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PSYCHIATRIC NEWS

inside

Ruiz Urges Colleagues To Keep Up Demands

Advocating for humane care is not an option; it's a professional and moral imperative for all psychiatrists, says APA's outgoing president.

BY CATHERINE F. BROWN

In a voice filled with passion and urgency, APA President Pedro Ruiz, M.D., instructed colleagues at APA's 2007 annual meeting last month in San Diego that they—along with him—must continue to work toward achieving the "promised land" for people with mental illness through eradicating barriers to mental health care and establishing a system in which high-quality, humane care is available to all.

"My fellow psychiatrists," said Ruiz at the meeting's Opening Session, "we must have the courage to do it. We must provide humane care. The future and image of APA and our profession depend on it. We must do it, and we will do it together with the National Alliance on Mental Illness [NAMI], Mental Health America, and any other advocacy group that has the courage to do it with us."

He spoke with particular intensity about mentally ill people who exist on the fringes of society and evoke little empathy from Americans living comfortable lives. Among them: people who have no health or mental health insurance, members of minority groups who cannot get culturally competent mental health care, homeless mentally ill individuals, mentally ill people who are warehoused in jails and prisons because of inadequate community mental health services and resources.

Ruiz continued, "It is our social responsibility, as psychiatrists and citizens, to ensure that humane care will not just be a privilege for some, but a right for all human beings who live in the United States, as well as in every country in the world. . . . What are we going to do? How much inhumane care do we have to observe in our daily practices and society at large before we say enough is enough?"

Ruiz himself reached that point many years ago, and his term as APA president gave him another national platform to continue his efforts to right these wrongs.

To an audience of about 1,000 psychiatrists and guests, he spoke of the many initiatives and actions he had undertaken during this past year to follow through on the theme he had selected for his presidency: "Addressing Patient Needs: Access, Parity, and Humane Care."

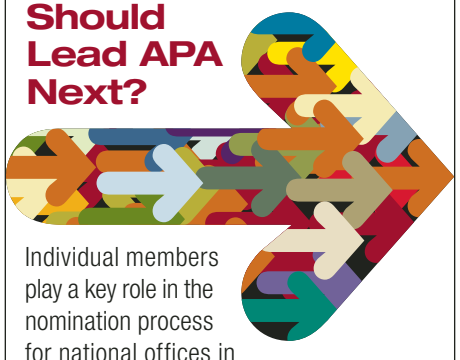
Ruiz reminded his audience that at last year's annual meeting he had said that addressing the three prongs of his presidential theme required APA to build "strong, genuine" partnerships with patient-oriented advocacy groups. He got to work on that task immediately by inviting Suzanne Vogel-Scibilia, M.D., the president of NAMI, to address the Board of Trustees at its July 2006 retreat and meeting. He and Vogel-Scibilia went on to plan a formal APA/NAMI leadership meeting that took place last December in which common issues and goals were identified (*Psychiatric News*, January 19). Both organizations appointed indi-

please see ***Ruiz*** *on page 10*

Credit: David Hathcox

APA President Pedro Ruiz, M.D., challenges his fellow psychiatrists to keep up the battle with him for mental health parity and access to high-quality, humane care.

Who Should Lead APA Next?



Individual members play a key role in the nomination process for national offices in the APA. The Nominating Committee, chaired by Pedro Ruiz, M.D., is receiving suggestions for candidates for the 2008 election for the offices of president-elect, secretary-treasurer, and trustee-at-large. Please help by submitting your suggestions to Dr. Ruiz using the online form at <www.psych.org/members/gov/election2008/2008electionnominee.cfm> or one of the other methods listed on page 24. Suggestions should be received at APA **no later than July 27.**

Diagnosis, Treatment of Youth For Depression Fell After FDA Alert

Researchers are troubled by data indicating that large numbers of young people with depression are being left untreated after the FDA issued its first advisory about the antidepressants in 2003.

BY EVE BENDER

Rates of the diagnosis and pharmacological treatment of depression among children and adolescents dropped sharply after October 2003, when the U.S. Food and Drug Administration (FDA) issued its first public health advisory informing health care professionals of an increased risk of suicidality among youngsters taking antidepressants.

These findings, which appeared in the June *American Journal of Psychiatry*, have heightened the concerns of researchers and clinicians alike that suicide rates among untreated children and adolescents will rise unchecked. In fact, a study published in the February *Pediatrics* revealed an 18.2 percent increase in suicide from 2003 to 2004 among youngsters under the age of 20 (*Psychiatric News*, March 2).

"We are seeing a treatment option that has been found to be safe and effective not being used for an illness that has very serious health and social consequences" for young people, first author Anne Libby, Ph.D., told *Psychiatric News*. "We are plac-

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Extending Parity Benefits to Children Gains Support in Senate

Mental health advocates hope that a parity mandate will be included in the State Children's Health Insurance Program reauthorization bill that the Senate is expected to consider later this summer.

BY RICH DALY

A bipartisan group of Senate leaders has introduced a bill to require mental health parity coverage for beneficiaries in every State Children's Health Insurance Program (SCHIP).

The measure, titled the Children's Mental Health Parity Act (S 1337), was introduced May 8 and would prohibit states from setting limits on coverage of mental health or substance abuse services that are lower than those set for other health care services for children.

Supporters of the bill, including APA and the American Academy of Child and Adolescent Psychiatry (AACAP), and bill sponsors Sen. John Kerry (D-Mass.) and Sen. Gordon Smith (R-Ore.) hope that the bill can be included as part of the SCHIP reauthorization set for Senate consideration this summer.

"You want to minimize trauma to kids as much as you can, and if they are already enrolled in SCHIP, then let's get them care through that program instead of the parents' having to give up custody to the state or take some other desperate approach to get care for them," said Lizbet Boroughs, deputy director of APA's Department of Government Relations.

SCHIP, which was enacted in August 1997, gave states new incentives to extend public health insurance coverage to low-income, uninsured children. Among the incentives are a higher federal match and greater flexibility to design their programs than allowed under Medicaid.

For many years, APA and other mental health advocates have been organizing legislative support to add a mental health parity requirement to SCHIP, but consideration of such a mandate was delayed until Congress was set to reauthorize SCHIP 10 years after it was launched.

In addition to prohibiting discriminatory limits on mental health care in SCHIP plans, the bill would eliminate a provision that allows states to lower the amount of mental health coverage to 75 percent of the coverage given in benchmark plans that states can use as models.

"As Congress begins to work on reauthorizing SCHIP, arbitrary and harmful limits on mental health care must be prohibited in this vital program," said David Shern, Ph.D., president and CEO of Mental Health America.

Parity in SCHIP is needed because mental illness affects about 1 in 5 U.S. children, and serious behavioral health problems impact the functioning of up to 9 percent of youngsters. Among low-income children, whose care SCHIP is designed to cover, the rates of mental health problems are even higher, according to advocates of the bill. About two-thirds of children with mental illness receive no treatment for their disorder. Under SCHIP, only about 40 percent of states offer full coverage of necessary services for children with complex mental health needs.

"Without early and effective intervention, affected children are less likely to do well in school and more likely to have compromised employment and earnings opportunities," Kerry said on the Senate floor. "Moreover, untreated mental illness may also increase a child's risk of coming into contact with the juvenile-justice system, and children with mental disorders are at a much higher risk for suicide."

"Mental health is integral to the health and well-being of all children," Thomas Anders, M.D., president of AACAP, wrote in a letter to senators. "Children coping with emotional and mental disorders must be identified, diagnosed, and treated to avoid the loss of critical developmental years that can never be recaptured."

The expansion of mental health care under SCHIP appears to be a popular idea in Congress, and several other bills also propose expanded coverage.

In late April, Sens. John Rockefeller (D-W. Va.) and Olympia Snowe (R-Maine) introduced a bill (S 1224), for example, that would reauthorize and expand SCHIP to cover 6 million additional children over the next 10 years and expand coverage of mental health and dental care.

The All Healthy Children Act (HR 1688), introduced by Rep. Bobby Scott (D-Va.) in March, would consolidate Medicaid and SCHIP into a single program with comprehensive mental health benefits.

The texts of S 1337, S 1224, and HR 1688 can be accessed online at <http://thomas.loc.gov> by searching on the respective bill number. ■

Australia Conference

The World Psychiatric Association is sponsoring an international congress from November 28 to December 2 in Melbourne, Australia, on the theme "Working Together for Mental Health: Partnership for Policy and Practice." The congress will be hosted by the Royal Australian and New Zealand College of Psychiatrists.

Online registration and more information are posted at <www.wpa2007melbourne.com>. Information is also available from Sharon Brownie at Sharon.brownie@ranzp.org. ■

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. Fax: (703) 907-1085 E-Mail: apa@psych.org
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Bill Defines Who Can Call Themselves Physicians

A bill cosponsored by the sole psychiatrist in Congress may end the practice by which health care professionals who haven't graduated from medical school advertise themselves as physicians.

BY MARK MORAN

APA, the AMA, and seven other medical organizations are hailing the introduction of legislation that would make it unlawful for health care professionals to misrepresent their qualifications to patients.

The Healthcare Truth and Transparency Act (HR 2260) was introduced last month by Rep. Jim McDermott (D-Wash.) and John Sullivan (R-Okla.) to help safeguard patients from misleading claims by nonphysicians about their qualifications and training. McDermott, Congress's only psychiatrist, is a member of APA.

The bill states that the legislation would make it "unlawful for any person who is a licensed health care service provider but who is not a medical doctor or doctor of osteopathic medicine to make any deceptive or misleading statement, or engage in any deceptive or misleading act, that deceives or misleads the public or a prospective or current patient that such person is a medical doctor or doctor of osteopathic medicine or has the same or equivalent education, skills, or training."

As described in the legislation, the types of statements or activities that would be prohibited include "advertising in any medium; making false statements regarding the education, skills, training, or licensure of such person; or in any other way describing such person's profession, skills, training, experience, education, or licensure in a fashion that reasonably causes the public, a potential patient, or current patient to believe that such person is a medical doctor or doctor of osteopathic medicine."

In separate statements following introduction of the bill, leaders of APA and the AMA said it would help protect patients and ensure that they can make informed decisions about whom they want to obtain their health care from.

"Patients shouldn't have to play roulette with their health care," said incoming APA President Carolyn Robinowitz, M.D., in a written statement. "Now is the time for truth and transparency in health care. Information is power—the power to make better choices, the power to protect you and your family's safety, and the power to keep costs in check by getting you the care you need the first time you seek it."

AMA Board of Trustees member William Hazel Jr., M.D., said in a statement that it is important for patients to know the qualifications of health care professionals caring for them. "The AMA and its medical specialty partners applaud Reps. John Sullivan and Jim McDermott for introducing legislation that protects patients by strengthening the Federal Trade Commission's authority to challenge misleading marketing by nonphysician medical providers," Hazel said.

Joining APA and the AMA in public support of the Sullivan and McDermott bill are the American Academy of Ophthalmology, American Academy of Otolaryngology–Head and Neck Surgery, American Society of Anesthesiologists, American Osteopathic Association, American College of Surgeons, American Academy of Orthopaedic Surgeons, and the American Society of Plastic Surgeons.

In a statement issued in conjunction with the introduction of the bill, Sullivan said that he believes that the overwhelming majority of American people support legislation to make it easier for them to understand the qualifications of their health care professionals.

"Patients today are confused about the health care system in general, especially about the differences in health care providers. We need to make changes to allow patients to understand who they are receiving care from, which is why I have reintroduced the Healthcare Truth and Transparency Act."

The text of the Healthcare Truth and Transparency Act can be accessed at <http://thomas.loc.gov> by searching on its bill number, HR 2260. ■

NIDA Products Take Science to Clinic

BY STEPHANIE WHYCHE

The National Institute on Drug Abuse (NIDA) has unveiled two new products to help drug-treatment clinicians team up with the agency to more quickly incorporate—or "blend"—cutting-edge, science-based interventions into clinical practice.

The two products are "Motivational Interviewing Assessment: Supervisory Tools for Enhancing Proficiency" (MIA: STEP) and "Promoting Awareness of Motivational Incentives" (PAMI).

MIA:STEP is designed for clinical supervisors to train front-line treatment providers to improve their motivational interviewing skills. It includes a new package treatment instrument to help providers better engage their patients and retain them in treatment.

PAMI includes tools providing information about science-based drug-treatment interventions called motivational incentives. NIDA explains that these incentives include vouchers, prizes, privileges, and other low- or no-cost positive reinforcements and describes the most therapeutic way to use them to retain patients in drug-treatment programs.

The products are part of NIDA's expanding portfolio of "Blending Teams" materials. To enhance their dissemination, NIDA is hosting a number of conferences around the country "to facilitate communication between researchers and treatment providers."

More information about NIDA's Blending Team products, initiatives, and conferences can be accessed at <www.drugabuse.gov/blending/>. ■

Military Needs to Build 'Culture of Support'

The need for improved mental health care for U.S. soldiers and Marines requires better funding, more training, and a new view of mental health.

BY AARON LEVIN

The U.S. armed forces are unable to meet the mental health needs of service members today and are not likely to do much better in the future without additional funding and staff, according to a draft report issued by the Department of Defense Task Force on Mental Health in May.

"The challenges are enormous, and the consequences of nonperformance are significant," said the report.

The task force is a joint military-civilian body, authorized by Congress, which conducted inquiries for a year before delivering the report to the secretary of defense.

A separate study, the Army Surgeon General's Mental Health Advisory Team IV (MHAT IV), surveyed 1,767 soldiers and Marines serving in Iraq and found that, among numerous factors, the level of combat, family separation, and multiple deployments placed the greatest stress on the troops' mental health. MHAT IV was established by the Office of the U.S. Army Surgeon General at the request of the commanding general of the multinational force in Iraq and supervised by its command surgeon.

The task force acknowledged existing work by the military services toward psychological health, but added that these efforts were falling short of the need. Task force members consulted experts, visited 38 military bases around the world, and listened to public testimony. The military health system lacks the resources and fully trained staff to meet peacetime needs for troops and their families, much less the increased demands posed by the fighting in Iraq and Afghanistan, they said.

Stigma remains a significant barrier to care, and current psychological screening procedures do not overcome the bias against seeking mental health services. There are also gaps in what services are available, where they are offered, and who receives them, said the report. Family members have poor access to services, and the myriad military organizations dealing with mental health are poorly coordinated and fall under different chains of command. Moreover, there are not enough active duty mental health professionals, and there will be fewer in the future without "substantial intervention."

Quality of treatment is not up to standard, either.

"There do not appear to be sufficient mechanisms in place to assure the use of evidence-based treatments or the monitoring of treatment effectiveness," said the report.

The task force recommended that the Department of Defense build a "culture of support for psychological health" by updating knowledge, improving access, increasing funding and training, and incorporating education about mental health in every phase of military life.

Finally, the task force noted that, as in civilian life, the medical and mental health systems place too much emphasis on short-term treatment models and not enough on long-term management of chronic disorders.

The MHAT IV evaluated the mental health of troops in Iraq from August 28-October 3, 2006. Its report was completed in November 2006, but was released only last month. The study was based on anonymous surveys filled out by troops and on information gathered from behavioral health and primary care personnel and others. Troops surveyed included 79 percent from active component forces, 8 percent from the Reserves, and 13 percent from the National Guard, although results were not broken down by service component.

Among the troops, combat exposure and the length of deployment had the greatest impact on mental health status, according to the report. Troops facing high levels of combat were two to three times more likely to screen positive for anxiety, depression, acute stress, or any mental health problem. For instance, 30 percent of troops who spent at least 56 hours a week patrolling outside their base camps screened positive for mental health problems, compared with 11 percent who spent 12 hours a week "outside the wire."

The more times troops were sent to Iraq and the longer they served there, the higher their rates of mental health and marital problems. About 27 percent of those returning to Iraq screened positive, compared with 17 percent of those on their first tour of duty there.

That indicates, said the report, that "previous deployment experience per se does not 'inoculate' soldiers against further increases in mental health issues."

The 2003-06 average annual suicide rate among troops in Iraq was 16.1 per 100,000, higher than the average Army rate of 11.6. Existing suicide prevention training was not designed for application in a combat zone, said the MHAT IV.

For the first time, MHAT IV asked troops questions about battlefield ethics. Only 38 percent of Marines and 47 percent of Army soldiers said that noncombatants should be treated with dignity and respect. Rates were higher among troops who had high combat exposure or screened positive for mental health problems. The report recommended improved battlefield ethics training to better prepare for encounters with civilians and to know how to report violations.

The MHAT IV found that very few military mental health care providers had been trained in combat and operational stress control. This training should be required before they ship out to Iraq, according to the report. Also recommended was more extensive mental health awareness training for troops, noncomissioned officers, and junior officers before, during, and after deployment. Allowing troops to remain at home for 18 to 36 months between deployments would allow them to recover their mental health more fully.

A summary of the Department of Defense Task Force on Mental Health's report is posted at <www.ha.osd.mil/dhb/meetings/2007-05/media/MHTF-Report_%20DRAFT_Executive_Summary_02MAY07.pdf>. "Mental Health Advisory Team IV Operation Iraqi Freedom Final Report" is posted at <www.armymedicine.army.mil/news/mhat/mhat_iv/MHAT_IV_Report_17NOV06.pdf>. ■

APA Urges Congress to Extend Types, Length of Care for All Vets

It's urgent that legislators address the dearth of mental health care for National Guard and Reserve members who now must depend on private health coverage when they return from combat missions, APA says.

BY RICH DALY

Adding three more years of eligibility for veterans' health care treatment to the existing two years of postcombat care new veterans may receive was among the measures APA urged members of Congress to support during recent testimony.

James H. Scully Jr., M.D., APA's medical director, told members of the House Veterans Affairs Committee in May that extending the coverage period would allow the symptoms of posttraumatic stress disorder (PTSD) and other combat-related mental illness to become clear in returning troops. This would make it more likely that they would receive the specialized care for which the Department of Veterans Affairs (VA) is often lauded.

Extended VA health care access "is especially important when it comes to monitoring PTSD and traumatic brain injury (TBI) as their effects can take time to become apparent," Scully stated.

He was on Capitol Hill to express APA's support for a bill, Returning Servicemember VA Healthcare Insurance Act of 2007 (HR 612), that would extend eligibility for VA health care following service in current and future military conflicts. The measure is sponsored by the chair of the committee, Rep. Bob Filner (D-Calif.).

Greater congressional funding is needed to expand knowledge related to the detection and treatment of TBI, Scully said. This relatively new area of mental health will have an impact on many Iraq and Afghan war veterans because of the extensive use of improvised explosive devices, which cause extensive head injuries.

Saul Rosenberg, Ph.D., a clinical and forensic psychologist at the University of California, San Francisco, and the San Francisco VA Medical Center, told members of the congressional committee that TBI is very treatable, though not much of the benefit from care is derived in the first six months after the injury is sustained. The increasing use of waiting lists for care within the VA "squander[s] the opportunity for the most effective care," he said.

Among those who urged expanded support and coverage for PTSD care was Beth Hudnall Stamm, Ph.D., director of Telehealth at the Institute of Rural Health at Idaho State University. She testified that the many homeless Vietnam-era veterans need a package of treatment and other types of support to prevent them from having to use much more expensive institutional care because their mental illness has gone untreated.

"We can move people from a position where they are a drain on society to where they are contributing," she said.

Among the immediate steps Congress could take to improve veterans' access to care overnight, Scully told committee members, is increasing reimbursements as a way to attract physicians and other health care professionals who do not participate in the system.

He also urged Congress to allow members of the National Guard and Reserves access to the VA system, which is experienced in providing mental health care. The lengthy combat exposure of these units in Iraq and Afghanistan and their dependence on private, postdeployment health care with weak mental health coverage will leave many untreated, Scully noted.

"Members of the National Guard now get their care from private employer-sponsored health insurance renowned for not covering quality mental health care," Scully said.

Members of Congress noted that part of the challenge of mental health care efforts is that the private-sector health care system does not provide the mental health detection and care that the military and VA systems are now urged to cover. But that difference does not excuse their obligation to the members of the military and veterans, Scully said.

"We could use our position to make changes that could become models for other parts of the community," Filner said.

Rep. Vic Snyder (D-Ark.) called for better mental health screening of military applicants to avoid recruitment of people at high risk of mental illness or addiction, "who are not going to do well in a military or combat environment."

The text of the Returning Servicemember VA Healthcare Insurance Act of 2007 can be accessed at <http://thomas.loc.gov> by searching on the bill number, HR 612. ■

Florence Meeting

The European Society of Child and Adolescent Psychiatry will hold its 13th international conference from August 25 to 29 in Florence, Italy, on the theme "Bridging the Gaps: Integrating Perspectives in Child and Adolescent Mental Health."

The meeting will bring together leading psychiatrists, researchers, health workers, and others interested in the welfare of children to consider ways to bridge the widely disparate knowledge in their respective disciplines by sharing models and developing integrated perspectives. Speakers will represent many countries.

Registration information is posted at <www.escap-net.org/web/index.php>. ■

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CONTRAINDICATIONS — ***QT Prolongation:*** Because of GEODON's dose-related prolongation of the QT interval and the known association of fatal arrhythmias with QT prolongation by some other drugs, GEODON is contraindicated in patients with a known history of QT prolongation (including congenital long QT syndrome), with recent acute myocardial infarction, or with uncompensated heart failure (see **WARNINGS**). Pharmacokinetic/pharmacodynamic studies between GEODON and other drugs that prolong the QT interval have not been performed. An additive effect of GEODON and other drugs that prolong the QT interval cannot be excluded. Therefore, GEODON should not be given with dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol, or tacrolimus. GEODON is also contraindicated with drugs that have demonstrated QT prolongation as one of their pharmacodynamic effects and have this effect described in the full prescribing information as a contraindication or a boxed or bolded warning (see **WARNINGS**). GEODON is contraindicated in individuals with a known hypersensitivity to the product. **WARNINGS—Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. GEODON (ziprasidone) is not approved for the treatment of patients with dementia-related psychosis (see Boxed Warning).** ***QT Prolongation and Risk of Sudden Death:*** **GEODON use should be avoided in combination with other drugs that are known to prolong the QT_c interval. Additionally, clinicians should be alert to the identification of other drugs that have been consistently observed to prolong the QT_c interval. Such drugs should not be prescribed with GEODON. A study directly comparing the QT/QT_c-prolonging effect of GEODON with several other drugs effective in the treatment of schizophrenia was conducted in patient volunteers. The mean increase in QT_c from baseline for GEODON ranged from approximately 9 to 14 msec greater than for four of the comparator drugs (risperidone, olanzapine, quetiapine, and haloperidol), but was approximately 14 msec less than the prolongation observed for thioridazine. In this study, the effect of GEODON on QT_c length was not augmented by the presence of a metabolic inhibitor (ketoconazole 200 mg bid). In placebo-controlled trials, GEODON increased the QT_c interval compared to placebo by approximately 10 msec at the highest recommended daily dose of 160 mg. In clinical trials the electrocardiograms of 2/2988 (0.06%) GEODON patients and 1/440 (0.23%) placebo patients revealed QT_c intervals exceeding the potentially clinically relevant threshold of 500 msec. In the GEODON patients, neither case suggested a role of GEODON. Some drugs that prolong the QT/QT_c interval have been associated with the occurrence of torsade de pointes and with sudden unexplained death. The relationship of QT prolongation to torsade de pointes is clearest for larger increases (20 msec and greater) but it is possible that smaller QT/QT_c prolongations may also increase risk, or increase it in susceptible individuals, such as those with hypokalemia, hypomagnesemia, or genetic predisposition. Although torsade de pointes has not been observed in association with the use of GEODON at recommended doses in premarketing studies, experience is too limited to rule out an increased risk. A study evaluating the QT/QT_c prolonging effect of intramuscular GEODON, with intramuscular haloperidol as a control, was conducted in patient volunteers. In the trial, ECGs were obtained at the time of maximum plasma concentration following two injections of GEODON (20 mg then 30 mg) or haloperidol (7.5 mg then 10 mg) given four hours apart. Note that a 30 mg dose of intramuscular GEODON is 50% higher than the recommended therapeutic dose. The mean change in QT_c from baseline was calculated for each drug using a sample-based correction that removes the effect of heart rate on the QT interval. The mean increase in QT_c from baseline for GEODON was 4.6 msec following the first injection and 12.8 msec following the second injection. The mean increase in QT_c from baseline for haloperidol was 6.0 msec following the first injection and 14.7 msec following the second injection. In this study, no patient had a QT_c interval exceeding 500 msec. As with other antipsychotic drugs and placebo, sudden unexplained deaths have been reported in patients taking GEODON at recommended doses. The premarketing experience for GEODON did not reveal an excess of mortality for GEODON compared to other antipsychotic drugs or placebo, but the extent of exposure was limited, especially for the drugs used as active controls and placebo. Nevertheless, GEODON's larger prolongation of QT_c length compared to several other antipsychotic drugs raises the possibility that the risk of sudden death may be greater for GEODON than for other available drugs for treating schizophrenia. This possibility needs to be considered in deciding among alternative drug products. Certain circumstances may increase the risk of the occurrence of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QT_c interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QT_c interval; and (4) presence of congenital prolongation of the QT interval. GEODON should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias (see CONTRAINDICATIONS, and see *Drug Interactions* under PRECAUTIONS). It is recommended that patients being considered for GEODON treatment who are at risk for significant electrolyte disturbances, hypokalemia in particular, have baseline serum potassium and magnesium measurements. Hypokalemia (and/or hypomagnesemia) may increase the risk of QT prolongation and arrhythmia. Hypokalemia may result from diuretic therapy, diarrhea, and other causes. Patients with low serum potassium and/or magnesium should be repleted with those electrolytes before proceeding with treatment. It is essential to periodically monitor serum electrolytes in patients for whom diuretic therapy is introduced during GEODON treatment. Persistently prolonged QT_c intervals may also increase the risk of further prolongation and arrhythmia, but it is not clear that routine screening ECG measures are effective in detecting such patients. Rather, GEODON should be avoided in patients with histories of significant cardiovascular illness, eg, QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. GEODON should be discontinued in patients who are found to have persistent QT_c measurements >500 msec.** ***Neuroleptic Malignant Syndrome (NMS):*** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported. ***Tardive Dyskinesia (TD):*** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients undergoing treatment with antipsychotic drugs. Although the prevalence of TD appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop TD. If signs and symptoms of TD appear in a patient on GEODON, drug discontinuation should be considered. ***Hyperglycemia and Diabetes Mellitus:*** Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON, and it is not known if GEODON is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia. **PRECAUTIONS —** ***General:*** Rash: In premarketing trials, about 5% of GEODON patients developed rash and/or urticaria, with discontinuation of treatment in about one-sixth of these cases. The occurrence of rash was dose related, although the finding might also be explained by longer exposure in higher-dose patients. Several patients with rash had signs and symptoms of associated systemic illness, e.g., elevated WBCs. Most patients improved promptly upon treatment with antihistamines or steroids and/or upon discontinuation of GEODON, and all patients were reported to recover completely. Upon appearance of rash for which an alternative etiology cannot be identified, GEODON should be discontinued. Orthostatic Hypotension: GEODON may induce orthostatic hypotension associated with dizziness, tachycardia, and, in some patients, syncope, especially during the initial dose-titration period, probably reflecting its α_1-adrenergic antagonist properties. Syncope was reported in 0.6% of GEODON patients. GEODON should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Seizures: In clinical trials, seizures occurred in 0.4% of GEODON patients. There were confounding factors that may have contributed to seizures in many of these cases. As with other antipsychotic drugs, GEODON should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older. Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia, and GEODON and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. **(See also Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis)**. Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, GEODON elevates prolactin levels in humans. Tissue culture experiments indicate that approximately one third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time. Potential for Cognitive and Motor Impairment: Somnolence was a commonly reported adverse event in GEODON patients. In the 4- and 6-week placebo-controlled trials, somnolence was reported in 14% of GEODON patients vs 7% of placebo patients. Somnolence led to discontinuation in 0.3% of patients in short-term clinical trials. Since GEODON has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about performing activities requiring mental alertness, such as operating a motor vehicle (including automobiles) or operating hazardous machinery until they are reasonably certain that GEODON therapy does not affect them adversely. Priapism: One case of priapism was reported in the premarketing database. Body Temperature Regulation: Although not reported with GEODON in premarketing trials, disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Suicide: The possibility of a suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. GEODON prescriptions should be written for the smallest quantity of capsules consistent with good patient management to reduce overdose risk. Use in Patients with Concomitant Illness: Clinical experience with GEODON in patients with certain concomitant systemic illnesses is limited. GEODON has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies. Because of the risk of QT_c prolongati on and orthostatic hypotension with GEODON, caution should be observed in cardiac patients (see ***QT Prolongation and Risk of Sudden Death*** in **WARNINGS** and Orthostatic Hypotension in **PRECAUTIONS**). ***Information for Patients:*** To ensure safe and effective use of GEODON, the information and instructions in the *Patient Information Section* should be discussed with patients. ***Laboratory Tests:*** Patients being considered for GEODON treatment who are at risk of significant electrolyte disturbances should have baseline serum potassium and magnesium measurements. Low serum potassium and magnesium should be repleted before treatment. Patients who are started on diuretics during GEODON therapy need periodic monitoring of serum potassium and magnesium. Discontinue GEODON in patients who are found to have persistent QT_c measurements >500 msec (see **WARNINGS**). ***Drug Interactions:*** (1) GEODON should not be used with any drug that prolongs the QT interval. (2) Given the primary CNS effects of GEODON, caution should be used when it is taken in combination with other centrally acting drugs. (3) Because of its potential for inducing hypotension, GEODON may enhance the effects of certain antihypertensive agents. (4) GEODON may antagonize the effects of levodopa and dopamine agonists. Effect of Other Drugs on GEODON: *Carbamazepine*, 200 mg bid for 21 days, resulted in a decrease of approximately 35% in the AUC of GEODON. *Ketoconazole*, a potent inhibitor of CYP3A4, 400 mg qd for 5 days, increased the AUC and C_{max} of GEODON by about 35%-40%. *Cimetidine,* 800 mg qd for 2 days, did not affect GEODON pharmacokinetics. Coadministration of 30 mL of *Maalox* did not affect GEODON pharmacokinetics. Population pharmacokinetic analysis of schizophrenic patients in controlled clinical trials has not revealed any clinically significant pharmacokinetic interactions with benztropine, propranolol, or lorazepam. Effect of GEODON on Other Drugs: In vitro studies revealed little potential for GEODON to interfere with the metabolism of drugs cleared primarily by CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4, and little potential for drug interactions with GEODON due to displacement. GEODON 40 mg bid administered concomitantly with *lithium* 450 mg bid for 7 days did not affect the steady-state level or renal clearance of lithium. GEODON 20 mg bid did not affect the pharmacokinetics of concomitantly administered *oral contraceptives*, ethinyl estradiol (0.03 mg) and levonorgestrel (0.15 mg). Consistent with in vitro results, a study in normal healthy volunteers showed that GEODON did not alter the metabolism of *dextromethorphan*, a CYP2D6 model substrate, to its major metabolite, dextrorphan. There was no statistically significant change in the urinary dextromethorphan/dextrorphan ratio. ***Carcinogenesis, Mutagenesis, Impairment of Fertility:*** Lifetime carcinogenicity studies were conducted with GEODON in Long Evans rats and CD-1 mice. In male mice, there was no increase in incidence of tumors relative to controls. In female mice there were dose-related increases in the incidences of pituitary gland adenoma and carcinoma, and mammary gland adenocarcinoma at all doses tested. Increases in serum prolactin were observed in a 1-month dietary study in female, but not male, mice. GEODON had no effect on serum prolactin in rats in a 5-week dietary study at the doses that were used in the carcinogenicity study. The relevance for human risk of the findings of prolactin-mediated endocrine tumors in rodents is unknown (see Hyperprolactinemia). Mutagenesis: There was a reproducible mutagenic response in the Ames assay in one strain of *S. typhimurium* in the absence of metabolic activation. Positive results were obtained in both the in vitro mammalian cell gene mutation assay and the in vitro chromosomal aberration assay in human lymphocytes. Impairment of Fertility: GEODON increased time to copulation in Sprague-Dawley rats in two fertility and early embryonic development studies at doses of 10 to 160 mg/kg/day (0.5 to 8 times the MRHD of 200 mg/day on a mg/m^2 basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m^2 basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m^2 basis). The fertility of female rats was reduced. ***Pregnancy— Pregnancy Category C:*** There are no adequate and well-controlled studies in pregnant women. GEODON should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. ***Labor and Delivery:*** The effect of GEODON on labor and delivery in humans is unknown. ***Nursing Mothers:*** It is not known whether, and if so in what amount, GEODON or its metabolites are excreted in human milk. It is recommended that women receiving GEODON should not breast feed. ***Pediatric Use:*** The safety and effectiveness of GEODON in pediatric patients have not been established. ***Geriatric Use:*** Of the approximately 4500 patients treated with GEODON in clinical studies, 2.4% (109) were 65 years of age or over. In general, there was no indication of any different tolerability for GEODON or of reduced clearance of GEODON in the elderly compared to younger adults. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to GEODON, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients. **ADVERSE REACTIONS —** ***Adverse Findings Observed in Short-term, Placebo-Controlled Trials:*** The following findings are based on the short-term placebo-controlled premarketing trials for schizophrenia (a pool of two 6-week, and two 4-week fixed-dose trials) and bipolar mania (a pool of two 3-week flexible-dose trials) in which GEODON was administered in doses ranging from 10 to 200 mg/day. ***Adverse Events Associated with Discontinuation:*** Schizophrenia: Approximately 4.1% (29/702) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 2.2% (6/273) on placebo. The most common event associated with dropout was rash, including 7 dropouts for rash among GEODON patients (1%) compared to no placebo patients (see **PRECAUTIONS**). Bipolar Mania: Approximately 6.5% (18/279) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 3.7% (5/136) on placebo. The most common events associated with dropout in the GEODON-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash and vomiting, with 2 dropouts for each of these events among GEODON patients (1%) compared to one placebo patient each for dystonia and rash (1%) and no placebo patients for the remaining adverse events. ***Adverse Events at an Incidence ≥5% and at Least Twice the Rate of Placebo:*** The most commonly observed adverse events associated with GEODON in schizophrenia trials were somnolence (14%) and respiratory tract infection (8%). The most commonly observed adverse events associated with the use of GEODON in bipolar mania trials were somnolence (31%), extrapyramidal symptoms (31%), dizziness (16%), akathisia (10%), abnormal vision (6%), asthenia (6%), and vomiting (5%). The following list enumerates the treatment-emergent adverse events that occurred during acute therapy, including only those events that occurred in 2% of GEODON patients and at a greater incidence than in placebo. Schizophrenia: Body as a Whole—asthenia, accidental injury, chest pain. Cardiovascular—tachycardia. Digestive—nausea, constipation, dyspepsia, diarrhea, dry mouth, anorexia. Nervous—extrapyramidal symptoms, somnolence, akathisia, dizziness. Respiratory—respiratory tract infection, rhinitis, cough increased. Skin and Appendages—rash, fungal dermatitis. Special Senses—abnormal vision. Bipolar Mania: Body as a Whole—headache, asthenia, accidental injury. Cardiovascular—hypertension. Digestive—nausea, diarrhea, dry mouth, vomiting, increased salivation, tongue edema, dysphagia. Musculoskeletal—myalgia. Nervous—somnolence, extrapyramidal symptoms, dizziness, akathisia, anxiety, hypesthesia, speech disorder. Respiratory—pharyngitis, dyspnea. Skin and Appendages—fungal dermatitis. Special Senses—abnormal vision. ***Dose Dependency:*** An analysis for dose response in the schizophrenia trials revealed an apparent relation of adverse event to dose for the following: asthenia, postural hypotension, anorexia, dry mouth, increased salivation, arthralgia, anxiety, dizziness, dystonia, hypertonia, somnolence, tremor, rhinitis, rash, and abnormal vision. ***Extrapyramidal Symptoms (EPS):*** The incidence of reported EPS for GEODON patients in the short-term, placebo-controlled schizophrenia trials was 14% vs 8% for placebo. Objectively collected data from those trials on the Simpson-Angus Rating Scale and the Barnes Akathisia Scale did not generally show a difference between GEODON and placebo. ***Vital Sign Changes:*** GEODON is associated with orthostatic hypotension (see **PRECAUTIONS**). ***Weight Gain:*** In short-term schizophrenia trials, the proportions of patients meeting a weight gain criterion of ≥7% of body weight were compared, revealing a statistically significantly greater incidence of weight gain for GEODON patients (10%) vs placebo patients (4%). A median weight gain of 0.5 kg was observed in GEODON patients vs 0.0 kg in placebo patients. Weight gain was reported as an adverse event in 0.4% of both GEODON and placebo patients. During long-term therapy with GEODON, a categorization of patients at baseline on the basis of body mass index (BMI) showed the greatest mean weight gain and the highest incidence of clinically significant weight gain (>7% of body weight) in patients with a low BMI (<23) compared to normal (23-27) or overweight (>27) patients.There was a mean weight gain of 1.4 kg for patients with a "low" baseline BMI, 0.0 kg for patients with a "normal" BMI, and a 1.3 kg mean weight loss for patients with a "high" BMI. ***ECG Changes:*** GEODON is associated with an increase in the QT_c interval (see **WARNINGS**). In schizophrenia trials, GEODON was associated with a mean increase in heart rate of 1.4 beats per minute compared to a 0.2 beats per minute decrease among placebo patients. ***Other Adverse Events Observed During the Premarketing Evaluation of GEODON:*** Frequent adverse events are those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. Schizophrenia: Body as a Whole — *Frequent:* abdominal pain, flu syndrome, fever, accidental fall, face edema, chills, photosensitivity reaction, flank pain, hypothermia, motor vehicle accident. Cardiovascular System — *Frequent:* tachycardia, hypertension, postural hypotension; *Infrequent:* bradycardia, angina pectoris, atrial fibrillation; *Rare:* first-degree AV block, bundle branch block, phlebitis, pulmonary embolus, cardiomegaly, cerebral infarct, cerebrovascular accident, deep thrombophlebitis, myocarditis, thrombophlebitis. Digestive System — *Frequent:* anorexia, vomiting; *Infrequent:* rectal hemorrhage, dysphagia, tongue edema; *Rare:* gum hemorrhage, jaundice, fecal impaction, gamma glutamyl transpeptidase increased, hematemesis, cholestatic jaundice, hepatitis, hepatomegaly, leukoplakia of mouth, fatty liver deposit, melena. Endocrine — *Rare:* hypothyroidism, hyperthyroidism, thyroiditis. Hemic and Lymphatic System — *Infrequent:* anemia, ecchymosis, leukocytosis, leukopenia, eosinophilia, lymphadenopathy; *Rare:* thrombocytopenia, hypochromic anemia, lymphocytosis, monocytosis, basophilia, lymphedema, polycythemia, thrombocythemia. Metabolic and Nutritional Disorders — *Infrequent:* thirst, transaminase increased, peripheral edema, hyperglycemia, creatine phosphokinase increased, alkaline phosphatase increased, hypercholesteremia, dehydration, lactic dehydrogenase increased, albuminuria, hypokalemia; *Rare:* BUN increased, creatinine increased, hyperlipemia, hypocholesteremia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hyperchloremia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. Musculoskeletal System — *Frequent:* myalgia; *Infrequent:* tenosynovitis; *Rare:* myopathy. Nervous System — *Frequent:* agitation, extrapyramidal syndrome, tremor, dystonia, hypertonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, hypesthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, buccoglossal syndrome, choreoathetosis, diplopia, incoordination, neuropathy; *Infrequent:* paralysis; *Rare:* myoclonus, nystagmus, torticollis, circumoral paresthesia, opisthotonos, reflexes increased, trismus. Respiratory System — *Frequent:* dyspnea; *Infrequent:* pneumonia, epistaxis; *Rare:* hemoptysis, laryngismus. Skin and Appendages — *Infrequent:* maculopapular rash, urticaria, alopecia, eczema, exfoliative dermatitis, contact dermatitis, vesiculobullous rash. Special Senses — *Frequent:* fungal dermatitis; *Infrequent:* conjunctivitis, dry eyes, tinnitus, blepharitis, cataract, photophobia; *Rare:* eye hemorrhage, visual field defect, keratitis, keratoconjunctivitis. Urogenital System — *Infrequent:* impotence, abnormal ejaculation, amenorrhea, hematuria, menorrhagia, female lactation, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; *Rare:* gynecomastia, vaginal hemorrhage, nocturia, oliguria, female sexual dysfunction, uterine hemorrhage. **Adverse Finding Observed in Trials of Intramuscular GEODON:** In these studies, the most commonly observed adverse events associated with the use of intramuscular GEODON (≥5%) and observed at a rate on intramuscular GEODON (in the higher dose groups) at least twice that of the lowest intramuscular GEODON group were headache (13%), nausea (12%), and somnolence (20%). **Adverse Events at an Incidence >1% in Short-Term Fixed-Dose Intramuscular Trials:** The following list enumerates the treatment-emergent adverse events that occurred in ≥1% of GEODON patients (in the higher dose groups) and at least twice that of the lowest intramuscular GEODON group. Body as a Whole—headache, injection site pain, asthenia, abdominal pain, flu syndrome, back pain. Cardiovascular—postural hypotension, hypertension, bradycardia, vasodilation. Digestive—nausea, rectal hemorrhage, diarrhea, vomiting, dyspepsia, anorexia, constipation, tooth disorder, dry mouth. Nervous—dizziness, anxiety, insomnia, somnolence, akathisia, agitation, extrapyramidal syndrome, hypertonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. Respiratory—rhinitis. Skin and Appendages—furunculosis, sweating. Urogenital—dysmenorrhea, priapism. **DRUG ABUSE AND DEPENDENCE—** ***Controlled Substance Class:*** GEODON is not a controlled substance. **OVERDOSAGE**—In premarketing trials in over 5400 patients, accidental or intentional overdosage of GEODON was documented in 10 patients. All patients survived without sequelae. In the patient taking the largest confirmed amount (3240 mg), the only symptoms reported were minimal sedation, slurring of speech, and transitory hypertension (BP 200/75).

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Pfizer U.S. Pharmaceuticals

MASTER THE FINE ART OF SLEEP

PRESCRIBE LUNESTA FIRST-LINE—FOR A FULL 7 TO 8 HOURS OF SLEEP

LUNESTA has been studied in large, well-controlled clinical trials in **all** of the following patient types:

- ✔ Patients With Insomnia Comorbid With Major Depressive Disorder
- ✔ Patients With Insomnia Comorbid With Generalized Anxiety Disorder
- ✔ Patients With Insomnia Comorbid With Rheumatoid Arthritis
- ✔ Patients With Insomnia Comorbid With Menopause

The failure of insomnia to remit after 7 to 10 days of treatment should be medically evaluated.

LUNESTA is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, LUNESTA administered at bedtime decreased sleep latency and improved sleep maintenance. LUNESTA is not indicated for the treatment of depression, generalized anxiety disorder, rheumatoid arthritis, or menopause.

Important Safety Information

LUNESTA, like other hypnotics, has CNS-depressant effects. Because of the rapid onset of action, LUNESTA should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients should not take LUNESTA unless they are prepared to get a full night's sleep. As with other hypnotics, patients receiving LUNESTA should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination (eg, operating machinery or driving a motor vehicle) after ingesting the drug, including potential impairment of the performance of such activities that may occur the day following ingestion of LUNESTA. In clinical trials, the most common adverse events associated with LUNESTA were unpleasant taste, headache, somnolence, dizziness, dry mouth, infection, and pain.

Any night or every night

Leave the rest to...

Lunesta®
(eszopiclone)C
1, 2 AND 3 MG TABLETS

LUNESTA has been classified as a Schedule IV controlled substance. Sedative hypnotics have produced withdrawal signs and symptoms following abrupt discontinuation. The risk of abuse and dependence increases with the dose and duration of treatment and concomitant use of other psychoactive drugs. The risk is also greater for patients who have a history of alcohol or drug abuse or history of psychiatric disorders. These patients should be under careful surveillance when receiving LUNESTA or any other hypnotic. Sedative/hypnotic drugs should be administered with caution to patients exhibiting signs and symptoms of depression. Suicidal tendencies may be present in such patients, and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

LUNESTA, like other hypnotics, may produce additive CNS-depressant effects when coadministered with other psychotropic medications, anticonvulsants, antihistamines, ethanol, and other drugs that themselves produce CNS depression. LUNESTA should not be taken with alcohol. Dosage adjustment may be necessary when LUNESTA is administered with other CNS-depressant agents because of the potentially additive effects.

Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hypnotic drugs is a concern in the treatment of elderly and/or debilitated patients. See dosage and administration in complete prescribing information.

Please see brief summary of complete prescribing information.

Lunesta®
(eszopiclone)©
1, 2 AND 3 MG TABLETS

BRIEF SUMMARY

INDICATIONS AND USAGE
LUNESTA is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, LUNESTA administered at bedtime decreased sleep latency and improved sleep maintenance.

CONTRAINDICATIONS
None known.

WARNINGS
Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypnotic drugs, including LUNESTA. Because some of the important adverse effects of LUNESTA appear to be dose-related, it is important to use the lowest possible effective dose, especially in the elderly (see **DOSAGE AND ADMINISTRATION in the Full Prescribing Information**).

A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of sedative/hypnotics. Some of these changes may be characterized by decreased inhibition (e.g., aggressiveness and extroversion that seem out of character), similar to effects produced by alcohol and other CNS depressants. Other reported behavioral changes have included bizarre behavior, agitation, hallucinations, and depersonalization. Amnesia and other neuropsychiatric symptoms may occur unpredictably. In primarily depressed patients, worsening of depression, including suicidal thinking, has been reported in association with the use of sedative/hypnotics.

It can rarely be determined with certainty whether a particular instance of the abnormal behaviors listed above are drug-induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

Following rapid dose decrease or abrupt discontinuation of the use of sedative/hypnotics, there have been reports of signs and symptoms similar to those associated with withdrawal from other CNS-depressant drugs (see **DRUG ABUSE AND DEPENDENCE**).

LUNESTA, like other hypnotics, has CNS-depressant effects. Because of the rapid onset of action, LUNESTA should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients receiving LUNESTA should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination (e.g., operating machinery or driving a motor vehicle) after ingesting the drug, and be cautioned about potential impairment of the performance of such activities on the day following ingestion of LUNESTA. LUNESTA, like other hypnotics, may produce additive CNS-depressant effects when coadministered with other psychotropic medications, anticonvulsants, antihistamines, ethanol, and other drugs that themselves produce CNS depression. LUNESTA should not be taken with alcohol. Dose adjustment may be necessary when LUNESTA is administered with other CNS-depressant agents, because of the potentially additive effects.

PRECAUTIONS
General
Timing Of Drug Administration: LUNESTA should be taken immediately before bedtime. Taking a sedative/hypnotic while still up and about may result in short-term memory impairment, hallucinations, impaired coordination, dizziness, and lightheadedness.

Use In The Elderly And/Or Debilitated Patients: Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hypnotic drugs is a concern in the treatment of elderly and/or debilitated patients. The recommended starting dose of LUNESTA for these patients is 1 mg (see **DOSAGE AND ADMINISTRATION in the Full Prescribing Information**).

Use In Patients With Concomitant Illness: Clinical experience with eszopiclone in patients with concomitant illness is limited. Eszopiclone should be used with caution in patients with diseases or conditions that could affect metabolism or hemodynamic responses.

A study in healthy volunteers did not reveal respiratory-depressant effects at doses 2.5-fold higher (7 mg) than the recommended dose of eszopiclone. Caution is advised, however, if LUNESTA is prescribed to patients with compromised respiratory function.

The dose of LUNESTA should be reduced to 1 mg in patients with severe hepatic impairment, because systemic exposure is doubled in such subjects. No dose adjustment appears necessary for subjects with mild or moderate hepatic impairment. No dose adjustment appears necessary in subjects with any degree of renal impairment, since less than 10% of eszopiclone is excreted unchanged in the urine.

The dose of LUNESTA should be reduced in patients who are administered potent inhibitors of CYP3A4, such as ketoconazole, while taking LUNESTA. Downward dose adjustment is also recommended when LUNESTA is administered with agents having known CNS-depressant effects.

Use In Patients With Depression: Sedative/hypnotic drugs should be administered with caution to patients exhibiting signs and symptoms of depression. Suicidal tendencies may be present in such patients, and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

Information For Patients: Patient information is printed in the complete prescribing information.

Laboratory Tests: There are no specific laboratory tests recommended.

Drug Interactions
CNS-Active Drugs

Ethanol: An additive effect on psychomotor performance was seen with coadministration of eszopiclone and ethanol 0.70 g/kg for up to 4 hours after ethanol administration.

Paroxetine: Coadministration of single doses of eszopiclone 3 mg and paroxetine 20 mg daily for 7 days produced no pharmacokinetic or pharmacodynamic interaction.

Lorazepam: Coadministration of single doses of eszopiclone 3 mg and lorazepam 2 mg did not have clinically relevant effects on the pharmacodynamics or pharmacokinetics of either drug.

Olanzapine: Coadministration of eszopiclone 3 mg and olanzapine 10 mg produced a decrease in DSST scores. The interaction was pharmacodynamic; there was no alteration in the pharmacokinetics of either drug.

Drugs That Inhibit CYP3A4 (Ketoconazole): CYP3A4 is a major metabolic pathway for elimination of eszopiclone. The AUC of eszopiclone was increased 2.2-fold by coadministration of ketoconazole, a potent inhibitor of CYP3A4, 400 mg daily for 5 days. C_{max} and $t_{1/2}$ were increased 1.4-fold and 1.3-fold, respectively. Other strong inhibitors of CYP3A4 (e.g., itraconazole, clarithromycin, nefazodone, troleandomycin, ritonavir, nelfinavir) would be expected to behave similarly.

Drugs That Induce CYP3A4 (Rifampicin): Racemic zopiclone exposure was decreased 80% by concomitant use of rifampicin, a potent inducer of CYP3A4. A similar effect would be expected with eszopiclone.

Drugs Highly Bound To Plasma Protein: Eszopiclone is not highly bound to plasma proteins (52-59% bound); therefore, the disposition of eszopiclone is not expected to be sensitive to alterations in protein binding. Administration of eszopiclone 3 mg to a patient taking another drug that is highly protein-bound would not be expected to cause an alteration in the free concentration of either drug.

Drugs With A Narrow Therapeutic Index

Digoxin: A single dose of eszopiclone 3 mg did not affect the pharmacokinetics of digoxin measured at steady state following dosing of 0.5 mg twice daily for one day and 0.25 mg daily for the next 6 days.

Warfarin: Eszopiclone 3 mg administered daily for 5 days did not affect the pharmacokinetics of (R)- or (S)-warfarin, nor were there any changes in the pharmacodynamic profile (prothrombin time) following a single 25-mg oral dose of warfarin.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: In a carcinogenicity study in Sprague-Dawley rats in which eszopiclone was given by oral gavage, no increases in tumors were seen; plasma levels (AUC) of eszopiclone at the highest dose used in this study (16 mg/kg/day) are estimated to be 80 (females) and 20 (males) times those in humans receiving the maximum recommended human dose (MRHD). However, in a carcinogenicity study in Sprague-Dawley rats in which racemic zopiclone was given in the diet, and in which plasma levels of eszopiclone were reached that were greater than those reached in the above study of eszopiclone, an increase in mammary gland adenocarcinomas in females and an increase in thyroid gland follicular cell adenomas and carcinomas in males were seen at the highest dose of 100 mg/kg/day. Plasma levels of eszopiclone at this dose are estimated to be 150 (females) and 70 (males) times those in humans receiving the MRHD. The mechanism for the increase in mammary adenocarcinomas is unknown. The increase in thyroid tumors is thought to be due to increased levels of TSH secondary to increased metabolism of circulating thyroid hormones, a mechanism that is not considered to be relevant to humans.

In a carcinogenicity study in B6C3F1 mice in which racemic zopiclone was given in the diet, an increase in pulmonary carcinomas and carcinomas plus adenomas in females and an increase in skin fibromas and sarcomas in males were seen at the highest dose of 100 mg/kg/day. Plasma levels of eszopiclone at this dose are estimated to be 8 (females) and 20 (males) times those in humans receiving the MRHD. The skin tumors were due to skin lesions induced by aggressive behavior, a mechanism that is not relevant to humans. A carcinogenicity study was also performed in which CD-1 mice were given eszopiclone at doses up to 100 mg/kg/day by oral gavage; although this study did not reach a maximum tolerated dose, and was thus inadequate for overall assessment of carcinogenic potential, no increases in either pulmonary or skin tumors were seen at doses producing plasma levels of eszopiclone estimated to be 90 times those in humans receiving the MRHD—i.e., 12 times the exposure in the racemate study.

Eszopiclone did not increase tumors in a p53 transgenic mouse bioassay at oral doses up to 300 mg/kg/day.

Mutagenesis: Eszopiclone was positive in the mouse lymphoma chromosomal aberration assay and produced an equivocal response in the Chinese hamster ovary cell chromosomal aberration assay. It was not mutagenic or clastogenic in the bacterial Ames gene mutation assay, in an unscheduled DNA synthesis assay, or in an *in vivo* mouse bone marrow micronucleus assay.

(S)-N-desmethyl zopiclone, a metabolite of eszopiclone, was positive in the Chinese hamster ovary cell and human lymphocyte chromosomal aberration assays. It was negative in the bacterial Ames mutation assay, in an *in vitro* ^{32}P-postlabeling DNA adduct assay, and in an *in vivo* mouse bone marrow chromosomal aberration and micronucleus assay.

Impairment Of Fertility: Eszopiclone was given by oral gavage to male rats at doses up to 45 mg/kg/day from 4 weeks premating through mating and to female rats at doses up to 180 mg/kg/day from 2 weeks premating through day 7 of pregnancy. An additional study was performed in which only females were treated, up to 180 mg/kg/day. Eszopiclone decreased fertility, probably because of effects in both males and females, with no females becoming pregnant when both males and females were treated with the highest dose; the no-effect dose in both sexes was 5 mg/kg (16 times the MRHD on a mg/m^2 basis). Other effects included increased preimplantation loss (no-effect dose 25 mg/kg), abnormal estrus cycles (no-effect dose 25 mg/kg), and decreases in sperm number and motility and increases in morphologically abnormal sperm (no-effect dose 5 mg/kg).

Pregnancy
Pregnancy Category C: Eszopiclone administered by oral gavage to pregnant rats and rabbits during the period of organogenesis showed no evidence of teratogenicity up to the highest doses tested (250 and 16 mg/kg/day in rats and rabbits, respectively; these doses are 800 and 100 times, respectively, the maximum recommended human dose [MRHD] on a mg/m^2 basis). In the rat, slight reductions in fetal weight and evidence of developmental delay were seen at maternally toxic doses of 125 and 150 mg/kg/day, but not at 62.5 mg/kg/day (200 times the MRHD on a mg/m^2 basis). Eszopiclone was also administered by oral gavage to pregnant rats throughout the pregnancy and lactation periods at doses of up to 180 mg/kg/day. Increased postimplantation loss, decreased postnatal pup weights and survival, and increased pup startle response were seen at all doses; the lowest dose tested, 60 mg/kg/day, is 200 times the MRHD on a mg/m^2 basis. These doses did not produce significant maternal toxicity. Eszopiclone had no effects on other behavioral measures or reproductive function in the offspring.

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

Labor And Delivery: LUNESTA has no established use in labor and delivery.

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

Pediatric Use: Safety and effectiveness of eszopiclone in children below the age of 18 have not been established.

Geriatric Use: A total of 287 subjects in double-blind, parallel-group, placebo-controlled clinical trials who received eszopiclone were 65 to 86 years of age. The overall pattern of adverse events for elderly subjects (median age = 71 years) in 2-week studies with nighttime dosing of 2 mg eszopiclone was not different from that seen in younger adults. LUNESTA 2 mg exhibited significant reduction in sleep latency and improvement in sleep maintenance in the elderly population.

ADVERSE REACTIONS
The premarketing development program for LUNESTA included eszopiclone exposures in patients and/or normal subjects from two different groups of studies: approximately 400 normal subjects in clinical pharmacology/pharmacokinetic studies, and approximately 1550 patients in placebo-controlled clinical effectiveness studies, corresponding to approximately 263 patient-exposure years. The conditions and duration of treatment with LUNESTA varied greatly and included (in overlapping categories) open-label and double-blind phases of studies, inpatients and outpatients, and short-term and longer-term exposure. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs.

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 tabulations that follow, 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 the patient was receiving therapy following baseline evaluation.

Adverse Findings Observed in Placebo-Controlled Trials
Adverse Events Resulting in Discontinuation of Treatment: In placebo-controlled, parallel-group clinical trials in the elderly, 3.8% of 208 patients who received placebo, 2.3% of 215 patients who received 2 mg LUNESTA, and 1.4% of 72 patients who received 1 mg LUNESTA discontinued treatment due to an adverse event. In the 6-week parallel-group study in adults, no patients in the 3 mg arm discontinued because of an adverse event. In the long-term 6-month study in adult insomnia patients, 7.2% of 195 patients who received placebo and 12.8% of 593 patients who received 3 mg LUNESTA discontinued due to an adverse event. No event that resulted in discontinuation occurred at a rate of greater than 2%.

Adverse Events Observed at an Incidence of ≥2% in Controlled Trials. The following lists the incidence (% placebo, 2 mg, 3 mg, respectively) of treatment-emergent adverse events from a Phase 3 placebo-controlled study of LUNESTA at doses of 2 or 3 mg in non-elderly adults. Treatment duration in this trial was 44 days. Data are limited to adverse events that occurred in 2% or more of patients treated with LUNESTA 2 mg (n=104) or 3 mg (n=105) in which the incidence in patients treated with LUNESTA was greater than the incidence in placebo-treated patients (n=99).[1]

Body as a whole: headache (13%, 21%, 17%), viral infection (1%, 3%, 3%). Digestive system: dry mouth (3%, 5%, 7%), dyspepsia (4%, 4%, 5%), nausea (4%, 5%, 4%), vomiting (1%, 3%, 0%). Nervous system: anxiety (0%, 3%, 1%), confusion (0%, 0%, 3%), depression (0%, 4%, 1%), dizziness (4%, 5%, 7%), hallucinations (0%, 1%, 3%), libido decreased (0%, 0%, 3%), nervousness (3%, 5%, 0%), somnolence (3%, 10%, 8%). Respiratory system: infection (3%, 5%, 10%). Skin and appendages: rash (1%, 3%, 4%). Special senses: unpleasant taste (3%, 17%, 34%). Urogenital system: dysmenorrhea* (0%, 3%, 0%), gynecomastia** (0%, 3%, 0%).

*Gender-specific adverse event in females

**Gender-specific adverse event in males

[1]Events for which the LUNESTA incidence was equal to or less than placebo are not listed, but included the following: abdominal dreams, accidental injury, back pain, diarrhea, flu syndrome, myalgia, pain, pharyngitis, and rhinitis.

Adverse events that suggest a dose-response relationship in adults include viral infection, dry mouth, dizziness, hallucinations, infection, rash, and unpleasant taste, with this relationship clearest for unpleasant taste.

The following lists the incidence (% placebo, 2 mg, 3 mg, respectively) of treatment-emergent adverse events from combined Phase 3 placebo-controlled studies of LUNESTA at doses of 1 or 2 mg in elderly adults (ages 65-86). Treatment duration in these trials was 14 days. Data are limited to events that occurred in 2% or more of patients treated with LUNESTA 1 mg (n=72) or 2 mg (n=215) in which the incidence in patients treated with LUNESTA was greater than the incidence in placebo-treated patients.[1]

Body as a whole: accidental injury (1%, 0%, 3%), headache (14%, 15%, 13%), pain (2%, 4%, 5%). Digestive system: diarrhea (2%, 4%, 2%), dry mouth (2%, 3%, 7%), dyspepsia (2%, 6%, 2%). Nervous system: abnormal dreams (0%, 3%, 1%), dizziness (2%, 1%, 6%), nervousness (1%, 0%, 2%), neuralgia (0%, 3%, 0%). Skin and appendages: pruritus: (1%, 4%, 1%). Special senses: unpleasant taste (0%, 8%, 12%). Urogenital system: urinary tract infection (0%, 3%, 0%).

[1]Events for which the LUNESTA incidence was equal to or less than placebo are not listed, but included the following: abdominal pain, asthenia, nausea, rash, and somnolence.

Adverse events that suggest a dose-response relationship in elderly adults include pain, dry mouth, and unpleasant taste, with this relationship again clearest for unpleasant taste. These figures cannot be used to predict the incidence of adverse events in the course of usual medical practice because patient characteristics and other factors may 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 physician with some basis for estimating the relative contributions of drug and non-drug factors to the adverse event incidence rate in the population studied.

Other Events Observed During The Premarketing Evaluation Of LUNESTA. Following is a list of modified COSTART terms that reflect treatment-emergent adverse events as defined in the introduction to the **ADVERSE REACTIONS** section and reported by approximately 1550 subjects treated with LUNESTA at doses in the range of 1 to 3.5 mg/day during Phase 2 and 3 clinical trials throughout the United States and Canada. All reported events are included except those already listed here or listed elsewhere in labeling, minor events common in the general population, and events unlikely to be drug-related. Although the events reported occurred during treatment with LUNESTA, they were not necessarily caused by it.

Events are listed in order of decreasing frequency according to the following definitions: **frequent** adverse events are those that occurred on one or more occasions in at least 1/100 patients; **infrequent** adverse events are those that occurred in fewer than 1/100 patients but in at least 1/1,000 patients; **rare** adverse events are those that occurred in fewer than 1/1,000 patients. Gender-specific events are categorized based on their incidence for the appropriate gender.

Frequent: chest pain, migraine, peripheral edema.

Infrequent: acne, agitation, allergic reaction, alopecia, amenorrhea, anemia, anorexia, apathy, arthritis, asthma, ataxia, breast engorgement, breast enlargement, breast neoplasm, breast pain, bronchitis, bursitis, cellulitis, cholelithiasis, conjunctivitis, contact dermatitis, cystitis, dry eyes, dry skin, dyspnea, dysuria, eczema, ear pain, emotional lability, epistaxis, face edema, female lactation, fever, halitosis, heat stroke, hematuria, hernia, hiccup, hostility, hypercholesteremia, hypertension, hypertonia, hypesthesia, incoordination, increased appetite, insomnia, joint disorder (mainly swelling, stiffness, and pain), kidney calculus, kidney pain, laryngitis, leg cramps, lymphadenopathy, malaise, mastitis, melena, memory impairment, menorrhagia, metrorrhagia, mouth ulceration, myasthenia, neck rigidity, neurosis, nystagmus, otitis externa, otitis media, paresthesia, photosensitivity, reflexes decreased, skin discoloration, sweating, thinking abnormal (mainly difficulty concentrating), thirst, tinnitus, twitching, ulcerative stomatitis, urinary frequency, urinary incontinence, urticaria, uterine hemorrhage, vaginal hemorrhage, vaginitis, vertigo, vestibular disorder, weight gain, weight loss.

Rare: abnormal gait, arthrosis, colitis, dehydration, dysphagia, erythema multiforme, euphoria, furunculosis, gastritis, gout, hepatitis, hepatomegaly, herpes zoster, hirsutism, hyperacusis, hyperesthesia, hyperlipemia, hypokalemia, hypokinesia, iritis, liver damage, maculopapular rash, mydriasis, myopathy, neuritis, neuropathy, oliguria, photophobia, ptosis, pyelonephritis, rectal hemorrhage, stomach ulcer, stomatitis, stupor, thrombophlebitis, tongue edema, tremor, urethritis, vesiculobullous rash.

DRUG ABUSE AND DEPENDENCE
Controlled Substance Class: LUNESTA is a Schedule IV controlled substance under the Controlled Substances Act. Other substances under the same classification are benzodiazepines and the nonbenzodiazepine hypnotics zaleplon and zolpidem. While eszopiclone is a hypnotic agent with a chemical structure unrelated to benzodiazepines, it shares some of the pharmacologic properties of the benzodiazepines.

Abuse, Dependence, and Tolerance
Abuse and Dependence: In a study of abuse liability conducted in individuals with known histories of benzodiazepine abuse, eszopiclone at doses of 6 and 12 mg produced euphoric effects similar to those of diazepam 20 mg. In this study, at doses 2-fold or greater than the maximum recommended doses, a dose-related increase in reports of amnesia and hallucinations was observed for both LUNESTA and diazepam.

The clinical trial experience with LUNESTA revealed no evidence of a serious withdrawal syndrome. Nevertheless, the following adverse events included in DSM-IV criteria for uncomplicated sedative/hypnotic withdrawal were reported during clinical trials following placebo substitution occurring within 48 hours following the last LUNESTA treatment: anxiety, abnormal dreams, nausea, and upset stomach. These reported adverse events occurred at an incidence of 2% or less. Use of benzodiazepines and similar agents may lead to physical and psychological dependence. The risk of abuse and dependence increases with the dose and duration of treatment and concomitant use of other psychoactive drugs. The risk is also greater for patients who have a history of alcohol or drug abuse or history of psychiatric disorders. These patients should be under careful surveillance when receiving LUNESTA or any other hypnotic.

Tolerance: Some loss of efficacy to the hypnotic effect of benzodiazepines and benzodiazepine-like agents may develop after repeated use of these drugs for a few weeks.

No development of tolerance to any parameter of sleep measurement was observed over six months. Tolerance to the efficacy of LUNESTA 3 mg was assessed by 4-week objective and 6-week subjective measurements of time to sleep onset and sleep maintenance for LUNESTA in a placebo-controlled 44-day study, and by subjective assessments of time to sleep onset and WASO in a placebo-controlled study for 6 months.

OVERDOSAGE
There is limited premarketing clinical experience with the effects of an overdosage of LUNESTA. In clinical trials with eszopiclone, one case of overdose with up to 36 mg of eszopiclone was reported in which the subject fully recovered. Individuals have fully recovered from racemic zopiclone overdoses up to 340 mg (56 times the maximum recommended dose of eszopiclone).

Signs And Symptoms: Signs and symptoms of overdose effects of CNS depressants can be expected to present as exaggerations of the pharmacological effects noted in preclinical testing. Impairment of consciousness ranging from somnolence to coma has been described. Rare individual instances of fatal outcomes following overdose with racemic zopiclone have been reported in European postmarketing reports, most often associated with overdose with other CNS-depressant agents.

Recommended Treatment: General symptomatic and supportive measures should be used along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. Flumazenil may be useful. As in all cases of drug overdose, respiration, pulse, blood pressure, and other appropriate signs should be monitored and general supportive measures employed. Hypotension and CNS depression should be monitored and treated by appropriate medical intervention. The value of dialysis in the treatment of overdosage has not been determined.

Poison Control Center: As with the management of all overdosage, the possibility of multiple drug ingestion should be considered. The physician may wish to consider contacting a poison control center for up-to-date information on the management of hypnotic drug product overdosage.

Rx only.

SEPRACOR 12/06

Children Suffering From Too Few MH Clinicians

A leading New Orleans psychiatrist tells congressional staff that more help is needed to reach children and youth before they plunge into mental health crises.

BY RICH DALY

Almost two years after Hurricane Katrina tore New Orleans apart, the region's devastated mental health system faces a serious shortage of the personnel needed to rebuild it.

General health and mental health leaders assessed the city's and state's mental health needs during a May congressional forum attended by staff from offices throughout Capitol Hill. They described a city overwhelmed by the immediate mental health care needs of many residents.

"In the short term the biggest challenge continues to be the [lack of a health care] workforce," said Frederick Cerise, secretary of the Louisiana Department of Health and Hospitals. "Hospitals say that if they had more people they could provide more beds."

The state launched a workforce initiative to recruit medical professionals nationwide to the area for a minimum of three years, but many professionals who are coming to the area are filling lucrative positions with private contractors, Cerise said. Further complicating the recruitment effort is the "piecemeal" rebuilding in the city, which has insufficient housing for even its smaller post-Katrina population.

"We've got a lot to do in terms of recruiting people back to the area," Cerise said.

That dearth of personnel has made it very difficult for the city and state to offer inpatient psychiatric care. New Orleans has only 20 adult public psychiatric beds, significantly fewer than the 99 such beds and 40 crisis unit beds available before the hurricane, according to Howard Osofsky, M.D., Ph.D., chair of psychiatry at Louisiana State University Health Sciences Center.

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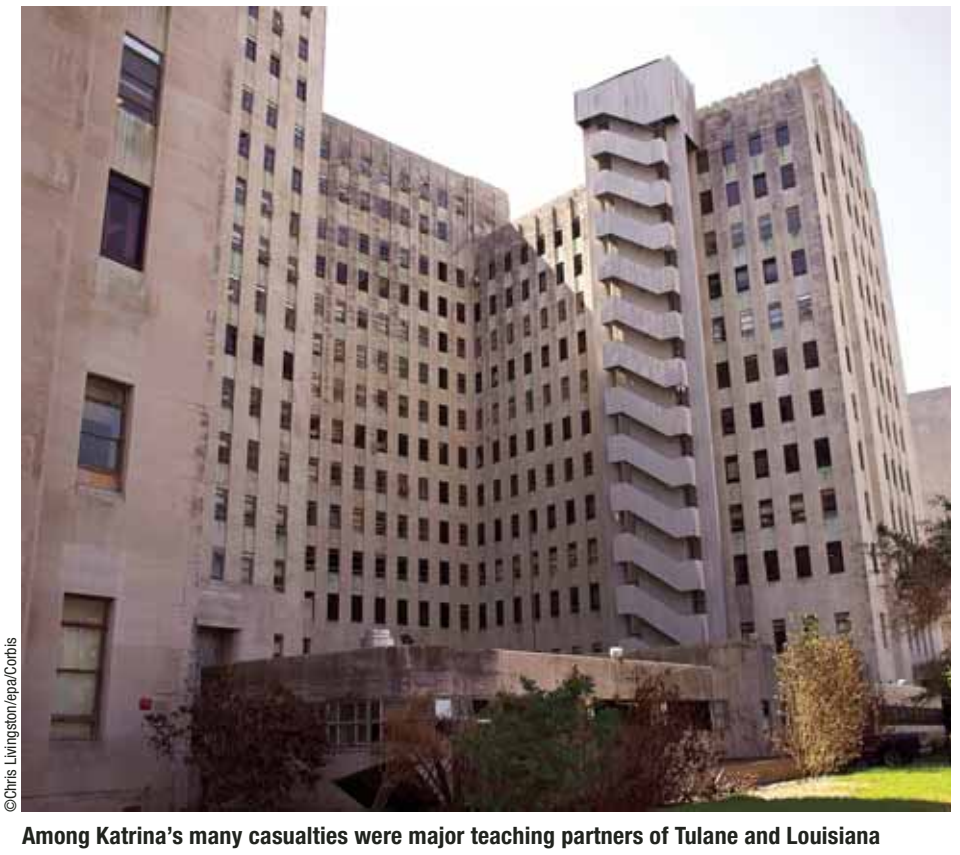

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Among Katrina's many casualties were major teaching partners of Tulane and Louisiana State University medical schools, including Tulane University Hospital and Clinic (above) and two campuses of the Medical Center of Louisiana at New Orleans, Charity (below) and University hospitals.

Cerise described an effort by state health officials to get private hospitals and clinics in the city to accept state funding for inpatient psychiatric beds, but only one accepted the offer. It will provide 12 new beds.

The limited public mental health services for children also have shrunk since the storm. New Orleans has only 15 child and adolescent public psychiatry beds—half of the number available before Katrina.

The 12,000 evidence-based mental health evaluations conducted by state mental health workers and the services they provided for displaced youngsters returning to the city after Katrina have shown that there is an enormous need for such care.

Data collected by the New Orleans school system indicate, for example, that 45 percent of students screened on their return to school this year displayed symptoms that qualify them for mental health care, 12 percent of fourth-grade students asked for counseling, and 25 percent of the students who asked for counseling showed "significant symptoms of depression," he said.

"There certainly is an increase in mental illness, some pre-existing and some new," Osofsky noted. He urged Congress to provide funding to restore school-based clinics for the city's youth, a population that usually responds best to preventive care and early interventions. Mental health care leaders have introduced more group treatment models for children and adolescents to address the trauma they have experienced and conditions that may arise from ongoing dislocations.

Extent of Need Documented

The anecdotal evidence presented to congressional staff of the increased mental health needs was reinforced by a survey of New Orleans area residents released in May by the Kaiser Family Foundation. The in-person survey of 1,500 randomly selected adults in the greater New Orleans area found that 15 percent rated their mental health as being worse than before the storm. Four percent also said they had begun taking psychiatric medication since Katrina.

The storm's impact on children was seen in the response of 4 percent of parents who said that their child shows signs of behavioral problems. Nine percent said their children didn't get needed general health care in the previous six months.

The hurricane's impact also took a toll on physical health. Twelve percent of those surveyed rated their physical health as worse after the storm, and 11 percent said a chronic condition had worsened since that disaster. Respondents further reported increased alcohol use, increased verbal or physical conflict in their relationships, and storm-related stress ending marriages or other personal relationships.

Residents sent a strong message about the need for additional health care services in New Orleans. Eighty-eight percent of respondents said there were insufficient hospitals, clinics, and other health facilities operating, while 89 percent said there were insufficient health care services for uninsured and low-income residents.

"It's a system in need of immediate help, not just long-term planning," said Diane Rowland, one of the survey's authors.

Future Plans Described

Cerise said the state's goals include establishing crisis-response services, adding psychiatric beds, jail-diversion programs, and supported-living programs. The state, he said, is committed to continuing the mental health programs started under the $80 billion in federal block grants provided for Louisiana after the storm.

Disagreements among health care leaders continue over what new form Charity Hospital should take, Officials are planning to replace the former facility for the city's poor—and a major teaching hospital—with a decentralized system of smaller facilities spread throughout the city.

Health officials also are designing a long-term mental health system that will replace the office-visit-based model of care with the "medical home model," in which a physician coordinates the overall care of each patient, Cerise said. The approach should increase the availability of physician contact through increased use of e-mail consultations and telemedicine—already in use in a neighboring county of New Orleans.

Osofsky urged funding for counselors and psychiatric nurses who would be available 24 hours a day and seven days a week. The city also needs to re-establish a crisis inpatient unit in a New Orleans hospital. The lack of such services in the city has resulted in increased incarceration of people with mental illness and mental health providers sending people to other parts of the state for care, he said.

"This means that children are separated from parents," Osofsky said.

More information on the Kaiser survey is posted at <www.kff.org>. ■

Conference to Address Transcultural Issues

The World Federation for Mental Health (WFMH) will sponsor the conference "Transcultural Mental Health in a Changing World: Building a Global Response" from October 29 to 31 at the Minneapolis Marriott Hotel City Center in Minneapolis, Minn. Collaborating with the WFMH are Minnesota-based mental health, health, social, and human service organizations.

According to the WFMH, the conference theme was chosen to highlight the major influence that culture plays in how individuals, communities, professionals, and service organizations perceive mental health and mental illnesses, and how mental health services are planned and delivered in a multicultural community. The Minneapolis-St. Paul area was selected as the conference location because of the many cultures represented among its residents.

The conference is aimed at psychiatrists, mental health professionals, and mental health advocates, among others.

The deadline for reserving a hotel room at the conference's reduced rate is October 5.

A conference registration form is posted at <www.wfmh.com/documents/MNCallforPapers.pdf>. Further Information is available by contacting Ellen Mercer, director of the WFMH Center for Transcultural Mental Health, at emercer@wfmh.com. ■

Kids' Hospitalizations Have Researchers Puzzled

There has been a dramatic surge in the hospitalization of children for bipolar disorder during the past few years. But an increase in the incidence of bipolar disorder among youth is probably not the reason.

BY JOAN AREHART-TREICHEL

Joseph Blader, Ph.D., an assistant professor of psychiatry, and Gabrielle Carlson, M.D., a professor of psychiatry at the State University of New York at Stony Brook, studied the rates of hospital discharges in the United States from 1996 through 2004.

Some interesting findings emerged with regard to bipolar disorder among children (aged 5 to 13) and adolescents (aged 14 to 18).

The number of bipolar disorder discharges increased fivefold in children—from 1.3 to 7.3 per 10,000 of the general population—and fourfold in adolescents—from 5.1 to 20.4 per 10,000 of the general population.

As a proportion of the total number of psychiatrically related discharges, children diagnosed with bipolar disorder constituted 10 percent in 1996 and 40 percent by 2004.

Moreover, bipolar disorder was one of the least-frequent psychiatric diagnoses recorded for child inpatients in 1996, but the most common in 2004. And while there were twice as many discharges of adolescents in 1996 for a depressive disorder than for a bipolar one, by 2004 the rates were about equal.

The findings are in press with *Biological Psychiatry*.

When *Psychiatric News* asked Kiki Chang, M.D., director of the Pediatric Bipolar Disorders Program at Stanford University, what he thought of these findings, he was astounded. The findings, he continued, are even more remarkable "when one considers that, at least in the San Francisco Bay area, inpatient beds have decreased during that time, and thresholds for admissions have been raised."

To which David Axelson, M.D., an assistant professor of psychiatry at the University of Pittsburgh and a pediatric bipolar authority, added, "The authors have clearly identified a remarkable increase in the proportion of hospitalized children and adolescents assigned a bipolar disorder diagnosis at discharge."

The reasons for this dramatic increase, however, are open to speculation at this point. It might reflect an "upcoding" of volatile, aggressive behavior in children with bipolar disorder to obtain reimbursement from managed care, Blader and Carlson proposed in their study report. "The survey years considered in this report coincided with payers' efforts to constrain the use of costly inpatient services."

Or it might mirror an increased recognition of pediatric bipolar disorder, Chang and Axelson suggested. "I think we have gotten better at identifying bipolar disorder in kids since 1996," Axelson said. "A bipolar diagnosis of 40 percent of child [psychiatric] admissions in 2004 does seem high, but I also think the [actual] rate is significantly more than the 10 percent rate [found] in 1996."

In contrast, Axelson conjectured, the upswing in bipolar discharges among youth during the period could be due to higher rates of hospital readmission. "During the study interval," he explained, "the admission criteria for hospitalizing children and adolescents became substantially more stringent. The length of hospital stays dropped, and readmission rates increased. Since kids with bipolar disorder have high rates of dangerous behavior, aggression, psychosis, and suicidality, I would expect that they would be proportionally more likely to meet the more stringent admission criteria and need readmission more often than [youth with] other diagnoses."

Race may have also played a role in the upswing, Blader and Carlson suggested. Demographic differences in bipolar diagnoses in the earlier survey years showed lower rates of the diagnosis among black youth, and especially among black boys, than among youth of other races. However, in the most recent survey years—2002 to 2004—bipolar discharges among black children increased markedly for both boys and girls and came to exceed the rates among white boys and girls. "It would be a positive development if this trend corrects a bias that led to misdiagnosis in the past," Blader and Carlson said.

None of these bipolar authorities, though, seems to believe that the upswing in bipolar discharges among youth is due to an increase in incidence of the illness among them. However, Chang did venture that it might reflect an "increase in the severity of childhood presentations of bipolar disorder."

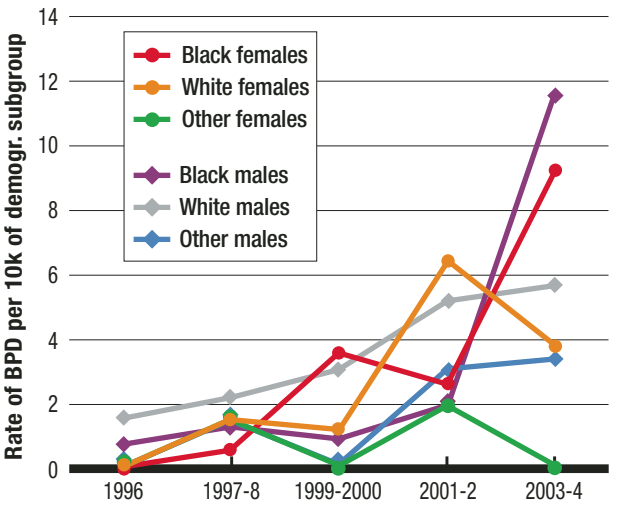
The new study was based on data provided by the National Hospital Discharge Survey, which the National Center for Health Statistics conducts annually. It captures patient-level information pertaining to discharges during the calendar year from nonfederal general hospitals, children's hospitals, and more specialized hospitals.

The study was funded by the National Institute of Mental Health and the National Alliance for Research on Schizophrenia and Depression.

An abstract of "Increased Rates of Bipolar Disorder Diagnoses Among U.S. Child, Adolescent, and Adult Inpatients, 1996-2004" is posted at <www.journals.elsevierhealth.com/periodicals/bps/article/PIIS0006322306014466/ab...>. ■

Child Hospitalizations Rise For Bipolar Disorder

From 1996 through 2004, the number of children discharged from American hospitals with a diagnosis of bipolar disorder dramatically increased. The increase was especially steep from 2002 through 2004 for black youngsters.



Source: Joseph Blader, Ph.D., and Gabrielle Carlson, M.D., *Biological Psychiatry,* in press

Strategies in Antistigma Battle Appear to Be Working

Stigma surrounding mental health problems and treatment lessened over the 1990s, which government researchers declared the Decade of the Brain. Young adults experienced the most improvement in attitudes.

BY EVE BENDER

Seeking treatment for mental health problems has become more acceptable since the early 1990s, according to a new study. The more positive attitudes toward treatment over time may have contributed to a growing demand for mental health services over recent years.

Data comparing attitudes toward mental health treatment in two nationally representative surveys showed that 27.1 percent of those surveyed between 1990 and 1992 reported being "very comfortable" with talking to a professional about personal problems, compared with 32.4 percent of those surveyed between 2001 and 2003.

The findings appeared in the May *Psychiatric Services*.

Lead author Ramin Mojtabai, M.D., Ph.D., told *Psychiatric News* that although he couldn't draw any definitive conclusions about these findings, he believed that a number of changes in the mental health field may have shifted attitudes for the better. Mojtabai is a PGY-3 resident in psychiatry at Beth Israel Medical Center in New York.

Throughout the 1990s there was an increase in direct-to-consumer marketing of antidepressants, he explained, and a surge in depression-prevention and suicide-screening programs. This may have had a positive effect on public attitudes toward treatment.

To detect these trends in attitudes about mental illness, Mojtabai compared data from respondents to the 1990-1992 National Comorbidity Study (NCS) with those from the 2001-2003 NCS–Replication (NCS-R), both of which studied mental health problems and treatment in the United States.

For the NCS, researchers interviewed 8,098 randomly selected people aged 15 to 54 in their homes. For the NCS-R 10 years later, they interviewed a separate, randomly selected sample of 9,282 adults over age 18 in their homes.

Three questions generated responses on attitudes toward mental health treatment: Participants reported whether they would seek help for a serious emotional problem on a scale ranging from "probably" to "definitely not," the degree to which they were comfortable talking about personal problems to a professional, and the degree to which they would be embarrassed if their friends knew they were getting professional help for an emotional problem (see chart). Responses to these questions were categorized on a scale from 0 to 3, with higher scores indicating more positive attitudes toward treatment.

Mojtabai found that 35.6 percent of respondents to the NCS reported that they would "definitely" go for professional help for a serious emotional problem, compared with 41.4 percent of NCS-R respondents. He also found that 33.7 percent of NCS respondents reported that they would not be embarrassed if friends knew about their getting professional help. This number jumped to 40.3 percent for respondents to the later survey.

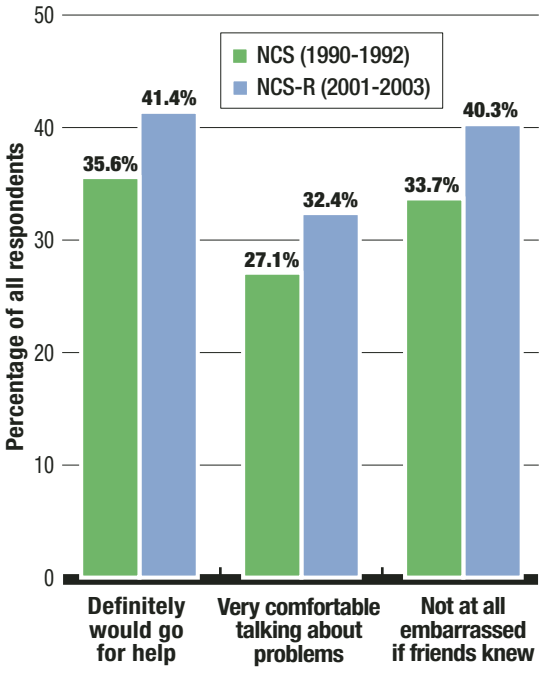
When Mojtabai analyzed the findings by age, he found that adults aged 18 to 34 in the NCS-R had more positive attitudes toward mental health treatment seeking than adults of the same age did in the original NCS. However, adults in the 35 to 54 age range showed little change in attitudes at the two time points.

"Although attitudes toward mental health treatment seeking improved in all generations," he said, "the improvement was greatest in the generation that was 15 to 24 years old in 1990 to 1992." This may be because they had more exposure to public-information campaigns and other positive media messages about mental illness,

please see ***Antistigma*** *on page 17*

Stigma Declining

Researchers analyzing data from the National Comorbidity Survey (NCS) and the NCS–Replication found in the early part of this decade more people reported feeling more comfortable and less embarrassed about seeking professional help than they had 10 years previously. The improvement was greatest in the generation that was 15 to 24 years old in 1990 to 1992.



Source: Ramin Mojtabai, M.D., Ph.D., *Psychiatric Services*, May 2007

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Advocacy Will Overcome Barriers To Better Care, Robinowitz Says

Building on the work of her predecessor, APA's incoming president challenges her colleagues to stand up and be counted as advocates for their profession and patients.

BY CATHERINE F. BROWN

After years of excelling as a pipe organist and earning a degree in music from Wellesley College, Carolyn Robinowitz began to hear a new tune from the muse in her head: perhaps there was a different instrument that she could use to touch the lives of others.

Indeed, there was—and it turned out to be a career in medicine and eventually psychiatry.

While the field of music may have lost a major professional talent, the field of psychiatry and an untold number of mentally ill individuals of all ages have benefited from her decision. Now in her latest leadership role in psychiatry as incoming president of APA, she has set even more challenges not only for herself, but for her fellow psychiatrists as well.

In a speech last month in the Opening Session of APA's 2007 annual meeting in San Diego, Robinowitz praised outgoing APA President Pedro Ruiz, M.D., as "amazing, brilliant, and energetic" and urged the psychiatrists in the audience to keep the momentum going by being active advocates for their profession and their patients. Doing so is imperative,

"APA continues its work helping nonmembers as well as those who pay. Are there free lunches? Should not all the beneficiaries of APA efforts contribute?"

Robinowitz observed, because psychiatry faces a dichotomy of "the best of times and worst of times."

On the positive side, she said, are the advances in science that have pushed psychiatry forward so that it now provides a wide array of psychotherapy and psychopharmacologic treatments that have been proven effective. Moreover, she continued, research has demonstrated that treatment of mental illness is cost-effective by lowering health care expenditures in general and keeping workers employed and productive. In contrast, untreated mental illness has been estimated to cost the U.S. economy $204 billion a year. Thus, adding mental health coverage to existing health insurance coverage is a sound investment and has been found to increase premiums by less than 1 percent—"pennies to do the right thing."

The alliances that APA has developed with patient advocacy groups, such as the National Alliance on Mental Illness, Mental Health America, and the Depression and Bipolar Support Association, are another plus for psychiatry. These alliances, Robinowitz noted, "have enhanced our strength and credibility in promoting greater research funding and adequate care. Working together has made this a patient issue, not just guilds promoting their pocketbooks. Policymakers are attentive to personal stories and are now much more appreciative of the impact of mental disorders and the need for care and cure."

Also, she continued, the willingness of celebrities to share their stories of mental illness and recovery has helped reduce stigma by bringing mental illness out of the closet and proving that treatment works.

Nonetheless, Robinowitz said, the negatives that psychiatry faces have hobbled its ability to deliver care because of poor public policy and ever-dwindling resources. Among the consequences she noted: 47 millions Americans have no health insurance, and 25 million Americans are underinsured because of discriminatory coverage of psychiatric treatment; growing numbers of mentally ill individuals are incarcerated in jails and prisons; the decline in antidepressant prescriptions following the FDA's addition of warnings to antidepressant labeling has been linked to a rise in suicide; managed care continues to emphasize short-term savings over long-term costs and patient distress; and Scientologists' antipsychiatry messages undermine psychiatry's credibility.

"Sadly, we contribute to the problems," Robinowitz told her audience. "How often and loudly do we speak, and do we speak effectively with one voice?

"We—psychiatrists—are the only professionals that can integrate the needs of patients and our care systems. We are the only people who can provide access to care, assess the care, and ensure quality. We are the only professionals trained in both the biological *and* psychological workings of the brain, mind, and body," she said to applause. "Thus, we have an intellectual as well as moral authority to commit to our core professional values and protect our patients without being paternalistic or maternalistic."

How can individual psychiatrists recommit to advocating for patients? "First," she said, "we must be members of APA." The APA leadership and staff, she noted, cannot succeed without the active involvement of psychiatrists as members of their professional organization.

Credit: David Hathcox

Incoming APA President Carolyn Robinowitz, M.D., tells psychiatrists that effective patient advocacy calls for them to "First, . . . be members of APA."

"Dissatisfaction with outcome—no, neither we nor any other medical organization has been successful in stopping the abuses of managed care; single-issue disagreements; or focus on subspecialty interests—yes, priorities are more easily set, but the small organizations look to the strength of APA to represent them—can lead members to leave in spite of a decade long national dues freeze. Yet APA continues its work helping nonmembers as well as those who pay. Are there free lunches? Should not all the beneficiaries of APA efforts contribute?"

After setting out her advocacy agenda for the coming year, Robinowitz asked every psychiatrist in the audience to join her by "working with colleagues in medicine, policymakers and advocacy groups, media, the business community, clergy, and the general public to educate, inform, and ensure that our patients no longer face discrimination and have access to appropriate care. Share your energy and expertise to promote our professional values. I ask each of you to stand and to make that commitment to work actively in your professional life."

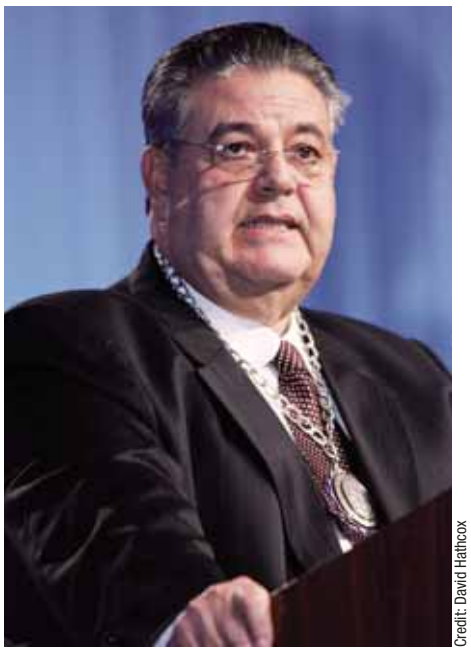
Her colleagues did not disappoint her. ■

Ruiz

continued from page 1

viduals to a work group to turn plans into action.

That professional ethics and values were central to Ruiz's presidency was evidenced in numerous ways throughout this past year. One was the selection process of *DSM-V's* leadership. At a time when medical researchers were being criticized for using funding by sources that had a vested interest in the studies' outcomes, Ruiz wanted "the most transparent and ethically driven policy that one could humanly design" for selecting leadership of *DSM-V.* The results were a rigorous screening process that all nominees of the *DSM-V* Task Force and working groups had to undergo and the creation of a conflict-of-interest disclosure form "that is second to none in the medical field."



Credit: David Hathcox

Another example was Ruiz's visit to Guantanamo Bay Naval Station last November. One reason that he accepted the invitation from the Department of Defense to visit the camp—marking his first return to Cuba since leaving there at the age of 21—was "to pay respect" to the psychiatrists and other health care personnel who were working there under "the most difficult and challenging circumstances. As your APA president, the well-being of even one APA member is as relevant, or even more important, to me than any political ideology, including my own."

He was among the APA leaders who opposed the participation of psychiatrists in the interrogation of prisoners and detainees, which led to the approval of an official position statement to that effect last year *(Psychiatric News,* June 16, 2006).

Paralleling Ruiz's initiatives to strengthen APA's relationship with advocacy groups were initiatives to do likewise with the National Institute of Mental Health, National Institute on Drug Abuse, and National Institute on Alcohol Abuse and Alcoholism.

Ruiz noted that the two psychiatrists in line to succeed him as APA president—Carolyn Robinowitz, M.D., and Nada Stotland, M.D., share his commitment to achieving humane care and have the personal and professional qualities needed to do so. "Thus, let's continue to use our principles, let's continue to use our values, and let's continue to operate our APA within a framework of social responsibility."

Nonetheless, the end of Ruiz's term as president does not mean it's time for him to step aside and let them and others carry on the battle.

"I am not planning to fade away," he declared to a standing ovation. "As long as there is a mental patient without access to health and mental health care, without full and comprehensive parity of psychiatric care and without receiving proper humane care, and who is still living in the shadows, whether in this country or in any other part of the world, I will return and join you in the trenches again, again, and again." ■

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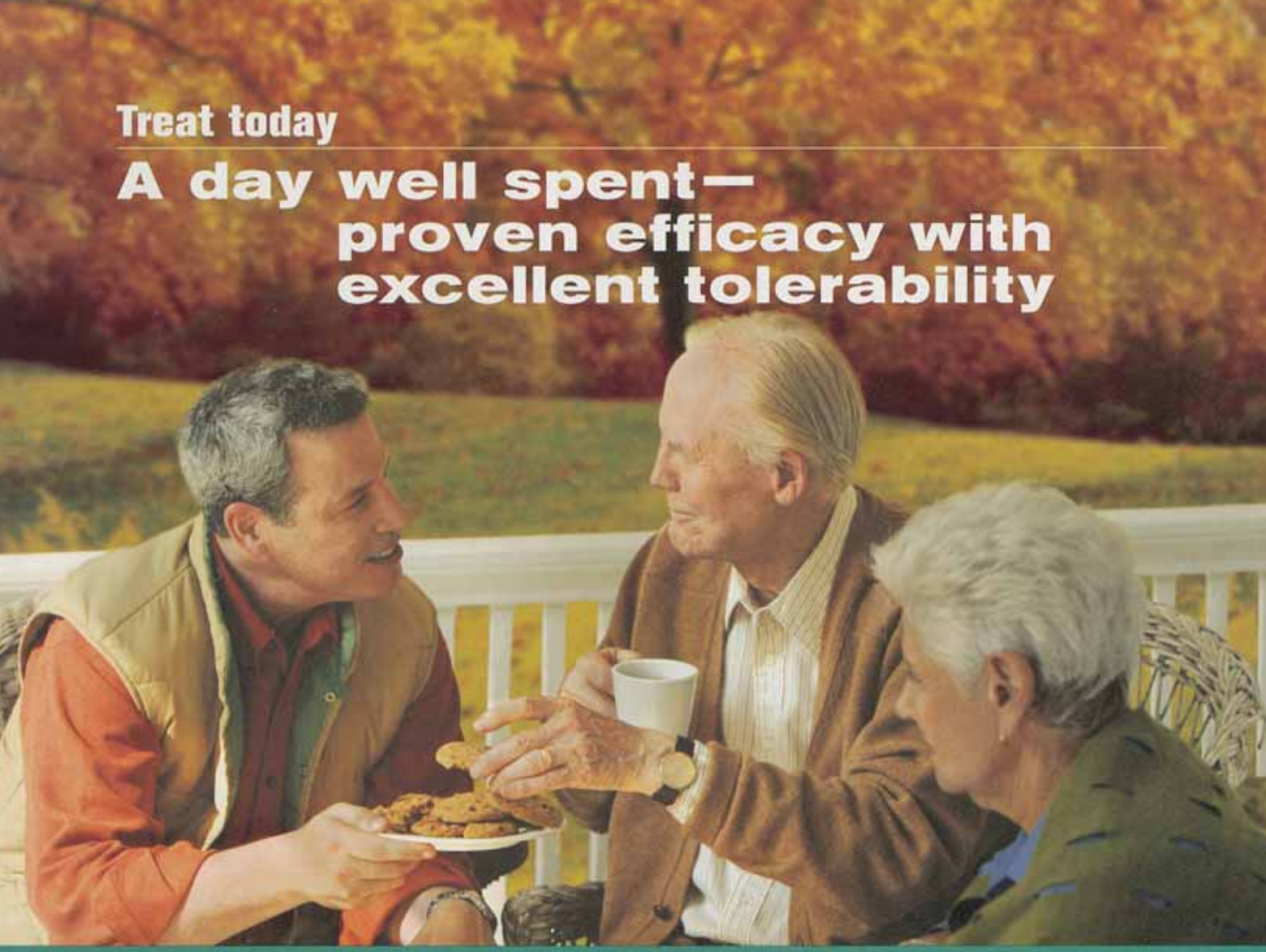

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References: 1. Reisberg B, Doody R, Stöffler A, Schmitt F, Ferris S, Möbius HJ, for the Memantine Study Group. Memantine in moderate-to-severe Alzheimer's disease. *N Engl J Med.* 2003;348:1333-1341. **2.** Tariot PN, Farlow MR, Grossberg GT, Graham 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. **3.** Cummings JL, Schneider E, Tariot PN, Graham SM, for the Memantine MEM-MD-02 Study Group. Behavioral effects of memantine in Alzheimer disease patients receiving donepezil treatment. *Neurology.* 2006;67:57-63. **4.** Data on file. Forest Laboratories, Inc. **5.** NAMENDA® (memantine HCl) Prescribing Information. Forest Pharmaceuticals, Inc., St Louis, Mo. **6.** Winblad B, Poritis N. Memantine in severe dementia: results of the 'M-BEST Study (Benefit and efficacy in severely demented patients during treatment with memantine). *Int J Geriatr Psychiatry.* 1999;14:135-146.

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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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Assembly Addresses Patient Care, Psychiatric Practice Concerns

The Assembly's wide-ranging agenda found representatives focusing on multiple issues with signficant impact on patient care and how psychiatrists practice their speciality.

BY KEN HAUSMAN

Access-to-care issues were prominent on the agenda of the APA Assembly during its three-day meeting last month in San Diego, with the representatives passing several action papers related to ensuring that patients can receive the psychiatric care they need and advocating for patients on several fronts.

This focus meshed well with a presentation by Rep. Susan Davis (D), who represents San Diego in Congress (and is married to a psychiatrist). "We need to build a health care system that maximizes patient access to the latest and best evidence-based care," she emphasized. "Mental health is just as vital as physical health for one's well-being. . . . When people have access to care, recovery is possible."

The Assembly discussed federal parity legislation that has the potential to override state parity laws. The group voted that APA should support legislation that best preserves state laws that provide greater coverage to patients than is included in some federal proposals. The action paper urged "full and informed" communication between APA and its district branches and state associations (DBs/SAs) and stated that any decision to endorse federal parity legislation "must be based on an assessment of the overall benefits to patients."

The goal of another access-related paper was to expand the number of state and federal facilities to which veterans can turn for assessment and treatment of posttraumatic stress disorder (PTSD) and related neuropsychiatric disorders. The authors maintained that the Department of Veterans Affairs sometimes fails to recognize and treat these disorders and could benefit from APA-generated PTSD-related training materials.

The Assembly also voted to have APA develop a policy statement saying that children who have been victims of physical or sexual abuse should not be forced to confront the alleged perpetrator during court proceedings, when such confrontations could harm the child.

Assembly members also urged APA to advocate with federal officials to have psychiatric medications included among medications in the Strategic National Stockpile, which is a resource the government can tap after disasters or terrorist attacks.

Several proposals that the Assembly adopted were directed toward the goal of advocating for the psychiatric profession. Among these were two calling for psychiatry to be "carved in" by insurance companies and federally qualified health centers.

Another paper sought to establish a work group to develop recommendations on ways APA could provide support, though not legal advice, to members who are sued for malpractice, and representatives also voted to have several APA committees discuss the feasibility of a "peer-to-peer support program" as a form of outreach to members in regions struck by natural or man-made disasters.

The Assembly voted to have APA increase its involvement in the development and implementation of health information technology to ensure that the needs of psychiatrists and their patients are considered by policymakers and to begin a pilot project in which members-in-training who are active in APA activities would spread the word to other residents in their regions about the value and benefits of APA membership. Programs in New York City will be the first targets of the pilot project.

In addition, Assembly members endorsed the appointment of an Assembly committee to address concerns that may be unique to Canadian APA members. The committee is to consist of three Canadian and two U.S. representatives. With the overwhelming focus of APA on political and health-system issues in the United States, the Assembly agreed that more attention should be paid to issues that impact Canadian psychiatrists. Representatives also asked APA's medical director to include issues of concern to Canadian members in his reports to the Assembly and to the membership in general.

Expressing its continuing concern about the power balance between it and the Board of Trustees, the Assembly revisited a proposal that would give it, in some circumstances not involving the Board's fiduciary responsibility to APA, the ability to override the Board when action papers from the Assembly are not approved by the Board. The Assembly endorsed a compromise that would have the speaker work with the Board to appoint a joint task force that would recommend a plan introducing additional checks and balances to increase the Assembly's influence.

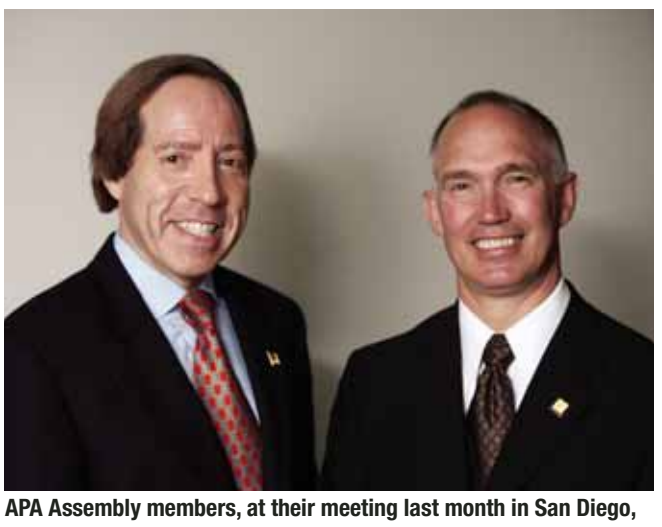
A proposal to have APA issue a call for more private funding of research and clinical trials that lead "to the commercial licensure of prescription marijuana" generated considerable controversy and was defeated by Assembly members. The proposal would have also urged APA to "recommend that patients be protected when in possession and/or using legal quantities of marijuana under physician supervision."

In addition to Rep. Davis, the Assembly heard from several other invited speakers.

please see ***Assembly*** *on page 26*

Clockwise from top right: **Michael Kalm, M.D.**, **David Duncan, M.D.**, and **Jason Hunziker, M.D.,** of the Utah Psychiatric Association congratulate each other after winning the Assembly's District Branch Best Practice Award for the DB's Soundbyte program with the Utah legislature; **Carol Trippitelli, M.D.**, chair of the Assembly Committee of Early Career Psychiatrists, presents its semiannual report; Colorado representative **Joanne Ritvo, M.D.**, waits her turn to speak during an Assembly debate; AMA Board member **William Hazel Jr., M.D.**, shows one of the advocacy resources AMA has prepared to help physicians fight scope-of-practice expansions by nonphysicians—this one addresses psychologist-prescribing privileges; **Stephen McLeod-Bryant, M.D.**, chair of the Assembly Committee of Representatives of Minority/Underrepresented Groups, urges members to attend the Institute on Psychiatric Services in New Orleans in October.

Photos by David Hathcox



Credit: David Hathcox

APA Assembly members, at their meeting last month in San Diego, elected Ronald Burd, M.D., of Fargo, N.D. (right), for speaker-elect and Gary Weinstein, M.D., of Louisville, Ky., for recorder. Burd, who just completed a term as the Assembly's recorder, defeated Herbert Peyser, M.D., a representative of the New York County District Branch. Weinstein, who was Area 5 representative, outpolled Joanne Ritvo, M.D., of Denver. Ritvo is a representative from the Colorado Psychiatric Society.

Good Communication Crucial In Prescribing for Pregnant Women

Treating pregnant patients who have psychiatric disorders is not easy. Contradictory research findings and the opinions of loved ones complicate the treatment process, according to risk managers.

BY EVE BENDER

Prescribing medications to pregnant patients with psychiatric problems can be risky business, so to speak. Psychiatrists should avail themselves of the most up-to-date findings on the use of medications during pregnancy to help patients make informed treatment decisions, according to risk-management experts.

"Weighing the risks and benefits of prescribing medications during pregnancy is complicated" by research findings that sometimes contradict one another and mixed messages from popular media that can confuse patients and their families, said Jacqueline Melonas, R.N., M.S., J.D., vice president of risk management at Professional Risk Management Services Inc., the administrator of the APA-endorsed Psychiatrists' Liability Insurance Program.

Several studies have reported that some infants exposed to selective serotonin reuptake inhibitors (SSRIs) in utero may experience neonatal abstinence syndrome, for instance, which includes agitation, feeding, and sleep disturbances.

In addition, the Food and Drug Administration (FDA) issued a public-health advisory in December 2005 about the risk that paroxetine could increase cardiac malformations of the fetus during the first trimester. In July 2006, the FDA alerted the public about an increased risk of neonatal persistent pulmonary hypertension with SSRI use.

Some studies have shown that discontinuing antidepressants while pregnant can raise the risk of depression relapse, which can also pose a risk to unborn children (*Psychiatric News*, April 7, 2006), and has been associated with low-weight babies or premature births.

According to Melonas, between 7 percent and 13 percent of women who are pregnant may experience depression, and many physicians share concern not just about how to ensure health for expectant mothers and their unborn babies, but also about malpractice claims if there is an adverse outcome in relation to the pregnancy.

She noted that some psychiatrists feel uncomfortable treating pregnant patients even if they do have good information about the risks and benefits of various treatments. "In such cases, it is best to transfer the patient to another psychiatrist's care" during pregnancy, she said.

Psychiatrists who do decide to care for the patient, however, must stay abreast of the latest scientific information and policy issues related to treatment of pregnant women with psychotropic medications, Melonas noted.

If there is legal action, "psychiatrists are expected to be responsible for knowing about the scientific information available to them at the time" of treatment, she said.

Good sources of information include peer-reviewed journal articles, practice guidelines, professional literature, and information from professional organiza-

please see ***Pregnant Women*** *on page 24*

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Psychiatrists should help pregnant patients sort through scientific data and other information when helping them decide whether to take a psychotropic medication.

Tips on Psychiatric Treatment of Pregnant Patients

- Stay current by reading the most up-to-date research findings, treatment guidelines, and policies on treating pregnant patients with psychotropic medications.
- Consult other providers who are expert in the treatment of pregnant patients when necessary.
- Be aware of outside influences on patients in regard to their decision to take medications during pregnancy. The opinions of loved ones and even the media can often be influential.
- Communicate openly and often with other members of patients' treatment teams, including obstetricians.
- Document the clinical basis of the decision-making process that led up to the treatment choice, details about treatment, information provided to patients about the treatment, and communications with other members of patients' treatment team.

Challenges May Be Daunting, But APA Helps Meet Them

BY ABIGAIL DONOVAN, M.D.

This is a difficult time to be a psychiatrist, and especially a psychiatrist in training. Over the past year, the field of psychiatry has witnessed many controversies and dilemmas. Medicare changes have complicated our patients' already complex lives. Many of our patients suffered an exacerbation of their symptoms, not through the natural course of illness, but through changes in medication mandated by their insurance.

There has been national media attention about "overmedicating" and "overdiagnosing" children with mental illness. At the same time, there are editorials about insufficient mental health treatment for youth, especially in the wake of national tragedies such as the massacre at Virginia Tech.

And while the media direct attention to the prescribing practices of psychiatrists, there are bills in state legislatures to allow psychologists to prescribe many of the same medications that psychiatrists do but with significantly less training. And despite public outcry about access to psychiatric services, mental health insurance parity is not yet a reality. What is a young psychiatrist to think?

As a psychiatrist in training, I find myself feeling anxious about practicing in a field with so much controversy and so many paradoxes of such great importance. I have never questioned becoming a psychiatrist—I know that I could do nothing else as fulfilling in my life; however, I am acutely aware of the challenges inherent to psychiatry, especially in the current political and social milieu. I worry about how to provide the best care for my patients within the constraints of inadequate mental health care insurance coverage. I worry about how the people who never reach my office will find mental health care, given the challenges of access. I worry about how the veterans returning from overseas will obtain appropriate mental health care for themselves and their families. I worry about the influence that the pharmaceutical industry has over psychiatric research and the comparatively scarce government funding as an alternative means for this research. And when I think that I have finally identified all of the important issues, a new editorial is published, new headline-making news is announced, a new question emerges.

In my residency, there is a mantra, repeated often throughout training, from the most senior faculty down to the intern class: "never worry alone."

We are taught that if you ever feel worried about a patient, a decision, a treatment, you should consult a supervisor to discuss the issue. I have made use of this opportunity on many occasions, even paging supervisors in the middle of the night to discuss a particularly difficult case. I am comfortable admitting that I am a worrier; in fact, I am quite accomplished at worrying. But the experience is much more tolerable when there is someone else to worry with you. Hence, my supervisors have grown accustomed to hearing my voice in the middle of the night: "Sorry to wake you, Dr. Prager, it's me again. . . ."

But who is there to worry with me about the state of mental health care in the United States? About access to psychiatric care? About all of the many complex issues the field of psychiatry is facing?

Until last year, I did not have an answer for these questions. Then, in May 2006, I began my term as the member-in-training trustee-elect on the APA Board of Trustees.

And over the past year I have realized that not only is APA acutely aware of the myriad difficult issues facing psychiatry today, but also that APA is actively working to address these issues.

Under the ambitious leadership of Dr. Pedro Ruiz, who just completed his year as APA president, APA has worked tirelessly to analyze barriers to psychiatric treatment and improve access to care, to advocate strongly for mental health care insurance parity, to address the mental health care needs of returning veterans, to fight psychologist-prescribing privileges, and to promote collaboration between other powerful organizations with similar goals.

In addition, APA is working to further the field as a whole, through revising its *Diagnostic and Statistical Manual* and by offering numerous fellowships, research grants, mentorship programs, and comprehensive practice guidelines for members-in-training and for more experienced psychiatrists. As a member of APA, I have come to realize that I no longer worry alone. In fact, APA has even gone a step farther than being alert to these issues; it is committed to resolving them. ■

Abigail Donovan, M.D., is a first-year child and adolescent psychiatry fellow at the Massachusetts General Hospital and McLean Hospital combined program.

Stunkard Weighs In on 50 Years Of Eating Disorders Research

After more than a half century of study, psychiatrist Albert Stunkard, M.D., continues to contribute new knowledge to the field of eating disorders.

BY LYNNE LAMBERG

A 16-year-old woman, more than 100 pounds overweight, told the physician treating her for depression that she had no appetite in the morning. She ate voraciously in the evening, however, and even rose from sleep to snack.

This unusual pattern of food consumption intrigued her therapist, Albert Stunkard, M.D., then a resident in psychiatry at the Johns Hopkins Hospital. Although the woman dropped out of treatment, Stunkard never forgot her.

After completing his residency in 1953, Stunkard started a fellowship in psychosomatic medicine at the New York Hospital-Cornell Medical Center. Assigned to the obesity clinic, he asked patients both what and when they ate.

Stunkard and his mentor at Cornell, neurologist Harold Wolff, M.D., published the first report on what they called the night eating syndrome (NES) in the July 1955 *American Journal of Medicine*. They described 20 obese patients with morning anorexia who commonly consumed at least a quarter of their total daily calories after their evening meal. None of their 38 healthy non-obese control subjects displayed this pattern.

Fifty-two years and 447 papers later, Stunkard, at age 85, continues to investigate NES and other eating disorders. In 2006 alone, he and colleagues published nine papers on NES and other eating disorders. He also has co-authored a book for patients and their families, published in 2004, *Overcoming Night Eating Syndrome: A Step-by-Step Guide to Breaking the Cycle* (New Harbinger Publications).

"At meetings, he's usually in the front row listening attentively or presenting his latest research findings," said James Mitchell, M.D., professor and chair of clinical neuroscience at the University of North Dakota School of Medicine and a specialist in eating disorders.

Stunkard, a professor of psychiatry at the University of Pennsylvania, chaired its Department of Psychiatry from 1962 to 1973 and later founded its Center for Weight and Eating Disorders. The National Institute of Mental Health has supported his research for more than four decades.

Stunkard's many honors include APA's Award for Research in both 1960 and 1980 and Distinguished Service Award in 1994. He received the Rhoda G. and Bernard G. Sarnat International Prize in Mental Health from the Institute of Medicine in 2004.

And no, Stunkard has never had a weight problem himself, nor have any of his close relatives, he reports. Once 6 feet tall, now slightly stooped, Stunkard weighs 163 pounds.

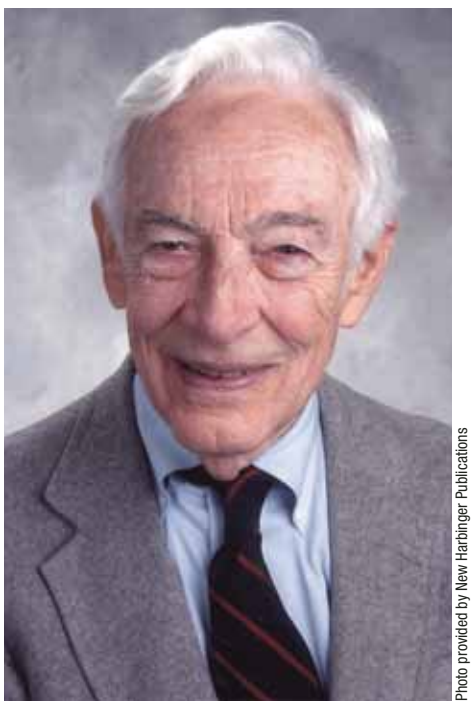


Photo provided by New Harbinger Publications

World War II Memoir Coming

Stunkard's career path, like that of many of his contemporaries, included time in the military. After graduating from the Columbia University College of Physicians and Surgeons in 1945, he completed a one-year internship in medicine at Massachusetts General Hospital. He then spent two years in the Army taking care of Japanese prisoners charged with war crimes at Sugamo Prison in Tokyo. His recently completed memoir of his experiences in Japan, *After the War: Remembrances of an American in Japan*, will be published this spring by EastBridge Books.

Stunkard started his psychiatric residency at Hopkins in 1948, planning to become a psychoanalyst. Psychosomatic medicine, however, proved more appealing. While still a resident, Stunkard conducted a placebo-controlled trial of a psychotropic agent. The *American Journal of Psychiatry* published his report on this study, his first paper, in December 1950.

He arrived at Cornell with no thought of exploring obesity, he told *Psychiatric News*. "But the glamorous diseases—migraine, ulcers, and hypertension—already had been claimed by other research fellows," he recalls. Wolff, a pioneer investigator in psychosomatic medicine, proposed that Stunkard study Buerger's disease. The young psychiatrist could not muster zeal for that disorder.

Then Stunkard's friend and former classmate at Columbia, Theodore VanItallie, M.D., piqued his interest with details of his own fledgling research on brain centers controlling hunger and satiety in rats. With Wolff's encouragement, Stunkard began to explore these issues in humans. He and VanItallie, a professor emeritus of medicine at Columbia, collaborated on studies of gastric hunger contractions, coming to view not only hunger but also satiety as an active process.

Twin Studies Influential

"Stunkard had the imagination to see that adoption studies and twin studies could clarify the role of genetics in the development of obesity," VanItallie asserts.

Using data from the Danish Adoption Registry, Stunkard and colleagues found that adopted children developed a body mass index (BMI) similar to that of their biological parents. "Genetic influences have an important role in determining human fatness in adults, whereas the family environment alone has no apparent effect," his group wrote in the January 23, 1986, *New England Journal of Medicine*.

Data from the large Swedish twin registry affirmed and extended the importance of genetics by showing that identical twins reared apart have a BMI as adults that is the same as that of twins raised together. Stunkard and colleagues reported these findings in the May 24, 1990, *New England Journal of Medicine*. In a study now in progress, his group is using the Swedish twin registry to explore genetic influences on NES.

He and colleagues also are conducting genetic studies of obesity among the Old Order Amish. Using linkage and association studies, they have identified a region on chromosome 7 that may be responsible, at least in part, for BMI and other obesity-related traits.

For an ongoing study at Penn that started in 1993, Stunkard's group recruited 40 obese pregnant women and 40 non-obese pregnant women and have followed their children from birth. By age 9, half of the children of obese mothers had become obese. "My guess is that most of the other half will become obese, too," Stunkard says. "No children of lean mothers have become obese."

Over the years, Stunkard has shown that the environment can lead to obesity in genetically vulnerable people. He was the first to show the now widely recognized inverse relationship between social class and obesity. He also designed a widely used eating assessment inventory and has documented the efficacy of psychological and pharmacological therapies, weight-loss regimens, and bariatric surgery on obesity.

He often returns to NES. Stunkard's group has reported that both normal-weight and obese individuals develop this disorder, and suggested NES may serve as a path to obesity.

"There's hardly an aspect of obesity that Stunkard hasn't investigated—from etiology, to treatment, to prevention of this disorder," said Thomas Wadden, Ph.D., director of Penn's Center for Weight and Eating Disorders.

"He has inspired many young investigators to pursue research in these areas," Wadden added. "He's the dean of our field." ■

Culture Can't Be Ignored In Treating HIV in Hispanics

Counseling Hispanic patients about HIV prevention requires an understanding of their culture and the development of a relationship over time.

BY MARK MORAN

Social, cultural, linguistic, and religious factors complicate efforts to discuss prevention of sexually transmitted diseases with Hispanics, a group in which HIV infection and AIDS are on the increase.

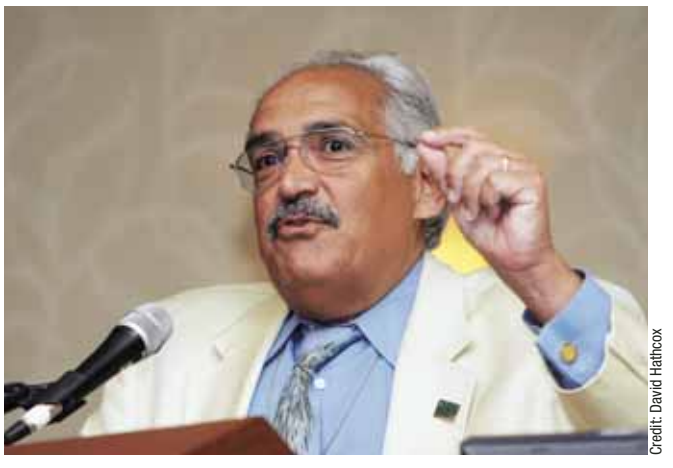
In an address at APA's 2007 annual meeting in San Diego, Francisco Fernandez, M.D., reported 2004 statistics from the Centers for Disease Control and Prevention showing that 20 percent of all new AIDS cases occur in Hispanic patients, though that ethnic group is just 14 percent of the U.S. population.

The number of new AIDS cases among Hispanics has increased steadily in the last 15 years, he observed, and is expected to keep climbing because the number of new HIV cases is increasing in this population as well.

Fernandez, who delivered the annual Simon Bolivar Award Lecture, is chair of APA's Committee on AIDS and chair of psychiatry and behavioral medicine at the University of South Florida. He is also a member of the *Psychiatric News* Editorial Advisory Board. His presentation was a highlight of "Hispanic Day," a series of special scientific and social events held the day before the annual meeting's official opening.

Fernandez underscored the need for epidemiological research focusing on "sub-ethnic" groups—especially women and intravenous drug users—to better target prevention efforts.

Among Hispanic men with AIDS, men who have sex with men make up 51 percent of all cases and intravenous drug users, 28 percent. Among Hispanic women with AIDS, intravenous drug users account for 32 percent of all cases.



Credit: David Hathcox

Francisco Fernandez, M.D.: "We have an excellent opportunity to talk about these issues with our patients, and they typically regard their mental health professional with a great deal of respect."

He stressed the importance of targeting HIV-positive individuals for preventive interventions aimed especially at safe-sex practices—most critically the proper use of condoms and disclosure of HIV status to sexual partners. "Every person infected with HIV was exposed by a person who was HIV positive," Fernandez said.

In the face of these upward trends in infection, psychiatrists and other clinicians working with Hispanic populations face a number of social, cultural, and linguistic barriers that make counseling about prevention difficult.

Principal among these are difficulties imposed by language. Fernandez presented statistics from the Commonwealth

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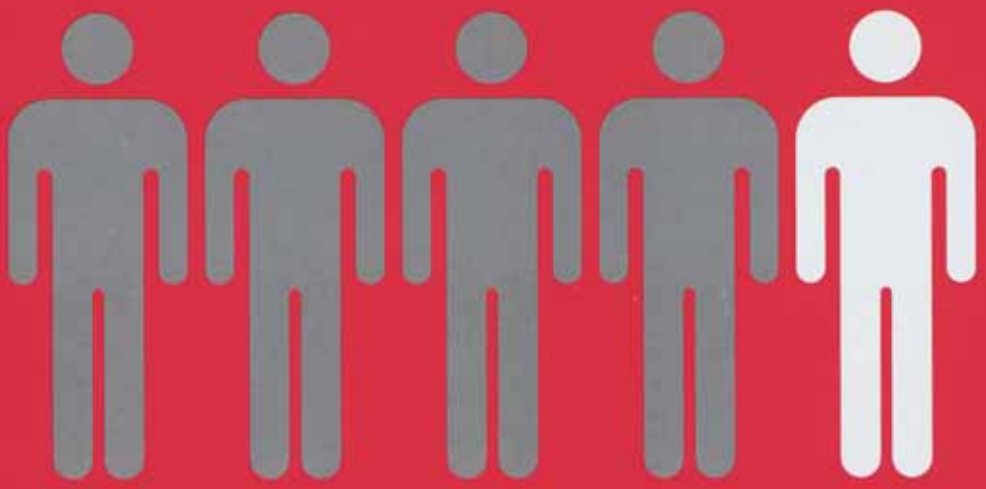

13% of patients had diabetes in the landmark CATIE schizophrenia study at baseline—4 times more common than in the general population.[1]

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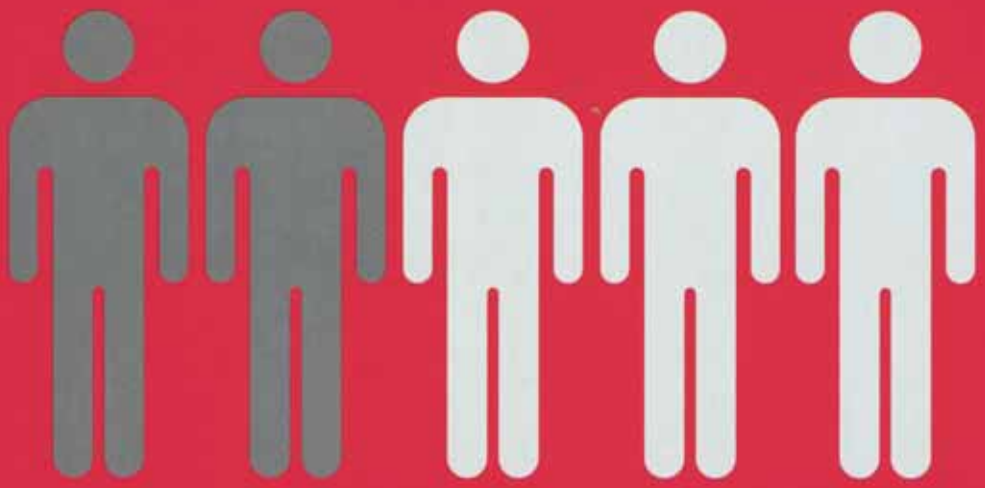

41% of all patients had the metabolic syndrome at baseline in the landmark CATIE schizophrenia study.[2]

Be aware.
Screen and monitor your patients.
Make a difference.

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For more information, please visit **www.MDLinx.com/metabolicmatters**

References: 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. **2.** 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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Depression Care May Extend Lives of Elderly Patients

Treating depression in older individuals can not only relieve their psychological distress, but possibly extend their lives as well.

BY JOAN AREHART-TREICHEL

At age 91 "Earl" was in remarkably good health and excited about attending his 70th college class reunion. He was particularly looking forward to seeing his old college friend "Frank" there. During the reunion, however, Frank died, and Earl became extremely depressed. Eight months later Earl died as well. Would Earl have lived closer to the century mark or even beyond if he had not been depressed?

Depression in older individuals has been strongly linked with an increased risk of dying from various medical illnesses (*Psychiatric News*, October 18, 2002). Also, several studies have suggested that treating older persons' depression can extend their lives.

One was the Enhancing Recovery in Coronary Heart Disease Patients (ENRICHED) trial. It found that use of a selective serotonin reuptake inhibitor was associated with a reduction in death over a 40-month period. The other was the Sertraline Anti-Depressant Heart Attack Randomized Trial (SADHART). It included subjects who had had a heart attack and were depressed. It found that there was a consistent trend, over a 24-week period, for subjects taking an antidepressant to have a lower death rate than subjects taking a placebo. However, the difference did not reach statistical significance (*Psychiatric News*, August 2, 2002).

Now a new study headed by Joseph Gallo, M.D., an associate professor of family medicine and community health at the University of Pennsylvania, reported in the May 15 *Annals of Internal Medicine*, further suggests that depression treatment can extend the lives of seniors.

The study included 396 people aged 60 or older with major depression and 203 with clinically significant minor depression. Half of those with major depression received care as usual in a primary care practice, and half received an experimental intervention. It was the same for those with less-severe depression. The intervention consisted of a depression-care manager working with a primary care physician to provide algorithm-based care.

The researchers then followed the subjects for about four years to determine which ones died and why. Finally they assessed whether there was any significant difference in the rates of death between the major-depression subjects who had received usual care and those who had received the intervention. They also evaluated whether there was any significant difference in the rates of death between the minor-depression subjects who had received usual care and those who had received the intervention. In each of these analyses, they took possibly confounding factors such as age, gender, education, smoking status, cardiovascular disease, stroke, diabetes, cancer, cognition, comorbid medical conditions, and suicidal ideation into consideration.

No significant differences in death rates were found for the minor-depression subjects, but significant differences were found for subjects with major depression. Specifically, major-depression subjects in the intervention arm of the study were significantly less likely to die over the follow-up period than were major-depression subjects in the usual-care arm. The risk of death was cut by 45 percent.

Moreover, the benefit seemed to be limited to a reduction in deaths due to cancer. The reason for this finding, Gallo told *Psychiatric News*, might be because the "cause of death from death certificates isn't as reliable as vital status (whether someone died or not). So we can't make too much of this particular observation. However, there could be biological reasons why depression and cancer are related, or depression could interfere with a person's cancer being adequately detected and treated."

Gallo also hypothesized as to why his study seemed to produce more positive results than the two cardiovascular studies cited above. "The persons in our study were, for the most part, community-dwelling older adults, while the persons in the other studies were identified after a cardiac event," he explained. "How depression affects medical illness and whether treatment affects mortality might differ depending on. . .how far along a person is in the course of their medical disease."

The take-home message from the two cardiovascular studies and their own, Gallo said, is that early treatment of depression in older individuals can not only relieve psychological distress, but may extend lives as well.

The study was financed by the National Institute of Mental Health.

"The Effect of a Primary Care Practice-Based Depression Intervention on Mortality in Older Adults" is posted at <www.annals.org/cgi/reprint/146/10/689.pdf>. ■

Culture

continued from facing page

Fund showing that among Asians, African Americans, Hispanics, and Caucasians, Hispanics experienced the most problems in terms of feeling understood and listened to by a doctor and being able to ask necessary questions.

"We don't do very well with the medical information that we give out," Fernandez said. He added that the use of pictograms to facilitate verbal communication can be helpful when talking to Hispanic patients.

Reticence to discuss sexual issues is especially problematic among Hispanic patients. "If you do surveys of Hispanic women, it is sexual silence that they point to as a factor in not wanting to bring up [sexual topics] because of a fear that the man in the room will think they are promiscuous. Both men and women report high levels of discomfort with sex, making it difficult to negotiate their sexual behaviors with others."

He noted, for instance, that Hispanic men report feeling uncomfortable having sex with lights on—a fact that renders proper use of condom more difficult, Fernandez said.

The prevalence of alcoholism among Hispanic populations is another complicating factor. "Alcohol impairs judgment and reduces the chance that you will behave and negotiate sexual encounters in a socially adaptive manner," Fernandez said.

Also, the network of gossip among tightly knit ethnic populations can also inhibit patients from seeking out treatment.

"It's a problem that in some places the HIV clinic is called 'Clinical Immunology' and in other places it is called the 'AIDS team,' " Fernandez said. "That's not a place where people are going to walk up to the front door, because of people's fear of the gossip network."

In general, treatment services aimed at prevention of HIV infection need to take into account these uniquely Hispanic cultural emphases:

- **Familismo:** Emphasis on the family as the primary social unit and source of support.
- **Simpático:** Importance in the culture of polite and cordial social relations.
- **Personalismo:** Hispanics prefer relationships with others that reflect a certain familiarity and warmth and are more likely to trust and collaborate with someone with whom they have exchanged pleasantries.
- **Fatalismo:** The belief that fate determines life outcomes, including HIV infection, and that fate is basically unbeatable.

For these reasons, Fernandez said, counseling Hispanic patients about prevention cannot easily be done in the three- to five-minute session recommended by the CDC, but requires the development of a relationship over time.

Nonetheless, a mental health professional may be the one clinician an Hispanic patient sees on a regular basis, Fernandez said. "We have an excellent opportunity to talk about these issues with our patients, and they typically regard their mental health professional with a great deal of respect." ■

When SSRI Fails in Elderly, Augmentation May Help

Many older patients who do not respond well to initial SSRI therapy for major depression can achieve recovery with augmented treatment.

BY AARON LEVIN

Half of elderly depressed patients who initially responded poorly to selective serotonin reuptake inhibitors (SSRIs) achieved recovery after a second medication was added to their regimen, according to University of Pittsburgh researchers. They also found that patients with clinically significant anxiety and higher medical burden took longer to recover than did other patients.

Augmenting antidepressant therapy is not a new idea in treating younger adults, but it has been used less commonly in older patients, study leader Mary Amanda Dew, Ph.D., a professor of psychiatry, psychology, and epidemiology at the University of Pittsburgh School of Medicine, told *Psychiatric News*.

The findings appear in the June *American Journal of Psychiatry*.

"Doctors have hesitated to add medications for older patients because they are concerned about the risks of polypharmacy, but this study shows response rates as good as those among younger ones," said Dew. Untreated or undertreated depression also carries risks, she said.

Many older individuals diagnosed with major depression do not respond well to the initial drug regimen prescribed for them, said Dew. Guidelines have been developed clinically, but there have been no studies in this age group following a protocol specifying the steps for augmentation.

So, Dew and her team monitored depression levels of 195 patients over age 70 during their treatment for unipolar major depressive disorder. They were being treated openly with the SSRI paroxetine, titrated from 10 mg to 40 mg, as needed. These patients also received interpersonal psychotherapy weekly until registering a clinical response, then biweekly for up to 16 weeks.

At that point, 90 patients (46.2 percent) had responded without relapse; 77 (39.5 percent) had an inadequate response; and 28 (14.4 percent) responded but experienced an early relapse. These last two groups were eligible for augmentation treatment, but 36 of them did not receive it, because they either withdrew consent or had worsening medical conditions that precluded continuation.

"Our findings show that the response to treatment and to augmentation among older people is at odds with the conventional thinking that assumes the young do better."

The treatment teams used a standardized protocol and expert consensus to decide which of three drugs to add to the paroxetine members of the target study group were receiving: sustained-release bupropion, nortriptyline, or lithium carbonate.

Patients who required and received augmented treatment had lower recovery rates than did those who responded well initially. After nearly a year, 86.7 percent of patients who didn't need augmentation had recovered. However, half (24 of 48) with an initial inadequate treatment response recovered, as did 66.7 percent (14 of 21) of those who relapsed.

The researchers recorded a variety of demographic, clinical, and medical comorbidity information in an attempt to predict outcomes. Besides their first response to treatment, only anxiety and a high gen-

please see ***Augmentation*** *on page 24*

Schizophrenia Scientist Comes Full Circle

This is the third in a four-part series profiling leaders in schizophrenia research. The subject of this profile, Thomas McGlashan, M.D., has been a pioneer in studying the prodromal phase and prevention of schizophrenia.

BY MARK MORAN

Psychiatrist Thomas McGlashan, M.D., recalls participating as a third-year medical student at the University of Pennsylvania in a research project with the late Martin Orne, M.D., who did groundbreaking empirical research in hypnosis and pain management.

Subjects were required to perform a mildly painful task, after which subjective experiences of pain were compared among those who were hypnotized, those given an analgesic medication, and those given a placebo.

"The subjective accounts of pain were utterly compelling," McGlashan said. "The subjects who were highly hypnotizable did not feel pain at all."

The experiment confirmed for him the brain's remarkable capacity for imposing its own reality, a phenomenon that had caught his attention a year before when he met his first patient with schizophrenia while on rotation in a psychiatric ward.

"She was a very nice woman who was profoundly paranoid and delusional," he recalls. "I was amazed and absolutely enthralled at how she could be so intact in many ways and so deteriorated in others.

"Especially fascinating was the conviction she had about her own reality," he said. "It was the first time I came face to face with the fact that reality doesn't exist out there—reality is created by the brain. And it was my first encounter with the mystery of the brain."

For the next 40 years, McGlashan would seek to understand the mechanisms behind the brain's creation of aberrant reality in patients with schizophrenia. In time he would put forward a developmental model of brain dysfunction that explained the disease and its varied symptoms and forms (see box on facing page).

But his insights into the developmental nature of brain dysfunction in schizophrenia were founded on intensive psychoanalytically oriented observation and treatment of the sickest patients early in his career.

McGlashan's own research on the long-term outcome of psychoanalytically treated, unmedicated patients would challenge that approach; but the strenuous effort to understand the person behind the disease would inform his more recent championing of psychosocial treatments for schizophrenia.

In recent years he has merged the neurodevelopmental approach to brain pathology in schizophrenia with population-based studies in Scandinavia and elsewhere to help forge a new understanding of the "prodromal" phase of the disease.

Ming Tsuang, M.D., distinguished University Professor of Psychiatry and director of the Center for Behavioral Genomics at the University of California, San Diego (UCSD), called McGlashan a "pioneer" on a frontier of schizophrenia research—the effort to apply psychosocial and pharmacotherapeutic treatments to at-risk individuals before the onset of acute psychosis.

"The future treatment of schizophrenia will be focused on early detection of the condition before the onset of psychosis," Tsuang told *Psychiatric News*. "Research on how to identify clinical features of the prepsychotic state has become of paramount importance, and in this area Thomas McGlashan has been a leader."

Tsuang is an investigator at Harvard and UCSD in the North American Prodrome Longitudinal Study (NAPLS), a project initiated by NIMH and that includes McGlashan and Scott Woods, M.D., at Yale University. In addition to Yale, Harvard, and UCSD, the NAPLS project includes Emory University, Hillside Hospital, UCLA, the University of North Carolina, and the University of Toronto.

"Ultimately, we would like to establish reliable diagnostic criteria for inclusion of the prodrome in *DSM-V*," Tsuang said. "In this effort, Thomas McGlashan's contribution has been indispensable."

Credit: Michael Marsland

Thomas McGlashan, M.D., has been a pioneer in the effort to apply psychosocial and pharmacotherapeutic treatments to at-risk individuals before the onset of psychosis.

Putting Painful Experiences in Perspective

Following medical school, McGlashan's interest in psychosis was whetted further during residency at the Massachusetts Mental Health Center.

The center's legendary director Elvin Semrad, M.D., insisted that severely disturbed patients could be engaged in a therapeutic relationship by therapists who were willing to sit with them and see the person behind the disease. McGlashan and fellow residents learned the value of helping patients with the task of—in Semrad's words—"acknowledging, bearing, and putting into perspective one's painful life experiences."

"Semrad was marvelous with these patients," McGlashan recalls. "He talked about how they have problems bearing the strength of their feelings, and he would try to bring patients to that capacity—the capacity to bear their own overwhelming feelings."

The Vietnam War era draft brought an unexpected change of course for McGlashan, when he received a draft deferment to finish his residency in exchange for a commitment to work in the U.S. Public Health Service at the National Institute of Mental Health's Psychopharmacology Research Branch.

"It would not have been my first choice," he said. "But I served as executive secretary for the branch and got to meet and spend a lot of time with the nation's experts on psychopharmacology. And I learned a lot about the ins and outs of clinical trials."

Later, he joined the NIMH intramural program working with William Carpenter, M.D., on a unit Carpenter was running for unmedicated, first-episode schizophrenia patients.

"The idea was to create a highly structured milieu with different things going on every hour during the day," McGlashan said. "It was a very lively and interesting setting with people for the most part getting better and going into remission without medication."

In January 1977 Carpenter published an article in the *American Journal of Psychiatry*, along with McGlashan and John Stauss, M.D., titled "Treatment of Acute Schizophrenia Without Drugs: An Investigation of Some Current Assumptions."

The article described a "small but significantly superior outcome" for a cohort of unmedicated patients who received intensive psychosocial treatment, compared with a control group of patients who received "usual" care including antipsychotic medication.

"We didn't write this paper to suggest it was a preferred treatment, but to alert people to the fact that patients can get better without drugs," McGlashan told *Psychiatric News*. "That experience was important to me—it has helped me avoid categorical thinking of the sort that says, 'This is the way it has to happen, and any deviation is malpractice.' "

Analytic Approach Reevaluated

In 1975 McGlashan joined Chestnut Lodge in Rockville, Md., where Frieda Fromm-Reichman, Ph.D., and Harold Searles, M.D., among others, had championed a psychoanalytic approach to treating schizophrenia.

He would stay there 15 years, and the enormous expenditure of attention to individual lives was unforgettable. "There were a lot of aspects that I came to disagree with, but I think the care that people got there was the best I've ever seen," he said.

But McGlashan now believes that for some patients the rigors of an analytic approach were disorganizing.

"They fill their lives with what is being created in their brain," he said. "If you rob them of external stimulation by not talking to them about what you think is real, they will fill up the space with delusions and hallucinations and all manner of disorganized thinking."

In fact, the futility of those efforts in time became impossible to ignore, and McGlashan undertook an extensive research project to follow long-term outcomes of patients treated at the lodge.

The results were dispiriting. In a paper in the June 1984 *Archives of General Psychiatry*—one of a series of reports on the follow-up study—he reported that of 163 schizophrenia patients followed for an average of 14 years after treatment at the lodge, about two-thirds were functioning marginally or worse.

If a measure of scientific integrity is the capacity to test and disprove one's own fondest hypotheses, the paper is a landmark. And it would help redirect efforts at the lodge.

"The results were not good news for the medical staff or the director, but they were taken seriously," McGlashan said. "In time things changed, and we began using medications regularly."

Rehabilitative services, remedial work, and sheltered workshops were initiated. "It was a belated embracement of community psychiatry," McGlashan recalls. "The staff were initially resistant until they saw that it made a clear difference. Patients didn't get well, but they did get better."

Treating Patients in the Prodrome

Is there something that survives from the effort to apply a psychodynamic approach to the treatment of schizophrenia?

"Seeing patients as people, not just cases," McGlashan said. "Also, I got a sense from knowing the life stories of these people that it was a developmental disorder. And I began to think that if we could intervene earlier, we might be able to lessen the severity and chronicity or even prevent the onset."

Today McGlashan is conducting population-based, public-health research projects aimed at preventing schizophrenia or diminishing severity and chronicity through early intervention during the

"prodrome"—the subclinical phase recognized as a precursor to acute psychosis.

The success of prevention efforts "is hard to prove," he said, "but I think it's well worth thinking about. The work that has been done on the prodrome shows you can identify people at high risk before onset, and a large percentage of these people do become psychotic within two years."

For the last 10 years, he has been working with colleagues in Scandinavia looking at duration of untreated psychosis in first-episode patients as a possible correlate of chronicity.

In a paper published last year in *Schizophrenia Bulletin*, they described an extensive public-health effort in one district of Norway to identify and treat first-episode patients aggressively earlier in their psychoses.

First-year follow-up data showed that the public-health effort was effective. "The patients were younger on average by five years [when they were identified and treated] and were less symptomatically ill and better functioning," McGlashan told *Psychiatric News*. "Clearly we were getting to people earlier in their illness when it was less severe."

A handful of treatment studies suggests that treatment during the prodrome can reduce severity of illness or delay onset of psychosis.

For instance, in the May 2006 *American Journal of Psychiatry*, McGlashan and colleagues reported a randomized trial at four North American clinics in the Prevention Through Risk Identification, Management, and Education project. Outpatients who met criteria for prodromal schizophrenia received olanzapine or placebo during a one-year, double-blind treatment period and no treatment during a one-year follow-up *(Psychiatric News*, May 5, 2006).

Results showed that 16.1 percent of olanzapine patients compared with 37.9 percent of placebo patients experienced a conversion to psychosis—a trend-level difference that fell just short of statistical significance. McGlashan believes that cognitive-behavioral therapy, cognitive-enhancement therapy, and other psychosocial approaches may also be effective as prodromal treatments.

And so the psychoanalyst-turned-developmental neuroscientist-turned public health researcher has come full circle.

"In many ways my thoughts about the future of schizophrenia treatment are going back to psychosocial forms of intervention, especially at these early phases," he said. "One of the most important things is to keep these young people engaged and keep them from withdrawing. The earlier you can intervene in the developmental process, the more psychosocial interventions are going to have an impact."

"Treatment of Acute Schizophrenia Without Drugs: An Investigation of Some Current Assumptions" is posted at <http://ajp.psychiatryonline.org/cgi/reprint/134/1/14>."Randomized, Double-Blind Trial of Olanzapine Versus Placebo in Patients Prodromally Symptomatic for Psychosis" is posted at <http://ajp.psychiatryonline.org/cgi/content/abstract/163/5/790>. ■

Pruning Key to Schizophrenia Model

What is schizophrenia? Any number of researchers have described its symptoms and variants, theorized about causes, or studied the involvement of neurotransmitters. But the underlying pathophysiology of this heterogenous disorder is like the tale of the blind men and the elephant—many people have a piece of it, but they don't get the entire picture.

And that's what Thomas McGlashan, M.D., and colleague Ralph Hoffman, M.D., sought to provide in a report in the May 2000 *Archives of General Psychiatry* describing a remarkable computer simulation of brain dysfunction in schizophrenia.

What they described was a model of "developmentally reduced synaptic connectivity." Essentially, a diminished number of synapses in the prefrontal cortex and other crucial parts of the brain, they said, is the "final common pathway to the symptoms and course of schizophrenia and, perhaps, to other psychotic disorders."

According to the model, the diminished synaptic density results from a variable combination of disturbances in brain development in utero or early infancy and disturbances in synaptic "pruning" during adolescence.

The adolescent period of accelerated synaptic pruning is critical and provides a neurobiological window into the developmental nature of schizophrenia. Just as one "prunes" a bush by cutting away excess branches to shape it more accurately to its purpose, synaptic "pruning" refers to the natural elimination of unnecessary synapses that occurs normally in adolescence, making the brain more organized and efficient.

It is the neurobiological counterpart to the way children and adolescents normally learn skills, from walking to navigating the social environment: with practice and refinement they gain mastery over all manner of habits of living. As they do so the superabundance of neuronal synapses provided them by nature early in life are "pruned": necessary connections are made more efficient, while unnecessary ones are eliminated.

"The neuron stays alive and healthy," McGlashan explained, "it simply has fewer synaptic connections with other neurons, like a sentence with fewer dependent clauses."

But in the person with schizophrenia, the process of pruning goes too far, diminishing a network of synapses that is often deficient from birth to begin with.

The result is that as the pruning progresses, the world is increasingly experienced as series of incomplete or redundant sentences. Like McGlashan's unmedicated patients who grew disorganized under the silence and relative disengagement of analysis (see article on facing page), the schizophrenic brain fills in the gaps of its incomplete sentences with "all manner of disorganized thinking."

More remarkably, the article describes a computer simulation of synaptic elimination created by Hoffman that models normal cognitive development and psychotic symptom formation.

In the paper, McGlashan and Hoffman describe how the model accounts for "important aspects of schizophrenia, including its unique symptoms, short- and long-term course, typical age of onset, neurodevelopmental deficits, limited neurodegenerative progression, sex differences, and more."

"Schizophrenia as a Disorder of Developmentally Reduced Synaptic Connectivity" is posted at <http://archpsyc.ama-assn.org/cgi/reprint/57/7/637.pdf>.

Does Parasite Play Role In Schizophrenia Etiology?

There is growing evidence that the parasite *Toxoplasma gondii* is implicated in certain cases of schizophrenia. First the evidence came from prenatal blood samples. Now it comes from young people developing symptoms of schizophrenia.

BY JOAN AREHART-TREICHEL

The case continues to build that the parasite *Toxoplasma gondii* is linked with some cases of schizophrenia.

In 2005 Alan Brown, M.D., an associate professor of clinical psychiatry and clinical epidemiology at the New York State Psychiatric Institute, and colleagues reported that serum antibodies taken from pregnant women 40 years earlier suggested a link between the parasite and the development of schizophrenia in their offspring (*Psychiatric News*, May 6, 2005).

And now Australian scientists have not only found that some young people acquiring schizophrenia possessed antibodies to *T. gondii*, but that such possession could be linked with the severity of their psychosis symptoms. The lead scientist was G. Paul Amminger, M.D., an associate professor of child and adolescent psychiatry at the University of Melbourne. Results appeared in the May 15 *Biological Psychiatry*.

"This is an interesting study," Brown told *Psychiatric News*. "A strength of the study is the fact that prodromal subjects are included, suggesting that lifestyle factors that co-exist with schizophrenia or other psychotic disorders don't explain the finding."

Amminger and his coworkers studied 105 young adults (average age 19) who were at very high risk of acquiring schizophrenia because of genetic risk plus a decrease in functioning, attenuated psychotic symptoms, or limited intermittent psychotic symptoms.

Subjects were evaluated for psychotic symptoms and their severity. Blood samples were also taken from each subject and sent to the Stanley Laboratory of Developmental Neurobiology in Baltimore to determine whether they contained antibodies to various infectious agents such as herpes simplex virus type 1, herpes simplex virus type 2, cytomegalovirus, Epstein-Barr virus, or the *T. gondii* parasite.

Seventy-two percent of subjects tested positive for Epstein-Barr virus; 48 percent for cytomegalovirus, 42 percent for herpes simplex virus Type 1, 31 percent for herpes simplex virus Type 2, and 17 percent for *T. gondii*.

Amminger and his coworkers then evaluated whether there was a connection between the severity of subjects' psychotic symptoms and having antibodies to any of these infectious agents. The answer was yes only for *T. gondii* and Epstein-Barr virus. Having antibodies to the parasite was significantly associated with more severe psychotic symptoms, while testing positive for Epstein-Barr antibodies was significantly associated with less severe ones.

The reason why Epstein-Barr-positive subjects had less severe symptoms than the other subjects is not clear, the scientists said. But they believe that their findings add to the argument that *T. gondii* is implicated in certain cases of schizophrenia.

The question then is when the parasitic infection is acquired. The researchers believe that it is probably a pre-existing infection, perhaps going back to the prenatal state. One reason is because of the research by Brown and colleagues cited above. Another is because they could find a significant link only between IgG antibodies to *T. gondii* and psychotic symptoms, not between IgM antibodies to *T. gondii* and such symptoms. Whereas an IgG antibody response may reflect either an active or reactivated infection, an IgM antibody only mirrors a recent one.

Amminger and his group are now attempting to see whether they can replicate their results in another cohort of subjects. They are also following their current cohort to determine whether *T. gondii* infection is truly involved in the transition from a pre-schizophrenia state to a full-blown case of the disorder in certain very-high-risk individuals. If a causal link is established, Amminger told *Psychiatric News*, then it would provide a rationale to determine whether antimicrobial drugs effective against *T. gondii*, such as trimethoprim-sulfamethoxazole or azithromycin, might be able to keep subthreshold psychotic symptoms from developing into full-blown schizophrenia.

The investigation was funded by the Stanley Medical Research Institute; National Health and Medical Research Council in Canberra, Australia; Janssen-Cilag, Australia; and the Karl-Hermann Spitzy Award by Bayer, Austria.

An abstract of "Antibodies to Infectious Agents in Individuals at Ultra-High Risk for Psychosis" is posted at <www.journals.elsevierhealth.com/periodicals/bps/article/PIIS000632230601273x/ab...>. ■

professional news

Antistigma

continued from page 8

Mojtabai speculated.

Data based on logistical regression analyses of treatment-seeking attitudes showed that black participants were 56 percent more likely to have a positive attitude toward treatment than were whites.

In addition, respondents with a history of mental health treatment were 68 times as likely to have a favorable attitude toward mental health treatment as those who didn't.

Mojtabai said future research should explore what specific factors impact attitude toward mental health treatment. "We also need to examine the impact of attitudes on service use," he noted.

An abstract of "Americans' Attitudes Toward Mental Health Treatment Seeking: 1990-2003" is posted at <http://ps.psychiatryonline.org/cgi/content/full/58/5/642>. ■

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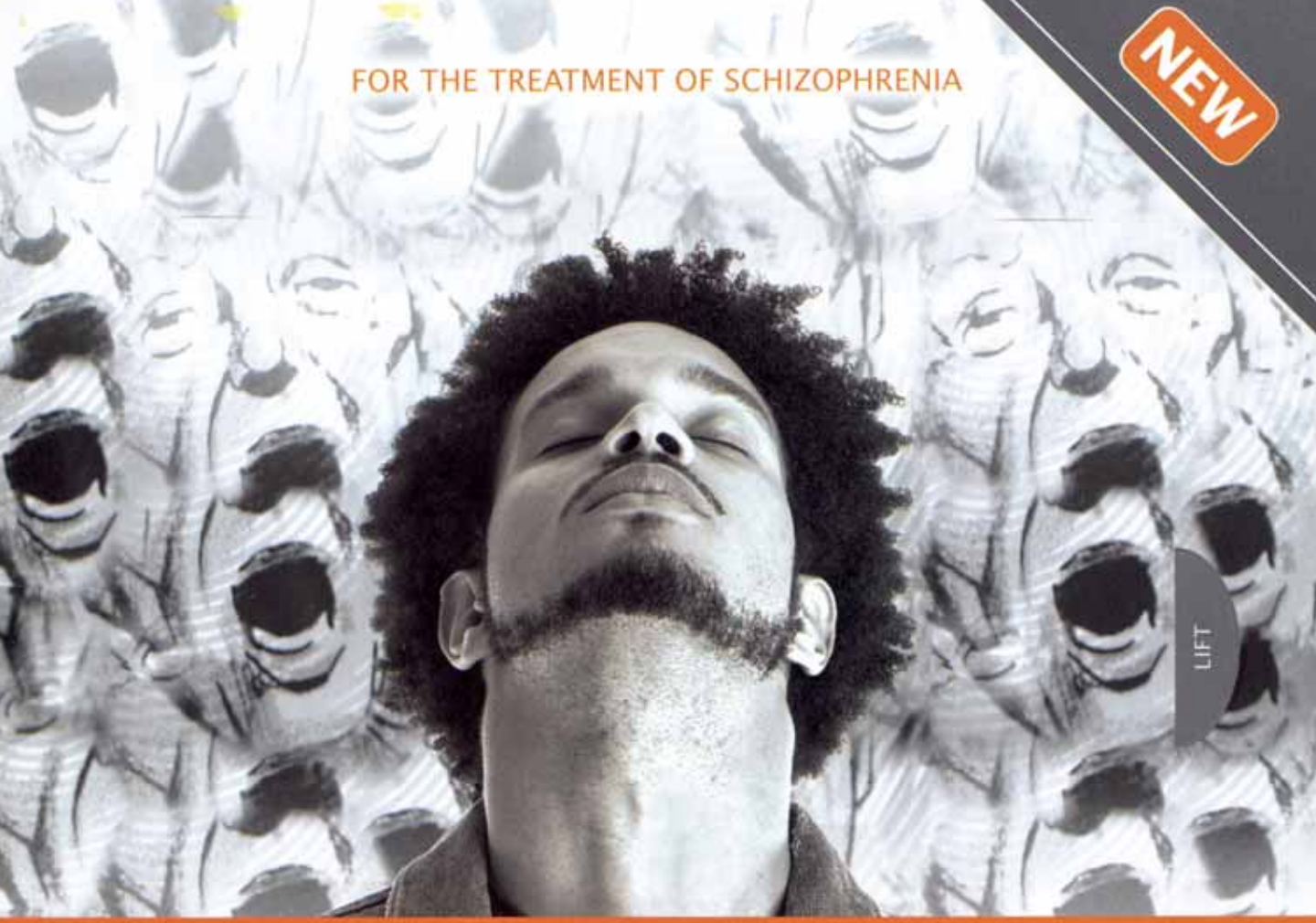

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Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Neither INVEGA™ (paliperidone) nor RISPERDAL® (risperidone) are approved for the treatment of patients with Dementia-Related Psychosis.

Commonly observed adverse events: The most commonly observed adverse events occurring at an incidence of ≥5% and at least 2 times placebo were: **INVEGA**: akathisia and extrapyramidal disorder; **RISPERDAL**: anxiety, somnolence, extrapyramidal symptoms, dizziness, constipation, nausea, dyspepsia, rhinitis, rash, and tachycardia.

QT Prolongation: INVEGA causes a modest increase in the corrected QT (QTc) interval. INVEGA should be avoided in combination with other drugs that are known to prolong the QTc interval, in patients with congenital long QT syndrome or a history of cardiac arrhythmias. Certain circumstances may increase the risk of torsades de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval.

Neuroleptic malignant syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported with the use of antipsychotic medications, including INVEGA and RISPERDAL. Clinical manifestations include muscle rigidity, fever, altered mental status and evidence of autonomic instability (see full Prescribing Information). Management should include immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, intensive symptomatic treatment and medical monitoring, and treatment of any concomitant serious medical problems.

Tardive dyskinesia (TD): TD is a syndrome of potentially irreversible, involuntary, dyskinetic movements that may develop in patients treated with antipsychotic medications. The risk of developing TD and the likelihood that dyskinetic movements will become irreversible are believed to increase with duration of treatment and total cumulative dose. Elderly patients appeared to be at increased risk for TD. Prescribing should be consistent with the need to minimize the risk of TD. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Please see accompanying brief summary of full Prescribing Information for INVEGA and RISPERDAL.

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Gastrointestinal: INVEGA should ordinarily not be administered to patients with pre-existing severe gastrointestinal narrowing. Rare instances of obstructive symptoms have been reported in patients with known strictures taking non-deformable formulations. INVEGA should only be used in patients who are able to swallow the tablet whole.

Cerebrovascular adverse events (CAEs): CAEs, including fatalities, have been reported in elderly patients with dementia-related psychosis taking atypical antipsychotics in clinical trials. Neither INVEGA nor RISPERDAL are approved for treating these patients.

Orthostatic hypotension and Syncope: INVEGA and RISPERDAL can cause orthostatic hypotension and syncope in some patients. Appropriate monitoring of orthostatic vital signs should be considered.

Seizures: INVEGA and RISPERDAL should be used cautiously in patients with a history of seizures.

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Extrapyramidal symptoms (EPS): Total EPS-related adverse events in the higher 9-mg and 12-mg treatment groups were 25% and 26%, respectively, versus 11% for the placebo group.

Weight gain: The proportion of subjects having a weight gain of ≥7% body weight were comparable to placebo (5%) for 3 mg (7%) and 6 mg (6%). A higher incidence was seen for 9 mg (9%) and 12 mg (9%).

Reference: 1. Data on file. Janssen LP, Titusville, NJ.

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Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks) in these subjects revealed a risk of death in the drug-treated subjects of between 1.6 to 1.7 times that seen in placebo-treated subjects. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated subjects was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. INVEGA™ (paliperidone) Extended-Release Tablets is not approved for the treatment of patients with dementia-related psychosis.

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Certain circumstances may increase the risk of the occurrence of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QTc interval; and (4) presence of congenital prolongation of the QT interval. The effects of paliperidone on the QT interval were evaluated in a double-blind, active-controlled (moxifloxacin 400 mg single dose), multicenter QT study in adults with schizophrenia and schizoaffective disorder, and in three placebo- and active-controlled 6-week, fixed-dose efficacy trials in adults with schizophrenia. In the QT study (n = 141), the 8 mg dose of immediate-release oral paliperidone (n=44) showed a mean placebo-subtracted increase from baseline in QTcLD of 12.3 msec (90% CI: 8.9; 15.6) on day 8 at 1.5 hours post-dose. The mean steady-state peak plasma concentration for this 8 mg dose of paliperidone immediate-release was more than twice the exposure observed with the maximum recommended 12 mg dose of INVEGA™ ($C_{max\ ss}$ = 113 and 45 ng/mL, respectively, when administered with a standard breakfast). In this same study, a 4 mg dose of the immediate-release oral formulation of paliperidone, for which $C_{max\ ss}$ = 35 ng/mL, showed an increased placebo-subtracted QTcLD of 6.8 msec (90% CI: 3.6; 10.1) on day 2 at 1.5 hours post-dose. None of the subjects had a change exceeding 60 msec or a QTcLD exceeding 500 msec at any time during this study. For the three fixed-dose efficacy studies, electrocardiogram (ECG) measurements taken at various time points showed only one subject in the INVEGA™ 12 mg group had a change exceeding 60 msec at one time-point on Day 6 (increase of 62 msec). No subject receiving INVEGA™ had a QTcLD exceeding 500 msec at any time in any of these three studies. **Neuroleptic Malignant Syndrome:** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability. Other signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Management should include: discontinuation of the antipsychotic and other drugs not essential to therapy; intensive symptomatic treatment and medical monitoring; and treatment of other serious medical problems. If a patient requires antipsychotic drugs after recovery from NMS, the reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences have been reported. **Tardive Dyskinesia:** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. The risk of developing and likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose. However, tardive dyskinesia can develop, after brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although it may remit, partially or completely, if the antipsychotic is withdrawn. Prescribing should be in a manner to minimize the occurrence. In patients who require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms should appear drug discontinuation should be considered. **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with all atypical antipsychotics. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. **Gastrointestinal:** Because the INVEGA™ tablet is non-deformable and does not appreciably change in shape in the gastrointestinal tract, INVEGA™ should ordinarily not be administered to patients with pre-existing severe gastrointestinal narrowing (pathologic or iatrogenic, for example: esophageal motility disorders, small bowel inflammatory disease, "short gut" syndrome due to adhesions or decreased transit time, past history of peritonitis, cystic fibrosis, chronic intestinal pseudoobstruction, or Meckel's diverticulum). There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of drugs in non-deformable controlled-release formulations. Because of the controlled-release design of the tablet, INVEGA™ should only be used in patients who are able to swallow the tablet whole (see PRECAUTIONS: Information for Patients). A decrease in transit time, e.g., as seen with diarrhea, would be expected to decrease bioavailability and an increase in transit time, e.g., as seen with gastrointestinal neuropathy, diabetic gastroparesis, or other causes, would be expected to increase bioavailability. These changes in bioavailability are more likely when the changes in transit time occur in the upper GI tract. **Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients With Dementia-Related Psychosis:** In placebo-controlled trials with risperidone, aripiprazole, and olanzapine in elderly subjects with dementia, there was a higher incidence of cerebrovascular adverse events (cerebrovascular accidents and transient ischemic attacks) including fatalities compared to placebo-treated subjects. INVEGA™ was not marketed at the time these studies were performed. INVEGA™ is not approved for the treatment of patients with dementia-related psychosis (see also Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis).

PRECAUTIONS

General: Orthostatic Hypotension and Syncope: Paliperidone can induce orthostatic hypotension and syncope in some patients because of its alpha-blocking activity. In pooled results of the three placebo-controlled, 6-week, fixed-dose trials, syncope was reported in 0.8% (7/850) of subjects treated with INVEGA™ (3, 6, 9, 12 mg) compared to 0.3% (1/355) of subjects treated with placebo. INVEGA™ should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of myocardial infarction or ischemia, conduction abnormalities), cerebrovascular disease, or conditions that predispose the patient to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Monitoring of orthostatic vital signs should be considered in patients who are vulnerable to hypotension. **Seizures:** Like other antipsychotic drugs, INVEGA™ should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold. **Hyperprolactinemia:** Like other drugs that antagonize dopamine D_2 receptors, paliperidone elevates prolactin levels and the elevation persists during chronic administration. Paliperidone has a prolactin-elevating effect similar to that seen with risperidone, a drug that is associated with higher levels of prolactin than other antipsychotic drugs. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. An increase in the incidence of pituitary gland, mammary gland, and pancreatic islet cell neoplasia (mammary adenocarcinomas, pituitary and pancreatic adenomas) was observed in the risperidone carcinogenicity studies conducted in mice and rats (see PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility). Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans, but the available evidence is too limited to be conclusive. **Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's dementia. INVEGA™ and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. **Suicide:** The possibility of suicide attempt is inherent in psychotic illnesses, and close supervision of high-risk patients should accompany drug therapy. **Potential for Cognitive and Motor Impairment:** Somnolence and sedation were reported in subjects treated with INVEGA™ (see ADVERSE REACTIONS). Antipsychotics, including INVEGA™, have the potential to impair judgment, thinking, or motor skills. Patients should be cautioned about performing activities requiring mental alertness, such as operating hazardous machinery or operating a motor vehicle, until they are reasonably certain that paliperidone therapy does not adversely affect them. **Priapism:** No cases of priapism have been reported in clinical trials with INVEGA™. **Thrombotic Thrombocytopenia Purpura (TTP):** No cases of TTP were observed during clinical studies with paliperidone. Although cases of TTP have been reported in association with risperidone administration, the relationship to risperidone therapy is unknown. **Body Temperature Regulation:** Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing INVEGA™ to patients who will be experiencing conditions which may contribute to an elevation in core body temperature. **Antiemetic Effect:** An antiemetic effect was observed in preclinical studies with paliperidone. This effect, if it occurs in humans, may mask the signs and symptoms of overdosage with certain drugs or of conditions such as intestinal obstruction, Reye's syndrome, and brain tumor. **Use in Patients with Concomitant Illness:** Clinical experience with INVEGA™ in patients with certain concomitant illnesses is limited (see CLINICAL PHARMACOLOGY: Pharmacokinetics: Special Populations: Hepatic Impairment and Renal Impairment in full PI). Patients with Parkinson's Disease or Dementia with Lewy Bodies are reported to have an increased sensitivity to antipsychotic medication. Manifestations of this increased sensitivity include confusion, obtundation, postural instability with frequent falls, extrapyramidal symptoms, and clinical features consistent with the neuroleptic malignant syndrome. INVEGA™ has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical trials. Because of the risk of orthostatic hypotension with INVEGA™, caution should be observed in patients with known cardiovascular disease (see PRECAUTIONS: General: Orthostatic Hypotension and Syncope). **Information for Patients:** Physicians are advised to discuss the following issues with patients for whom they prescribe INVEGA™. **Orthostatic Hypotension:** Patients should be advised that there is risk of orthostatic hypotension, particularly at the time of initiating treatment, re-initiating treatment, or increasing the dose. **Interference With Cognitive and Motor Performance:** As INVEGA™ has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that INVEGA™ therapy does not affect them adversely. **Pregnancy:** Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with INVEGA™. **Nursing:** Patients should be advised not to breast-feed an infant if they are taking INVEGA™. **Concomitant Medication:** Patients should be advised to inform their physicians if they are taking, or plan to take, any prescription or over-the-counter drugs, as there is a potential for interactions. **Alcohol:** Patients should be advised to avoid alcohol while taking INVEGA™. **Heat Exposure and Dehydration:** Patients should be advised regarding appropriate care in avoiding overheating and dehydration. **Administration:** Patients should be informed that INVEGA™ should be swallowed whole with the aid of liquids. Tablets should not be chewed, divided, or crushed. The medication is contained within a nonabsorbable shell designed to release the drug at a controlled rate. The tablet shell, along with insoluble core components, is eliminated from the body; patients should not be concerned if they occasionally notice something that looks like a tablet in their stool. **Drug Interactions: Potential for INVEGA™ to Affect Other Drugs** – Paliperidone is not expected to cause clinically important pharmacokinetic interactions with drugs that are metabolized by cytochrome P450 isozymes. *In vitro* studies in human liver microsomes showed that paliperidone does not substantially inhibit the metabolism of drugs metabolized by cytochrome P450 isozymes, including CYP1A2, CYP2A6, CYP2C8/9/10, CYP2D6, CYP2E1, CYP3A4, and CYP3A5. Therefore, paliperidone is not expected to inhibit clearance of drugs that are metabolized by these metabolic pathways in a clinically relevant manner. Paliperidone is also not expected to have enzyme inducing properties. At therapeutic concentrations, paliperidone did not inhibit P-glycoprotein. Paliperidone is therefore not expected to inhibit P-glycoprotein-mediated transport of other drugs in a clinically relevant manner. Given the primary CNS effects of paliperidone (see ADVERSE REACTIONS), INVEGA™ should be used with caution in combination with other centrally acting drugs and alcohol. Paliperidone may antagonize the effect of levodopa and other dopamine agonists. Because of its potential for inducing orthostatic hypotension, an additive effect may be observed when INVEGA™ is administered with other therapeutic agents that have this potential (see PRECAUTIONS: General: Orthostatic Hypotension and Syncope). **Potential for Other Drugs to Affect INVEGA™** – Paliperidone is not a substrate of CYP1A2, CYP2A6, CYP2C9, and CYP2C19, so that an interaction with inhibitors or inducers of these isozymes is unlikely. While *in vitro* studies indicate that CYP2D6 and CYP3A4 may be minimally involved in paliperidone metabolism, *in vivo* studies do not show decreased elimination by these isozymes and they contribute to only a small fraction of total body clearance. **Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis:** Carcinogenicity studies of paliperidone have not been performed. Carcinogenicity studies of risperidone, which is extensively converted to paliperidone in rats, mice, and humans, were conducted in Swiss albino mice and Wistar rats. Risperidone was administered in the diet at daily doses of 0.63, 2.5, and 10 mg/kg for 18 months to mice and for 25 months to rats. A maximum tolerated dose was not achieved in male mice. There were statistically significant increases in pituitary gland adenomas, endocrine pancreas adenomas, and mammary gland adenocarcinomas. The no-effect dose for these tumors was less than or equal to the maximum recommended human dose of risperidone on a mg/m^2 basis (see risperidone package insert). An increase in mammary, pituitary, and endocrine pancreas neoplasms has been found in rodents after chronic administration of other antipsychotic drugs and is considered to be mediated by prolonged dopamine D_2 antagonism and hyperprolactinemia. The relevance of these tumor findings in rodents in terms of human risk is unknown (see PRECAUTIONS: General: Hyperprolactinemia). **Mutagenesis:** No evidence of genotoxic potential for paliperidone was found in the Ames reverse mutation test, the mouse lymphoma assay, or the *in vivo* rat micronucleus test. **Impairment of Fertility:** In a study of fertility, the percentage of treated female rats that became pregnant was not affected at oral doses of paliperidone of up to 2.5 mg/kg/day. However, pre- and post-implantation loss was increased, and the number of live embryos was slightly decreased, at 2.5 mg/kg, a dose that also caused slight maternal toxicity. These parameters were not affected at a dose of 0.63 mg/kg, which is half of the maximum recommended human dose on a mg/m^2 basis. The fertility of male rats was not affected at oral doses of paliperidone of up to 2.5 mg/kg/day, although sperm count and sperm viability studies were not conducted with paliperidone. In a subchronic study in Beagle dogs with risperidone, which is extensively converted to paliperidone in dogs and humans, all doses tested (0.31-5.0 mg/kg) resulted in decreases in serum testosterone and in sperm motility and concentration. Serum testosterone and sperm parameters partially recovered, but remained decreased after the last observation (two months after treatment was discontinued). **Pregnancy: Pregnancy Category C:** In studies in rats and rabbits in which paliperidone was given orally during the period of organogenesis, there were no increases in fetal abnormalities up to the highest doses tested (10 mg/kg/day in rats and 5 mg/kg/day in rabbits, which are 8 times the maximum recommended human dose on a mg/m^2 basis). In rat reproduction studies with risperidone, which is extensively converted to paliperidone in rats and humans, increases in pup deaths were seen at oral doses which are less than the maximum recommended human dose of risperidone on a mg/m^2 basis (see risperidone package insert). Use of first generation antipsychotic drugs during the last trimester of pregnancy has been associated with extrapyramidal symptoms in the neonate. These symptoms are usually self-limited. It is not known whether paliperidone, when taken near the end of pregnancy, will lead to similar neonatal signs and symptoms. There are no adequate and well controlled studies of INVEGA™ in pregnant women. INVEGA™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Labor and Delivery:** The effect of INVEGA™ on labor and delivery in humans is unknown. **Nursing Mothers:** In animal studies with paliperidone and in human studies with risperidone, paliperidone was excreted in the milk. Therefore, women receiving INVEGA™ should not breast-feed infants. **Pediatric Use:** Safety and effectiveness of INVEGA™ in patients < 18 years of age have not been established. **Geriatric Use:** The safety, tolerability, and efficacy of INVEGA™ were evaluated in a 6-week placebo-controlled study of 114 elderly subjects with schizophrenia (65 years of age and older, of whom 21 were 75 years of age and older). In this study, subjects received flexible doses of INVEGA™ (3 to 12 mg once daily). In addition, a small number of subjects 65 years of age and older were included in the 6-week placebo-controlled studies in which adult schizophrenic subjects received fixed doses of INVEGA™ (3 to 15 mg once daily, see CLINICAL PHARMACOLOGY: Clinical Trials in full PI). Overall, of the total number of subjects in clinical studies of INVEGA™ (n = 1796), including those who received INVEGA™ or placebo, 125 (7.0%) were 65 years of age and older and 22 (1.2%) were 75 years of age and older. 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 response between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. This drug is known to be substantially excreted by the kidney and clearance is decreased in patients with moderate to severe renal impairment (see CLINICAL PHARMACOLOGY: Pharmacokinetics: Special Populations: Renal Impairment in full PI), who should be given reduced doses. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (see DOSAGE AND ADMINISTRATION: Dosing in Special Populations in full PI).

ADVERSE REACTIONS

The information below is derived from a clinical trial database for INVEGA™ consisting of 2720 patients and/or normal subjects exposed to one or more doses of INVEGA™ for the treatment of schizophrenia. Of these 2720 patients, 2054 were patients who received INVEGA™ while participating in multiple dose, effectiveness trials. The conditions and duration of treatment with INVEGA™ varied greatly and included (in overlapping categories) open-label and double-blind phases of studies, inpatients and outpatients, fixed-dose and flexible-dose studies, and

short-term and longer-term exposure. Adverse events were assessed by collecting adverse events and performing physical examinations, vital signs, weights, laboratory analyses and ECGs. Adverse events during exposure were obtained by general inquiry and recorded by clinical investigators using their own terminology. Consequently, to provide a meaningful estimate of the proportion of individuals experiencing adverse events, events were grouped in standardized categories using MedDRA terminology. The stated frequencies of adverse events represent the proportions of individuals who experienced 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 Observed in Short-Term, Placebo-Controlled Trials of Subjects with Schizophrenia** The information presented in these sections were derived from pooled data from the three placebo-controlled, 6-week, fixed-dose studies based on subjects with schizophrenia who received INVEGA™ at daily doses within the recommended range of 3 to 12 mg (n = 850). Adverse Events Occurring at an Incidence of 2% or More Among INVEGA™-Treated Patients with Schizophrenia and More Frequent on Drug than Placebo Table 1 enumerates the pooled incidences of treatment-emergent adverse events that were spontaneously reported in the three placebo-controlled, 6-week, fixed-dose studies, listing those events that occurred in 2% or more of subjects treated with INVEGA™ in any of the dose groups, and for which the incidence in INVEGA™-treated subjects in any of the dose groups was greater than the incidence in subjects treated with placebo. **Treatment-Emergent Adverse Events in Short-Term, Fixed-Dose,Placebo-Controlled Trials in Adult Subjects with Schizophrenia.* Body System or Organ Class** (Dictionary-derived Term) Percentage of Patients Reporting Event INVEGA™ Placebo (N=355) first, INVEGA™ dosage once daily 3 mg (N=127) second, 6 mg N=235) third, 9 mg (N=246) fourth, 12 mg (N=242) fifth, **Total no. subjects with adverse events** 66, 72, 66, 70, 76; **Cardiac disorders:** Atrioventricular block first degree 1, 2, 0, 2, 1; Bundle branch block 2, 3, 1, 3, <1; Sinus arrhythmia 0, 2, 1, 1, <1; Tachycardia 7, 14, 12, 12, 14; **Eye disorders:** Vision blurred 1, 1, <1, 0, 2; **Gastrointestinal disorders:** Abdominal pain upper 1, 1, 3, 2, 2; Dry mouth 1, 2, 3, 1, 3; Dyspepsia 4, 2, 3, 2, 5; Nausea 5, 6, 4, 4, 4; Salivary hypersecretion <1, 0, <1, 1, 4; **General disorders**: Asthenia 1, 2, <1, 2, 2; Fatigue 1, 2, 1, 2, 2; Pyrexia 1, 1, <1, 2, 2; **Investigations:** Blood insulin increased 1, 2, 1, 1, <1; Blood pressure increased 1, 2, <1, <1, 1; Electrocardiogram QT corrected interval prolonged 3, 3, 4, 3, 5; Electrocardiogram T wave abnormal 1, 2, 1, 2, 1; **Musculoskeletal and connective tissue disorders**: Back pain 1, 1, 1, 1, 2; Pain in extremity 1, 0, 1, 0, 2; **Nervous system disorders**: Akathisia 4, 4, 3, 8, 10; Dizziness 4, 6, 5, 4, 5; Dystonia 1, 1, 1, 5, 4; Extrapyramidal disorder 2, 5, 2, 7, 7; Headache 12, 11, 12, 14, 14; Hypertonia 1, 2, 1, 4, 3; Parkinsonism 0, 0, <1, 2, 1; Somnolence 7, 6, 9, 10, 11; Tremor 3, 3, 3, 4, 3; **Psychiatric disorders**: Anxiety 8, 9, 7, 6, 5; **Respiratory, thoracic and mediastinal disorders**: Cough 1, 3, 2, 3, 2; **Vascular disorders**: Orthostatic hypotension 1, 2, 1, 2, 4: *Table includes adverse events that were reported in 2% or more of subjects in any of the INVEGA™ dose groups and which occurred at greater incidence than in the placebo group. Data are pooled from three studies; one included once-daily INVEGA™ doses of 3 and 9 mg, the second study included 6, 9, and 12 mg, and the third study included 6 and 12 mg (see CLINICAL PHARMACOLOGY: Clinical Trials in full PI). Events for which the INVEGA™ incidence was equal to or less than placebo are not listed in the table, but included the following: constipation, diarrhea, vomiting, nasopharyngitis, agitation, and insomnia. **Dose-Related Adverse Events in Clinical Trials:** Based on the pooled data from the three placebo-controlled, 6-week, fixed-dose studies, adverse events that occurred with a greater than 2% incidence in the subjects treated with INVEGA™, the incidences of the following adverse events increased with dose: somnolence, orthostatic hypotension, salivary hypersecretion, akathisia, dystonia, extrapyramidal disorder, hypertonia and Parkinsonism. For most of these, the increased incidence was seen primarily at the 12 mg, and in some cases the 9 mg dose. **Common and Drug-Related Adverse Events in Clinical Trials** Adverse events reported in 5% or more of subjects treated with INVEGA™ and at least twice the placebo rate for at least one dose included: akathisia and extrapyramidal disorder. **Extrapyramidal Symptoms (EPS) in Clinical Trials:** Pooled data from the three placebo-controlled, 6-week, fixed-dose studies provided information regarding treatment-emergent EPS. Several methods were used to measure EPS: (1) the Simpson-Angus global score (mean change from baseline) which broadly evaluates Parkinsonism, (2) the Barnes Akathisia Rating Scale global clinical rating score (mean change from baseline) which evaluates akathisia, (3) use of anticholinergic medications to treat emergent EPS, and (4) incidence of spontaneous reports of EPS. For the Simpson-Angus Scale, spontaneous EPS reports and use of anticholinergic medications, there was a dose-related increase observed for the 9 mg and 12 mg doses. There was no difference observed between placebo and INVEGA™ 3 mg and 6 mg doses for any of these EPS measures. **Percentage of Patients INVEGA™** Placebo (N=355) first, INVEGA™ dosage once daily 3 mg (N=127) second, 6 mg N=235) third, 9 mg (N=246) fourth, 12 mg (N=242) fifth, **EPS Group:** Parkinsonism [a] 9, 11, 3, 15, 14; Akathisia [b] 6, 6, 4, 7, 9; Use of anticholinergic medications [c] 10, 10, 9, 22, 22: [a]: For Parkinsonism, percent of patients with Simpson-Angus global score > 0.3 (Global score defined as total sum of items score divided by the number of items). [b]: For Akathisia, percent of patients with Barnes Akathisia Rating Scale global score ≥ 2. [c]: Percent of patients who received anticholinergic medications to treat emergent EPS. **Percentage of Patients INVEGA™** Placebo (N=355) first, INVEGA™ dosage once daily 3 mg (N=127) second, 6 mg N=235) third, 9 mg (N=246) fourth, 12 mg (N=242) fifth, **EPS Group**: Overall percentage of patients with EPS-related AE 11.0, 12.6, 10.2, 25.2, 26.0; Dyskinesia 3.4, 4.7, 2.6, 7.7, 8.7; Dystonia 1.1, 0.8, 1.3, 5.3, 4.5; Hyperkinesia 3.9, 3.9, 3.0, 8.1, 9.9; Parkinsonism 2.3, 3.1, 2.6, 7.3, 6.2; Tremor 3.4, 3.1, 2.6, 4.5, 3.3: Dyskinesia group includes: Dyskinesia, Extrapyramidal disorder, Muscle twitching, Tardive dyskinesia Dystonia group includes: Dystonia, Muscle spasms, Oculogyration, Trismus. Hyperkinesia group includes: Akathisia, Hyperkinesia. Parkinsonism group includes: Bradykinesia, Cogwheel rigidity, Drooling, Hypertonia, Hypokinesia, Muscle rigidity, Musculoskeletal stiffness, Parkinsonism. Tremor group includes: Tremor. **Adverse Events Associated with Discontinuation of Treatment in Controlled Clinical Studies:** Overall, there was no difference in the incidence of discontinuation due to adverse events between INVEGA™-treated (5%) and placebo-treated (5%) subjects. The types of adverse events that led to discontinuation were similar for the INVEGA™-and placebo-treated subjects, except for Nervous System Disorders events which were more common among INVEGA™-treated subjects than placebo-treated subjects (2% and 0%, respectively), and Psychiatric Disorders events which were more common among placebo-treated subjects than INVEGA™-treated subjects (3% and 1%, respectively). **Demographic Differences in Adverse Reactions in Clinical Trials:** An examination of population subgroups in the three placebo-controlled, 6-week, fixed-dose studies did not reveal any evidence of differences in safety on the basis of age, gender or race (see PRECAUTIONS: Geriatric Use). **Laboratory Test Abnormalities in Clinical Trials:** In the pooled data from the three placebo-controlled, 6-week, fixed-dose studies, between-group comparisons revealed no medically important differences between INVEGA™ and placebo in the proportions of subjects experiencing potentially clinically significant changes in routine hematology, urinalysis, or serum chemistry, including mean changes from baseline in fasting glucose, insulin, c-peptide, triglyceride, HDL, LDL, and total cholesterol measurements. Similarly, there were no differences between INVEGA™ and placebo in the incidence of discontinuations due to changes in hematology, urinalysis, or serum chemistry. However, INVEGA™ was associated with increases in serum prolactin (see PRECAUTIONS: General: Hyperprolactinemia). **Weight Gain in Clinical Trials:** In the pooled data from the three placebo-controlled, 6-week, fixed-dose studies, the proportions of subjects having a weight gain of ≥ 7% of body weight were similar for INVEGA™ 3 mg and 6 mg (7% and 6%, respectively) and placebo (5%), but there was a higher incidence of weight gain for INVEGA™ 9 mg and 12 mg (9% and 9%, respectively). **Other Events Observed During the Premarketing Evaluation of INVEGA™:** The following list contains all serious and non-serious treatment-emergent adverse events reported at any time by individuals taking INVEGA™ during any phase of a trial within the premarketing database (n = 2720), except (1) those listed in Table 1 above or elsewhere in labeling, (2) those for which a causal relationship to INVEGA™ use was considered remote, and (3) those occurring in only one subject treated with INVEGA™ and that were not acutely life-threatening. Events are classified within body system categories using the following definitions: *very frequent* adverse events are defined as those occurring on one or more occasions in at least 1/10 subjects, *frequent* adverse events are defined as those occurring on one or more occasions in at least 1/100 subjects, *infrequent* adverse events are those occurring on one or more occasions in 1/100 to 1/1000 subjects, and *rare* events are those occurring on one or more occasions in less than 1/1000 subjects. **Blood and Lymphatic System Disorders:** *rare*: thrombocytopenia; **Cardiac Disorders:** *frequent:* palpitations; *infrequent*: bradycardia; **Gastrointestinal Disorders:** *frequent:* abdominal pain; *infrequent*: swollen tongue; **General Disorders:** *infrequent:* edema; **Immune Disorder:** *rare*: anaphylactic reaction; **Nervous System Disorders:** *rare*: coordination abnormal; **Psychiatric Disorders:** *infrequent*: confusional state; **Respiratory, Thoracic and Mediastinal Disorders:** *frequent*: dyspnea; *rare*: pulmonary embolus; **Vascular Disorders:** *rare*: ischemia, venous thrombosis; **Adverse Events Reported With Risperidone**; Paliperidone is the major active metabolite of risperidone. Adverse events reported with risperidone can be found in the ADVERSE REACTIONS section of the risperidone package insert.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: INVEGA™ (paliperidone) is not a controlled substance.

For more information on symptoms and treatment of overdosage, see full Prescribing Information.

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RISPERDAL®
(RISPERIDONE)
TABLETS/ORAL SOLUTION

RISPERDAL® M-TAB®
(RISPERIDONE)
ORALLY DISINTEGRATING TABLETS

Brief Summary of Full Prescribing Information for Schizophrenia and Bipolar Mania. CLINICAL STUDIES FOR OTHER INDICATIONS WILL HAVE DIFFERING ADVERSE EVENTS AND SAFETY CONCERNS. PLEASE SEE FULL PI FOR THIS INFORMATION REGARDING RISPERDAL® FOR AUTISM.

Increased Mortality in Elderly Patients with Dementia–Related Psychosis
Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10 week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. RISPERDAL® (risperidone) is not approved for the treatment of patients with Dementia-Related Psychosis.

INDICATIONS AND USAGE: RISPERDAL® (risperidone) is indicated for the treatment of schizophrenia. **Monotherapy:** RISPERDAL® is indicated for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder. **Combination Therapy:** The combination of RISPERDAL® with lithium or valproate is indicated for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder.

CONTRAINDICATIONS: RISPERDAL® (risperidone) is contraindicated in patients with a known hypersensitivity to the product.

WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. RISPERDAL® (risperidone) is not approved for the treatment of dementia-related psychosis (see Boxed Warning). Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability. Other signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Management should include: discontinuation of the antipsychotic and other drugs not essential to therapy; intensive symptomatic treatment and medical monitoring; and treatment of other serious medical problems. If a patient requires antipsychotic drugs after recovery from NMS, the reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences have been reported. **Tardive Dyskinesia:** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. The risk of developing and likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose. However, tardive dyskinesia can develop, after brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although it may remit, partially or completely, if the antipsychotic is withdrawn. Prescribing should be in a manner to minimize the occurrence. In patients who require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms should appear drug discontinuation should be considered. **Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients With Dementia-Related Psychosis:** Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73-97) in trials of risperidone in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with risperidone compared to patients treated with placebo. RISPERDAL® is not approved for the treatment of patients with dementia-related psychosis. (See also **Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis.**) **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including RISPERDAL®. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment.

PRECAUTIONS: General: Orthostatic Hypotension: RISPERDAL® (risperidone) may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose-titration period, probably reflecting its alpha-adrenergic antagonistic properties. Syncope was reported in 0.2% (6/2607) of RISPERDAL®-treated patients in Phase 2 and 3 studies. The risk of orthostatic hypotension and syncope may be minimized by limiting the initial dose to 2 mg total (either QD or 1 mg BID) in normal adults and 0.5 mg BID in the elderly and patients with renal or hepatic impairment (see DOSAGE AND ADMINISTRATION in full PI). Monitoring of orthostatic vital signs should be considered in patients for whom this is of concern. A dose reduction should be considered if hypotension occurs. RISPERDAL® should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemia, heart failure, or conduction abnormalities), cerebrovascular disease, and conditions which would predispose patients to hypotension, e.g., dehydration and hypovolemia. Clinically significant hypotension has been observed with concomitant use of RISPERDAL® and antihypertensive medication. **Seizures:** RISPERDAL® should be used cautiously in patients with a history of seizures. **Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's dementia. RISPERDAL® and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. (See also **Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis.**) **Hyperprolactinemia:** As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. An increase in pituitary gland, mammary gland, and pancreatic islet cell neoplasia (mammary adenocarcinomas, pituitary and pancreatic adenomas) was observed in the risperidone carcinogenicity studies conducted in mice and rats (see PRECAUTIONS – Carcinogenesis, Mutagenesis, Impairment of Fertility). Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time. **Potential for Cognitive and Motor Impairment:** Somnolence was a commonly reported adverse event associated with RISPERDAL® treatment, especially when ascertained by direct questioning of patients. This adverse event is dose-related. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that RISPERDAL® therapy does not affect them adversely. **Priapism:** Rare cases of priapism have been reported. **Thrombotic Thrombocytopenic Purpura (TTP):** A single case of TTP was reported in a 28 year-old female patient receiving RISPERDAL® in a large, open premarketing experience (approximately 1300 patients). She experienced jaundice, fever, and bruising, but eventually recovered after receiving plasmapheresis. The relationship to RISPERDAL® therapy is unknown. **Antiemetic Effect:** Risperidone has an antiemetic effect in animals; this effect may also occur in humans, and may mask signs and symptoms of overdosage with certain drugs or of conditions such as intestinal obstruction, Reye's syndrome, and brain tumor. **Body Temperature Regulation:** Disruption of body temperature regulation has been attributed to antipsychotic agents. Caution is advised when prescribing for patients who will be exposed to temperature extremes. **Suicide:** The possibility of a suicide attempt is inherent in patients with schizophrenia and bipolar mania, including children and adolescent patients, and close supervision of high-risk patients should accompany drug therapy. **Use in Patients With Concomitant Illness:** Clinical experience with RISPERDAL® in patients with certain concomitant systemic illnesses is limited. Patients with Parkinson's Disease or Dementia with Lewy Bodies who receive antipsychotics, including RISPERDAL®, are reported to have an increased sensitivity to antipsychotic medications. Manifestations of this increased sensitivity have been reported to include confusion, obtundation, postural instability with frequent falls, extrapyramidal symptoms, and clinical features consistent with the neuroleptic malignant syndrome. Caution is advisable in using RISPERDAL® in patients with diseases or conditions that could affect metabolism or hemodynamic responses. Increased plasma concentrations of risperidone and 9–hydroxyrisperidone occur in patients with severe renal impairment and in patients with severe hepatic impairment. A lower starting dose should be used in such patients. **Information for Patients:** Physicians are advised to discuss the following issues with patients for whom they prescribe RISPERDAL®: **Orthostatic Hypotension:** Patients should be advised of the risk of orthostatic hypotension, especially during the period of initial dose titration. **Interference With Cognitive and Motor Performance:** Since RISPERDAL® has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that RISPERDAL® therapy does not affect them adversely. **Pregnancy:** Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. **Nursing:** Patients should be advised not to breast-feed an infant if they are taking RISPERDAL®. **Concomitant Medication:** Patients should be advised to inform their physicians if they are taking, or plan to take, any prescription or over-the-counter drugs, since there is a potential for interactions. **Alcohol:** Patients should be advised to avoid alcohol while taking RISPERDAL®. **Phenylketonurics:** Phenylalanine is a component of aspartame. Each 4 mg RISPERDAL® M-TAB® Orally Disintegrating Tablet contains 0.84 mg phenylalanine; each 3 mg RISPERDAL® M-TAB® Orally Disintegrating Tablet contains 0.63 mg phenylalanine; each 2 mg RISPERDAL® M-TAB® Orally Disintegrating Tablet contains 0.42 mg phenylalanine; each 1 mg RISPERDAL® M-TAB® Orally Disintegrating Tablet contains 0.28 mg phenylalanine; and each 0.5 mg RISPERDAL® M-TAB® Orally Disintegrating Tablet contains 0.14 mg phenylalanine. **Drug Interactions:** The interactions of RISPERDAL® and other drugs have not been systematically evaluated. Given the primary CNS effects of risperidone, caution should be used when RISPERDAL® is taken in combination with other centrally acting drugs and alcohol. Because of its potential for inducing hypotension, RISPERDAL® may enhance the hypotensive effects of other therapeutic agents with this potential. RISPERDAL® may antagonize the effects of levodopa and dopamine agonists. Chronic administration of clozapine with risperidone may decrease the clearance of risperidone. **Carbamazepine and Other Enzyme Inducers:** In a drug interaction study in schizophrenic patients, 11 subjects received risperidone titrated to 6 mg/day for 3 weeks, followed by concurrent administration of carbamazepine for an additional 3 weeks. During co-administration, the plasma concentrations of risperidone and its pharmacologically active metabolite, 9–hydroxyrisperidone, were decreased by about 50%. Plasma concentrations of carbamazepine did not appear to be affected. The dose of risperidone may need to be titrated accordingly for patients receiving carbamazepine, particularly during initiation or discontinuation of carbamazepine therapy. Co-administration of other known enzyme inducers (e.g., phenytoin, rifampin, and phenobarbital) with risperidone may cause similar decreases in the combined plasma concentrations of risperidone and 9–hydroxyrisperidone, which could lead to decreased efficacy of risperidone treatment. **Fluoxetine and Paroxetine:** Fluoxetine (20 mg QD) and paroxetine (20 mg QD) have been shown to increase the plasma concentration of risperidone 2.5-2.8 fold and 3-9 fold respectively. Fluoxetine did not affect the plasma concentration of 9–hydroxyrisperidone. Paroxetine lowered the concentration of 9–hydroxyrisperidone by about 10%. When either concomitant fluoxetine or paroxetine is initiated or discontinued, the physician should re-evaluate the dosing of RISPERDAL®. The effects of discontinuation of concomitant fluoxetine or paroxetine therapy on the pharmacokinetics of risperidone and 9–hydroxyrisperidone have not been studied. **Lithium:** Repeated oral doses of risperidone (3 mg BID) did not affect the exposure (AUC) or peak plasma concentrations (C_{max}) of lithium (n=13). **Valproate:** Repeated oral doses of risperidone (4 mg QD) did not affect the pre-dose or average plasma concentrations and exposure (AUC) of valproate (1000 mg/day in three divided doses) compared to placebo (n=21). However, there was a 20% increase in valproate peak plasma concentration (C_{max}) after concomitant administration of risperidone. **Digoxin:** RISPERDAL® (0.25 mg BID) did not show a clinically relevant effect on the pharmacokinetics of digoxin. **Drugs That Inhibit CYP 2D6 and Other CYP Isozymes:** Risperidone is metabolized to 9–hydroxyrisperidone by CYP 2D6, an enzyme that is polymorphic in the population and that can be inhibited by a variety of psychotropic and other drugs (see CLINICAL PHARMACOLOGY in full PI). Drug interactions that reduce the metabolism of risperidone to 9–hydroxyrisperidone would increase the plasma concentrations of risperidone and lower the concentrations of 9–hydroxyrisperidone. Analysis of clinical studies involving a modest number of poor metabolizers (n≅70) does not suggest that poor and extensive metabolizers have different rates of adverse effects. No comparison of effectiveness in the two groups has been made. *In vitro* studies showed that drugs metabolized by other CYP isozymes, including 1A1, 1A2, 2C9, 2C19, and 3A4, are only weak inhibitors of risperidone metabolism. There were no significant interactions between risperidone and erythromycin (see CLINICAL PHARMACOLOGY in full PI). **Drugs Metabolized by CYP 2D6:** *In vitro* studies indicate that risperidone is a relatively weak inhibitor of CYP 2D6. Therefore, RISPERDAL® is not expected to substantially inhibit the clearance of drugs that are metabolized by this enzymatic pathway. In drug interaction studies, risperidone did not significantly affect the pharmacokinetics of donepezil and galantamine, which are metabolized by CYP 2D6. **Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis:** Carcinogenicity studies were conducted in Swiss albino mice and Wistar rats. Risperidone was administered in the diet at doses of 0.63, 2.5, and 10 mg/kg for 18 months to mice and for 25 months to rats. These doses are equivalent to 2.4, 9.4, and 37.5 times the maximum recommended human dose (MRHD) for schizophrenia (16 mg/day) on a mg/kg basis or 0.2, 0.75, and 3 times the MRHD (mice) or 0.4, 1.5, and 6 times the MRHD (rats) on a mg/m^2 basis. A maximum tolerated dose was not achieved in male mice. There were statistically significant increases in pituitary gland adenomas, endocrine pancreas adenomas, and mammary gland adenocarcinomas. These findings are considered to be prolactin-mediated. The relevance for human risk of the findings of prolactin-mediated endocrine tumors in rodents is unknown (see PRECAUTIONS, General - Hyperprolactinemia). **Mutagenesis:** No evidence of mutagenic potential for risperidone was found. **Impairment of Fertility:** Risperidone (0.16 to 5 mg/kg) was shown to impair mating, but not fertility, in Wistar rats in three reproductive studies at doses 0.1 to 3 times the maximum recommended human dose (MRHD) on a mg/m^2 basis. **Pregnancy: Pregnancy Category C:** The teratogenic potential of risperidone was studied in three Segment II studies in Sprague-Dawley and Wistar rats (0.63-10 mg/kg or 0.4 to 6 times the maximum recommended human dose [MRHD] on a mg/m^2 basis) and in one Segment II study in New Zealand rabbits (0.31-5 mg/kg or 0.4 to 6 times the MRHD on a mg/m^2 basis). The incidence of malformations was not increased compared to control in offspring of rats or rabbits given 0.4 to 6 times the MRHD on a mg/m^2 basis. In three reproductive studies in rats (two Segment III and a multigenerational study), there was an increase in pup deaths during the first 4 days of lactation at doses of 0.16-5 mg/kg or 0.1 to 3 times the MRHD on a mg/m^2 basis. It is not known whether these deaths were due to a direct effect on the fetuses or pups or to effects on the dams. There was no no-effect dose for increased rat pup mortality. In one Segment III study, there was an increase in stillborn rat pups at a dose of 2.5 mg/kg or 1.5 times the MRHD on a mg/m^2 basis. In a cross-fostering study in Wistar rats, toxic effects on the fetus or pups, as evidenced by a decrease in the number of live pups and an increase in the number of dead pups at birth (Day 0), and a decrease in birth weight in pups of drug-treated dams were observed. In addition, there was an increase in deaths by Day 1 among pups of drug-treated dams, regardless of whether or not the pups were cross-fostered. Risperidone also appeared to impair maternal behavior in that pup body weight gain and survival (from Day 1 to 4 of lactation) were reduced in pups born to control but reared by drug-treated dams. These effects were all noted at the one dose of risperidone tested, i.e., 5 mg/kg or 3 times the MRHD on a mg/m^2 basis. Placental transfer of risperidone occurs in rat pups. There are no adequate and well-controlled studies in pregnant women. However, there was one report of a case of agenesis of the corpus callosum in an infant exposed to risperidone *in utero*. The causal relationship to RISPERDAL® therapy is unknown. Reversible extrapyramidal symptoms in the neonate were observed following postmarketing use of risperidone during the last trimester of pregnancy. RISPERDAL® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Labor and Delivery:** The effect of RISPERDAL® on labor and delivery in humans is unknown. **Nursing Mothers:** In animal studies, risperidone and 9–hydroxyrisperidone are excreted in milk. Risperidone and 9–hydroxyrisperidone are also excreted in human breast milk. Therefore, women receiving risperidone should not breast-feed. **Pediatric Use:** The safety and effectiveness of RISPERDAL® in pediatric patients with schizophrenia or bipolar mania have not been established. **Tardive Dyskinesia:** In clinical trials in 1885 children and adolescents with autistic disorder or other psychiatric disorders treated with risperidone, 2 (0.1%) patients were reported to have tardive dyskinesia, which resolved on discontinuation of risperidone treatment (see WARNINGS – Tardive Dyskinesia). **Weight Gain:** In long-term, open-label trials (studies in patients with autistic disorder or other psychiatric disorders), a mean increase of 7.5 kg after 12 months of RISPERDAL® treatment was observed, which was higher than the expected normal weight gain (approximately 3 to 3.5 kg per year adjusted for age, based on Centers for Disease Control and Prevention normative data). The majority of that increase occurred within the first 6 months of exposure to RISPERDAL®. The average percentiles at baseline and 12 months, respectively, were 49 and 60 for weight, 48 and 53 for height, and 50 and 62 for body mass index. When treating patients with RISPERDAL®, weight gain should be assessed against that expected with normal growth. (See also ADVERSE REACTIONS.) **Somnolence:** Somnolence was frequently observed in placebo-controlled clinical trials of pediatric patients with autistic disorder. Most cases were mild or moderate in severity. These events were most often of early onset with peak incidence occurring during the first two weeks of treatment, and transient with a median duration of 16 days. (See also ADVERSE REACTIONS.) Patients experiencing persistent somnolence may benefit from a change in dosing regimen. **Hyperprolactinemia, Growth, and Sexual Maturation:** Risperidone has been shown to elevate prolactin levels in children and adolescents as well as in adults (see PRECAUTIONS - Hyperprolactinemia). In double-blind, placebo-controlled studies of up to 8 weeks duration in children and adolescents (aged 5 to 17 years), 49% of patients who received risperidone had elevated prolactin levels compared to 2% of patients who received placebo. In clinical trials in 1885 children and adolescents with autistic disorder or other psychiatric disorders treated with risperidone, galactorrhea was reported in 0.8% of risperidone-treated patients and gynecomastia was reported in 2.3% of risperidone-treated patients. The long-term effects of risperidone on growth and sexual maturation have not been fully evaluated. **Geriatric Use:** Clinical studies of RISPERDAL® in the treatment of schizophrenia did not include sufficient numbers of patients aged 65 and over to determine whether or not they respond differently than younger patients. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, a lower starting dose is recommended for an elderly patient, reflecting a decreased pharmacokinetic clearance in the elderly, as well as a greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy (see CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION in full PI). While elderly patients exhibit a greater tendency to orthostatic hypotension, its risk in the elderly may be minimized by limiting the initial dose to 0.5 mg BID followed by careful titration (see PRECAUTIONS). Monitoring of orthostatic vital signs should be considered in patients for whom this is of concern. This drug is substantially excreted by the kidneys, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (see DOSAGE AND ADMINISTRATION in full PI). **Concomitant use with Furosemide in Elderly Patients with Dementia-Related Psychosis:** In placebo-controlled trials in elderly patients with dementia-related psychosis, a higher incidence of mortality was observed in patients treated with furosemide plus risperidone when compared to patients treated with risperidone alone or with placebo plus furosemide. No pathological mechanism has been identified to explain this finding, and no consistent pattern for cause of death was observed. An increase of mortality in elderly patients with dementia-related psychosis was seen with the use of RISPERDAL® regardless of concomitant use with furosemide. RISPERDAL® is not approved for the treatment of patients with dementia-related psychosis. (See **Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis**.)

ADVERSE REACTIONS: Associated With Discontinuation of Treatment: Bipolar Mania: In the US placebo-controlled trial with risperidone as monotherapy, approximately 8% (10/134) of RISPERDAL®-treated patients discontinued treatment due to an adverse event, compared with approximately 6% (7/125) of placebo-treated patients. The adverse events associated with discontinuation and considered to be possibly, probably, or very likely drug-related included paroniria, somnolence, dizziness, extrapyramidal disorder, and muscle contractions involuntary. Each of these events occurred in one RISPERDAL®-treated patient (0.7%) and in no placebo-treated patients (0%). In the US placebo-controlled trial with risperidone as adjunctive therapy to mood stabilizers, there was no overall difference in the incidence of discontinuation due to adverse events (4% for RISPERDAL® vs. 4% for placebo). **Incidence in Controlled Trials: Commonly Observed Adverse Events in Controlled Clinical Trials: *Bipolar Mania:*** In the US placebo-controlled trial with risperidone as monotherapy, the most commonly observed adverse events associated with the use of RISPERDAL® (incidence of 5% or greater and at least twice that of placebo) were somnolence, dystonia, akathisia, dyspepsia, nausea, parkinsonism, vision abnormal, and saliva increased. In the US placebo-controlled trial with risperidone as adjunctive therapy to mood stabilizers, the most commonly observed adverse events associated with the use of RISPERDAL® were somnolence, dizziness, parkinsonism, saliva increased, akathisia, abdominal pain, and urinary incontinence. *Adverse Events Occurring at an Incidence of 2% or More Among RISPERDAL®-Treated Patients - Bipolar Mania*: Adverse events that occurred at an incidence of 2% or more, and were more frequent among patients treated with flexible doses of RISPERDAL® (1-6 mg daily as monotherapy and as adjunctive therapy to mood stabilizers, respectively) than among patients treated with placebo. Reported adverse events were classified using the World Health Organization preferred terms. *Incidence of Treatment-Emergent Adverse Events in a 3-Week, Placebo-Controlled Trial-Monotherapy in Bipolar Mania.* **Body System/Preferred Term: Central & peripheral nervous system:** Dystonia, Akathisia, Dizziness, Parkinsonism, Hypoaesthesia **Psychiatric:** Somnolence, Agitation, Manic reaction, Anxiety, Concentration impaired **Gastrointestinal system:** Dyspepsia, Nausea, Saliva increased, Mouth dry **Body as a whole - general:** Pain, Fatigue, Injury **Respiratory system:** Sinusitis, Rhinitis, Coughing **Skin and appendages:** Acne, Pruritus **Musculo-Skeletal:** Myalgia, Skeletal pain **Metabolic and nutritional:** Weight increase **Vision disorders:** Vision abnormal **Cardiovascular, general:** Hypertension, Hypotension **Heart rate and rhythm:** Tachycardia. *Incidence of Treatment-Emergent Adverse Events in a 3-Week, Placebo-Controlled Trial – Adjunctive Therapy in Bipolar Mania.* **Body System/Preferred Term: Gastrointestinal system:** Saliva increased, Diarrhea, Abdominal pain, Constipation, Mouth dry, Tooth ache, Tooth

Dads' Parenting Styles May Raise Child's Obesity Risk

Identifying the cause or causes of childhood obesity is becoming a matter of urgency not just in the United States, but also in other developed countries. And one of the contributors to obesity may be youngsters' fathers.

BY JOAN AREHART-TREICHEL

Childhood obesity is growing around the world at an alarming rate. One can hear about it on American, German, or French television. One can read about it in the scientific literature. For example, researchers at the Royal Children's Hospital in Melbourne, Australia, recently found that more than a fifth of Australian preschool children are overweight or obese.

The epidemic is sparking scientific interest in the psychological impact of being overweight on youngsters. and prompting a hunt for causes. Candidates include a superabundance of fast-food restaurants serving gargantuan proportions, not enough exercise, and certain personality and behavior traits (*Psychiatric News*, September 16, 2005; May 18). And now an Australian study suggests that dads could be contributing to childhood obesity as well.

The study was conducted by Melissa Wake, M.D., an associate professor of community child health at the Royal Children's Hospital in Melbourne, and colleagues. She reported findings at a meeting of the Pediatric Academic Societies in Toronto in May. Results are also in press with *Pediatrics*.

The study included nearly 5,000 4-year-olds and 5-year-olds and their parents. Fifteen percent of the children were overweight or obese, according to body mass index (BMI) measurements. Forty percent of the mothers and 60 percent of the fathers were themselves overweight or obese, according to BMI measurements.

Mothers and fathers completed scales assessing parental behavior, and depending on what they had reported on the scales, each parent was categorized as having an authoritative, permissive, or disengaged parenting style.

After taking the parents' BMI status into consideration, Wake and her coworkers attempted to see whether there was any relationship between both fathers' and mothers' parenting styles and their children's BMI status. The answer was no regarding mothers, but yes regarding fathers. Those fathers who had a permissive or a disengaged parenting style were significantly more likely to have heavier children than were the fathers who set clear limits.

"This study of a large cross-section of Australian preschoolers has, for the first time, suggested that fathers could be at the front line in preventing early childhood obesity," Wake concluded in a prepared statement. "Mothers are often blamed for their children's obesity, but this study suggests that for more effective prevention, perhaps we should focus on the whole family."

The study will be posted at <http://pediatrics.aappublications.org/>. ■

Philanthropists Hope Gift Produces Developmental-Disorder Breakthrough

A gift to NYU's Child Study Center funds its Asperger Institute to increase knowledge about a spectrum of related developmental disorders.

BY STEPHANIE WHYCHE

A private donation of $30 million has been made to the New York University (NYU) Child Study Center to establish a new facility known as the Asperger Institute.

The gift has launched two complimentary initiatives: $20 million to finance educational programs, clinical services, and cutting-edge research; and $10 million earmarked for a capital campaign for the university's new Center of Excellence in Child Mental Health.

The donors, Michael Statfeld Recanati and Ira Statfeld Recanati, were recognized as having made the "largest single contribution ever received by the center," according to a statement from the center.

"We embraced the idea of the Asperger Institute because we saw the prospect for breakthrough research that would make dramatic, tangible improvements in the quality of life for families with children who have Asperger syndrome," said Michael Statfeld Recanati in the statement. He and his partner, Ira Statfeld Recanati, serve on the board of the NYU Child Study Center.

Asperger syndrome (cited in *DSM-IV-TR* as "Asperger's disorder") is believed to have a U.S. prevalence rate of 1 in 300 people, according to the statement. It's increasingly being described as a "syndrome" by experts and lay people alike who view it as part of a spectrum of developmental disorders that includes autism.

"Children and adolescents with Asperger syndrome often have difficulty accomplishing early development tasks involving language, motor skills, communication, and socialization," the statement read.

Lynda Geller, Ph.D., a specialist in autism spectrum disorders who served more than two decades on the faculties of Georgetown University and Stony Brook University medical schools, is the clinical director of the Asperger Institute. Her chief responsibilities at the institute are to develop an educational program for gifted students with Asperger syndrome in grades 8 to 12 and to develop a clinical program that will provide evaluations and treatment services for children, adolescents, and adults with Asperger syndrome or related conditions.

*please see **Gift** on facing page*

When the Cheering Stops, Depression Often Sets In

After professional football players retire, the body battering they endured may stop, but many are then assaulted by depression, pain, and difficulty adjusting to a very different life.

BY DAVID MILNE

Retired professional football players experience levels of depression similar to those for the general U.S. population, but they also endure high levels of chronic pain that exacerbate their depression, suggests a recent study.

Results of the study, based on answers to the Patient Health Questionnaire's nine-item depression scale (PHQ-9) sent to 3,377 members of the NFL Players Association, Retired Players Section, are published in the April *Medicine and Science in Sports and Exercise*, the journal of the American College of Sports Medicine.

In addition to pain, participants were asked about nutrition, exercise, alcohol use, and smoking, as well as other health issues.

Nearly 15 percent of the 1,594 who responded reported moderate to severe depression, said Thomas Schwenk, M.D., the George A. Dean, M.D., chair and Professor of Family Medicine at the University of Michigan Health System and associate director of the U-M Depression Center.

"But almost half reported problems with pain, putting them at significant additional risk for depression and associated difficulties," he added.

Respondents were categorized as experiencing zero to mild depression (84.5 percent of respondents) or moderate to severe depression (14.7 percent). They were also categorized according to whether difficulty with pain was absent or only somewhat common (51.7 percent) versus quite or very common (47.6 percent).

Trouble sleeping, financial difficulties, marital or relationship problems, and problems with fitness, exercise, and aging were issues also frequently reported by the retired athletes. And all were strongly correlated with the presence of moderate to severe depression and with quite or very common difficulty with pain.

The same complaints were even more commonly reported by those who had both moderate to severe depression and quite or very common difficulty with pain, compared with those who had low scores in both these areas.

"In addition to the strong link between depression and pain, the relationship between these conditions and other issues also was notable," said co-author Eric Hipple, a retired Detroit Lions quarterback, now outreach coordinator for the U-M Depression Center.

He said that NFL retirees who had moderate to severe depression were 11 times more likely to report trouble sleeping than those not depressed or mildly depressed. Similarly, those with moderate-to-severe depression were nearly eight times more likely to report that they do not exercise and have experienced a loss of fitness and seven times more likely to report financial difficulties.

The authors considered PHQ-9 scores of 0-9 as indicating no to mild depression and scores of 10-27 moderate to severe depression.

Retired players who scored high on the pain measures also had more problems in these same areas.

The moderately to severely depressed retired players were much more likely to have problems with a lack of social support or friendships; with the use of prescription medication, alcohol, or other drugs; and trouble with the transition to life after football.

Many said they would feel weak or embarrassed if they asked for help with their health problems, which acted as a barrier to solving those problems. Many dealt with their health and other issues using spiritual means or by talking with family and friends. Other roadblocks to seeking professional help included a lack of insurance coverage and a lack of recognition that these problems were important.

"What our research tells us is that this population of retired professional athletes would benefit from a proactive educational and clinical outreach programs, possibly beginning even before retirement, as a way to help improve the likelihood that retired NFL players will achieve a high quality of life after football," Hipple told *Psychiatric News*. Schwenk noted that because of these factors and others, the shift from being a professional athlete to retired is a very challenging transition.

The authors recommended that future studies explore the hypothesis that the physical disabilities and chronic pain experienced by professional athletes cause significant difficulty with maintaining their fitness levels in retirement, thus placing them at higher risk for depression.

The study was supported in part by a grant from the National Football League Players Association.

An abstract of "Depression and Pain in Retired Professional Football Players" can be accessed at <www.ms-se.com> by searching the April issue contents and clicking on the article title. ■

Gift

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Geller told *Psychiatric News* that initially six to eight students will be recruited to enroll this fall in the launch of the program. She said that in addition to an innovative educational curricula, the program will provide specialized social, emotional, and learning support.

Institute staff will carry out its mission by collaborating with established world-class research scientists, as well as other NYU institutions.

More information about the Asperger Institute is posted at <www.aboutourkid.org/aboutus/programs/asperger.html>. ■

Stigma Can Arise From Surprising Sources

Bringing a person with schizophrenia into classrooms to talk with students might not only increase their openness to people with the illness, but prepare students for helping their peers who might be developing it.

BY JOAN AREHART-TREICHEL

Due to the stigma of mental illness that abounds in society, it is no surprise that many members of the general public want to keep their distance from individuals with schizophrenia. But perhaps less expectedly, relatives of individuals with the illness and mental health care workers may want to do so as well.

These findings emerged from a recent survey conducted in Austria. It was headed by W. Wolfgang Fleischhacker, M.D., chair of biological psychiatry at Medical University Innsbruck. Results were published in the April *Acta Psychiatrica Scandinavica*.

Fleischhacker and his coworkers wanted to learn more about how the general public, relatives of schizophrenia patients, and mental health personnel view social contact with individuals who have schizophrenia. They included in their study a nationally representative sample of some 1,000 Austrians; some 1,500 Austrian nonphysician mental health professionals, and about 400 Austrians who had relatives with schizophrenia. All three groups received the same structured questionnaire. Additional questions were posed according to the specific target group.

They found that mental health staff and relatives were generally more likely to accept contact with individuals with schizophrenia than the general public was. However, just as the general public was increasingly reluctant to have contact as it became more intimate, the same was essentially true of relatives and mental health staff. Specifically, all three groups were most open to having a person with schizophrenia as a neighbor, less open to having such an individual as an employee or family member, and the least open to having such a person care for their child. A recent Swiss inquiry produced similar results (*Psychiatric News*, November 17, 2006).

The reasons why the three groups wanted to maintain social distance as intimacy increased were, however, not always the same. For example, the major driving factor in all three groups was perceived dangerousness of people with schizophrenia. But members of the public who lived in rural areas, as well as those who believed that schizophrenia does not respond well to treatment, also tended to distance themselves from individuals with the illness. Furthermore, older relatives were more reluctant to make social contact than younger relatives. As for mental health personnel, those who were less educated were more averse to social contact than were those who were better educated.

These findings, the investigators believe, can help shape future antistigma programs. For example, because age and education seem to influence whether people are open to contact with those with schizophrenia, better education about schizophrenia, and especially better education directed at youth might be fruitful.

Also, as they pointed out, "Schizophrenia being a disorder that commonly befalls younger patients, better-informed students would not only have a better understanding for people with schizophrenia, but also a higher likelihood of detecting this disorder in early stages in their peers, thereby indirectly helping to improve overall outcomes."

In neighboring Germany, in fact, persons with schizophrenia are being brought into classrooms to talk with students, and the exposure has led to marked changes in attitude (*Psychiatric News*, August 15, 2003).

An abstract of "Patterns of Social Distance Towards People Suffering From Schizophrenia in Austria: A Comparison Between the General Public, Relatives, and Mental Health Staff" is posted at <www.blackwell-synergy.com/doi/abs/10.1111/j.1600-0447.2006.00882.x>. ■

Nominations Sought

Nominations are now being accepted for the 2008 APA/NIMH Vestermark Psychiatry Educator Award. APA and the National Institute of Mental Health (NIMH) have jointly sponsored this award since 1969. It is named for the late Seymour Vestermark, M.D., the first director of the NIMH Psychiatry Education Branch.

The award consists of a plaque and a $1,000 cash award. The winner will be invited to present a lecture on a topic related to psychiatric education at APA's 2008 annual meeting in Washington, D.C.

Nomination packets should include a letter or letters focusing on the nominee's contributions to psychiatric education and a current curriculum vitae. Nominees will be evaluated on the nature, scope, and quality of their educational contributions, activities, and leadership. The number and volume of supporting letters are not considered in selection.Nominations must be postmarked no later than August 1.

Nominations should be mailed to Vestermark Award Committee, c/o Nancy Delanoche, Office of Graduate and Undergraduate Education, APA, 1000 Wilson Boulevard, Suite 1825, Arlington, Va. 22209. ■

Dialogue, Not Propaganda

Thank you for publishing the article in the March 2 issue about the use of propaganda to create hatred of and violence toward "others." I have seen that kind of manipulative propaganda many times in the media, including network news programs. By disseminating news reports and photographic or video images that in effect portray these "others" as the enemy, the media are perpetuating hatred and justifying violence and war.

Despite some of the images shown on television that may have suggested otherwise, I know that most people throughout the world, including people in Arab countries, were shocked and saddened by the events of 9/11. Most Arabic people were empathic and sympathetic concerning the loss of lives. More recently, I saw news footage of American soldiers who, prior to their departure for the war in Iraq, were watching a clip of a video taken immediately after 9/11 of "some Arabs" who appeared to look happy about the terrorist attacks. Such reports only incite hatred and violence and validate and justify a war that is wounding or killing thousands of people on both sides and resulting in millions of Iraqi refugees living under horrendous circumstances.

We, as psychiatrists, have ethical, social, moral, and medical obligations to demand an end to the war in Iraq, as well as conflicts in other places. We, along with other mental health professionals, should encourage dialogue and compromise, as we do with our patients, to prevent more casualties and more mental illness. It is also our obligation to work toward ending the use of the media as a propaganda tool that spreads fear and violence.

As physicians, our major responsibility is to heal others, so why are we doing nothing to help stop the wars in Iraq and other places and put an end to the huge public health disasters they cause? It seems to me that we are abdicating our responsibilities as physicians.

YASSAR KANAWATI, M.D.
Marietta, Ga.

Hunt's On for Medicare Docs

A statement by Rep. Frank Pallone Jr. (D-N.J.) in an article in the April 6 issue—"While doctors don't seem to be refusing Medicare patients yet"—does not reflect reality. In the Atlanta area, I'm aware of a number of patients who are having a hard time finding private doctors willing to see them. I'm having to suggest that they go to facilities where doctors are employees. Several months ago I began to stop seeing new Medicare patients as reimbursement rates have been cut by over 14 percent. Medicare bureaucracy is getting worse. It is a strong negative reinforcer!

EDWARD NIX, M.D.
Atlanta, Ga.

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.

Omega-3s *Do* Offer Hope

The headline on the news article on the trial of omega-3 fatty acids in the April 6 issue was strikingly misleading. While the open-label trial found "some improvement in manic symptoms in children with bipolar illness," the headline proclaimed, "Latest Hope for Omega-3 Fatty Acids Shot Down for Child Bipolar Illness."

I'd say the quoted finding of a 30 percent reduction in the Young Mania Rating Scale scores in half the subjects is quite hopeful. The concern about "nonspecific study effects" is a concern in all research and shouldn't lead us to reject such a safe, sensible approach to a very difficult clinical challenge.

SUSAN M. EHRLICH, M.D.
Farmville, N.C.

APA Seeks Nominations for Human Rights Award

APA members are asked to submit nominations for APA's 2008 Human Rights Award. The award is conferred yearly on an individual and an organization whose efforts 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.

The recipients will receive a plaque at the Convocation of Fellows at APA's 2008 annual meeting.

APA's Council on Global Psychiatry will determine the recipients of the award.

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

APA's 100% Club Picks Up Another Member Program

The psychiatry residency training program at St. Luke's-Roosevelt Hospital Center in New York City 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 is 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.

Said Scott Masters, M.D., the director of the training program, "To be a resident in psychiatry and to not be a member of APA means missing out on the most important extra-residency learning opportunity available to trainees. I am proud that each of our 36 residents has become a member-in-training of APA and that many have become active as workshop and postor presenters at our national meetings. Our residents have quickly learned the value of meeting residents from other programs and practicing psychiatrists and researchers from around the nation at annual meetings and New York County District Branch events. Our residents have come to develop a professional identity that is deeper and more established than being just a member of a training program or department of psychiatry. St. Luke's-Roosevelt is proud to be the latest member of the 100% Club."

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. ■

First row, left to right: **Ronit Chernobelsky, M.D., Colette Haward, M.D., Abigail Herron, D.O., Doreen Zarfati, M.D., Elishka Caneva, M.D., Marc Epstein, D.O., Agnieszka Wisniewska, M.D., Richard Rosenthal, M.D. (psychiatry chair).** ***Second row, left to right:*** **Scott Masters, M.D. (training director), Clark Johnson, M.D., Jen Pula, M.D., Nieves Cuervo, M.D., Jayaraju Raju, M.D., Elissa Miller, M.D., Luminita Ciumpavu, M.D., Lisa Coram, D.O., Oana Guran, M.D., Nadya Friedman, M.D., Alexandru Serghi, M.D.** ***Third row, left to right:*** **Robert Milton, M.D., Gony Weiss, M.D., Katya Frischer, M.D., David Mysels, M.D., Tara Kerner, D.O., Isaac Nagel, M.D.** ***Back row, left to right:*** **John Cooke, M.D., Jelena Veselinovic, M.D., Ileana Benga, M.D., Chhewang Norsang, M.D., Krste Rodzevski, M.D., Jon Slaughter, M.D., Lidia Klepacz, M.D., Bachaar Arnaout, M.D. (Not photographed: Glenn Brottman, M.D., Virginia Corpuz, M.D., Gavin Friedman, M.D., Guitelle St. Victor Hamidan, M.D., Marty Newman, M.D.)**

Your Input Invited on Future Leaders

APA's Nominating Committee invites you to suggest candidates for nomination for national offices. Please fill out the form below and send it to APA **for receipt no later than July 24.**

These are my suggestions for candidates for national office:

President-elect _____

_____

Secretary-Treasurer _____

_____

Trustee-at-Large _____

_____

Return this form to **Pedro Ruiz, M.D.**
APA Nominating Committee
1000 Wilson Boulevard, #1825, Arlington, Va. 22209
Attention: Chanda Brooks

You may also submit your suggestions by fax to (703) 907-7852, by e-mail to cbrooks@psych.org, or online at <www.psych.org/members/gov/election2008/2008electionnominee.cfm>.

legal news

Pregnant Women

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tions and government agencies, according to Melonas.

Communication is another essential part of managing treatment in pregnant patients—not just between the treating psychiatrist and the patient's obstetrician, but between all clinicians on the treatment team, and of course between the psychiatrist and patient.

To help patients make an informed decision about whether to take a psychotropic medication during pregnancy, the psychiatrist should discuss the risks and benefits of the proposed treatment, alternatives to the proposed treatment, the risks and benefits of those alternatives, and the risks and benefits of doing nothing.

While helping patients make a decision about treatment, Melonas pointed out that psychiatrists should consider a number of variables that may impact the decision. For instance, how do patients' significant others view the treatment dilemma, and how do they communicate this to the patient? How are patients affected by media attention on the topic? Are patients competent to make a decision about treatment?

What psychiatrists want to avoid, Melonas said, is leaving patients with a great deal of scientific information about the risks and benefits of taking medication during pregnancy without helping them sort through the information and their feelings about treatment options.

Finally, psychiatrists must document in patients' charts the clinical basis for the agreed-upon treatment as well as all baseline laboratory testing results, a comprehensive medical history, and the results of physical exams required before medications were prescribed. Communications with patients, family members, and other physicians should also be documented.

More information about various risk management strategies is posted online at <www.prms.com>. ■

clinical & research news

Augmentation

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eral medical burden appeared to be associated with a longer time to recovery. Given the sample size, they did not break out response by the drugs used to augment treatment.

"Our findings show that the response to treatment and to augmentation among older people is at odds with the conventional thinking that assumes the young do better," said Dew. The study indicates the value of a wider range of options for treating this age cohort, she said.

"For older adults, we need a wider set of strategies for treating depression," said Dew. "Although many patients can't or won't take an additional drug, augmentation is one more possibility, like switching medications or using psychotherapy."

Dew and her colleagues are continuing research that compares switching medications with augmenting them.

The study was funded by the National Institute of Mental Health.

"Recovery From Major Depression in Older Adults Receiving Augmentation of Antidepressant Pharmacotherapy" is posted at <http://ajp.psychiatryonline.org/cgi/content/full/164/6/892>. ■

APA FELLOWS INDUCTED AT APA'S 2007 ANNUAL MEETING IN SAN DIEGO

The following APA members were inducted as fellows or distinguished fellows of APA for 2006, according to APA's Office of Membership. They were honored at the Convocation of Fellows at APA's 2007 annual meeting in San Diego. Criteria for becoming a fellow or distinguished fellow are posted in chapter 5 of APA's Operations Manual at <www.psych.org/members/download.cfm?file=196>.

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Depression

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ing kids with untreated depression at risk for suicide."

Libby is an assistant professor of psychiatry at the University of Colorado.

Using the PharMetrics Patient-Centric Database, Libby and her research team examined more than 60,000 paid claims for patients aged 5 to 18 who had been diagnosed with new episodes of depression between October 1998 and September 2005.

The database includes paid medical, specialty, facility, and pharmacy claims from more than 85 managed care plans and 4 million enrollees across the nation, according to the report.

The researchers traced the rates of depression diagnosis, antidepressant prescription patterns, and the use of psychotherapy and other treatments for pediatric enrollees with depression over the seven-year period.

Even Diagnostic Rates Dropped

Libby and her colleagues noted that the FDA first raised a red flag about antidepressants in October 2003 when it issued a public health advisory about a possible increased risk of both suicidal ideation and suicide attempts in children and adolescents taking antidepressants.

The researchers selected the 2003 advisory as the "policy action of interest," according to the report, and measured trends in diagnosis and antidepressant prescription in relation to the advisory's release.

The rate of new episodes of depression diagnosed among male and female enrollees steadily increased from 1998 to 2004. For instance, from 1999 to 2004, the rate of depression diagnoses increased from 3 to 5 per 1,000 youngsters, according to the report. By September 2005, however, the rate was back to 1999 levels, which was a "significant deviation from the historical trend."

After analyzing the findings by gender, the researchers found that the historical trend from 1999 to 2004 would have predicted that 3.8 per 1,000 boys be diagnosed with a new episode of depression; however, the observed rate in September 2005 was only 2.3 per 1,000 boys.

For girls, the predicted rate of new depression episodes was also higher than the actual rate: 3.5 per 1,000 girls had a new episode of depression in September 2005, whereas the predicted rate based on the historical trend was 6 per 1,000.

The researchers not only noted a drop in the number of new episodes of depression diagnosed among children and adolescents, but also discovered telling shifts in the types of providers diagnosing the new episodes. In the preadvisory period, nonpediatrician primary care physicians diagnosed about 24 percent of all new episodes of depression, while psychiatrists diagnosed more than 22 percent.

Researchers predicted that by September 2005, almost 40 percent of all new episodes of pediatric depression would be diagnosed by primary care doctors, but the actual figure was only about 27 percent. In contrast, psychiatrists diagnosed a higher percentage of episodes than was predicted—24.2 percent versus a predicted 20.4 percent.

The fact that primary care doctors diagnosed fewer new episodes of depression in children and adolescents than was predicted while psychiatrists diagnosed more cases may indicate that nonpsychiatrist physicians felt that specialty care was necessary after the FDA advisory, Libby speculated.

SSRI Fill Rates Fall Below Projections

During the preadvisory period, a little over 59 percent of the children and adolescents who had been diagnosed with depression filled a prescription for an SSRI within 30 days of being diagnosed, according to the report. In the postadvisory period, the average was 55 percent.

Based on preadvisory trends, Libby and her colleagues predicted that 67.4 percent of young enrollees with depression would fill prescriptions for SSRIs by September 2005, but found that only 28.6 percent did.

According to Robert Valuck, Ph.D., one of the report's co-authors and an associate professor of pharmacy at the University of Colorado, "we are looking at youth with a new diagnosis of depression, for which FDA-approved treatment exists with fluoxetine and for which clinical guidelines recommend pharmacologic treatment. So arguably, most of these youth should be receiving antidepressants."

The researchers then examined whether physicians were substituting other forms of treatment for antidepressants, but for the most part, the answer was no. For instance, average annual psychotherapy rates did not change significantly after the initial FDA advisory.

In the Phar-Metrics data, psychotherapy was counted if patients had at least one psychotherapy visit within 180 days of a diagnosis of depression and was not distinguished by type.

However, the findings did buck researchers' predictions based on regression analyses: by September 2005, the observed rate of psychotherapy received by depressed patients (40 percent) was significantly higher than preadvisory trends would have predicted.

"This measure indicates only that patients had at least one visit, and of course one visit does not equal an effective treatment program of psychotherapy," Libby noted.

Libby and Valuck said they would like to continue to follow diagnostic and antidepressant prescription rates to see if the downward trends continue or whether they turn around over time.

"The fact that we are seeing evidence of a large number of kids with untreated depression is troubling and suggests that they are left at risk for something we have the technology to treat," Libby said.

"This paper supports previous findings that the FDA black-box warning has had a significant impact on the diagnosis and treatment of depression in children and adolescents," Darrel Regier, M.D., M.P.H., told *Psychiatric News*.

Regier is director of the American Psychiatric Institute for Research and Education and APA's Division of Research.

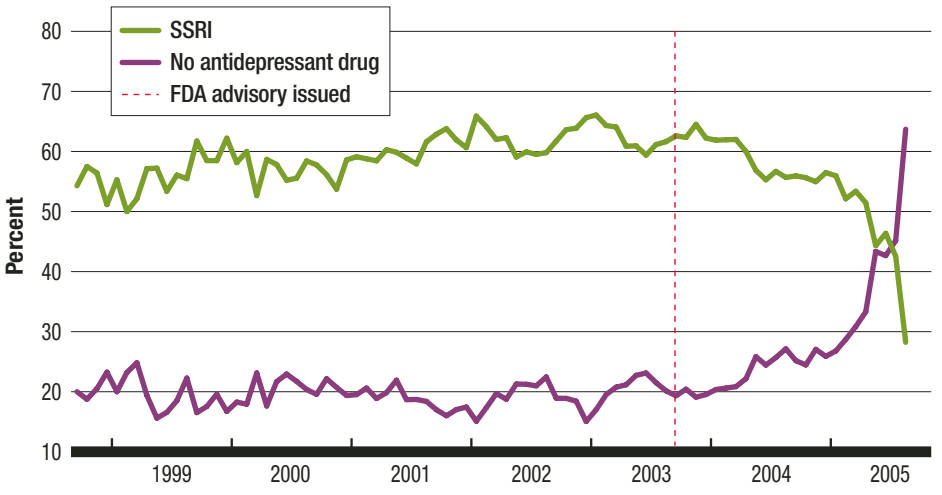
He also cited an article by Jeff Bridge, Ph.D., in the April 18 *Journal of the American Medical Association* indicating that the benefits of antidepressants for children and adolescents outweigh the risks of suicidal thoughts and attempts that have been associated with antidepressants.

When these findings are considered in the light of those by the federal Centers for Disease Control and Prevention and in other studies that "child and adolescent rates have increased in concert with declining depression diagnosis and treatment rates, the overall public health impact of the FDA warning needs to be re-evaluated," he said.

"Decline in Treatment of Pediatric Depression After FDA Advisory on Risk of Suicidality With SSRIs" is posted online at <ajp.psychiatryonline.org/cgi/content/abstract/164/6/884>. ■

SSRI Prescriptions Drop After 2003 Advisory

Researchers analyzed more than 60,000 paid claims for children and adolescents with a new episode of depression from the Phar-Metrics Patient-Centric Database. They found that the rate of enrollees with a new episode of depression who filled a prescription for an SSRI began a steady decline after a 2003 FDA advisory on the potential increased risk of suicidality with antidepressants. At the same time, the rate of enrollees with a new episode of depression who received no antidepressant rose.



Source: Anne Libby, Ph.D., et al., *American Journal of Psychiatry*, June 2007

association news

Assembly

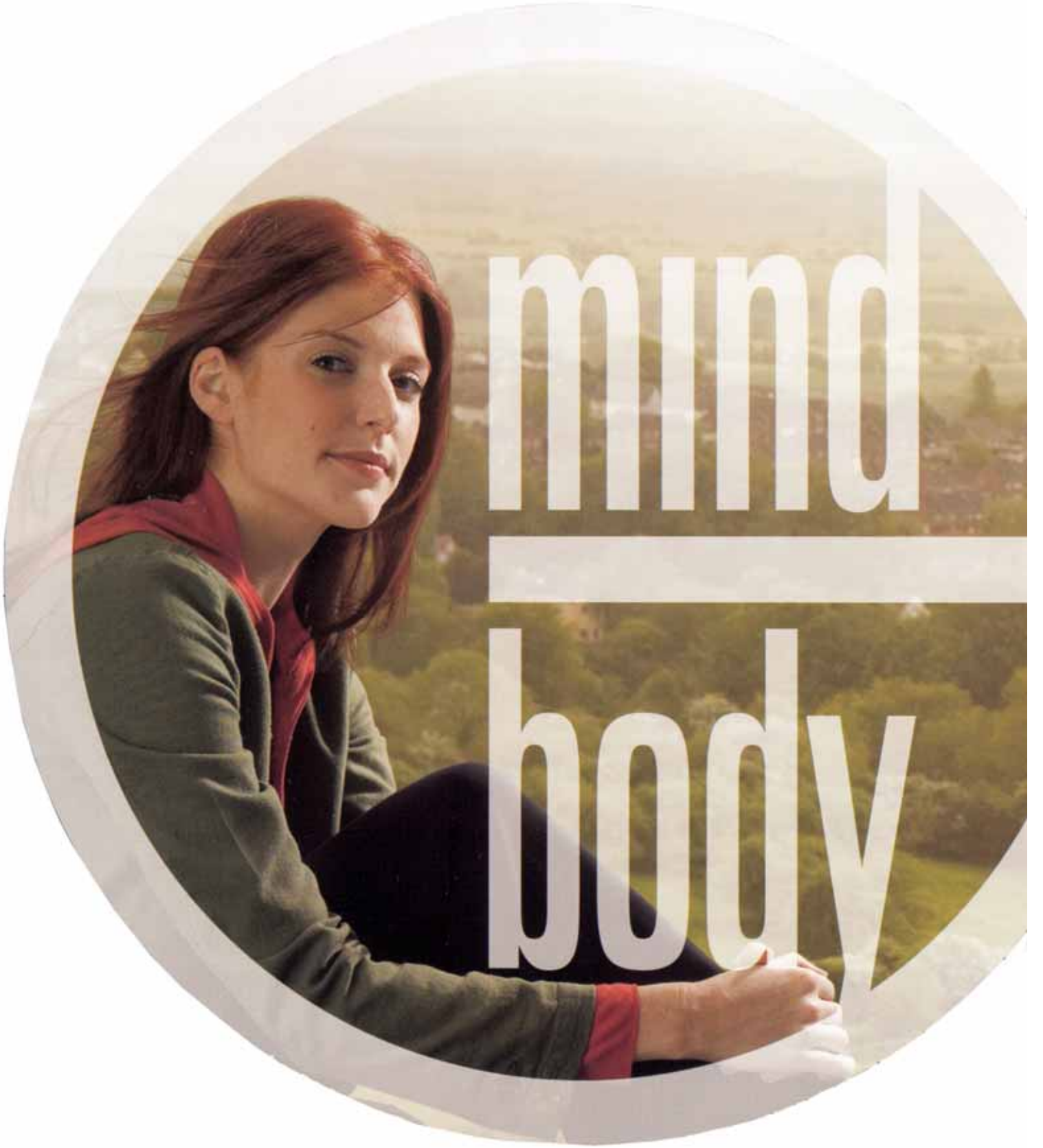
continued from page 11

David Shern, M.D., president and CEO of Mental Health America talked about the group's mission and decision to change its name from the National Mental Health Association (*Psychiatric News*, April 6).

AMA Board member William Hazel Jr., M.D., an orthopedic surgeon, expressed the AMA's solidarity with APA on scope-of-practice issues involving psychologists and asked Assembly members to lend their support to other medical specialists as they combat scope-of-practice expansions sought by other nonphysicians. He also lamented the disappearance of psychiatrists from the medical staffs of community hospitals and urged psychiatrists to be more involved in those settings. "We miss the collegiality," he said.

Finally, Prof. Sheila Hollins, president of the United Kingdom's Royal College of Psychiatrists, talked about the way England's National Health System deals with patients who have or may have a mental illness and changes that may soon reshape some facets of that system. ■

Because she does not like to compromise…

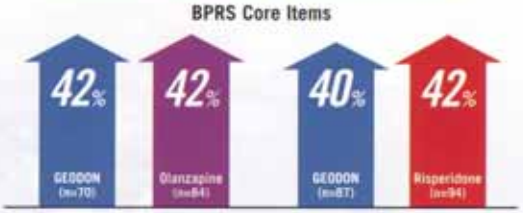

mind
body

IN SCHIZOPHRENIA

Treat With the Body in Mind

CHOOSE COMPARABLE POWER...

Consistent results in acute head-to-head studies[1-3]

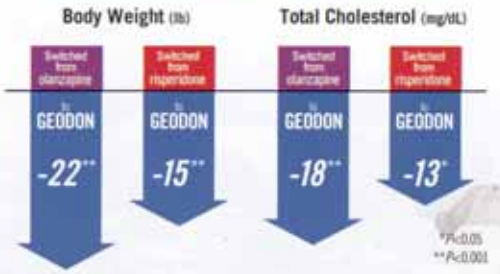


A 6-week, double-blind, randomized study of GEODON vs olanzapine and an 8-week, double-blind, randomized study of GEODON vs risperidone.

- BPRS core items include hallucinatory behavior, unusual thought content, conceptual disorganization, and suspiciousness
- Comparable efficacy was maintained in double-blind extension studies
  —up to 1 year vs risperidone[1]
  —up to 6 months vs olanzapine[4]

...WITHOUT COMPROMISING METABOLIC PARAMETERS

Significant results in switch studies after 1 year[1,5]



Two 1-year open-label extensions of 6-week, open-label switch studies in patients suboptimally controlled due to partial response or poor tolerability.

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

In the acute head-to-head studies...

- In the GEODON vs olanzapine study, olanzapine significantly increased body weight (8 lb vs 2 lb for GEODON, $P<0.0001$)[1,2]
- In the GEODON vs risperidone study, risperidone increased body weight (2 lb vs 0 lb for GEODON, $P<0.01$)[1,3]

GEODON is indicated for the treatment of schizophrenia.

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. GEODON is not approved for the treatment of patients with dementia-related psychosis.

GEODON is contraindicated in patients with a known history of QT prolongation, recent acute myocardial infarction, or uncompensated heart failure, and should not be used with other QT-prolonging drugs. GEODON has a greater capacity to prolong the QT_c interval than several antipsychotics. In some drugs, QT prolongation has been associated with torsade de pointes, a potentially fatal arrhythmia. In many cases this would lead to the conclusion that other drugs should be tried first.

Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON, and it is not known if GEODON is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia.

In short-term schizophrenia trials, 10% of GEODON-treated patients experienced a weight gain of ≥7% of body weight vs 4% for placebo. In the same short-term trials, the most common adverse events were somnolence (14%) and respiratory tract infection (8%).

Pfizer

CHOOSE GEODON®
(ziprasidone HCl) **Oral Capsules**

Please see brief summary of prescribing information, including boxed warning, on adjacent page.

BRIEF SUMMARY. See package insert for full prescribing information.

Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10 week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. GEODON (ziprasidone) is not approved for the treatment of patients with Dementia-Related Psychosis.

INDICATIONS—GEODON Capsules is indicated for the treatment of schizophrenia and acute manic or mixed episodes associated with bipolar disorder with or without psychotic features. GEODON® (ziprasidone mesylate) for Injection is indicated for acute agitation in schizophrenic patients.

CONTRAINDICATIONS — *QT Prolongation:* Because of GEODON's dose-related prolongation of the QT interval and the known association of fatal arrhythmias with QT prolongation by some other drugs, GEODON is contraindicated in patients with a known history of QT prolongation (including congenital long QT syndrome), with recent acute myocardial infarction, or with uncompensated heart failure (see **WARNINGS**). Pharmacokinetic/pharmacodynamic studies between GEODON and other drugs that prolong the QT interval have not been performed. An additive effect of GEODON and other drugs that prolong the QT interval cannot be excluded. Therefore, GEODON should not be given with dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol, or tacrolimus. GEODON is also contraindicated with drugs that have demonstrated QT prolongation as one of their pharmacodynamic effects and have this effect described in the full prescribing information as a contraindication or a boxed or bolded warning (see **WARNINGS**). GEODON is contraindicated in individuals with a known hypersensitivity to the product. **WARNINGS—Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. GEODON (ziprasidone) is not approved for the treatment of patients with dementia-related psychosis (see Boxed Warning). *QT Prolongation and Risk of Sudden Death:*** **GEODON use should be avoided in combination with other drugs that are known to prolong the QT_c interval. Additionally, clinicians should be alert to the identification of other drugs that have been consistently observed to prolong the QT_c interval. Such drugs should not be prescribed with GEODON. A study directly comparing the QT/QT_c-prolonging effect of GEODON with several other drugs effective in the treatment of schizophrenia was conducted in patient volunteers. The mean increase in QT_c from baseline for GEODON ranged from approximately 9 to 14 msec greater than for four of the comparator drugs (risperidone, olanzapine, quetiapine, and haloperidol), but was approximately 14 msec less than the prolongation observed for thioridazine. In this study, the effect of GEODON on QT_c length was not augmented by the presence of a metabolic inhibitor (ketoconazole 200 mg bid). In placebo-controlled trials, GEODON increased the QT_c interval compared to placebo by approximately 10 msec at the highest recommended daily dose of 160 mg. In clinical trials the electrocardiograms of 2/2988 (0.06%) GEODON patients and 1/440 (0.23%) placebo patients revealed QT_c intervals exceeding the potentially clinically relevant threshold of 500 msec. In the GEODON patients, neither case suggested a role of GEODON. Some drugs that prolong the QT/QT_c interval have been associated with the occurrence of torsade de pointes and with sudden unexplained death. The relationship of QT prolongation to torsade de pointes is clearest for larger increases (20 msec and greater) but it is possible that smaller QT/QT_c prolongations may also increase risk, or increase it in susceptible individuals, such as those with hypokalemia, hypomagnesemia, or genetic predisposition. Although torsade de pointes has not been observed in association with the use of GEODON at recommended doses in premarketing studies, experience is too limited to rule out an increased risk. A study evaluating the QT/QT_c prolonging effect of intramuscular GEODON, with intramuscular haloperidol as a control, was conducted in patient volunteers. In the trial, ECGs were obtained at the time of maximum plasma concentration following two injections of GEODON (20 mg then 30 mg) or haloperidol (7.5 mg then 10 mg) given four hours apart. Note that a 30 mg dose of intramuscular GEODON is 50% higher than the recommended therapeutic dose. The mean change in QT_c from baseline was calculated for each drug using a sample-based correction that removes the effect of heart rate on the QT interval. The mean increase in QT_c from baseline for GEODON was 4.6 msec following the first injection and 12.8 msec following the second injection. The mean increase in QT_c from baseline for haloperidol was 6.0 msec following the first injection and 14.7 msec following the second injection. In this study, no patient had a QT_c interval exceeding 500 msec. As with other antipsychotic drugs and placebo, sudden unexplained deaths have been reported in patients taking GEODON at recommended doses. The premarketing experience for GEODON did not reveal an excess of mortality for GEODON compared to other antipsychotic drugs or placebo, but the extent of exposure was limited, especially for the drugs used as active controls and placebo. Nevertheless, GEODON's larger prolongation of QT_c length compared to several other antipsychotic drugs raises the possibility that the risk of sudden death may be greater for GEODON than for other available drugs for treating schizophrenia. This possibility needs to be considered in deciding among alternative drug products. Certain circumstances may increase the risk of the occurrence of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QT_c interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QT_c interval; and (4) presence of congenital prolongation of the QT interval. GEODON should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias (see CONTRAINDICATIONS, and see *Drug Interactions* under PRECAUTIONS). It is recommended that patients being considered for GEODON treatment who are at risk for significant electrolyte disturbances, hypokalemia in particular, have baseline serum potassium and magnesium measurements. Hypokalemia (and/or hypomagnesemia) may increase the risk of QT prolongation and arrhythmia. Hypokalemia may result from diuretic therapy, diarrhea, and other causes. Patients with low serum potassium and/or magnesium should be repleted with those electrolytes before proceeding with treatment. It is essential to periodically monitor serum electrolytes in patients for whom diuretic therapy is introduced during GEODON treatment. Persistently prolonged QT_c intervals may also increase the risk of further prolongation and arrhythmia, but it is not clear that routine screening ECG measures are effective in detecting such patients. Rather, GEODON should be avoided in patients with histories of significant cardiovascular illness, eg, QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. GEODON should be discontinued in patients who are found to have persistent QT_c measurements >500 msec. *Neuroleptic Malignant Syndrome (NMS):*** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported. ***Tardive Dyskinesia (TD):*** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients undergoing treatment with antipsychotic drugs. Although the prevalence of TD appears to be higher among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop TD. If signs and symptoms of TD appear in a patient on GEODON, drug discontinuation should be considered. ***Hyperglycemia and Diabetes Mellitus:*** Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON, and it is not known if GEODON is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia. **PRECAUTIONS — *General:*** Rash: In premarketing trials, about 5% of GEODON patients developed rash and/or urticaria, with discontinuation of treatment in about one-sixth of these cases. The occurrence of rash was dose related, although the finding might also be explained by longer exposure in higher-dose patients. Several patients with rash had signs and symptoms of associated systemic illness, e.g., elevated WBCs. Most patients improved promptly upon treatment with antihistamines or steroids and/or upon discontinuation of GEODON, and all patients were reported to recover completely. Upon appearance of rash for which an alternative etiology cannot be identified, GEODON should be discontinued. Orthostatic Hypotension: GEODON may induce orthostatic hypotension associated with dizziness, tachycardia, and, in some patients, syncope, especially during the initial dose-titration period, probably reflecting its α_1-adrenergic antagonist properties. Syncope was reported in 0.6% of GEODON patients. GEODON should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Seizures: In clinical trials, seizures occurred in 0.4% of GEODON patients. There were confounding factors that may have contributed to seizures in many of these cases. As with other antipsychotic drugs, GEODON should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older. Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia, and GEODON and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. **(See also Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis).** Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, GEODON elevates prolactin levels in humans. Tissue culture experiments indicate that approximately one third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time. Potential for Cognitive and Motor Impairment: Somnolence was a commonly reported adverse event in GEODON patients. In the 4- and 6-week placebo-controlled trials, somnolence was reported in 14% of GEODON patients vs 7% of placebo patients. Somnolence led to discontinuation in 0.3% of patients in short-term clinical trials. Since GEODON has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about performing activities requiring mental alertness, such as operating a motor vehicle (including automobiles) or operating hazardous machinery until they are reasonably certain that GEODON therapy does not affect them adversely. Priapism: One case of priapism was reported in the premarketing database. Body Temperature Regulation: Although not reported with GEODON in premarketing trials, disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Suicide: The possibility of a suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. GEODON prescriptions should be written for the smallest quantity of capsules consistent with good patient management to reduce overdose risk. Use in Patients with Concomitant Illness: Clinical experience with GEODON in patients with certain concomitant systemic illnesses is limited. GEODON has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies. Because of the risk of QT_c prolongation and orthostatic hypotension with GEODON, caution should be observed in cardiac patients (see ***QT Prolongation and Risk of Sudden Death*** in **WARNINGS** and Orthostatic Hypotension in **PRECAUTIONS**). ***Information for Patients:*** To ensure safe and effective use of GEODON, the information and instructions in the *Patient Information Section* should be discussed with patients. ***Laboratory Tests:*** Patients being considered for GEODON treatment who are at risk of significant electrolyte disturbances should have baseline serum potassium and magnesium measurements. Low serum potassium and magnesium should be repleted before treatment. Patients who are started on diuretics during GEODON therapy need periodic monitoring of serum potassium and magnesium. Discontinue GEODON in patients who are found to have persistent QT_c measurements >500 msec (see **WARNINGS**). ***Drug Interactions:*** (1) GEODON should not be used with any drug that prolongs the QT interval. (2) Given the primary CNS effects of GEODON, caution should be used when it is taken in combination with other centrally acting drugs. (3) Because of its potential for inducing hypotension, GEODON may enhance the effects of certain antihypertensive agents. (4) GEODON may antagonize the effects of levodopa and dopamine agonists. Effect of Other Drugs on GEODON: *Carbamazepine*, 200 mg bid for 21 days, resulted in a decrease of approximately 35% in the AUC of GEODON. *Ketoconazole*, a potent inhibitor of CYP3A4, 400 mg qd for 5 days, increased the AUC and C_{max} of GEODON by about 35%-40%. *Cimetidine*, 800 mg qd for 2 days, did not affect GEODON pharmacokinetics. Coadministration of 30 mL of *Maalox* did not affect GEODON pharmacokinetics. Population pharmacokinetic analysis of schizophrenic patients in controlled clinical trials has not revealed any clinically significant pharmacokinetic interactions with benztropine, propranolol, or lorazepam. Effect of GEODON on Other Drugs: In vitro studies revealed little potential for GEODON to interfere with the metabolism of drugs cleared primarily by CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4, and little potential for drug interactions with GEODON due to displacement. GEODON 40 mg bid administered concomitantly with *lithium* 450 mg bid for 7 days did not affect the steady-state level or renal clearance of lithium. GEODON 20 mg bid did not affect the pharmacokinetics of concomitantly administered *oral contraceptives*, ethinyl estradiol (0.03 mg) and levonorgestrel (0.15 mg). Consistent with in vitro results, a study in normal healthy volunteers showed that GEODON did not alter the metabolism of *dextromethorphan*, a CYP2D6 model substrate, to its major metabolite, dextrorphan. There was no statistically significant change in the urinary dextromethorphan/dextrorphan ratio. ***Carcinogenesis, Mutagenesis, Impairment of Fertility:*** Lifetime carcinogenicity studies were conducted with GEODON in Long Evans rats and CD-1 mice. In male mice, there was no increase in incidence of tumors relative to controls. In female mice there were dose-related increases in the incidences of pituitary gland adenoma and carcinoma, and mammary gland adenocarcinoma at all doses tested. Increases in serum prolactin were observed in a 1-month dietary study in female, but not male, mice. GEODON had no effect on serum zprolactin in rats in a 5-week dietary study at the doses that were used in the carcinogenicity study. The relevance for human risk of the findings of prolactin-mediated endocrine tumors in rodents is unknown (see Hyperprolactinemia). Mutagenesis: There was a reproducible mutagenic response in the Ames assay in one strain of *S. typhimurium* in the absence of metabolic activation. Positive results were obtained in both the in vitro mammalian cell gene mutation assay and the in vitro chromosomal aberration assay in human lymphocytes. Impairment of Fertility: GEODON increased time to copulation in Sprague-Dawley rats in two fertility and early embryonic development studies at doses of 10 to 160 mg/kg/day (0.5 to 8 times the MRHD of 200 mg/day on a mg/m² basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m² basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m² basis). The fertility of female rats was reduced. ***Pregnancy—Pregnancy Category C:*** There are no adequate and well-controlled studies in pregnant women. GEODON should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. ***Labor and Delivery:*** The effect of GEODON on labor and delivery in humans is unknown. ***Nursing Mothers:*** It is not known whether, and if so in what amount, GEODON or its metabolites are excreted in human milk. It is recommended that women receiving GEODON should not breast feed. ***Pediatric Use:*** The safety and effectiveness of GEODON in pediatric patients have not been established. ***Geriatric Use:*** Of the approximately 4500 patients treated with GEODON in clinical studies, 2.4% (109) were 65 years of age or over. In general, there was no indication of any different tolerability for GEODON or of reduced clearance of GEODON in the elderly compared to younger adults. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to GEODON, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients. **ADVERSE REACTIONS — *Adverse Findings Observed in Short-term, Placebo-Controlled Trials:*** The following findings are based on the short-term placebo-controlled premarketing trials for schizophrenia (a pool of two 6-week, and two 4-week fixed-dose trials) and bipolar mania (a pool of two 3-week flexible-dose trials) in which GEODON was administered in doses ranging from 10 to 200 mg/day. ***Adverse Events Associated with Discontinuation:*** Schizophrenia: Approximately 4.1% (29/702) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 2.2% (6/273) on placebo. The most common event associated with dropout was rash, including 7 dropouts for rash among GEODON patients (1%) compared to no placebo patients (see **PRECAUTIONS**). Bipolar Mania: Approximately 6.5% (18/279) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 3.7% (5/136) on placebo. The most common events associated with dropout in the GEODON-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash and vomiting, with 2 dropouts for each of these events among GEODON patients (1%) compared to one placebo patient each for dystonia and rash (1%) and no placebo patients for the remaining adverse events. ***Adverse Events at an Incidence ≥5% and at Least Twice the Rate of Placebo:*** The most commonly observed adverse events associated with GEODON in schizophrenia trials were somnolence (14%) and respiratory tract infection (8%). The most commonly observed adverse events associated with the use of GEODON in bipolar mania trials were somnolence (31%), extrapyramidal symptoms (31%), dizziness (16%), akathisia (10%), abnormal vision (6%), asthenia (6%), and vomiting (5%). The following list enumerates the treatment-emergent adverse events that occurred during acute therapy, including only those events that occurred in 2% of GEODON patients and at a greater incidence than in placebo. Schizophrenia: Body as a Whole—asthenia, accidental injury, chest pain. Cardiovascular—tachycardia. Digestive—nausea, constipation, dyspepsia, diarrhea, dry mouth, anorexia. Nervous—extrapyramidal symptoms, somnolence, akathisia, dizziness. Respiratory—respiratory tract infection, rhinitis, cough increased. Skin and Appendages—rash, fungal dermatitis. Special Senses—abnormal vision. Bipolar Mania: Body as a Whole—headache, asthenia, accidental injury. Cardiovascular—hypertension. Digestive—nausea, diarrhea, dry mouth, vomiting, increased salivation, tongue edema, dysphagia. Musculoskeletal—myalgia. Nervous—somnolence, extrapyramidal symptoms, dizziness, akathisia, anxiety, hypesthesia, speech disorder. Respiratory—pharyngitis, dyspnea. Skin and Appendages—fungal dermatitis. Special Senses—abnormal vision. ***Dose Dependency:*** An analysis for dose response in the schizophrenia trials revealed an apparent relation of adverse event to dose for the following: asthenia, postural hypotension, anorexia, dry mouth, increased salivation, arthralgia, anxiety, dizziness, dystonia, hypertonia, somnolence, tremor, rhinitis, rash, and abnormal vision. ***Extrapyramidal Symptoms (EPS):*** The incidence of reported EPS for GEODON patients in the short-term, placebo-controlled schizophrenia trials was 14% vs 8% for placebo. Objectively collected data from those trials on the Simpson-Angus Rating Scale and the Barnes Akathisia Scale did not generally show a difference between GEODON and placebo. ***Vital Sign Changes:*** GEODON is associated with orthostatic hypotension (see **PRECAUTIONS**). ***Weight Gain:*** In short-term schizophrenia trials, the proportions of patients meeting a weight gain criterion of ≥7% of body weight were compared, revealing a statistically significantly greater incidence of weight gain for GEODON patients (10%) vs placebo patients (4%). A median weight gain of 0.5 kg was observed in GEODON patients vs 0.0 kg in placebo patients. Weight gain was reported as an adverse event in 0.4% of both GEODON and placebo patients. During long-term therapy with GEODON, a categorization of patients at baseline on the basis of body mass index (BMI) showed the greatest mean weight gain and the highest incidence of clinically significant weight gain (>7% of body weight) in patients with a low BMI (<23) compared to normal (23-27) or overweight (>27) patients. There was a mean weight gain of 1.4 kg for patients with a "low" baseline BMI, 0.0 kg for patients with a "normal" BMI, and a 1.3 kg mean weight loss for patients with a "high" BMI. ***ECG Changes:*** GEODON is associated with an increase in the QT_c interval (see **WARNINGS**). In schizophrenia trials, GEODON was associated with a mean increase in heart rate of 1.4 beats per minute compared to a 0.2 beats per minute decrease among placebo patients. ***Other Adverse Events Observed During the Premarketing Evaluation of GEODON:*** Frequent adverse events are those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. Schizophrenia: Body as a Whole—*Frequent:* abdominal pain, flu syndrome, fever, accidental fall, face edema, chills, photosensitivity reaction, flank pain, hypothermia, motor vehicle accident. Cardiovascular System—*Frequent:* tachycardia, hypertension, postural hypotension; *Infrequent:* bradycardia, angina pectoris, atrial fibrillation; *Rare:* first-degree AV block, bundle branch block, phlebitis, pulmonary embolus, cardiomegaly, cerebral infarct, cerebrovascular accident, deep thrombophlebitis, myocarditis, thrombophlebitis. Digestive System—*Frequent:* anorexia, vomiting; *Infrequent:* rectal hemorrhage, dysphagia, tongue edema; *Rare:* gum hemorrhage, jaundice, fecal impaction, gamma glutamyl transpeptidase increased, hematemesis, cholestatic jaundice, hepatitis, hepatomegaly, leukoplakia of mouth, fatty liver deposit, melena. Endocrine—*Rare:* hypothyroidism, hyperthyroidism, thyroiditis. Hemic and Lymphatic System—*Infrequent:* anemia, ecchymosis, leukocytosis, leukopenia, eosinophilia, lymphadenopathy; *Rare:* thrombocytopenia, hypochromic anemia, lymphocytosis, monocytosis, basophilia, lymphedema, polycythemia, thrombocythemia. Metabolic and Nutritional Disorders—*Infrequent:* thirst, transaminase increased, peripheral edema, hyperglycemia, creatine phosphokinase increased, alkaline phosphatase increased, hypercholesteremia, dehydration, lactic dehydrogenase increased, albuminuria, hypokalemia; *Rare:* BUN increased, creatinine increased, hyperlipemia, hypocholesteremia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hyperchloremia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. Musculoskeletal System—*Frequent:* myalgia; *Infrequent:* tenosynovitis; *Rare:* myopathy. Nervous System—*Frequent:* agitation, extrapyramidal syndrome, tremor, dystonia, hypertonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, hypesthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, buccoglossal syndrome, choreoathetosis, diplopia, incoordination, neuropathy; *Infrequent:* paralysis; *Rare:* myoclonus, nystagmus, torticollis, circumoral paresthesia, opisthotonos, reflexes increased, trismus. Respiratory System—*Frequent:* dyspnea; *Infrequent:* pneumonia, epistaxis; *Rare:* hemoptysis, laryngismus. Skin and Appendages—*Infrequent:* maculopapular rash, urticaria, alopecia, eczema, exfoliative dermatitis, contact dermatitis, vesiculobullous rash. Special Senses—*Frequent:* fungal dermatitis; *Infrequent:* conjunctivitis, dry eyes, tinnitus, blepharitis, cataract, photophobia; *Rare:* eye hemorrhage, visual field defect, keratitis, keratoconjunctivitis. Urogenital System—*Infrequent:* impotence, abnormal ejaculation, amenorrhea, hematuria, menorrhagia, female lactation, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; *Rare:* gynecomastia, vaginal hemorrhage, nocturia, oliguria, female sexual dysfunction, uterine hemorrhage. **Adverse Finding Observed in Trials of Intramuscular GEODON:** In these studies, the most commonly observed adverse events associated with the use of intramuscular GEODON (≥5%) and observed at a rate on intramuscular GEODON (in the higher dose groups) at least twice that of the lowest intramuscular GEODON group were headache (13%), nausea (12%), and somnolence (20%). **Adverse Events at an Incidence >1% in Short-Term Fixed-Dose Intramuscular Trials:** The following list enumerates the treatment-emergent adverse events that occurred in ≥1% of GEODON patients (in the higher dose groups) and at least twice that of the lowest intramuscular GEODON group. Body as a Whole—headache, injection site pain, asthenia, abdominal pain, flu syndrome, back pain. Cardiovascular—postural hypotension, hypertension, bradycardia, vasodilation. Digestive—nausea, rectal hemorrhage, diarrhea, vomiting, dyspepsia, anorexia, constipation, tooth disorder, dry mouth. Nervous—dizziness, anxiety, insomnia, somnolence, akathisia, agitation, extrapyramidal syndrome, hypertonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. Respiratory—rhinitis. Skin and Appendages—furunculosis, sweating. Urogenital—dysmenorrhea, priapism. **DRUG ABUSE AND DEPENDENCE — *Controlled Substance Class:*** GEODON is not a controlled substance. **OVERDOSAGE** — In premarketing trials in over 5400 patients, accidental or intentional overdosage of GEODON was documented in 10 patients. All patients survived without sequelae. In the patient taking the largest confirmed amount (3240 mg), the only symptoms reported were minimal sedation, slurring of speech, and transitory hypertension (BP 200/95).

References: 1. Data on file. Pfizer Inc, New York, NY. **2.** Simpson GM, Glick ID, Weiden PJ, Romano SJ, Siu CO. Randomized, controlled, double-blind multicenter comparison of the efficacy and tolerability of ziprasidone and olanzapine in acutely ill inpatients with schizophrenia or schizoaffective disorder. *Am J Psychiatry.* 2004;161:1837-1847. **3.** Addington DEN, Pantelis C, Dineen M, Benattia I, Romano SJ. Efficacy and tolerability of ziprasidone versus risperidone in patients with acute exacerbation of schizophrenia or schizoaffective disorder: an 8-week, double-blind, multicenter trial. *J Clin Psychiatry.* 2004;65:1624-1633. **4.** Simpson GM, Weiden P, Pigott T, Murray S, Siu CO, Romano SJ. Six-month, blinded, multicenter continuation study of ziprasidone versus olanzapine in schizophrenia. *Am J Psychiatry.* 2005;162:1535-1538. **5.** Weiden PJ, Loebel A, Yang R, Lebovitz H. Course of weight & metabolic benefits 1 year after switching to ziprasidone. Presented at: American Psychiatric Association Annual Meeting; May 1-6, 2004; New York, NY.

Revised November 2006

Opportunities with McLean Hospital -

Psychiatrist

McLean Hospital is inviting applications for the position of Psychiatrist in charge in our geriatric psychiatry program. This a 0.75 FTE position with opportunities to add additional duties for a 1.0 FTE. Duties will include the provision of direct clinical services to 9 inpatients. Some additional paid vacation coverage and weekend rounding are included. Participation in the service's educational activities and program development are expected.

Applicants must have an M.D. and board certification in Psychiatry with added qualifications in Geriatric Psychiatry, and must be eligible for licensure in the Commonwealth of MA. The ideal candidate should have knowledge and expertise in geriatric psychiatric disorders, managed care experience in the delivery of psychiatric services, and one year or more of post-training clinical and/or clinical research experience. Qualified women and minority candidates are encouraged to apply.

Salary, recruitment package, and academic rank will be commensurate with qualifications and experience.

Applicants should submit a curriculum vitae along with the names and addresses of three references to the Search Committee Chair:

James Ellison, M.D., M.P.H.
Clinical Director, Geriatric Psychiatry Program
McLean Hospital
115 Mill Street
Belmont, MA 02478

Review of applications will begin immediately and continue until the position is filled.

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PSYCHIATRIST

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 a BE/BC psychiatrist. 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. This is a full time faculty position 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. Position will remain 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

West Virginia University is an affirmative action/equal opportunity employer.

New Hampshire Hospital Medical Director

DARTMOUTH MEDICAL SCHOOL. The Department of Psychiatry is seeking a senior faculty member to serve as Medical Director of New Hampshire Hospital, in Concord, NH.

New Hampshire Hospital (NHH) provides acute and chronic hospital services for citizens of New Hampshire. The hospital first opened in 1842; its 230 acute care beds are housed in a beautiful 17 year-old facility. Through a longstanding successful collaboration between the State of New Hampshire and the Department of Psychiatry at Dartmouth, the hospital provides outstanding clinical services, is a sought-after teaching and training site, and has partnered with research groups to improve targeted aspects of care and to build new knowledge.

The NHH Medical Director will serve as the chief clinical officer of New Hampshire Hospital. The NHH Medical Director is part of the Senior Leadership of the Department of Psychiatry and will work closely with the Chair to lead the Department and to further extend the established state-academic partnership. The role will include supporting and facilitating excellent clinical care, supporting New Hampshire Hospital's function as an outstanding teaching and training site, and facilitating research activities that serve the mission of both New Hampshire Hospital and the Department.

The ideal candidate will have a passion for public sector care, a patient-centered clinical orientation, excellent clinical leadership skills, sound interpersonal skills, administrative experience, and a strong academic background. The candidate must be a board certified psychiatrist.

Curriculum vitae and three letters of reference should be sent to:

Alan I. Green, M.D., Raymond Sobel Professor and Chairman
Department of Psychiatry, Dartmouth-Hitchcock Medical Center
1 Medical Center Drive, Lebanon, NH 03756

Dartmouth College is an Equal Opportunity/Affirmative Action Employer and encourages applications from women and members of minority groups.

DON'T MISS OUT!! JOIN THE CURRENT EXPANSION!!

The VA Medical Center, Marion, IL is seeking full and part-time, Board certified Psychiatrists to join our rapidly expanding multidisciplinary Behavioral Medicine Team. Positions provide treatment to an adult psychiatric population with diverse diagnoses including Major Affective Disorders, Psychotic Disorders, PTSD and Substance Use Disorders. Incumbent is supported by well-qualified administrative staff, addiction therapists and clinical therapists. Programs include: PTSD Clinical Team, Mental Health Intensive Case Management (ACT), Mental Health in Primary Care, Compensated Work Therapy, and Substance Use Disorders.

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Call or submit CV to:
VA Medical Center
Attn: Human Resources
2401 West Main Street
Marion, Illinois 62959
Phone: 618-993-4128/Fax: 618-993-4148

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ALBUQUERQUE, NM

PHS is New Mexico's largest private, non-profit integrated healthcare system. The Behavior Medicine Program is a full-service psychiatry department with 2 adult and 1 child/adolescent inpatient units, a multidisciplinary outpatient department, intensive outpatient treatment, emergency and consultative programs.

We have an opening for an adult or geriatric psychiatrist who is interested in varied professional life including inpatient, outpatient and emergency/consultative care.

This is a full time employed position with the 500+ provider Presbyterian Medical Group. Competitive salary and benefit package, includes malpractice insurance and relocation allowance.

Additional information about PHS may be found at www.PHS.org

For MD benefits info click on tab for ´Careers´ and then from the left drop down menu under ´Careers´ choose ´Physicians´ and then ´Physician Benefits´.

Contact: Kay Kernaghan, Physician Recruiter, PHS at kkernagh@phs.org or 1-866-757-5263.

PRESBYTERIAN

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Seeking psychiatrists to join a progressive team of community mental health center professionals. Both positions are 100% out-patient with no required on-call, evenings or weekends. Excellent benefit package including generous leave time, health, dental, vision, life, disability, malpractice insurance and retirement plan. National Health Services Corps loan repayment or J-1 Visa placement possible.

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Send resume and letter of interest to:

Dr. George P. Weigly, CEO
Tri-County Mental Health &
Counseling Services, Inc.
90 Hospital Drive, Athens, Ohio 45701
or call 740-594-5045

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The Department of Psychiatry at Dartmouth Medical School is conducting a national search for two academic Child and Adolescent Psychiatrists at the Assistant or Associate Professor level. The successful candidates will oversee multidisciplinary diagnostic, evaluation and medication clinics, supervise general residents and advanced trainees in Child and Adolescent Psychiatry, and develop research interests within areas consistent with the mission of the section, including but not limited to: ADHD, PTSD, and Autism Spectrum Disorders.

Ideal candidates will have a strong interest in general child and adolescent psychiatry. One position involves greater participation in residency training which will transition over 3 years to assume responsibility for directing the child and adolescent residency training program. Graduates of triple board programs are desirable but not a necessary condition of employment.

Dartmouth-Hitchcock Medical Center is a 347 bed tertiary care academic medical center and a leading research and clinical referral resource in northern New England. Dartmouth is located in the Upper Valley area of New Hampshire/Vermont, 2 hours north of Boston. The child and adolescent program currently includes 5 child and adolescent psychiatrists, two doctoral level child psychologists, a child neuro-psychologist and one Masters level therapist. Outpatient and Consultation-Liaison services are provided for the full range of child and adolescent disorders at the main hospital campus. Inpatient services are provided at the Philbrook Center in Concord, New Hampshire at the New Hampshire State Hospital. Board eligibility followed by certification is an expectation of employment.

The Department of Psychiatry offers an attractive salary and comprehensive benefits package. We have a beautiful, state of the art facility situated in a wonderful rural area with many recreational opportunities, high quality schools and an excellent quality of life.

Please send letter of interest, curriculum vitae and 3 letters of reference to:

Craig Donnelly, MD
Chair, Search Committee
DHPA
One Medical Center Drive
Lebanon, NH 03756
Craig.L.Donnelly@hitchcock.org

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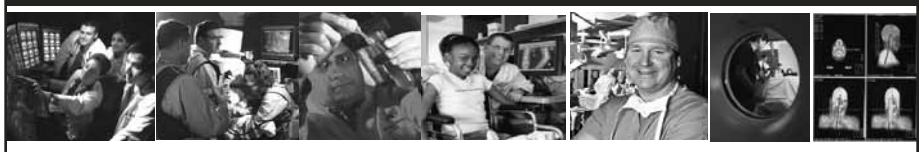

Adult and Child and Adolescent Psychiatrists & Psychologists
Scott & White/Texas A&M College of Medicine
Temple and College Station Clinics

The Department of Psychiatry at Scott & White and Texas A&M College of Medicine is seeking outstanding candidates to join our nationally recognized Department of Psychiatry. Currently, we have openings for **Adult Psychiatrists** and **Child and Adolescent Psychologists** at our College Station Clinic. In addition, the department is seeking additional **Child and Adolescent Psychiatrists** for openings at our main facility in Temple. These positions will include clinical care, teaching of medical students and residents, and working within a group practice model. Candidates with solid clinical training, as well as interest and experience in behavioral medicine are preferred. Our department in Temple includes 12 full time Psychiatrists, 4 Psychologists and multiple allied health professionals providing clinical care to the majority of insured residents in Central Texas and the North Austin area. The division in College Station includes 2 full time Psychiatrists and 4 full-time Psychologists, offering a wide variety of preclinical and clinical teaching opportunities as the College of Medicine expands its campus in College Station. We are a full service Psychiatric Department with specialty clinics and programs. We have a diverse faculty with a close sense of collegiality.

Scott & White is the largest multi-specialty practice in Texas, with more than 530 physicians and research scientists who care for patients at Scott & White Memorial Hospital in Temple and within the 15 regional clinic system networked throughout Central Texas. The College Station clinic is the largest of the regional clinics, with more than 80 physicians from all specialties networked to the main campus and hospital in Temple. Over $250 million in expansions are currently underway, including two new hospitals and three regional clinics. Led by physicians with a commitment to patient care, education and research, Scott & White is listed among the "Top 100 Hospitals" in America and serves as the clinical educational site for The Texas A&M Health Science Center College of Medicine. Additionally, the 180,000-member Scott & White Health Plan is the #1 health plan in Texas.

Temple is centrally located less than 1 hour North of Austin, 2 hours South of Dallas, 3 hours West of Houston, and 2 hours North of San Antonio, making it an ideal place to live and/or commute to. College Station is 90 minutes west of Houston, 90 minutes east of Austin, and 3 hours south of Dallas, and is home to Texas A&M University. Scott & White offers a competitive salary and comprehensive benefit package, which begins with four weeks vacation, three weeks CME and a generous retirement plan. For additional information regarding these positions, please contact: **Jason Culp, Physician Recruiter, Scott & White Clinic, 2401 S. 31st, Temple, TX 76508. (800) 725-3627 jculp@swmail.sw.org** Scott & White is an equal opportunity employer. A formal application must be completed to be considered for these positions. For more information on Scott & White, please visit our web site at: www.sw.org

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Coalinga State Hospital, in conjunction with UC Irvine, is inviting applications for psychiatrists.

Coalinga State Hospital is the first new State psychiatric hospital built in California in over 50 years. With its 1,500 beds, almost exclusively devoted to the treatment of sexually violent predators, it is a state-of-the-art facility. It is closely affiliated with the University of California, Irvine School of Medicine, and will train medical students and residents. A forensic fellowship program is being developed.

This is an excellent opportunity for a Board Certified or Board Eligible clinician interested in general adult psychiatry as well as forensic psychiatry. Coalinga State Hospital's salary package is competitive and we offer job security, flexible work schedules, and a generous California State benefit package, including paid leave, medical insurance, and CalPERS Retirement. J-1 visa applicants accepted.

Call us today regarding impending salary increases!

Coalinga State Hospital is a young organization with an idealistic staff. We invite you to come and visit our new facility and to meet our staff; travel expenses may be covered. Coalinga is located in the San Joaquin Valley, equidistant from Los Angeles, San Francisco, and Sacramento, and only two hours from the coast and National Parks.

If you are interested in discussing any of our psychiatric positions, please contact.

Barbara Morris
(559) 935-7275
BMorris@csh.dmh.ca.gov

www.dmh.ca.gov/Statehospitals/Coalinga
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CALIFORNIA DEPARTMENT OF Mental Health

PSYCHIATRISTS

The Department of Veterans Affairs, Central Texas Veterans Health Care System (CTVHCS), is accepting applications for several positions for board-certified Psychiatrists at Temple and Waco, Texas. CTVHCS is affiliated with the Texas A&M University Health Science Center. Applicants with interest in teaching and research will be given preference. CTVHCS offers competitive salaries and excellent benefits.

Applicants are required to have expertise in treatment of at least one of the following patient populations: the seriously mentally ill, PTSD or provision of mental health in primary care clinics.

In addition to its close proximity to the metropolitan Austin area famous for its live entertainment, Central Texas offers affordable housing, excellent schools, one of the lowest costs of living in the country and year-round recreational opportunities highlighted by the lakes and rivers of the Texas Hill Country. Texas has no state income tax.

Candidates must be US citizens or permanent residents, as well as possess a valid and unrestricted medical license in at least one state. Reasonable accommodation provided to any applicant with disabilities. Applicants are subject to drug testing. *EOE*

Please Fax or send CV to:

Mary P. Doerfler, Physician Recruiter
Central Texas Veterans Health Care System
1901 Veterans Memorial Drive, Temple, TX 76504
FAX (254) 743-0007 , Voice (254) 743-0049
E-mail to Mary.Doerfler@va.gov

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Director of Psychiatry: Saint Elizabeths Hospital seeks an experienced physician leader to serve as Director of Psychiatry for a 400-bed public mental health hospital. Saint Elizabeths has a fully accredited general psychiatry residency, is affiliated with Georgetown University's forensic fellowship and is a teaching hospital for medical students and psychiatry residents from Georgetown, George Washington and Howard Universities.

A successful candidate must have a proven track record of medical leadership, a strong clinical background, and an unswerving commitment to superior clinical quality and patient safety. He or she must also be a creative thinker, with the ability to provide innovative ideas to provide superior clinical care, to assure efficient use of resources, and the organizational skills to help assure successful implementation.

Residency Director: A full time Director of the Psychiatry Residency program is sought to lead a 32-resident program and direct implementation and assessment of innovative educational programs. There is ample opportunity for scholarly activities and active collaboration with other Washington psychiatry training directors.

The successful applicant of each position will be employed by the hospital and appointed to the full time faculty of the Department of Psychiatry and Behavioral Sciences of the George Washington University. Applicants must be license eligible in the District of Columbia and be Board Certified in General Psychiatry. Academic rank will be commensurate with qualifications.

Please send a complete resume and CV by mail or electronically to: Steven Steury, MD, MS, Chief Clinical Officer, Department of Mental Health, 64 New York Ave, NE, Washington, DC 20002 or steven.steury@dc.gov

WORKING TOGETHER. MAKING A DIFFERENCE.

Iowa Health Physicians, the state's largest physician group, is searching for a **BE/BC Adult Psychiatrist** to join a highly respected group in Des Moines, IA.

Practice Highlights

- Located on the campus of Iowa Lutheran Hospital, the largest private hospital-based mental health facility in the state.
- Inpatient and outpatient responsibilities.
- A growing community, in need of an additional Psychiatrist.
- Teaching opportunities available.
- Call schedule 1:4.

Organization Description

- Iowa Health Physicians is a non-profit 250-member physician group.
- We pride ourselves on providing the highest quality patient care with innovative ways of approaching the health care delivery system.
- Highly competitive salary and compensation plan.

For more information please contact: Jessica Meisner at (888) 343-4912. To expedite consideration, please email your CV to meisnejj@ihs.org or fax to (319) 739-2750.

IOWA HEALTH
PHYSICIANS AND CLINICS

Staff Psychiatrist

Hall-Brooke Behavioral Health Services (Westport, CT)

Hall-Brooke Behavioral Health Services is recruiting a full-time psychiatrist to join an expanding clinical service at our Norwalk and Westport, CT campuses. Responsibilities include combined inpatient and outpatient care, with minimal weekend and call requirements.

Our 76-bed hospital has adult, geriatric, women's, addiction, and child/adolescent services, and affiliations with St. Vincent's Medical Center in Bridgeport, CT and the Columbia University Department of Psychiatry in New York offer opportunities for career development. Job responsibilities may be tailored to suit specific skill areas or interests.

Interested candidates should contact

Stewart Levine, MD, Interim Medical Director,
Hall-Brooke Behavioral Health Services,
47 Long Lots Road, Westport, CT, 06880,
Phone: (203) 221-8842;
Fax: (203) 226-8616; Email: slevine@stvincents.org. EOE

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Aspen Regional Health

PSYCHIATRIST - Aspen Region, Alberta, Canada

Aspen Regional Health is seeking a second psychiatrist for the St. Therese Healthcare Centre & Community Mental Health Clinic in St. Paul, Alberta. An expansion of the inpatient psychiatric unit from 10 to 20 beds is expected to be completed by Summer, 2007.

St. Paul is located approximately two hours from the provincial capital City of Edmonton. Aspen serves over 175,000 residents in 118 communities and a geographic area in excess of 110,000 square kilometers.

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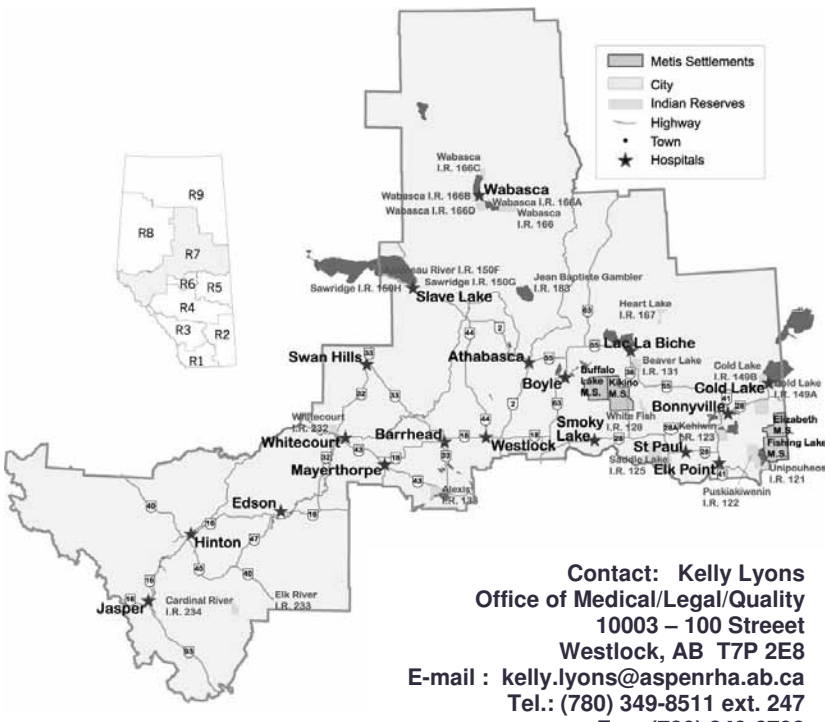

Contact: Kelly Lyons
Office of Medical/Legal/Quality
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Westlock, AB T7P 2E8
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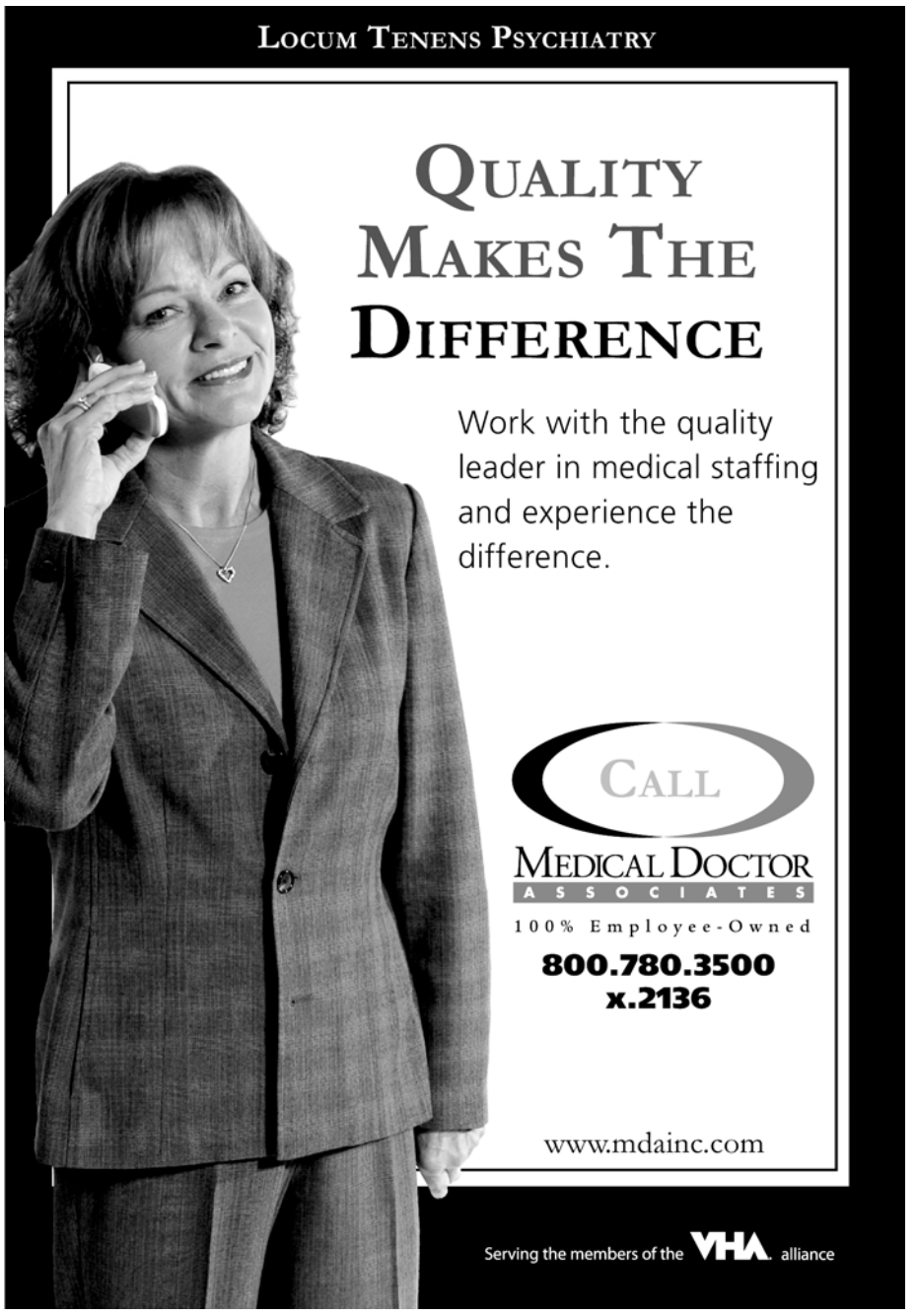

DARTMOUTH MEDICAL SCHOOL

The Department of Psychiatry, in a unique collaboration with the State of New Hampshire, is seeking a PSYCHIATRIST to join our faculty for inpatient responsibilities at the New Hampshire Hospital.

New Hampshire Hospital is a 132-bed acute psychiatric facility located in Concord, NH. New Hampshire Hospital is the clinical and research core facility for an innovative, statewide, comprehensive mental health system. Psychiatrists with expertise in general inpatient psychiatry, neuropsychiatry or forensic psychiatry are encouraged to apply.

Academic duties include teaching and supervision of medical students and residents. Research opportunities available and encouraged. Candidates should be Board certified or eligible in Psychiatry. Academic rank and salary consistent with experience.

Curriculum vitae and three letters of reference should be sent to:

William C. Torrey, M.D., Medical Director
Dartmouth-Hitchcock Medical Center
Department of Psychiatry
1 Medical Center Drive
Lebanon, NH 03756

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Please send CV/references to **judy.brant@providence.org**. For more information, please call toll-free 1-866-504-8178 or visit us on the Web.

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HEALTHCARE

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We currently have the following BE/BC Psychiatrist opportunities available:

Unity Hospital Behavioral Health Services-Fridley, MN
1 Adult Outpatient Physician

- Unity Hospital is a 275-bed facility with a psychiatric consult service, a 24-bed inpatient substance abuse rehabilitation that averages 14,500 patient visits annually. Northtown clinic is located on the Unity campus with five psychiatrists providing outpatient services.
- This position is 100% outpatient.
- We will consider full-time or part-time.
- Outpatient call only.

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1 Adult Inpatient Physician

- Mercy Hospital is a 271-bed facility with 32 Adult psychiatric beds.
- Typical overall average daily inpatient census is 26-27 with an average of 3-10 consults per day.
- Patient population consists of adult men and women, over the age of 18 with a 6-7 day average length of stay.
- This position is 100% inpatient.
- We will consider full-time, part-time, locums or casual weekend call coverage.
- Call is one night per week and occasional weekend coverage, weekend call covers consults only.

Mercy and Unity Hospitals Behavioral Health Services is a single specialty group of psychiatrists that provide services to both hospitals. We provide services addressing the needs of mental health and substance abuse treatment tailored to the needs of the individual.

We offer a competitive salary, comprehensive benefits package and malpractice insurance.

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The correctional mental health care field is among the fastest-growing segments of behavioral health today, and **MHM Services** is America's progressive leader in that dynamic field. Here, you'll be serving one of the most clinically interesting and medication-compliant populations. You will also have the time to initiate change, track progress and conduct more follow-up than you would in other settings.

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Our incomes average higher than those in other mental health settings, and you will enjoy regular working hours. Our extraordinary benefits include paid malpractice insurance, and much more. National Health Service Corp (NHSC) Loan Repayment Program is available, as well as J-1 and H1B Visa Waivers.

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For information or to apply, contact: **Dawn Sechrest** at: **(866) 604-2800** or e-mail resume indicating desired location to: **dsechrest@mhm-services.com**. Visit our website at: **www.mhm-services.com**

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Issue	Deadline (Friday, 2 p.m. E.T.)
July 20	July 6
August 3	July 20

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Forensic services are provided in the Bureau on outpatient and/or inpatient basis at the following facilities *: FCC Allenwood (PA), FCI Atlanta (GA), FMC Butner (NC), FMC Carswell (TX), FCC Coleman (FL), FCI Danbury (CT), FMC Devens (MA), FCC Forrest City (AR), FCC Lompoc (CA), MDC Los Angeles (CA), FDC Miami (FL), FCC Oakdale (LA), FCC Petersburg (VA), USMCFP Springfield (MO), FCI Terminal Island (CA), FCC Terre Haute (IN), FCC Tucson (AZ), FCC Victorville (CA)

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ALABAMA

Established SSG practice is recruiting for Psychiatry. Option of Adult General Psychiatry versus Inpatient Hospitalist Psychiatry work and partnership track position versus employee arrangement. Metro location, excellent school systems, recreational and cultural activities, easy access to mountains and gulf beaches. For additional information, send CV to medplankab@aol.com or contact (205) 870-7068.

Mountain Lakes Behavioral Healthcare, located in beautiful northeast Alabama, has an excellent opportunity to practice general psychiatry in a community mental health center setting. We have an immediate full time opening in our Scottsboro Office in Jackson County (45 minutes from Huntsville). Looking for someone interested in a diversified caseload and varied work settings. Very good working conditions; eager, cooperative treatment team; competitive salary and benefits. Board certified or Board eligible. J-1; H1-B welcome. Contact: Jerome E. Johnson, email jjohnson@mlbhc.com; (256) 582-3203.

Excellent salary, full benefits, and partnership track with dynamic group. Metropolitan city is culturally diverse with excellent schools and very high quality of life. Contact Jim Ault at St. John Associates, jault@stjohnjobs.com or 800-737-2001. Visit www.stjohnjobs.com for more opportunities nationwide.

ALASKA

ANCHORAGE: Child Psychiatrist. Inpatient & residential treatment center. Join a great staff & physician team. Outstanding compensation potential - salary, benefits & bonus. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

ARIZONA

Assistant or Associate Professor, Clinical Psychiatry
or Professor, Clinical Psychiatry
University of Arizona (UPH Hospital-Kino)

The University of Arizona's Department of Psychiatry is recruiting adult psychiatrists to join a progressive and growing academic department located in the beautiful southwest with academic appointments as Assistant or Associate Professor, Clinical Psychiatry, or Professor, Clinical Psychiatry, depending on applicant's qualifications. Individual must be board-certified or -eligible in Psychiatry and have current credentials to practice medicine in the United States. Incumbent will provide clinical care in an inpatient facility with adult and geriatric populations. Other duties may include supervising and teaching adult psychiatry residents and medical students. Competitive salary and excellent benefits package offered. For more complete information about the positions, and to apply, go to **http://www.uacareertrack.com** and reference job **#36355**. If you have questions, please contact **Lesley Bailey, Human Resources, Dept. of Psychiatry, 1501 N. Campbell Avenue, P.O. Box 245002, Tucson, AZ 85724-5002; (520) 626-3819 or lbailey@email.arizona.edu** . Review of applications is ongoing until positions are filled.

The University of Arizona is an EEO/AA Employer-M/W/D/V.

Psychiatrist, The Southern Arizona VA Health Care System (SAVAHCS) is recruiting for two full-time, BC/BE psychiatrists to cover inpatient/consultant liaison services. Academic experience and research interest is a major plus. Responsibilities include direct patient care, supervision and education of residents/medical students from our affiliate the Univ of AZ. Academic rank and tenure status commensurate with qualifications/experience. Selection process begins immediately, continuing until filled. EEO/AA - M/W/D/V. Clinical contact: Dr. David Emelity, (520) 629-1792. Submit CV to: Bonnie Steggerda, HR Specialist, 3601 S 6th Ave (9-05), Tucson, AZ 85723; 520 629-1803 or Bonnie.Steggerda@va.gov

INNOVATIVE ADOLESCENT PSYCHIATRIST:

Seeking a psychiatrist who knows how to reach kids, someone who "thinks outside the box," to join two other psychiatrists and a friendly staff. Mingus Mountain Academy is a long-stay residential treatment center for adjudicated adolescent girls, based on an open campus, positive peer culture model. We offer treatment that blends eastern and western approaches. Thoughtful psychiatric diagnosis and careful use of prescription medications are integrated with acupuncture, Chinese and western herbs, and homeopathy, in a multidisciplinary approach which includes psychotherapy, sports and equine therapy, and an NCA-accredited public charter school on site, in order to reach these young women at a critical time in their lives.

Salary range $155,000 - 180,000 based on experience, excellent benefits, 4 day work week. Mingus Mountain Academy is located in National Forest near Prescott, Arizona, a four season community with pleasant summers and mild winters. Contact: Ginger Flaumenhaft, MMA Human Resources Dept., 602-335-2045, Fax: 602-335-1311, email: gflaumenhaft@mmaaz.com

ARKANSAS

INCREDIBLE FINANCIAL OPPORTUNITY - MEDICAL DIRECTOR POSITION - Very Different from Most Places You've Ever Spoken To - Horizon Health seeks a Medical Director on a 10-bed geropsychiatric unit and IOP in a general hospital convenient to Fort Smith. Offering an income guarantee and outstanding directorship stipend, or can just offer stipend for the psychiatrist who already has a practice in the area. Please **call Terry B. Good at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

CALIFORNIA

Faculty Positions - UCSD

The Dept. of Psychiatry at the University of California, San Diego, is currently recruiting for contracted positions at the assistant or associate clinical professor level. We are seeking board-certified or board-eligible psychiatrists with a California medical license to practice in our community outpatient clinics. Preference will be given to candidates with a strong track record in clinical care, teaching experience and an interest or experience in clinical research. The positions offer flexible scheduling, along with potential teaching and research opportunities. The appointment level will be determined by the candidate's qualifications, and the salary is based on UC staff psychiatrist pay scales. Applicants should send their curriculum vitae and other supporting documents to: Attn: Dr. Lohr and Dr. Soliman, Search Committee K, UCSD Dept. of Psychiatry, 9500 Gilman Drive, La Jolla, CA 92093-0603. UCSD is an equal-opportunity employer.

Santa Cruz County Mental Health Services. Employment opportunities available in psychiatry for the Mental Health Division of the Health Services Agency. For More information visit our website at: www.santacruzcountyjobs.com or contact Yana Jacobs, MFT Adult Teams Manager (831) 454-4539. For general information call: (831) 454-4466.

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Join our team of competent, committed, and caring medical staff. Live and work in our ideal climate within minutes of Southern California beaches and the greater L.A. metropolitan areas' vast array of cultural, educational, sporting and recreation opportunities, with some of the most affordable housing in California.

The County of Riverside in beautiful Southern California is seeking general adult and sub-specialty trained psychiatrists to serve the growing needs of clients in our rapidly expanding County-operated public mental heath system. Be a part of our new and innovative behavioral health service programs.

We offer excellent compensation for psychiatrists through regular employment (up to $169,480., non-Bd.C., $178,802., Bd.C., $187, 813. Mult.Bd.C.) with a great benefit package, including retirement (3%@60); or Per Diem hourly rates ($94.95/h Resident, $100.16/h non-Bd.C., $105.65/h Bd.C., $113.25/h Child). Psychiatrists are needed for acute inpatient, psychiatric ER, outpatient clinic and correctional work throughout our large geographic area, including Riverside, the Palm Springs/Indio area, and other smaller rapidly growing communities in the County. California license required.

For more information please contact Jerry L. Dennis, MD, Medical Director (Ph: 951-358-4621). Please send CV to Tiffany Mott by E-mail to tmott@rc-hr.com or Mail to:

County of Riverside
Department of Mental Health
4095 County Circle Dr.
Riverside, Ca. 92503

Enjoy a balanced life while using your clinical expertise. United Behavioral Health is the leading provider of emotional wellness services. UBH is looking for a licensed, board certified psychiatrist for our office in San Francisco. Managed care experience is strongly preferred for this Medical Director role.

Contact jfriedman@uhc.com, 952-936-3869 for more details or apply at www.unitedhealthgroup.com/careers.

ADULT PSYCHIATRIST JOB OPPORTUNITIES

Due to expanding programs, the UCSF Department of Psychiatry at San Francisco General Hospital is seeking full time/part time psychiatrists for inpatient/outpatient settings. Ideal candidates would be ABPN Board-certified or Board-eligible psychiatrists; MD or DO licensed by the State of California; and have demonstrated interest in working with underserved and culturally diverse populations in a public setting. Bilingual and/or bicultural abilities are desirable. Compensation commensurate with experience; excellent benefits.

Interested applicants should send or fax ([415] 206-8942) their resume and names and addresses/telephone numbers of three references to: Susan Brekhus, UCSF Department of Psychiatry, San Francisco General Hospital, 1001 Potrero Avenue, Suite 7M, San Francisco, CA 94110. For additional information, you are welcome to call or email Susan Brekhus at (415) 206-3805 or email susan.brekhus@sfdph.org, Francis Lu, MD, Professor of Clinical Psychiatry at (415) 206-8984 or Francislumd@aol.com.

UCSF seeks candidates whose experience, teaching, research, or community service has prepared them to contribute to our commitment to diversity and excellence. UCSF is an affirmative Action/equal opportunity employer. All qualified applicants are encouraged to apply, including minorities and women.

PSYCHIATRISTS
San Francisco Bay Area - Alameda County Behavioral Health Care Services - offers a full range of accessible mental health, alcohol and drug services to clients throughout all parts of the County. We are actively recruiting for full-time, part-time and services-as-needed Psychiatrists to provide psychiatric evaluation and treatment to children, adolescents and adults in the Outpatient Services and Criminal Justice Mental Health Program.
Our network of services currently consists of over 400 individual practitioners, more than 90 community-based agencies, 20 hospitals and other institutions. Clients and their family members can now find geographically accessible services throughout all parts of the County. Services are available in all languages and are provided by a multicultural and multidisciplinary panel of service providers, many of whom have developed specialties that meet the often unique needs of our clientele. For more information, please visit: www.acbhcs.org

Physician III (Psych Option) $69.19-$84.01/hr.
Physician III SAN (Psych Option) $90.71/hr.

Additional Compensation to Base Salary:
5% Board Eligibility/Certification; 5% Child Psychiatry Specialty; 5% Lead Psychiatrist; 5% Criminal Justice

Min Req: Possession of a valid license to practice medicine in CA & completion of residency in psychiatry.

We offer highly competitive salaries and an extensive benefit package. Please contact Karl D. Adler, MD via his assistant Bernie Mullen at BMullen@acbhcs.org or (510) 567-8106, and apply on-line at www.acgov.org

Mental health consumers and bilingual applicants are strongly encouraged to apply
EOE

Psychiatrist/Outpatient Mental Health Clinic

VA Central California Health Care System (VACCHCS) is seeking a full-time psychiatrist to work in our outpatient Mental Health Clinic. The psychiatrist will work with a multidisciplinary mental health team treating veterans with a full range of diagnoses including mood disorders, anxiety disorders, psychotic disorders and substance abuse. Duties will include psychiatric evaluation, psychiatric medication management and coordination of the veteran's overall mental health care. The multidisciplinary team is comprised of psychiatrists, psychologists, nurse practitioners, nurses, licensed clinical social workers, and addiction therapists. The VA is a core training site for the University of California San Francisco (UCSF)-Fresno Residency Training Program in several specialties to include psychiatry, internal medicine and surgical specialties. As such, opportunities for resident supervision and clinical research will also be available. Board Certification in Psychiatry is preferred (although board eligible psychiatrist may apply). Fresno is located in the beautiful San Joaquin Valley, 3 hours from San Francisco, 4 hours from Los Angeles and 2 hours from three national parks, including Yosemite, and year-round recreation. Interested applicants should submit their CV and three references to Eva Gosselin, HR Specialist, VACCHCS (05), 2615 E. Clinton, Fresno, CA 93703-2223, phone (559) 241-6454 or e-mail eva.gosselin@va.gov CA license is required. EOE

UCSF DEPARTMENT OF PSYCHIATRY
SAN FRANCISCO GENERAL HOSPITAL

Due to expanding programs, the Department of Psychiatry of the School of Medicine, University of California, San Francisco (UCSF) seeks psychiatrists to serve as clinician-teachers at San Francisco General Hospital, a major teaching hospital of UCSF. The clinician-teacher role offers the opportunity to teach UCSF residents, medical students, and other trainees; to provide clinical leadership for multidisciplinary staff at the unit or team level; and to develop a defined area of scholarship and/or clinical research. The inpatient service features the award-winning Ethnic/Minority Psychiatric Inpatient Programs. Other services include the Psychiatric Emergency Service, community case management programs, and the Divisions of Psychosocial Medicine; Substance Abuse and Addiction Medicine; and Infants, Children, and Adolescent Services. Ideal candidates would be ABPN Board-certified or Board-eligible psychiatrists with inpatient and/or outpatient experience, a commitment to an academic career as a clinician-teacher, and demonstrated interest in working with underserved and culturally diverse populations in a public setting. Bilingual and/or bicultural abilities are desirable.

- Compensation: $130,000-$200,000 + dependent on qualifications and experience
- Relocation package
- Outstanding benefits package

Interested applicants should send or fax ([415] 206-8942) their resume and names and addresses/telephone numbers of three references to: Susan Brekhus, UCSF Department of Psychiatry, San Francisco General Hospital, 1001 Potrero Avenue, Suite 7M, San Francisco, CA 94110. For additional information, you are welcome to call or email Susan Brekhus at (415) 206-3805 or email susan.brekhus@sfdph.org, Francis Lu, MD, Professor of Clinical Psychiatry at (415) 206-8984 or Francislumd@aol.com.

UCSF seeks candidates whose experience, teaching, research, or community service has prepared them to contribute to our commitment to diversity and excellence. UCSF is an affirmative Action/equal opportunity employer. All qualified applicants are encouraged to apply, including minorities and women.

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FACULTY POSITIONS - UCSD

The Department of Psychiatry at UCSD (http://psychiatry.ucsd.edu/) has openings for two full-time academic faculty positions at the Assistant or Associate Professor level. We are seeking academic psychiatrists, psychologists or social workers with experience in addictive disorders and/or the criminal justice system. Individuals who are licensed in their disciplines in the State of California will be preferred strongly. Applicants should have a track record in clinical service, teaching and program administration. Additional preference will be given to those who have a demonstrated research track record of productivity, success in peer reviewed research grants and supervisory experience in research. The academic rank and series for each position will be determined by individual academic qualifications and achievements. Salary based upon University of California pay scales. Closing date: June 20, 2007. Candidates should send curriculum vitae and other supporting documents to: Search Committee CCARTA, UCSD Department of Psychiatry, 9500 Gilman Drive, La Jolla, CA 92093-0603

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Chief of Psychiatry
County of Santa Cruz

Santa Cruz County Mental Health and Substance Abuse Services is seeking a Chief of Psychiatry to work closely with the management team and psychiatry staff to provide leadership in our recovery-oriented services. For more information and to apply online visit our website at www.santacruzcountyjobs.com and/or contact Leslie Tremaine, Director of Mental Health and Substance Abuse at (831) 454-4514 or Nisha Patel, Personnel Officer at (831) 454-4463. For general information call (831) 454-4466.

SHASTA COUNTY COMMUNITY MENTAL HEALTH

Adult/Youth Psychiatrist: Shasta County Community Mental Health is looking for a board-certified/board-eligible psychiatrist interested in both Adults and Youths. Positions open for U.S. Citizens and/or J-1 waivered or H1-B visa candidates, for immediate openings. Experience in addictionology welcomed. We are located in beautiful Northern California, with an abundance of outdoor recreational opportunities in and around Redding. Our agency has a full continuum of mental health care with active outpatient services, and chemical dependency program. Benefits include paid vacation, sick leave, CME benefits, malpractice insurance, deferred compensation plans, weekend call compensation, medical/dental/vision insurance. ***Starting Salary Range:*** $146,321 - $186,750, depending on experience. Also, an additional 5% if certified in Adult Psychiatry, and an additional 5% (total of 10%) if certified in both Adult and Youth Psychiatry and assigned to Youth Systems of Care Program. Faculty Positions (optional) - UC Davis Affiliate. Contact Trish Erickson (530) 225-5925 or Fax CV to (530) 225-5929. EOE.

COLORADO

DURANGO Alpine Clinic is seeking BC/BE psychiatrist to join our well-established multidisciplinary group. 100% outpatient; adults and children; full or part-time. Elevation of 6500 feet, at the base of the pristine San Juan Mountains. Email CV to drlynn@gobrainstorm.net or fax to (970) 385-4909, attn Lynn Partridge, MD.

PSYCHIATRIC POSITIONS

Due to significant growth of our community Pikes Peak Mental Health Center is looking for the following psychiatrists.

ADULT or CHILD PSYCHIATRIST
(Interest in Adult Developmental Disabilities Population)

ADULT OR GERIATRIC PSYCHIATRIST
(Interest in Geriatric Population)

We offer competitive salary and robust benefits package. Relocation costs are negotiable.

Forward CV/Resume to: Fred Michel, MD, Medical Director, FredM@ppbhg.org; 719-339-3890; or Sue Allen, Admin Asst, SueA@ppbhg.org. Pikes Peak Mental Health, 220 Ruskin Drive, Colo Springs, CO 80910. EOE

To see complete job description and to apply, please visit our website at www.ppbhg.org

Pikes Peak Behavioral Health Group

Psychiatrist
Denver

The Colorado Permanente Medical Group, P.C. seeks a full-time BC/BE Psychiatrist to join our multi-specialty integrated healthcare organization and work in an outpatient staff model in collaboration with non-physician mental heath professionals who offer support and consultation to our colleagues in primary care. CPMG is a physician-governed group providing services for the non-profit Kaiser Foundation Health plan; Colorado's most experienced Integrated Health care system. CPMG offers a stable practice environment, competitive compensation, generous benefits/pension plan and reasonable call. Enjoy one of the best practice and lifestyle opportunities in the nation! Please contact Chantal Papez: 303-344-7302, or e-mail your CV to: Chantal.papez@kp.org. EOE, M/F, V/H.

DENVER: Staff Psychiatrist & Medical Director - salaried employment or independent contractor. Highlands is a new Universal Health Services (UHS) hospital offering inpatient/partial programs for children, adolescents & adults. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Medical Director

Horizon Health, the nation's leader in Psychiatric Contract Management seeks a **Medical Director** for a **10-bed Gero-psych** unit at **Colorado Plains Medical Center**, a 50-bed acute-care hospital located in Fort Morgan, CO, serving a two-county area of 35,000. The hospital is fully accredited by JCAHO, and has a Level III Trauma Center, a 24-hour Emergency Room and many other services including diagnostic imaging services such as MRI, Nuclear Medicine, CT, Radiography, ACR-certified Mammography and Ultrasound. Rehab services include Physical, Occupational and Speech Therapies. Other services include Cardiopulmonary, Surgery, complete Lab Services, Obstetrics, Social Services, Dietary and Home Health.

Fort Morgan is big enough to have it all, and small enough to be a delightful home town. Fort Morgan has been thriving on the eastern plains of Colorado since it was established in 1884. The city now serves as the commercial and retail hub for all of Northeastern Colorado, and continues to grow into the 21st Century. Fort Morgan is located 80 miles northeast of Denver on U.S. Interstate 76 and U.S. Highway 34, less than an hour's drive to Denver International Airport.

The successful candidate will be responsible for a 10-bed gero unit with an official opening of November 1, 2007. Would like to have psychiatrist on board by August, 2007. Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. EOE.

CONNECTICUT

GENERAL PSYCHIATRY-CT

Busy two-person provider of behavioral healthcare services seeks a BE/BC psychiatrist to join their private practice providing adult psychiatric services. Practice is affiliated with a suburban community hospital offering a full continuum of mental health services. The practice is offering a competitive salary and benefits package and partnership potential.

ATTRACTIVE SOUTHERN NEW ENGLAND LIVING

Our central CT location offers a choice of upscale suburban communities with first-rate schools and is a short distance from professional sporting events, concerts, ballet, gourmet dining, and theatre. The coastal beaches of Long Island Sound are within easy reach and in just two hours, you can enjoy Boston, New York and the ski slopes of Vermont.

To learn more about this opportunity, call toll-free, Christine Bourbeau, Director of Physician Recruitment at 800.892.3846/860.585.3300 or fax/email your resume to 860.585.3036. EOE.

Email address: cbourbeau@brishosp.chime.org

PUTNAM, CT - ATTENDING PSYCHIATRIST/Faculty Position. UMass Memorial Medical Center, Department of Psychiatry, is seeking a full-time psychiatrist for an inpatient position with our affiliate, Day Kimball Hospital in Connecticut. Multiple career opportunities exist! Work in a collegial setting where clinical care, education and research are valued. A competitive salary, excellent benefits and progressive incentive plan. Academic rank commensurate with experience. Interested applicants send CV to Alan P. Brown, M.D., Vice Chairman for Clinical Services, Department of Psychiatry, UMass Memorial Medical Center, 55 Lake Avenue North, Worcester, MA 01655 or email BrownA01@ummhc.org AA/EOE

PSYCHIATRIC NURSE PRACTITIONER

Full-time APRN for progressive community mental health center with onsite PHP. Provide medication management for dually diagnosed adults in a multidisciplinary team environment. Excellent salary & benefits, 40 hour workweek M-F, flextime. No weekends, holidays or on-call. CT license required. Bi-lingual helpful. EOE

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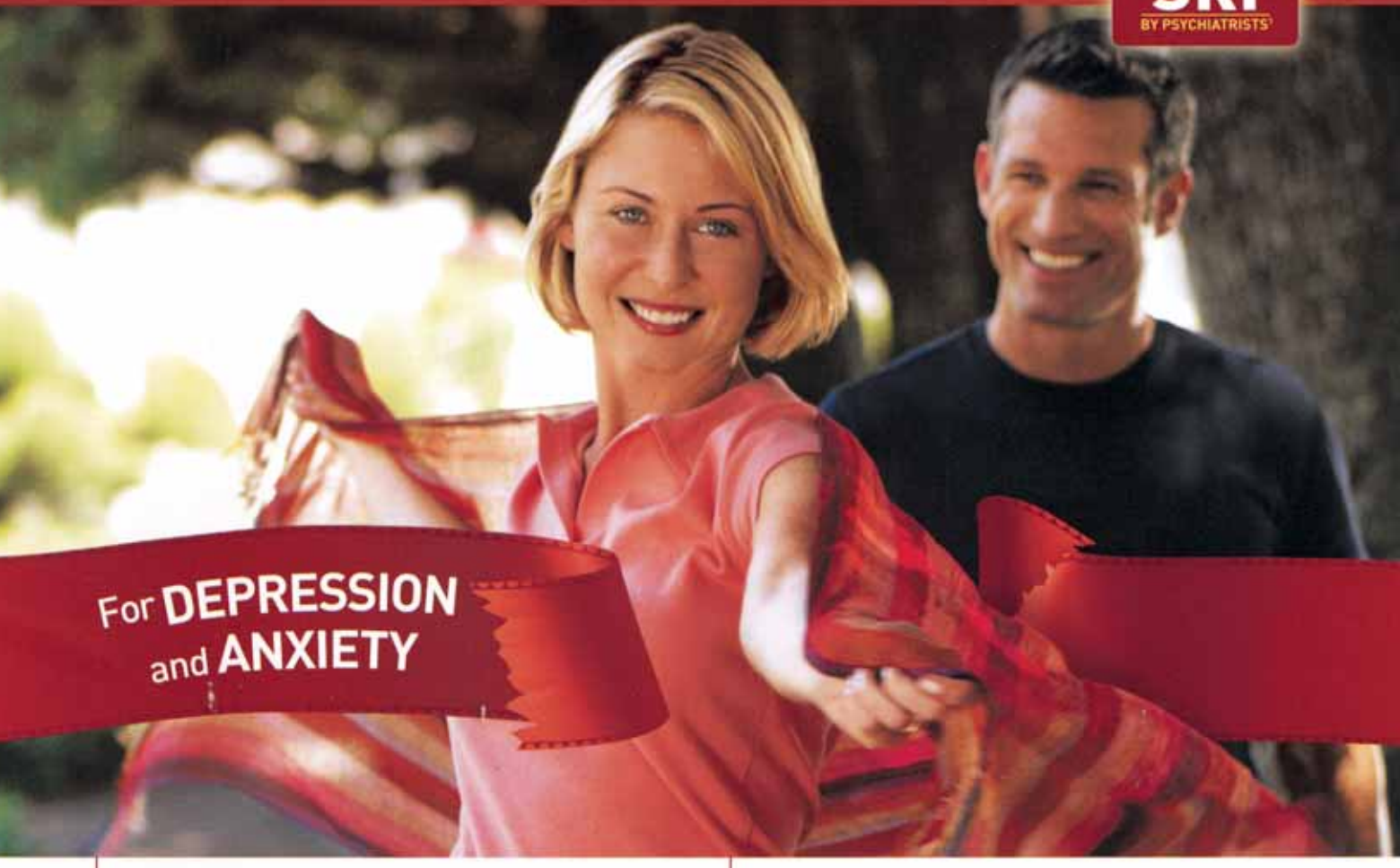
A POWERFUL SSRI that's well tolerated

#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. Twelve-month rolling average. November 2006. **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.; 2006.

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

Rx Only

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 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. 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. 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 and DOSAGE AND ADMINISTRATION—Discontinuation of Treatment with Lexapro, in full prescribing information for a description of the risks of discontinuation of Lexapro). 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.** ***Serotonin Syndrome:*** The development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including Lexapro treatment, particularly with concomitant use of serotonergic drugs (including triptans) and with drugs which impair metabolism of serotonin (including MAOIs). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The concomitant use of Lexapro with MAOIs intended to treat depression is contraindicated (see **CONTRAINDICATIONS** and **WARNINGS - Potential for Interaction with Monoamine Oxidase Inhibitors.**) If concomitant treatment of Lexapro with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **PRECAUTIONS - Drug Interactions**).The concomitant use of Lexapro with serotonin precursors (such as tryptophan) is not recommended (see **PRECAUTIONS - Drug Interactions**). **PRECAUTIONS** Information for Patients Patients should be cautioned about the risk of serotonin syndrome with the concomitant use of Lexapro and triptans, tramadol or other serotonergic agents. **Drug Interactions *Serotonergic Drugs:*** Based on the mechanism of action of SNRIs and SSRIs including Lexapro, and the potential for serotonin syndrome, caution is advised when Lexapro is coadministered with other drugs that may affect the serotonergic neurotransmitter systems, such as triptans, linezolid (an antibiotic which is a reversible non-selective MAOI), lithium, tramadol, or St. John's Wort (see **WARNINGS - Serotonin Syndrome**). The concomitant use of Lexapro with other SSRIs, SNRIs or tryptophan is not recommended (see **PRECAUTIONS - Drug Interactions**). ***Triptans:*** There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of Lexapro with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **WARNINGS - Serotonin Syndrome**). **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 nonsteroidal 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**). Infants exposed to SSRIs in late pregnancy may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN). PPHN occurs in 1-2 per 1000 live births in the general population and is associated with substantial neonatal morbidity and mortality. In a retrospective, case-control study of 377 women whose infants were born with PPHN and 836 women whose infants were born healthy, the risk for developing PPHN was approximately six-fold higher for infants exposed to SSRIs after the 20th week of gestation compared to infants who had not been exposed to antidepressants during pregnancy. There is currently no corroborative evidence regarding the risk for PPHN following exposure to SSRIs in pregnancy; this is the first study that has investigated the potential risk. The study did not include enough cases with exposure to individual SSRIs to determine if all SSRIs posed similar levels of PPHN risk. When treating a pregnant woman with Lexapro during the third trimester, the physician should carefully consider both the potential risks and benefits of treatment (see **DOSAGE AND ADMINISTRATION** in full prescribing information). Physicians should note that in a prospective longitudinal study of 201 women with a history of major depression who were euthymic at the beginning of pregnancy, women who discontinued antidepressant medication during pregnancy were more likely to experience a relapse of major depression than women who continued antidepressant medication. **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**). One placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients. Anyone considering the use of Lexapro in a child or adolescent must balance the potential risks with the clinical need. **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 post marketing experience and were not observed during the premarketing evaluation of escitalopram: abnormal gait, acute renal failure, aggression, akathisia, allergic reaction, anger, angioedema, atrial fibrillation, choreoathetosis, delirium, delusion, diplopia, dysarthria, dyskinesia, dystonia, ecchymosis, erythema multiforme, extrapyramidal disorders, fulminant hepatitis, hepatic failure, hypoaesthesia, hypoglycemia, hypokalemia, INR increased, gastrointestinal hemorrhage, glaucoma, grand mal seizures (or convulsions), hemolytic anemia, hepatic necrosis, hepatitis, hypotension, leucopenia, myocardial infarction, myoclonus, neuroleptic malignant syndrome, nightmare, nystagmus, orthostatic hypotension, pancreatitis, paranoia, photosensitivity reaction, priapism, prolactinemia, prothrombin decreased, pulmonary embolism, QT prolongation, rhabdomyolysis, seizures, serotonin syndrome, SIADH, spontaneous abortion, Stevens Johnson Syndrome, tardive dyskinesia, thrombocytopenia, thrombosis, torsade de pointes, toxic epidermal necrolysis, ventricular arrhythmia, ventricular tachycardia and visual hallucinations.

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DISTRICT OF COLUMBIA

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Incumbent provides leadership to BOP psychiatrists on professional issues; defines psychiatry program for the agency including the development of evaluation standards, clinical practice guidelines, and performance measures; reviews and monitors the delivery of BOP psychiatry services recommending corrective action changes as appropriate; serves as a liaison between the BOP and governmental/extra-governmental consultants in areas of program review, assessment, and psychiatry administrative functions; advises the Medical Director on psychiatry policies; develops short-range goals and formulates long-range objectives, plans, and programs for the delivery of cost-effective psychiatric services.

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www.kahimohala.org

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The qualified candidate will possess 3-5 years experience in an inpatient setting, preferably with administrative/supervisory experience and HI license or license eligibility. The incumbent will be an integral member of our interdisciplinary team.

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ILLINOIS

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Chair, Department of Behavioral Sciences

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Rick Sumner, Ph.D.
Chair, Search Committee for Chair of Behavioral Science
Rush University Medical Center
600 South Paulina, Rm 507
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KANSAS

THE UNIVERSITY OF KANSAS SCHOOL OF MEDICINE-WICHITA
Position Announcement

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Contact Information:
Dr. Russell Scheffer,
Chair of Psychiatry and Behavioral Sciences
Ms. Lisa Brommer,
Director of Human Resources
KUSM-W
1010 North Kansas
Wichita KS 67214
316-293-3525

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THE UNIVERSITY OF KANSAS SCHOOL OF MEDICINE-WICHITA
Position Announcement

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The Kansas University School of Medicine-Wichita is seeking exceptional candidates for a child and adolescent psychiatrist. This individual will also serve as assistant residency program director. Other responsibilities include in-patient and outpatient psychiatric services, medical student and resident education, and providing call and weekend rounds.

About the University of Kansas School of Medicine-Wichita

KUSM-W is a community-based medical school located in Wichita, Kansas. Its core mission is to provide quality medical education and improve the quality of healthcare for the people of Kansas. The school achieves its mission in partnership with medical centers, health agencies, and clinicians in the city and throughout the state. See http://wichita.kumc.edu/ for more information.

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Director of Human Resources
KUSM-W
1010 North Kansas
Wichita KS 67214
316-293-3525

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THE UNIVERSITY OF KANSAS SCHOOL OF MEDICINE-WICHITA
Position Announcement

Clinical Instructors
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The University of Kansas School of Medicine-Wichita
KUSM-W is a community-based medical school located in Wichita, Kansas. Its core mission is to provide quality medical education and to improve the quality of healthcare for the people of Kansas. The School achieves its mission in partnership with medical centers, health agencies, and clinicians in the city and throughout the state. See http://wichita.kumc.edu/psych/ for more information on the Department of Psychiatry and Behavioral Sciences.

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LOUISIANA

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Medical Director
Central LA State Hospital
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Ref# APSYN4.

The Louisiana Office of Mental Health is seeking psychiatrists to work across the state in a variety of positions. We have a unique mental health care delivery system that is transforming itself in a number of ways to better meet the needs of our citizens. With the challenges we are facing from the 2006 hurricane season, our system has had to be creative and responsive. Come be a part of the recovery of our beautiful state! Positions are available in urban and rural areas, inpatient and outpatient facilities, and forensic and civil settings; adult and child psychiatrists are needed. For more information, please contact Kathleen Crapanzano, M.D., Office of Mental Health Medical Director, 628 PO Box 4049, Baton Rouge, LA 70821-4049 or phone at 225-342-2550 or e-mail at kcrapanz@dhh.la.gov.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY, TULANE UNIVERSITY SCHOOL OF MEDICINE in New Orleans, LA, is recruiting for several general and forensic psychiatrists (clinical track) for our growing department, at the Assistant/Associate Professor level. Candidates must have completed an approved general psychiatry residency and be board certified/eligible in general psychiatry and forensic psychiatry, respectively. Responsibilities will include direct patient care, teaching of medical students and house officers (including those in our accredited forensic psychiatry fellowship program), and research (clinical and basic science) at various state hospitals, state correctional institutions, and at Tulane University Health Sciences Center. Time allocations will be based upon individual situations. Applicants must be eligible to obtain a Louisiana medical license. Applications will be accepted until suitable qualified candidates are found. Send CV and list of references to John W. Thompson, Jr., M.D., Vice Chair, Adult Psychiatry and Director, Division of Forensic Neuropsychiatry, Tulane University School of Medicine, Department of Psychiatry and Neurology, 1440 Canal Street TB53, New Orleans, LA 70112. For further information onsite, please contact Dan Winstead, MD, Chair of Psychiatry and Neurology, at 504-473-5246 or winstead@tulane.edu. Tulane is strongly committed to policies of nondiscrimination and affirmative action in student admission and in employment.

MAINE

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. EOE. **www.acadiahospital.org**

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.

Child Psychiatrist - Waterville, Maine
(No call & No weekends)
Our organization operates the largest Medication Clinic in the region, and we are looking for a Child Psychiatrist to join our team. BE/BC with Maine Medical License or immediate eligibility for licensure. Contact: Mike Walsh, Kennebec Behavioral Health: Telephone (207) 873-2136; Fax (207) 877-8427; e-mail mwalsh@kbhmaine.org.

Adult Psychiatrist - Waterville, Maine
(No Call & No Weekend Coverage)
Our organization operates the largest Medication Clinic in the region, and we are looking for an Adult Psychiatrist to join our team. BE/BC with Maine Medical License or immediate eligibility for licensure. Apply to: Mike Walsh, Kennebec Behavioral Health: Telephone (207) 873-2136; Fax (207) 877-8427; e-mail mwalsh@kbhmaine.org.

MARYLAND

Medical Director - Humanim, a large and established human services organization, is seeking a Board Certified Psychiatrist for the position of Medical Director for our Outpatient Mental Health Clinic. The Medical Director is responsible for ensuring the quality of mental health services to adults, children, and adolescents, and for providing leadership to a team of psychiatrists, psychiatry residents, psychologists, and social workers. We offer a unique opportunity to work in a clinic setting within a human services organization that offers a wide array of adjunct services. Humanim is located in Howard County, MD, convenient to Washington D.C and Baltimore. F/T or P/T option with a competitive compensation package. Please send resume with cover letter, and salary requirements to jobs@humanim.com

Hospital Based Psychiatrist - Humanim is seeking Board Certified psychiatrists to become part of our team, providing hospital based psychiatry services in Howard County. P/T contractual positions are available with options for day, evening, and weekend shifts. Please send resume with cover letter, and salary requirements to jobs@humanim.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 Hospitals, 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 Robert Wisner-Carlson, MD, Acting Clinical Director at 410-724-3078 or P.O. Box 1000, 8450 Dorsey run Road, Jessup, MD 20794 (wisnerr@dhmh.state.md.us.)

BALTIMORE - The Walter P. Carter Center, an 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 email at LCohen@psych.umaryland.edu .

PT Psychiatrist needed in well established psychiatric practice in Gaithersburg, MD starting in July 07. 15-20 hours per week to treat adolescents and adults, child experience a plus. Schedule flexible, BC only, experience in meds. management a must. Mail CV to GMPS, 9055 Shady Grove Ct. Gaithersburg, MD 20877 or fax to 301/948-4333.

GERIATRIC PSYCHIATRY-NEUROPSYCHIATRY FACULTY POSITIONS AT JOHNS HOPKINS

The Department of Psychiatry at Johns Hopkins Bayview is recruiting for ***two*** junior faculty positions in its growing Geriatric Psychiatry & Neuropsychiatry programs. Under the leadership of a new Chair, the Department is growing its clinical care and translational research programs in memory disorders, dementia, and Alzheimer's disease. The focus for the new positions is treatment development, clinical trials, biomarkers, and/or brain imaging. The new faculty will be provided with resources to develop their career, and will be mentored in the highly successful Johns Hopkins academic environment. Fellowship training in geriatric psychiatry or neuropsychiatry is preferred. Faculty appointment at the Instructor or Assistant Professor rank is envisioned depending on qualifications. Johns Hopkins University offers a comprehensive salary program and excellent benefits in a smoke and drug free workplace. EOE/AA/D/V. The successful candidate(s) for this position will be subject to a pre-employment background check. Applicants should send a brief letter of interest and Curriculum Vitae to Constantine Lyketsos, MD, Althouse Professor and Chair, Department of Psychiatry, Johns Hopkins Bayview, 5300 Alpha Commons Drive, Baltimore, Maryland 21224. Email: kostas@jhmi.edu

University of Maryland Department of Psychiatry Consultation Liaison Faculty Position. The Department of Psychiatry at the University of Maryland School of Medicine is seeking a consultation liaison psychiatrist to join its faculty. The University of Maryland School of Medicine Division of CL Psychiatry faculty includes 4 psychiatrists and 1 psychologist and maintains an ACGME-accredited Psychosomatic Medicine Fellowship program. In addition the Division is an active training site for psychiatry residents and medical students. The primary responsibilities of the position include heading one of the inpatient consultation teams within the medical center, supervising and teaching trainees, and providing consultation services to the transplant program. Additional outpatient consultation opportunities are also available. Fellowship training in Psychosomatic Medicine or comparable clinical experience is preferred. Interested candidates should submit a cover letter and a CV to Mark J. Ehrenreich, M.D., Director, Division of CL Psychiatry, University of Maryland Medical Center, Box 349, 22 South Greene Street, Baltimore, MD 21201 or via email at mehrenre@psych.umaryland.edu
The University of Maryland is an AA, EOE, ADA employer. Minorities and women are encouraged to apply.

MASSACHUSETTS

North Shore Medical Center (NSMC), a member of Partners Psychiatry and Mental Health, is seeking qualified Psychiatrists for the following positions:

Medical Director of Adult Psychiatry. This is an excellent opportunity for a Psychiatrist with strong clinical and interpersonal skills to provide leadership, clinical supervision, and clinical care on a highly regarded Adult Inpatient service located at Salem Hospital. Option of outpatient responsibilities is available as well. Opportunity exists for an integrated position with either McLean Hospital or Massachusetts General Hospital (MGH) for an appropriate interested candidate, with McLean/MGH opportunities to be based on the candidate's interests and expertise.

Child Psychiatrist for a unique, integrated NSMC/Partners position based at NSMC and either MGH or McLean Hospital. This full-time position has been designed to combine the collegial clinical atmosphere and salary range of at top-rated community-based hospital with the academic and research opportunities of an academic medical center. NSMC responsibilities include ½-time inpatient work at the Hunt Center and/or ½-time outpatient work at North Shore Children's Hospital. The Hunt Center is a highly regarded strength-based, low-restraint program for children and adolescents up to age 15. The outpatient program includes the innovative MCPAP consultation service for primary care pediatricians. The MGH/McLean component offers a variety of teaching and research options based on the qualified candidate's interests and expertise. **Please note that for those who prefer, a ½-time to full-time position at NSMC is also available.**

Geriatric/Consultation-Liaison Psychiatrist. This ¾-time to full-time position offers the opportunity for a wide variety of clinical responsibilities, including Inpatient Geriatric Psychiatry on an excellent unit with a strong interdisciplinary approach, Consultation-Liaison Psychiatry, and Outpatient Geriatric and Adult Psychiatry. Also option for participation in an outstanding Nursing Home Consultation team. The specific job description will be shaped to meet the qualified applicants clinical interests and skills. Opportunity exists for an integrated position with either McLean Hospital or Massachusetts General Hospital (MGH) for an appropriate interested candidate, with McLean/MGH opportunities to be based on the candidate's interests and expertise.

NSMC provides an excellent, collegial work environment, strong clinical and administrative support, and highly competitive salary and benefit packages. Opportunity for academic appointment is available through McLean or MGH. NSMC is an equal opportunity employer.

Please send cover letter and CV by email to Mark Schechter, M.D. at
mschechter@partners.org, or by mail to
Mark Schechter, M.D.
Chairman, Department of Psychiatry,
North Shore Medical Center
81 Highland Avenue
Salem, MA 01970

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 working with the Director of Forensic Psychiatry Training in coordination of training experiences, seminars, and other 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.

BOSTON & SUBURBS! Part-time & fulltime - NO CALL. Salary, benefits & bonus.
Jamaica Plain, Attleboro & Pembroke: Child and General Psychiatrists for inpatient/partial programs. Salary, benefits and bonus potential offered. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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INPATIENT ATTENDING PSYCHIATRIST at the Beth Israel Deaconess Medical Center, Boston. This position within the Department of Psychiatry includes clinical care on a 25 bed unit and psychiatry residency, medical student, and other teaching responsibilities. Interest and experience in research is desirable. Underrepresented minorities are encouraged to apply. A Harvard Medical School appointment is available. Please contact Dr. Mary Anne Badaracco, Chief of Psychiatry, at 185 Pilgrim Road, Boston, MA 02215, Tel 617-632-0907, Fax 617-632-7990 or email mbadarac@bidmc.harvard.edu.

The VA Medical Center in Northampton, Massachusetts is seeking two full-time, board certified/eligible psychiatrists to join our growing Mental Health staff. Opportunities exist in both inpatient and outpatient settings as well as in specialized programs. Teaching is available through our affiliation with the Dartmouth Medical School as well as our psychology internship program, social work and PA student rotations.

Northampton is an active, diversified Medical Center, with three satellite outpatient clinics, 85 psychiatry beds, a 66 bed Nursing Home Care Unit and a co-located 180 bed Veterans Homeless Shelter. Programs include inpatient and outpatient general psychiatry, inpatient PTSD, substance abuse, compensated work therapy, homeless program and a Primary Mental Health Clinic that is fully integrated with Primary Care.

Salary will be commensurate with experience/education. The VA offers a full benefit package that includes health and life insurance, 401 K, vacation, sick leave, educational leave and 10 paid holidays. Possible relocation expenses.

Northampton is located in the heart of Western Massachusetts' "five college area" and abounds in cultural attractions. Two hours from Boston, three hours from Times Square, yet in its own cultural base, the area is ideal for raising a family. Please call Mrs. Connie Podolski, Mental Health Service AO with questions (phone number 413 584-4040, ext. 2321) or send/fax CV to:

Michelle Zehelski,
Human Resources (05-HR)
Northampton VA Medical Center
Leeds, Massachusetts 01053

FAX: (413) 582-3146

Consultation Psychiatrist Wanted

Full/part time position available for a consultation psychiatrist at Mount Auburn Hospital, a Harvard Medical School teaching hospital. Responsibilities include performing psychiatric consultations on medical, surgical and ICU inpatients as well as ED evaluations. Board certification in adult psychiatry required. The optimal candidate will have completed a fellowship in psychosomatic medicine. HMS academic appointment available. Some teaching required. Minimal weekend call. Generous compensation and benefits package. Send CV and three letters of reference to:

Manuel N Pacheco, MD
Director of Consultation and Emergency Services
Department of Psychiatry
Mount Auburn Hospital
330 Mount Auburn Street
Cambridge, Massachusetts 02138

THE 1ST CHOICE IN PSYCHIATRIC RECRUITMENT
North of Boston
Medical Director for community hospital
For more information contact:
YVONNE CHAMBERS
(800) 783-9152 FAX (270) 782-1055
www.fcspsy.com
admin@fcspsy.com

The Berkshires~ Western Massachusetts

Child Psychiatrist
Berkshire Medical Center, in Pittsfield, MA, is currently seeking a BC/BE Child & Adolescent Psychiatrist, with interest in community mental health, for its integrated mental health and substance abuse treatment network. Academic appointment possible through teaching affiliation with UMASS Medical School. Competitive salary and benefits package, including relocation. The Berkshires is a 4-season resort community with endless cultural and recreational opportunities. Excellent public and private schools make this an ideal family location, just 2 ½ hours from both Boston and New York City. Please send CV, or contact: Alex Sabo, MD Phone: 413-447-2162, asabo@bhs1.org, Fax: 413-447-2041 www.berkshirehealthysystems.org

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PSYCHIATRIST, CONCORD, MA: Emerson Hospital Behavioral Health Services seeks Board Certified, full or part-time staff psychiatrist for busy 29-bed locked inpatient unit with associated partial hospital and addictions rehabilitation programs. Expertise in substance abuse, geriatrics and/or consultation liaison desirable. Excellent salary and benefits. Private practice opportunities available. Concord and surrounding communities offer excellent quality of living and superb schools. Contact: Robert Stern, MD, Director, Behavioral Health Services, **Emerson Hospital**, 133 ORNAC, Concord, MA 01742. Phone: **978-287-3512**. e-mail to: rstern@emersonhosp.org.
Not a J-1 or H1B visa opportunity.

Vice Chair, Child and Adolescent Psychiatry
University of Massachusetts Medical School
UMass Memorial Health Care
Worcester, MA

The University of Massachusetts Medical School and UMass Memorial Health Care are recruiting for a Vice Chair of Child and Adolescent Psychiatry due to an expansion of clinical, training, and research activities and goals. Candidates must be Board Certified in Child and Adolescent Psychiatry and have strong administrative and research experience. The Division has 20 Child and Adolescent Psychiatrists and 16 faculty from a range of other disciplines. Faculty work in a variety of settings, including Public Sector State Hospital, Community Mental Health Center, University Hospital, Mental Health Services Research Center, Shriver Center (MR/DD) and Brudnick Neuropsychiatric Research Institute. Areas of academic strength include mental health services research, public sector adolescent inpatient continuing care, primary care integration, systems of care and intensive home and community-based services, addiction, psychopharmacology, mental retardation and developmental disabilities, juvenile justice/law and psychiatry, preclinical imaging and molecular research, trauma, and sexual abuse. The Division of Child Psychiatry oversees a large network of clinical services in Central MA, and the Department's Center for Mental Health Services Research has funding to develop a Mental Health Research Network throughout the State. There is a fully accredited child psychiatry residency, including an innovative combined adult/child psychiatry track.

The Vice Chair position is supported by a competitive salary and excellent benefits. To apply, please send CV and letter of interest to Douglas Ziedonis, MD, MPH, Chair, Department of Psychiatry, University of Massachusetts Medical School and UMass Memorial Health Care, 55 Lake Avenue N., Worcester, MA 01655 or e-mail: ziedonid@ummhc.org AA/EOE

The Berkshires~ Western Massachusetts

Adult Psychiatrist
Berkshire Medical Center, in Pittsfield, MA, is currently seeking a BC/BE Adult Psychiatrist, with interest in community mental health, for its integrated mental health and substance abuse treatment network. Academic appointment possible through teaching affiliation with UMASS Medical School. Competitive salary and benefits package, including relocation. The Berkshires is a 4-season resort community with endless cultural and recreational opportunities. Excellent public and private schools make this an ideal family location, just 2 ½ hours from both Boston and New York City. Please send CV, or contact: Alex Sabo, MD Phone: 413-447-2162, asabo@bhs1.org, Fax: 413-447-2041 www.berkshirehealthysystems.org

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Health & Education Services, Inc.

Health & Education Services, Inc., a large behavioral health agency headquartered in Beverly with locations throughout the Greater North Shore and lower Merrimack Valley areas, is seeking:

Psychiatrist: [Salem, MA] Per Diem, one 4-hr day (negotiable). Exciting opportunity for Psychiatrist interested in working with a progressive multidisciplinary team providing wrap-around services to 38 adult DMH clients. The perfect candidate would enjoy working closely with staff and clients in the clinical process by providing comprehensive services addressing a wide array of client needs. ***Resumes to: K. Gillis, ACT Director, HES, 41 Mason St., Salem, MA 01970, fax 978-825-5617, or e-mail kgillis@hes-inc.org***

EOE/AA

MEDICAL DIRECTOR - ANNUAL SALARY OF $230K TO $240K - NORTH OF BOSTON / Horizon Health seeks a Board Certified psychiatrist to be Medical Director of a 22-bed adult unit and a 25-bed geropsychiatric unit in a very impressive general hospital in a great location. This is an all inpatient position; salaried with benefits. Extra compensation for weekend call. Please **call Terry B. Good, Horizon Health, at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

Director of Child and Adolescent Psychiatry
Consultation-Liaison & Addictions

UMass Memorial Medical Center/UMass Medical School, Worcester: Full-time faculty position as Director of Child and Adolescent Consultation Liaison. This role includes working closely with Pediatrics, the Emergency Mental Health Service, and an Adolescent Addiction Unit. Must be BC/BE in child and adolescent psychiatry and prior experience in adolescent addiction psychiatry. Position includes supported time for teaching, supervision, and research. Training includes residents in child and adolescent psychiatry, pediatric residents, and medical students. The Department of Psychiatry at UMMMC/UMMS has a strong commitment to integrating mental health and primary care. Areas of academic strength include mental health services research, addictions, psychopharmacology, trauma, mental retardation and developmental disabilities. The Adolescent Addictions Unit is a new model program, and the Child Psychiatry Emergency Service is located in a new dedicated space. Competitive salary and excellent benefits from UMass Memorial Medical Group, Inc. To apply, please send C.V. and letter of interest to Peter Metz, MD, Director of Child Psychiatry, 55 Lake Avenue N., Worcester, MA 01655 or e-mail: peter.metz@umassmed.edu AA/EOE

MICHIGAN

GRAND RAPIDS: Staff Psychiatrist. Inpatient & outpatient - general & specialty programs. Great work environment and collegial staff. Salary & benefits. Contact Joy Lankswert @ 866-227-5415; email joy.lankswert@uhsinc.com

MINNESOTA

Psychiatrist - Child and Adolescent Psychiatry

The Department of Psychiatry at the University of Minnesota is seeking a psychiatrist, board eligible or board certified in Child and Adolescent Psychiatry, for 100% full-time faculty appointment. The Department of Psychiatry has made substantial growth in specialized services and clinical research in recent years and the successful candidate will have the opportunity for practice in a leading hospital and participating in clinical research. Based upon individual qualifications, this position will be appointed at the rank of Instructor or Assistant Professor in the clinical scholar track. Responsibilities include inpatient care at Fairview University Medical Center/Riverside Campus. Academic responsibilities include full participation in overall departmental and interdisciplinary activities including teaching of medical students, residents, and fellows along with research and service activities. Qualifications: MD degree, completion of a Child and Adolescent Fellowship, licensed or eligible in Minnesota. Applications will be reviewed upon receipt and position will remain open until filled. If interested, please submit a letter of interest and CV to: Thomas Mackenzie, MD, Chair, Search Committee, F282/2A West Building, 2450 Riverside Avenue, Minneapolis, MN 55454-1495. Email: macke001@umn.edu. The University of Minnesota is an equal opportunity educator and employer.

Psychiatrist - Clinical Research, Bipolar Disorders

The Department of Psychiatry at the University of Minnesota seeks a senior clinical investigator at the level of Professor or Associate Professor (tenure track or clinical scholar track) who can participate with other leadership at the Executive Council level in the development of the Department's clinical research program. Recently there has been substantial evidence indicating the difficulties in the treatment of bipolar disorder and the paucity of neuropsychiatric data in this illness. The University seeks leadership in a clinical research program in this arena. Therefore, the primary focus of this position will be to develop a bipolar disorder program in the Department of Psychiatry. Additionally, this individual would coordinate clinical programs - both inpatient and outpatient - with clinical research studies. Required qualifications include an MD degree, board certification in adult psychiatry, past experience in the development of clinical research programs and expertise in the area of bipolar disorder. Minnesota licensure must be in hand by the start date.

Applications will be reviewed upon receipt and the position will remain open until filled. If interested, please submit a letter of interest and curriculum vitae to: Jon Grant, MD, Chair, Search Committee, Department of Psychiatry, University of Minnesota, F282/2A West, 2450 Riverside Avenue, Minneapolis, MN 55454-1495. The University of Minnesota is an equal opportunity educator and employer.

Psychiatrist

The University of Minnesota is seeking a psychiatrist with special interest and expertise in Outpatient Psychiatric Consultation. The successful candidate would have the opportunity to develop an innovative consulting practice in a newly completed multi-specialty ambulatory care center. The proposed treatment team will include psychiatry, health psychology, addictions medicine, primary care physicians and specialists, delivering patient care in a highly collaborative, or even 'shared care' model. This position is a full-time faculty position in the Clinical Scholar track at the University of Minnesota with salary and rank commensurate with experience and academic accomplishments. Qualifications for this position include board certification or eligibility, demonstrated success in the supervision and teaching of residents and medical students, and excellent clinical skills with experience in consultation psychiatry. Psychiatrists with expertise in collaborative care models and a strong consultation/liaison background, as well as those with program development and administrative experience are strongly encouraged to apply. Please send a letter of interest and curriculum vitae to: Kathryn J. Curdue, MD, Search Committee Chair, Department of Psychiatry, University of Minnesota, 2450 Riverside Avenue, Minneapolis, MN 55454, curd0002@umn.edu. The University of Minnesota is an equal opportunity educator and employer.

Psychiatrist - Addiction Psychiatry

The Department of Psychiatry at the University of Minnesota seeks a board-certified psychiatrist with expertise in addictions for a full-time, clinical scholar track (yearly renewable) appointment. This position will confer the rank of Assistant and will entail a special commitment to teaching and excellence in clinical care. Faculty in the Clinical Scholar Track provides significant coverage of inpatient psychiatric and comorbid psychiatric/substance abuse patients. Concurrent with the treatment of the inpatient population, the individual will be responsible for teaching and supervision of psychiatry residents, medical students and Pharm D. students. This position also requires organization and coordination of didactic lecture series and case conferences as well as direct care of a limited number of outpatient cases. In addition, this position will provide psychiatric services in the areas of mental illness and chemical dependency at the Hazelden Foundation. The successful candidate must demonstrate evidence of excellence in teaching, previous involvement in clinical research or related scholarly study, demonstrated evidence of commitment to quality patient care and related clinical services. Required qualifications: board certification in adult psychiatry. Desired qualifications: addiction psychiatry fellowship, CAQ in addiction psychiatry, five years of post-residency experience, two years experience in clinical research and demonstrated success in supervision and teaching of residents and students. Minnesota licensure must be in hand by the start date.

Applications will be reviewed upon receipt and position will remain open until filled. If interested, please submit a letter of interest and CV to: Ellen Buchanan, MD, Chair, Search Committee, Department of Psychiatry, University of Minnesota, F282/2A West Building, 2450 Riverside Avenue, Minneapolis, MN 55454-1495. The University of Minnesota is an equal opportunity educator and employer.

In-patient/Out-patient Psychiatrist

Earn your living where you can live your life. St. Joseph's Medical Center, a 162-bed, JCAHO, acute-care, community referral hospital located in Brainerd, MN has an exciting opportunity for a BC/BE Psychiatrist to join our established practice of four psychiatrists and two mental health nurse practitioners. Enjoy a practice of **in-patient and out-patient, a collegial and friendly environment and a call rotation of 1:6**. Located just 125 miles north of the Twin Cities, Brainerd MN is situated among 465 pristine lakes, dozens of award winning golf courses, 100+ miles of paved trails, excellent schools and short commutes. We provide comprehensive and passionate care to over 100,000 people in 50-60 mile service region. Excellent compensation and benefit package. Contact: Nancy Juntunen, Physician Recruitment at nancy.juntunen@sjmcmn.org , 218-454-5800 or visit our website at www.sjmcmn.org . AA/EOE

Consulting Psychiatrist

Freeborn County Mental Health Center has an opening for a board certified psychiatrist to work on a contract basis at an hourly rate of up to $200. Minimum 2 days per week, possibility of full time position. We are a licensed Rule 29 mental health center located in Albert Lea, Minnesota, 90 miles south of the Twin Cities. The psychiatrist works with a team including psychotherapists, case managers, and registered nurses to serve a variety of clients including those with severe and persistent mental illness. There are no on-call or after-hours responsibilities. Must carry own liability insurance. Contact Howard Walker, Ph.D. at 507-377-5442 or howard.walker@co.freeborn.mn.us.

MISSISSIPPI

Medical Director
Northern Mississippi

The gateway city of northern Mississippi has an opportunity for a Psychiatrist to oversee a 19-bed adult psychiatric program located within a 164-bed acute care hospital. Corinth, Mississippi is a city extremely rich in history and provides close proximity to Tupelo, MS and Memphis, TN. Offering competitive Salary, benefits, malpractice insurance or Stipend. Location provides an excellent opportunity to establish your own private practice! For more information contact Diane Odom 972-420-4083, Fax 972-420-8233, diane.odom@horizonhealth.com

MISSOURI

Seeking State Licensed, fully accredited psychiatrist experienced in a variety of disorders including eating disorders and addictions. Position requires approx. 30 hours per week. Additional outpatient opportunities exist. Competitive salary/benefits. Submit C.V./Resume to: Box P-513, Psychiatric News Classifieds, American Psychiatric Publishing, Inc., Wilson Blvd., Suite 1825, Arlington, VA 22209

An Hour From St. Louis -
Seeking a Psychiatrist for a 10-bed Geropsychiatric Unit in a general hospital an hour from St. Louis. Offering a salary of $200k plus benefits. Position consists of inpatient & outpatient clinical care and part-time administrative duties such as QA, UR, heading up treatment team, etc. Relocation package is available, however, commuting from St. Louis is also acceptable. Please **call Terry B. Good, Horizon Health, at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072. EOE

Small Town Living - BIG Opportunity - Horizon Health is seeking a Medical Director for a well-established 12-bed geropsychiatric unit based in a med/surg hospital. Can offer salary with benefits & productivity bonus, or practice guarantee and directorship stipend. Very low stress work environment; very experienced, quality staff in place; a great place to work! AAA rated public school system; wonderfully diversified economy. 38 minutes from Cape Girardeau; about two hours from St. Louis and Memphis. Please **call Terry B. Good, Horizon Health, at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072. EOE

MONTANA

PSYCHIATRIST-Seeking full-time board certified psychiatrist to fill staff position in VA Montana Healthcare System. 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. Competitive salary, benefits and liability included. Additional information can be found at www.vacareers.va.gov. Fax curriculum vitae to 406-447-7916 or call at 406-447-7310 for additional information. EOE.

BILLINGS: Yellowstone Boys and Girls Ranch is seeking a BE/BC child/adolescent psychiatrist or general psychiatrist with appropriate experience, to serve as staff psychiatrist. YBGR is an accredited psychiatric residential treatment facility, with an excellent national reputation, providing long term treatment to seriously emotionally disturbed youth. Our current population includes 110 boys and girls, ages 6 to 18, from all around the nation, with an average length of stay of over one year. Staff psychiatrists provide evaluations, diagnosis, and pharmacotherapy and serve as leaders of multidisciplinary treatment teams. Salary and benefits are negotiable and competitive. Employment responsibilities and environment are very gratifying. Montana's mountains and streams are close by, and this position allows time to enjoy them. Check out www.ybgr.org to learn more about our organization and then call for more details. Contact Joseph D. Rich, MD, Medical Director, at 406-651-2813 or jdrich@yahoo.com.

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# 27716PY. *For more opportunities, visit www.cejkasearch.com*

NEBRASKA

Psychiatrist-Clinical Services Director
Omaha, Nebraska!

DUE TO GROWTH, Horizon Health seeks Psychiatrists for a NEW freestanding psychiatric hospital located in Omaha, Nebraska. Innovative 64-bed adult psychiatric hospital scheduled to open November of 2007.

Psychiatrists will be hired as Clinical Service Directors to oversee hospital program, which will provide sub-acute, acute, and crises intervention services. Clinical Service Directors will be responsible for administrative duties, clinical direction, patient care, and private practice. Ideal candidate will have active Nebraska license, Board Certification and experience working in Community Mental Health, State Hospital, and Private Practice settings. Attractive stipend, practice guarantee, and relocation provided.

Please contact Diane Odom, 972-420-4083, Fax 972-420-8233, e-mail: **diane.odom@horizonhealth.com**

NEVADA

The University of Nevada School of Medicine is currently seeking candidates to fill the following positions in Las Vegas and Reno:

PHYSICIAN/MEDICAL DIRECTOR
MOJAVE ACF SERVICES
LAS VEGAS

Physician/Medical Director at the Mojave Adult, Child and Family Services (MACFS) facilities in Las Vegas, Nevada. The position is responsible for performing the duties of a clinical physician which include evaluation and treatment of patients at MACFS outpatient clinics - examining and evaluating patients, diagnosing, treating illnesses, ordering and interpreting tests and other related duties; providing administrative management such as supervising MACFS medication clinics; quality medical assurance in collaboration with the Director of Nursing and ensuring clinical standards review and evaluation. Review of applications will begin mid June and continue until the position is filled. Requirements: MD, DO or equivalent from an accredited institution; completion of a residency program in family medicine, psychiatry or related discipline; and three years experience as a physician with at least one year experience in a student health center or comparable health care delivery environment. Administrative and supervisory experience is preferred.

CHILD & ADOLESCENT PSYCHIATRIST
ASSISTANT/ASSOCIATE PROFESSOR
RENO

Child and Adolescent Psychiatrist who will contribute to our fellowship training program, support hospital psychiatry at West Hills Hospital's University Service, and teach at both the medical student and the general graduate medical education level. The position will be rounding with fellows and residents; provide on-site supervision and consultation to other clinicians; and provide outpatient follow-up in a practice setting or through service contracts. The position will also be engaged in curriculum development, seminar teaching of residents and fellows, and attend departmental staff meetings. This position may be involved with future funded research projects.

MD or equivalent degree. Successful completion of an accredited GME program in Psychiatry and Child and Adolescent Psychiatry.

CHILD & ADOLESCENT PSYCHIATRIST
ASSISTANT/ASSOCIATE PROFESSOR
LAS VEGAS

Full-time faculty member to join at the rank of Assistant or Associate Professor in Las Vegas. One half-day a week, the incumbent will round with residents at University Medical Center on the pediatric unit. Four half-days, will be spent teaching didactics etc. for our current trainees, supervise residents and students and work on the establishment of a child and adolescent psychiatry fellowship.

MD or equivalent degree. Successful completion of an accredited GME program in Psychiatry.

GENERAL PSYCHIATRIST
ASSISTANT PROFESSOR
LAS VEGAS

Full-time faculty member to join the Department at the rank of Assistant Professor in Las Vegas. This position will be responsible for supporting outpatient psychiatry functions in our new offices, admitting inpatients at Montevista Hospital, supervising residents on site, and didactics and seminars for medical students and residents.

70% of the incumbent's time will be spent performing clinical work, rounding with residents, providing on-site supervision, consulting to other clinicians, and providing outpatient care in our practice setting and, as needed, through service contracts. The balance of the time, the incumbent will be engaged in curriculum development, seminar teaching of residents and third year medical students, and attending staff meetings at the department.

MD or equivalent degree. Successful completion of an accredited GME program in Psychiatry.

The State of Nevada has no state income tax. Candidates must be eligible for an unrestricted Nevada medical license and malpractice insurance coverage. For complete information and to apply on-line, visit www.unrsearch.com. AA/EEO. Women and under-represented groups are encouraged to apply.

POSITIONS AVAILABLE IN LAS VEGAS, RENO, AND RURAL NEVADA. Systems fully JCAHO accredited in Reno and Las Vegas; Active Psychiatric Residency teaching and affiliation available; System expanding; Currently hiring BE/BC psychiatrists; hospital and community based. Two new state of the art acute psychiatric hospitals. Limited call responsibilities; Relocation assistance; Salary up to $166,000; Good Benefit and Retirement packages. No State income tax. J1 applicants welcome
Contact and send CV to David A. Rosin, MD; State Medical Director MHDS; 6161, W. Charleston Blvd, Las Vegas, NV, 89146 mddirect@snamhs.nv.gov or Phone 702-486-6050; fax 702-486-0451

NEW HAMPSHIRE

ADULT PSYCHIATRIST

Monadnock Family Services is a community mental health center offering assessment, counseling, support, education and referral services to children and adults of all ages. Position available with an innovative behavioral health agency with a 100-year history. Monadnock Family Services is a leader in area health and social services, alliances, and partnerships. Creative, innovative and supportive climate in the beautiful Monadnock region of N.H. - 90 miles from Boston; near many excellent recreational and cultural activities. MFS is seeking a 5-day per week general psychiatrist to work primarily with adult clients (including the geriatric population) with persistent mental illness for our community mental health center. The psychiatrist in this position works as a clinical leader in an interdisciplinary team consisting of various mental health professionals who provide services based in the recovery and evidence-based practice models of treatment. Candidate must be Board Certified or eligible in psychiatry, have current credentials to practice medicine in the US, and have a desire to work with individuals with severe and persistent mental illness. Competitive salary and fringe benefits with generous vacation leave, 11 paid holidays and sabbatical program. Infrequent on-call coverage required. *Our staff enjoys a generous benefit package, including health, dental, flexible-spending plan and company-provided LTD, AD&D and Life insurance and 3 weeks of vacation during the first year of employment.*
Please send resumes in confidence to: MONADNOCK FAMILY SERVICES ATTN: Human Resources, 17 93rd Street, Dept. PN, Keene, NH 03431 Or to Humanresources@mfs.org

PSYCHIATRIST
Portsmouth, NH

Beautiful Seacoast area with four seasons, 55 minutes from Boston. Expanding private, nonprofit community mental health center seeks two psychiatrists, one child and adolescent and one adult, to join a staff of seven psychiatrists, for outpatient care. Vibrant collegial atmosphere with competitive salary and excellent benefits package.

Interested candidates should send cover letter and C.V. to W.M. Hanna. M.D., Medical Director.

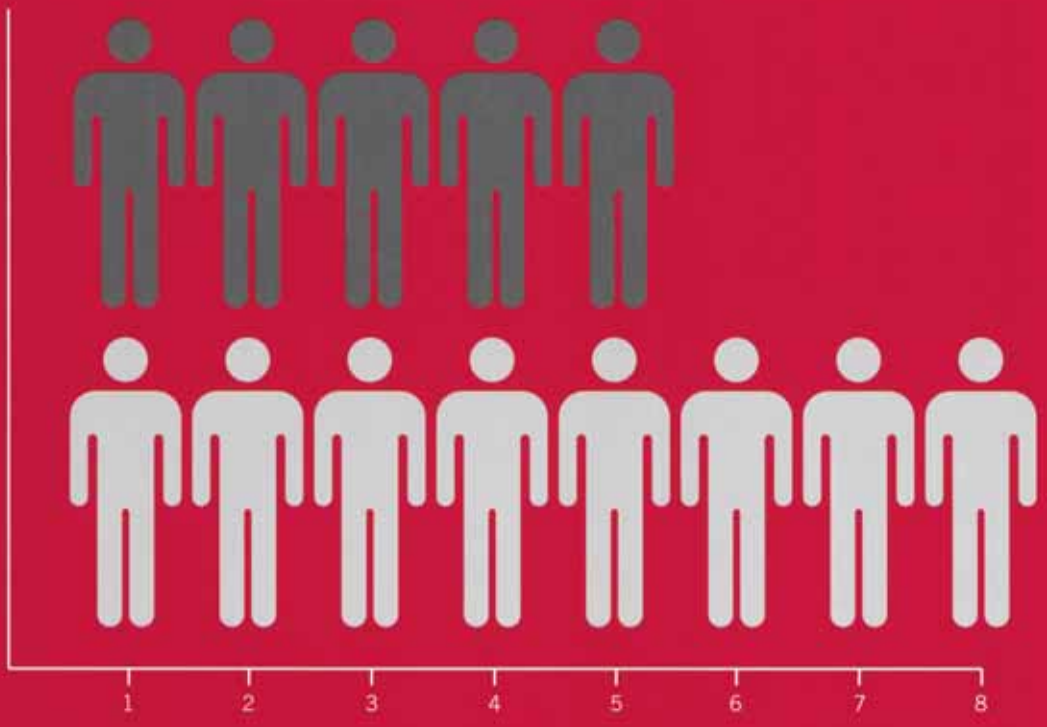
Seacoast Mental Health Center, Inc.
1145 Sagamore Avenue
Portsmouth, NH 03801
Fax: 603-433-5093

NEW JERSEY

Child/Adol. or Adult Psychiatrists

Child/Adol. or Adult Psychiatrists - needed for growing multi-disciplinary group in affluent community in North/Central N.J. NO Managed Care! Please fax CV to (908) 598-2408.

KNOWTHEFACTS



People with severe mental illness die up to 3 decades earlier, on average, than the general population.[1,2]

Be aware.
Screen and monitor your patients.
Make a difference.

Pfizer

KNOWTHEFACTS

Heart disease is a leading cause of death in patients with severe mental illness.[1,2]

Major risk factors include[3]

- Weight gain
- Diabetes
- High blood pressure
- High cholesterol
- Smoking

Be aware.
Screen and monitor your patients.
Make a difference.

References: 1. Colton CW, Manderscheid RW. Congruencies in increased mortality rates, years of potential life lost, and causes of death among public mental health clients in eight states. *Prev Chronic Dis* [serial online]. 2006 April;3(2). Available at: http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm. Accessed December 7, 2006. **2.** Miller BJ, Paschall CB III, Svendsen DP. Mortality and medical comorbidity among patients with serious mental illness. *Psychiatr Serv.* 2006;57:1482-1487. **3.** *Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Executive Summary.* Bethesda, Md: National Institutes of Health, National Heart, Lung, and Blood Institute; 2001. NIH publication 01-3670.

GZ279361

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Englewood, NJ (Bergen County) - An easy drive to NYC and Newark -
Horizon Health seeks a Psychiatrist to join our Medical Director's practice in NJ. This is an inpatient & outpatient position (adult and geriatric); salaried with benefits. Please **call Terry B. Good, Horizon Health, at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

NEW MEXICO

Mental Health Resources, Inc. of Clovis, New Mexico has a vacancy in its psychiatric services department for a general psychiatrist who is comfortable providing services for both adult and children. Applicants would need to be eligible for New Mexico medical licensure and comfortable in a small town of slightly less than 50,000 population in a rural environment. E-mail address is: mhrnewmex@yucca.net

NEW YORK CITY & AREA

ALBERT EINSTEIN COLLEGE OF MEDICINE Of Yeshiva University Department of Psychiatry and Behavioral Sciences

The Sound View Throgs Neck Community Mental Health Center

PSYCHIATRISTS - Full-time. Adult Outpatient Program and Continuing Day Treatment and MICA Program.
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, M.D., 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.**

BC/BE Psychiatrists

Child/Adolescent & Adult Brooklyn, Bronx & Manhattan Full Time/Part Time/Fee for Service

YAI/Premier Healthcare is a nationally recognized, well-established NYC diagnostic & treatment center for people with disabilities and their families. We are currently seeking NY Licensed psychiatrists. Brooklyn Heights, Sheepshead Bay and Throgs Neck, Bronx & Manhattan.
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

Child and Adolescent Psychiatrist
P/T positions available (afternoons, evenings and weekends) in a Brooklyn Community Mental Health Center. Spanish speaking a plus. Excellent compensation. NO CALL
Fax resume to (718) 553-6769

Westchester Suburb or Upper Manhattan Child or Adol, FT or 1/2 time - choose either Westchester (easy 35 min NYC drive) **or** Manhattan. Options for teaching & priv prac. Little mg'd care, no call, no evenings/weekends! Strong C/A group. 917-710-2456 or toacp@aol.com

NEW YORK STATE

STAFF PSYCHIATRIST, SARATOGA COUNTY. SALARY: $156,267 plus excellent benefits. **QUALIFICATIONS:** License to practice medicine in New York State and Board eligibility to practice psychiatry. Applies psychiatric expertise to the planning, coordination and operation of the mental health and mental retardation services provided within Saratoga County. Submit resume to: William Baker, Personnel Director, 40 McMaster St., Ballston Spa, NY 12020, FAX (518) 884-4752 or email jobinfo @govt.co.saratoga.ny.us.

AA/EOE

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.

Forensic Psychiatry / Child Psychiatry: St. Lawrence Psychiatric Center, a fully accredited EO-AAE, seeks BC/BE Psychiatrists licensed to practice medicine in NYS (or eligible to obtain NYS license) to work either full or part time at a new 80 bed Sex Offender Treatment Program (Additional training in forensic psychiatry is helpful, but not required) or Child Psychiatrists to work in a Child and Adolescent unit. We are designated by the Federal Government as M.H.P.S.A. In addition to salary ($148,922 to $159,164) and guaranteed additional compensation by voluntary participation in an on-call program, we offer an excellent benefit package including: malpractice insurance, health insurance, paid vacation, holiday and sick time, excellent retirement plan and educational and professional leaves.

Situated on the scenic St. Lawrence Seaway in northern New York State, SLPC is located in Ogdensburg, NY, an idyllic rural community offering many cultural, educational and economic opportunities. Historic and international metropolitan cultures are a reasonable driving distance away in Ottawa and Montreal, Canada and Syracuse, New York. Ogdensburg's location on the St. Lawrence River and its close proximity to the Adirondack Mountains and Canada offers easy access to a wide variety of unspoiled natural areas and rich cultures and provides abundant recreational opportunities throughout the year.

Submit letter of interest to: Hari Sanghi, MD, Clinical Director, St. Lawrence Psychiatric Center, 1 Chimney Point Drive, Ogdensburg, NY 13669 or at slmdhls@omh.state.ny.us . If you have questions, call (315) 541-2117.

Ulster County Mental Health, an outpatient mental health clinic with a wide range of services, has a position for a full-time psychiatrist. We are located in the beautiful Hudson Valley, two hours north of NYC. Competitive salary, good benefits, on-site psychopharmacology supervision and collegial atmosphere. No on-call or weekends. Part-time position a possibility. Send CV to Mary Barber, MD, Medical Director, Fax #845-340-4094.

BC Psychiatrist-F/T or P/T to join large multidisciplinary behavioral practice with managed care population in Westchester and Putnam Counties, NY. Child and adolescent specialization a plus. Equity participation possible for solid candidate. Fax CV to 845-279-5447 or email to djorlo@comcast.net

NORTH CAROLINA

Endowed Professor of Geriatric Psychiatry at Wake Forest University

A generous endowment has established the Kate Mills Snider Professorship in Geriatric Psychiatry. The Snider Professor will serve as Director of The Kate Mills Snider Geriatric Outreach (GO) Program, which serves the Winston-Salem area and is intended to be a national resource for research and education in mental health outreach services for the elderly. Staff members on the GO Program are also funded through the endowment.

Position requires a strong background in Geriatric Psychiatry including Board certification and academic leadership experience.

Rank and salary: Commensurate with experience and qualifications.

Wake Forest University School of Medicine is an Equal Opportunity, Affirmative Action Employer.

Contact:
Burton V. Reifler MD, MPH, Professor and Emeritus Chair
breifler@wfubmc.edu
Department of Psychiatry
Wake Forest University School of Medicine
Medical Center Blvd.
Winston-Salem, NC 27157-1087

Adult Staff Psychiatrists Charlotte, North Carolina

CAROLINAS HEALTHCARE SYSTEM has opportunities for full-time adult staff psychiatrists at its Behavioral Health Center. The center is part of a 777-bed regional teaching facility nestled in the heart of Charlotte. Join an outstanding team of psychiatrists in a very collegial working environment. Two of the openings are within the Center's division specializing in the comprehensive multidisciplinary care of patients with severe and persistent mental illness and involves work with Community Support Teams as well as inpatient work. The other opening is for a full-time Emergency Room psychiatrist at Behavioral Health. Generous compensation and excellent benefits package offered. Interested applicants should fax their CV to 704-355-5033. Attention Elaine Haskell, or for more information call 800-847-5084, or email elaine.haskell@carolinashealthcare.org

(EOE).

Naval Hospital, Camp Lejeune, NC is recruiting for a

MEDICAL OFFICER (PSYCHIATRIST)

Responsible for treatment of active duty and reserve members of the Armed Forces from local commands. Clientele may include military dependents and retirees.

- To provide psychiatric treatment of both outpatient and inpatients. Duties include evaluation, treatment, and disposition of mental disorders in the Mental Health Clinic. Professional knowledge of psychiatric principles and techniques obtained with a MD or DO Degree and at least 4 years of postgraduate accredited residency training.

Set your sails in our direction and apply now! E-mail your resume to code52resumix.ne@navy.mil and include NE-DH-MCP-07-0290-NR in subject line. Please insert your resume into the body of your email message, since we cannot accept attachments. Or mail your resume to U.S. Department of the Navy, Human Resources Service Center-Northeast, Code 52, Attn: NE-DH-MCP-07-0290-NR, 111 S. Independence Mall East, Philadelphia, PA 19106-2598

Direct inquiries may be made to the Civilian Personnel Office, Naval Hospital, Glenda Milligan, (910) 450-3066. EOE

Coastal North Carolina

Brynn Marr Hospital, a private, free standing 88 bed psychiatric hospital and adolescent residential treatment center seek a BC/BE Child Psychiatrist or BC/BE General Psychiatrist with adolescent specialty training for full time employment. Located on the beautiful coastal corridor in Onslow county, Brynn Marr Hospital of Jacksonville, NC welcomes inquiries by contacting CEO Sarah.Wiltgen@psysolutions.com or by calling (910) 577-2717.

BC/BE Psychiatrist Needed in Beautiful Mountains of Western North Carolina!!!

Park Ridge Medical Associates is seeking a board certified/board eligible psychiatrist to join a thriving, established practice. Ideal candidate will have experience working with inpatient programs, outpatient practice and patients in nursing facilities. Competitive salary, plus bonus potential and full benefits available. Located in the beautiful mountains of western North Carolina, between Asheville and Hendersonville, the area is home to abundant natural beauty, friendly atmosphere, a wealth of year-round outdoor activities, rich history, and lively local arts and music scene

This position is within Park Ridge Medical Associates, a hospital-owned multi-specialty group employing over 45 physicians. Park Ridge Medical Associates provides practice management, including billing & collections, compliance & risk management and managed care contracting.

Park Ridge Medical Associates is owned by Park Ridge Hospital, a not-for-profit acute care hospital, owned and operated by the Adventist Health System. Park Ridge is fully accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and American Osteopathic Association (AOA).

For more information, please contact:

Danielle W. Ball, Park Ridge Hospital - Business Development, 100 Hospital Drive, Hendersonville NC 28792

Office - (828) 650-2746; Fax - (828) 650-2728; Danielle.ball@ahss.org

Staff Psychiatrist - Convenient to Outer Banks, NC and Norfolk/VA Beach - Horizon Health has a very attractive salaried position with benefits in a general hospital located in an area that is becoming one of THE places to retire in NC. This position will be primarily outpatient with some inpatient. What could be better: low stress small town living with a wonderful climate and easy drive to the coast plus a very rewarding professional opportunity. Join two other psychiatrists making call 1 in 3. Please **call Terry B. Good at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

CONVENIENT TO RALEIGH AND GREENVILLE - FANTASTIC COMPENSATION PACKAGE - Horizon Health seeks a Psychiatrist for a Medical Director position on a 34-bed adult unit and 16-bed CD unit in a very impressive general hospital in Rocky Mount. This is an inpatient and outpatient position. Offering a salary with benefits or practice guarantee and stipend. Enjoy the wonderful climate and quality of life this lovely location offers-only 45 minutes from Raleigh and Greenville & an easy drive to the mountains or the beach. Please **call Terry B. Good at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

Faculty Positions

The newly established Center of Excellence for Research and Treatment of Bipolar Disorder (CERT-BD), under the direction of Jair C. Soares, M.D., in the Department of Psychiatry at the University of North Carolina at Chapel Hill, has established two, full-time positions, Assistant Professor tenure track or Clinical Assistant Professor fixed term track, with 50% effort protected for research. Applicants should have a strong interest in bipolar disorder research and treatment and a demonstrated track record in providing quality clinical care. In addition, applicants should have the teaching skills necessary to enable them to successfully provide educational and training experiences for fellows, residents and medical students in a major academic/health care environment. The successful candidate should have an established record of scholarly achievement, including peer-reviewed publications. Special consideration will be given to Adult or Child and Adolescent Psychiatrists with current extramural funding.

Applicants must have an M.D., BC/BE and be eligible for North Carolina licensure. Salary will be commensurate with experience. Applicants should forward curriculum vita and three letters of reference to David R. Rubinow, M.D., Meymandi Distinguished Professor of Psychiatry and Chair, Department of Psychiatry, Campus Box 7160, University of North Carolina, Chapel Hill, NC 27599-7160. The Departmental of Psychiatry's website is www.med.unc.edu/psychiatry.htm. *The University of North Carolina at Chapel Hill is an Equal Opportunity employer.*

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER, SALISBURY, NC is seeking full time staff psychiatrists. Must be board eligible (within 2 years after residency graduation) or board certified, and must be eligible for a faculty appointment at Wake Forest University School of Medicine. Duties may include not only clinical assignments, but also teaching and supervision of residents and students. Research opportunities available. Opportunities in:

- General Inpatient and Outpatient Psychiatry
- Post Traumatic Stress Disorder Programs
- Iraq and Afghanistan Combat Veterans Services
- Buprenorphine Clinic
- Traumatic Brain Injury Services

Candidate must be U.S. citizen, and proficient in spoken and written English [(38 U.S.C. 7402 (d)]. Liberal benefits with 401K, 26 days paid vacation and paid federal holidays. Student loan repayment program available. Salisbury is a lovely, historic town in the Piedmont section of North Carolina, less than one hour from Winston-Salem and Charlotte and an easy drive to the Blue Ridge Parkway. Excellent cost of living and a rich cultural heritage.

Call for VA application form, and forward a current CV (addressing teaching responsibilities, if applicable) to: Janet Rasmussen, Human Resources Specialist (05C-JR), W.G. "Bill" Hefner VA Medical Center, 1601 Brenner Avenue, Salisbury, NC 28144. Phone (704) 638-9000, ext. 2880. May FAX to (704) 638-3322, or Email to Janet.Rasmussen@med.va.gov. EOE.

NORTH DAKOTA

PSYCHIATRIST

Recruiting BC/BE general psychiatrist to join department of four in an integrated non-profit community health system of 185 physicians in upper Midwest. Altru Hospital is a 277-bed state-of-the-art facility serving a 22 county area with a referral area of 225,000. Practice is in-patient and out-patient. Medical school at the University of North Dakota offers teaching opportunities and medical staff membership. Grand Forks a city of 65,000 offers excellent schools, community theater, symphony, big name concerts and the excitement of college athletics. Quick access to the Minnesota lake country provides opportunities for boating, fishing and other outdoor activities. Competitive compensation and benefit package. Contact Jean Keller, Phone: 1-800-437-5373; Fax: 701-780-6641; Email: jkeller@altru.org . Visit our website at www.altru.org . Sorry, not a J1 opportunity.

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

OHIO

Consultation-liaison psychiatrist for active, respected, academically oriented consultation liaison service in 360 bed general hospital. Four psychiatrists, one advanced practice nurse, one social worker assigned to service. After care clinic associated with service. Supervision of residents, medical students, allied personnel, direct care. Competitive salary, practice plan, academic appointment. If interested, please contact R T Segraves, MD, PHD, Professor and Chairperson of Psychiatry, MetroHealth Medical Center, Cleveland, Ohio (rsegraves@metrohealth.org) In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity.

Geropsychiatrist needed. MetroHealth Medical Center, a major teaching hospital associated with Case School of Medicine, has a major strategic initiative in geriatric medicine, involving a new facility dedicated to geriatric care, a Medicare managed care product, 325 long term care beds, contractual arrangements with 12 nursing homes, 17 certified geriatricians, established geriatric fellowship. Fantastic opportunity for geriatric psychiatrist to develop geropsychiatry program and fellowship. Collaborative research opportunities. Competitive salary, practice plan, academic appointment. Geropsychiatry boards and /or fellowship preferred but not required. If interested, please contact R T Segraves, MD, PhD, Professor and Chairperson of Psychiatry, MetroHealth Medical Center, Cleveland, Ohio, 44109. (rsegraves@metrohealth.org). In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity.

CINCINNATI AREA -
Staff Psychiatrist position available on adult and geropsychiatric services in a very impressive not-for-profit general hospital in a suburb of Cincinnati-only 8 miles from the University of Cincinnati Medical School. Work consists of inpatient and outpatient work along with medical floor consults; nursing home consults are optional. Offering excellent salary with benefits. Please **call Terry B. Good, Horizon Health, at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

OHIO: 100% OUTPATIENT and FLEXIBLE Child & Adolescent Psychiatrist needed for CMHC. Four-day week possible. NO patient quota. NO CALL. Private Practice on the side acceptable. Great comp & full benefits. Susan Springer 800.575.2880 ext 315
sspringer@medsourceconsultants.com

DO WE HAVE A GREAT JOB FOR YOU?

Staff Psychiatrists are being recruited for: *Cincinnati *Columbus *Dayton *Athens *Cleveland *Massillon *Cambridge
An Administrator is needed for our Appalachian Behavioral Healthcare.
Competitive salaries are paid to each position for a 40 hour, Monday to Friday, workweek. Malpractice insurance is paid and a generous benefit package is provided. Academic affiliations are possible for the successful candidate. Interested? Contact:
Dale Svendsen, M.D., Medical Director
Demetra Mutchler, Recruitment Manager
Ohio Department of Mental Health
mutchlerda@mhmail.mh.state.oh.us
(614) 466-9916 or fax (614) 752-9699

Psychiatrist
Cleveland, Ohio

Outstanding opportunity for a Psychiatrist to join thriving private practice and also practice on a 10-bed geropsych inpatient unit in the greater Cleveland area. Salary, Benefits, Productivity Bonus, and Partnership track available. Geropsych experience and Board Certification preferred. Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. EOE.

OKLAHOMA

Geriatric and/or Child/Adolescent Psychiatrist BE/BC is needed for a freestanding psychiatric facility in **Lawton, Oklahoma**. Excellent salary and benefits. For additional information please contact **PsychPros Executive Search: Dr. Diane Castelli at 888.651.8367 ext. 35 or e-mail letter of interest and CV to dianec@psychpros.com**

OREGON

PRIVATE PRACTICE: Unique opportunity for solo practitioner to share office space and overhead/operating expenses with 10 well-established, well-esteemed psychodynamically oriented solo private practice psychiatrists in remodeled historic home in NW Portland. Please contact Dr. Richard Alden (503-228-5909 ext.110) for further information.

PSYCHIATRIST/INPATIENT DIRECTOR
Portland, Oregon

Northwest Permanente, PC, a stable, physician-managed, multi-specialty group providing care to 490,000 members of Kaiser Permanente in Oregon and Southwest Washington has an excellent opportunity for a BC Psychiatrist to provide program leadership and oversight of clinical services at a new Residential and Inpatient Psychiatry Unit at our medical center in suburban Portland.

Our new associate will need inpatient management experience and be comfortable working as part of an interdisciplinary team. Knowledge in psychiatric evaluation and diagnosis, somatic treatments including use of psychotropic medication and psychotherapies (individual, group and family) is required. The Department of Mental Health region-wide consists of a multidisciplinary staff of over 130 mental health professionals who provide a full range of professional services to Kaiser patients.

We offer a collegial and professionally stimulating practice in one of the most successful managed care programs in the country. In addition to a quality lifestyle associated with the beautiful Pacific Northwest, we offer a competitive salary and benefit package, which includes a generous pension program, professional liability coverage, sabbatical leave, and more.

To submit a CV and receive additional information, please visit our Web site http://physiciancareers.kp.org/nw/ and click on Career Opportunities. For more information please call (800) 813-3763. **No J1 opportunities**. We are an Equal Opportunity Employer and value diversity within our organization.

PENNSYLVANIA

Medical Director
Aetna Behavioral Health
King of Prussia, PA office
Aetna Behavioral Health is looking for a board certified psychiatrist with clinical and managed care experience to take a leadership role in a new and innovative approach to behavioral health care management.
Full benefit package. Salary commensurate with experience.
Submit CV http://aetna.com/working
under Req 16535 or contact hasleys@aetna.com
609-708-2281

The Philadelphia VA Medical Center (PVAMC) and the Department of Psychiatry at the University of Pennsylvania's School of Medicine seeks candidates for an Associate or Full Professor position in either the non-tenure clinician-educator track or the tenure track. Track and rank will be commensurate with experience. The successful applicant will be accomplished in the area of Psychiatry. Expertise in the specific area of Behavioral Health Services is required. Responsibilities include serving as Associate Chief of Staff (ACOS) for Behavioral Health Services at the Philadelphia VA Medical Center. The PVAMC is a tertiary care facility that offers comprehensive surgical, medical, and psychiatric care to include special emphasis programs, MIRECC (Mental Illness Research Educational & Clinical Center), CESATE (Center of Excellence in Substance Abuse Treatment & Education), alcohol and drug dependence treatment, 39 inpatient bed unit and rehabilitative care. PVAMC is affiliated with the University of Pennsylvania School of Medicine, with fully integrated residency and fellowship programs. The ACOS of Behavioral Health provides clinical, academic, research & managerial leadership for all behavioral health programs at PVAMC & maintains collaboration between the University & PVAMC. Behavioral Health Services at PVAMC is a multi-disciplinary organization that employs over 95 staff at PVAMC and its Community Based Outpatient Clinics in Fort Dix and Turnersville, NJ, as well as Horsham and Philadelphia, PA sites. The Behavioral Health Service has an annual operating budget in excess of $11,000.000. In addition, the MIRECC and CESATE have annual hard funding for research with an annual operating budget of $2,400.000.

Candidates must be qualified for and be expected to maintain a faculty appointment as Associate Professor or Professor in the tenure or the non-tenure clinician-educator track. Applicants must have an M.D. degree and have demonstrated excellent qualifications in Education, Research, and Clinical Care. Evidence of scholarship is required in the clinician-educator track. Board Certification/Board Eligibility in Psychiatry required. PA license or eligibility required.

Successful candidates must have experienced senior level responsibility for the direction of a comparable service in a similar environment and have demonstrated excellence in research as evidenced by training & publication in peer-reviewed journals. Experience as an extramurally funded investigator is desirable.

Please submit curriculum vitae and a letter of interest to: Dr. Martin Heyworth, Dr. Dwight L. Evans, c/o Diane Daniels, Philadelphia VA Medical Center, Human Resources (05), University & Woodland Avenues, Philadelphia, PA 19104; email PVAMCJOBS@va.gov, Reference 01-Psychiatry. The closing date for receipt of applications is September 1, 2007.

The University of Pennsylvania and the Philadelphia VA Medical Center are equal opportunity, affirmative action employers. Women and minority candidates are strongly encouraged to apply.

STATE COLLEGE: Child or General Psychiatrist to see children & adults -outpatient only.
CLARION- General Psychiatrist for inpatient and partial programs.
SHIPPENSBURG-near Harrisburg. General/Addiction Psychiatrist. Inpatient & sub acute. Salary, bonus, & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Pittsburgh Area - Horizon Health has an outstanding opportunity available with a stable, highly successful Psychiatry group practice. Located in one of the fastest growing counties in western PA 25 minutes from downtown Pittsburgh, this area offers a diverse industrial base set in a scenic, tranquil setting but yet is so close to a wonderful metropolitan city. They are offering a salary with benefits (with future partnership availability). Position would involve inpatient and outpatient work. Please **call Terry B. Good, Horizon Health, at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@ horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

RHODE ISLAND

Psychiatrists
Providence, RI

MedOptions has opportunities for adult and geriatric psychiatrists at an established outpatient clinic on the campus of a leading psychiatric hospital.

We offer a flexible schedule and opportunities to work in both outpatient and inpatient settings if desired. Our psychiatrists are supported by a full service organization.

MedOptions is a leading provider of behavioral health services in Southern New England, serving 15,000 patients in 260 facilities.

We offer a very competitive compensation package as either an employee or independent contractor. Relocation assistance available. Visit our website at www.medoptionsinc.com. For consideration, please contact Marianne Wright, Director of Recruiting, MedOptions at 800-370-3651, ext 164, email: mwright@medoptionsinc.com.

MedOptions™

SOUTH CAROLINA

GREENVILLE: Child or General Psychiatrist (willing to see some adolescents). Inpatient & partial programs. Beautiful city and community to live in! Salary, benefits & bonus potential. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Medical Director
1 hour from MYRTLE BEACH!

Due to growth, a Medical Director is needed for a new 12-bed geriatric psychiatric program scheduled to open July of 2007! Behavioral Health program is part of 372-bed hospital system, which serves patient needs in a nine-county area. Located in Florence, South Carolina (1 hour from Myrtle Beach) where the living costs are relatively low and the residents are known for their southern hospitality. Physician will be responsible for overseeing the geriatric psych program. Competitive Stipend and lucrative private practice potential. Board Certified required. Contact Diane Odom, 972-420-4083, fax 972-420-8233, diane.odom@horizonhealth.com

TENNESSEE

Enjoy a 37.5 hour work week!

Lakeshore Mental Health Institute is a 160-bed facility located in Knoxville, Tennessee on a 200-acre mountain view setting over looking the picturesque Tennessee River. Lakeshore has a full-time position open for a BC/BE Psychiatrist. Competitive salary for a 37.5 hour work week. Earn extra money through voluntary on call coverage. Knoxville is rated as the most affordable city in the US and is nestled in the foothills of the Great Smoky Mountains National Park. Knoxville is home to a rich arts community and to the University of Tennessee, the state's highly rated flagship public university. No state or city income tax. Excellent benefits including malpractice coverage, 100% employer funded pension, 401K tax-deferred retirement with employer contribution, health insurance (employer pays 80% of premium), paid sick leave, paid vacation, paid time off for CME and 11 paid holidays per year. **Enjoy practicing psychiatry and enjoy your life!** Call Bert Simpson, MD, Clinical Director at (865) 583-8768 or e-mail to bert.simpson@state.tn.us.
The State of TN is an Equal opportunity, Equal Access, Affirmative Action Employer.

East Tennessee State University - College of Medicine - Department of Psychiatry and Behavioral Sciences - Assistant/Associate or Full Professor - 820410, 811950. Full time position available for one or more Child Psychiatrists. Essential Functions: Responsibilities include training of psychiatric residents and medical students, clinical service, research activities and the potential for administrative opportunities. Salary is competitive with funding available through the medical school, faculty private practice and extramural contracts. ETSU is located in the Tri-Cities area, rated #1 place in North America in cost-of-living, crime rate, climate and health care. **Applicants should submit an ETSU application, CV and two letters of reference to Merry N. Miller, M.D., Chair, Department of Psychiatry and Behavioral Sciences, ETSU, Box 70567, Johnson City, TN 37614-1707. Telephone inquiries should be made at 423-439-2235 or e-mail at loveday@etsu.edu. AA/EOE**

TEXAS

AUSTIN: Busy private practice group seeking adult and/or child psychiatrist. Texas license and BE/BC required. Primarily out-patient. In patient optional. Ample referrals. Office well staffed and equipped. Austin is a great place to live and raise a family. Contact Neuropsychiatric Associates of Austin @ (512) 454-5716 or e-mail np_associates@prodigy.net.

Come to beautiful San Antonio, Texas!!

Psychiatrists

The Center for Health Care Services, a 2006 APA Gold Award winner, is actively seeking full-time/part-time/contract psychiatrists for our Adult & Child Programs. The Center Psychiatrists are at the leading edge of the delivery of mental health service, providing assessment and treatment of clients, and leadership of a team of skilled and dedicated mental health professionals. Must be board eligible or board certified.

The Center offers:
- *Attractive salary*
- *Excellent benefits package, including retirement benefits and an internal CME program.*

San Antonio offers:
- *Great climate year round*
- *Ranked among the best value cost of living*
- *Arts, Theatre, Sports and Entertainment, Amusement parks and more*
- *Easy access to beaches, Mexico, the Texas Hill Country, more*

If you are interested in learning more about service at The Center, please submit your C.V. in confidence to:

The Center for Health Care Services
Attn: HR Director
3031 IH 10 West
San Antonio, Texas 78201
Fax: 210-731-1310
staffing@chcs.hhscn.org

EOE

West Texas VA Health Care System
300 Veterans Blvd
Big Spring, TX 79720

We welcome you to join our health care team. WTVAHCS is located in a Family-orientated community with an excellent quality of life for families. Located in the heart of West Texas, with mild winters, and access to golf, hunting, fishing, hiking, riding, and camping; yet is within driving distance to larger cities.

The WTVAHCS is currently accepting applications for PSYCHIATRIST with BC/BE in Psychiatry and the specialty areas of Outpatient consultation & Post Traumatic Stress Disorder.

WTVAHCS is committed to excellence in clinical care. The Mental Health Care Line of WTXVAHCS provides outpatient mental health services to approximately 4,000 veterans per year in the areas of Consultation, Substance Dependence, Comprehensive Mental Health and Health Care for Homeless Veterans

Compensation for physicians will be determined by compensation panel based on qualifications, credentials, experience, and local area compensation. In addition to an attractive salary, the VA offers 10 paid holidays, 26 Vacation days per year and 13 sick leave days per year, Health and Life Insurance coverage and an attractive retirement package including a tax deferred savings plan, Child Care Tuition Assistance Program, Educational Debt Reduction Program, Guaranteed Hours, and a Stable Work Environment.

Interested applicants should contact, fax or email a CV/Resume to Erlinda Rios, Human Resources Specialist at (432) 263-7361 Ext 7017; Fax: (432) 264-4863; or: Erlinda.Rios@med.va.gov

The Price of Freedom is visible here

Psychiatrist or PCP experienced in Geriatrics Clinical, Supervisory and Administrative Responsibility with Geriatric Psychiatry Group. FT $200,000.00/yr compensation DOE. Benefits+Bonus.
Chart Review, Supervision of NP/PA, Phone Consults. PT 5 - 20hrs/mth $100.00+/hr DOE $1000.00/mth min.
Expertise in psychopharmacology, psychotherapy, community or geriatric psychiatry desired.
Willingness to work with multidisciplinary team.
Will train on special needs of Geriatric Population. TX license required. Positions available in Houston and San Antonio.
Visit: www.seniorpsychiatry.com/Fax CV: 800-318-0120/Email: hr@seniorpsychiatry.com

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SAN ANGELO: General /Geriatric or Child Psychiatrist for private practice. Service Directorship and caseload stipend offered. Great practice opportunity & income potential.Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

VERMONT

PSYCHIATRIST

Northwestern Counseling & Support Services, Inc. is seeking a BE/BC full-time outpatient Psychiatrist to join our CMHC. Nearby beautiful Lake Champlain and the Green Mountains, between Burlington, VT and Montreal. Experience with adult SPMI population and children preferred. Salaried with generous benefits and paid time off to enjoy VT! www.ncssinc.org May qualify for National Health Service Loan Repayment assistance. Responses:

Ted Mable, Ed.D., Executive Director
NCSS, Inc.
107 Fisher Pond Road
St. Albans, VT 05478
(802) 524-6554

Lakeshore haven! - Adult psychiatrist needed for community mental health program. Position is all outpatient and minimal call schedule. J1 and federal loan repayment opportunity. Competitive Salary plus great benefits. Contact Christian Brown 800-575-2880 x329.
Email: cbrown@medsourceconsultants.com

VIRGINIA

VA COMMONWEALTH UNIV: Dept. of Psychiatry recruiting BE/BC psychiatrist faculty positions: 1) **Medical Director of Affective Disorders Program** - 50% Inpatient and 50% outpatient responsibilities to include teaching rounds on 10-bed team, supervision of teaching clinic and faculty practice or city mental health clinic services. Fellowship in mood disorders or post-residency experience preferred. 2) **Geropsychiatrist** 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. Opportunities for collaborative and independent research available for all positions. VCU is a large urban university with robust health science campus and 750-bed university hospital. Department of Psychiatry employs over 90 full time faculty and is nationally ranked in federally funded research. Richmond, the State Capital, has moderate climate and rich mix of history with modern facilities. Excellent suburban housing and quality public/private schools. Send CV to Mary Swartz, Human Resources, Department of Psychiatry, VCU/MCV, Box 980710, Richmond, VA 23298. VCU is an EEO/AA employer. Women, minorities, persons with disabilities encouraged to apply.

CARILION
FINDING BETTER WAYS

Psychiatrist
Carilion Clinic - Virginia

Carilion Roanoke Memorial Hospital in Roanoke, Virginia, has an opening for a full-time BE/BC adult Psychiatrist at Carilion Medical Center, an 825-bed teaching/tertiary referral center with 32 acute adult psychiatric beds. The responsibilities include inpatient/outpatient clinical services, directs consultation/liaison and emergency services for the Department of Psychiatry and Behavioral Medicine, along with teaching medical students, and supervising residents in psychiatry. Call coverage is 1:10. In collaboration with Virginia Tech, the Carilion Clinic is establishing its own allopathic medical school with a problem-based learning curriculum.

Carilion New River Valley Medical Center in nearby Radford, Virginia has an opening for a full time BE/BC adult Psychiatrist for Saint Albans Behavioral Health, a new, 36-bed wing of the Medical Center. The inpatient psychiatry unit includes an ECT suite, intensive treatment area, geriatric observation, and adjacent outpatient offices for continuity of care. Saint Albans is a training site for medical students at Via College of Osteopathic Medicine on the campus of Virginia Tech in nearby Blacksburg. Call coverage is 1:7.

These positions include a competitive base salary with a potential for a substantial bonus for quality and meeting productivity targets. For more information or to submit your CV and cover letter for consideration contact:

Rhonda B. Creger, Senior Physician Recruiter
800-856-5206 or rhondac@carilion.com
Visit Carilion at www.carilion.com
EEO/AA

WASHINGTON

Puyallup, WA - Psychiatry

Fabulous opportunity! The growing community of Puyallup, Washington is seeking a BC/BE psychiatrist who is searching for a practice with plenty of flexibility and growth opportunities. This position includes both a psychiatric consultation practice within a medical hospital environment as well as a private practice component within an outpatient office setting. This is an opportunity to be both part of a psychiatric team and to establish a solo practice which would be unique in this community where there are currently no other private psychiatric practices. We are located very close to Seattle/Tacoma and all the activities associated with large cities or you can choose a more rural lifestyle in the smaller communities outside of the Puyallup area. Qualified applicants must be flexible, self-motivated, and committed to program development and patient care. If you would like more information concerning this opportunity, please Email your CV to *MultiCare Health System Provider Services at providerservices@multicare.org or fax your CV to 866-264-2818.*

Refer to opportunity #535-645

Three months in beautiful Seattle:
November 2007 to February 2008
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.

BC/BE Psychiatrist needed for a new VA Outpatient Clinic in Wenatchee, Washington. The psychiatrist will provide direct patient care, as well as consultation to medical providers, and will work together with a master's level therapist and substance abuse counselor. Wenatchee is a wonderful smaller city on the east side of the Cascade mountains, with abundant sunshine, unlimited outdoor recreation, and easy access to the Spokane and Seattle metro areas.

VA employees enjoy a generous benefits package and competitive pay. Benefits include:
Salaried position
Malpractice coverage
Excellent retirement program
Generous paid vacation/sick/CME days
Ten paid holidays

Call or send resume to:
Donna Dehart-Ray, Administrative Assistant
to Chief of Staff
VA Medical Center
4815 N. Assembly Street
Spokane, WA 99205
Phone: 509-434-7204
Fax: 509-434-7100

An Equal Employment Opportunity

Western Washington State: Adult/Geriatric/Forensic Psychiatrist (BE/BC with a WA state license) applications considered. Western State Hospital is a fully accredited (JCAHO) and certified (CMS) 997 bed hospital serving adult, geriatric and forensic populations. Annual salary of $149,700. Excellent benefits, including hospitalization/medical insurance, retirement and vacation leave, plus optional deferred income plan. Send CV to Norma Jones, Medical Staff Coordinator; Western State Hospital; 9601 Steilacoom Blvd. SW; Lakewood, WA 98498-7213. E-Mail: JONESNL2@DSHS.WA.GOV.

PRACTICE OPPORTUNITY AVAILABLE

Join a well-established group of three psychiatrists in central Seattle. We can provide expert credentialing service, HIPAA compliance, billing service, accounting programs, a strong referral base, computer expertise, and a pleasant office setting with a nice view and reasonable overhead.

Shahm Martini, M.D.
206-381-0610

Private Practice Opportunity-Spokane
BE/BC Psychiatrist to join 4 others in busy, well established group. No start up costs. Flexible practice, shared overhead, Minimal call. Eastern WA is a tertiary referral center with 500k Plus Catchment pop, teaching opportunities, good schools, affordable housing, abundant cultural, recreational resources for rural or urban living. 509-455-9090 or davidg6789@aol.com

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Pacific Northwest - Inpatient and Outpatient Psychiatrists

Highline West Seattle Mental Health/West Seattle Psychiatric Hospital is a large community mental health agency located in the Emerald city of Seattle. We have FT positions available in our psychiatric hospital and PT in our outpatient mental health center. Seattle offers a full, contemporary urban experience, with excellent schools and culture, surrounded by incredible mountains and outdoor recreation. Our salary is competitive; benefits include all the standard insurances, CME, approx. 1 month leave, etc. Please contact Jeff Skolnick, MD-Chief Medical Officer 206-933-7127 or JeffS@Highline.Org

WEST VIRGINIA

Directorship Position / An Hour from Charleston - Live Like a King/Queen and Leave Big City Stresses Behind - Horizon Health has an outstanding inpatient/outpatient opportunity minutes from the OH state line and 2 hours from Columbus and Canton. Offering salary with benefits or practice guarantee with administrative stipend. **Sign-on bonus or Assistance with Student Loan repayment is an option.** Live/work in a beautiful, friendly community with affordable housing and a low cost of living surrounded by a variety of recreational choices. The crime rate in WV is next to the lowest in the nation. Please **call Terry B. Good, Horizon Health, at 1-866-865-7380**, Fax #: 804-684-5663; email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

WISCONSIN

PSYCHIATRIST

Waukesha County Mental Health Center

The Waukesha County Mental Health Center is recruiting for a full-time Psychiatrist for our free-standing 28 bed (two fourteen bed units) adult acute psychiatric facility. The full-time Psychiatrist serves is responsible for direct care for an assigned patient caseload and will work directly with the full-time Chief Psychiatrist and one part-time psychiatrist. The staff psychiatrist is responsible for the diagnosis, care, treatment and planning for psychiatric patients, and directs the activities of the interdisciplinary team. The staff psychiatrist participates in activities of the medical staff and in the systematic planning and review of health services of the hospital as assigned. Call is 1 in 4.5 and shared with the other psychiatrists of the mental health center.

Educational requirements include degree from a recognized medical school; completion of an approved internship and three years of approved residency training in psychiatry. Possession of or eligibility to obtain a license to practice medicine in the State of Wisconsin, and board certification in psychiatry or eligibility are required.

The 2007 salary range for the Psychiatrist position is $134,739- $165,703. Our benefit package includes vacation, holidays, sick time, health, dental and life insurance, CME time, deferred compensation program, professional liability insurance, retirement program and the opportunity for private practice on site.

Waukesha County is located in southeast Wisconsin, next to the Milwaukee Metropolitan area, two hours northwest of Chicago, 30 minutes from downtown Milwaukee and approximately one hour from Madison. Waukesha County (pop. 360,000) is one of the fastest growing counties in Wisconsin.

Interested individuals should contact James Rutherford, MD, Chief Psychiatrist at 262-548-7950 or at jrutherford@waukeshacounty.gov for more information about the position.

For information about the benefits package, contact Renee Gage, Senior Human Resources Analyst, in our Human Resources Department at 262-548-7053 or at rgage@waukeshacounty.gov.

Applicants should submit a CV and completed application to Human Resources at:

Waukesha County
Administration Center
Human Resources
1320 Pewaukee Road, Rm 160
Waukesha, WI 53188
(262) 548-7044
Hearing Impaired Number (262) 548-7903
Equal Opportunity Employer
www.waukeshacounty.gov

MEDICAL COLLEGE OF WISCONSIN FACULTY OPPORTUNITY

DIRECTOR OF THE DIVISION OF CHILD & ADOLESCENT PSYCHIATRY

The Department of Psychiatry and Behavioral Medicine of the Medical College of Wisconsin is seeking a board-certified Child & Adolescent Psychiatrist to lead its Division of Child & Adolescent Psychiatry and to serve as the Medical Director of the Children's Hospital of Wisconsin Department of Psychiatry. The successful candidate will have demonstrable administrative, clinical, and academic leadership experience. Successful grantsmanship and experience managing a Clinical Trials Program is preferred. Academic credentials must support an appointment at the rank of Associate Professor or Professor.

The Medical College of Wisconsin is a private freestanding medical school in Milwaukee, Wisconsin, and is an equal opportunity/affirmative action employer. The MCW Department of Psychiatry and Behavioral Medicine is internationally recognized and one of the top psychiatry departments in NIH funding. The Children's Hospital of Wisconsin is consistently ranked as one of the "Top 10" pediatric hospitals in the country. Applicants must have a Wisconsin medical license prior to employment start date.

Interested candidates should submit a letter outlining interest and experience, a CV, and three professional references to: Laura Roberts, MD, Chairman, Department of Psychiatry and Behavioral Medicine, Medical College of Wisconsin, 8701 Watertown Plank Road, Milwaukee, WI 53226. Questions: Please call Beverly at 414-456-7240, or e-mail: bpernitz@mcw.edu

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JOB TITLE: Psychiatrist - Civil Program
TAGLINE: Positions are available for two general psychiatrists and two child/ adolescent psychiatrists at Mendota Mental Health Institute in Madison, Wisconsin

DESCRIPTION:
Mendota Mental Health Institute, a 250-bed JCAHO-accredited state psychiatric hospital with a proud history of innovative public mental health care is seeking Board Certified or Board Eligible general psychiatrists to fill two positions on the Adult Assessment and Treatment Unit (AATU). Patients are involuntary, and admitted for acute stabilization, pharmacotherapy, and aftercare planning. We are also recruiting Board Certified or Board Eligible child/adolescent psychiatrists to work on our Childrens' Assessment and Treatment Unit and the Adolescent Male Treatment Unit. CATU is a 15 bed inpatient unit which delivers intensive psychiatric treatment to preadolescent patients from throughout the state of Wisconsin. AMTU provides similar assessment and treatment services to boys aged 12-18.

Length of stay at MMHI is determined by clinical necessity, rather than by funding resources. These positions involve psychiatric evaluation, treatment planning, and psychopharmacologic care delivery within a multidisciplinary treatment team model. **There is no on-call requirement, and little or no managed care involvement.** Starting salary is between $137,638 and $178,931 per year, depending on experience and qualifications. Salary scale is periodically adjusted as per union contract. Individuals may earn supplemental pay for Board Certification(s), and voluntary on-call duties are compensated through comp time and extra pay. The State of Wisconsin offers excellent healthcare and retirement benefits. Faculty appointments are available through the University of Wisconsin and Medical College of Wisconsin. Our staff of 20 distinguished psychiatrists represent all psychiatric subspecialties, and work within a collegial and mutually supportive environment. Come live and work with us in Madison, our state capital, consistently voted one of the nation's most livable cities, with a Big 10 university noted for its academic and research accomplishments, excellent community schools, low crime rate, diverse cultural resources, and plentiful outdoor recreational opportunities.

CONTACT:
TO APPLY: send an Application for State Employment (OSER-DMRS-38) which can be obtained on the internet at http://oser.state.wi.us/application.asp , or call our request line at (608) 267-9893 (voice) or (888) 701-1251 (TextNet). Please send also: a copy of your current medical license, documentation of 3 years residency in psychiatry, a copy of your Board Certification (if applicable), and a current CV to: Veronica Law, DHFS, Bureau of Personnel and Employment Relations, 1 West Wilson St., Room 555, P.O. Box 7850, Madison, WI 53707-7850 ; FAX (608) 267-2147. Applications will be accepted until institutional needs are met. FOR MORE INFORMATION: please contact Kenneth Casimir, M.D., Medical Director at 608-301-1044 or casimkc@dhfs.state.wi.us or contact Judy Mayfield (Dr. Casimir's administrative assistant) at 608-301-1045.

WYOMING

Acute care adult psychiatrist needed! An ideal heartland location enables one to enjoy life in western style. 50% C/L, 50% IP clinical duties, lite call, travel, salary to $200k! J1s. Call D. Featherston @ 800-575-2880 x314 dfeatherston@medsourceconsultants.com

Canada

Head of Pharmacogenetics Clinic/ Clinician Researcher
Department of Psychiatry

The Department of Psychiatry, University of Toronto in collaboration with the Centre for Addiction and Mental Health (CAMH) invites applications from qualified academic psychiatrist with expertise in pharmacogenetics and experience in working with diverse communities. The appointment will be at the rank of Assistant Professor or higher and will commence October 2007. The Pharmacogenetics Clinic Head will provide consultation, assessment, and treatment recommendations regarding the patient's drug metabolism status and risk for side effects based on molecular genetic investigations. The candidate will establish an independent program of research focused on the molecular strategies that will lead to the development of new therapeutics/approaches in the treatment of mental illness.

Applicants must comply with the following requirements: expertise in developing and providing services to marginalized communities and advocating for those services demonstrated effectiveness in clinical teaching and the ability to enhance inter-professional linkages and knowledge development through research; have an established track record in the area of research including peer-reviewed publications and grants; be eligible to practice Psychiatry in the province of Ontario (or have credentials that can be recognized). The ability to communicate effectively with international collaborators is also important, and in addition to fluency in English and French, fluency in German and Italian is considered an asset. Salary to be commensurate with qualifications and experience. Position is open till filled. **A cover letter, curriculum vitae and 3 contact references should be sent to:**

Human Resources, Centre for Addiction and Mental Health,
1001 Queen Street West,
Toronto, Ontario M6J 1H4.
Fax: (416) 583-4316 - Email: Jobs@camh.net

Vice-President/Chief, Research
Centre for Addiction and Mental Health (CAMH)

As a world-leading research facility, community-based organization, and education/training institute, CAMH provides a unique combination of programs in clinical care, research, policy, education, and health promotion. Fully affiliated with the University of Toronto, Canada's largest and most prestigious research-intensive university, CAMH is one of the few institutions worldwide with deep expertise in all four major areas of mental health and addictions research: biomedical, clinical, health systems and services, and population/public health.

In addition to assuming responsibility for the executive oversight of the Program and its team of 700 (including principal investigators, research support staff, students, and volunteers), the VP/Chief, Research will lead in developing a strategy to address the positioning of CAMH Research within the changing landscape of the provincial health system.

As an international leader, CAMH seeks, for this position, an outstanding scientist of considerable stature. A unique combination of qualifications is required: scientific leadership ability, an exceptional track record of scientific achievement and international recognition, a research philosophy that is rooted in clinical/community practice, and the ability to work in a complex environment. The successful candidate will demonstrate disciplinary breadth, a record of accomplishments in translational/multidisciplinary research, and experience in leading change. S/he will possess an MD or equivalent, substantial clinical experience, and/or a PhD in a relevant area. S/he will be qualified for appointment at the Associate or Full Professor level.

CAMH and the University of Toronto are strongly committed to diversity within their communities and especially welcome applications from visible minority group members, women, Aboriginal persons, persons with disabilities, members of sexual minority groups, and others who may contribute to the further diversification of ideas. All qualified persons are encouraged to apply; however, Canadians and permanent residents of Canada will be given priority. Applications will be accepted immediately and will be reviewed on a continuing basis, with the Search Committee's consideration of candidates beginning in mid-July. Information requests and applications, which must include a letter of interest, a c.v., and the names of and contact information for three referees, should be e-mailed to Helen.xue@rayberndtson.ca.

Fellowships

PSYCHOANALYTIC TRAINING PROGRAM and PSYCHODYNAMIC PSYCHOTHERAPY PROGRAM of adults, children and adolescents at the first training center in the U.S. Combine a distinguished history with modern training. TREATMENT CENTER with broad referral base. PACELLA PARENT CHILD CENTER. **The New York Psychoanalytic Society & Institute, Inc.;** 247 East 82nd Street; New York, NY 10028; (212) 879-6900; www.psychoanalysis.org

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GERIATRIC PSYCHIATRY-NEUROPSYCHIATRY FELLOWSHIP POSITIONS AT JOHNS HOPKINS

The Department of Psychiatry at Johns Hopkins Bayview is recruiting for ***two*** Fellowship positions in its growing Geriatric Psychiatry & Neuropsychiatry programs. Under the leadership of a new Chair, the Department is growing its clinical care and translational research programs in memory disorders, dementia, and Alzheimer's disease, with special interests in treatment development, clinical trials, biomarkers, and/or brain imaging. In the highly stimulating Johns Hopkins academic environment, fellows will have the option of completing accredited fellowships in Geriatric Psychiatry OR Neuropsychiatry, AND/OR undergoing clinical research training under a recently funded NIA Training Grant (T32 program) in "Aging Related Neuropsychiatric Disorders" in collaboration with the Department of Neurology. Johns Hopkins University offers a comprehensive salary program and excellent benefits in a smoke and drug free workplace. EOE/AA/D/V. The successful candidate(s) for this position will be subject to a pre-employment background check. Applicants should send a brief letter of interest and Curriculum Vitae to Constantine Lyketsos, MD, Althouse Professor and Chair, Department of Psychiatry, Johns Hopkins Bayview, 5300 Alpha Commons Drive, Baltimore, Maryland 21224. Email: kostas@jhmi.edu

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Geriatric Psychiatry Fellowship

The Department of Psychiatry of the State University of Buffalo School of Medicine and Biomedical Sciences (SMBS) has openings for two newly ACGME-accredited PGY 5 Geriatric Psychiatry fellows to begin July 2007. The fellows will participate in a clinical milieu emphasizing understanding the psychiatric aspects of medical conditions along with the medical aspects of psychiatric conditions in the elderly. Rotations will include: Geriatrics, Neurology, Hospice, Day Rehabilitation, Home Health Care, SNF, Inpatient, Outpatient, C/L and Telepsychiatry. Fellows will have the unusual opportunity through collaborative consultation-liaison work to develop clinical expertise and professional relationship skills working closely with trainees and faculty in geriatric medicine and neurology. They will participate in a comprehensive didactic program in preparation for the ABPN geriatric psychiatry certification. Assistance and collaboration with a scholarly effort will be available during the year. Contact the Geriatric Psychiatry Division for additional information and submit an application including your CV, your letter of interest, three letters of reference including one from your residency training program director to:

Sandra Gilliam
Program Coordinator
Office of Graduate Medical Education
462 Grider St
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(716) 961-6955
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Steven Dubovsky, MD
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INFANT PSYCHIATRY FELLOWSHIP. The Section of Child and Adolescent Psychiatry at Tulane University Health Sciences Center is seeking a full-time Fellow in Infant Psychiatry. This one or two year fellowship includes clinical and research experiences with the multidisciplinary Infant Mental Health group at Tulane. Completion of a fellowship in Child and Adolescent Psychiatry preferred. Faculty appointment at the Instructor level is possible. Applications will be accepted until a suitable qualified candidate is found. Applicants should send letter of interest, updated CV and list references to Charles Zeanah, MD, Vice Chair and Director of Child and Adolescent Psychiatry, 1440 Canal Street TB52, New Orleans, LA 70112. Interested eligible applicants may obtain further information regarding this position by contacting Dr. Zeanah at 504-988-5402 or czeanah@tulane.edu. Tulane is strongly committed to policies of non-discrimination and affirmative action in student admission and in employment.

RICHMOND - ACCREDITED GERIATRIC PSYCHIATRY FELLOWSHIP. Geriatric Psychiatry Program at the Virginia Commonwealth University Health System, affiliated with Piedmont Geriatric Hospital (PGH), recruiting for two fellows for 2007-2008 academic year. PGH is a specialty geriatric state hospital located in Burkeville, VA, 45 minutes from Richmond. Competitive salary and allowances. Fellowship offers broad-based training in inpatient/outpatient geriatric psychiatry focusing on both acute and chronic disease. Specific rotations include dementia clinic, nursing homes, geropsychiatric state hospital, university hospital/clinic geropsychiatry service, psychometric assessment and neuroimaging; also offers research and teaching experience. Applicants must demonstrate good communication skills, and have completed approved residency in psychiatry. J-1 APPLICANTS ELIGIBLE. Send CV to Suzanne Thibault, Program Coordinator, P.O. Box 980710, Richmond, VA 23298-0710. EEO/AA employer.

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Meetings & Conferences

NADD 24th ANNUAL CONFERENCE, *Physical & Mental Wellness: Promising Practices (ID/MH)*, 10/24-10/26/07, Atlanta, GA - Also announcing availability of the *Diagnostic Manual for Persons with Intellectual Disability (DM-ID)* - textbook or clinical guide - For information see www.thenadd.org.

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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); the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN); treatment of generalized anxiety disorder (GAD).

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.

Serotonin Syndrome—The development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including Cymbalta treatment, particularly with concomitant use of serotonergic drugs (including triptans) and with drugs which impair metabolism of serotonin (including MAOIs). Serotonin syndrome symptoms may include mental status changes (eg, agitation, hallucinations, coma), autonomic instability (eg, tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (eg, hyperreflexia, incoordination) and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea).

The concomitant use of Cymbalta with MAOIs intended to treat depression is contraindicated (*see* CONTRAINDICATIONS *and* WARNINGS, Potential for Interaction with MAOIs).

If concomitant treatment of Cymbalta with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (*see* PRECAUTIONS, Drug Interactions).

The concomitant use of Cymbalta with serotonin precursors (such as tryptophan) is not recommended (*see* PRECAUTIONS, Drug Interactions).

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, elevation of ALT >3 times the upper limit of normal occurred in 1% (39/3732) of Cymbalta-treated patients 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. Orthostatic Hypotension and Syncope—Orthostatic hypotension and syncope have been reported with therapeutic doses of duloxetine. Syncope and orthostatic hypotension tend to occur within the first week of therapy but can occur at any time during duloxetine treatment, particularly after dose increases. The risk of blood pressure decreases may be greater in patients taking concomitant medications that induce orthostatic hypotension (such as antihypertensives) or are potent CYP1A2 inhibitors (*see* CLINICAL PHARMACOLOGY, Drug-Drug Interactions, *and* PRECAUTIONS, Drug Interactions) and in patients taking duloxetine at doses above 60 mg daily. Consideration should be given to discontinuing duloxetine in patients who experience symptomatic orthostatic hypotension and/or syncope during duloxetine therapy. Effect on Blood Pressure—In clinical trials across indications, relative to placebo, duloxetine treatment was associated with mean increases of up to 2.1 mm Hg in systolic blood pressure and up to 2.3 mm Hg in diastolic blood pressure. There was no significant difference in the frequency of sustained (3 consecutive visits) elevated blood pressure. In a clinical pharmacology study designed to evaluate the effects of duloxetine on various parameters, including blood pressure at supratherapeutic doses with an accelerated dose titration, there was evidence of increases in supine blood pressure at doses up to 200 mg BID. At the highest 200 mg BID dose, the increase in mean pulse rate was 5.0-6.8 bpm and increases in mean blood pressure were 4.7-6.8 mm Hg (systolic) and 4.5-7 mm Hg (diastolic) up to 12 hours after dosing. 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% (2/2327) of duloxetine-treated patients and 0.1% (1/1460) of placebo-treated patients. No activation of mania or hypomania was reported in DPNP or GAD placebo-controlled trials. 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—Duloxetine has not been systematically evaluated in patients with a seizure disorder, and such patients were excluded from clinical studies. In placebo-controlled clinical trials, seizures/convulsions occurred in 0.04% (3/8504) of patients treated with duloxetine and 0.02% (1/6123) of placebo-treated patients. Cymbalta should be prescribed with care in patients with a history of a seizure disorder. Hyponatremia—Cases of hyponatremia (some with serum sodium lower than 110 mmol/L) have been reported and appeared to be reversible when Cymbalta was discontinued. Some cases were possibly due to the syndrome of inappropriate antidiuretic hormone secretion (SIADH). The majority of these occurrences have been in elderly individuals, some in patients taking diuretics or who were otherwise volume depleted. 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 placebo-controlled clinical trials of up to 10 weeks duration, the following symptoms occurred at a rate greater than or equal to 2% and at a significantly higher rate in either the MDD or GAD 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. As observed in DPNP trials, Cymbalta treatment worsens glycemic control in some patients with diabetes. 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, Cymbalta was associated with a small increase in mean fasting blood glucose as compared to placebo. In the extension phase of these studies, which lasted up to 52 weeks, mean fasting blood glucose increased by 12 mg/dL in the Cymbalta group and decreased by 11.5 mg/dL in the routine care group. HbA_{1c} increased by 0.5% in the Cymbalta and by 0.2% in the routine care groups. 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. Serotonergic Drugs—Based on the mechanism of action of SNRIs and SSRIs, including Cymbalta and the potential for serotonin syndrome, caution is advised when Cymbalta is coadministered with other drugs that may affect the serotonergic neurotransmitter systems, such as triptans, linezolid (an antibiotic which is a reversible non-selective MAOI), lithium, tramadol, or St. John's Wort (*see* WARNINGS, Serotonin Syndrome). The concomitant use of Cymbalta with other SSRIs, SNRIs, or tryptophan is not recommended (*see* PRECAUTIONS, Drug Interactions). Triptans—There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of Cymbalta with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (*see* WARNINGS, Serotonin Syndrome). 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/m² 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/m² 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/m² 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/m² 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/m² 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/m² 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/m² basis, in rats; 15 times the MRHD and 7 times the human dose of 120 mg/day on a mg/m² 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/m² basis in rats; 3 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m² 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/m² 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.

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 premarketing clinical studies of Cymbalta for MDD, 5.9% (143) were 65 years of age or over. Of the 1074 patients in the DPN premarketing studies, 33% (357) were 65 years of age or over. Premarketing clinical studies of GAD did not include sufficient numbers of subjects age 65 or over to determine whether they respond differently from younger subjects. In the MDD and DPN studies, 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. As with other antidepressants, Cymbalta has been associated with cases of clinically significant hyponatremia (*see* Hyponatremia, *under* PRECAUTIONS).

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.

Cymbalta has also been evaluated for safety in 668 patients with GAD representing 95 patient-years of exposure. These 668 patients participated in 9- or 10-week placebo-controlled trials at doses ranging from 60 to 120 mg once daily. Of these 668 patients, 449 were exposed for at least 2 months to Cymbalta.

In the full cohort of placebo-controlled clinical trials for any indication, safety has been evaluated in 8504 patients treated with duloxetine and 6123 patients treated with placebo. In clinical trials, a total of 23,983 patients have been exposed to duloxetine. In duloxetine 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). Generalized Anxiety Disorder—Approximately 16% of the 668 patients who received Cymbalta in the GAD placebo-controlled trials discontinued treatment due to an adverse event, compared with 4% of the 495 patients receiving placebo. Nausea (Cymbalta 3.7%, placebo 0.2%), vomiting (Cymbalta 1.4%, placebo 0%), and dizziness (Cymbalta 1.2%, placebo 0.2%) 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.

Generalized Anxiety Disorder—Treatment-emergent adverse events that occurred in 2% or more of patients treated with Cymbalta in the premarketing acute phase of GAD placebo-controlled trials (doses of 60-120 mg once daily) (N=668 Cymbalta; N=495 placebo) and with an incidence greater than placebo were: Eye Disorders—vision blurred; Gastrointestinal Disorders—nausea, dry mouth, constipation, diarrhea, vomiting, abdominal pain, dyspepsia; General Disorders and Administration Site Conditions—fatigue; Metabolism and Nutrition Disorders—appetite decreased; Nervous System Disorders—dizziness, somnolence, tremor, paraesthesia; Psychiatric Disorders—insomnia, libido decreased, agitation, orgasm abnormal; Reproductive System and Breast Disorders—ejaculation delayed, erectile dysfunction; Respiratory, Thoracic and Mediastinal Disorders—yawning; Skin and Subcutaneous Tissue Disorders—hyperhidrosis; Vascular Disorders—hot flushes.

The following events were reported by at least 2% of patients treated with Cymbalta for GAD and had an incidence ≤ placebo: nasopharyngitis, upper respiratory tract infection, heachache, pollakiuria, and musculoskeletal pain (includes myalgia, neck pain).

The most commonly observed adverse events in Cymbalta-treated GAD patients (incidence ≥5% and at least twice the incidence in placebo patients) were: nausea; fatigue; dry mouth; somnolence; constipation; insomnia; appetite decreased; hyperhidrosis; libido decreased; vomiting; ejaculation delayed; and erectile dysfunction.

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 5 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, 9-10 weeks in GAD, 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***—In clinical trials across indications, relative to placebo, duloxetine treatment was associated with mean increases of up to 2.1 mm Hg in systolic blood pressure and up to 2.3 mm Hg in diastolic blood pressure, averaging up to 2 mm Hg. There was no significant difference in the frequency of sustained (3 consecutive visits) elevated blood pressure (*see* PRECAUTIONS). Duloxetine treatment, for up to 13 weeks in placebo-controlled trials typically caused a small increase in heart rate compared to placebo of up to 3 beats per minute. ***Weight Changes***—In placebo-controlled clinical trials, MDD and GAD patients treated with Cymbalta for up to 10 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 duloxetine-treated patients and placebo-treated patients in clinical trials lasting up to 13 weeks. No clinically significant differences were observed for QTc, QT, PR, and QRS intervals between duloxetine-treated and placebo-treated patients. There were no differences in clinically meaningful QTcF elevations between duloxetine and placebo. In a positive-controlled study in healthy volunteers using duloxetine up to 200 mg BID, no prolongation of the corrected QT interval was observed.

Postmarketing Spontaneous Reports—Adverse events reported since market introduction that were temporally related to duloxetine therapy and not mentioned elsewhere in labeling include: anaphylactic reaction, angioneurotic edema, erythema multiforme, extrapyramidal disorder, glaucoma, hallucinations, hypersensitivity, hypertensive crisis, rash, Stevens-Johnson Syndrome, supraventricular arrhythmia, trismus, 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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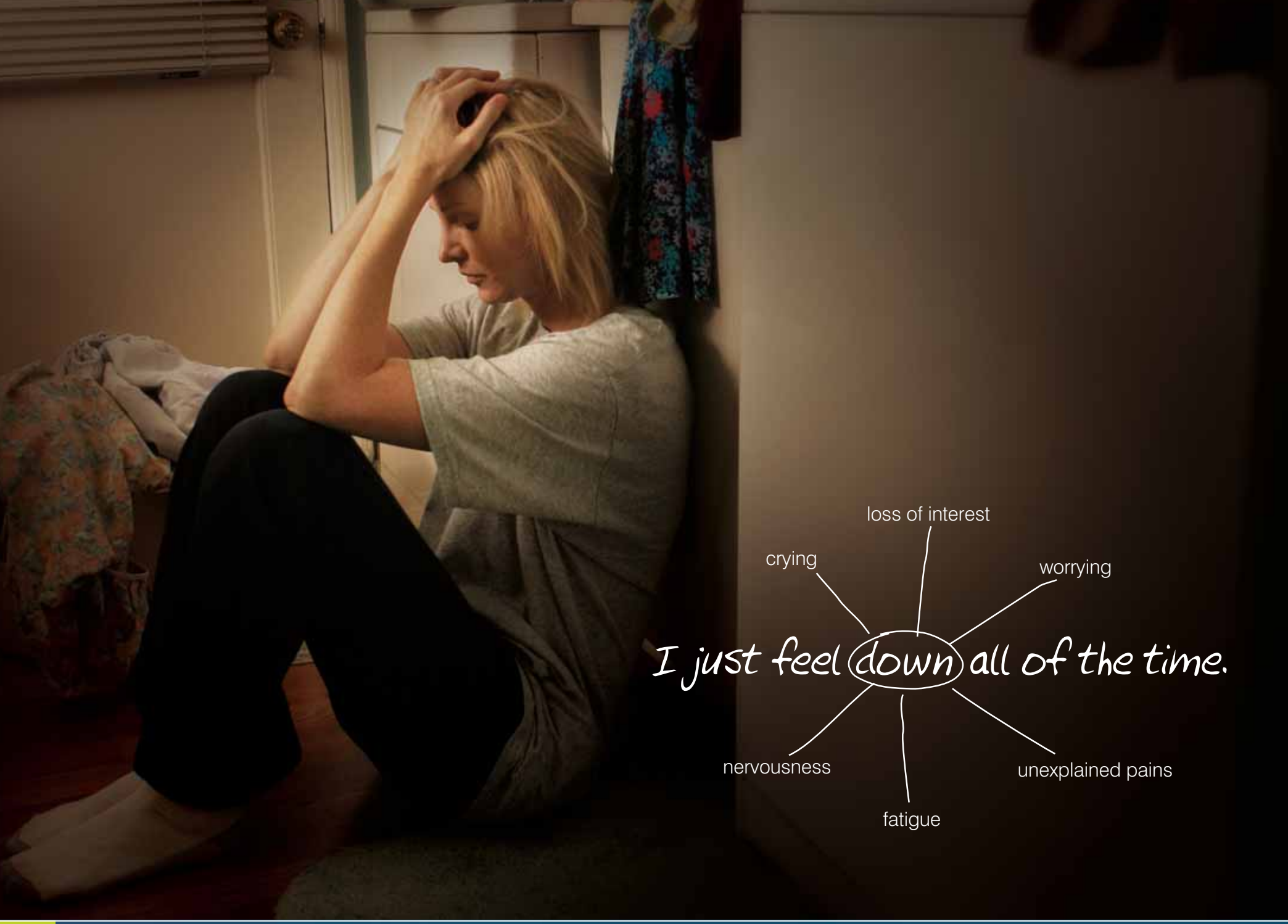

Treat the symptoms of depression your patients talk about, and those they don't. When patients don't express all their symptoms to you, it can make treating depression to remission more complex. Cymbalta is indicated for major depressive disorder (MDD) and treats the emotional, anxious, and painful somatic symptoms of depression.[1a-c,2]* Cymbalta also offers high rates of remission, so patients can feel more like themselves again.[1d]† To learn more about treating beyond the obvious, visit www.insidecymbalta.com

NOW indicated for generalized anxiety disorder (GAD)

*Cymbalta 60 mg/day vs placebo ($P \leq .05$) by MMRM for major depressive disorder (MDD) on mean change in HAM-D_{17} Total Score, Maier Subscale, Psychic Anxiety, and Visual Analog Scale.

MMRM=Mixed-effects Models Repeated Measures analysis

† Remission=HAM-D_{17} Total Score ≤7, 43% vs 27% placebo, $P \leq .001$, 4 pooled studies.

References: **1.** Data on file, Lilly Research Laboratories; a: CYM20060101A; b: CYM20060101B; c: CYM20050315S; d: CYM20060101C.
2. Fava M, et al. *J Clin Psychiatry.* 2004;65(4):521-530.

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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.

Development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including Cymbalta treatment, particularly with concomitant use of serotonergic drugs, including triptans. Concomitant use is not recommended.

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.

Cases of orthostatic hypotension and/or syncope as well as cases of hyponatremia have been reported.

As observed in DPNP clinical trials, Cymbalta treatment worsens glycemic control in some patients with diabetes. In the extension phases up to 52 weeks, an increase in HbA_{1c} in both the Cymbalta (0.5%) and routine care groups (0.2%) was noted.

Most common adverse events (≥5% and at least twice placebo) in premarketing clinical trials were:

MDD: nausea, dry mouth, constipation, fatigue, decreased appetite, somnolence, and increased sweating. **DPNP:** nausea, somnolence, dizziness, constipation, dry mouth, increased sweating, decreased appetite, and asthenia. **GAD:** nausea, fatigue, dry mouth, somnolence, constipation, insomnia, appetite decreased, increased sweating, libido decreased, vomiting, ejaculation delayed, and erectile dysfunction.

See Brief Summary of full Prescribing Information, including Boxed Warning, on adjacent page.

Lilly