymbalta treatment, for up to 9 weeks in MDD or 13 weeks in DPN placebo-controlled clinical trials, was associated with small mean increases from baseline to endpoint in ALT, AST, CPK, and alkaline phosphatase; infrequent, modest, transient, abnormal values were observed for these analytes in Cymbalta-treated patients when compared with placebo-treated patients (*see* PRECAUTIONS). ***Vital Sign Changes***—Cymbalta treatment, for up to 9 weeks in MDD placebo-controlled clinical trials of 40 to 120 mg daily doses caused increases in blood pressure, averaging 2 mm Hg systolic and 0.5 mm Hg diastolic compared to placebo and an increase in the incidence of at least one measurement of systolic blood pressure over 140 mm Hg (*see* PRECAUTIONS). Cymbalta treatment, for up to 9 weeks in MDD placebo-controlled clinical trials and for up to 13 weeks in DPN placebo-controlled trials caused a small increase in heart rate compared to placebo of about 2 beats per minute. ***Weight Changes***—In MDD placebo-controlled clinical trials, patients treated with Cymbalta for up to 9 weeks experienced a mean weight loss of approximately 0.5 kg, compared with a mean weight gain of approximately 0.2 kg in placebo-treated patients. In DPN placebo-controlled clinical trials, patients treated with Cymbalta for up to 13 weeks experienced a mean weight loss of approximately 1.1 kg, compared with a mean weight gain of approximately 0.2 kg in placebo-treated patients. ***Electrocardiogram Changes***—Electrocardiograms were obtained from 321 Cymbalta-treated patients with MDD and 169 placebo-treated patients in clinical trials lasting up to 8 weeks. The rate-corrected QT (QTc) interval in Cymbalta-treated patients did not differ from that seen in placebo-treated patients. No clinically significant differences were observed for QT, PR, and QRS intervals between Cymbalta-treated and placebo-treated patients. Electrocardiograms were obtained from 528 Cymbalta-treated patients with DPN and 205 placebo-treated patients in clinical trials lasting up to 13 weeks. The rate-corrected QT (QTc) interval in Cymbalta-treated patients did not differ from that seen in placebo-treated patients. No clinically significant differences were observed for QT, PR, QRS, or QTc measurements between Cymbalta-treated and placebo-treated patients.

Postmarketing Spontaneous Reports—Adverse events reported rarely since market introduction that were temporally related to Cymbalta therapy include: hallucinations, rash, and urinary retention. The following adverse events were reported very rarely: alanine aminotransferase increased, alkaline phosphatase increased, anaphylactic reaction, angioneurotic edema, aspartate aminotransferase increased, bilirubin increased, extrapyramidal disorder, glaucoma, hepatitis, hyponatremia, jaundice, orthostatic hypotension (especially at the initiation of treatment), serotonin syndrome, Stevens-Johnson Syndrome, syncope (especially at initiation of treatment), syndrome of inappropriate antidiuretic hormone secretion (SIADH), and urticaria.

DRUG ABUSE AND DEPENDENCE: ***Controlled Substance Class***—Duloxetine is not a controlled substance. ***Physical and Psychological Dependence***—In animal studies, duloxetine did not demonstrate barbiturate-like (depressant) abuse potential. In drug dependence studies, duloxetine did not demonstrate dependence-producing potential in rats.

While Cymbalta has not been systematically studied in humans for its potential for abuse, there was no indication of drug-seeking behavior in the clinical trials. However, it is not possible to predict on the basis of premarketing experience the extent to which a CNS-active drug will be misused, diverted, and/or abused once marketed. Consequently, physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse of Cymbalta (eg, development of tolerance, incrementation of dose, drug-seeking behavior).

OVERDOSAGE: There is limited clinical experience with Cymbalta overdose in humans. In premarketing clinical trials, cases of acute ingestions up to 1400 mg, alone or in combination with other drugs, were reported with none being fatal. Postmarketing experience includes reports of overdoses, alone or in combination with other drugs, with duloxetine doses of almost 2000 mg. Fatalities have been very rarely reported, primarily with mixed overdoses, but also with duloxetine alone at a dose of approximately 1000 mg. Signs and symptoms of overdose (mostly with mixed drugs) included serotonin syndrome, somnolence, vomiting, and seizures. ***Management of Overdose***—There is no specific antidote to Cymbalta, but if serotonin syndrome ensues, specific treatment (such as with cyproheptadine and/or temperature control) may be considered. In case of acute overdose, treatment should consist of those general measures employed in the management of overdose with any drug.

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Important Safety Information:

- **Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.**
- **Patients started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.**
- **Cymbalta is not approved for use in pediatric patients.**

Cymbalta should not be used concomitantly with monoamine oxidase inhibitors (MAOIs) or thioridazine and not in patients with a known hypersensitivity or with uncontrolled narrow-angle glaucoma.

Clinical worsening and suicide risk: All adult and pediatric patients being treated with an antidepressant for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially when initiating drug therapy and when increasing or decreasing the dose. A health professional should be immediately notified if the depression is persistently worse or there are symptoms that are severe, sudden, or were not part of the patient's presentation. If discontinuing treatment, taper the medication.

Cymbalta should not be administered to patients with any hepatic insufficiency or patients with end-stage renal disease (requiring dialysis) or severe renal impairment (CrCl <30 mL/min).

Postmarketing, severe elevations of liver enzymes or liver injury with a hepatocellular, cholestatic, or mixed pattern have been reported.

Cymbalta should generally not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease.

Most common adverse events (≥5% and at least twice placebo) in MDD premarketing clinical trials were: nausea, dry mouth, constipation, fatigue, decreased appetite, somnolence, and increased sweating. Most common adverse events in diabetic peripheral neuropathic pain (DPNP) premarketing clinical trials were: nausea, somnolence, dizziness, constipation, dry mouth, increased sweating, decreased appetite, and asthenia.

See Brief Summary of full Prescribing Information, including Boxed Warning, on adjacent page.

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