

# PSYCHIATRIC NEWS

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At the Pastor's School at the Kafakumba Training Center in Zambia, Mary Kay Smith, M.D. (left), discusses HIV and AIDS prevention with a group of African pastors-in-training. The students will return to their communities throughout Africa to spread her teachings to others. See page 10.

## Risperidone Approved to Treat Schizophrenia in Children

FDA-requested pediatric studies provide valuable clinical evidence on the safety, efficacy, and dosage of antipsychotic drugs in children and adolescents.

BY JUN YAN

The U.S. Food and Drug Administration (FDA) has approved the use of risperidone (Risperdal) in children and adolescents to treat schizophrenia and mania or mixed episodes of bipolar I disorder, making it the first atypical antipsychotic drug approved for either disorder in young patients.

The FDA announced last month that risperidone is approved for the treatment of schizophrenia in adolescents aged 13 to 17 and for the short-term treatment of manic or mixed episodes of bipolar I disorder in children and adolescents aged 10 to 17. Risperidone was approved in October 2006 for treating irritability associated with autistic disorders in children and adolescents aged 5 to 16 years.

The approval is based on clinical studies conducted by the manufacturer, Janssen, a Johnson & Johnson subsidiary, at the request of the FDA under the federal Best Pharmaceuticals for Children Act (BCPA). Previously, the FDA had not approved an antipsychotic drug for treatment of schizophrenia in younger patients, and only lithium had been approved for the treatment

of bipolar disorder in children as young as 12. The BCPA provides an incentive for drug companies that are directly asked by the FDA to conduct much-needed drug trials in children by extending drug patents or exclusivity period for six months.

This approval is notable because antipsychotic drugs have been prescribed in an off-label manner for children and adolescents for many years, with little evidence-based guidance. Randomized, blinded, controlled studies of these drugs in pediatric populations have been rare. Practitioners have to rely primarily on the drugs' known effects in adult patients and anecdotal information in children while using a trial-and-error approach.

Two studies lasting six and eight weeks were conducted on a total of 417 patients aged 13 to 17 with schizophrenia. Risperidone at a dosage ranging from 0.15 mg/day to 6 mg/day resulted in significantly greater reduction in total Positive and Negative Syndrome Scale (PANSS) scores than did placebo. Most notably, dosage higher than 3 mg/day did not lead

*please see Risperidone on page 23*

## AMA Campaigns For Tax Credits To Bring Coverage To the Uninsured

The AMA is promoting a national insurance plan it helped craft that is based largely on tax credits, but its leaders say that other options need to be considered as well.

BY RICH DALY

The AMA launched a multimillion-dollar media campaign in August to promote its proposals to provide health insurance to the record number of uninsured Americans.

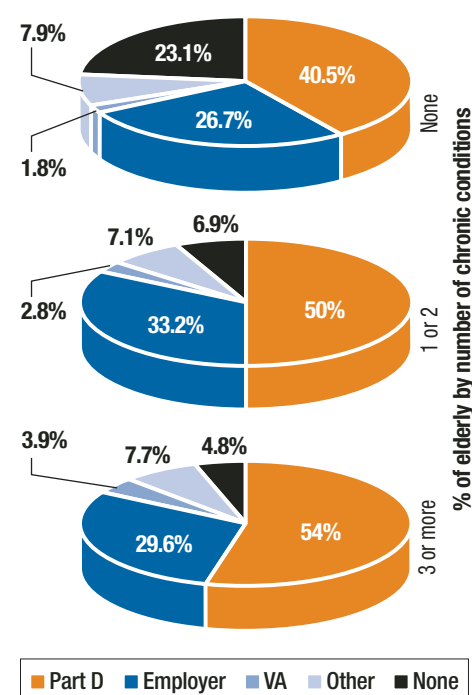
The AMA campaign, called "Voices for the Uninsured," is spending \$5 million initially to coincide with the 2008 U.S. presidential election. It involves newspaper, television, and radio ads that will run in early-primary states including Iowa, New Hampshire, and South Carolina. The campaign will go national next year and will include lobbying Congress to pass comprehensive insurance legislation.

The campaign was announced the week before the latest census figures showed the

*please see AMA on page 23*

### Part D: Top Resource For Chronically Ill

Medicare Part D is the primary source of drug coverage for more seniors than any other program. Enrollment is particularly high among elderly people with multiple prescriptions. See article on page 4.



Source: National Survey of Seniors and Prescription Drugs, 2006

## GOVERNMENT NEWS

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Opponents of expanding federal health insurance for children insist that it will foster considerable switching from private to public programs and send costs soaring.

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More evidence accrues showing the value of mental health courts in preventing crime and getting people the care they need.

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In her work to fight the HIV/AIDS pandemic in Africa, an Ohio psychiatrist teaches prevention techniques by transforming her students into a human immune system.

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Premenstrual dysphoric disorder may be due, at least in part, to a surge of progesterone activating the amygdala in the luteal phase of the menstrual cycle.

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The prodrome may be a distinct dimension of schizophrenia and provide clues that could help prevent the illness or signal the need to start treatment.

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Referrals to specialty care for children with suspected developmental delays more than double with the use of an easy-to-use, inexpensive screening tool.

## ASSOCIATION NEWS

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The thousands of evaluations that registrants filled out during and after the 2007 annual meeting show high levels of satisfaction with the program's content.

# Insurer Hopes Payment Change Spurs More Addiction Treatment

Starting patients on buprenorphine often requires multiple visits and close monitoring. Recognizing this, an insurance company improves compensation for physicians who provide this complex treatment.

BY JUN YAN

Cigna Behavioral Health (CBH), a nationwide managed care organization and subsidiary of Cigna Corp., has begun to reimburse physicians for office-based buprenorphine induction treatment at a higher rate than for regular office visits.

Sublingual buprenorphine is one of the few pharmacological treatments approved by the Food and Drug Administration for treating individuals with opioid dependence. It is a Schedule III narcotic and the only medication approved to treat opioid dependence at physician offices under the Drug Addiction Treatment Act of 2000.

The induction phase of buprenorphine treatment costs more than a routine office visit, because it requires close supervision of the patient at the physician's office as the patient undergoes opioid withdrawal. The induction phase may involve several visits and intense monitoring, according to guidelines in the approved prescribing information provided by the Center for Substance Abuse Treatment (CSAT). Physicians must titrate the dose of buprenorphine until the patient can be put safely on an effective maintenance dose.

To prescribe buprenorphine for outpatient treatment, physicians must first receive training and certification and register with CSAT. Compared with methadone (a Schedule II narcotic), buprenorphine gives patients a favorable alternative because the induction visits are conducted at a physician's office, as opposed to designated clinics, and the maintenance therapy can be achieved in the privacy of patients' homes.

In May CBH announced that it had adopted the new physician-reimbursement policy to improve its members' access to the treatment and to encourage more physicians in its network to initiate buprenorphine treatment.

In an interview with *Psychiatric News*, Doug Nemecek, M.D., national medical director at CBH, explained that the program was implemented after providers told CBH that some patients had to pay out of pocket for buprenorphine induction because the reimbursement rate for these visits was too low, and managed care plans have no mechanism for determining compensation for the complex and sometimes lengthy visits.

"Improving the coverage for buprenorphine use in the treatment of opioid dependence is a welcome step forward," Eric Strain,

M.D., a professor at the Department of Psychiatry and Behavioral Sciences at Johns Hopkins University School of Medicine and chair of APA's Council on Addiction Psychiatry, commented to *Psychiatric News*. "I am very pleased to hear that Cigna intends to increase the availability of buprenorphine for patients, given the effectiveness of treatment for opioid dependence."

Earlier this year, Cigna instructed its network physicians who are authorized to prescribe buprenorphine to bill induction visits using CPT code H0033. Three sessions are initially authorized with additional induction visits covered upon clinical review.

Buprenorphine is a partial agonist of the mu-opioid receptor and an antagonist of the kappa-opioid receptor. Used alone or in combination with naltrexone, sublingual tablet formulations of buprenorphine (Subutex and Suboxone) are approved for medication-assisted treatment for opioid dependence. CSAT stated that buprenorphine has "maximal effects less than those of full agonists like heroin and methadone" and "carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists." Because of the partial agonist property, buprenorphine also produces less severe withdrawal symptoms than full opioid agonists.

*Additional information on buprenorphine for treatment of opioid dependence is posted at <<http://buprenorphine.samhsa.gov>>.* ■

## Papers Invited

The Association for the Advancement of Philosophy and Psychiatry will hold its 20th annual meeting May 3 and 4, 2008, in Washington, D.C., on the theme "Political Extremism and Psychopathology." Papers are invited on such questions as these: What role, if any, does psychopathology play in the lives of extremists? Are there coherent ways of distinguishing between healthy and pathological political ideologies? What specific insights can cognitive neurobiology, psychodynamic theory, or evolutionary psychology offer to political scientists? Should psychiatry have a public role in discussing public figures' possible psychopathology?

*Abstracts should be 600 words or fewer and sent by November 15 to Donald Mender at [donald.mender@yale.edu](mailto:donald.mender@yale.edu). Acceptances will be e-mailed by January 1, 2008.* ■

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## We've Come a Long Way

BY CAROLYN ROBINOWITZ, M.D.

September is Women in Medicine Month. It coincides nicely with the upcoming 25th anniversary of the founding of the Association of Women Psychiatrists (AWP).

When I entered medical school in the 1960s, our class had eight women, an unusually high number—almost 10 percent. Five women graduated—one left medical school, another took time off, and one transferred. There were three women in my 16-member residency group, and two of my four colleagues in a child psychiatry fellowship were women.

As the proportion of women in medicine grew, so did the number and proportion of women in psychiatry. Today, of the total number of APA members, 35 percent are women, while the current proportion of women residents—53 percent—predicts a future in which the number of women members will equal that of men.

Psychiatry as a specialty, and APA in particular, have long welcomed women's participation, and women have attained many leadership roles. APA's first woman president was Dr. Carol Nadelson in 1986; I am the sixth, and Dr. Nada Stotland, president-elect, will be the seventh. Currently, all four of the APA officers are women.

Still, women physicians, including psychiatrists, earn less than their male colleagues, even when considering position descriptions and hours worked, and they continue to be underrepresented in positions of power and leadership in medicine. Similar limits are seen in professions such as law, business, and engineering. Many hypotheses have been offered to explain these inequities: while marriage and child rearing may play a part, acculturation, social attitudes, and expectations seem to exert a greater influence. Women also voice a need for more mentoring and networking.

The AWP was founded by Dr. Alexandra (Allie) Symonds, along with a small group of other dynamic women psychiatrists to address these challenges. This independent organization focuses on women's concerns. It fosters recognition of women psychiatrists throughout their careers, promotes leadership opportunities for women psychiatrists, and addresses needs of women patients.

AWP members communicate via an active e-mail list serve and Web site. Content ranges from current research or ideas related to women's health to national and international referrals for psychiatric care. The Web site <www.womenpsych.org> provides more information about the organization and access to past and current issues of its newsletter, *News for Women in Psychiatry*. As AWP approaches its "silver anniversary," it has become a vibrant and active organization of more than 2,500 women at every professional level (residents and early-, mid-, and senior-career psychi-

atrists) from across the United States and abroad.

AWP meets yearly in conjunction with the APA annual meeting and involves APA leadership in its programs. It also interacts regularly with APA's Committee on Women, the APA Women's Caucus, and APA staff.

Peer mentorship at each career level is a major focus. AWP's goal of recognizing women psychiatrists for excellence in women's clinical care, outstanding community service, and innovative research in women's mental health has been addressed through a number of named awards including the AWP-APA Alexandra Symonds Award, which is an endowed lectureship presented at APA meetings recognizing a woman psychiatrist whose work has enhanced the lives of women patients and/or women physicians; the Marian I. Butterfield, M.D., Early Career Psychiatrist Award, which honors an early career psychiatrist who has exhibited exceptional leadership and commitment and made significant contributions to women's mental health; the Leah J. Dickstein Award, which is presented to a woman medical student who has shown outstanding creativity, energy, and leadership; the Alexandra Symonds Distinguished Service Award, which is conferred on an AWP member for mentorship and a career dedicated to women's mental health; and the Martin Symonds Man of Good Conscience Award, which recognizes men who, through their professional activities, have facilitated women's promotion and leadership. In addition, a fellowship honors women psychiatry residents who have shown excellence in an area of women's mental health, and the Symonds Fellowship honors a woman psychiatry resident who has made significant achievements in psychoanalysis.

As the number of women in psychiatry continues to increase, women may no longer hold minority status in many settings, but may still face the institutionalized and covert sexism, glass ceilings, and brick walls that have long contributed to their underrepresentation.

Our patients, colleagues, partners, and family members continue to experience inequities in personal and professional arenas. As a profession and professional organization, we must work to remove all such disparities. Not only is this focus the right thing to do, but supporting good care, professional development, and the participation and success of all underrepresented groups enriches our field.

Congratulations to the AWP on this important milestone, and best wishes for continued success in your work.

I would like to thank Dr. Tana Grady-Weliky, president of the AWP, for providing extensive information about AWP's history and activities. ■



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# SCHIP Expansion Bedeviled By Cost Concerns

Increased “crowd out” of people in private insurance to publicly funded programs is a leading argument of opponents of SCHIP expansion.

BY RICH DALY

Opponents and advocates of a massive expansion of the State Children’s Health Insurance Program (SCHIP) agree that some privately insured children will switch to a publicly backed health program if they are made eligible, but the two sides differ on whether that “crowd out” is reason enough to not expand coverage. The argument has been a key issue in the ongoing legislative battle to reauthorize and expand SCHIP. Each chamber of Congress has passed a bill to expand the federal and state insurance program, but President Bush has argued the expansion is too large and would crowd out too many children already privately insured (*Psychiatric News*, September 7). The House and Senate are negotiating compromises on the two bills (HR 3162 and S 1893) passed before the August recess, which would insure an additional 5 million or 4 million uninsured, respectively, beyond the 6 million children already covered under SCHIP.

These proposed SCHIP enrollees do not include new enrollees crowded out of private insurance. The Congressional Budget Office (CBO) estimates that the program expansions in the House bill would cover 2.4 million minors with private insurance and other health coverage, and the Senate bill would add 2.1 million such children.

President Bush had proposed a smaller expansion of the program and has promised to veto the House and Senate versions.

The impact of crowding out such children, who are overwhelmingly healthy, is that their participation and their families’ participation in private employers’ health plans help hold down their overall costs because children’s expenses are well below their premium payments, according to Janet Trautwein, vice president of government affairs for the National Association of Health Underwriters, who joined other officials in an Alliance for Health Reform discussion of the issue in August.

She and other critics of the larger expansions said the government could more efficiently achieve broader insurance coverage through a subsidy of private insurer plans, beyond existing tax breaks.

“Our research found it would be less expensive for the government to subsidize those plans,” she said.

However, CBO research indicates that the Senate and House approaches are among the most efficient plans offered to cover a larger number of uninsured children with the smallest amount of crowd out, said CBO Director Peter Orszag.

Supporters of the SCHIP expansion bills said they each include measures to encourage states to focus the programs on children without insurance coverage.

“Crowd out is an inevitable byproduct of any effort to increase government coverage,” said Lisa Dubay, Ph.D., an associate professor of health policy management at Johns Hopkins Bloomberg School of Public Health.

However, Dubay said, no evidence has emerged to indicate that crowd out has led any employers to reduce coverage.

The issue of crowd out was again raised during Congress’s August recess when the Centers for Medicare and Medicaid Services (CMS) ordered new restrictions on the income thresholds of SCHIP-funded programs, which would limit states to covering children whose family incomes are up to 250 percent of the federal poverty level, or \$42,925 a year for a family of three (see chart).

The order directs any state that seeks to expand eligibility for SCHIP-funded children’s health plans to those earning more than that 250 percent of the federal poverty level to adopt “crowd-out strategies,”

designed to prevent those who might otherwise pay for coverage from private insurers from enrolling in government plans. They include a mandatory one-year waiting period during which individuals must be uninsured before they receive coverage.

Ann Clemency Kohler, New Jersey’s deputy commissioner of human services, said such crowd-out mandates would have a major impact in New Jersey and other high-cost states, where children from families with incomes up to 350 percent of the federal poverty level are eligible for SCHIP.





“We have an incredibly high cost of living,” she said. “Families with those incomes are actually doing poorly, and the state wants to help them.”

She and other expansion advocates said the data indicate that many of the children had insurance earlier in the year they enrolled in SCHIP but lost that insurance through their parents’ job loss or discontinuation of insurance coverage by a parent’s employer.

Another mandate from the August CMS order requires states to certify that at least 95 percent of children already eligible for health care coverage under

## 2007 Federal Poverty Limits

Federal poverty guidelines are used to determine who qualifies for Medicaid and SCHIP. Whether to limit SCHIP participation to children in households under 250% of the federal poverty level is at the heart of the current SCHIP reauthorization fight.

Persons in family or household	48 Contiguous States and D.C.	Alaska	Hawaii
	\$10,210	\$12,770	\$11,750
	\$13,690	\$17,120	\$15,750
	\$17,170	\$21,470	\$19,750
	\$20,650	\$25,820	\$23,750
For each additional person, add	\$3,480	\$4,350	\$4,000

Source: Federal Register, January 24, 2007

SCHIP are receiving that coverage before expanding above 250 percent of the federal poverty level. Kohler said that level of SCHIP enrollment has never been achieved by any state. The administrative attempts to reduce crowd out may never go into effect, according to some critics, because congressional leaders are likely to override them legislatively before they go into effect. Further information on insurance crowd out is posted at <[www.allhealth.org/event\\_reg.asp?bi=112](http://www.allhealth.org/event_reg.asp?bi=112)>. ■

# Seniors Paying More for Drugs Under Part D Than Other Plans

Older people in Part D plans were twice as likely as those in private plans to avoid or delay filling prescriptions due to the cost of the medications.

BY RICH DALY

Senior citizens with chronic illness were more likely to receive prescription drug coverage through the Medicare Part D program, which began at the start of 2006, than through other options, but that program was likely to cost them significantly more than other coverage, according to a recent survey.

The results of the survey, conducted in fall 2006 by the Kaiser Family Foundation, Commonwealth Fund, and Tufts-New England Medical Center, were published in the August *Health Affairs*.

The survey included a national, random sample of more than 16,000 seniors and looked at their out-of-pocket spending and cost-related experiences, broken out by type of drug coverage, with a more in-depth look at the experiences of seniors with low incomes.

The survey found that a larger share of seniors in Part D than those in employer-sponsored or VA insurance programs spent more than \$300 monthly, despite taking a similar or smaller number of medications. Part D enrollees were twice as likely to spend at least \$300 monthly as seniors with employer-sponsored coverage, and they were three times as likely to do so as were VA beneficiaries.

The differing impact of drug costs on chronically ill enrollees was even more pronounced than among Medicare beneficia-

ries in general. Among seniors with multiple chronic illnesses, Part D enrollees took the same number of medications as others, on average, but spent “significantly more out of pocket” with significantly higher rates of cost-related nonadherence. The survey found that 11 percent of chronically ill Part D enrollees, 8 percent in employer plans, and 7 percent in the VA spent more than \$300 monthly on prescriptions.

The survey results also indicated that older Americans enrolled in a Medicare Part D plan had more medication-access problems than those who relied on other sources of drug coverage, such as employer-sponsored coverage or benefits from the VA.

Part D enrollees decided against or delayed filling or refilling prescriptions at twice the rate of seniors who got their prescription coverage through employer plans or the VA. Part D enrollees were more than twice as likely as seniors in employer plans to delay or avoid filling or refilling prescriptions because of cost, which the researchers called “cost-related nonadherence.”

The study authors said that more research is needed to clarify the reason for the higher spending by Part D beneficiaries, but they said it was likely attributable, in part, to the coverage gap that exposes Part D enrollees to 100 percent cost sharing after their total spending exceeds a

certain threshold. The so-called “donut hole” coverage gaps are rare in employer-sponsored plans and are not a feature of VA benefits. “We still have a lot of work to do to make sure that Medicare beneficiaries—particularly those who are most vulnerable because of low incomes or chronic illness—can get the drugs they need and are not subject to burdensome out-of-pocket costs,” said Karen Davis, president of the Commonwealth Fund, in a written statement.

## Medication Switching Common

The survey reported that another notable change in Part D enrollees’ prescription-drug practices was a high level of medication switching. One-fourth of Part D enrollees reported switching to a cheaper medication than the one they were originally prescribed after they enrolled in a Part D plan, with little variation by income. The change included moving from a high-cost to a lower-cost brand-name drug or from a brand-name drug to a generic drug.

“The relatively high rate of switching to cheaper medications might be a function of beneficiaries moving into plans that use financial incentives (such as tiered copayments) and cost-management tools (such as step therapy) to steer enrollees toward lower-cost medications,” the survey authors said.

The survey also identified aspects of the Part D program that had a particular impact on the approximately 6 million low-income enrollees eligible for both Medicare and Medicaid, known as dual eligibles. Dual eligibles include many beneficiaries please see *Part D* on facing page



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NAMENDA® (memantine HCl) is indicated for the treatment of moderate to severe Alzheimer's disease.

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

**Namenda**  
memantine HCl



**Extending memory and function**

**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.

 **Forest Pharmaceuticals, Inc.**

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For more details, please visit [www.namenda.com](http://www.namenda.com).  
Please see brief summary of Prescribing Information on the adjacent page.

62-1009392

11/06



# Namenda

memantine HCl

## Rx Only

## Brief Summary of Prescribing Information.

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

### INDICATIONS AND USAGE

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

### CONTRAINDICATIONS

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

### PRECAUTIONS

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

### Neurological Conditions

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

### Genitourinary Conditions

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

### Special Populations

#### Hepatic Impairment

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

#### Renal Impairment

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

### Drug-Drug Interactions

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

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

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

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

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

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

### Carcinogenesis, Mutagenesis and Impairment of Fertility

There was no evidence of carcinogenicity in a 113-week oral study in mice at doses up to 40 mg/kg/day (10 times the maximum recommended human dose [MRHD] on a mg/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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/m<sup>2</sup> 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 postpartum period. The no-effect dose for these effects was 6 mg/kg, which is 3 times the MRHD on a mg/m<sup>2</sup> 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, infected 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, hypertension, 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, paranoia, 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/m<sup>2</sup> 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 overdose 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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# APA Urges CMS to Rethink Medicare Rule Changes

APA is urging CMS to hold contractors and subcontractors of the Medicare Advantage and Medicare Part D prescription drug plans accountable for ensuring that the plans work as intended.

BY MARK MORAN

**A**PA has filed comments on two recently proposed rules by the Centers for Medicare and Medicaid Services (CMS).

One proposed rule affects privacy of physician information; the other urges CMS to hold contractors and subcontractors in certain Medicare programs accountable for following requirements aimed at ensuring that the programs work for the maximum benefit of beneficiaries.

The first rule would allow CMS to disclose sensitive data about physicians without physician consent or knowledge about how the data were being used or by

**“There are many troubling implications to this proposed rule, which substantially contravenes existing law and sound public policy. . . .”**

whom; it could also prevent physicians from correcting records that are erroneous, including Medicare-fraud and other investigative records, and it would impede physicians’ defense in investigations, according to APA.

The four record-keeping systems that the federal government proposes to exempt from protections under the Privacy Act are the Automated Survey Processing Environment Complaints/Incidents Tracking System (ACTS), the Health Insurance Portability and Accountability Act Information Tracking System (HITS), the Organ Procurement Organizations System (OPOS), and the Fraud Investigation Database (FID).

ACTS is a Windows-based program whose primary purpose is to track and process complaints and inci-

dents reported against health care facilities regulated by CMS and state agencies. HITS is an electronic repository of results of investigations for determining whether HIPAA violations have occurred as charged in a complaint and referring them to law enforcement entities as necessary. OPOS is a Windows-based program whose purpose is to track and process complaints reported against organ procurement organizations. The FID system contains the name, work address, work phone number, Social Security number, provider identification number, and other identifying demographics of individuals alleged to have violated provisions of the Social Security Act related to Medicare, Medicaid, HMO/managed care, and the State Children’s Health Insurance Program.

In a notice published in the May 25 *Federal Register*, CMS stated that the exemptions are necessary to protect the integrity of investigations. But APA believes the proposed rule is unfair to physicians.

“There are many troubling implications to this proposed rule, which substantially contravenes existing law and sound public policy, including CMS’s own stringent policies against abridging Privacy Act rights, except for compelling reasons,” wrote APA Medical Director James H. Scully Jr., M.D., in comments submitted to CMS. “The proposed exemption would allow disclosure of reputation-damaging records, even if they are erroneous. Losing these Privacy Act protections, especially for accessing and correcting agency records, would prevent physicians from adequately defending themselves from unwarranted complaints and investigations.”

In response to the second proposed rule, APA is urging CMS to hold contractors and subcontractors of the Medicare Advantage and Medicare Part D prescrip-

tion drug plans accountable for complying with programmatic and data-reporting requirements to ensure that the programs provide beneficiaries with the benefits to which they are entitled.

APA’s comments were in response to a proposed federal rule that CMS announced on May 25 concerning revisions to Medicare Advantage and Part D drug-benefit contract determinations, appeals, and intermediate sanctions processes. The comments were contained in a letter by Scully.

“The program compliance control that CMS can exert on subcontractors through [Medicare Advantage and Part D prescription drug plans] is crucial to protecting beneficiaries and ensuring consistency across plans,” he wrote.

Since the beginning of the Part D program in January 2006, psychiatric patients have experienced ongoing problems accessing necessary medications, sometimes resulting in serious health outcomes (*Psychiatric News*, May 18 and July 20).

“CMS’s proposed regulations should also be revised to require Medicare Advantage plans and Part D plan sponsors to affirmatively report standardized

Part D information on a regular basis to CMS from their own books and those of their subcontractors,” he continued. “CMS should hold the principal contractors accountable for providing these reports. As with other program elements, appropriate sanctions should also be instituted for noncompliance with reporting requirements.”

APA’s comments on “Exemption of Certain Systems of Records Under the Privacy Act” can be accessed at <[www.psych.org/members/advocacy\\_policy/reg\\_comments/regulatory\\_comments.cfm](http://www.psych.org/members/advocacy_policy/reg_comments/regulatory_comments.cfm)>. The Federal Register notice is posted at <<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/E7-10143.htm>>.

APA’s comments on “Revisions, Medicare Advantage, and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions” can be accessed at <[www.psych.org/members/advocacy\\_policy/reg\\_comments/regulatory\\_comments.cfm](http://www.psych.org/members/advocacy_policy/reg_comments/regulatory_comments.cfm)>. The Federal Register notice is posted at <<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-2579.htm>>. ■

## Part D

*continued from facing page*

with psychiatric drug prescriptions. The survey found that 1 in 5 dual eligibles said they needed to obtain “special permission” from the Part D insurance plan that covered them to get a prescription filled, which was double the rate of higher-income Part D beneficiaries.

The researchers attributed the higher rate of special permission required for dual eligibles to the nature of the medications they are prescribed or their plan’s use of tools such as prior authorization, which might restrict access to “the high-cost medications used disproportionately by dual eligibles.”

Many of the findings on access difficulties and higher costs reflected problems in the first year of the program identified in a study by the American Psychiatric Institute for Research and Education (APIRE), of psychiatric patients’ experience with Part D. The study was the first to compile clinically detailed, national data on the impact of drug-plan management practices under Medicare Part D on dual-eligible psychiatric patients’ medication access, compliance, and clinical outcomes (*Psychiatric News*, May 18 and July 20).

The APIRE survey of 1,183 psychiatrists in the first eight months of 2006 and another 1,600 in the last four months of that year reported clinically detailed information on one systematically selected, dual-eligible Part D patient under the care of each surveyed psychiatrist.

The study found that large numbers of patients had problems filling their prescriptions and that many psychiatrists reported changing or discontinuing their patients’ clinically indicated medications rather than pursuing appeals or exceptions. A growing number of psychiatrists also had to ask drug plans for exemptions to their drug coverage rules so that patients could get needed psychotropic medications.

Other problems identified in the APIRE study were difficulty accessing medication refills and insurance-plan requirements to switch to a different medication because clinically preferred medication refills were not covered or approved.

“Medicare Prescription Drug Benefit Progress Report: Findings From a 2006 National Survey of Seniors” is posted at <<http://content.healthaffairs.org/cgi/content/full/blthaff.26.5.w630/DC1>>. ■

## Application Deadline

The Certification in Psychiatric Administration and Management is offered yearly in conjunction with APA’s annual meeting. The next application deadline for certification candidates (including letters of reference) is January 31, 2008. Early applications are encouraged to allow candidates adequate preparation time.

More information is available from Crystal Garner at [cgarner@psych.org](mailto:cgarner@psych.org) or online at <[www.psych.org/edu/cert-psych.cfm](http://www.psych.org/edu/cert-psych.cfm)>. ■

## Chassin Named

The Joint Commission has named Mark R. Chassin, M.D., as its new president, effective January 1, 2008. He will succeed Dennis O’Leary, M.D., who will become president emeritus on that same date. Chassin is currently the Edmond A. Guggenheim Professor of Health Policy and chair of the Department of Health Policy at Mount Sinai School of Medicine.

The Joint Commission evaluates and accredits nearly 15,000 health care organizations and programs in the United States and is the nation’s predominant standards-setting and accrediting body in health care, according to its Web site. ■

## Would You Like to Serve APA?

APA President-elect Nada Stotland, M.D., invites voting members of APA to indicate their interest in serving on APA councils and committees. Members who are willing to share their expertise and make a significant time commitment to serve APA, the field of psychiatry, and its patients through component service are asked to submit their names and other information noted below or nominate a colleague for consideration. Stotland is looking for APA members who represent the varied demographics of the APA membership and patient populations and who bring the expertise necessary to implement component work.

A list of APA components is available in the Members Corner section of the APA Web site at <[www.psych.org](http://www.psych.org)>. If you are interested, please send your contact information, the name of the component(s) on which you would like to serve, and a one-page description of your background, experience, and qualifications. You are also encouraged to nominate fellow APA members who would be willing to serve.

Materials may be e-mailed to [appointments@psych.org](mailto:appointments@psych.org), preferably as PDF attachments. Those who do not have access to e-mail may mail the materials to Nada Stotland, M.D., APA President-Elect, c/o Appointments Coordinator, APA, Suite 1825, 1000 Wilson Boulevard, Arlington, Va. 22209.

# Mental Health Courts: A Strategy That Works

Criminal defendants with mental illness stay out of jail longer when they are enrolled in programs that divert them from the prison system to the mental health system.

BY AARON LEVIN

Mental health courts offer an alternative to sending still more people with mental illness to jail. Judges, public defenders, district attorneys, case managers, therapists, probation officers, and psychiatrists together closely supervise defendants selected for these diversion programs, helping with housing, medical care, psychotherapy, education, and job training or coaching.

The goal is to prevent these defendants from committing more crimes and to

**"I speculate that the people selected are seen as less threatening to the community, but the community needs to take a chance on a wider group."**

help them find a place in the community. Offenders who complete the program can have charges dropped or expunged (*Psychiatric News*, April 21, 2006).

About 90 mental health courts operate around the country, yet little is known about the extent to which they reduce the chances of a defendant's committing another crime.

Now a study of the mental health court in San Francisco documents reduced levels of recidivism, as measured by the time to re-offending, although questions remain about what accounts for outcomes and who gets to participate in the programs.

Dale McNeil, Ph.D., a professor of clinical psychology in the Department of Psychiatry, and Renée Binder, M.D., a professor in residence in the Psychiatry and the Law Program at the University of California, San Francisco, compared 170 criminal defendants who entered the mental health court with 8,067 other offenders who received treatment as usual, consisting of passage through the criminal justice system. All subjects had been diagnosed with some mental illness, and two-thirds were charged with felonies. Defendants selected for diversion included a higher proportion of persons with developmental disabilities or severe mental illness—like schizophrenia, delusional disorder, or bipolar disorder—than the control group.

The researchers used a propensity weighting system to overcome nonrandom assignment and intention-to-treat analysis to include all offenders enrolled in the program, not just those who completed its requirements.

Participation in the mental health court program predicted a longer time before offenders faced any new charge or a new violent charge, wrote McNeil and Binder in the September *American Journal of Psychiatry*.

After at least six months of follow-up, 81 (48 percent) of the enrollees had completed the program, 45 (26 percent) were still in it, and 44 (26 percent) had left, whether voluntarily, for noncompliance, or other reasons. The mental health

court graduates remained at a lower risk of recidivism even after they left the court's supervision, according to follow-up analysis.

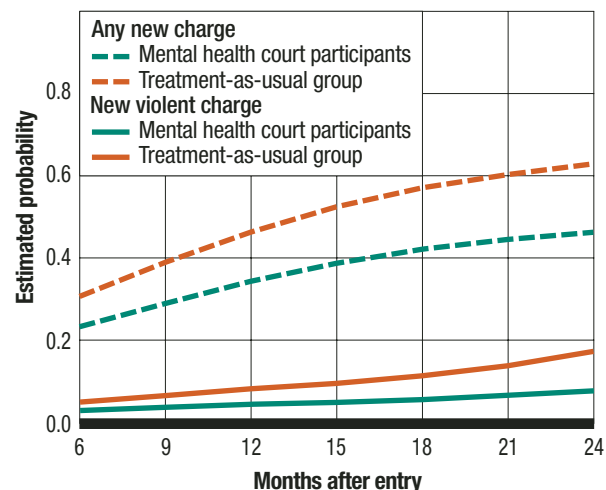
At 18 months, mental health court participants were 26 percent less likely to be charged with any new crime and 54 percent less likely to be charged with a violent crime, they said (see chart).

Their findings, said McNeil and Binder, "provide evidence of the potential for mental health courts to achieve their goal of reducing recidivism among people with mental disorders who are in the criminal justice system."

Furthermore, since many defendants in the San Francisco program were charged

## Mental Health Courts Reduce Recidivism

Defendants' participation in mental health court was found to reduce the average likelihood of any new charges being filed. Violence was uncommon in the mental health court participants and other defendants, but new violent charges were less likely with participation.



Source: Dale McNeil, Renée Binder, *American Journal of Psychiatry*, September 2007

with violent crimes or felonies, results with this more-difficult population argued for expanding the use of mental health courts beyond individuals who have committed minor offenses, as is the case in some other areas, they said.

Other studies have shown that outcomes vary little between violent and nonviolent offenders or for those diagnosed with more severe illness, said mental health court expert Henry Steadman, Ph.D., of Policy Research Associates in Delmar, N.Y., in an interview with *Psychiatric News*. "No research shows that a particular type of person does more poorly."

Steadman directed a study of 21 mental health court programs sponsored by the Substance Abuse and Mental Health Services Administration. He found that 42,518 screenings, assessments, and evaluations resulted in 32,917 decisions about whether to divert them to a treatment program. Only 2,001 of those decisions recommended diversion to mental health courts, and 1,237 of those were accepted by judges.

Although many decisions were needed to divert a few individuals, ultimately, disproportionate groupings by age, race, and gender predicted those chosen to take part.

Enrollees were more likely to be older, white, and female, wrote Steadman in the study published in the August *Psychiatric Services*. "That could represent bias, or it could result from the mechanism of assessment."

An array of people feed information into the system, he said—prosecutors, judges, mental health experts, public health nurses in the jails—making it hard to tease out the source of any overrepresentation of a particular demographic.

"I speculate that the people selected are seen as less threatening to the community, but the community needs to take a chance on a wider group," he said.

The study did not look at clinical data or outcomes.

These mental health courts may have benefits for society that go beyond just reducing crime. A recent study, described as the first of its kind, of 352 defendants by the RAND Corporation in courts in Pennsylvania, "Justice, Treatment, and

*please see Courts on page 22*

## Jail-Diversion Program Would Go Statewide If Legislation Succeeds

A Michigan program offers inmates with mental illness treatment, not incarceration.

BY DAVID MILNE

A pilot program in Genesee County, Mich., will defer jail or prison sentences of certain offenders with mental illness if they plead guilty and participate in a year-long, court-ordered treatment program.

The program was approved in August by district, circuit, and probate court judges and entails collaboration among the three courts, Genesee County Community Mental Health (CMH), the county sheriff's department, and various local police agencies.

Legislation for a similar statewide diversion program was recently introduced by state Sen. Liz Brater (D) of Ann Arbor. Brater's concept is modeled after 76 Michigan drug courts that give nonviolent drug offenders the chance to get clean without being incarcerated (*Psychiatric News*, August 17). But the Genesee County program model is thought by mental health officials to have a better chance of being passed by the state legislature.

The mental health courts were slated to begin September 1, but it will be months before financial arrangements

are worked out. A bill to fund the program from the budget of the Department of Corrections is now being debated in the Michigan Senate.

Inmates eligible for diversion will include those diagnosed with schizophrenia, schizoaffective disorder, or bipolar disorder. They must be capable of understanding the requirements of the program and not present a danger. Some cases will need approval from the prosecutor, the victim, or both. All cases involving sexual offenses and homicide will be excluded.

Steven Mays, clinical liaison for CMH, said offenders with mental illness respond well to the structured setting of a mental health court. As court case manager, he will cross-check the jail population with Genesee County Community Mental Health records to identify inmates with a history of mental illness.

Screened inmates will be brought before Genesee Probate Judge Jennie Barkey, who will conduct the hearings. After arraignment, she will offer the person a chance to enter treatment as a con-

dition of bond. In a later hearing the person will be asked to sign an agreement to participate in mental health court, enter a guilty plea, and consent to a treatment regimen.

Barkey said the program's success will depend on providing structure in the lives of offenders with mental illness and ensuring they take their medications. She believes these conditions give them the tools to live successfully in society.

Earlier Barkey and several other local officials had visited Akron, Ohio, to study a mental health court that's been operating successfully there for about five years.

"We are seeing the proliferation of all kinds of specialty courts," Michigan Psychiatric Society President Jed Magen, D.O., M.S., told *Psychiatric News*. "There is an adolescent drug court near us where we hold training activities for our residents," he added.

Magen is chair of the Department of Psychiatry in the College of Human Medicine and the College of Osteopathic Medicine at Michigan State University.

Considering the wide variety of cases most judges see, Magen thinks it unreasonable to expect them to have the skills and knowledge needed to channel people into various kinds of diversionary programs.

"Specialty courts are very useful in that regard," he continued, "but their success is always predicated on having sufficient resources to achieve their goals. That can be a huge problem." ■



NEW

## INTRODUCING



**The First Prodrug Stimulant**

**Significant efficacy  
throughout the day,  
even at 6 PM<sup>1</sup>**



### IMPORTANT SAFETY INFORMATION

Vyvanse should not be taken by patients who have advanced arteriosclerosis; symptomatic cardiovascular disease; moderate to severe hypertension; hyperthyroidism; known hypersensitivity or idiosyncrasy to sympathomimetic amines; agitated states; glaucoma; a history of drug abuse; or during or within 14 days after treatment with monoamine oxidase inhibitors (MAOIs).

Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses in ADHD. Physicians should take a careful patient history, including family history, and physical exam, to assess the presence of cardiac disease. Patients who report symptoms of cardiac disease such as exertional chest pain and unexplained syncope should be promptly evaluated. Use with caution in patients whose underlying medical condition might be affected by increases in blood pressure or heart rate.

New psychosis, mania, aggression, growth suppression, and visual disturbances have been associated with the use of stimulants. Use with caution in patients with a history of psychosis, seizures or EEG abnormalities, bipolar disorder, or depression. Growth monitoring is advised during prolonged treatment.

**Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to drug dependence. Particular attention should be paid to the possibility of subjects obtaining amphetamines for non-therapeutic uses or distribution to others and the drugs should be prescribed or dispensed sparingly. Misuse of amphetamine may cause sudden death and serious cardiovascular adverse events.**

The most common adverse events reported in clinical studies of Vyvanse were loss of appetite, insomnia, abdominal pain, and irritability.

*Please see Brief Summary of Prescribing Information, including Boxed Warning, on adjacent page.*

**Reference: 1.** Biederman J, Krishnan S, Zhang Y, et al. Efficacy and tolerability of lisdexamfetamine dimesylate (NRP-104) in children with attention-deficit/hyperactivity disorder: a phase III, multicenter, randomized, double-blind, forced-dose, parallel-group study. *Clin Ther.* 2007;29:450-463.

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# Early Signs From Massachusetts Give Hope to MH Advocates

This first-of-its-kind state universal insurance plan aims to expand coverage to more than 500,000 residents, including an estimated 100,000 with mental illness.

BY RICH DALY

The rollout of Massachusetts’s comprehensive health care system this summer has provided the widest statewide insurance coverage in the nation, while

maintaining one of the most generous mental health parity requirements for insurance plans.

When Chapter 58 of the Acts of 2006 became law on April 12, 2006, its goal was to achieve nearly universal health cover-

age for Massachusetts residents. The program, which faces a three-year rollout, began enrolling residents last summer, and the individual participation mandate was launched on July 1. The health plan’s key aspects include the following: an affordable health insurance option to be offered by every private insurer; a subsidized insurance plan for low-income residents; employer insurance requirements, such as annual fees based on the number of uninsured employees; individual insurance requirements, which add an annual tax assessment to residents who cannot prove they have insurance coverage; expansion of the State Children’s Health Insurance Program (SCHIP) and Medicaid (MassHealth) programs; a

merger of the individual and small-group insurance markets; and increased payments to and quality reporting for hospitals and physicians.

## Successes Noted

The complex plan is still in its early stages, but mental health advocates said preliminary successes included the plan’s basic design, which continues a strong mental health parity insurance require-

“Although what we have is not total parity, it does provide substantial coverage.”

ment enacted in the state’s 2000 parity law. That law requires all private insurance plans to cover the costs of the diagnosis and treatment of major mental disorders, such as schizophrenia and bipolar disorder, to the same extent that they cover physical disorders. The law also bars some health insurance plans from placing stricter annual or lifetime dollar or unit-of-service limitations on coverage of qualifying mental disorders than those placed on other types of health conditions.

Mental health advocates in the 2006 legislature had to fight for the continuation of parity, which then-Gov. Mitt Romney (R) proposed cutting to lower the cost of mandated insurance.

“Although what we have is not total parity, it does provide substantial coverage,” said state Rep. Ruth Balser (D), a leading mental health advocate in the legislature.

The parity required in the final law was considered a starting point, and Balser has introduced legislation (HB 1871) to expand the requirement to full parity for all conditions listed in *DSM-IV*.

A further indication of early success has been the public’s aggressive acceptance of the insurance. The number of Massachusetts residents covered by MassHealth and Commonwealth Care, the new, publicly subsidized insurance program for low-income residents, increased by 122,000 in the year since the law was signed. That is about one-third of the 372,000 Massachusetts residents whom state health officials estimated were uninsured in June 2006, according to a May report by the Blue Cross/Blue Shield of Massachusetts Foundation. Commonwealth Care had 105,000 people enrollees, significantly more than the 70,000 that state planners had estimated would be signed up by last month.

## Psychiatrists Have ‘Guarded Hopefulness’

The early signs of success indicate that the plan will benefit many of the state residents who were without insurance and provide some level of mental health care coverage for the estimated 100,000 residents who need that type of care, according to Tobia Fisher, policy director at NAMI Massachusetts.

“Any time you expand access to mental health care, it’s a good thing for the commonwealth,” Fisher said in an interview with *Psychiatric News*.

Whether the increased coverage for mental health care will translate into

*please see Massachusetts on page 22*

### Vyvanse™ (lisdexamfetamine dimesylate)

CII

Rx Only

**BRIEF SUMMARY:** Consult the Full Prescribing Information for complete product information.

**AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINE FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.**

**MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.**

#### INDICATIONS AND USAGE

Vyvanse is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD).

The efficacy of Vyvanse in the treatment of ADHD was established on the basis of two controlled trials in children aged 6 to 12, who met DSM-IV® criteria for ADHD (see CLINICAL TRIALS).

A diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD; DSM-IV®) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before age 7 years. The symptoms must cause clinically significant impairment, in social, academic, or occupational functioning, and be present in two or more settings, e.g., at school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the inattentive Type, at least six of the following symptoms must have persisted for at least 6 months: lack of attention to details/caerless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful. For the Hyperactive-Impulsive Type, at least six of the following symptoms must have persisted for at least 6 months: fidgeting/squirming; leaving seat; inappropriate running/climbing; difficulty with quiet activities; “on the go”; excessive talking; blurring answers; can’t wait turn. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

**Special Diagnostic Considerations:** Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of the required number of DSM-IV® characteristics.

**Need for Comprehensive Treatment Program:** Vyvanse is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician’s assessment of the chronicity and severity of the child’s symptoms.

**Long-Term Use:** The effectiveness of Vyvanse for long-term use, i.e., for more than 4 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Vyvanse for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

#### CONTRAINDICATIONS

Advanced atherosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma.

Agitated states.

Patients with a history of drug abuse.

During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crises may result).

#### WARNINGS

##### Serious Cardiovascular Events

##### Sudden Death and Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems

Children and Adolescents

Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant drug (see CONTRAINDICATIONS).

Adults

Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS).

##### Hypertension and other Cardiovascular Conditions

Stimulant medications cause a modest increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 bpm), and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g., those with pre-existing hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia (see CONTRAINDICATIONS).

**Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications**

Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

##### Psychiatric Adverse Events

##### Pre-Existing Psychosis

Administration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with pre-existing psychotic disorder.

##### Bipolar Illness

Particular care should be taken in using stimulants to treat ADHD patients with comorbid bipolar disorder because of concern for possible induction of mania in such patients. Prior to initiating treatment with a stimulant, patients with comorbid bipolar disorder exhibiting 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.

##### Emergence of New Psychotic or Manic Symptoms

Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without prior history of psychotic illness or mania can be caused by stimulant medications at usual doses. If such symptoms occur, consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate. In a pooled analysis of multiple short-term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 3482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.

##### Aggression

Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical trials and the postmarketing experience of some medications indicated for the treatment of ADHD. Although there is no systematic evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment for ADHD should be monitored for the appearance of or worsening of aggressive behavior or hostility.

##### Long-Term Suppression of Growth

Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturally-occurring subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less weight in weight over 3 years), without evidence of growth rebound during this period of development. In a controlled trial of amphetamine (d to l enantiomer ratio of 3:1) in adolescents, mean weight change from baseline within the initial 4 weeks of therapy was -1.1 lbs. and -2.8 lbs., respectively, for patients receiving 10 mg and 20 mg of amphetamine (d to l enantiomer ratio of 3:1). Higher doses were associated with greater weight loss within the initial 4 weeks of treatment. In a controlled trial of lisdexamfetamine in children ages 6 to 12 years, mean weight loss from baseline after 4 weeks of therapy was -0.9, -1.9, and -2.5 lb., respectively, for patients receiving 30 mg, 50 mg, and 70 mg of lisdexamfetamine, compared to a 1 lb weight gain for patients receiving placebo. Higher doses were associated with greater weight loss with 4 weeks of treatment. Careful follow-up for weight in children ages 6 to 12 years who received lisdexamfetamine over 12 months suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a slowing in growth rate measured by body weight as demonstrated by an age- and sex-normalized mean change from baseline in percentile of -13.4 over 1 year (average percentile at baseline and 12 months were 60.6 and 47.2, respectively). Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining weight as expected may need to have their treatment interrupted.

##### Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizure, in patients with prior EEG abnormalities in absence of seizures, and very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

##### Visual Disturbance

Difficulties with accommodation and blurring of vision have been reported with stimulant treatment.

#### PRECAUTIONS

**General:** The least amount of Vyvanse feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdose. Vyvanse should be used with caution in patients who use other sympathomimetic drugs.

**Tics:** Amphetamines have been reported to exacerbate motor and phonic tics and Tourette’s syndrome. Therefore, clinical evaluation for tics and Tourette’s syndrome in children and their families should precede use of stimulant medications.

**Information for Patients:** Amphetamines may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or vehicles; the patient should therefore be cautioned accordingly.

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

##### Drug Interactions:

**Urinary acidifying agents**—These agents (ammonium chloride, sodium acid phosphate, etc.) increase the concentration of the ionized species of the amphetamine molecule, thereby increasing urinary excretion. Both groups of agents lower blood levels and efficacy of amphetamines.

**Adrenergic blockers**—Adrenergic blockers are inhibited by amphetamines.

**Antidepressants, tricyclic**—Amphetamines may enhance the activity of tricyclic antidepressants or sympathomimetic agents; d-amphetamine with desipramine or protriptyline and possibly other tricyclics cause striking and sustained increases in the concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated.

**MAO inhibitors**—MAO inhibitors, such as well as a metabolite of furazolidone, slow amphetamine metabolism. This slowing potentiates amphetamines, increasing their effect on the release of norepinephrine and other monoamines from adrenergic nerve endings; this can cause headaches and other signs of hypertensive crisis. A variety of toxic neurological effects and malignant hyperpyrexia can occur, sometimes with fatal results.

**Antihistamines**—Amphetamines may counteract the sedative effect of antihistamines.

**Antihypertensives**—Amphetamines may antagonize the hypotensive effects of antihypertensives.

**Chlorpromazine**—Chlorpromazine blocks dopamine and norepinephrine receptors, thus inhibiting the central stimulant effects of amphetamines and can be used to treat amphetamine poisoning.

**Ethosuximide**—Amphetamines may delay intestinal absorption of ethosuximide.

**Haloperidol**—Haloperidol blocks dopamine receptors, thus inhibiting the central stimulant effects of amphetamines.

**Lithium carbonate**—The anorectic and stimulatory effects of amphetamines may be inhibited by lithium carbonate.

**Meperidine**—Amphetamines potentiate the analgesic effect of meperidine.

**Methenamine therapy**—Urinary excretion of amphetamines is increased, and efficacy is reduced by acidifying agents used in methenamine therapy.

**Norepinephrine**—Amphetamines enhance the adrenergic effect of norepinephrine.

**Phenobarbital**—Amphetamines may delay intestinal absorption of phenobarbital; co-administration of phenobarbital may produce a synergistic anticonvulsant action.

**Phenytoin**—Amphetamines may delay intestinal absorption of phenytoin; co-administration of phenytoin may produce a synergistic anticonvulsant action.

**Propoxyphene**—In cases of propoxyphene overdose, amphetamine CNS stimulation is potentiated and fatal convulsions can occur.

**Veratrum alkaloids**—Amphetamines inhibit the hypotensive effect of veratrum alkaloids.

**Drug/Laboratory Test Interactions:** Amphetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amphetamines may interfere with urinary steroid determinations.

**Carcinogenesis/Mutagenesis and Impairment of Fertility:** Carcinogenicity studies of lisdexamfetamine have not been performed.

No evidence of carcinogenicity was found in studies in which d, l-amphetamine (enantiomer ratio of 1:1) was administered to mice and rats in the diet for 2 years at doses of up to 30 mg/kg/day in male mice, 19 mg/kg/day in female mice, and 5 mg/kg/day in male and female rats. Lisdexamfetamine dimesylate was not clastogenic in the mouse bone marrow micronucleus test *in vivo* and was negative when tested in the *E. coli* and *S. typhimurium* components of the Ames test and in the L5178Y/TK<sup>+</sup> mouse lymphoma assay *in vitro*.

Amphetamine (d to l enantiomer ratio of 3:1) did not adversely affect fertility or early embryonic development in the rat at doses of up to 100 mg/kg/day.

**Pregnancy:** Pregnancy Category C. Reproduction studies of lisdexamfetamine have not been performed.

Amphetamine (d to l enantiomer ratio of 3:1) had no apparent effects on embryofetal morphological development or survival when orally administered to pregnant rats and rabbits throughout the period of organogenesis at doses of up to 6 and 16 mg/kg/day, respectively. Fetal malformations and death have been reported in mice following parenteral administration of dextroamphetamine sulfate at 50 mg/kg/day or greater to pregnant animals. Administration of these doses was also associated with severe maternal toxicity. A number of studies in rodents indicate that prenatal or early postnatal exposure to amphetamine (d- or d,l-) at doses similar to those used clinically can result in long term neurochemical and behavioral alterations. Reported behavioral effects include learning and memory deficits, altered locomotor activity, and changes in sexual function.

There are no adequate and well-controlled studies in pregnant women. There has been one report of severe congenital bony deformity, tracheo-esophageal fistula, and anal atresia (vater association) in a baby born to a woman who took dextroamphetamine sulfate with the last trimester of pregnancy. Amphetamines should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nonteratogenic Effects:** Infants born to mothers dependent on amphetamine have an increased risk of premature delivery and low birth weight. Also, these infants may experience symptoms of withdrawal as demonstrated by dysphoria, including agitation, and significant lassitude.

**Usage in Nursing Mothers:** Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from nursing.

**Pediatric Use:** Vyvanse is indicated for use in children aged 6 to 12 years.

A study was conducted in which juvenile rats received oral doses of 4, 10, or 40 mg/kg/day of lisdexamfetamine from day 7 to day 63 of age. These doses are approximately 0.3, 0.7, and 3 times the maximum recommended human daily dose of 70 mg on a mg/m<sup>2</sup> basis. Dose-related decreases in food consumption, bodyweight gain, and crown-rump length were seen; after a four week drug-free recovery period bodyweights and crown-rump lengths had significantly recovered in females but were still substantially reduced in males. Time to vaginal opening was delayed in females at the highest dose, but there were no drug effects on fertility when the animals were mated beginning on day 85 of age.

In a study in which juvenile dogs received lisdexamfetamine for 6 months beginning at 10 weeks of age, decreased bodyweight gain was seen in all doses tested (2.5, and 12 mg/kg/day, which are approximately 0.5, 1, and 3 times the maximum recommended human daily dose on a mg/m<sup>2</sup> basis). This effect partially or fully reversed during a four week drug-free recovery period.

**Use in Children under Six Years of Age:** Lisdexamfetamine dimesylate has not been studied in 3-5 year olds. Long-term effects of amphetamines in children have not been well established. Amphetamines are not recommended for use in children under 3 years of age.

**Geriatric Use:** Vyvanse has not been studied in the geriatric population.

#### ADVERSE EVENTS

The premarketing development program for Vyvanse included exposures in a total of 404 participants in clinical trials (348 pediatric patients and 56 healthy adult subjects). Of these, 348 pediatric patients (ages 6 to 12) were evaluated in two controlled clinical studies (one parallel-group and one crossover), one open-label extension study, and one single-dose clinical pharmacology study. The information included in this section is based on data from the 4-week parallel-group controlled clinical trial in pediatric patients with ADHD. 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 tables and listings that follow, MedRA 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.

**Adverse events associated with discontinuation of treatment:** Ten percent (21/218) of Vyvanse-treated patients discontinued due to adverse events compared to 1% (1/72) who received placebo. The most frequent adverse events leading to discontinuation and considered to be drug-related (i.e., leading to discontinuation in at least 1% of Vyvanse-treated patients and at a rate at least twice that of placebo) were ECG voltage criteria for ventricular hypertrophy, tic, vomiting, psychomotor hyperactivity, insomnia, and rash (2/218 each; 1%).

**Adverse events occurring in a controlled trial:** Adverse events reported in a 4-week clinical trial in pediatric patients treated with Vyvanse or placebo are presented in the table below.

The prescriber should be aware that these figures cannot be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those 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 practicing 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 following adverse events that occurred in at least 5% of the Vyvanse patients and at a rate twice that of the placebo group (Table 1): Upper abdominal pain, decreased appetite, dizziness, dry mouth, irritability, insomnia, nausea, vomiting, and decreased weight.

The following additional adverse reactions have been associated with the use of amphetamine, amphetamine (d to l enantiomer ratio of 3:1), or Vyvanse:

Cardiovascular: Palpitations, tachycardia, elevation of blood pressure, sudden death, myocardial infarction. There have been isolated reports of cardiomyopathy associated with chronic amphetamine use.

Central Nervous System: Psychotic episodes at recommended doses, overstimulation, restlessness, dizziness, euphoria, dyskinesia, dysphoria, depression, tremor, headache, exacerbation of motor and phonic tics and Tourette’s syndrome, seizures, stroke.

Gastrointestinal: Dryness of the mouth, unpleasant taste, diarrhea, constipation.

Allergic: Urticaria, hypersensitivity reactions including angioedema and anaphylaxis.

Skin: Skin rashes, including Stevens Johnson Syndrome and toxic epidermal necrolysis have been reported.

Endocrine: Impotence, changes in libido.

**DRUG ABUSE AND DEPENDENCE**

Controlled Substance Class

Vyvanse is classified as a Schedule II controlled substance.

Amphetamines have been extensively abused. Tolerance, extreme psychological dependence, and severe social disability have occurred. There are reports of patients who have increased the dosage of amphetamine administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with amphetamines may include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

##### Human Studies

In a human abuse liability study, when equivalent oral doses of 100 mg lisdexamfetamine dimesylate and 40 mg immediate release d-amphetamine sulfate were administered to individuals with a history of drug abuse, lisdexamfetamine 100 mg produced subjective responses on a scale of “Drug Liking Effects”, “Amphetamine Effects”, and “Stimulant Effects” that were significantly less than d-amphetamine immediate release 40 mg. However, oral administration of 150 mg lisdexamfetamine produced increases in positive subjective responses on these scales that were statistically indistinguishable from the positive subjective responses produced by 40 mg of oral immediate-release d-amphetamine and 200 mg of diethylpropion (C-IV).

Intravenous administration of 50 mg lisdexamfetamine to individuals with a history of drug abuse produced positive subjective responses on scales measuring “Drug Liking”, “Euphoria”, “Amphetamine Effects”, and “Benzedrine Effects” that were greater than placebo but less than those produced by an equivalent dose (20 mg) of intravenous d-amphetamine.

##### Animal Studies

In animal studies, lisdexamfetamine produced behavioral effects qualitatively similar to those of the CNS stimulant d-amphetamine. In monkeys trained to self-administer cocaine, intravenous lisdexamfetamine maintained self-administration at a rate that was statistically less than that for cocaine, but greater than that of placebo.

##### OVERDOSE

Individual response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses. Symptoms: Manifestations of acute overdose with amphetamines include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

**Treatment:** Consult with a Certified Poison Control Center for up to date guidance and advice. Management of acute amphetamine intoxication is largely symptomatic and includes gastric lavage, administration of activated charcoal, administration of a cathartic and sedation. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Acidification of the urine increases amphetamine excretion, but is believed to increase risk of acute renal failure if myoglobinuria is present. If acute severe hypertension complicates amphetamine overdose, administration of intravenous phentolamine has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine intoxication.

The prolonged release of Vyvanse in the body should be considered when treating patients with overdose.

Manufactured by: New River Pharmaceuticals Inc., Blacksburg, VA 24060. Made in USA.

Distributed by: Shire US Inc., Wayne, PA 19087

For more information call 1-800-828-2088, or visit [www.Vyvanse.com](http://www.Vyvanse.com)

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**Because she does not like to compromise...**





mind

body

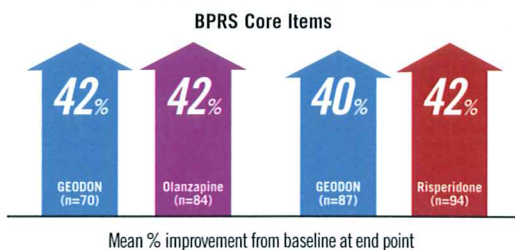


IN SCHIZOPHRENIA

# Treat With the Body in Mind

## CHOOSE COMPARABLE POWER...

Consistent results in acute head-to-head studies<sup>1-3</sup>

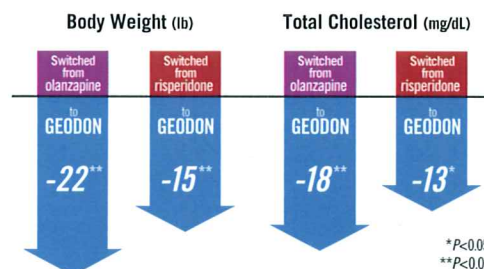


A 6-week, double-blind, randomized study of GEODON vs olanzapine and an 8-week, double-blind, randomized study of GEODON vs risperidone.

- 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<sup>1</sup>
  - up to 6 months vs olanzapine<sup>4</sup>

## ...WITHOUT COMPROMISING METABOLIC PARAMETERS

Significant results in switch studies after 1 year<sup>1,5</sup>



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<sup>5</sup>
- 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,  $P<0.0001$ )<sup>1,2</sup>
  - In the GEODON vs risperidone study, risperidone increased body weight (2 lb vs 0 lb for GEODON,  $P<0.01$ )<sup>1,3</sup>

CHOOSE  
**GEODON**<sup>®</sup>  
(ziprasidone HCl) Oral Capsules

GEODON is indicated for the treatment of acute manic or mixed episodes associated with bipolar disorder and 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<sub>c</sub> 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.**

As with all antipsychotic medications, a rare and potentially fatal condition known as neuroleptic malignant syndrome (NMS) has been reported with GEODON. NMS can cause hyperpyrexia, muscle rigidity, diaphoresis, tachycardia, irregular pulse or blood pressure, cardiac dysrhythmia, and altered mental status. If signs and symptoms appear, immediate discontinuation, treatment, and monitoring are recommended.

Prescribing should be consistent with the need to minimize tardive dyskinesia (TD), a potentially irreversible dose- and duration-dependent syndrome. If signs and symptoms appear, discontinuation should be considered since TD may remit partially or completely.

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 include the risk of rash, orthostatic hypotension, and seizures.

The most common adverse events associated with GEODON in bipolar mania were somnolence, extrapyramidal symptoms, dizziness, akathisia, and abnormal vision.

In short-term schizophrenia trials, the most commonly observed adverse events associated with GEODON at an incidence of  $\geq 5\%$  and at least twice the rate of placebo were somnolence and respiratory tract infection.

In short-term schizophrenia clinical trials, 10% of GEODON-treated patients experienced a weight gain of  $\geq 7\%$  of body weight vs 4% for placebo.



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 (median 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<sup>®</sup> (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, levomethadylacetate, dolasetron mesylate, procabrol, 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 interval. Additionally, clinicians should be alert to the identification of other drugs that have been consistently observed to prolong the QT interval. Such drugs should not be prescribed with GEODON. A study directly comparing the QT/QTc prolonging effect of GEODON with several other drugs effective in the treatment of schizophrenia was conducted in patient volunteers. The mean increase in QT, 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 length was not augmented by the presence of a metabolic inhibitor (ketconazole 200 mg bid). In placebo-controlled trials, GEODON increased the QT 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 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/QTc 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/QTc 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/QTc 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 QTc 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 QTc from baseline for GEODON was 4.6 msec following the first injection and 12.8 msec following the second injection. The mean increase in QTc 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 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 QTc 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 interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QT 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 these 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 QTc 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, e.g., QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. GEODON should be discontinued in patients who are found to have persistent QTc 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  $\alpha_1$ -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<sub>2</sub> 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. **Praprisms:** One case of praprisms 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 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 QTc 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. Ketconazole, a potent inhibitor of CYP3A4, 400 mg qd for 5 days, increased the AUC and C<sub>max</sub> of GEODON by about 35%-40%. *Cimetidine*, 800 mg qid 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 benzperone, 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, dextrophan. There was no statistically significant change in the urinary dextromethorphan/dextrophan 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<sup>2</sup> basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m<sup>2</sup> basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m<sup>2</sup> 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, hyposthesia, 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, hypotonia, 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 QTc interval (see **WARNINGS**). In schizophrenia trials, GEODON was associated with a mean increase in heart rate of 1.4 beats per minute compared to 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, plebeitis, 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 globulin/transported 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, monocytes, basophilia, lymphedema, polycythemia, thrombocytopenia. **Metabolic and Nutritional Disorders**—Infrequent: thirst, transaminase increased, peripheral edema, hypoglycemia, creatine phosphokinase increased, alkaline phosphatase increased, hypercholesterolemia, dehydration, lactic dehydrogenase increased, albuminuria, hypokalemia; Rare: BUN increased, creatine increased, hyperlipemia, hypochlosterolemia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hypersthenia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. **Musculoskeletal System**—Frequent: myalgia; Infrequent: tenosynovitis; Rare: myopathy. **Nervous System**—Frequent: agitation, extrapyramidal syndrome, tremor, dystonia, hypotonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, paresthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, baclofensyndrome, choreoathetosis, diplopia, incoordination, neuropathy; Infrequent: paralysis; Rare: myoclonus, nystagmus, torticollis, circumscribed paresthesia, opisthotonus, reflexes increased, trismus. **Respiratory System**—Frequent: dyspnea; Infrequent: pneumonia, epistaxis; Rare: hemoptysis, laryngismus. **Skin and Appendages**—Frequent: 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 claudication, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; Rare: glycosuria, 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 in 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, hypotonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. **Respiratory**—rhinitis. **Skin and Appendages**—fungal dermatitis, sweating. **Urogenital**—dysmenorrhea, priapism. **DRUG ABUSE AND DEPENDENCE—Controlled Substance Class:** GEODON is not a controlled substance. **OVERDOSEAGE**—In premarketing trials in over 5400 patients, accidental or intentional overdose 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 J, 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 PJ, 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, Levovitz 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.



# Dramatic Increase Found In Soldier Suicides

Better documentation reveals a sharp rise in suicide among U.S. Army soldiers and spurs efforts at prevention.

BY AARON LEVIN

That soldiers die in the line of fire in wartime is a sad, but expected, fact of military life. When they die by their own hand, however, it is another matter.

The U.S. Army announced in August that 99 soldiers committed suicide in 2006. That translates to a rate of 17.3 per 100,000. There were 948 soldiers who attempted suicide.

The completed suicides represented a jump over previous years in both absolute numbers and suicide rate. There were 67 suicides in 2004 (or 10.8 per 100,000 soldiers) and 87 in 2005 (12.8 per 100,000) (see graph).

As of June 30 of this year, there were 44 suicides among active-duty soldiers (including reserves and National Guard), 17 during deployment to Iraq or Afghanistan.

Although data had been gathered and analyzed for 2005, the 2006 report was the first

using a new reporting system to be made public, said Col. Elspeth Ritchie, MC, psychiatry consultant to the Army surgeon general.

“We consider every case a tragedy and try to learn how to prevent future suicides,” she said.

The Army has long gathered data on suicide to guide suicide prevention efforts, Ritchie told *Psychiatric News*.

The psychological autopsy was originally the method of choice for determining a cause of death, but its narrative form meant it could not be analyzed by computer. The Army Office of Health Affairs decided in 2001 that it would be used only in equivocal cases of suicide or homicide.

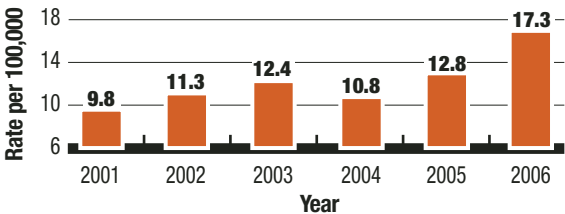
In 2004 the Army began using the Army Suicide Event Report (ASER)—a standardized, 12-page, Web-based report—to collect data on suicide-related events that result in death, hospitalization,

or evacuation. These events include both suicide attempts and completed suicides. The number of attempts rose from 2005 to 2006, too, but that may be partly due to more thorough reporting, said Ritchie.

Not all events result in immediate ASER notifications to the Army’s Suicide Risk Management and Surveillance Office at Madigan Army Medical Center in Tacoma, Wash., although the Army has pushed commanders and others to file the reports

## Suicides in U.S. Army Rise

Confirmed suicides of U.S. Army soldiers rose to their highest levels in recent years despite increased prevention efforts. Part of the increase, however, may be due to improved data collection. Epidemiological associations between the suicides and relationship problems caused controversy after the report’s release in August.



Source: U.S. Army Medical Command, August 2007

## Demographics on U.S. Army Suicides in 2006

U.S. Army soldiers who killed themselves were more likely to be young, white, male, and serving in the regular Army component. Women soldiers were disproportionately likely to attempt, but not complete, suicide. Note: Army data are based on regular active-duty soldiers only (n = 502,790 for Fiscal 2006), with the exception of the item labeled “Component” below, which includes regular, reserve, and National Guard (n = 1,039,053 for Fiscal 2006). Data may not add up to expected totals due to missing item responses.

	Total in Army		Suicide Attempt		Completed	
	No.	%	No.	%	No.	%
<b>Gender</b>						
Male	431,415	86%	669	71%	73	88%
Female	70,345	14%	278	29%	10	12%
<b>Race/ethnicity</b>						
Asian/Pacific Islander	18,700	4%	24	3%	4	5%
African American	104,028	21%	123	13%	13	15%
Caucasian	309,178	62%	646	68%	54	64%
Hispanic	53,279	11%	82	9%	7	8%
Other/DK/missing	16,573	3%	73	8%	6	7%
<b>Age range</b>						
Under 25	201,582	40%	638	70%	39	49%
25-29	112,834	22%	145	16%	14	18%
30-39	136,103	27%	114	12%	14	18%
40+	51,274	10%	20	2%	13	16%
<b>Component</b>						
Regular	501,863	48%	852	91%	75	91%
Reserve	189,975	18%	38	4%	5	6%
National Guard	346,243	33%	43	5%	2	2%
<b>Marital status</b>						
Never married	—	—	477	51%	41	49%
Married	274,652	55%	334	36%	30	36%
Legally separated	—	—	19	2%	2	2%
Divorced	—	—	62	7%	5	6%
Widowed	—	—	0	0%	0	0%
Don't know	—	—	45	5%	5	6%

Source: U.S. Army Behavioral Health Technology Office

## Army Expands Suicide Education

The Army’s newest antisuicide strategy focuses less on high-risk soldiers and instead combines teaching and awareness on the part of all service members, said Col. Elspeth Ritchie, MC, psychiatry consultant to the Army surgeon general.

Mandatory training about suicide throughout the service is coupled with getting platoon mates, sergeants, and officers to recognize the signs that fellow soldiers are in psychological distress.

“Suicide can be a preventable tragedy for soldiers, families, civilians, and communities,” said an all-Army message from the deputy chief of staff’s office in August. “Every effort must be made to understand and inform our Army personnel of the risk factors involved, and to provide training, education, and awareness of professional help at every level.”

Among other materials, a series of pocket cards warns soldiers and officers about signs of suicidal behavior and offers tips on what to say and how to act if they appear.

One card reads in part: “Be a good friend. Listen. Don’t leave your buddy alone! Secure any weapons. Take your buddy immediately to the chain of command or to medical care!”

U.S. Army resources on suicide prevention are posted at <<http://www.armyg1.army.mil/hr/suicide.asp>> and <<http://chppm-www.apgea.army.mil/dhpw/Population/combat.aspx>>.

promptly. Some delays result from extended investigations by either the service’s Criminal Investigation Division, which scrutinizes all completed suicides, or the Armed Forces Medical Examiner’s Office. The Army analyzed data from the 85 ASERs for 2006 received by March 1, 2007. (Information released after the Army released its report raised the official number of completed suicides in 2006 to 101.)

In 2006 overall age-adjusted suicide rates for 85 active soldiers (excluding the National Guard or Reserve) were slightly lower than those in the general population. Once adjustments were made for gender, the rate for male soldiers remained lower than that for U.S. men aged 17 to 45, but the rate for women soldiers was higher than that for their age group.

The Army report included a number of factors linked to soldiers’ suicides. Firearms (either military or personal) were used in 71 percent of the completed suicides, but nonfatal attempts most often involved overdoses or self-cutting.

### War-Zone Setting Not Determinant

The most common setting for suicide in 2006 was in a “garrison duty environment,” that is, a base located away from war zones.

“I can understand why returning to garrison duty might increase the chances of suicide,” said Paul Ragan, M.D., an associate professor of psychiatry at Vanderbilt University and a former Navy psychiatrist who served during the Gulf War in 1991, in an interview.

“Military units are structured environments and provide an immediate support group that may dissolve back in garrison,” he said. “Sometimes bad news gets held off until you return home.”

There were 24 suicides among soldiers serving in Iraq and three in Afghanistan in 2006, almost one-third of the 85 ASERs analyzed.

Moreover, 52 of the soldiers whose suicides were analyzed (62 percent) had served at least once in active theaters of war—Iraq, Afghanistan, or Kuwait. Numbers were too small to evaluate risk of multiple deployments to war zones. The Army found an increased, but not significant, trend toward suicides in the early months of deployment. There was some suggestion that exposure to combat increased risk after leaving the war zones, but this, too, was inconclusive.

By comparison, the Marine Corps, a smaller force with roughly similar combat exposure but different deployment patterns, recorded 24 suicides in 2006, a rate

of 12.4 per 100,000. Four of those suicides occurred in the war zones.

Some epidemiological patterns emerged from analysis of the data, although the numbers—and possible conclusions—vary owing to incomplete responses and missing data, said Bentson McFarland, M.D., Ph.D., a professor of psychiatry, public health, and preventive medicine at Oregon Health and Science University, in an interview.

“Rates appear to be based on Armed Forces Medical Examiner reports, whereas the more detailed tables are based on the completed questionnaires,” he said. “This form of reporting is not uncommon.”

Given that caveat, the report said that young, unmarried, junior enlisted, white soldiers were most likely to complete suicide. Suicide completers were less likely to belong to ethnic minority groups.

“The Army numbers of completed minority suicides are very small,” said McFarland. “But it is unlikely there would be statistically significant differences between Army and national data” for completed suicides by members of minority groups.

### Search Is On for Risk Factors

Overall, 55 percent of soldiers are married, but married soldiers accounted for only 36 percent of completed suicides. Marital status varied depending on location, though. Among troops who killed themselves in theaters of war, only 30 percent were married, while 52 percent of completers outside the war zones were married, indicating some protective effect of marriage while deployed.

The Army looked for other potential risk factors among the troops.

“It was not uncommon for individuals to have had prior self-injurious events, past psychiatric diagnoses, and/or prior outpatient or other mental health care, although most completed suicides (n=52) did not have a reported diagnosed psychiatric disorder,” said the report. “The most frequently reported stressors included failed or failing relationships (especially marriage), legal problems, work-related problems, and excessive debt.”

Thirty-six percent of suicide attempts and 19 percent of completed suicides were by soldiers who had an outpatient mental health visit within 30 days of the event.

Perhaps the most controversial finding in the Army’s report was that 55 percent of the completed suicides in 2006 were associated with failed marital relationships and

*please see Soldiers on page 21*



## Mission Not Impossible For Ohio Psychiatrist

Whether working in the rural areas of Ohio or in the bush country of sub-Saharan Africa, psychiatrist Mary Kay Smith, M.D., embodies the idea that integrating different perspectives is vital to learning.

BY EVE BENDER

Each summer, Mary Kay Smith, M.D., boards a plane in Toledo, Ohio, and arrives at her destination many hours later on the other side of the world. She spends the following month or so living, working, and teaching in sub-Saharan Africa. Her students

all leads back to sports-related injuries she sustained in her youth.

"I went to medical school to be an orthopedic surgeon," she explained in an interview with *Psychiatric News*. "I was athletic in my youth and had undergone four knee surgeries by the time I was in high school."

school and realized that orthopedic surgery was not what I wanted to do on a long-term basis." It struck her one day while driving on I-75 in Ohio that psychiatry was what she loved.

Smith did her psychiatry residency at the Medical College of Ohio and embarked on a fifth year of training in a program that exposes psychiatry residents around Ohio to public mental health in different regions in the state through the Ohio Department of Mental Health.

Today, she is director of that program in Northwest Ohio. Residents are exposed to different settings encountered in public-sector psychiatry, including correctional institutions, homeless shelters, clinics, courtrooms, and various community services. In addition, university faculty members present two series of commu-

"Mary Kay has a great deal of energy and has been quite successful at getting residents who finish her program to enter public psychiatry," Svendsen said.

Smith is also a member of the *Psychiatric News* editorial board.

### Fighting the AIDS Pandemic

Smith, through her role as chair of missions at a local United Methodist church and her work in psychiatry, participated in a treatment team meeting in 2000 for a young man from Africa who had been studying in Toledo to take part in a mission to provide medical care to people in Africa. He'd been diagnosed with bipolar disorder and was hospitalized for more than a month after a psychotic episode, Smith noted.

In the meeting, Smith met a relative of the young man, who told her that if the



- 1 The Kafakumba Training Center in Zambia is surrounded by hundreds of acres of banana trees and aloe vera plants. The profits from their sale help to fund the training activities.
- 2 The Rev. Kosongo Munza, former director of the Pastor School, brought Mary Kay Smith, M.D., to the school from the U.S. to teach HIV and AIDS prevention. Munza died in 2005.
- 3 Smith poses with Jeane, one of the children from a neighboring village. Many of Jeane's relatives have died from AIDS, Smith said.
- 4 A daughter of one of the pastors-in-training attends a weekly bonfire on the grounds of the training center, where faculty and students gather to sing and socialize.
- 5 Smith and Pastor Diaman Mainsa enact the role of T-lymphocytes seeking out bacteria in the body for the pastors-in-training.
- 6 Local villagers work in a wood factory on the grounds of the training center.
- 7 Smith and her husband, the Rev. Julian Davies, Ph.D., M.Div., bring the pastors-in-training shirts from the University of Toledo. The shirts are used in role-playing exercises.
- 8 The Rev. John Enright and Josh Davies, Smith's son, stroll through the many acres of banana crops growing at the training center.



are eager for information she passes on to them, not because they must remember it for a test, but because they will use it to save the lives of the men, women, and children they encounter daily.

Since 2001, Smith, who is an assistant professor and director of public and community psychiatry at the University of Toledo College of Medicine, has been traveling to Zambia to teach about HIV/AIDS and its prevention at the Kafakumba Training Center near Ndola to hundreds of United Methodist pastors-in-training. Pastors are often the first people contacted by those experiencing health problems, including AIDS and psychiatric illness.

Smith's path to Africa began with her work in Ohio in education and public-sector psychiatry. And oddly enough, it

In her mid-teens, Smith was inspired by her orthopedic surgeon to learn more about the surgeries that healed her and many others. "Whenever I had days off from school, I'd find a ride to a hospital in Toledo. . . I'd hang out and watch total knee and hip replacement surgeries," she said.

### Bridging Academia and Public Psychiatry

As an undergraduate at the University of Toledo, Smith majored in biology, chemistry, and psychology. "Psychology classes were fun for me, and I found the subject matter to be incredibly interesting," she noted.

Smith described her educational evolution as a classic example of bait and switch. "The bait for me was orthopedic surgery. The switch was when I got to medical

nity conferences each year so that mental health professionals in rural Ohio can expand their knowledge.

"I think it's important to expose residents to public-sector psychiatry not only with the hope that they will consider practicing in those settings, but also so that they can learn about the recovery of people with serious mental illnesses," she noted.

Along with the two residency training directors in her department, Smith designs the public-sector and community-based curriculum for psychiatry residents, which is "spectacular," according to Dale Svendsen, M.D., director of the Ohio Department of Mental Health, and includes courses on spirituality, administrative psychiatry, recovery, and the integration of child and adolescent psychiatry with pediatrics.

hospitalized family member had experienced a psychotic episode in Congo, he would likely have been suspected of possession by evil spirits and would not have a chance at recovery. The relative was the Rev. Kasongo Munza, and he happened to run a school for Methodist pastors in Africa, he told Smith. "He wanted me to visit Zambia in order to teach our approach to dealing with psychiatric illness" to the pastors at the training center, she remarked. Munza also believed that her status as a woman physician would be important to the pastors who came to Kafakumba from five countries in sub-Saharan Africa.

Smith began teaching at the Kafakumba Training Center the following summer—not just about the causes and treatments of



mental illness, but also about prevention of HIV/AIDS.

According to the HIV/AIDS information Web site Avert.org, an estimated 24.5 million adults and children were living with HIV in sub-Saharan Africa at the end of 2005. During that year, an estimated 2 million people died from AIDS in the area.

In Zambia, where the training center is located, 1 in 6 adults is living with HIV, and 98,000 people died of AIDS in 2005, according to the site. In addition, life expectancy at birth has fallen below 40 years, and 710,000 children have been orphaned because parents have died of AIDS.

Smith called the need for education about HIV/AIDS and its prevention in Africa “staggering.” It is not uncommon,

## Illness Attributed to Evil Spirits

She explained that since many native Africans attribute illness to evil spirits, those who are stricken with disease often seek the assistance of traditional healers and pastors, “who sit at the interface of the physical and spiritual worlds.”

Though they use the Bible as the basis of their teachings and sermons, it is not uncommon for pastors to refer people who are ill or have lost their “life force” to prophets or diviners for help. People who are not healthy or have no children are also considered devoid of life force, said Smith.

The prophets and diviners then contact the spirits of the ill person’s ancestors and ask them to remove the evil spirits, spell, or curse, thereby removing the person’s illness and restoring the life force.

The pastors accept her instruction and have told her more than once, “Mama Mary Kay, our tribal traditions are failing us. Your explanation makes sense,” Smith said.

## Immune System Takes the Stage

To help the pastors understand the immune system, Smith engages them in role-playing exercises.

The pastors wear different colored shirts to distinguish themselves as B-lymphocytes, different types of T-lymphocytes, antibodies, phagocytes, and bacteria, for instance, and each person interacts with the others based on what their cellular function is. Together, they make up the human immune system.

Smith’s pupils take various instructional methods and information and teach

about the cultures of the African people and to understand their traditions, and rather than disparaging them, valued and respected them,” he said.

This enabled her to take inherently Western concepts that were once foreign to her students and integrate them into the various educational approaches she uses, including “drama” or role-playing exercises of the human immune system.

“As the play unfolds,” Enright explained, “people are able to understand what the virus is doing to the body. Combined with the scientific knowledge she shares, this drama is then taken to the villages and re-enacted, and people are made to understand HIV and AIDS.”

“What she does is miraculous, and we are deeply grateful,” he said.



Credit: Josh Davies



Credit: Mary Kay Smith, M.D.



Credit: Josh Davies



Credit: Mary Kay Smith, M.D.

Credit: Anna Davies



Credit: Mary Kay Smith, M.D.

she noted, for the pastors attending the 16-month program at Kafakumba to preside over multiple funerals each day for people who have died of AIDS in their communities.

For Smith, arriving in Zambia and teaching a group of about 100 pastors-in-training about HIV/AIDS prevention was not as easy as, say, educating medical students in Ohio.

In Zambia, Smith would be challenged by deeply rooted traditions and beliefs in presenting a Western perspective of disease and treatment. Her job when she first arrived at the training center was to listen and learn—Smith recalls hours spent talking with Munza on his porch as he described the cultures and traditions of the Luba people.

Strict adherence to traditional beliefs often leads communities to pursue only spiritual solutions to stem the increasing rate of new HIV infections. Unfortunately, Smith said, many of those same traditions promote the rapid spread of HIV.

“That’s where I come in,” Smith said, who teaches the pastors about the immune system, science, and HIV prevention. But she is cautious about her approach. “I never tell them that their beliefs are wrong.”

Instead, she begins by reviewing traditional African beliefs and traditions and then describes the Western approach to illness and disease management. She presents information in line with the United Nations AIDS Comprehensive Prevention Program, which is translated into Swahili and French for those who don’t speak English.

in their communities in Zambia and other countries in sub-Saharan Africa. Some even become politically active by pushing legislatures to implement HIV prevention, screening, and testing in different settings.

Smith also teaches her students about the causes and treatments of major psychiatric disorders—the symptoms of which are also believed to be caused by evil spirits in many of these African regions.

“Mary Kay has been an extremely valuable colleague who has come into this environment and against all odds has done a very good job,” Rev. John Enright told *Psychiatric News*. Enright’s parents founded the pastor’s school a half century ago, and he now oversees Kafakumba Training Center. “She was eager to learn

On the basis of pastors’ reports that have been submitted to Smith detailing their efforts to teach others in their own countries, she estimates that her HIV/AIDS prevention instruction has reached more than 40,000 people in six African countries. Still, she noted, this is not enough.

“I have a really hard time getting to sleep at night after being asked by villagers and pastors, ‘Do Americans know what is going on with us in Africa, with thousands dying every day?’” and pondering the seemingly endless need for medical help and prevention training, Smith noted.

“I know that what I’m doing is helping to meet a grossly unmet need in some small way,” she said. “But in the end, I am only one person. The developing world deserves more.” ■



## Teen Researchers Raise Awareness About Consequences of Bullying

Young students from around the country decide that one strategy that could stop bullying is investigating its prevalence and then raising public awareness about the troubling issue.

BY EVE BENDER

When high school student Fabianna Pergolizzi became aware of the Child Abuse Prevention Services program and its survey on bullying, she realized that perhaps she was not alone in having to endure the taunts and harassment of her classmates.

To find out more about the prevalence of bullying, she rallied a group of friends from around the United States and, with permission from the Child Abuse Prevention Services program, enlisted them to distribute the survey to the middle schools in Miami, Durham, N.C., Baltimore, and Palo Alto, Calif., during the 2005-06 school year. Pergolizzi, 16, distributed the survey to students at the middle school she previously attended in Naples, Fla.

The other students involved in the project were Darren Richmond, 16, who attends Miami Beach Senior High School; Samantha Macario, 14, who attends Gunn High School in Palo Alto; Zoe Gan, 14, who attends East Chapel Hill High School in Chapel Hill, N.C.; and Paul Auster, 18, who attends Yeshiva

Lev Hatorah, a college in Israel (he was in high school in Baltimore at the time the survey took place). Together, the five students joined forces to establish Project Anti-Bully.

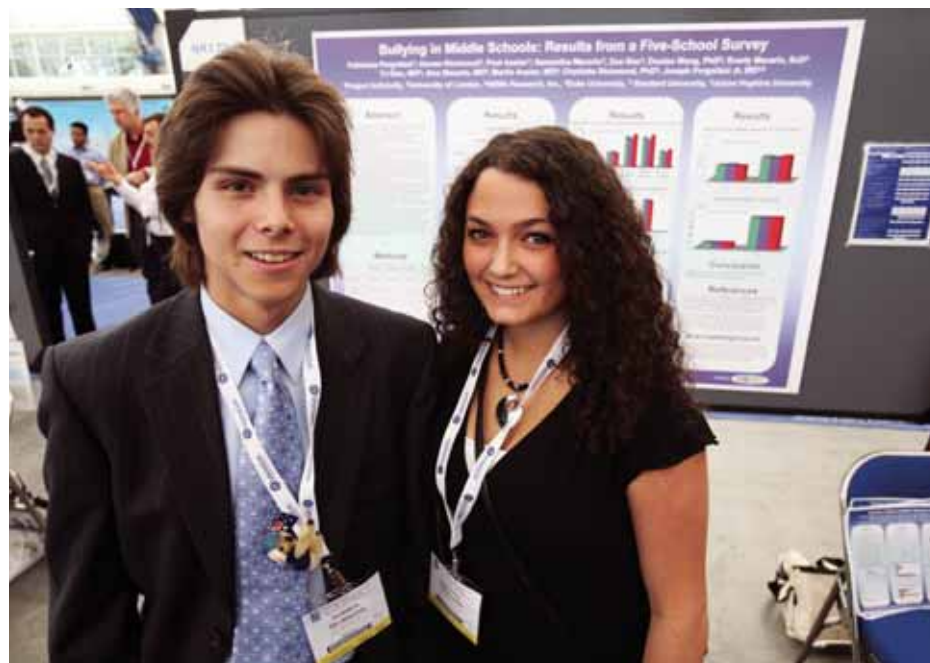
Of the 586 seventh and eighth graders surveyed, their responses revealed that almost half of them (45.1 percent) had been bullied. The most common response was to ignore the bully (34 percent), but reactions differed by gender—40.2 percent of girls reported ignoring the bully, while only 25.7 percent of boys did.

Boys were more likely to retaliate, with 38.8 percent of them saying they reacted by hitting or pushing the bully; 17.7 percent of girls acknowledged doing so.

Of the students surveyed, 40 percent reported having bullied other students.

Among 466 students who witnessed bullying, about 55 percent said they did nothing, and only 7 percent told an adult.

"This is a big problem," Pergolizzi told *Psychiatric News*. "Some kids were afraid [to report the bully], and others



At APA's annual meeting last May in San Diego, Darren Richmond and Fabianna Pergolizzi became the youngest annual meeting presenters in APA history. The high school students presented information on the prevalence rates of bullying.

said they didn't think the bullying was their business."

In Pergolizzi's case, she had a close relationship with her parents, so did not hesitate to tell them that she'd been bullied at school. But she is worried, however, that many of her peers feel they have nowhere to turn.

Said Richmond, the co-principal investigator, "We recommend that kids tell an adult when they are being bullied so that the bullying will stop."

Other findings showed that about a quarter of those surveyed reported being cyberbullied at least some of the time. Cyberbullying was defined in the survey as using the Internet, cell phones, or other forms of technology to harass, threaten, or embarrass someone.

The researchers also found that a higher proportion of girls reported feeling safe in school (82 percent) than did boys (67 percent).

*please see Bullying on page 23*

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**IMPORTANT SAFETY INFORMATION** - Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Antidepressants increased the risk of suicidality (suicidal thinking and behavior) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of antidepressants in children, adolescents or young adults must balance the risk to clinical need. Patients of all ages started on antidepressant therapy should be closely monitored and observed 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. Verispan Weekly VONA Data (Retail Only). Twenty-four-week rolling average. September 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.; 2007.

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

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Visit the LEXAPRO website at [www.lexapro.com](http://www.lexapro.com)



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

**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 Catechol**). MAOIs are contraindicated in patients with a hypersensitivity to selegiline or placebo or any of the inactive ingredients in **Lexapro**. **WARNINGS** **Warnings—Clinical Worsening and Suicide Risk** **Clinical Worsening and Suicide Risk** In 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 (or suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been an ongoing-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidal ideation in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increased the risk of suicidal thoughts and actions in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies showed an increase in the incidence of suicidal thoughts or actions in children and adolescents taking placebo in clinical studies compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 anti-

depressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs. placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1. TABLE 1. Age Range and Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated. Drug-Related Increases:  $<18$  (4 additional cases), 18-24 (5 additional cases), Drug-Related Decreases: 25-64 (1 fewer case),  $\geq 65$  (6 fewer cases). No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicidality. It is unknown whether the suicidality risk extends to long-term use, i.e., beyond several months. However, there is substantial evidence from drug-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression. All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of course of 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 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 in 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 Zoloft, for a description of the risks of discontinuation).

of Lexapro). Families and caregivers of 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. **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 serotonergic 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 SSRI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days should be allowed after stopping Lexapro.

not starting an MAOI. Serotonin syndrome has been reported in two patients who were concomitantly receiving linezolid, an antibiotic which is a reversible monoamine oxidase inhibitor (MAOI). **Serotonin Syndrome:** The development of a potentially life-threatening serotonin syndrome can occur with SNRIs and SSRIs, including Lexapro treatment, particularly with concurrent use of serotonergic drugs (including tricyclics) and with drugs which impair metabolism of serotonin (including MAOIs). Symptoms of serotonin syndrome usually change rapidly and include hyperreflexia, rigidity, hyperlocomotion, autonomic instability (e.g., tachycardia, labile blood pressures), hyperthermia, nausea/vomiting, diarrhea, and/or confusion. **Contraindications and Warnings:** Concomitant use of Lexapro with other serotonergic agents (e.g., hyperreflexia, rigidity, hyperlocomotion, autonomic instability, hyperthermia, nausea/vomiting, diarrhea, and/or confusion) (see **CONTRAINDICATIONS AND WARNINGS - Potential for Interaction with Monoamine Oxidase Inhibitors**). If MAOI 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 (e.g., tryptophan) is not recommended (see **PRECAUTIONS - Drug Interactions**). **PRECAUTIONS General Discontinuation of Treatment with Lexapro** During marketing of Lexapro and other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesia 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 over time 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 **DOSE AND ADMINISTRATION**). **Abnormal Bleeding:** Published case reports have documented the occurrence of bleeding episodes in patients treated with selective serotonin reuptake inhibitors with serotonergic activity. 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. The use of a nonsteroidal anti-inflammatory drug (NSAID) or aspirin potentially 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 potentialized. (See **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. **Hypomania:** Cases of hypomania 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. Hypomania 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 major hypomania was associated in one (0.1%) of 715 patients treated with Lexapro. Activation of mania/hypomania has also been reported in a small proportion of patients with major depressive disorder 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 testing for potential pro-seizure activity. In clinical trials of Lexapro, cases of seizure have been reported in association with Lexapro treatment. Like other drugs effective in the treatment of major depressive disorder, Lexapro should be used cautiously in patients with a seizure disorder. **Concomitant Use 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, although 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 does not affect their ability to engage in such activities. **Use in Patients with Concomitant Serious 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 **DOSE AND ADMINISTRATION**). 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 cautiously in such patients (see **DOSE AND ADMINISTRATION**). **Information for Patients:** Physicians are advised to discuss the following issues with patients prior to caution in such patients (see **DOSE AND ADMINISTRATION**). **Information for Patients:** Physicians are advised to discuss the following issues with patients prior

who may prescribe Lexapro. Patients should be cautious about the risk of serotonin syndrome when the concomitant use of Lexapro and oxytocin, tramadol or other serotonergic agents. In a study in normal volunteers, Lexapro 10 mg/day did not impair psychomotor performance. The effect of Lexapro on psychomotor coordination, judgment, or thinking has not been systematically examined in controlled studies. Because psychotropic drugs may impair judgment, thinking, or motor skills, 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. Patients should be told that, although Lexapro has not been shown in experiments with normal subjects to increase the mental and motor skills impairments caused by alcohol, the concomitant use of Lexapro and alcohol in depressed patients is not advised. Patients should be made aware that escitalopram (the active isomer of Lexapro (citalopram hydrobromide) and that the two medications should not be taken concomitantly. Patients should be advised to inform their physician if they are taking or have taken, or plan to take, any prescription or over-the-counter drugs, as there is a potential for interactions. Patients should be cautioned about the concomitant use of Lexapro and SSRIs, especially other drugs that affect coagulation since the combined use of psychotropic drugs that interfere with serotonin reuptake and these agents has been associated with an increased risk of bleeding. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. Patients should be advised to notify their physician if they are breastfeeding an infant. However, breastfeeding with Lexapro is considered safe. Patients should be advised to continue with Lexapro therapy as directed by their physician and to inform their health care professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Lexapro and should counsel them in its appropriate use. A patient Medication Guide should be provided. "Antidepressant Medicines, Depression and other Serious Mental Illness, and Suicide Thoughts or Actions" is available for Lexapro. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking Lexapro: **Clinical Worsening and Suicide Risk:** Patients, their families, and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during anti-depressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to look for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk of suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication. **Laboratory Tests:** There are no specific laboratory tests recommended. **Concomitant Administration with Risperidone Citalopram:** Since escitalopram is the active isomer of racemic citalopram (Cilexal), the two agents should not be coadministered. **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 administered 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 titration.

Rx Only

**Warnings:** Initiation and dose increases (**WARNINGS - Serotonin Syndrome**). The Drugs - Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other potentially acting drugs. Alcohol - Although Lexapro did not potentiate the cognitive and motor effects of alcohol in clinical trials, 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 45% 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 - Co-administration 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 Celebrex - 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 placebo 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 theophylline (single dose of 400 mg) did not affect the pharmacokinetics of theophylline. The effect of theophylline on the pharmacokinetics of escitalopram has not been studied. **Adverse Effects:** Adverse effects of escitalopram were similar to those reported for racemic citalopram. The most common adverse effects observed in clinical trials were increased sweating, dry mouth, decreased appetite, constipation, dizziness, headache, fatigue, insomnia, and nausea. 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. Ketorolac - Combined administration of racemic citalopram (40 mg) and ketorolac (200 mg), a potent CYP3A4 inhibitor, decreased the  $C_{max}$  and AUC of ketorolac 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 -C219 Inhibitors - *In vitro* studies indicated that CYP3A4 and -C219 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 CYP2D6 5A202B6 - *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 CYP2D6 drug 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 62% 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 may require dosage adjustments. **Contraindications:** Concomitant use of escitalopram with monoamine oxidase inhibitors (MAOI) is contraindicated. ECG and electrocardiogram. **Cardiac Disease, Mutagenesis, Impairment of Fertility:** Citalopram was administered in the diet to MURRHO strain mice and CORN W 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/vivo* unscheduled DNA synthesis (UDS) system 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  $\geq$  32 mg/kg/day. Gestation duration was increased at 48 mg/kg/day. **Pregnancy:** Pregnancy Category C. In a rat embryofetal development study, oral administration of escitalopram (56, 112, or 150 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased fetal body weight and associated delays in ossification at the two higher doses (approximately 56 times the maximum recommended human dose [MRHD] of 20 mg/day on a body surface area [ $m^2$ ] basis). Maternal toxicity (clinical signs and decreased body weight gain and food consumption), mild at 56 mg/kg/day, was present at all of the doses tested. The developmental no-effect dose of 56 mg/kg/day is approximately 28 times the MRHD on a  $m^2$  basis. No teratogenicity was observed at any of the doses tested (as high as 75 times the MRHD on a  $m^2$  basis). When female rats were treated with escitalopram (6, 12, 24, or 48 mg/kg/day) during pregnancy and through weaning, slightly increased offspring mortality and growth retardation were noted at 48 mg/kg/day which is approximately 24 times the MRHD on a  $m^2$  basis. Slight maternal toxicity (clinical signs and decreased body weight gain and food consumption) was seen at this dose. Slightly increased offspring mortality was seen at 24 mg/kg/day. The no-effect dose was 12 mg/kg/day which is approximately 6 times the MRHD on a  $m^2$  basis. In animal reproduction studies, racemic citalopram has been shown to have no adverse effects on embryofetal and postnatal development, including teratogenic effects, when administered at doses greater than human therapeutic doses. In two rat embryofetal development studies, oral administration of racemic citalopram (32, 56, or 112 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased fetal body weight and associated delays in ossification at the two higher doses (approximately 56 times the maximum recommended human dose [MRHD] of 20 mg/day on a body surface area [ $m^2$ ] basis). This dose was also associated with maternal toxicity (clinical signs, decreased body weight gain). The developmental no-effect dose was 56 mg/kg/day. In a rabbit study, no adverse effects on embryofetal development were observed at doses of racemic citalopram of up to 16 mg/kg/day. Thus, teratologic effects of racemic citalopram were observed at a maternally toxic dose in the rat and were not observed in the rabbit. When female rats were treated with racemic citalopram (48, 128, or 32 mg/kg/day) from late gestation through weaning, increased offspring mortality during the first 4 days after birth and persistent offspring growth retardation were observed at the highest dose. The no-effect dose was 128 mg/kg/day. Similar effects on offspring mortality and growth were seen when dams were treated throughout gestation and early lactation at doses  $\geq$  24 mg/kg/day. A no-effect dose was not determined in that study. There are no adequate and well-controlled studies in pregnant women; therefore, escitalopram should be used during pregnancy only if the potential benefits justifies the potential risk to the fetus. **Pregnancy-Nonteratogenic Effects:** Neonates exposed to Lexapro and/or 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, 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 20<sup>th</sup> 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; thus, 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 **DOSEAGE AND ADMINISTRATION**). Physicians should note that in a prospective longitudinal study of 201 women with a history of major depressive disorder who were euthymic at the beginning of pregnancy, women who discontinued antidepressant medication during pregnancy were more likely to experience depression during pregnancy. **Lactation:** Escitalopram is excreted in breast milk. The extent of excretion is not known. **Nursing Mothers:** Breastfeeding, 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 reportedly recovered 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. Any consideration of 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 differences in 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 **DOSEAGE AND ADMINISTRATION**). Of 4422 patients in clinical studies of racemic citalopram, 357 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 264 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



# Stress, Anxiety Raise Risk That G.I. Illness Will Become Severe

People who develop irritable bowel syndrome after a gut infection often expect too much of themselves and push themselves too much while ill. Thus they might benefit from cognitive-behavioral therapy.

BY JOAN AREHART-TREICHEL

About of gastroenteritis caused by bacteria or viruses can evolve into irritable bowel syndrome (IBS). And when this happens, personality factors seem to be involved, a new study suggests.

The research was conducted by Meagan Spence, Ph.D., an honorary lecturer in occupational medicine at the University of Auckland in New Zealand, and by Rona Moss-Morris, Ph.D., a professor of health psychology at the University of Southampton in England. Results were published in the August *Gut*.

The study included 620 individuals who had visited their primary care doctors because of symptoms of gastroenteritis and who had tested positive for the *Campylobacter* bacterium. At the time of diagnosis, the researchers had the subjects complete a questionnaire that included standardized measures of mood, perceived stress, perfectionism, negative illness beliefs, and illness behaviors. The researchers then followed the subjects for six months to determine whether any developed IBS. Forty-nine did. Finally, the researchers compared the psychological profiles of the 49 who devel-

oped IBS with the psychological profiles of the subjects who did not develop IBS.

They found that subjects who developed IBS had significantly higher levels of perceived stress, anxiety, and somatization at the time of *Campylobacter* diagnosis than did those who did not develop IBS. They also tended to see the consequences of having an infection as more distressing and as having a greater impact on their lives than did the subjects who did not get IBS. Furthermore, they were significantly more likely to remain active while acutely ill until they felt forced to rest—what the researchers called an “all-or-nothing response.”

Thus, perceived stress, anxiety, and unrealistic personal expectations appear to characterize those individuals who develop IBS following gastroenteritis, the researchers believe. And such an outlook may persist once a person has developed IBS, thereby perpetuating the condition.

In contrast, they found no more depression in the group that developed IBS than in the group that did not, contrary to what some retrospective studies

have found. This is the result that may most interest psychiatrists, Spence told *Psychiatric News*. It suggests that “depression may not be as important as anxiety levels and more subtle psychological variables such as illness beliefs and perceived stress [in development of IBS]. This result has important implications for prevention and early intervention in the development of IBS.”

“I thought the study was very interesting,” Steven Field, M.D., a New York City gastroenterologist who is studying to become a psychodynamic psychotherapist, said in an interview. “I’m not surprised that [gastroenteritis-provoked IBS] is correlated more with anxiety than with depression. Most IBS patients tend to be more anxious than depressed, in my experience.”

When asked whether the results of the study also apply to IBS patients whose IBS is not triggered by a bout of gastroenteritis, Field said, “I think they do, because it shows that personality can be a substrate for the development of these symptoms.”

IBS patients could benefit from cognitive-behavioral therapy, Spence and Moss-Morris said. Field agreed. In fact, “cognitive-behavioral therapy is used in many instances for the treatment of IBS,” he said.

The study was funded by the University of Auckland.

*An abstract of “The Cognitive Behavioral Model of Irritable Bowel Syndrome: A Prospective Investigation of Patients with Gastroenteritis” is posted at <<http://gut.bmj.com/cgi/content/abstract/56/8/1066>>. ■*

# Brain Imaging Suggests Origin Of Premenstrual Dysphoric Disorder

Anxiety and depression can drive some women to distraction in the week before menstruation. The condition—premenstrual dysphoric disorder—may be due in part to a surge in progesterone exciting the amygdala.

BY JOAN AREHART-TREICHEL

The biology of premenstrual dysphoric disorder (PMDD) is far from clear.

Reproductive hormones have been thought to be implicated because women experience its symptoms during the luteal phase of the menstrual cycle—the two weeks or so following ovulation where the reproductive hormones progesterone and estrogen are elevated. However, the levels of progesterone and estrogen at this phase of the menstrual cycle are no higher in PMDD subjects than in non-PMDD ones, so the cause of PMDD must be due to more than just elevations in progesterone and estrogen.

A study published in the June 19 advance online version of *Molecular Psychiatry* supports such a hypothesis. It has found that a dose of progesterone can activate the amygdala in mentally and physically healthy young women. Thus PMDD may be due, at least in part, to an excess of progesterone in the luteal phase exciting the amygdala, the researchers believe.

ing the luteal phase of their menstrual cycles. Again they were shown visual stimuli known to robustly engage the amygdala, and again fMRI was used to measure amygdala reactivity.

The researchers then compared amygdala reactivity, finding that it was significantly greater under the influence of progesterone than in the control situation. In contrast, progesterone did not influence neural activity in other brain areas any more than the control situation did.

Thus, even though the results were obtained in women without PMDD, the imaging results implied that PMDD may be due, at least in part, to a surge in progesterone during the luteal phase of the menstrual cycle and subsequent amygdala activation.

The researchers also suggested that progesterone-induced amygdala activity could affect the processing in other brain regions relevant for mood regulation. For example, they found that progesterone decreased the functional connection of the amygdala with the fusiform gyrus, a brain region involved in the processing of angry or fearful face stimuli, and that progesterone increased the functional coupling of the amygdala with the dorsal anterior cingulate gyrus, a brain region activated during the evaluation of threatening stimuli.

Recently, a variation in the ESR1 gene, which codes for an estrogen

*please see PMDD on page 20*

## LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION

(3% and <1%); Anorgasmia\* (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. \*Primarily ejaculatory delay †Denominator used was for males only (N=225 Lexapro; N=188 placebo). ‡Denominator used was for female only (N=490 Lexapro; N=404 placebo). **Generalized Anxiety Disorder Table 3** 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 3). **TABLE 3: 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\* (14% and 2%); Anorgasmia\* (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 †Primarily ejaculatory delay. ‡Denominator used was for males only (N=182 Lexapro; N=195 placebo) ‡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 4** 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 4: 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 5** shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-controlled trials. **TABLE 5: 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 change 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 change 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) 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 2 & 3**, 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, dys-equilibrium, 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 limbs, fever, hot flashes, 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, menstrua 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 node **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, chorea thetosis, delirium, delusion, diplopia, dysarthria, dyskinesia, dystonia, echymosis, erythema multiforme extrapyramidal disorders, fulminant hepatitis, hepatic failure, hypoesthesia, hypoglycemia, hypokalemia, INF 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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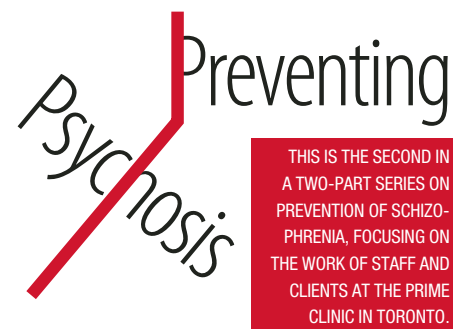
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## Deconstructing Schizophrenia Offers Hope for Better Treatment

The idea that the symptoms of schizophrenia may exist along a continuum has spurred interest in the development of a “dimensional” definition that might include the prodrome as a distinct dimension of schizophrenia.

BY MARK MORAN



“Alex” (not his real name) said he was having a hard time keeping up in school. At 30, he was working full time and taking classes at the University of Toronto.

He is a striver, a perfectionist perhaps, intent on doing well and making good. “When things get hectic and I push myself to the limit, I get real stressed out, and I start to isolate,” he said.

And there were occasional voices he heard. “I was working in the kitchen, cleaning my stove,” he recalled, “when I heard the voice of my mother saying very loud, ‘Good job! Good job!’ I was shocked and I was scared, but I just kept going.”

Alex said it was his girlfriend, concerned that he was talking to himself a lot, who urged him to seek the attention of a mental health professional. A psychologist in the Toronto area, recognizing his symptoms as suggestive of a thought disorder, referred him to the PRIME (Prevention Through Risk Identification, Management, and Education) Clinic in downtown Toronto, at the Centre for Addiction and Mental Health, Canada’s leading addiction and mental health teaching hospital.

Following extensive testing, Alex was found to have the signs of “prodromal” schizophrenia, the pre-psychotic stage that schizophrenia researchers believe precedes an acute psychotic episode. Now he comes to the clinic periodically to talk to therapists and to psychometric “raters” who assess his progress (or his deterioration) and to participate in a multicenter study looking at the efficacy of alternative methods for preventing or delaying the onset of schizophrenia.

Alex is a beneficiary of, and participant in, a unique public health effort on a far frontier of schizophrenia research. PRIME in Toronto is one of approximately 20 schizophrenia prevention clinics in North America, and one of eight receiving funding from the National Institute of Mental Health as part of the North American Prodrome Longitudinal Study (NAPLS).

“We get young people aged 14 to 30 who are having perceptual abnormalities of some kind,” said Jean Addington, Ph.D., lead investigator at PRIME Clinic. “They won’t be having full-blown psychosis, but they may think they are hearing things and that it’s happening more often than it should.

“You get a range of symptoms from very mild to quite severe within this not-yet-psychotic stage, and the condition is usually accompanied by a decline in functioning,” she said. “They may be suspicious and feel that they need to be watchful, but at the same time they know it’s kind of strange to think that way.”

### ‘Is Something Not Quite Right?’

Alex’s pathway to PRIME was paved with good fortune—the helpful girlfriend, the knowledgeable psychologist, and his own driven nature, determined to do well and to be an effective worker and student. His presence at the clinic—and the likely fact that countless others at risk for schizophrenia will never make it there—highlights the importance to prevention efforts of sustained and vigorous outreach to the community.

Andrea Reynolds, education coordinator at PRIME, told *Psychiatric News* that reaching the public in the greater Toronto area with the message about prevention has required a wide range of strategies that include canvassing hospitals, specialists, general practitioners, mental health professionals, staff at public high schools, guidance counselors, and print and broadcast media.

At one time, Toronto subway commuters might have seen a PRIME Clinic poster in the train depicting a group of smiling

teenagers with a headline above: “Is Something Not Quite Right?” Aimed at the adolescent who knows somehow that he or she doesn’t fit into the portrait of happy adolescence, the poster targets individuals who are experiencing the symptoms of prodromal schizophrenia and encourages them to contact PRIME (see poster).

“Finding the people in the community is the biggest challenge in this work,” said Scott Woods, M.D., principal investigator in the Enhancing the Prospective Prediction of Psychosis study at Yale University, one of the eight NAPLS sites. “There isn’t a *DSM* category for prodromal schizophrenia, and your average mental health professional doesn’t know that much about it. We go out in the community and give between 50 and 100 talks every year in the community, focusing on the local area of New Haven.”

Staff at PRIME Clinic say the shooting in April at Virginia Tech and the ensuing publicity about the shooter’s untreated mental illness may give the cause of prevention some new traction. In the mean-

“Among those people we are seeing with a ‘little bit of psychosis,’ are there protective factors that keep them from becoming fully psychotic?”

time, they wonder whom they are missing in their outreach efforts, particularly since their numbers don’t match the generally accepted prevalence rate of 1 percent for schizophrenia, even assuming that everyone being seen at the prevention clinic were to convert to psychosis.

“My guess is that we are getting the squeaky wheel that requires grease,” said PRIME Clinic psychiatrist Irvin Epstein, M.D. “These are people who are more likely to tell someone that they are having problems or who really aren’t doing well.”

Epstein believes that some of these with the most severe symptoms—like Alex with his occasional episodes of hearing voices—are those who are experiencing the precursors to the more frightening positive symptoms of psychosis.

“Where we aren’t doing such a great job is in reaching those people who are experiencing the softer, negative symptoms,” Epstein said. “These are people who, instead of hearing voices, may be withdrawing from their friends, feeling uncomfortable around others, and lacking in motivation or direction.”

If the behavioral manifestations are only subtly differ-

ent, the underlying neuroanatomical differences are not, Epstein said, noting that functional imaging studies have shown changes in the dorsolateral prefrontal cortex to be responsible for negative symptoms and changes in personality and executive functioning.

“These are much more dangerous because they are the symptoms that are usually refractory to treatment,” he said. “But these are the same people who don’t typically get to our clinic.”

### Schizophrenia Gets Deconstructed

So, where is the line between prodromal psychosis and full-blown schizophrenia?

Maria Haarmans, M.A., a therapist at PRIME who works with Alex and other clients, said that a distinguishing feature of those who have converted to psychosis is a conviction about the reality of their abnormal experiences: the prodromal client may hear a voice and know it isn’t real, while the patient is convinced it is.

Woods observed, “The prodromal symptom is like schizophrenia, but instead of hallucinations, people experience milder perceptual abnormalities that don’t have as much content. Instead of believing the FBI is monitoring their thoughts, feelings, and actions, they may simply think that people are watching them.”

But if the line between those nameless individuals in the community with a “quieter” form of psychosis who never come to clinical attention and a patient like Alex with disturbing and disrupting symptoms is a faint but scientifically valid one—and if the line between Alex’s prodromal symptoms and full-blown schizophrenia is equally valid scientifically—then it would seem to suggest that the symptoms of schizophrenia, as a developmental disorder, exist along a continuum.

Today a popular theme at scientific conferences is “deconstructing” schizophrenia, breaking it down into stages or domains of pathology along the continuum and developing interventions appropriately targeted to each stage or domain. The concept has ignited a debate about the validity of the traditional categorical description of the disorder according to rigid *DSM* criteria and spurred interest in the development of a “dimensional” definition that might include the prodrome as a distinct dimension of schizophrenia.

The July issue of the *Schizophrenia Bulletin*, which can be accessed at <www.schizophreniabulletin.oxfordjournals.org>, featured several articles on the theme “Deconstructing Psychosis.”

Addington said that the idea of schizophrenia existing along a continuum suggests that just as it is possible to be “a little bit depressed,” it may be possible to be a “little bit psychotic.” At the farthest, or earliest, end of the developmental continuum, symptoms may “fade to normal,” consisting of unusual thoughts or beliefs that never cause them to come to the attention of others. These individuals find a way to live quietly with the symptoms and never seek treatment.

She believes the idea can help to destigmatize psychosis, diluting its toxic associations with bizarre or violent or criminal

*please see Schizophrenia on facing page*



**is something not quite right?**

THE PRIME CLINIC HELPS YOUNG PEOPLE AGES 14 - 30 WHO HAVE BECOME DISTRESSED BY CHANGES IN THEIR THOUGHTS, PERCEPTIONS, AND FEELINGS AND WHO MAY BE AT RISK OF DEVELOPING PSYCHOSIS.

SIGNS INCLUDE:

- trouble concentrating or thinking clearly
- confusion about what is real or imaginary
- hearing voices or seeing things that aren't really there
- feeling suspicious or paranoid
- disorganized speech, racing or slowed-down thoughts
- irrational ideas of special identity or abilities
- problems with social activities, at work or at school

**PRIME clinic** PREVENTION THROUGH RISK IDENTIFICATION, MANAGEMENT AND EDUCATION.

Mental and emotional changes are the early signs that someone could be at risk for psychosis. These signs are vague; sometimes people barely notice them. If you or someone you know is experiencing changes like these, the PRIME Clinic can help.

People who have a family member who has a mental illness, and who are now experiencing their own difficulty in functioning, are also encouraged to contact us.

FOR HELP OR MORE INFORMATION CALL **PRIME at 416 260-4188**

 **camh**  
Centre for Addiction and Mental Health  
Centre de recherche et de soins en santé mentale

This poster was placed in Toronto subway cars to spread the word about PRIME Clinic and prevention of schizophrenia. Scott Woods, M.D., a prevention researcher at Yale University, says, “Finding the people in the community is the biggest challenge in this work.”



# Clinical Features Point to Five Alcoholic Subtypes

Americans with alcohol dependence tend to fit into one of five personality types, putting to rest theories that there is a "typical alcoholic."

BY JOAN AREHART-TREICHEL

A study in press with *Drug and Alcohol Dependence* provides what may be the clearest picture yet of Americans with alcohol dependence.

The study analyzed the clinical features of 1,484 Americans found to be alcohol-dependent through the 2001-2002 National Epidemiological Survey on Alcohol and Related Conditions and then grouped those persons according to their clinical features.

The study found that there is no such thing as a "typical alcoholic," rather that alcohol-dependent subjects tend to fall into five subtypes—young adult, young antisocial, intermediate familial, functional, and chronic severe.

- **Young adult subtype.** This is the most common alcohol-dependent subtype, constituting 32 percent of alcohol-dependent Americans. They are typically young, male adult drinkers with relatively low rates of co-occurring substance abuse and other mental disorders. They have a 22 percent rate of familial alcoholism and rarely seek help for their drinking.

- **Young antisocial subtype.** This is the second most common category of alcohol-dependent individuals, constituting 21 percent of alcohol-dependent Americans. They are apt to be in their mid-20s and to have started drinking early. About half come from families with alcoholism, and about half have a diagnosis of antisocial personality disorder. Three-fourths of these individuals smoke cigarettes; two-thirds meet criteria for marijuana abuse or dependence. About a fourth use cocaine, and about a fifth abuse opioids. About one-third seek treatment for their drinking problem.

- **Intermediate familial subtype.** Nineteen percent of alcohol-dependent Americans fall into this category. They tend to be middle-aged, with about half coming from families in which a member has alcoholism. Almost half have experienced a major depression, and almost a quarter have been diagnosed with bipolar disorder. About one-fifth abuse marijuana or cocaine. One quarter of these people seek treatment for their drinking problem.

- **Functional subtype.** Nineteen percent of alcohol-dependent Americans fall into this category. They are, on average, older than other subtype members and tend to drink in an excessive, although less severe, manner than other subtypes. They have the highest family income, are college-educated, and are most likely to be married. They also include the highest proportion of retired individuals. From a psychosocial perspective, they represent the highest functioning subtype of alcohol-dependent persons. Nonetheless, they

may still ultimately be at significant risk of the biomedical consequences of alcohol dependence. Seventeen percent seek treatment for their drinking problem.

- **Chronic severe subtype.** This is the smallest category of alcohol-dependent Americans, constituting 9 percent of them. The subtype is composed mostly of middle-aged persons who had early onset of drinking. Over three-fourths come from families afflicted with alcoholism. This subtype has the highest probability of all the subtypes of having both first- and second-degree family members with alcohol dependence. Almost half have antisocial personality disorder. Of all the subtypes, they have the highest rate of major depression, social phobia, and bipolar, anxiety, and panic disorders. Over three-fourths smoke cigarettes. They often abuse substances in addition to alcohol. Two-thirds seek help for their drinking. They are the largest subgroup who seek treatment.

## Unexpected Results Found

In an interview with *Psychiatric News*, lead researcher Howard Moss, M.D., associate director for clinical and translational research at the National Institute on Alcohol Abuse and Alcoholism, said the study's findings were unexpected.

"We were surprised that so many of the individuals who met diagnostic criteria for alcohol dependence were young adults. We thought we were going to see a substantial proportion of folks with alcohol dependence being of the chronic recurring subtype that is seen in Veterans Administration hospitals and in other kinds of settings where people treat chronic disease. Another surprise was the breakout in terms of family history of alcohol problems and the fact that only about half the sample had familial transmission of alcohol dependence."

The study results suggest that certain therapies might work better with certain subtypes than with others, Moss said. In fact, he and his coworkers will now be attempting to see whether certain types of therapies work best for this or that subtype. Until such results are obtained, how should individuals in the various categories be treated?

## Treatment Choices Vary

"The young adult variety may be addressed with screening and brief intervention techniques rather than much more expensive approaches to therapeutic intervention," Moss advised. "It may also be—and again this is speculation, as we have to do the studies—that certain types of pharmacotherapies that are now available could be better targeted to this subgroup. For example, this subgroup might benefit from pharmacotherapy that reduces the reinforcing effect of alcohol."

Since the antisocial group has the worst prognosis of any of the subtypes, Moss said, "the focus there has to be on complete abstinence and elimination of other forms of substance abuse and also mainstreaming their behaviors so that they are much more like the rest of society."

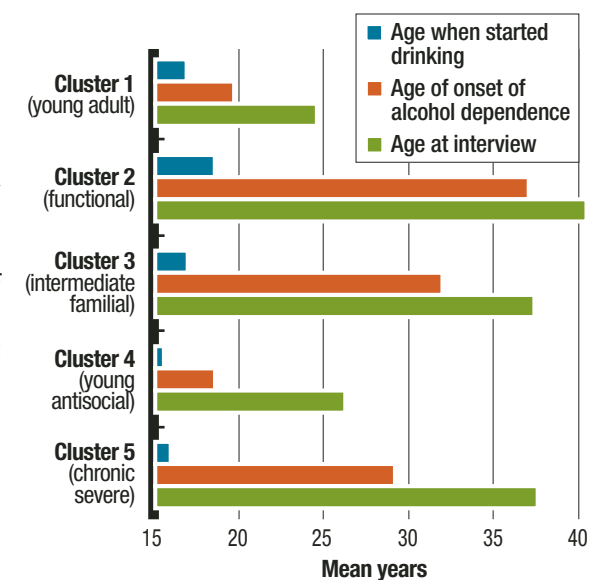
"The functional subtype," Moss emphasized, "represents individuals who essentially have fewer psychosocial consequences from their alcohol dependence. So the focus of the therapy there needs to be on recognition of the impairment that their alcohol dependence is producing in their life and also focusing on either abstinence or a return to a much less hazardous level of drinking."

As for individuals with chronic severe alcohol dependence, "We would certainly assume that they are going to need substantial treatment," said Moss. "They might benefit from therapies that are directed toward relapse prevention." Furthermore, this group is going to have substantial psychiatric comorbidity, he pointed out, "so we have to simultaneously address their alcohol-use disorder as well as manage their psychopathology."

Charles O'Brien, M.D., Ph.D., a professor of psychiatry at the University of Pennsylvania, who was unaffiliated with the study, told *Psychiatric News* that this study marks an important step in subcategorizing alcoholism because it includes a community sample rather than simply

## There Is No Prototypic "Alcoholic"

Five subtypes of alcohol-dependent Americans have been identified—young adult, functional, intermediate familial, young antisocial, and chronic severe. The subtypes start drinking at various ages and also become alcohol dependent at various ages.



Source: Howard Moss, M.D., et al., *Drug and Alcohol Dependence*, in press

examining the 25 percent who present for treatment; it is based on a large dataset, and the five subtypes seem quite recognizable based on the data used: family history, age of onset, and presence of other psychiatric disorders.

"The next step," he said, "[is to identify] biomarkers for even more precise subcategories, such as genotype or biochemical test."

An abstract of "Subtypes of Alcohol Dependence in a Nationally Representative Sample" can be accessed at <[www.sciencedirect.com/science/journal/03768716](http://www.sciencedirect.com/science/journal/03768716)> by clicking on "Articles in Press." ■

## Schizophrenia

continued from facing page

behavior, and also points the way to future research.

"What happens to the persons who don't go on to develop psychosis?" she wonders. "Among those people we are seeing with a 'little bit of psychosis,' are there protective factors that keep them from becoming fully psychotic?"

Alex's prognosis remains uncertain, but he said that PRIME Clinic has taught him skills for taking the heat off when the stress of his own endeavors gets too high—"positive chilling out," he called it—and he looks forward to taking a break someday from the hectic atmosphere of busy Toronto.

He expressed relief that he found PRIME before the vigorous party scene in Toronto found him, saying it might have spelled his ruin. "I wouldn't be sitting here with you today," Alex said.

He added that his mother and family, as well as his girlfriend, have been extraordinarily supportive of the help he receives at the clinic.

But how would he feel about telling his friends he was at risk for schizophrenia?

"I would be embarrassed a little to tell friends, but I would be able to explain it," he replied. "I would use it as an opportunity to talk about it and deal with it."

"At first I was scared, but it has really changed my perspective," he said. "[The

staff at the clinic] have helped me to know other people feel the same kind of stresses and that the stuff I go through is normal. I don't ignore my problems, but I don't focus on them either."

More information on PRIME Clinic is posted at <[www.camh.net/Care\\_Treatment/Program\\_Descriptions/Mental\\_Health\\_Programs/PRIME\\_Clinic/index.html](http://www.camh.net/Care_Treatment/Program_Descriptions/Mental_Health_Programs/PRIME_Clinic/index.html)>. ■

## VA Head Resigns

James Nicholson has resigned as U.S. secretary of Veterans Affairs, effective no later than October 1. Nicholson had served as head of the VA since February 2005. A successor has not yet been appointed. ■

## APA Wants To Help!

If any of your patients are being denied access to their appropriate drugs under the Medicare Part D prescription drug program, call (800) 343-4671. More information is available from Ellen Jaffe of APA's Office of Health Care Systems and Financing at (703) 907-8591 or [ejaffe@psych.org](mailto:ejaffe@psych.org).



# New Study Questions Common Bipolar Depression Treatment

Antidepressants are often prescribed to treat patients with bipolar depression, but this strategy may be counterproductive to those with concomitant manic symptoms.

BY JUN YAN

**A**lthough many patients with bipolar depression remain symptomatic despite the use of mood stabilizers, the effectiveness and risk of adding an antidepressant to their medication regimen remains controversial. A study in the September *American Journal of Psychiatry* adds weight to the opinion that, at least for a subpopulation of patients who have simultaneous manic symptoms and full-blown depression, adjunctive antidepressants provide few benefits and may even exacerbate mania.

The study was based on the naturalistic treatments and patient outcomes collected in the nonintervention phase of the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) study, in which practitioners were given no particular guidelines regarding adjunctive antidepressants. Specifically, the research-

ers investigated whether antidepressants plus standard mood stabilizers succeeded in bringing patients out of a depressive episode faster than mood stabilizers alone.

STEP-BD, which was funded by the National Institute of Mental Health and conducted between 1998 and 2005, is the largest national research program on the treatment of patients with bipolar disorder. It sought to clarify treatment effectiveness and patients' disease course and outcomes in real-life clinical settings. The study design included both naturalistic treatment components and randomized, controlled, interventional treatments.

Among the first 2,000 patients enrolled in the naturalistic phase of STEP-BD, the authors chose a subgroup of 335 patients taking mood stabilizers who met the *DSM-IV* criteria for a full depressive episode while also having two or more manic symptoms. Patients with depression and

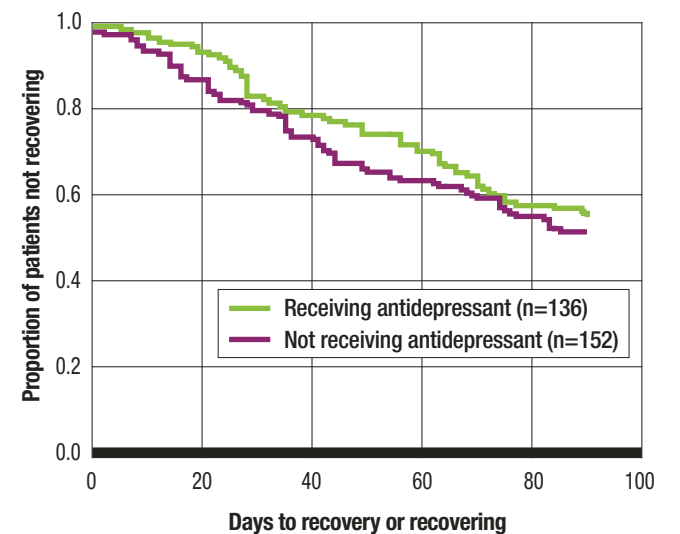
subsyndromal mania were included because they were more likely to be prescribed an antidepressant than those who met the diagnosis of mixed episode, the authors said. About half of the patients in the subgroup (145) were treated with an adjunctive antidepressant before or at the time of enrollment; the remainder were not.

The time to recovering (defined as four weeks of two or fewer unequivocally present affective symptoms) or recovery (eight weeks of two or fewer affective symptoms) was not significantly different between patients taking an antidepressant with a mood stabilizer and those taking a mood stabilizer only. In other words, the addition of an antidepressant did not hasten patient recovery from a depressive episode.

The authors then expanded their analysis to a total of 445 patients with bipolar depression and any number of manic

## Antidepressants Do Not Hasten Bipolar Depression Recovery

The length of time to recovery or recovering (defined as 4 or 8 weeks of  $\leq 2$  unequivocally present affective symptoms, respectively) from a depressive episode is not significantly different between patients taking antidepressants and mood stabilizers and patients taking only mood stabilizers. All patients had bipolar depression at baseline with two or more manic symptoms (analysis excluded 47 patients with bipolar disorder not otherwise specified).



Source: Joseph Goldberg, M.D., et al., *American Journal of Psychiatry*, September 2007

symptoms at baseline as well as those with no manic symptoms. For those who had one or more manic symptoms at baseline, adding an antidepressant was significantly associated with increased severity *please see **Bipolar** on page 18*

# Psychosocial Benefits Accrue When Psychotherapy Part of Treatment

Treatment for bipolar depression combining intensive psychotherapy and mood stabilizers is found to outperform mood stabilizers alone in improving patient functioning and life satisfaction.

BY JUN YAN

**T**reatment consisting of a nine-month course of intensive psychotherapy and mood-stabilizing medication for patients with bipolar depression has been found to improve the patients'

overall functioning, relationship functioning, and life satisfaction, according to a study published in the September *American Journal of Psychiatry*. These psychosocial benefits of intensive psychotherapy further support its use in the treatment of bipolar depression.

Patients in the study, conducted by David Miklowitz, Ph.D., and other researchers who participated in the National Institute of Mental Health's Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD), had been diagnosed with bipolar I or bipolar II depression. They received treatment for acute depressive episodes when they were randomly assigned to undergo either 30 one-hour sessions of intensive psychotherapy over nine months or three one-hour sessions of collaborative-care educational counseling over six weeks.

Three types of psychotherapy were offered in the intervention group, depending on the study sites' expertise and the availability of patients'

family members. Cognitive-behavioral therapy helped patients learn to change negative self-statements and dysfunctional beliefs. Interpersonal and social rhythm therapy emphasized the regularity of sleep/wake rhythms to maintain mood stability. Family-focused therapy sessions involved the patient and at least one family member, and effective communication and problem-solving skills were taught to both. In contrast, the collaborative care included providing the patients with a self-care workbook and an educational videotape about bipolar disorder and three one-hour sessions focused on implementing self-management tools and developing a relapse-prevention plan.

Of the 152 patients who participated in the study between September 1999 and July 2005 and had functioning assessment data available for analyses, 84 received intensive psychotherapy and 68 received collaborative care. Patients in the intensive psychotherapy group had statistically significantly better overall functioning as measured by the total score on the Longitudinal Interval Follow-Up Evaluation-Range of Impaired Functioning Tool (LIFE-RIFT) over the study period.

The intensive psychotherapy group also did better in the relationship functioning and satisfaction domains within the LIFE-RIFT, but there was no significant difference in the scores of work/role functioning and recreation domains between the intensive psychotherapy group and the collaborative care group.

The three types of psychotherapy appeared to be comparable in effectiveness in all measurements of functioning.

"Although the impact of intensive psychotherapy on functional improvement

demonstrated modest effect sizes compared with collaborative care, given the significant functional impairment associated with bipolar disorder, even modest gains are clinically meaning," Stephen M. Strakowski, M.D., wrote in an accompanying editorial.

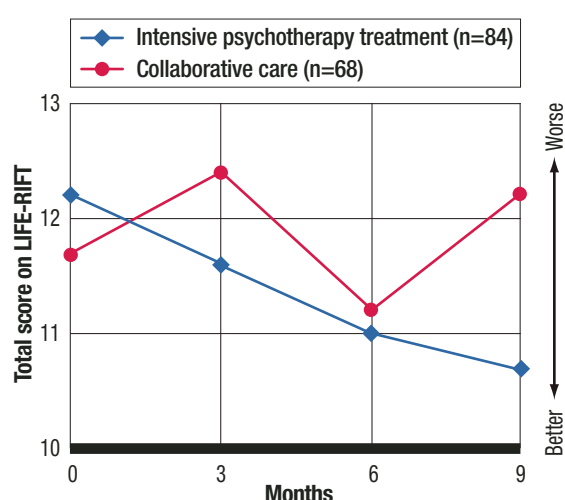
In an article in the April *Archives of General Psychiatry*, the same authors reported the clinical outcomes of this STEP-BD study (*Psychiatric News*, May 4). Patients with bipolar depression receiving adjunctive intensive psychotherapy saw statistically significant improvement in terms of year-end recovery rates and shorter time to recovery compared with the patients in collaborative care. The social-functioning benefits documented in this study strengthened the role of intensive, long-term psychotherapy, rather than brief education, in the treatment plan.

The STEP-BD study involved 19 clinical centers and associated community partners across the country (see article above). A number of substudies were conducted within the overall program (see article above), which reflected "real-world" clinical practice for treatment of bipolar disorder and continue to generate clinical data for guiding optimal treatment approaches and future research directions.

*"Intensive Psychosocial Intervention Enhances Functioning in Patients With Bipolar Depression: Results From a 9-Month Randomized Controlled Trial" is posted at <<http://ajp.psychiatryonline.org/cgi/content/full/ajp;164/9/1340>>. An abstract of "Psychosocial Treatments for Bipolar Depression" is posted at <<http://archpsyc.ama-assn.org/cgi/content/abstract/64/4/419>>. ■*

## Intensive Psychotherapy Improved Total Functioning

Compared with three one-hour sessions of collaborative care involving education, intensive psychotherapy consisting of 30 one-hour sessions for nine months resulted in significantly better overall functioning, as measured by Longitudinal Interval Follow-Up Evaluation-Range of Impaired Function Tool (LIFE-RIFT), in patients with bipolar depression and receiving medication treatment.



Source: David Miklowitz, Ph.D., et al., *American Journal of Psychiatry*, September 2007



# Depression Treatment Continuity Crucial During, After Pregnancy

Ninety-three percent of women with depression in a large regional health plan received some form of treatment, either medication or "mental health visits."

BY MARK MORAN

Women with a history of depression are at greater risk of postpartum depression than are women without such a history, and psychiatrists need to be sensitive to this association, suggest findings from a study to be published in the October *American Journal of Psychiatry*.

Researchers found that about one in seven women was identified with and treated for depression in a period spanning 39 weeks prior to pregnancy and 39 weeks after pregnancy.

In addition, in more than half of the women who were diagnosed with depression before pregnancy, the depression reoccurred later in the pregnancy or after the baby was born.

Patricia Dietz, Dr.P.H., lead author of the report, said the study underscores the need for continuity of care before, during, and after pregnancy for women of child-bearing years. Dietz is an epidemiologist with the Centers for Disease Control and Prevention.

"Because depression can be a chronic condition, we found reoccurrence happened during pregnancy as well as during the postpartum period," Dietz told *Psychiatric News*.

In the study, Dietz and colleagues analyzed the prevalence of depression and treatment types received for depression among members of the Kaiser Permanente Northwest health plan. They used a validated algorithm to identify members with at least one pregnancy between January 1, 1998, and December 31, 2001.

Women with a pregnancy ending in one or more live births and continuously enrolled from 39 weeks before pregnancy through 39 weeks after pregnancy were eligible. Maternal depression was identified from the medical records. Depression treatment included antidepressant medication and/or "mental health visits."

Treatment for depression was defined as receiving at least one dispensing of antidepressant medication identified through pharmacy records or at least one mental health visit identified through electronic medical records with a depression or dysthymia diagnosis.

They found that among 4,398 continuously enrolled women with eligible pregnancies ending in live births, 678 (15.4 percent) had depression during at least one pregnancy phase.

Of women identified with depression during the 39 weeks following pregnancy, 54.2 percent had depression diagnoses either during or preceding pregnancy.

"For clinicians, this means asking women during the initial prenatal care visit about any previous experiences with depression," Dietz told *Psychiatric News*.

"If a woman reports previous experiences, then the clinician should begin a dialogue with the patient regarding her mental health and check in with her throughout the pregnancy and at the six-week postpartum visit to assess how she is doing."

"It is also important to note that approximately half of the women who were diagnosed with depression during pregnancy and approximately half of the women who were diagnosed during the postpartum period did not have a previous diagnosis in the study period," she said. "Therefore, clinicians should be aware that depression can be experienced by any of their patients, not just those women with a previous history of depression. Asking women a two-question screen can be an efficient way to identify women with depression, as some women may be reluctant to discuss it with their prenatal care provider."

Dietz said the two questions are: During the past month, have you been bothered by feeling down, depressed, or hopeless? During the past month have you often been bothered by little interest or pleasure in doing things?

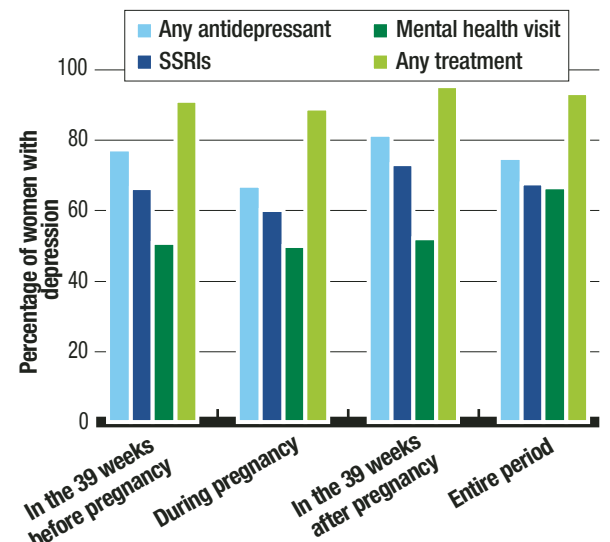
The study also offered what looks like good news: the vast majority of women with depression in this large regional health plan received some form of treatment for depression, either medication or mental health visits (see chart).

"We were encouraged that over 93 percent of women with a depression diagnosis during the study period received some kind of treatment, which suggests that women similar to those at Kaiser Permanente Northwest will seek treatment when diagnosed," Dietz said.

"We did not know what level of antidepressant use during pregnancy we would find in this study because we were not aware of any previously published percentages of antidepressant use among depressed pregnant patients," Dietz said. "Given women's

## Most Women Received Treatment for Depression

In a study of 4,398 women whose pregnancies ended in a live birth, 678 were identified with depression before, during, or after the pregnancy. Of that number, 93.4% received at least one form of treatment for depression. Antidepressant treatment was the most common form of treatment during each time period.



Source: Patricia Dietz, Dr.P.H., *American Journal of Psychiatry*, October 2007

general reluctance to use any type of medication during pregnancy, we had expected to see an increase in the use of mental health visits during pregnancy, which we did not."

please see **Pregnancy** on page 23

# Simple Screening Tool Identifies Kids With Development Delays

Busy pediatricians enlist parents' help to better identify developmental delays in children who may need special care.

BY JUN YAN

Early intervention improves outcomes for children with developmental delays, but performing routine, formal developmental screening as recommended by the American Academy of Pediatrics can be a challenge for busy pediatricians. The experience of pediatric staff at a large medical practice in Eugene,

Ore., however, has demonstrated that a systematic screening program in which parents fill out a validated assessment questionnaire can dramatically increase the number of children identified with potential problems that required further evaluation.

The program is described and its effects are analyzed in an article in the August *Pediatrics* by Hollie Hix-Small, Ph.D., and colleagues.

In the period between April 1, 2005, and March 1, 2006, a simple process was incorporated in routine well-child visits at 12 or 24 months. At each visit, a parent or caregiver was given the Ages and Stages Questionnaire (ASQ), a 30-item, screening tool for monitoring child development, which has been shown to be valid and reliable for children between 4 months and 5 years old. Participants in the program had the option to complete the questionnaire at home and mail it in or complete the questionnaire at the medical office.

The research staff reviewed the completed ques-

tionnaires and referred children with suspected developmental problems to the Program for Infants and Toddlers (part C of the Individuals with Disabilities Education Act [IDEA], a federal grant program) based on predetermined criteria for ASQ scores. Meanwhile, pediatricians at the practice independently saw these children as a part of standard care, documented their ratings of each child's developmental status and determined whether the child needed a referral to the same part C agency evaluation. The pediatricians were unaware of the children's ASQ scores.

The result was impressive: out of 1,428 children who were seen at the practice, 107 children were referred to an IDEA part C agency for further developmental evaluations. That represented a 224-percent increase over the period April 2003 to March 2004, when only 33 referrals were made. On the basis of their clinical impression alone, physicians referred 45 children, while researchers identified and referred 82 children on the basis of ASQ scores. Only 20 were cases overlapping from both processes.

Of all the referrals, 25 children were screened out by the state's part C agency as "no concern," 38 met the eligibility criteria for IDEA part C special-education services immediately, and 44 were scheduled for future screening because of suspected developmental delays.

Once a child is referred to a part C agency, the agency contacts the parents or caregiver and conducts further evaluations to determine whether the child is eligible for state-provided care.

The authors cited the importance of early intervention, which requires

please see **Tool** on page 18

## Parent Questionnaire Picked Up Problems

In an 11-month period of well-child visits at the age of 12 or 24 months at a large practice, the parent- or caregiver-completed Ages and Stages Questionnaire identified more children for early developmental delay evaluation than did pediatricians. The agency's evaluation deemed 82 (77%) of 107 referred children to be either eligible for placement in special care programs or in need of further monitoring, including 39 (63%) of the 62 referred cases identified through the questionnaire alone (that is, not identified by pediatricians).

1,428 cases	No physician or ASQ referral n = 1,321 (93%)			
	Physician and ASQ referral n = 20 (1.4%)	No concerns n = 0 (0%)	Monitor n = 8 (40%)	Eligible and placed n = 12 (60%)
	Physician only referral n = 25 (1.8%)	No concerns n = 2 (8%)	Monitor n = 13 (52%)	Eligible and placed n = 10 (40%)
	ASQ only referral n = 62 (4.3%)	No concerns n = 23 (37%)	Monitor n = 23 (37%)	Eligible and placed n = 16 (26%)

Source: Hollie Hix-Small, Ph.D., et al., *Pediatrics*, August 2007



## Regulatory Briefs

• The labeling information for *Adderall* (mixed salts of a single-entity amphetamine product, Shire) and *methylphenidate hydrochloride* (Methylin, Alliant Pharmaceuticals) chewable tablets and oral solution was revised in June. Notably, the “Precaution” section of the package inserts was revised to refer to the medication guide. Medication guides explaining the risks and benefits of the three drug products are designed for patients by the U.S. Food and Drug Administration (FDA).

*The new package inserts and medication guides for these drugs can be accessed at <[www.fda.gov/medwatch/safety/2007/jun07.htm](http://www.fda.gov/medwatch/safety/2007/jun07.htm)>.*

• The FDA rejected the New Drug Application (NDA) for the investigational schizophrenia drug *bifeprunox*, developed by Wyeth and its partner Solvay Pharmaceuticals. The drug was deemed not approvable at this time for the indications cited in their application to the FDA—the acute treatment of schizophrenia and the maintenance of stable adult patients with schizophrenia. According to a press release by Wyeth on August 10, the FDA concluded that the data on the drug’s efficacy, compared with other similar drugs, were not sufficient for approval. The agency also requested further information on the metabolism of bifeprunox and adverse-event details related to a patient death during one of the clinical trials. Bifeprunox is a partial dopamine D<sub>2</sub> receptor agonist similar to aripiprazole. Wyeth said in a press release that the FDA’s letter acknowledged bifeprunox’s effectiveness in the long-term maintenance study and indicated the possibility for approving such a claim if a second maintenance study is conducted and yields positive results.

• The European Medicines Agency (EMA) recommended in a July 19 press release that a contraindication be added to *rimonabant* (marketed as Acomplia in Europe) for patients with ongoing major depression who are being treated with an antidepressant. Rimonabant has been approved in the European Union for the treatment of obesity since June 2006, but the NDA (under the proposed brand name of Zimulti) that Sanofi-Synthelabo had submitted to the FDA was rejected because of safety concerns regarding potential psychiatric adverse effects. The EMA’s Committee for Medicinal Products for Human Use (CHMP) evaluated the drug’s safety data and concluded that the drug’s benefits outweigh its risks except in patients with ongoing major depression or those being treated with antidepressants. The CHMP also recommended adding a warning that rimonabant should be discontinued if a patient develops depression and including additional warnings on the drug’s psychiatric safety profile in the prescribing information.

• The FDA approved *armodafinil* (Nuvigil) tablets (manufactured by Cephalon) in June for improving wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome (as an adjunct to treatment

of underlying obstruction), narcolepsy, and shift-work sleep disorder. Armodafinil is an isomer of *modafinil* (Provigil), also approved for these sleep disorders. Armodafinil has a longer half life than modafinil.

## Research Briefs

• *D-cycloserine*, a broad-spectrum oral antibiotic originally developed to treat tuberculosis, may be effective as an adjunct to behavioral therapy in the treatment of obsessive-compulsive disorder (OCD), researchers at the University of Minnesota discovered. In a study published online in *Biological Psychiatry* on June 22, Matt Kushner, Ph.D., and colleagues compared D-cycloserine with placebo in patients with OCD. Ten 125 mg doses of D-cycloserine or placebo were given in a random, double-blind fashion to 15 and 17 patients, respectively; one dose was taken approximately two hours before each exposure/ritual prevention therapy session. Fourteen patients (93.3 percent) in the D-cycloserine group completed all 10 sessions, compared with 11 (64.7 percent) in the placebo group. During the first four therapy sessions, patients taking D-cycloserine reported a significantly greater decrease in obsession-related distress compared with the placebo group.

## clinical & research news

### Bipolar

*continued from page 16*

of mania (measured by the Young Mania Rating Scale) at the three-month follow-up visit.

STEP-BD researchers led by Gary Sachs, M.D., of the Department of Psychiatry at the Massachusetts General Hospital/Harvard University Medical School had found in another study that giving antidepressants to patients who had bipolar depression but no concomitant manic symptoms and were already on mood stabilizers increased neither the percentage of patients who achieved recovery nor their risk of switching to mania, compared with patients taking only mood stabilizers (*New England Journal of Medicine*, April 26).

That study “found that antidepressants neither help nor harm these bipolar patients in a more ‘pure’ depressive episode who had no manic symptoms. Our study looked at a different group of patients with depression plus manic symptoms,” said Joseph Goldberg, M.D., the lead author of the current *American Journal of Psychiatry* study and director of the Affective Disorders Program at Silver Hill Hospital in New Canaan, Conn., in an interview with *Psychiatric News*.

“In previously collected data, we had found that about half of patients with bipolar depression had subsyndromal mania that does not meet the *DSM-IV* definition of a mixed episode, while only a third had ‘pure’ depression without manic symptoms.” These data were presented at APA’s 2007 annual meeting.

Despite the lack of evidence clearly supporting their advantages, antidepressants

The D-cycloserine group reached the study endpoint (50 percent reduction in Subjective Units of Distress) two sessions earlier than the placebo group. However, after the entire 10 sessions, the patients remaining in the placebo group tended to catch up.

D-cycloserine is a glutamatergic partial N-methyl-D-aspartate agonist and is known to facilitate a process called “extinction learning,” in which it manipulates memory processes and causes the “extinction” of learning-related, externally cued fear in animals and humans. Researchers have speculated that the drug can enhance the extinction learning in psychotherapy and thus improve the effectiveness of the therapy.

The study was funded through grants from the Obsessive-Compulsive Foundation and the Minnesota Medical Foundation.

*An abstract of “D-Cycloserine Augmented Exposure Therapy for Obsessive-Compulsive Disorder” can be accessed at <[www.sciencedirect.com/science/journal/00063223](http://www.sciencedirect.com/science/journal/00063223)> by clicking on “Next vol/iss.”*

• *Donepezil* (Aricept) showed favorable efficacy compared with placebo in enhancing the cognition and global functioning of patients with severe Alzheimer’s disease. A randomized, double-blind, placebo-con-

trolled study was published in the July 31 *Neurology*; the study was sponsored by Eisai and Pfizer, which develop and market the drug worldwide.

Patients with severe Alzheimer’s disease (defined as Mini-Mental State Examination [MMSE] score between 1 and 12 and Functional Assessment Staging score no less than 6) were given donepezil 10 mg (n=176) or placebo (n=167) once daily for 24 weeks. Compared with the placebo group, the donepezil group saw statistically significant improvement, defined as change from baseline (p=0.0001) in clinical endpoints measured by the Severe Impairment Battery, the Clinician’s Interview-Based Impression of Change-Plus caregiver input, and MMSE scores. However, other indicators such as the Neuropsychiatric Inventory scores, activity of daily living, caregiver burden, and resource utilization measurements did not show significant difference between the two groups. The adverse events observed in the trial were consistent with those reported in patients with mild and moderate Alzheimer’s disease, for whom donepezil is an FDA-approved treatment.

*“Donepezil Preserves Cognition and Global Function in Patients With Severe Alzheimer Disease” is posted at <<http://neurology.org/cgi/content/full/69/5/459>>.* ■

are widely prescribed to bipolar patients experiencing a depressive episode, as Ross Baldessarini, M.D., and colleagues reported in the January *Psychiatric Services*. This finding may reflect the difficulty in detecting manic symptoms when depression is the predominant feature.

In addition, long-term observational data published by Lewis Judd, M.D., of the Department of Psychiatry at the University of California, San Diego, and colleagues in the *Archives of General Psychiatry* (June 2002 and December 2005) have shown that depressive episodes and symptoms consume a much larger portion of patients’ lives and cause more disability and mortality than do manic symptoms.

Goldberg and colleagues pointed out in their article that “practitioners often fail to

recognize manic symptoms during bipolar mixed states” or “underappreciate manic or hypomanic symptoms” during depressive episodes. They suggested that psychiatrists should be more vigilant in detecting signs of mania during a depressive episode that are below the threshold of *DSM-IV*-defined mixed episodes.

Even if a patient is clearly experiencing a depressive episode, the clinician “should be conscientious of any concomitant manic symptoms,” Goldberg recommended. “One should be very cautious with the use of antidepressants in these patients.”

*“Adjunctive Antidepressant Use and Symptomatic Recovery Among Bipolar Depressed Patients With Concomitant Manic Symptoms: Findings From the STEP-BD” is posted at <<http://ajp.psychiatryonline.org/cgi/content/full/164/9/1348>>.* ■

## Tool

*continued from page 17*

early detection of signs or symptoms, to achieve optimal outcomes for children with developmental delays. Although the American Academy of Pediatrics has published guidelines for identifying infants and young children with developmental disorders, busy pediatricians may find it challenging to use these algorithms during routine visits. In contrast, the ASQ can be completed by parents or caregivers at home and potentially teach them possible signs to look for in children.

“One anecdotal observation in the clinic was that often the act of filling out the ASQ increased the parent’s observa-

tional skills for child development,” Hix-Small told *Psychiatric News*.

The authors estimated that the cost of incorporating the screening program, including distributing the ASQ to parents or caregivers upon check-in and collecting the forms at the clinic or by postage-paid mail, was only \$1.61 to \$2.43 per patient. Kevin Marks, M.D., one of the study authors and a physician at the medical practice group, noted that “the ASQ screening system was found to be feasible [and] low cost and did not impede office flow.”

*An abstract of “Impact of Implementing Developmental Screening at 12 and 24 Months in a Pediatric Practice” is posted at <<http://pediatrics.aappublications.org/cgi/content/abstract/120/2/381>>.* ■



# Great Reviews Follow 2007 Annual Meeting

Those who attended APA's annual meeting in San Diego last spring praised the high quality of its sessions, according to a report evaluating feedback from registrants.

BY EVE BENDER

The sessions held at the annual meeting in San Diego were well-received by attendees, according to data compiled from nearly 5,500 evaluation forms and described in a report issued by APA's Department of Continuing Medical Education.

About 90 percent of respondents rated the quality of the annual meeting sessions as "excellent," and about the same percentage reported that the sessions met their educational objectives.

Total attendance for the San Diego meeting reached 17,853, which is close in size to the 2005 meeting in Atlanta.

Excluding exhibitors, press, and staff, there were 14,584 registrants at the meeting, of whom 5,708 were APA members and 8,876 were nonmembers or guests.

The largest numbers of the APA members came from California (1,427) and New York (1,072).

Almost half of registrants (45 percent) were from outside the United States. Overall, 6,619 attendees came from other countries. Canada had the largest registration, with 812, followed by the Netherlands (527) and France (361).

More than 130 reporters from major media outlets traveled to San Diego to cover the meeting.

According to the report, 63 percent of the evaluation respondents attended a workshop during the meeting, and 92 percent of them reported the quality of the workshops they attended to be good or excellent. The vast majority of those who attended a medical update or advances-in-research session (92 percent) also reported that the sessions were excellent.

In addition, there was a great deal of praise for the lack of bias in the industry-supported symposia, according to the report of the evaluations. As part of a continuing effort to ensure that industry-supported symposia are free of bias, they have for several years been monitored by psychiatry residents. This year, an audience-response system was also used to evaluate the sessions.

Approximately 60 percent of evaluation respondents surveyed said their practices would be enhanced by the annual meeting sessions they attended, and 27 percent said the meeting sessions validated their current treatment practices.

Only 3 percent of respondents reported that they would change their practices as a result of their participation in the meeting. Among the changes they planned to make were using medications in different ways, changing prescription patterns for patients with bipolar disorder, watching for signs of

metabolic syndrome, and using alternative strategies in treating mental health problems more confidently.

Evaluation respondents' suggestions for future meetings included expanding the number of media sessions offered, bringing the Internet Village back to the meeting, and placing a daily log back into the annual meeting program book.

Respondents also asked that future meetings continue to address topics

such as psychiatric disorders in children and adolescents, the mental health of soldiers and their families, advances in treatment for bipolar disorder, and new treatments for schizophrenia, among others.

More than 81 percent of evaluation respondents (4,300) indicated that they plan to attend the 2008 APA meeting in Washington, D.C. That meeting will take place from May 3 to 8. ■

## Hammersley Praised for Contributions

BY KEN HAUSMAN

Donald Hammersley, M.D., who helped lead APA for 26 years, died at age 82 in Bethesda, Md., on July 16. He had congestive heart failure and diabetes. Hammersley was deputy medical director of APA from 1971 to 1988, and prior to that spent 10 years directing the Association's professional-services and professional-education projects. In these posts he had a major say in decisions affecting issues such as accreditation standards for a wide range of psychiatric facilities, the fight for better insurance coverage for mental illness treatment, especially its inclusion in the new Medicare program, and peer-review and quality-assurance criteria.

Hammersley was also the editor of the APA journal *Hospital and Community Psychiatry* (now *Psychiatric Services*) from 1970 through 1980.

Hammersley graduated from medical school at the University of Wisconsin and received his psychiatric training at the Menninger School of Psychiatry in Topeka, Kan., and had a long tenure as a member of its board of trustees.

Former APA President John Talbott, M.D., who succeeded Hammersley as editor of *Hospital and Community Psychiatry*, called him "one of the nicest, kindest, and most generous gentlemen I've ever encountered. Never wanting credit or the limelight, he was willing to help everyone, however he could, to help APA, American psychiatry, and the patients we serve." Talbott added that he is "especially grateful" for Hammersley's "heartfelt support of the care of patients who were severely and chronically mentally ill and of those working in public systems of care."

APA President Carolyn Robinowitz, M.D., who worked closely with Hammersley for many years when she headed APA's education division, called him "a marvelous advocate for our profession and our patients."

She noted that while he was a soft-spoken and modest man, he was "a highly effective problem solver who was especially skilled at seeing the covert and underlying issues, as well as getting diverse and disparate groups to put aside differences and work cooperatively." ■

## APA's 100% Club Picks Up Another Member Program

The psychiatry residency training program at Cedars-Sinai Medical Center (CSMC) is the latest residency program to have all of its psychiatry residents become members of APA. It is affiliated with the University of California at Los Angeles, School of Medicine.

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.

"The Cedars-Sinai Psychiatry Residency Program is committed to training

residents in the biopsychosocial model as contemporary psychiatrists and clinical leaders," said Waguih W. IsHak, M.D., the program director. "The training program values the five themes of intellectual curiosity, hard work, strong camaraderie, individual attention, and quality of life. There is a special focus on integrating psychopharmacology and psychotherapy skills in a multidisciplinary setting, with emphasis on cultural sensitivity and evidence-based psychiatry. CSMC residents also complete subspecialty rotations—child and adolescent, geriatric, addiction, and research psychiatry—during the second year of training to identify unique areas of interest and spark interest in future career possibilities. The residents then go on to regularly present on these special topics at APA's annual meetings. They are regularly awarded national fellowships and scholarships, which contribute significantly to their professional growth through exposure to nationally known mentors. The Cedars-Sinai clinical programs and training activities are complemented by expanding research activities in a unique setting: a large, nonprofit, tertiary-care community medical cen-



Front row, left to right: Sunita Garg, M.D., Amy Dewar, M.D., Monisha Vasa, M.D. (chief resident), Rekha Raja, D.O., Yvonne Neely (academic program coordinator). Middle row, left to right: Waguih W. IsHak, M.D. (program director), Carla Mandili, M.D., Elsa Lee, M.D., Lucy Sloninsky, M.D., Lina Augius, M.D., Tara Klein, M.D., Norana Caivano, M.D., Viet Bui, M.D. Top row, left to right: Mark Rapaport, M.D. (department chair), Maged Botros, M.D., Stephanie Stewart, M.D., Pantea Farhadi, M.D., Amir Ettelal, M.D., Eugene Lee, M.D., Nishant Kumar, D.O., Chris Willmer, M.D., Daniel Pimstone, M.D., Tony Knight, M.D.

ter with world-class clinical and research programs that address the needs of a very diverse patient population."

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. ■



## Conflicts of Interest

At our APA annual meeting in San Diego in May, I attended a symposium that continues to trouble me. It was unlike any other APA symposium I have attended over the past 40 years. Various speakers presented different kinds of evidence about the ways large pharmaceutical houses distort the results of clinical trials and mislead psychiatrists about the relative merits of their products. One shocked clinician finally asked the question that I imagined was on everyone's mind—I paraphrase her words, "How am I to sort my way through all this misinformation so I can do what is best for my patients?" One of the speakers suggested that she subscribe to his independent newsletter. But the reality is that most ordinary practitioners continue to be awash in misinformation.

Perhaps the most troubling moment for me came when the discussant for the symposium, one of the most distinguished psychiatrists in the world, put the various presentations in perspective. What it boiled down to was that huge sums of money are at stake, it is a high-risk industry, and the pharmaceutical companies are not entirely evil. Most experts who know anything and whose opinions are worth having will be retained by drug companies, so the legalistic approach of focusing on conflicts of interest will eliminate only

the knowledgeable experts from decision-making panels.

All this I had heard before, but then he confirmed a shocking and fraudulent practice of misinformation that one of the presenters had described. Drug companies control their own clinical research, have it written up by science-writing firms created for that purpose, and then shop it around to find an academic with the right credentials to be the first author. The academic's resume grows, the career prospers, more captive experts are created, and the drug company plants more misinformation in our journals.

Other psychiatrists at the symposium seemed well aware of this fraudulent collaboration; I was not. But when the symposium discussant acknowledged that he had

himself been asked to participate in this kind of obvious deception, I was compelled to believe it exists. The discussant then said, "We all know who is doing it, and the solution is to shame them." I am not one of the "we" who knows who the academics are who have done this or who are doing it, but surely it is an offense equal to plagiarism.

Unfortunately the discussant did not identify any of the offenders who have done or are doing this, so to my knowledge the shaming did not begin at that May symposium in San Diego. I would therefore like to remind the "we who all know" that section 2 of APA's principles of ethics require us to "strive to report physicians. . . engaging in fraud or deception to appropriate entities." Someone once said about the medi-

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cal profession that medical etiquette is more important than medical ethics. Unless the shaming begins, that damning judgment will once again be proven correct.

ALAN STONE, M.D.  
Cambridge, Mass.

## clinical & research news

### PMDD

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receptor, was found to distinguish women with PMDD from women without it (*Psychiatric News*, August 17). If PMDD is indeed due to an elevated level of progesterone exciting the amygdala, then how does this gene variant fit into the picture? Van Wingen told *Psychiatric News* that he didn't know, but added, "Our results indicate that progesterone modulates the interactions between the amygdala and prefrontal cortex." Thus, it's possible, he speculated, that PMDD could be due to a surge in progesterone exciting the amygdala and then to the prefrontal cortex not being able to halt the excitement due to altered estrogen sensitivity.

Although PMDD is not officially recognized as a mental disorder in *DSM*, it is listed in the *DSM-IV-TR* appendix as a condition worthy of further study. The U.S. Food and Drug Administration has approved four medications to treat the condition—the antidepressants fluoxetine (marketed as Sarafem), sertraline (Zoloft), and paroxetine controlled-release (Paxil CR), and the oral contraceptive drospirenone and ethinyl estradiol combination (Yaz).

The study was funded by the Radboud University Nijmegen Medical Center, the European Union, and the Swedish Research Council.

An abstract of "Progesterone Selectively Increases Amygdala Reactivity in Women" is posted at [www.nature.com/mp/journal/vaop/ncurrent/abs/4002030a.html](http://www.nature.com/mp/journal/vaop/ncurrent/abs/4002030a.html). ■

**NONSCHEDULED ROZEREM—  
ZERO  
EVIDENCE OF ABUSE OR DEPENDENCE**

\*Rozerem™ (ramelteon) is indicated for the treatment of insomnia characterized by difficulty with sleep onset. Rozerem can be prescribed for long-term use.

**Important safety information**

Rozerem should not be used in patients with hypersensitivity to any components of the formulation, severe hepatic impairment, or in combination with fluvoxamine. Failure of insomnia to remit after a reasonable period of time should be medically evaluated, as this may be the result of an unrecognized underlying medical disorder. Hypnotics should be administered with caution to patients exhibiting signs and symptoms of depression. Rozerem has not been studied in patients with severe sleep apnea, severe COPD, or in children or adolescents. The effects in these populations are unknown. Avoid taking Rozerem with alcohol. Rozerem has been associated with decreased testosterone levels and increased prolactin levels. Health professionals should be mindful of any unexplained symptoms possibly associated with such changes in these hormone levels. Rozerem should not be taken with or immediately after a high-fat meal. Rozerem should be taken within 30 minutes before going to bed and activities confined to preparing for bed. The most common adverse events seen with Rozerem that had at least a 2% incidence difference from placebo were somnolence, dizziness, and fatigue.

Please see adjacent Brief Summary of Prescribing Information.



## Soldiers

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another 14 percent with failed, nonspousal relationships.

"Based on past research, relationship problems and personal resilience are primary causes of a range of dysfunctions, from [being] AWOL, through family problems, to suicide," said military sociologist David Segal, Ph.D., a professor at the University of Maryland. Deployment plays a role, but not a primary one.

"Resilient people in strong relationships are likely to weather repeated deployments well, particularly if they are members of the active forces," Segal told *Psychiatric News*. "By contrast, soldiers low in resilience, who are in troubled relationships,

are more likely to be affected negatively by the stress of deployment, or any stress."

Several veterans' organizations have protested that the report's conclusions place too much blame on spouses and relationships while ignoring the family strains induced by 12- to 15-month separations.

"Longer, repeated tours are increasing the risks," wrote Iraq and Afghanistan Veterans of America executive director Paul Rieckhoff on the Military.com Web site. "Our troops are facing serious mental health problems, and they aren't getting the treatment they need."

Ragan agreed. "Saying that suicide doesn't reflect the effects of multiple deployments stretches the bounds of credulity," he said. He also noted that while numbers were small, the rate of completed suicide among

women (n=10) in the Army was twice that of U.S. women aged 17 to 45.

The Army also used a general suicide rate for the United States as a comparator, but there is considerable geographic variation, possibly reflecting the difficulty of accessing care in rural areas, said Ragan.

"Nevertheless, by the Army's own criteria, this is a significant elevation of suicide," he said.

Deployment can create strains on relationships in many ways, especially among the youngest soldiers, who have had the briefest married lives, said Ragan: "You have an emotional connectedness with your wife. You're close beforehand, then you both learn to live apart, and then when you return, the distance has to be dealt with."

The longer-term implications of the 2006 suicide figures will depend on whether they represent a trend or an exception.

"Regarding the possible rise in suicides, one would want at least five years of data to examine time trends," said McFarland, co-author of a recent study on suicide among male veterans.

Finally, sociologist Segal argued for caution in tracing the roots of military suicides.

"It is such a rare event that it is difficult to pin down its antecedents statistically," he said.

*The U.S. Army Suicide Event Report is posted at <[www.iava.org/documents/ASER%202006%20Report.pdf](http://www.iava.org/documents/ASER%202006%20Report.pdf)>. Army suicide-prevention resources are posted at <<http://chppm-www.apgea.army.mil/dhbw/Readiness/suicide.aspx>>. ■*

# You can prescribe Rozerem for as long as you need to\*

Clinical studies show no evidence of potential abuse, dependence, or withdrawal†

- **First and only**—nonscheduled prescription insomnia medication... not a controlled substance and can be prescribed for long-term use¹
- **First and only**—prescription insomnia medication that targets the normal sleep-wake cycle¹
- **First and only**—prescription insomnia medication with no evidence of abuse potential in clinical studies¹
- **First and only**—prescription insomnia medication that does not promote sleep by CNS depression¹
- **One simple 8-mg dose¹**

†Rozerem is not a controlled substance. A clinical abuse liability study showed no differences indicative of abuse potential between Rozerem and placebo at doses up to 20 times the recommended dose (N=14). Three 35-day insomnia studies showed no evidence of rebound insomnia or withdrawal symptoms with Rozerem compared to placebo (N=2082).¹,²

Please visit [www.rozerem.com](http://www.rozerem.com)

**Rozerem™**  
ramelteon 8-mg tablets

*Proven for sleep.  
Nonscheduled for added safety.*



Massachusetts

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increased access to psychiatric care in particular is less certain. Gene Fierman, M.D., president of the Massachusetts Psychiatric Society (MPS), said his members “have guarded hopefulness” that the plan will open access to care but also see early signs of trouble.

Although more state residents will have coverage for psychiatric care, their access will be limited by a documented shortage of psychiatrists. This situation was detailed in the Massachusetts Medical Society’s “2007 Physician Workforce Study,” which identified physician shortages in primary care, psychiatry, and other areas of medicine.

“We will create more demand for services [with the new law], and my question is how is that demand going to be met,” Fierman said, in an interview.

The new plan also fails to address policies by insurance companies that tightly restrict payments to psychiatrists in general and child psychiatrists in particular, which force many people with insurance coverage to seek care outside of their insurance network. The MPS has had discussions with insurance companies on the low reimbursements and the extensive paperwork psychiatrists are required to fill out, Fierman said, but little progress on improving the situation has been made.

The impact on public clinics of the plan’s MassHealth expansion also remains unclear. The public mental health clinics

now employ few psychiatrists after money-saving initiatives “de-professionalized” them from a model in which leadership was provided largely by psychiatrists to one generally organized around counselors.

Specific approaches that the low-cost health insurance plans require from each insurance company also remain a question. One plan, for example, opted to provide access to a large number of specialists but tightly restrict the number of primary care physicians from which its beneficiaries can seek care.

“Everyone is very hopeful that this state plan will open up access to mental health care, but given problems already facing psychiatrists, one wonders how this increasing demand will be met,” Fierman said.

Mental health advocates achieved some of their primary goals by having the new law adhere to Massachusetts’s existing mental health parity law, Fisher said. Another achievement was the broad access it granted to psychiatric medications.

Brian Rosman, director of research at Health Care for All, a patient-advocacy group, said the next push related to maximizing the mental health benefit will come during a September meeting by a Massachusetts policy committee in which there will be a discussion of whether to add medications without generic alternatives to the no-deductible list. State regulators had interpreted the law to require that low-cost insurance plans could not charge a deductible for generic medications but could charge for name-brand medications.

“That has a big impact on people with mental illness, who often need these drugs,” Rosman said.

Further proposed legislative changes to the plan will include the MPS-backed push for full parity coverage for all mental illness and substance abuse care in Massachusetts.

“Substance abuse is a very big concern, and for now we continue to insufficiently cover it,” Balser said.

*A description of the coverage in the Massachusetts health plan is posted at <www.kff.org/uninsured/upload/7494-02.pdf>. The bill to expand Massachusetts parity legislation is posted at <www.mass.gov/legis/bills/house/185/bt01pdf/bt01871.pdf>. ■*

Courts

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Cost,” found that participation in the jail-diversion program resulted in an increased use of mental health services and a decrease in jail time during the first year after entry into the program. Higher mental health care costs were almost balanced by the reduced costs for keeping the individual locked up. A two-year follow-up found a “dramatic” reduction in jail costs, although most of that came at the end of the second year, as mental health care costs leveled off.

Steadman agreed with McNeil and Binder that more intensive research is needed to support the case for mental health courts.

“All case studies show promising results,” he said. “Now we need to use the same research methods in many different courts and look at for whom mental health courts work. What are their demographics, their social history, and their clinical history?”

*“Effectiveness of a Mental Health Court in Reducing Criminal Recidivism and Violence” is posted at: <http://ajp.psychiatryonline.org/cgi/content/full/164/9/1395>. “Factors in Disproportionate Representation Among Persons Recommended by Programs and Accepted by Courts for Jail Diversion” is posted at <http://ps.psychiatryonline.org/cgi/content/full/58/8/1095>.*

*The RAND report, “Justice, Treatment, and Cost,” is posted at: <www.rand.org/pubs/technical\_reports/TR439>. ■*



Brief Summary of Prescribing Information

ROZEREM™ (ramelteon) Tablets

INDICATIONS AND USAGE

ROZEREM is indicated for the treatment of insomnia characterized by difficulty with sleep onset.

CONTRAINDICATIONS

ROZEREM is contraindicated in patients with a hypersensitivity to ramelteon or any components of the ROZEREM formulation.

WARNINGS

Since 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 a reasonable period 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 cognitive or behavioral abnormalities, may be the result of an unrecognized underlying psychiatric or physical disorder and requires further evaluation of the patient. As with other hypnotics, exacerbation of insomnia and emergence of cognitive and behavioral abnormalities were seen with ROZEREM during the clinical development program.

ROZEREM should not be used by patients with severe hepatic impairment.

ROZEREM should not be used in combination with fluvoxamine (see PRECAUTIONS: Drug Interactions).

A variety of cognitive and behavior changes have been reported to occur in association with the use of hypnotics. In primarily depressed patients, worsening of depression, including suicidal ideation, has been reported in association with the use of hypnotics.

Patients should avoid engaging in hazardous activities that require concentration (such as operating a motor vehicle or heavy machinery) after taking ROZEREM.

After taking ROZEREM, patients should confine their activities to those necessary to prepare for bed.

PRECAUTIONS

General

ROZEREM has not been studied in subjects with severe sleep apnea or severe COPD and is not recommended for use in those populations.

Patients should be advised to exercise caution if they consume alcohol in combination with ROZEREM.

Use in Adolescents and Children

ROZEREM has been associated with an effect on reproductive hormones in adults, e.g., decreased testosterone levels and increased prolactin levels. It is not known what effect chronic or even chronic intermittent use of ROZEREM may have on the reproductive axis in developing humans (see Pediatric Use).

Information for Patients

Patients should be advised to take ROZEREM within 30 minutes prior to going to bed and should confine their activities to those necessary to prepare for bed.

Patients should be advised to avoid engaging in hazardous activities (such as operating a motor vehicle or heavy machinery) after taking ROZEREM. Patients should be advised that they should not take ROZEREM with or immediately after a high-fat meal.

Patients should be advised to consult their health care provider if they experience worsening of insomnia or any new behavioral signs or symptoms of concern.

Patients should consult their health care provider if they experience one of the following: cessation of menses or galactorrhea in females, decreased libido, or problems with fertility.

Laboratory Tests

No standard monitoring is required.

For patients presenting with unexplained amenorrhea, galactorrhea, decreased libido, or problems with fertility, assessment of prolactin levels and testosterone levels should be considered as appropriate.

Drug Interactions

ROZEREM has a highly variable intersubject pharmacokinetic profile (approximately 100% coefficient of variation in C<sub>max</sub> and AUC). As noted above, CYP1A2 is the major isozyme involved in the metabolism of ROZEREM; the CYP2C2 subfamily and CYP3A4 isozymes are also involved to a minor degree.

**Effects of Other Drugs on ROZEREM Metabolism**  
**Fluvoxamine (strong CYP1A2 inhibitor):** When fluvoxamine 100 mg twice daily was administered for 3 days prior to single-dose co-administration of ROZEREM 16 mg and fluvoxamine, the AUC<sub>0-∞</sub> for ramelteon increased approximately 130-fold, and the C<sub>max</sub> increased approximately 70-fold, compared to ROZEREM administered alone. ROZEREM should not be used in combination with fluvoxamine (see WARNINGS). Other less potent CYP1A2 inhibitors have not been adequately studied. ROZEREM should be administered with caution to patients taking less strong CYP1A2 inhibitors.

**Rifampin (strong CYP enzyme inducer):** Administration of rifampin 600 mg once daily for 11 days resulted in a mean decrease of approximately 80% (40% to 90%) in total exposure to ramelteon and metabolite M-II, (both AUC<sub>0-∞</sub> and C<sub>max</sub>) after a single 32 mg dose of ROZEREM. Efficacy may be reduced when ROZEREM is used in combination with strong CYP enzyme inducers such as rifampin.

**Ketoconazole (strong CYP3A4 inhibitor):** The AUC<sub>0-∞</sub> and C<sub>max</sub> of ramelteon increased by approximately 84% and 36%, respectively, when a single 16 mg dose of ROZEREM was administered on the fourth day of ketoconazole 200 mg twice daily administration, compared to administration of ROZEREM alone. Similar increases were seen in M-II pharmacokinetic variables. ROZEREM should be administered with caution in subjects taking strong CYP3A4 inhibitors such as ketoconazole.

**Fluconazole (strong CYP2C9 inhibitor):** The total and peak systemic exposure (AUC<sub>0-∞</sub> and C<sub>max</sub>) of ramelteon after a single 16 mg dose of ROZEREM was increased by approximately 150% when administered with fluconazole. Similar increases were also seen in M-II exposure. ROZEREM should be administered with caution in subjects taking strong CYP2C9 inhibitors such as fluconazole.

Interaction studies of concomitant administration of ROZEREM with fluoxetine (CYP2D6 inhibitor), omeprazole (CYP1A2 inducer/CYP2C19 inhibitor), theophylline (CYP1A2 substrate), and dextromethorphan (CYP2D6 substrate) did not produce clinically meaningful changes in either peak or total exposures to ramelteon or the M-II metabolite.

**Effects of ROZEREM on Metabolism of Other Drugs**  
Concomitant administration of ROZEREM with omeprazole (CYP2C19 substrate), dextromethorphan (CYP2D6 substrate), midazolam (CYP3A4 substrate), theophylline (CYP1A2 substrate), digoxin (p-glycoprotein substrate), and warfarin (CYP2C9 [S]/CYP1A2 [R] substrate) did not produce clinically meaningful changes in peak and total exposures to these drugs.

Effect of Alcohol on Rozerem

**Alcohol:** With single-dose, daytime co-administration of ROZEREM 32 mg and alcohol (0.6 g/kg), there were no clinically meaningful or statistically significant effects on peak or total exposure to ROZEREM. However, an additive effect was seen on some measures of psychomotor performance (i.e., the Digit Symbol Substitution Test, the Psychomotor Vigilance Task Test, and a Visual Analog Scale of Sedation) at some post-dose time points. No additive effect was seen on the Delayed Word Recognition Test. Because alcohol by itself impairs performance, and the intended effect of ROZEREM is to promote sleep, patients should be cautioned not to consume alcohol when using ROZEREM.

Drug/Laboratory Test Interactions

ROZEREM is not known to interfere with commonly used clinical laboratory tests. In addition, *in vitro* data indicate that ramelteon does not cause false-positive results for benzodiazepines, opiates, barbiturates, cocaine, cannabinoids, or amphetamines in two standard urine drug screening methods *in vitro*.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Carcinogenesis

In a two-year carcinogenicity study, B6C3F<sub>1</sub> mice were administered ramelteon at doses of 0, 30, 100, 300, or 1000 mg/kg/day by oral gavage. Male mice exhibited a dose-related increase in the incidence of hepatic tumors at dose levels ≥ 100 mg/kg/day including hepatic adenoma, hepatic carcinoma, and hepatoblastoma. Female mice developed a dose-related increase in the incidence of hepatic adenomas at dose levels ≥ 300 mg/kg/day and hepatic carcinoma at the 1000 mg/kg/day dose level. The no-effect level for hepatic tumors in male mice was 30 mg/kg/day (103-times and 3-times the therapeutic exposure to ramelteon and the active metabolite M-II, respectively, at the maximum recommended human dose [MRHD] based on an area under the concentration-time curve [AUC] comparison). The no-effect level for hepatic tumors in female mice was 100 mg/kg/day (827-times and 12-times the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC).

In a two-year carcinogenicity study conducted in the Sprague-Dawley rat, male and female rats were administered ramelteon at doses of 0, 15, 60, 250 or 1000 mg/kg/day by oral gavage. Male rats exhibited a dose-related increase in the incidence of hepatic adenoma and benign Leydig cell tumors of the testis at dose levels ≥ 250 mg/kg/day and hepatic carcinoma at the 1000 mg/kg/day dose level. Female rats exhibited a dose-related increase in the incidence of hepatic adenoma at dose levels ≥ 60 mg/kg/day and hepatic carcinoma at the 1000 mg/kg/day dose level. The no-effect level for hepatic tumors and benign Leydig cell tumors in male rats was 60 mg/kg/day (1,429-times and 12-times the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC). The no-effect level for hepatic tumors in female rats was 15 mg/kg/day (472-times and 16-times the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC).

The development of hepatic tumors in rodents following chronic treatment with non-genotoxic compounds may be secondary to microsomal enzyme induction, a mechanism for tumor generation not thought to occur in humans. Leydig cell tumor development following treatment with non-genotoxic compounds in rodents has been linked to reductions in circulating testosterone levels with compensatory increases in luteinizing hormone release, which is a known proliferative stimulus to Leydig cells in the rat testis. Rat Leydig cells are more sensitive to the stimulatory effects of luteinizing hormone than human Leydig cells. In mechanistic studies conducted in the rat, daily ramelteon administration at 250 and 1000 mg/kg/day for 4 weeks was associated with a reduction in plasma testosterone levels, in the same study, luteinizing hormone levels were elevated over a 24-hour period after the last ramelteon treatment; however, the durability of this luteinizing hormone finding and its support for the proposed mechanistic explanation was not clearly established.

Although the rodent tumors observed following ramelteon treatment occurred at plasma levels of ramelteon and M-II in excess of mean clinical plasma concentrations at the MRHD, the relevance of both rodent hepatic tumors and benign rat Leydig cell tumors to humans is not known.

Mutagenesis

Ramelteon was not genotoxic in the following: *in vitro* bacterial reverse mutation (Ames) assay; *in vitro* mammalian cell gene mutation assay using the mouse lymphoma TK<sup>+</sup> cell line; *in vivo/in vitro* unscheduled DNA synthesis assay in rat hepatocytes; and *in vivo* micronucleus assays conducted in mouse and rat. Ramelteon was positive in the chromosomal aberration assay in Chinese hamster lung cells in the presence of S9 metabolic activation.

Separate studies indicated that the concentration of the M-II metabolite formed by the rat liver S9 fraction used in the *in vitro* genetic toxicology studies described above, exceeded the concentration of ramelteon; therefore, the genotoxic potential of the M-II metabolite was also assessed in these studies.

Impairment of Fertility

Ramelteon was administered to male and female Sprague-Dawley rats in an initial fertility and early embryonic development study at dose levels of 6, 60, or 600 mg/kg/day. No effects on male or female mating or fertility were observed with a ramelteon dose up to 600 mg/kg/day (786-times higher than the MRHD on a mg/m<sup>2</sup> basis). Irregular estrus cycles, reduction in the number of implants, and reduction in the number of live embryos were noted with dosing females at ≥ 60 mg/kg/day (79-times higher than the MRHD on a mg/m<sup>2</sup> basis). A reduction in the number of corpora lutea occurred at the 600 mg/kg/day dose level. Administration of ramelteon up to 600 mg/kg/day to male rats for 7 weeks had no effect on sperm quality and when the treated male rats were mated with untreated female rats there was no effect on implants or embryos. In a repeat of this study using oral administration of ramelteon at 20, 60 or 200 mg/kg/day for the same study duration, females demonstrated irregular estrus cycles with doses ≥ 60 mg/kg/day, but no effects were seen on implantation or embryo viability. The no-effect dose for fertility endpoints was 20 mg/kg/day in females (26-times the MRHD on a mg/m<sup>2</sup> basis) and 600 mg/kg/day in males (786-times higher than the MRHD on a mg/m<sup>2</sup> basis) when considering all studies.

Pregnancy: Pregnancy Category C

Ramelteon has been shown to be a developmental teratogen in the rat when given in doses 197 times higher than the maximum recommended human dose [MRHD] on a mg/m<sup>2</sup> basis. There are no adequate and well-controlled studies in pregnant women. Ramelteon should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

The effects of ramelteon on embryo-fetal development were assessed in both the rat and rabbit. Pregnant rats were administered ramelteon by oral gavage at doses of 0, 10, 40, 150, or 600 mg/kg/day during gestation days 6-17, which is the period of organogenesis in this species. Evidence of maternal toxicity and fetal teratogenicity was observed at doses greater than or equal to 150 mg/kg/day. Maternal toxicity was chiefly characterized by decreased body weight and, at 600 mg/kg/day, ataxia and decreased spontaneous movement. At maternally toxic doses (150 mg/kg/day or greater), the fetuses demonstrated visceral malformations consisting of diaphragmatic hernia and minor anatomical variations of the skeleton (irregularly shaped scapula). At 600 mg/kg/day, reductions in fetal body weights and malformations including cysts on the external genitalia were additionally observed. The no-effect level for teratogenicity in this study was 40 mg/kg/day (1,892-times and 45-times higher than the therapeutic exposure to ramelteon and the active metabolite M-II, respectively, at the MRHD based on an area under the concentration-time curve [AUC] comparison). Pregnant rabbits were administered ramelteon by oral gavage at doses of 0, 12, 60, or 300 mg/kg/day during gestation days 6-18, which is the period of organogenesis in this species. Although maternal toxicity was apparent with a ramelteon dose of 300 mg/kg/day, no evidence of fetal effects or teratogenicity was associated with any dose level. The no-effect level for teratogenicity was, therefore, 300 mg/kg/day (11,862-times and 99-times higher than the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC).

The effects of ramelteon on pre- and post-natal development in the rat were

studied by administration of ramelteon to the pregnant rat by oral gavage at doses of 0, 30, 100, or 300 mg/kg/day from day 6 of gestation through parturition to postnatal (lactation) day 21, at which time offspring were weaned. Maternal toxicity was noted at doses of 100 mg/kg/day or greater and consisted of reduced body weight gain and increased adrenal gland weight. Reduced body weight during the post-weaning period was also noticed in the offspring of the groups given 100 mg/kg/day and higher. Offspring in the 300 mg/kg/day group demonstrated physical and developmental delays including delayed eruption of the lower incisors, a delayed acquisition of the righting reflex, and an alteration of emotional response. These delays are often observed in the presence of reduced offspring body weight but may still be indicative of developmental delay. An apparent decrease in the viability of offspring in the 300 mg/kg/day group was likely due to altered maternal behavior and function observed at this dose level. Offspring of the 300 mg/kg/day group also showed evidence of diaphragmatic hernia, a finding observed in the embryo-fetal development study previously described. There were no effects on the reproductive capacity of offspring and the resulting progeny were not different from those of vehicle-treated offspring. The no-effect level for pre- and post-natal development in this study was 30 mg/kg/day (39-times higher than the MRHD on a mg/m<sup>2</sup> basis).

Labor and Delivery

The potential effects of ROZEREM on the duration of labor and/or delivery, for either the mother or the fetus, have not been studied. ROZEREM has no established use in labor and delivery.

Nursing Mothers

Ramelteon is secreted into the milk of lactating rats. It is not known whether this drug is excreted in human milk. No clinical studies in nursing mothers have been performed. The use of ROZEREM in nursing mothers is not recommended.

Pediatric Use

Safety and effectiveness of ROZEREM in pediatric patients have not been established. Further study is needed prior to determining that this product may be used safely in pre-pubescent and pubescent patients.

Geriatric Use

A total of 654 subjects in double-blind, placebo-controlled, efficacy trials who received ROZEREM were at least 65 years of age; of these, 199 were 75 years of age or older. No overall differences in safety or efficacy were observed between elderly and younger adult subjects.

ADVERSE REACTIONS

Overview

The data described in this section reflect exposure to ROZEREM in 4251 subjects, including 346 exposed for 6 months or longer, and 473 subjects for one year.

Adverse Reactions Resulting in Discontinuation of Treatment

Six percent of the 3594 individual subjects exposed to ROZEREM in clinical studies discontinued treatment owing to an adverse event, compared with 2% of the 1370 subjects receiving placebo. The most frequent adverse events leading to discontinuation in subjects receiving ROZEREM were somnolence (0.8%), dizziness (0.5%), nausea (0.3%), fatigue (0.3%), headache (0.3%), and insomnia (0.3%).

**ROZEREM Most Commonly Observed Adverse Events in Phase 1-3 trials**  
The incidence of adverse events during the Phase 1 through 3 trials (% placebo, n=1370; % ramelteon [8 mg], n=1250) were: headache NOS (7%, 7%), somnolence (3%, 5%), fatigue (2%, 4%), dizziness (3%, 5%), nausea (2%, 3%), insomnia exacerbated (2%, 3%), upper respiratory tract infection NOS (2%, 3%), diarrhea NOS (2%, 2%), myalgia (1%, 2%), depression (1%, 2%), dysgeusia (1%, 2%), arthralgia (1%, 2%), influenza (0, 1%), blood cortisol decreased (0, 1%).

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of other drugs, and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

DRUG ABUSE AND DEPENDENCE

ROZEREM is not a controlled substance.

**Human Data:** See the CLINICAL TRIALS section, Studies Pertinent to Safety Concerns for Sleep-Promoting Agents, in the Complete Prescribing Information.

**Animal Data:** Ramelteon did not produce any signals from animal behavioral studies indicating that the drug produces rewarding effects. Monkeys did not self-administer ramelteon and the drug did not induce a conditioned place preference in rats. There was no generalization between ramelteon and midazolam. Ramelteon did not affect rotarod performance, an indicator of disruption of motor function, and it did not potentiate the ability of diazepam to interfere with rotarod performance.

Discontinuation of ramelteon in animals or in humans after chronic administration did not produce withdrawal signs. Ramelteon does not appear to produce physical dependence.

OVERDOSAGE

Signs and Symptoms

No cases of ROZEREM overdose have been reported during clinical development.

ROZEREM was administered in single doses up to 160 mg in an abuse liability trial. No safety or tolerability concerns were seen.

Recommended Treatment

General symptomatic and supportive measures should be used, along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. As in all cases of drug overdose, respiration, pulse, blood pressure, and other appropriate vital signs should be monitored, and general supportive measures employed.

Hemodialysis does not effectively reduce exposure to ROZEREM. Therefore, the use of dialysis in the treatment of overdosage is not appropriate.

Poison Control Center

As with the management of all overdosage, the possibility of multiple drug ingestion should be considered. The physician may contact a poison control center for current information on the management of overdosage.

Rx only

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05-11224 Revised: Apr., 2006

L-RAM-00029

References: 1. Rozerem package insert, Takeda Pharmaceuticals America, Inc. 2. Johnson MW, Suess PE, Griffiths RR. Ramelteon: a novel hypnotic lacking abuse liability and sedative adverse effects. Arch Gen Psychiatry. 2006;63:1149-1157.



number of uninsured Americans rose 2.2 million in 2006 to 47 million. The Current Population Survey found that 15.8 percent of Americans lacked coverage last year, up from 15.3 percent in 2005. The increase equaled 1998 as the year with the highest percentage of uninsured people over the last two decades.

The impact on children was troublesome as well, according to data from the U.S. Census Bureau, which found that 11.7 percent of U.S. citizens under age 18 had no health insurance in 2006, up from 10.9 percent in the previous year. The percentage of uninsured children has increased two years in a row after declining for at least five years, according to the census data.

“It is unconscionable that the number of uninsured children has substantially increased over the past year,” said AMA Board member Joseph Heyman, M.D., in a written statement. “Children are our future, and for kids to get a good start in

life, they need access to regular visits to the doctor.”

The AMA’s insurance campaign supports tax credits for the purchase of health insurance and for increasing federal funds to expand government health programs such as the State Children’s Health Insurance Program (SCHIP) and Medicaid. Both houses of Congress have passed SCHIP expansions but President Bush has threatened to veto both versions because of their cost (*Psychiatric News*, September 7).

The AMA insurance proposal was created with several other groups as part of an alliance called the Health Coverage Coalition for the Uninsured, which includes AARP and the U.S. Chamber of Commerce.

However, AMA leaders said the 250,000-member organization could support other approaches.

“If [elected officials] don’t like our plan, then let’s meet and come up with a common plan,” said Nancy Nielsen, M.D., AMA president-elect, during an August press conference.

These adverse effects in adult patients were similarly observed in pediatric studies. Weight gain linked to risperidone was reported in 14 percent of 103 patients who participated in the long-term, open-label extension of one of the schizophrenia studies assessed by the FDA. The average weight increase was 9.0 kg (19.8 lb) after eight months. In the three-week clinical trial of children with bipolar I disorder, a significantly higher weight gain was seen in the risperidone group than in the placebo group.

Another notable adverse effect seen in pediatric as well as adult patients taking atypical antipsychotics is elevated prolactin levels, which were as frequent as 87 percent in these pediatric trials. Milk production and enlarged breasts have also been reported.

The recommended risperidone dosage for adolescents with schizophrenia is initially 0.5 mg daily, titrated upward by 0.5 to 1 mg daily depending on tolerability, up to a maximum of 3 mg daily. For the treatment of bipolar mania in pediatric patients, risperidone should be initiated at 0.5 mg once daily and titrated upward by 0.5 to 1 mg daily as tolerated, to a target dose of 2.5 mg daily.

Thomas Laughren, M.D., director of the FDA’s Division of Psychiatry Products, and Dianne Murphy, M.D., director of its office of Pediatric Therapeutics, both emphasized at the press conference that the dose and response data obtained from these studies provide important insight for practitioners when they treat younger patients. A key finding “is that there didn’t seem to be any higher efficacy from the higher doses compared to the lower doses,” said Laughren. “We see this as a major benefit coming out of the pediatric program, which is a better understanding of dose response.”

Laughren acknowledged that the agency’s requests for pediatric studies had been issued for other antipsychotics and that studies of those drugs are underway or under review.

**The updated prescribing information for risperidone is posted at <[www.risperdal.com/risperdal/shared/pi/risperdal.pdf](http://www.risperdal.com/risperdal/shared/pi/risperdal.pdf)>. ■**

Nielsen said part of the campaign aims to educate the public and political candidates that people without insurance are not just among the ranks of those who are homeless or unemployed. As many as 82 percent of people without health insurance are in working families.

The AMA doesn’t endorse candidates for president but is urging presidential hopefuls to incorporate its proposals into their health care platforms.

“We want candidates to make a commitment to reducing the number of uninsured,” Nielsen said.

Although APA has not endorsed the AMA plan specifically, APA President Carolyn Robinowitz, M.D., said that the Association does support any effort that will increase Americans’ access to health

care, including treatment for mental illness. Many uninsured Americans end up using emergency rooms as their main source of medical care, Robinowitz told *Psychiatric News*, which means they are unlikely to receive preventive care and early interventions that avoid further suffering and save money that will have to be spent on acute care.

“Even the business community has realized the long-term benefits from wide access to quality health care,” Robinowitz said, citing business groups’ recent support for Senate mental health parity legislation that their earlier opposition had stalled.

**More information on the AMA’s “Voice for the Uninsured” campaign is posted at <[www.ama-assn.org/ama/pub/category/17712.html](http://www.ama-assn.org/ama/pub/category/17712.html)>. ■**

## community news

## Bullying

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With the mentorship of Charlotte Richmond, Ph.D., Darren’s mother, and Joseph Pergolizzi Jr., M.D., Fabianna’s father, the younger Richmond and Pergolizzi compiled their findings into an abstract and poster format and submitted them to APA for presentation at the 2007 annual meeting in San Diego. At the meeting, they became the youngest presenters in APA annual meeting history.

Duolao Wang, Ph.D., a statistician from the University of London, performed the data analysis for the project, and Everly Macario, Sc.D., facilitated teleconferences between the students and assisted them with editing the poster abstract and writing a manuscript for journal submission.

The students dedicated their poster to Jeffrey Johnston, a Florida middle-school student who was a victim of cyberbullying. Johnston committed suicide in June 2005.

During the process of creating the poster, HB 575, the Jeffrey Johnston Stand Up for All Students Act, also known as the “Anti-Bullying Bill” passed in the Florida House in April of this year. The bill prohibits bullying and harassment of any student or employee at a public school and requires school districts to adopt policies prohibiting bullying and harassment,

Pergolizzi said she plans to participate in the effort to pass the bill by submitting data from Project Anti-Bully to legislators.

In order to raise awareness in schools, Pergolizzi and Richmond also presented the findings to their teachers and classmates. After Richmond presented the survey results to those in his middle school, the school established “peace ambassadors”—student volunteers who welcome new students and assist classmates who are bullying victims.

The school also staged assemblies with dramatic performances in which bullying was a theme, and in their classes students were encouraged to write and create art about bullying.

At the middle school surveyed in Chapel Hill, anti-bullying posters appear in classrooms, and teachers now discuss bullying with students in health class.

Pergolizzi noted that she and her colleagues conducted the survey again during the 2006-07 school year and are analyzing the results.

“We hope that with this project, we have taken the first step toward putting an end to bullying,” Pergolizzi said. With Project Anti-Bully, “we hope to encourage teachers and parents to talk to students about bullying and let them know they are not alone.”

**More information about Project Anti-Bully is posted at <[www.projectbully.com](http://www.projectbully.com)>. ■**

## clinical & research news

## Pregnancy

continued from page 17

More predictably, however, treatment with antidepressants during pregnancy was lower than it was prior to pregnancy (77 percent) or after pregnancy (81.5 percent).

APA president-elect Nada Stotland, M.D., who reviewed the study, said it underscores the need for clinicians to keep up with the ever-changing literature on the treatment of depression during pregnancy. She noted that APA and the American College of Obstetricians and Gynecologists will soon release a brief summary of the literature along with an outline for making treatment decisions.

“Clinicians need to remember that childbearing age encompasses a wide range of ages, and women in all kinds of life situations can become pregnant,” Stotland said. “Most pregnancies are not planned. Many women are on antidepressants. Not uncommonly, women discover that they are pregnant only after having taken medication for the first, crucial weeks and months of pregnancy.

“Therefore the possibility of pregnancy should be taken into account whenever postpubertal and premenopausal women are treated for depression. That does not mean that medication should be withheld; it means that clinicians should discuss the possibility of and implications of pregnancy when discussing treatment options.”

**“Clinically Identified Maternal Depression Before, During, and After Pregnancies Ending in Live Birth” will be posted online at <[ajp.psychiatryonline.org](http://ajp.psychiatryonline.org)> under the October issue. ■**

## Risperidone

continued from page 1

to better efficacy, but increased the number of adverse events.

A third study, this one lasting three weeks, was conducted in 169 children with bipolar I disorder aged 10 to 17 who were experiencing a manic or mixed episode. The two dose groups treated with risperidone had a significantly greater reduction in Young Mania Rating Scale (YMRS) scores than the placebo group. The dose group who received 3 to 6 mg/day of risperidone did no better than the group who received 0.5 to 2.5 mg/day.

### APA Says FDA’s Action Important

“Schizophrenia and bipolar disorders are severely disabling to patients and devastating to their families,” said APA President Carolyn Robinowitz, M.D., in a press release in response to the FDA approval. “For many children with these disorders, the FDA’s action today provides additional information to guide treatment options in these special populations. We anticipate that the approval of this medication will encourage federal research agencies to accelerate urgently needed studies of mental disorders in children.”

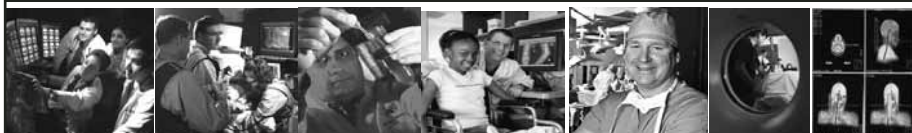
The off-label use of psychoactive drugs in younger patients and the lack of adequate clinical evidence in this population have been sources of controversy. The varying degrees of suicide risk associated with antidepressant use among pediatric and adolescent populations and adult age groups is an example of the complex effects that require more clinical studies. Misconceptions about mental illness have exacerbated public confusion over medications to treat these disorders.

### Controversy Over Adverse Events

In recent years, atypical antipsychotics have been the subject of emerging safety concerns, especially regarding glucose metabolism and significant weight gain, which led the FDA to mandate a label warning for all atypical antipsychotics (*Psychiatric News*, October 17, 2003).



## Top 100 Hospital recruiting top physicians and research scientists



### 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.

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## 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.

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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**

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1901 Veterans Memorial Drive, Temple, TX 76504  
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## ■ Adult Outpatient Psychiatrist

The Zucker Hillside Hospital of the North Shore-Long Island Jewish Health System is seeking full-time, board certified/eligible Psychiatrists for its Adult Outpatient Department. Located 15 miles from New York City on the border of Nassau and Queens County, Zucker Hillside offers a comprehensive continuum-of-care in an academic, teaching milieu. Duties include direct patient care and resident supervision, with opportunities to participate in ongoing research at our NIMH-supported Research Center in Schizophrenia. Academic appointment at the Albert Einstein College of Medicine. Competitive salary and benefits, with additional weekend compensation optional for interested candidates. Submit CV to: **John M. Kane, MD, Chairman, Department of Psychiatry, 75-59 263rd Street, Glen Oaks, New York 11004. (718) 470-8141; Email: Psychiatry@lij.edu**

**North Shore LIJ** North Shore-Long Island Jewish Health System

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American Psychiatric Association



PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH

# SUBSTANCE USE DISORDERS,

SECOND EDITION

A New Practice Guideline course is available online on the APA website.  
[www.psych.org/cme](http://www.psych.org/cme).

## *Practice Guideline for the Treatment of Patients with Substance Use Disorders, Second Edition*

### COURSE DESCRIPTION

The course includes the complete guideline, board-type vignette style multiple-choice questions based on the guideline, and discussion of answers with links back into the guideline text. The course is presented in an easy to use format. Progress is tracked as you move through the course. The new Substance Use Disorders course provides up to 8 AMA PRA Category 1 Credits and allows APA members to print a certificate on completion of the course.

### COURSE OBJECTIVE

To improve patient care for substance use disorders by incorporating the principles of the guideline into individual practice.

### Practice Guideline Courses are Free to APA members

Non APA members may complete APA practice guideline courses for a fee of \$60.00 per course.

● APA Practice guideline courses may be a helpful aide in preparation for ABPN certification and recertification examinations as well as part of a practical lifelong learning program. 12 practice guideline courses are available on the APA website  
[www.psych.org/cme](http://www.psych.org/cme)

● The APA is accredited by the ACCME to provide continuing medical education for physicians. The APA designates this educational activity for a maximum of 8 AMA PRA Category 1 Credit(s)<sup>TM</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.

For further information, please contact:

American Psychiatric Association, Division of Education, [cgarner@psych.org](mailto:cgarner@psych.org).  
Visit our website at [www.psych.org/cme](http://www.psych.org/cme)

## 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.

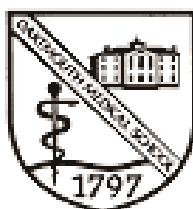
New Hampshire Hospital is a 132-bed acute psychiatric facility located in Concord, NH. New Hampshire Hospital is the clinical and research core facility for an innovative, statewide, comprehensive mental health system. Psychiatrists with expertise in general inpatient psychiatry, neuropsychiatry or forensic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

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



## Minority Research Training in Psychiatry

Through its National Institute of Mental Health-funded Program for Minority Research Training in Psychiatry (PMRTP), the American Psychiatric Institute for Research and Education (APIRE) is seeking to increase the number of minority psychiatrists going into psychiatric research.

The program provides medical students and psychiatric residents with funding for stipends, travel expenses, and tuition for an elective or summer experience in a research environment. Stipends are also available for one- or two-year post-residency fellowships for minority psychiatrists. Deadlines for applications are December 1 for residents seeking a year or more of training and for post-residency fellows; or three months before training is to begin for medical students. Summer medical students who will start their training by June 30 should submit their applications by April 1.

Training takes place at research-oriented departments of psychiatry in major U.S. medical schools and other appropriate sites nationwide. An individual at the site (the research "mentor") oversees the research training experience.

The PMRTP is administered by the American Psychiatric Institute for Research and Education (APIRE). The director of the program is Darrel A. Regier, M.D., M.P.H.; the project manager is Ernesto A. Guerra. An advisory committee of senior researchers and minority psychiatrists developed guidelines for applicants and criteria for selection. The members of this committee evaluate and select trainees.

For more information,

Call: 1-800-852-1390 or 703-907-8622

E-mail: [eguerra@psych.org](mailto:eguerra@psych.org)

Write to PMRTP at the American Psychiatric Institute for Research and Education, 1000 Wilson Blvd, Ste. 1825  
Arlington, VA 22209-3901



## South Texas Veterans Health Care System



The South Texas Veterans Health Care System (STVHCS) serves one of the largest primary service areas in the nation. STVHCS is comprised of three divisions and has an annual operating budget of \$460 million. San Antonio is surrounded by beautiful Texas hill-country and offers an exceptional suburban lifestyle, excellent schools, and the festive atmosphere of an international city.

**Opportunity:** Associate Chief of Staff, Mental Health

**Location:** San Antonio

**Job Description:** Oversight responsibility for mental health operations for STVHCS, including strategic planning, establishment of policies and procedures, and performance monitoring.

**Opportunity:** Board-certified or board-eligible Psychiatrists

**Location:** San Antonio and other South Texas locations

**Job Description:** Provide treatment to an adult psychiatric population with diverse diagnoses including major affective disorders, psychotic disorders, PTSD, and substance use disorders.

**Selected Benefits:** Competitive compensation package  
Education debt reduction program  
Eligibility for relocation incentive  
Eligibility for academic appointment in the Department of Psychiatry at the University of Texas Health Science Center at San Antonio

**Contact:** Mr. Enrique Salas  
Human Resources Specialist  
210.617.5300 x14952  
Enrique.Salas@va.gov

## 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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and neurotic mental illness. Full-time, part-time and PRN positions are available at facilities across the country.

As a Wexford professional, you'll be challenged every day, but you'll also enjoy the rewards that come from helping people that truly need your assistance. We offer competitive salaries and benefits, incredible mobility within our national network, and the opportunity to use our Telemedicine service, which enables long-distance reviews of medical information and the ability to consult with other healthcare experts across the country.

For consideration, please contact Staffing Consultant Anna Vozar at 1-800-903-3616; FAX: 1-888-937-4471; E-mail: [avozar@wexfordhealth.com](mailto:avozar@wexfordhealth.com). For a complete list of opportunities or to apply, please visit our website at: [www.wexfordhealth.com](http://www.wexfordhealth.com).

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## PSYCHIATRIC MEDICAL DIRECTOR

DIVISION OF FORENSIC SERVICES

SALARY \$175,000

In coordination with the Chief Medical Officer and the Associate Commissioner of the Division of Forensic Services, the Psychiatric Medical Director will function as the lead consultant for issues related to the forensic and sex offender populations. In this position, the incumbent will:

- Develop and administer policies, standards and programs relating to the clinical and psychiatric inpatient services provided by Forensic facilities and programs operated by the OMH.
- Provide clinical support, consultation and guidance to the Clinical Directors of the Forensic Psychiatric Centers, Regional Forensic Units and Sex Offender Treatment Programs operated by OMH.
- Review and provide expert consultation for Criminal Procedure Law patients remanded to the custody of the OMH Commissioner in a variety of settings.
- Serve as a liaison to State and local criminal justice agencies, including the Department of Correctional Services, Division of Parole and Commission of Corrections, pertaining to the delivery of mental health services to criminal justice populations.
- Provide clinical expertise to staff in the Bureau of Sex Offender Evaluation and Treatment for cases involving individuals who have committed sex offenses and who are approaching the end of their criminal sentence to determine if they should be recommended for civil management.
- Issue clinical advisories to the field regarding treatments and medication use for forensic patients.
- Develop strategies to improve access to forensic Psychiatry, including the recruitment and retention of forensic psychiatrists and medical specialists in programs across the State.
- Participate in defining core clinical competencies for staff.
- Consult with the Division of Quality Management on matters concerning risk management and quality of care in Forensic Psychiatric Centers, Regional Forensic Units and Sex Offender Treatment Programs operated by OMH.

**QUALIFICATIONS:** Candidates must possess a license to practice medicine in New York State, certification in Psychiatry by the American Board of Psychiatry and Neurology, eligibility for full and unconditional participation in the Medicaid and Medicare programs, and two (2) years of post board certification professional experience as a member of the psychiatric staff of a psychiatric hospital and/or in the psychiatry department of a general hospital. One (1) year of this experience must have included the clinical supervision of other psychiatrists, psychiatric residents or fellows. Preferred candidates will have extensive experience with forensic and/or sex offender populations. Recruitment will remain open until the position is filled.

Please send resumes to:

**NYS Office of Mental Health, ATTN: Sharon Nania**  
**Bureau of Central Office Personnel Services**  
**44 Holland Avenue, Albany, NY 12229**  
**Fax: (518) 486-3897**  
**Email: OMHHRM@OMH.STATE.NY.US**

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Issue	Deadline (Friday, 2 p.m. E.T.)
October 19	September 21
November 2	October 19

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MHM Services, Inc. is the nation's leading provider of correctional healthcare staffing. As one of the largest employers of mental health professionals in the nation, MHM Services is always looking for dedicated individuals who want a career that is both professionally rewarding and provides greater balance with less stress in their day to day life.

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800-729-1601 x5106  
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[www.mhm-services.com](http://www.mhm-services.com)



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## ALABAMA

**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, [ejohnson@mlbhc.com](mailto:ejohnson@mlbhc.com); (256) 582-4240 ext. 106.

## ALASKA

**Fairbanks Memorial Hospital in Fairbanks, AK**, is looking for a full-time, adult, inpatient Psychiatrist to join our exceptional team. We have a 20-bed inpatient unit, staffed with a Nurse Director, RNs, an LPN, CNAs, Psych Techs, Counselors, an OT, Social Workers and a Medical Director.

FMH is committed to continually upgrading the level of care in our close-knit community and invite you to join us. Come experience the Alaskan way of life, full of adventure and beauty, and work at a top-notch facility.

For more information, call 888.303.5402 or e-mail [Suzan.Bast@bannerhealth.com](mailto:Suzan.Bast@bannerhealth.com). Check out our Web site at [www.fmhdc.com](http://www.fmhdc.com).

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## 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 **Alesia Gillis, Human Resources, Dept. of Psychiatry, 1501 N. Campbell Avenue, P.O. Box 245002, Tucson, AZ 85724-5002; (520) 626-3819 or [agillis@email.arizona.edu](mailto:agillis@email.arizona.edu)**. Review of applications is ongoing until positions are filled.

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## CALIFORNIA

### UC DAVIS SCHOOL OF MEDICINE DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

**Associate Residency Program Director.** The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting an Associate/Full Professor of Clinical Psychiatry to serve as Associate Residency Program Director of a growing general psychiatry residency program with 32 approved positions. The program is distinguished by excellence in 1) Clinical experiences in the academic, public sector, and private sector settings; 2) Innovative combined training program in psychiatry-family practice and psychiatry-internal medicine; 3) Specialized tracks in research and teaching for residents and a diverse patient population, residents and faculty. The academic series for this appointment is the teacher/clinician series. The faculty member is expected to engage in scholarly activities leading to publication of papers, book chapters and books. The individual selected will also supervise residents and treat patients in the department's outpatient clinic. The successful candidate should be board certified in general psychiatry, be eligible for a California Medical license, should have a passion for residency education and teaching and be committed to pursuing an academic career.

**For full consideration, applications must be received by October 31, 2007. Position is open until filled, but no later than December 31, 2007. Interested candidates should email a curriculum vitae and letter of interest in response to Position # PY-01R-08 to Cecilia Mafnas, Academic Personnel Specialist at [cecilia.mafnas@ucdmc.ucdavis.edu](mailto:cecilia.mafnas@ucdmc.ucdavis.edu) or UCDMC Department of Psychiatry and Behavioral Sciences, 2230 Stockton Blvd. Sacramento, CA 95817.** In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

<http://www.ucdmc.ucdavis.edu/psychiatry/>

**Central Coast:** Unique private practice situation for well-qualified psychiatrist (or two). Solidly established small outpatient group in one of the nation's most desirable places to live seeks bc/be child or general psychiatrist to fill vacancy and another for planned expansion. Competitive reimbursement, great work environment, excellent benefits, opportunity for shared ownership. Submit CV, questions, contact info to Susan Lewis at [cpc@cpcgroup.org](mailto:cpc@cpcgroup.org).

**Crownview Medical Group in beautiful and exclusive Coronado** (San Diego) seeks a full time psychiatrist for its dynamic and growing practice which consists of inpatient, outpatient and very limited call. Competitive salary commensurate with experience or 75/25 split. Fax resume to (619)435-5401.

### 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.

### Central California Opportunity of a Lifetime!

Live in "the jewel" of Central California with a growing population of over 100,000 and enjoy an abundance of cultural and recreational activities along with affordable housing. This is an inpatient adult psychiatrist position in a hospitalist model at a 68-bed behavioral health facility. Work with a team of therapists, social workers, and nurses in providing consultation, pharmacotherapy, and psychotherapy to inpatients with diverse cases. The call coverage is one weekday night per week and one weekend in every four. This is truly an opportunity of a lifetime! Call 1-888-229-9495 for more information. **Send your CV to Tina Wilkins [wilkinstina@earthlink.net](mailto:wilkinstina@earthlink.net) or fax it to 916-536-9281.**

### GREATER BAY AREA - Modesto, California

General & Child Psychiatrists needed, for unique, stable County Mental Health system in a welcoming community. Serve both public & private sector patients, in both inpatient/outpatient settings that have been benchmarked for their quality. Possibilities for Resident teaching & consultation with a full range of providers. When patients require hospitalization, inpatient & outpatient staff work **TOGETHER** to optimize care. Stanislaus County is located only 1 1/2 hours from both San Francisco and Yosemite, enjoying the best of both worlds.

**Excellent** salary scale, with steps from \$159K to \$194K; **PLUS** full benefits; **PLUS** 5% additional for each of following: Inpatient, General Boards, Child Boards; **PLUS** extra for limited On-Call; **PLUS** Union-negotiated increases already set for next few years. Negotiable hourly contract also an option. Fax CV to Marshall Lewis, MD, 209-558-8641 or call 209-558-4639.

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**UC DAVIS SCHOOL OF MEDICINE  
DEPARTMENT OF PSYCHIATRY AND  
BEHAVIORAL SCIENCES**

**Health Sciences Assistant/Associate Clinical Professor.** The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting for a Health Sciences Assistant/Associate Clinical Professor in the clinician/teaching series to serve as teaching attending at the Mental Health Treatment Center located next to the UC Davis Medical Center in Sacramento. The Treatment Center has a crisis unit and a 100 bed inpatient unit that is staffed by UC Davis faculty, residents, and medical students. The Center also has three dually-trained medicine-psychiatry faculty and its own primary care physician on site. Experience in teaching and supervision of medical students, residents, and other mental health professional is highly desirable. The successful candidate should be board eligible or certified in general psychiatry, be in possession of a California Medical license, and have an interest in psychiatric education and training. The successful candidate will lecture in seminars and case conferences, and provide group and individual supervision of clinical cases. The incumbent will provide clinical teaching for general psychiatry residents, psychology fellows, medical students and other mental health professionals including timely and appropriate evaluation of trainee performance.

**For full consideration, applications must be received by January 31, 2008. Position is open until filled, but no later than June 30, 2008. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-03R-08 to Cecilia Mafnas at [Cecilia.mafnas@ucdmc.ucdavis.edu](mailto:Cecilia.mafnas@ucdmc.ucdavis.edu)** In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

<http://www.ucdmc.ucdavis.edu/psychiatry/>

**The Department of Veterans Affairs Medical Center, Long Beach, California,** is seeking a Board Certified/Board Eligible Psychiatrist to work with the Buprenorphine Treatment program for patients with opiate dependence. Knowledge of substance abuse is required. Psychiatrist (preferable ASAM or Addiction Psychiatry certified), will work in the development of buprenorphine treatment program for patients with opiate dependence. Requires knowledge of substance abuse and ability to prescribe Buprenorphine (Suboxone), detox and/ or maintain opiate addicted patients on outpatient basis using Suboxone. This is a new treatment program designed to reach veterans with Substance Use Disorder, specifically, opiate dependence, either singly or dually diagnosed with other mental health diagnoses Duties will include clinical assignments along with teaching and supervision of residents and students. Candidate must possess excellent skills, both clinical and administrative. There are ample benefits and recruitment incentives and assistance with re-payment of student loans are possible. The VA is an Equal Opportunity Employer. **To find out more about this exciting opportunity contact Larry Albers, MD, Chief of Mental Health at: [larry.albers@va.gov](mailto:larry.albers@va.gov) (562-826-5758)**

**Assoc. Medical Director Position/Northern CA - the Beautiful Northwest** - An incredible inpatient/outpatient opportunity (salaried or practice opportunity) awaits you. If you love the beauty of northern CA but want an area where the cost of living in CA is lower and the opportunity for a very lucrative practice is much higher, then please consider this. Live and work in a culture-rich college town away from all of the professional and personal hassles of large city life only minutes from the gorgeous Sierra foothills and only an hour and a half from Napa Valley and Sacramento. Also an easy drive to the Bay Area, Lake Tahoe, and Reno. Please call **Terry B. Good, Horizon Health, at 1-866-865-7380**, Fax #: 804-684-5663; Email: [terry.good@horizonhealth.com](mailto:terry.good@horizonhealth.com). Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

**UC DAVIS SCHOOL OF MEDICINE  
DEPARTMENT OF PSYCHIATRY AND  
BEHAVIORAL SCIENCES**

**Luke and Grace Kim Endowed Professorship in Cultural Psychiatry.** The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting an Associate/Full Professor of Clinical Psychiatry to be the holder of the Luke and Grace Kim Endowed Professorship in Cultural Psychiatry and Director of Cultural Psychiatry in the Department. The appointment is in the teacher/clinician series. The successful applicant is expected to engage in scholarly activities leading to the publication of peer-reviewed papers, book chapters, monographs and books. The candidate should have a well-established track record in cultural psychiatry as reflected in publications and grants from private foundations and state and federal agencies. A research background in cultural psychiatry and experience collaborating with other investigators to develop culturally-based research projects is highly desired. The candidate should have experience teaching medical students and residents about cultural psychiatry and other clinically-related topics. National prominence in the field of cultural psychiatry is desired. Experience in working in a community mental health setting with culturally diverse patient populations and with county and state governments in delivering culturally competent mental health services is also desired. The applicant should be board certified in general psychiatry and licensed or license-eligible to practice medicine in California.

The Department of Psychiatry and Behavioral Sciences has a multi-award winning Diversity Advisory Committee which has made major contributions to the teaching of diversity and cultural competence to medical students and residents. The Diversity Advisory Committee has 10-12 faculty members, three of whom have received awards from the UC Davis Chancellor for their outstanding achievements in promoting diversity throughout the UC Davis Community. The Department of Psychiatry has grown tremendously over the last decade with approximately 75 psychiatrists and psychologists, 350 employees and annual direct costs in research funding of approximately \$10 million.

**For full consideration, applications must be received by December 31, 2007. Position is open until filled, but no later than March 31, 2008. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-02R-08 to Cecilia Mafnas, Academic Personnel Specialist at [cecilia.mafnas@ucdmc.ucdavis.edu](mailto:cecilia.mafnas@ucdmc.ucdavis.edu) or UCDMC Department of Psychiatry and Behavioral Sciences, 2230 Stockton Blvd. Sacramento, CA 95817.** In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

<http://www.ucdmc.ucdavis.edu/psychiatry/>

**The VA Long Beach Healthcare System currently has an opening for a part time board certified or board eligible psychiatrist** to provide outpatient care at our community clinics located in Anaheim and Whittier/Santa Fe Springs. Three days a week will be spent at Whittier/Santa Fe Springs and 2 days a week in Anaheim. The ideal candidate would provide excellent clinical care and work well with other mental health professionals and primary care providers in the clinics. Competitive salary negotiable, depending on qualifications. There are ample benefits and recruitment incentives and assistance with re-payment of student loans are possible. The Veterans Administration is an Equal Opportunity Employer. **To find out more about this exciting opportunity contact: Larry Albers, MD, Chief of Mental Health at: [larry.albers@va.gov](mailto:larry.albers@va.gov) (562-826-5758)**

**Ventura County Behavioral Health (VCBH)**

Ventura County Behavioral Health is looking for **full & part-time Psychiatrists** to provide comprehensive services for acute and chronically mentally ill clients in an outpatient setting.

**Programs:  
Child & Adolescent  
Adult**

**Qualifications:** Candidates will have Completed their residency/fellowship and Be ABPN board eligible or Certified.

**VCBH:** Offers an opportunity to work as part of an integrated multi-disciplinary treatment team, providing treatment, rehabilitation and case management to a wide array of clients. This **southern California coastal community** provides a unique opportunity for your personal and professional growth and offers a great place to live and raise a family. (EOE)

Bi-lingual applicants are highly encouraged to apply.

**Send CV to:**

Division Manager, Pam Fisher, Psy.D  
1911 Williams Dr, Oxnard CA 93036  
(805) 981-2240 or Fax: (805) 981-2262  
Email: [pam.fisher@ventura.org](mailto:pam.fisher@ventura.org)

**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: \$154,000-\$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](mailto:susan.brekhus@sfdph.org), Francis Lu, MD, Professor of Clinical Psychiatry at (415) 206-8984 or [francis.lu@sfdph.org](mailto:francis.lu@sfdph.org).

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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**Department of Psychiatry  
Olive View - UCLA Medical Center**

Los Angeles Department of Health Services is seeking psychiatrists to serve as clinician-teachers at Olive View-UCLA Medical Center, a major teaching hospital affiliated with the University of California, Los Angeles. The clinician-teacher role offers the opportunity to teach San Fernando VA - UCLA residents, UCLA medical students and other trainees; to provide clinical leadership for multidisciplinary staff; and to develop clinical research and teaching programs. Other services include the Psychiatric Emergency Service and the Consultation-Liaison Service. 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. Olive View - UCLA Medical Center is a vibrant academic hospital nestled in the hills of northeast Los Angeles, approximately 25 minutes from West Los Angeles.

Compensation:  
Outstanding benefits package

Interested applicants should send or fax (818 364 3554) their resume and names and address of three references to: Alex Kopelowicz, M.D., Chair, Department of Psychiatry, Olive View Medical Center, Room 6D-129, Sylmar, CA 91342. For additional information, you are welcome to call (818 364 3343) or email Dr. Kopelowicz at [AKopelowicz@ladhs.org](mailto:AKopelowicz@ladhs.org) or Dr. Vicki Hendrick at [VHendrick@ladhs.org](mailto:VHendrick@ladhs.org).

**FACULTY POSITIONS - UCSD**

The Department of Psychiatry at UCSD (<http://psychiatry.ucsd.edu/>) is seeking candidates for a full-time academic faculty position at the full Professorial level. Child Psychiatrist candidates must be board eligible/certified and have a research track record of experience in child/adolescent trauma as a result of child abuse, traumatic loss and/or domestic violence and/or neglect. Individuals must be or be able to become licensed in the State of California and preference will be given to those M.D.s who are board certified in child and adolescent psychiatry. Those who apply should have a proven track record in research, clinical psychiatry academic-related settings and a capacity to head a research program in child abuse. A demonstrated research track record of productivity and demonstrated success in obtaining peer reviewed research grants is required. The candidate's academic rank and series will be determined by their individual academic qualifications and achievements with salary based upon University of California salary scales. The University of California, San Diego is an equal opportunity and affirmative action employer. Candidates should send curriculum vitae and other supporting documents by October 31, 2007 to Search Committee C2, UCSD Department of Psychiatry, 9500 Gilman Drive, La Jolla, CA 92093-0603.

**SHASTA COUNTY COMMUNITY MENTAL HEALTH**

**Adult and/or 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 waived 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.



**UC DAVIS SCHOOL OF MEDICINE  
DEPARTMENT OF PSYCHIATRY AND  
BEHAVIORAL SCIENCES**

**Health Sciences Assistant/Associate Clinical Professor.** The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting for a Health Sciences Assistant/Associate Clinical Professor in the clinician/teaching series to serve as teaching attending at the Adult Psychiatry Support Services Clinic located next to the UC Davis Medical Center in Sacramento. The Clinic is staffed with four UC Davis faculty, two general psychiatry residents, and 23 medical students. Experience in teaching and supervision of medical students, residents, and other mental health professional is highly desirable. The successful candidate should be board eligible or certified in general psychiatry, be in possession of or eligible for a California Medical license, and have an interest in psychiatric education and training. The successful candidate will lecture in seminars and case conferences, and provide group and individual supervision of clinical cases. The incumbent will provide clinical teaching for general psychiatry residents, psychology fellows, medical students and other mental health professionals including timely and appropriate evaluation of trainee performance.

**For full consideration, applications must be received by January 31, 2008. Position is open until filled, but no later than June 30, 2008. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-05R-08 to Cecilia Mafnas at Cecilia.mafnas@ucdmc.ucdavis.edu.** In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

<http://www.ucdmc.ucdavis.edu/psychiatry/>

**UC DAVIS SCHOOL OF MEDICINE  
DEPARTMENT OF PSYCHIATRY AND  
BEHAVIORAL SCIENCES**

**Health Sciences Assistant Clinical Professor in the Law and Psychiatry Division.** The University of California, Davis, Department of Psychiatry and Behavioral Sciences invites applications for a full-time academic psychiatrist to serve at the Assistant Clinical Professor level and to be a member of the department's Law and Psychiatry Division. This person will serve as an attending psychiatrist on the County of Sacramento's Jail Psychiatric Service, a forensic psychiatry teaching service staffed by UC Davis faculty and be involved in other clinical and teaching responsibilities administered by the Law and Psychiatry Division. The successful candidate will provide evaluation and treatment of patients as well as clinical supervision of medical students and residents who rotate through the service. Experience in teaching and supervision of forensic psychiatry fellows, psychiatry residents, medical students and allied mental health professionals is required. The individual must be licensed, or eligible for licensure, in the state of California, and be board certified or eligible in general psychiatry. Completion of fellowship training in forensic psychiatry is highly desirable. Appointment will be at a level commensurate with experience and qualifications.

**For full consideration, applications must be received by December 31, 2007. Position is open until filled, but no later than March 31, 2008. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-04R-08 to Cecilia Mafnas at Cecilia.mafnas@ucdmc.ucdavis.edu.** In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

<http://www.ucdmc.ucdavis.edu/psychiatry/>

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**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 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](http://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% Lead Psychiatrist; 25% 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](http://www.acgov.org)

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

**New Salaries Approved  
Great Psychiatrist Opportunities**

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 health 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 Email to [tmott@rc-hr.com](mailto:tmott@rc-hr.com) or Mail to:

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

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**COLORADO**

**Psychiatrist  
Denver**

The Colorado Permanente Medical Group, P.C. seeks a full-time BC/BE Adult Psychiatrist or Child and Adolescent Psychiatrist to join our multi-specialty integrated healthcare organization and work in an outpatient staff model in collaboration with non-physician mental health 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](mailto:Chantal.papez@kp.org). EOE, M/F, V/H.

**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.

Forward CV/Resume to: Fred Michel, MD, Medical Director, [FredM@ppbhg.org](mailto:FredM@ppbhg.org); 719-339-3890; or Sue Allen, Admin Asst, [SueA@ppbhg.org](mailto: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](http://www.ppbhg.org)

**Pikes Peak Behavioral Health Group**

**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. Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email [mark.blakeney@horizonhealth.com](mailto:mark.blakeney@horizonhealth.com). EOE.

**General Psychiatrist** - Immediate opening at Colorado State Hospital with good patient/staff ratio. 40-hour workweek with no required night or weekend work. Four day work week possible, providing time for limited private practice or other outpatient work. Position carries University of Colorado Medical School faculty appointment. Teaching medical student desirable. Please contact A.O. Singleton, III, M.D. @ (719) 546-4637 for more information.

**CONNECTICUT**

**Part Time Out-Patient Adult/Adolescent  
Opportunity in Manchester, CT**

Eastern Connecticut Health Network offers a 20-hour Psychiatric position working with adult and adolescent patients. Call 2-3 times per month with extra call compensation, no weekend call. Excellent colleagues, warm community hospital, with competitive salary and generous benefits including CME. Send CV or inquires to Dr. Stephen Alloy, 150 N. Main St., Manchester, CT 06040 or via email at [salloy@echh.org](mailto:salloy@echh.org).

**Coastal, Connecticut**

Enjoy a pure outpatient practice with no call responsibilities. Successful and well-run non-profit full range behavioral health center seeks an Adult Psychiatrist. Strong salary and full benefit package will be offered to the ideal candidate. Live in one of many perfect New England beach communities with cultural amenities, fine restaurants, and great schools. A short drive from Providence, Boston, or New York City. Will sponsor J1 & H1B.

**Coastal, Connecticut**

Located one hour from Pittsburgh, an extremely popular, financially strong accredited hospital with a highly trained staff is looking for a Psychiatrist to join them. Opportunity for subspecialty work in addition to General Adult Psychiatry. Strong assistance from PAs and NPs. Position offers attractive above average compensation, full benefits and relocation package. Sophisticated country setting with all amenities related to a metro area. Sign-on and loan repayment available.

**John McCusker**  
**800.504-3411 [johnm@alphaps.org](mailto:johnm@alphaps.org)**  
**View available opportunities at**  
**[www.alphaps.org](http://www.alphaps.org)**

**INCREDIBLE INPATIENT/OUTPATIENT PRACTICE OPPORTUNITY in an area nationally known as one of the MOST BEAUTIFUL residential communities in America!** Located in the picturesque northwest corner of Connecticut, Sharon is an area with a great need for more psychiatrists. If being your own boss and the freedom of private practice is of interest, this is the perfect place to get established. Or if you have an outpatient practice already in the surrounding area, this would be a very lucrative addition to your current income. Exceptional prep schools, parks, and recreation. Contact Terry B. Good at Horizon Health, 866-865-7380; Fax: 804-684-5663; E-mail: [terry.good@horizonhealth.cm](mailto:terry.good@horizonhealth.cm). EOE

**DELAWARE**

**DOVER: General Psychiatrist** - Inpatient & Partial programs. Administrative/clinical title and duties an option. Offering base salary, benefits and more... Contact Joy Lankswert @ 866-227-5415 or email [joy.lankswert@uhsinc.com](mailto:joy.lankswert@uhsinc.com)

**FLORIDA**

**Psychiatry busy solo practice for sale in South Florida** Prime Location. Fee for service, no insurance with great expansion potential. Fax inquiries to: 561-482-9582.

**FT. MYERS/MERBOURNE/ORLANDO/DAYTONA/MIAMI/FORT LAUDERDALE/OCALA/GAINESVILLE** - Psychiatrists needed for rapidly expanding Nursing Home Service. Great support. No call. Average Salary 210K + benefits. Part-time available. Some travel required. Must have FL Medicare & FL Medicaid provider #s. Call Mike at 866-936-5250.



## Psychiatrist

Full-time position available in outpatient clinic of JCAHO accredited comprehensive community mental health center located in Jacksonville, FL. Position will also involve participation in on-call roster for inpatient services. (Other psychiatrist opportunities available periodically; please inquire.) Florida licensure and BE/BC required. Competitive salary with comprehensive benefits package. Contact Dr. Robert Sommers, President, RBHS, P. O. Box 19249, Jacksonville, FL 32245. e-mail: rbhsPRES@bellsouth.net. Fax: (904) 743-5109. Phone: (904) 743-1883, ext. 219.

**Boca Raton Prestigious/Upscale Psychiatric Group** in sunny seaside resort town seeks psychiatrist. Outpatient Practice. Partnership track in a friendly and collegial work environment. Must have FL license prior to hire. Fax Resume to: 561 392 9170 or e-mail BocaPsych@yahoo.com

**Located along South Florida's east coast just minutes from the Atlantic Ocean**, CARF accredited community mental health center is seeking a part-time/full-time inpatient and outpatient psychiatrists to provide comprehensive psychiatric care to adults. Must be Board Certified (or eligible). Excellent salary and benefits package, great staff and a lovely coastal community. Seeking applications directly from candidates. (No recruitment firms please!) Send/Fax CV: HR, New Horizons, 4500 W. Midway Rd., Ft. Pierce, FL 34981 FAX (772) 468-5606 EOE/AA/V/M/F/DFWP www.nhtcinc.org

**STAFF PSYCHIATRIST / MEDICAL DIRECTOR** - Daytona Beach - Miles of sandy beaches & excellent opportunities with flexible scheduling and limited on-call. Florida license required, clinical research preferred. Expanding medical staff with opportunities for professional growth in many areas. Excellent benefit package including professional liability insurance. For confidential consideration, please send or fax resume to Human Resources.

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**Atlantic Coast organization needs a fifth psychiatrist for ALL OUTPATIENT practice.** Combine a strong salary, full benefits, gorgeous beaches, and great lifestyle options. Contact Jim Ault at St. John Associates, 1-800-737-2001 or jault@stjohnjobs.com. Visit www.stjohnjobs.com.

**New Port Richey - Fantastic Practice Opportunity in a Coastal Location** - If being your own boss and having the freedom to set your own work schedule is what you've wanted, then please call me. This is an opportunity to open an inpatient and outpatient private practice (adult and geriatric) in the fifth fastest growing county in FL. Or if you have a practice already, adding our inpatient component to your income could be extremely lucrative. Call is 1 in 4. 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.

## GEORGIA

**Quiet Country Setting** close to large metro area in Beautiful NW GA. Community Mental Health Opportunity for BC/BE Psychiatrist FT, excellent benefits and competitive salary, 1:4 call with additional pay. 30 bed residential crisis unit with superb support staff. Extra call available if desired. Send CV to DrGroover@HighlandRivers.org or call 706-270-5003 ext 114

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## IDAHO

**CONVENIENT TO THE NATION'S BEST SKI RESORTS, NATIONAL PARKS AND SALT LAKE CITY** - Horizon Health has a salaried position with benefits for a psychiatrist on an adult inpatient/outpatient psychiatric service in beautiful Pocatello-located in the western foothills of the Rocky Mtns. along the Oregon Trail. Enjoy a four season climate where clear, sunny and dry are the norm. The city has 32 parks, a zoo, state university indoor sports arena, skate park, swimming complex, plus much more. Live like a king/queen where your money goes so much farther—lower cost of living & housing costs well below the national average. 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.

## ILLINOIS

**PSYCHIATRIST EDUCATOR:** Assist. Prof., Univ. of IL Coll. of Medicine at Peoria, Dept. of Psychiatry & Behav. Medicine is seeking a brd-cert./elig. PSYCHIATRIST to join a collegial community-based psychiatry department. Primary responsibilities include classroom/clinical teaching and outpt. clinical care. Applications accepted until position is filled. Reply to: Peter Alahi, M.D., Chair, Psychiatry Search Committee, Dept. of Psychiatry & Behav. Medicine, UIC College of Medicine at Peoria, 221 NE Glen Oak Ave., 7 West, Peoria, IL 61636; Phone (309) 671-2165; FAX (309) 671-8384 e-mail: palahi@uic.edu The University of Illinois is an AA/EO Employer.

**Addiction Psychiatry Fellowship** - This is a PGY 5 position, to begin July 1, 2008, at the University of Illinois at Chicago, Department of Psychiatry. Fellow will acquire expertise in treating addictions through comprehensive training in a variety of inpatient, outpatient, and consultative settings. Teaching and research opportunities included in fellowship. Rodney Eiger, M.D., Fellowship Director.

**Behavioral Neurology and Neuropsychiatry Fellowship** is a UCNS-accredited program (PGY 5 and 6) offered through the Departments of Psychiatry and Neurology at the University of Illinois at Chicago. This interdisciplinary fellowship is open to individuals who have completed an ACGME-accredited residency training program in Psychiatry or Neurology and are eligible for the ABPN. The program trains psychiatrists and neurologists as skilled clinicians, researchers, and educators in neurodegenerative diseases, neuropsychiatric and neurobehavioral syndromes, as well as in cognitive neuroscience. Applications are being accepted for a 2-year position starting July 1, 2008.

**PRIME Residency** - This is a PGY 4 position, to begin July 1, 2008 at the Jesse Brown VA Med Ctr/University of Illinois at Chicago, Department of Psychiatry. The trainee will receive psychiatric consultation-liaison training as a member of a primary care team (PRIME) and will educate primary care team about identification and management of common psychiatric disorders. Resident will participate in ongoing didactic programs and the telepsychiatry clinic. Opportunities for clinical research, electives in ECT, home care, addiction and geriatric psychiatry available. Supervision is provided by faculty from the Depts of Psychiatry and Medicine at JBVA Medical Center and the University of Illinois at Chicago.

**Women's Mental Health Fellowship** - This is a one-year, PGY 4 or 5 position, to begin July 1, 2008 at the University of Illinois at Chicago, Department of Psychiatry. We are seeking an exceptional candidate who wants to develop expertise in reproductive and gender-linked psychiatric disorders. Our program has received the ACP Award for Creativity in Psychiatric Education, and the APA Gold Award in recognition of our pioneering work in women's mental health.

**USMLE Step 3 required for PGY 4 and above positions.** For the above 4 positions contact: Robert W. Marvin, MD, Director Residency Training, by mail: 912 S. Wood St., MC 913, Chicago, IL 60612; by e-mail: recruit@psych.uic.edu; or by phone: (312) 996-3583, on or before December 31, 2007. Detailed descriptions are posted on the Residency web site: <http://www.psych.uic.edu/education/residents/fellowships>. The UIC and JBVA are AA/EOE.

## INDIANA

### Psychiatrists wanted

Midtown Community Mental Health Center, Indianapolis, IN is seeking several BC/BE Psychiatrists. Seeking one (1) outpatient psychiatrist to work with ACT Team as well as provide care for patients with SMI. Seeking one (1) psychiatrist to work in our Adult Outpatient services.

Need to be licensed to practice medicine in the state of Indiana. J-1 Visa applicants are welcome. Comparable salary and benefits package plus paid malpractice insurance.

Send CV to Steve Fekete, M.D., Medical Director, Midtown CMHC, 850 N. Meridian St., Indianapolis, IN 46204 or FAX: 317-554-2721. Telephone: 317-554-2703.

**90 minutes from downtown Chicago.** Join very stable practice with 10 psychiatrists in a renowned university community. Contact Jim Ault at St. John Associates, jault@stjohnjobs.com or 800-737-2001. Visit [www.stjohnjobs.com](http://www.stjohnjobs.com) for more opportunities nationwide.

## KANSAS

### MEDICAL DIRECTOR

Valeo Behavioral Health Care, the leading provider of comprehensive mental health and substance abuse services for adults in Topeka, KS seeks a **Medical Director** to provide outpatient medical/psychiatric services to their consumers. This is an excellent opportunity for a Psychiatrist with strong clinical and interpersonal skills to provide leadership, clinical supervision, and clinical care in an Adult outpatient mental health setting. Valeo is licensed by the State of Kansas and nationally accredited by the Commission on the Accreditation of Rehabilitation Facilities (CARF). Valeo has served the behavioral health care needs of Shawnee County residents since 1967.

With cultural amenities to rival big cities, Topekan revel in numerous outdoor activities, excellent healthcare facilities, technologically advanced education, and a below-average cost of living. Topeka is located 50 miles east of Kansas City on Interstate I-70 and less than an hours drive to KCI airport.

The ideal candidate would be ABPN Board-certified or Board-eligible psychiatrists; MD or DO licensed by the State of Kansas; and have demonstrated interest in working with underserved and culturally diverse population with at least five years of administrative experience in a mental health setting. Compensation commensurate with experience; excellent benefit package.

Interested applicants submit a CV to Valeo Behavioral Health Care, Human Resources, 5401 SW 7th Street, Topeka, KS 66606 or fax it to 785 273-7489. For questions contact: Shawna Mercer, Human Resources, 785-273-2252 ext 5205 or email smercer@valeotopeka.org. Valeo is an EOE.

## KENTUCKY

**LOUISVILLE area:** Medical Director for inpatient/outpatient - adolescents & adults. Limited call - great salary & benefits. Will consider part-time or fulltime. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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## LOUISIANA



### BC/BE Psychiatrist

**OCHSNER ST. ANNE GENERAL HOSPITAL is seeking:**

- A BC/BE Psychiatrist for an employed position in Raceland, Louisiana
- Located 40 miles from New Orleans with a population of approximately 40,000
- Not-for-profit critical access hospital providing inpatient & outpatient services with high quality, cost-effective emergency, medical & surgical care
- Part of nationally renowned health system of 7 hospitals, 600+ member physician group, and 28 health centers
- Very competitive salary and benefits
- Family-oriented community with year-round outdoor activities
- Favorable malpractice environment in Louisiana
- J-1 visa candidates are welcome to apply
- Ochsner Health System is an equal opportunity employer.

Please email CVs to: [profrecruiting@ochsner.org](mailto:profrecruiting@ochsner.org) or call (800) 488-2240.

Ref# APSYN4.

**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](mailto:winstead@tulane.edu). Tulane is strongly committed to policies of non-discrimination and affirmative action in student admission and in employment.



**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 2005 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](mailto:kcrapanz@dhh.la.gov).



## CENTRAL LOUISIANA STATE HOSPITAL CHILD AND ADOLESCENT PSYCHIATRIST

Central Hospital, a 132 bed Joint Commission approved psychiatric inpatient facility, and the Louisiana Office of Mental Health, seek a board eligible/certified child and adolescent psychiatrist to act as the medical director of a 16 bed adolescent inpatient unit. This psychiatrist will work with a dedicated and cohesive multi-disciplinary team providing a full range of integrated therapeutic services to patients aged 13 to 17 with emotional and behavioral disorders. We are looking for a solid clinician with strong leadership and communication skills. CLSH is located in the Pineville/Alexandria area of central Louisiana and is within driving distance to Lafayette (the heart of Cajun country), Baton Rouge, and New Orleans. Affordable housing, good schools, and a family oriented community make this area a wonderful place to live. Position is full time with some flexibility in the work schedule. Light call is on weekdays only and is primarily by phone. Salary range is competitive. A relocation stipend may be available. Benefits include annual/sick leave, retirement system with pension, life/health insurance, and tax sheltered savings program. Malpractice included. Academic appointment is potentially available to the appropriate candidate. Interested parties should forward a letter of interest and a c.v. in confidence to:

L. Lee Tynes, MD, PhD  
Medical Director  
Central LA State Hospital  
PO Box 5031  
Pineville, LA 71361-5031  
ltynes@dhh.la.gov  
telephone: 318-484-6203  
EOE

**Medical Director  
Baton Rouge, LA**

A Medical Director is needed for a 19-bed geriatric psychiatric program in Baton Rouge, Louisiana. In this position, the Medical Director will be responsible for a complete practice experience working on inpatient program, which would include admission, diagnosis, treatment, management, and discharge of patients. Excellent Stipend offered with lucrative private practice potential. For more information please contact Diane Odom, 972-420-4083, fax 972-420-8233, e-mail diane.odom@horizonhelath.com

## Crossroads Regional Hospital Alexandria, Louisiana

Our hospital is seeking psychiatrists to apply for immediate openings. J1 waiver available.

## FULL TIME EMPLOYMENT

- Salary more than \$175,000/yr +Bonus

(or)

## TO ESTABLISH FULL TIME PRACTICE

- Hospital guarantees net annual income of \$200,000
- Additional income belongs to practitioner
- Hospital will provide funds to start practice and other expenses.

The hospital is a 70-bed freestanding psychiatric hospital, providing adult, child, adolescent and geriatric inpatient services. The hospital also has partial day program and intensive outpatient programs.

Alexandria is the biggest city in central Louisiana, located on interstate 49 and within driving distance to Lafayette, Baton Rouge and Dallas.

## Please apply with CV to:

P. Nelakurthi  
Bayou Health Care, LLC.,  
5425 Brittany Dr, Suite A,  
Baton Rouge, LA 70808  
Fax: 225-766-6400  
Email: hradmin@crossroadshospital.org

**To advertise contact  
Pamela Trujillo  
703-907-7330,  
classads@psych.org**

## 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](http://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 mwash@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 mwash@kbhmaine.org.

## MARYLAND

## Psychiatrist

**Springfield Hospital Center** - a 405 bed psychiatric inpatient 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@dhhm.state.md.us. EOE

## Faculty Position Assistant Professor (Tenure Track) Department of Psychiatry

The Department of Psychiatry at the Uniformed Services University of the Health Sciences, Bethesda, MD is seeking to fill an Assistant Professor, tenure-track, teaching and research position. The Department is comprised of twenty full-time faculty and has active research interests in the neurobiology and behavior of stress, PTSD, anxiety, depression, and substance abuse. The successful candidate will participate in and develop medical student and resident education, a research program and provide clinical care. Individuals who hold an M.D., have completed an approved psychiatric residency and are board eligible/certified are invited to apply. Send curriculum vitae, description of current and anticipated research interests and the names and addresses of four references to: Robert J. Ursano, M.D., Chairman, Department of Psychiatry, Uniformed Services University, 4301 Jones Bridge Road, Bethesda, MD 20814 (psychiatry@usuhs.mil). Review of applications is ongoing. The University is an affirmative action/equal opportunity employer.

**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.

**PT Psychiatrist**-Well established, Pvt, Multi-Discipline Grp Practice in Montgomery County MD, has an immediate opening for BC adult/adolescent psychiatrist. 15-20 Hrs wky. Flexible schedule. Team approach. Email CV apcadmin2@verizon.net or fax to 301-258-7482.

**Staff psychiatrist needed in Cumberland, MD:** Examine, diagnose & treat patients with psychiatric disorders. Min. Req.: M.D., BC/BE in Psychiatry, license to practice in MD, + 36 months training/completion of psychiatry residency. 40 hrs/wk. Send CV & cover letter to Western Maryland Health System, 12400 Wilowbrook Rd., Cumberland, MD. ATTN: HR. No phone calls. EOE.

**Beautiful Baltimore Maryland!** Northeast of Washington DC, very close to the Chesapeake Bay! Community teaching Hospital has 1 Adult Need! 100% INPATIENT. This is a full time permanent position. See 8-12 patients a day and some consults. Competitive salary and BONUSES with comprehensive benefits package! To find out more about this opportunity please contact Loree Frazitta at 800-735-8261 Ext. 216 or email lfrazitta@medsourceconsultants.com

## MASSACHUSETTS

### Inpatient Staff Psychiatrist Bridgewater State Hospital

MHM Correctional Services, the nation's leader in correctional mental health, has recently contracted with the Massachusetts Department of Correction including Bridgewater State Hospital. Under new leadership, and with increased salaries and excellent benefits package, Bridgewater State Hospital offers a unique and challenging practice opportunity to qualified psychiatrists. Explore the benefits of working with MHM and the highly qualified psychiatry team at BSH. To apply or inquire, contact Dawn Sechrest: 866-604-2800 or email CV to: dsechrest@mhm-services.com

**UMass Memorial Medical Center, Department of Psychiatry**-is seeking a half-time Consultation-Liaison psychiatrist to provide services at its tertiary medical center and assist in training programs. Specialty training and/or research experience a plus. Full-time employment with other responsibilities may be available. Academic opportunities and rank commensurate with experience. Applicants should send letter of interest and CV to Alan Brown, MD, Vice Chairman for Clinical Services, Department of Psychiatry, UMMC, 55 Lake Avenue North, Worcester, MA 01655 or e-mail BrownA01@ummc.org AA/EOE

## CAMBRIDGE: Inpatient Unit Director/ Attending Psychiatrist

**Position available at Cambridge Health Alliance Department of Psychiatry, Harvard Medical School.** Full time inpatient unit Medical Director with clinical responsibility for a 9 patient team on an 18-bed teaching service. Clinical care is provided through a multidisciplinary team approach with psychiatrist leadership. The inpatient medical director will also oversee provision of care on the unit, lead quality initiatives on the unit, oversee teaching of residents, medical students and psychology interns, and demonstrate commitment to clinical excellence.

The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment to improving the health of our communities, coupled with a strong academic tradition, make this an ideal opportunity for candidates interested in caring for underserved populations in a rich clinical environment. We have strong adult and child residency training programs which provide opportunities for teaching. Academic appointment, as determined by the criteria of Harvard Medical School, is anticipated.

Qualifications: Board-certified, demonstrated commitment to public sector populations, strong clinical skills, strong leadership and management skills, team oriented, problem solver. Bilingual and/or bicultural abilities are desirable. Competitive compensation, excellent benefit package. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. **CV & letter to Derri Shtasel, MD, Dept. of Psychiatry, 1493 Cambridge Street, Cambridge, MA 02139. Fax 617-665-2521. Email: DShtasel@challiance.org** (email preferred).

## CAMBRIDGE Health Alliance: Women's Health

**Position available at Cambridge Health Alliance Department of Psychiatry, Harvard Medical School.** Part time opportunity in Women's Health/outpatient C/L Psychiatry. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment to improving the health of our communities, coupled with a strong academic tradition, make this an ideal opportunity for candidates interested in caring for underserved populations in a rich clinical environment. We have strong adult and child residency training programs and a fellowship training program in Psychosomatic Medicine (C/L) which provide opportunities for teaching. Academic appointment, as determined by the criteria of Harvard Medical School, is anticipated.

Qualifications: BE/BC, demonstrated commitment to public sector populations, experience in women's mental health, strong clinical skills, excellent collaborator, problem solver. Bilingual and/or bicultural abilities and training in C/L Psychiatry are desirable. Competitive compensation, excellent benefit package. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. **CV & letter to Derri Shtasel, MD, Dept. of Psychiatry, 1493 Cambridge Street, Cambridge, MA 02139. Fax 617-665-2521. Email: DShtasel@challiance.org** (email preferred).

**Lawrence** - Excellent opportunity for a motivated psychiatrist to work in a collegial atmosphere with 25 plus physicians in our multi-specialty neuroscience group located 20 miles north of Boston. We offer competitive salary, benefits, and partnership potential as well as a minimal on-call schedule. Send C.V. to Howard M. Gardner, M.D., Medical Director, New England Neurological Associates, P.C., Riverwalk, 354 Merrimack Street, Lawrence, MA 01843. Visit us on the web at [www.neneuro.com](http://www.neneuro.com).

**BOSTON & SUBURBS!** Part-time & fulltime - NO CALL. Salary, benefits & bonus offered. **Jamaica Plain, Brookline, Attleboro, Pembroke locations.** Child, General & Geriatric Psychiatrists for inpatient/partial programs. Moonlighting DOC shifts also available. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com



## Research Faculty Positions

### University of Massachusetts Medical School

#### Department of Psychiatry

##### Worcester, MA

The University of Massachusetts Medical School Department of Psychiatry is recruiting for Research Faculty positions (full and part-time) to join our expanding Clinical & Translational Research team. Opportunities exist for leadership positions as well as researchers.

Candidates must have strong research background, experience, and interest in mentoring junior faculty. Areas of research interest include mental health services, primary care integration, program evaluation, addiction, psychosocial interventions, psychopharmacology, developmental disabilities, law and psychiatry, imaging, biostatistics, and trauma.

These positions are 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 North, Worcester MA 01655 or e-mail Denise Barrett at barrettd@ummhc.org AA/EOE

**Boston North Shore:** Northeast Hospital Corporation, a locally-based nonprofit medical and psychiatric system recently named one of the nation's top 100 integrated healthcare systems by Solucient, has opportunities for board certified or eligible psychiatrists at two of its facilities:

**Beverly Hospital; inpatient or inpatient/C and L combination.** Help take this general hospital psychiatry program to the next level! Two positions available, including Medical Director position for experienced psychiatrist with leadership skill; C/L fellowship training a plus. Salary is competitive with an excellent benefit package including generous time off and reimbursement for malpractice insurance and CME. Limited call, and lucrative coverage opportunities are available.

**BayRidge Hospital:** This well-established 62-bed psychiatric hospital located in Lynn, a teaching site for Boston University Medical School, has a full-time position for an inpatient psychiatrist. Work with an excellent and supportive staff in a friendly atmosphere. There is no required night call, but lucrative coverage opportunities are available. Salary is competitive with an excellent benefit package including generous time off, and reimbursement for malpractice insurance and CME.

Contact: Barry Ginsberg, M.D., Chief, Department of Psychiatry. Phone (781) 477-6965, Fax (781) 477-6967; email address: bginsber@nhs-healthlink.org

#### STAFF PSYCHIATRIST

Opportunity for a Board-Certified/Board-Eligible Psychiatrist to join the expanding Mental Health Service at the Northampton VAMC. Experience or specialized training in geriatrics is highly desired, teaching, PTSD, and/or primary care psychiatry are a plus. Northampton is an active, diversified Medical Center, with 3 satellite outpatient clinics, a 16-bed substance abuse/compensated work therapy Psycho-social Residential Rehabilitation Treatment Program, 85 psychiatric inpatient beds, and 66 nursing home care unit beds. Specialized programs include PTSD, substance abuse, chronically mentally ill, and acute psychiatry. Opportunities are currently available for teaching residents as well as psychology and social work interns. Congenial work atmosphere, stimulating colleagues, and minimal night and weekend duties make this a very pleasant place to work. Northampton is located in the heart of the "five college" area of Western Massachusetts 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. This Medical Center is affiliated with Dartmouth Medical School for education and research. Competitive salary and federal benefits. EOE employer. Send CV to: Michelle Zehelski, Human Resource Staffing Clerk (05-HR), Northampton VA Medical Center, Leeds, MA 01053, (413) 584-4040, ext. 2124; FAX (413) 582-3146.

## SUPERVISORY PSYCHIATRIST

Opportunity for a Board-Certified/Board-Eligible Psychiatrist to join the expanding Mental Health Service at the Northampton VAMC. Experience or specialized training in geriatrics is highly desired, teaching, PTSD, supervisory experience and/or primary care psychiatry are a plus. This is a leadership position that includes supervision of psychiatrists and exciting program development opportunities to meet the needs of the new veteran population. Northampton is an active, diversified Medical Center, with 3 satellite outpatient clinics, a 16-bed substance abuse/compensated work therapy Psycho-social Residential Rehabilitation Treatment Program, 85 psychiatric inpatient beds, and 66 nursing home care unit beds. Specialized programs include PTSD, substance abuse, chronically mentally ill, and acute psychiatry. Opportunities are currently available for teaching residents as well as psychology and social work interns. Congenial work atmosphere, stimulating colleagues, and minimal night and weekend duties make this a very pleasant place to work. Northampton is located in the heart of the "five college" area of Western Massachusetts 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. This Medical Center is affiliated to the Dartmouth Medical School. Competitive salary and federal benefits. EOE employer.

Send CV to: Michelle Zehelski, Human Resource Staffing Clerk (05-HR), Northampton VA Medical Center, Leeds, MA 01053, (413) 584-4040, ext. 2124; FAX (413) 582-3146.

## MICHIGAN

### Medical Director Sault Ste. Marie, MI

**Horizon Health**, in partnership with **War Memorial Hospital in Sault Ste. Marie, MI**, seeks a **Medical Director** for a new 20-bed Adult Inpatient Psychiatric Program. The Upper Peninsula of Michigan is known as one of the most beautiful locations in all of the U.S., abounding in outdoor/recreational activities and possessing some of the most breathtaking scenery in North America. Excellent practice and income opportunity with employment contract offered through the hospital. Additional Medical Director stipend offered through Horizon Health. Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. EOE.

**GRAND RAPIDS: General & Child Psychiatrists.** Inpatient & outpatient for general & specialty programs. Great practice & patient care, collegial staff and community to live in. Top salary, benefits and more. Contact Joy Lankswert @ 866-227-5415; email joy.lankswert@uhsinc.com

**Rochester Hills, MI - Very Lucrative Practice Opportunity** - If being your own boss and having the freedom to set your own work schedule is what you've wanted, then please call me. This is an opportunity to open an inpatient (adult) and outpatient private practice in the Detroit area. Or if you have a practice already, adding our inpatient component to your income could be extremely lucrative. We will help market your practice in the area. Call is 1 in 4. 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. EOE

## MINNESOTA

### ROCHESTER, MINNESOTA ADULT PSYCHIATRIST

Olmsted County Community Services Behavioral Health Unit seeks a Board Certified adult psychiatrist for their Assertive Community Treatment Team. This multi-disciplinary team serves 100 Serious and Persistently Mentally Ill Adults. 32 hours per week, 8:00 a.m. to 5:00 p.m. Annual salary range depending on experience \$139K- 153K plus full benefits. No on call, no weekends, no holidays. Contact: Nancy Kolaas, 507-287-2243 or kolaas.nancy@co.olmsted.mn.us.

## Central Minnesota-Lake Country

**Fulfilling career. Fulfilling quality of life.** St. Joseph's Medical Center, a 162-bed, JCAHO, acute-care, community referral hospital located in Brainerd, MN has excellent opportunity for a BC/BE psychiatrist to join an established practice providing in-patient and out-patient psychiatric care of adolescents through geriatric. Enjoy a friendly and collegial relationship with five other psychiatric providers and experienced staff at the 22-bed unit. In-patient call coverage is 1:6. Out-patient clinic services at the SJMC's psychiatric clinic as well as other community clinics. Excellent compensation package including relocation and sign-on bonus. Located an easy drive just 125 miles north of the Twin Cities, Brainerd MN is situated among 450+ 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. Contact: Nancy Juntunen, Physician Recruitment at nancy.juntunen@sjmcmn.org , 218-454-5800. www.sjmcmn.org ; www.explorebrainerdlakes.com AA/EOE

## MISSISSIPPI

### BC/BE Psychiatrist

North Mississippi State Hospital (NMSH), a facility of the Department of Mental Health, is seeking a Board-certified or Board-eligible psychiatrist. NMSH is a 50-bed acute care psychiatric facility located in Tupelo, Mississippi. Treatment and services are prepared and carried out through an interdisciplinary approach by a team of professionals including psychiatrists, psychologists, medical doctors, nurse practitioners, nurses, social workers, and others. Qualifications include graduation from an accredited School of Medicine and a license to practice (or immediate eligibility for licensure) in the State of Mississippi. Competitive benefits offered by the State of Mississippi. Please send DV to: Johnny Anderson, Director of Human Resources, North Mississippi State Hospital, 1937 Briar Ridge Road, Tupelo, MS 38804, Phone 662.690.4222, FAX 662.690.5733; Email janderson@nmsh.state.ms.us.

## MISSOURI

### CHILD PSYCHIATRIST

A Board Certified, or Board Eligible Child Psychiatrist to provide psychiatric services to children, adolescents, and their families is being sought by Community Treatment, Inc. COM-PREA is a comprehensive not for profit mental health and chemical abuse treatment center located a few minutes south of St. Louis, MO. This full time position requires proven ability to work as a member of a treatment team, monitor client care, and skills to document client contacts, interventions and medications of clients. Apply on line at www.comtrea.org or email resume to hrs@comtrea.org. E.O.E.

### PSYCHIATRIST

Southwest Missouri Psychiatric Rehabilitation Center, a state run In-patient facility serving both acute and long-term clients, located in the scenic Ozarks of Southwest Missouri is seeking a half-time Psychiatrist. The position will have an active role as lead member of an interdisciplinary treatment setting dedicated to quality service. Minimum qualifications include: M.D. or D.O. with residency completion in psychiatry, board eligible or board certified, and licensed to practice in Missouri. The facility is located in a relaxed rural setting within a short driving distance of major metropolitan and lake resort areas. Salary and schedule negotiable.

Please forward Curriculum Vita to:  
**Human Resources, Southwest Missouri Rehabilitation Center,  
1301 Industrial Parkway  
East, El Dorado Springs, Missouri 64744,  
Fax to 417-876-1004 or e-mail  
james.stacy@dmh.mo.gov**

The Missouri Department of Mental Health does not deny employment or services because of race, sex, creed, marital status, national origin, disability or age of applicants or employees.

## MEDICAL DIRECTOR/EXECUTIVE VICE PRESIDENT

Community Treatment, Inc., a comprehensive not for profit mental health and chemical abuse treatment center located minutes south of St. Louis, MO, is seeking a Medical Director to carry out the purpose, policies and programs of their Medical Services Division. Will be involved in administration and management, facilitate program development, participate in community/public relations and perform direct psychiatric services. This full time position requires Board Certification, five years experience in psychiatric service delivery and three years supervisory experience. Apply on line at www.comtrea.org or email resume to hrs@comtrea.org. E.O.E.

### POPLAR BLUFF GATEWAY TO THE OZARKS

Busy Group Practice seeks additional BC/BE psychiatrist to see adults & adolescents. Out-patient only Mon. - Fri. 8am - 5pm. **No Call.** Competitive salary with bonus incentive plus medical, dental, disability, life and malpractice insurance and an excellent retirement plan. **J-1s encouraged to apply.** Located in the foothills of the Ozarks, Poplar Bluff serves a population of 150,000 and has a diversified economy, AAA-rated public schools, and low cost-of-living. **www.poplarbluffchamger.org** Additional info on our website: www.kneibert-clinic.com Please call **Tom Warner: (573) 778-7175; or Email: twarner@kneibertclinic.com or mail CV to: 686 Lester St., Poplar Bluff, MO 63901.**

**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 of \$210k plus benefits plus an extremely lucrative bonus plan.** A practice guarantee and directorship stipend is also an option. Very low stress work environment; very experienced, quality staff in place that make the psychiatrist's life so much easier; 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.

## NEBRASKA

**Nebraska Psychiatry!** Great Opportunity! Nebraska Hospital seeks Adult Psychiatrist! Wonderful support staff, AMAZING SALARY, great benefits package! Will consider J-1's. Compensation over 200k! One of many J-1 opportunities available across the country! For more information on this opportunity or others located nationwide, contact Lindsay McCartney at: (800) 735-8261 ext 213; FAX your CV to: (703)-995-0647 or Email: lmccartney@medsourceconsultants.com

## Issue Deadlines:

**Oct 19 issue - Oct 5**

**Nov 2 issue - Oct 19**

**Nov 16 issue - Nov 2**

**Dec 7 issue - Nov 21**



## NEVADA

### SOUTHERN NEVADA ADULT MENTAL HEALTH SERVICES

**ADULT PSYCHIATRISTS:** Southern Nevada Adult Mental Health Services, a JCAHO accredited State Agency, is recruiting BC/BE adult psychiatrists to join an integrated community mental health system of 50 psychiatrists and allied mental health providers in Las Vegas, NV. Area qualified for J1/H1 visa psychiatrists. Our practice is focused on the seriously mentally-ill and our philosophy is based on the community recovery model. In-patient and out-patient positions are available. Rawson-Neal is a 235 bed state-of-the-art facility which includes a 30-bed psychiatric observation unit. Community clinics offer walk-in, counseling, medication and pharmacy services. Treatment support programs include residential, case coordination and PACT/ACT teams. Specialized community services are available for co-occurring disorders, seniors, court diversion and more. Competitive salary, excellent benefits, limited on-call and malpractice make this an attractive opportunity. Teaching affiliation with the University of Nevada School of Medicine and relocation package are also available. Nevada has NO STATE INCOME TAX.

For additional information see our web site <http://mhds.state.nv.us/sn/index.shtml>.

Submit letter of interest and CV to Jackie Arellano @ [jarellano@snamhs.nv.gov](mailto:jarellano@snamhs.nv.gov)

## NEW HAMPSHIRE

### PSYCHIATRIST Portsmouth, NH

Beautiful Seacoast area with four seasons, 55 minutes from Boston. Expanding private, non-profit 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

### 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](mailto:Humanresources@mfs.org)

**New Hampshire - Medical Director** - Full-time BE/BC fellowship-trained geriatric psychiatrist Program includes 10-bed inpatient unit, an outpatient clinic, and nursing homes. Physician will be a hospital employee and will enjoy a four-day work week with light call of 1:4. Salaried position with comprehensive benefits. Contact Michelle "Mickey" Conner at [mconner@hortonsmithassociates.com](mailto:mconner@hortonsmithassociates.com) or call 866-464-3428.

## NEW JERSEY

### PSYCHIATRISTS Earn up to \$200K plus benefits

Get inside the criminal mind and make a difference. University Correctional HealthCare (UCHC), a branch of the University of Medicine and Dentistry of New Jersey (UMDNJ), currently has regular (full-time and part-time) and per diem openings for psychiatrists throughout the state. We are dedicated to providing excellent mental health and rehabilitative services to our patients.

As a psychiatrist, you will have the unique opportunity to work with interesting patients and stimulating colleagues within the New Jersey Department of Corrections' prisons. We offer a comprehensive benefits package and a salary of up to \$200,000 depending upon location, board certification, and experience. You will work with a multidisciplinary team and a state-of-the-art medical record. With minimal call, flexible hours, no managed care, no insurance forms, and an emphasis upon treatment rather than paperwork, isn't it time you discovered the difference you can make with University Correctional HealthCare.

Please apply via our website at [www.umdny.edu/hrweb](http://www.umdny.edu/hrweb) or e-mail our Medical Director, Rusty Reeves, M.D., at [reevesdo@umdny.edu](mailto:reevesdo@umdny.edu). UMDNJ is an affirmative action/equal employment opportunity M/F/H/V and is a member of the University Health System of New Jersey.

**Psychiatrist** - Established, for profit outpatient mental health practice with offices in South Jersey and Philadelphia. Immediate opening for experienced Adult Psychiatrist and Child and Adolescent Psychiatrist. Excellent referral base and reputation. Private practice model within comprehensive multi-disciplinary group of highly qualified clinicians. Fax CV to 856-985-8148 or call 856-983-3866 ext. 3018.



**P/T Psychiatrist** (10 hrs per week) in Program for Assertive Community Treatment (PACT). Responsibilities include: Psychiatric evaluation and medication management in a community & office setting; provide education regarding psychiatric disorders & their treatments; participate in the formulation of treatment plans as a member of an interdisciplinary team; and other duties as assigned. Must possess a current NJ medical license, DEA registration & NJ CDS registration; Board Certified; & a valid driver's license. Please email or fax CV w/ salary requirements to: [jillp@careplusnj.org](mailto:jillp@careplusnj.org) Fax: 201-265-6908 EOE

## NEW YORK STATE

### Psychiatrist / Mental Health Nurse Practitioner

Psychiatric Services of Orange and Sullivan is seeking Psychiatry providers to join this successful Psychiatric practice in Chester, New York. The candidate should be interested in a full time private practice providing Psychiatric evaluations, follow-up visits and medication management. Scheduling is flexible, but a minimum of 40 hours of patient care is required per week. Hospital affiliations are optional. New York State licensure, board certification or eligibility in psychiatry are essential. The candidate should feel comfortable treating children and adolescents as well as adults and seniors. We offer a competitive compensation and benefit package. Interested parties should forward a letter of interest and a CV in confidence to the [ludwigsengroup@frontiernet.net](mailto:ludwigsengroup@frontiernet.net) or fax to 845-858-4540.

## GREATER BINGHAMTON HEALTH CENTER

### ADULT PSYCHIATRISTS 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 adult inpatient facility and **CHILD/ADOLESCENT PSYCHIATRISTS** for its Child/Adolescent Behavioral Health Center. Abundant on-site CME. Salaried, permanent positions with excellent New York State benefits. No evening or weekend call required. Compensated optional call available. Enjoy the reasonable cost of living Central New York offers with easy access to NYC and other major cities.

Submit CV to:  
Human Resources  
Greater Binghamton Health Center  
425 Robinson St., Binghamton, NY 13904  
Fax: (607) 773-4117. EOE/AEE

### Albany/Saratoga Springs New York

### Associate Medical Director of Behavioral Health

WellPoint is the largest health benefits company in America and is an independent licensee of the Blue Cross and Blue Shield Association. Our success reflects the excellence and dedication of our associates. We are currently seeking an experienced individual to provide leadership for the clinical and quality activities of the Medical Director, ensuring the integrity of our clinical programs.

Responsibilities include providing daily support to clinicians, participating in peer-to-peer discussions and office visits with providers and physicians, participating in physician on-call rotation for a 24x7 pre-certification unit, assisting in appeal reviews, medical policy and technology assessments, setting and implementing QI initiatives, and credentialing.

Board certified Psychiatrist (MD or DO), 5+ years clinical experience with medical management, excellent communication, negotiation, and leadership skills.

Please contact Christine Solet at **800-445-3020 x7549**, e-mail [christine.solet@wellpoint.com](mailto:christine.solet@wellpoint.com), or apply online at [www.wellpoint.com](http://www.wellpoint.com). EOE, M/F/D/V

## NORTH CAROLINA

**Beautiful and Historic Metropolitan city in North Carolina!** Short drive to **Raleigh!!!** Local health care system looking for many psychiatrists to join their already dynamic team! Openings for **Adult Outpatient, Adult ER, Adult Inpatient/Outpatient, and Child & Adolescent Outpatient!!!** Lucrative salary offered for all positions plus highly competitive bonus structure in place bringing most physician's compensations to 250K!!!! Potential sign on bonus and relocation offered as well! For more information on this or any of our other hundreds of opportunities nationwide, contact Ariana Sanjabi @ 800-735-8261 x 214; fax your CV to 703-995-0647 or email: [asanjabi@medsourceconsultants.com](mailto:asanjabi@medsourceconsultants.com).

### Private Practice Opportunities in North Carolina.

**Carolina Partners in Mental HealthCare, PLLC** is seeking BE/BC psychiatrists for our practices in Raleigh, Chapel Hill and Wake Forest, NC. Private outpatient practices, full partnership from day one - no investment required. FT, PT flexible. Carolina Partners has seven offices in Raleigh, Durham, Chapel Hill, Pittsboro and Wake Forest, North Carolina. Good opportunity to control your life and clinical practice, while making a good income! Contact Executive Director or send CV to: Carolina Partners in Mental HealthCare, 1502 W. Hwy 54, Suite 103, Durham, NC 27707. Phone 919-967-9567; Fax 801-729-9867; EMail [carolinapartners@bellsouth.net](mailto:carolinapartners@bellsouth.net).

**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](mailto:Janet.Rasmussen@med.va.gov). EOE.



### "Make Your Match with PracticeMatch" Nash Health Care Systems Ranked Among NC's Best Hospitals

### Adult Psychiatry Position - Employed or Private You Decide

Various Employment Options Available  
Compensation Commensurate with Experience  
Comprehensive Benefits Include Paid Malpractice if Employed  
Serve Only One Hospital  
Country Club Setting  
50 Bed In-Patient Facility  
Service Area Over 400,000  
EMR System  
1:4 Call

*"Nash Health Care Systems' work to deliver the best health care providers, technology, and techniques for our patients is the passion that drives us."*

Contact: Amanda Patton, 800-489-1440 x6559  
[amanda.patton@practicematch.com](mailto:amanda.patton@practicematch.com)  
[www.practicematch.com/nash](http://www.practicematch.com/nash)



### "Make Your Match with PracticeMatch" Manage and Develop New Programs Modern JCAHO Mental Health In-Patient Hospital is Looking for a New Psychiatry Medical Director

Employed Medical Director Position  
Compensation Based on Level of Experience  
Manage and Develop New Programs  
Comprehensive Benefits Include Paid Malpractice  
Serve Only One Hospital  
Country Club Setting  
50 Bed In-Patient Facility - JCAHO Accredited  
Service Area Over 400,000  
EMR System  
Must Have Some Medical Director Experience 1:4 Call

*"Nash Health Care Systems' work to deliver the best health care providers, technology, and techniques for our patients is the passion that drives us."*

Contact: Amanda Patton, 800-489-1440 x6559  
[amanda.patton@practicematch.com](mailto:amanda.patton@practicematch.com)  
[www.practicematch.com/nash](http://www.practicematch.com/nash)



### 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](mailto:elaine.haskell@carolinashealthcare.org)

(EOE).

**Eastern NC - 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](mailto:terry.good@horizonhealth.com). Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

**CLOSE TO RALEIGH AND GREENVILLE - VERY LUCRATIVE COMPENSATION PACKAGE** - Horizon Health seeks a Psychiatrist for a Medical Director position on an adult unit and CD unit in a very impressive general hospital in Rocky Mount. Offering a salary with benefits plus bonus plan or practice guarantee and stipend. What a great location! Enjoy the wonderful climate and quality of life this lovely area 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](mailto:terry.good@horizonhealth.com). Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

## OHIO

### PSYCHIATRISTS NEEDED

The Ohio Department of Mental Health is recruiting:

**Staff Psychiatrists** in Athens, Cambridge, Cleveland, Columbus, Cincinnati, and Toledo for the Behavioral Healthcare facilities.

**Assistant Medical Director** is needed in Massillon

Competitive salaries are offered for a Monday to Friday, 8-5, work week. Academic affiliations are possible at all locations and malpractice insurance is paid. Educational loan reimbursements along with a generous benefit package are available for the right candidates. Ohio's educational and recreational opportunities support a strong family life.

J-1 opportunities are also available in ODMH. To learn more, contact:

Dale Svendsen, M.D. Medical Director  
Demetra Mutchler, Recruitment Manager  
[mutchlerda@mh.state.oh.us](mailto:mutchlerda@mh.state.oh.us)  
(614) 466-9916

### CINCINNATI SUBURB - GEROPSYCH

Staff Psychiatrist position available on 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 with some medical floor consults; nursing home work is available if desired as well as work on adult unit. 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](mailto:terry.good@horizonhealth.com). Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

### PSYCHIATRIST - COLUMBUS, OHIO

Provide outpatient psychiatric care and psychiatric consultation services to veterans at the Columbus VA and/or satellite Community Based Outpatient Clinics.

Non-citizen applicants will be considered if no US citizens are available. Require a BC/BE or equivalent experience and possess a valid and unrestricted license.

Applications will be accepted on a continuous basis.

Salary range from \$91,530 to \$175,000, in addition we offer recruitment incentives, reimbursement for relocation expenses and the opportunity to apply for the Employee Debt Reduction Program.

Benefits include:

- 26 days of paid vacation/personal leave
- 13 days of paid sick leave
- 15 days of paid military leave
- 10 paid Federal holidays
- Family & Medical Leave
- Generous retirement package
- Group life insurance plans with the majority of premium paid by the Federal government
- Term life insurance, family and additional coverage options
- Manageable workload - no night or weekend call
- Liability protection

For more information, contact Laurie Benn at (614)257-5507 or (888)615-9448 or Laurie.Benn2@va.gov

Columbus VA Outpatient Clinic,  
Columbus, Ohio  
EOE/Random Drug Screen



### 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](mailto:mark.blakeney@horizonhealth.com). EOE.

## OREGON

### Bend, Oregon

Private practice opportunity with a group of five psychiatrists in Bend, Oregon. The practice is a "virtual group practice" where we share call coverage, office expense and general hospital inpatient responsibilities at St. Charles Medical Center. The practice you establish is your practice with referral assistance from the group and a modest buy in. There is also a hospital practice development agreement from St. Charles, as well as moving and interview expenses paid. We are a congenial group. We also close the office on Fridays to enjoy the outdoor and recreational opportunities that Bend has. Bend is rated as one of the top places to live in the country. Bend is the "Aspen of Oregon" with wonderful skiing in the Cascade range at Mt. Bachelor, world class mountain biking, cycling, fly fishing and kayaking. Bend is a three and a half hour drive from Portland, Oregon and a four and a half hour drive from the beautiful coast of Oregon.

Call Magnus Lakovics, MD, Medical Director for Behavioral Health St. Charles Medical Center at 541-390 4418 or email CV and I will call you at [mlakovics@msn.com](mailto:mlakovics@msn.com)

### CHILD PSYCHIATRIST Salem, 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 Child Psychiatrist with our group in Salem, Oregon, 45 miles south of Portland, in the lush Willamette Valley.

The majority of the practice will include children and teens, but there is also a small percentage of adult work. Position requires experience in medication consultation, crisis intervention, and all treatment modalities. Involves direct clinical work with outpatients as well as providing consultation to other mental health professionals and medical specialists. The Department of Mental Health region-wide consists of a multi-disciplinary 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 the lifestyle associated with the Pacific Northwest, we provide a predictable work schedule, and a generous salary/benefit.

To submit your CV and learn more about this opportunity, please visit our website <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.

### 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 multi-disciplinary 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 Sunbury, PA

A Medical Director is needed for a 12-bed geriatric psychiatric program located within a 123-bed hospital. In this position, the Medical Director will be responsible for a complete practice experience working on inpatient program, which would include admission, diagnosis, treatment, management, and discharge of patients. Excellent Stipend offered with lucrative private practice potential. Sunbury, PA is located 1 hour north of Harrisburg, PA. For more information please contact Diane Odom, 972-420-4083, fax 972-420-8233, e-mail [diane.odom@horizonhelath.com](mailto:diane.odom@horizonhelath.com)



**Pennsylvania**-70 miles east of Pittsburgh - Memorial Medical Center, affiliated with Conemaugh Health System is seeking a BC/BE Child and Adolescent psychiatrist as Director of Child and Adolescent and an Adult Psychiatrist interested in seeing child and adolescent patients to join our hospital based psychiatry practice. Position will have Administrative and clinical responsibilities. Highly competitive compensation package, including a signing. The hospital is the largest and most comprehensive health care provider in west central Pennsylvania that provides a full range of services to thousands of patients and their families every year. Beautiful and family friendly community, one of the nation's lowest crime rates, a diversified economic base, outstanding school systems, short commutes and big-city amenities without big city hassles. Call **Mary Lynn Mahla** at (814) 534-3221 Email: [mmahla@conemaugh.org](mailto:mmahla@conemaugh.org) or fax at 814-534-3895

**Riverside Care, Inc. is expanding!** Currently seeking psychiatrists to assist existing medical staff in six outpatient treatment facilities in Southeastern and Eastern Pennsylvania. The psychiatrist is responsible for consultation and education including direct psychiatric services to patients and psychotropic medication management. Qualifications: must have a current PA State license w/ valid registration, a DO or MD degree, and completed a 3 yr residency in adult psychiatry. Current DEA registration and excellent organizational, verbal, and written skills a must. Please apply at [www.eaglevillehospital.org](http://www.eaglevillehospital.org) or fax resume to 610-539-8319.

**The Department of Psychiatry at the University of Pennsylvania School of Medicine** seeks candidates for an Assistant or Associate Professor position in the tenure track. Rank will be commensurate with experience. The successful applicant will have experience in the field of behavioral neuroscience with a focus on neuropharmacologic or neurogenetic approaches to psychiatric disorders. Responsibilities include interacting closely with members of the National Center for Drug Discovery Group focused on stress neurobiology/neuroplasticity. Applicants must have an M.D. or Ph.D. or M.D./ Ph.D. degree and have demonstrated excellent qualifications in Research. Candidates interested in interdisciplinary research with emphasis on behavioral neuropharmacology of stress, anxiety, & mood disorders are of particular interest. Strong academic background required. Demonstrated teaching excellence required for Associate Professor rank. Newly renovated laboratory space available. Please submit curriculum vitae, a letter of interest, and 3 reference letters to: Dwight L. Evans, M.D.; Irwin Lucki, Ph.D.; REF#68 @ A. Plotnick, Dept. of Psychiatry, Univ. of Penn School of Medicine, 305 Blockley Hall, 423 Guardian Dr., Phila., PA 19104 [plotnick@mail.med.upenn.edu](mailto:plotnick@mail.med.upenn.edu)  
The University of Pennsylvania is an equal opportunity, affirmative action employer. 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 Psychiatrist. Inpatient & sub acute programs for general psychiatric & addiction services. Salary, bonus, & benefits. Contact Joy Lankswert @ 866-227-5415 or email [joy.lankswert@uhsinc.com](mailto:joy.lankswert@uhsinc.com)

**Minutes from PHILADELPHIA!!!** Enjoy all the amenities of this historic exciting metropolitan city. Well established facilities have several opportunities available! 1. Adult psychiatrist 2. Director of Drug and Alcohol Residential Treatment Facility 3. Director of Inpatient Unit 4. C&A psychiatrist. Positions come with excellent salary and full benefits package. For more information on this or any of our other hundreds of opportunities nationwide, contact Carrley Ward @ 800-735-8261 x 219; fax your CV to 703-995-0647 or email: [cward@medsourceconsultants.com](mailto:cward@medsourceconsultants.com).



## RHODE ISLAND



**THE 1ST CHOICE IN  
PSYCHIATRIC RECRUITMENT  
Providence**

BC Child Psychiatrist all Out Patient  
For more information contact:  
**YVONNE CHAMBERS**  
(800) 783-9152 FAX (270) 782-1055  
[www.fcspsy.com](http://www.fcspsy.com)  
[admin@fcspsy.com](mailto:admin@fcspsy.com)

## SOUTH CAROLINA

**Associate Medical Director  
Spartanburg, SC**

**Horizon Health**, the nation's leader in psychiatric contract management, has an outstanding opportunity for a Psychiatrist to join thriving 15-bed geropsych inpatient unit in beautiful **Spartanburg, SC**. Associate Medical Director stipend of **\$150 per hour**. Enjoy a mix of both Outpatient and Inpatient practice. Flexible hours and part-time arrangement 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](mailto:mark.blakeney@horizonhealth.com). EOE.

**AIKEN:** Great location & family oriented community. **Child Psychiatrist** for inpatient & partial program patient care. Salary & benefits offered. Contact Joy Lankswert @ 866-227-5415 or email [joy.lankswert@uhsinc.com](mailto:joy.lankswert@uhsinc.com)

**ONE HOUR FROM MYRTLE BEACH & COLUMBIA - Medical Director, Inpatient and Outpatient Geriatric Psychiatry** - Due to growth, Horizon Health has an opening on a new 12-bed geriatric psychiatry program in a general hospital in Florence-a lovely area. The Behavioral Health program is part of a 372-bed hospital system that serves a nine-county area. The cost of living is relatively low in Florence and the residents are known for their southern hospitality. Offering directorship stipend and income guarantee, however, salary with benefits may be an option. Board Certification in Adult Psychiatry is required. Contact Terry B. Good, 866-865-7380, Fax: 804-684-5663; E-mail: [terry.good@horizonhealth.com](mailto:terry.good@horizonhealth.com). EOE

## TENNESSEE

**East Tennessee State University - College of Medicine - Department of Psychiatry and Behavioral Sciences - Two Full-Time Positions - General Psychiatrist and Child Psychiatrist - 770160, 814300 - RE-ADVERTISED.** Full-time positions available for General Psychiatrist and Child Psychiatrist. General Psychiatrist position may include inpatient and/or outpatient. Responsibilities include training of psychiatric residents and medical students and research activities. 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 a 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 [lovedayc@etsu.edu](mailto:lovedayc@etsu.edu). AA/EOE**

**Add an email/website link to  
your ad for only \$50!**

**Director of Residency Training  
Department of Psychiatry,  
Vanderbilt University**

Vanderbilt University is recruiting a Residency Training Director for the Department of Psychiatry. We are seeking an outstanding psychiatrist with strong academic credentials, significant executive or program administration experience, and the energy and vision to lead the residency program. The current Director is becoming Director of the Child & Adolescent Psychiatry Division of our Department. The program trains a total of 32 residents over four years and is fully accredited by the ACGME. The residents train at the Vanderbilt University Hospital, the Vanderbilt Psychiatric Hospital and the Nashville VA Hospital. The department has prominent research programs in mood, psychotic and substance-related disorders and benefits from the resources in molecular neuroscience, neuroimaging, and psychology research at Vanderbilt University. Vanderbilt is located in Nashville, Tennessee, an area with significant educational and cultural opportunities. This position offers a competitive salary.

To apply, candidates should send a letter of interest, CV, and the names of three persons to contact for references to: Sherron Buchanan, Assistant to Chair, Department of Psychiatry, 1601 23rd Ave. South, Suite 3060, Nashville, TN 37212

Vanderbilt University is an Affirmative Action/Equal Opportunity Employer with a strong institutional commitment to diversity in all areas.

## TEXAS

**Austin Psychiatrist looking for BE/BC**, Texas licensed Psychiatrist to join busy, well established out-patient private practice in Central Austin. Stable and competent support staff. Contact Robert E. Cantu M.D., P.A. at (512) 469-0536 or email [rcantumd@austin.rr.com](mailto:rcantumd@austin.rr.com).

**PSYCHIATRISTS: The Mental Health Mental Retardation Authority of Harris County (MHMRA)** in Houston, Texas is one of the largest mental health centers in the United States. Demands have created the need for additional psychiatrists throughout the Agency.

### Outpatient Clinics

Work a regular 8 to 5 PM, Monday through Friday schedule

Full-time and Part-time available

### Harris County Jail

Positions are to provide coverage for 7 days per week; 24-hours per day

Day, night, and weekend shifts are available  
These positions will be mostly medication management and psychiatric evaluations.

Physician assistant or advanced practice nurse with prescriptive authority may be considered for clinic and jail positions

**Texas licensure is required for all positions**

MHMRA offers competitive salary plus a generous benefit package. Houston offers excellent quality of life, lower than average cost of living, no state sales tax and exciting cultural, entertainment, sporting and tourists venues. **Contact Charlotte Simmons at (713) 970-7397, or submit your C.V. to [charlotte.simmons@mhmra.org](mailto:charlotte.simmons@mhmra.org), fax 713-970-3386, or apply online at [www.mhmra.org](http://www.mhmra.org).**

**HOUSTON** - The Menninger Department of Psychiatry and Behavioral Sciences of Baylor College of Medicine is seeking an experienced board-certified psychiatrist for **Chief of Psychiatry at Ben Taub General Hospital**, a major teaching, service, and research hospital of the College. Applicants with a current Texas Medical license and/or community hospital experience are encouraged to apply. Please send a confidential CV and any additional information which might be of use to the search committee to John Oldham, MD, Baylor College of Medicine, Department of Psychiatry, One Baylor Plaza, BCM350, Houston, TX 77030 or email [joldham@menninger.edu](mailto:joldham@menninger.edu) Baylor College of Medicine is an Equal Opportunity, Affirmative Action and Equal Access employer.



**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:

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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  
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3031 IH 10 West  
San Antonio, Texas 78201  
Fax: 210-731-1310  
[staffing@chcs.hhscn.org](mailto:staffing@chcs.hhscn.org)**

**EOE**

**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](mailto:np_associates@prodigy.net).

**Texas Forest Country - The Burke Center, a JCAHO accredited CMHC** serving East Texas, has an opening for either a full-time **general or child psychiatrist**. The position is outpatient only, M-F, 8-5, primarily based in Nacogdoches. Other options include part time employment, contract arrangements, and providing services by telemedicine from your home. Enjoy an excellent lifestyle with a 40-hour week, no call, competitive salary, fantastic benefits, low cost of living, and great recreational opportunities in nearby national forests. Houston is less than 2 hours away. Please fax or email CV to:

Mark Janes, M.D.  
Fax: (936) 634-8601  
Email: [markj@burke-center.org](mailto:markj@burke-center.org).

**HOUSTON - Endowed Chair for Senior Investigator in Mood Disorders at Baylor College of Medicine (BCM) and Houston VA** The Menninger Department of Psychiatry and Behavioral Sciences at BCM and the Houston Michael E. DeBakey Veterans Affairs Medical Center are recruiting an established independent investigator at mid-career or senior level to direct BCM senior programs in Mood and/or Anxiety Disorders. Requirements include doctoral degree in behavioral, medical, or social sciences related to Mood and/or Anxiety Disorders with a history of sustained federal funding, administrative and mentoring experience. Applicants must be United States citizens.

For more information, please visit our websites at <http://www.bcm.edu/psychiatry> and <http://www.hsrh.houston.med.va.gov>.

Applicants should email cover letter, CV and 6 names of references to: Thomas Kosten, M.D., Vice Chair of Psychiatry, c/o: [doloresr@bcm.edu](mailto:doloresr@bcm.edu). Baylor College of Medicine is an Equal Opportunity, Affirmative Action, and Equal Access employer.

**McALLEN and SAN ANGELO: Diverse TX locations offering great practice opportunities & income potential.** General, Geriatric or Child Psychiatrist - private practice. Service Directorship & caseload stipend offered as well as other practice start up support. Contact Joy Lankswert @ 866-227-5415 or email [joy.lankswert@uhsinc.com](mailto:joy.lankswert@uhsinc.com)

## VIRGINIA

**Central State Hospital** is seeking a psychiatrist with expertise in Public and/or Forensic Psychiatry. Applicants must be licensed or eligible for licensing by the Virginia Board of Medicine (Board certification is preferred.) CSH offers an outstanding benefits package, competitive salaries (up to \$173,289 based on training and experience), a high quality of life, and career enhancement opportunities. For more information on CSH and to apply for this position, please visit our website: [www.csh.dmhmrns.virginia.gov](http://www.csh.dmhmrns.virginia.gov) EEO/AA

Central State Hospital  
26317 W. Washington Street  
Petersburg, VA 23803  
p: 804-524-4451/7111

e: [employment@csh.dmhmrns.virginia.gov](mailto:employment@csh.dmhmrns.virginia.gov)

### Chair, Addictions Psychiatry

The Department of Psychiatry, Medical College of Virginia at Virginia Commonwealth University, in collaboration with VCU Institute for Drug and Alcohol Studies, is recruiting a strong academic leader to chair the Division of Addiction Psychiatry. Doctoral level applicant should have career commitment to addictions research and a track record of research/funding. Responsible for developing teaching and clinical programs needed to support teaching/research. Resources available to support an expanded research program. Funded ACGME accredited Fellowship Program. We have strong programs in psychiatric genetics, epidemiology, pharmacology, toxicology, and women's health. Laboratory and community based research are active areas for collaboration. New Dean is a strong supporter of psychiatric research. Department of Psychiatry has over 85 full-time faculty, 38 residents, multiple fellowships and research centers. VCU is a large urban university with robust health science campus and 750-bed university hospital. Richmond, the State Capital, has moderate climate, a rich history, cultural activities, excellent choices for urban, suburban, or country living, outstanding public/private schools. See comparative cost of living via Internet at [www.coli.org/](http://www.coli.org/). Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Women, persons with disabilities, and minorities are encouraged to apply. Send applications to Joel J. Silverman, M.D., Chairman, c/o Marie Baker-Roach, Department of Psychiatry, MCV/VCU Box 980710, Richmond, VA 23298.

**VIRGINIA COMMONWEALTH UNIVERSITY:** Dept. of Psychiatry recruiting BE/BC faculty psychiatrist at **Assistant or Associate Professor level**, for mixed inpatient-outpatient position. Inpatient responsibilities include daily teaching rounds on nine beds acute inpatient unit, and outpatient work includes supervision, faculty practice, and visiting community geriatric locations. Fellowship in geriatrics preferred. Pursuit of scholarly work encouraged and supported. VCU is a large urban university with robust health science campus and 750 beds university hospital. Department of Psychiatry employs over 85 full time faculty and is nationally ranked in federally funded research. Richmond, the State Capital, has moderate climate and a rich mix of historical and contemporary facilities. Excellent suburban housing, public/private schools. Internet provides comparative cost of living. Send CV to Marie Baker-Roach, Human Resources, Department of Psychiatry, VCU/MCV, Box 980710, Richmond, VA 23298. VCU is an EEO/AA employer. Women, minorities, and persons with disabilities encouraged to apply.

**Virginia Licensed Psychiatrist** to join a large multi-disciplinary group of providers w/ several locations in the Virginia Beach area. Excellent compensation & benefits. Fax Resume to: Christian Psychotherapy Service, 757-497-1327 or call 757-490-0377.



## Child Psychiatrist

Virginia Commonwealth University: Medical College of Virginia Hospitals, Division of Child & Adolescent Psychiatry in the Department of Psychiatry, recruiting Virginia license-eligible BE/BC child psychiatrist faculty as Inpatient/ Outpatient attending. Position located in professional shortage area; J-1 candidates welcome to apply. Will be responsible for administration and clinical care as well as teaching and supervision of medical students, residents and child fellows. In addition, consultation work with community agencies will be available. Interest in teaching and academic work, as well as ability to work on interdisciplinary team, required. Department has nine fulltime child psychiatrists and child research institute, over 85 fulltime faculty and well-funded research in genetics, addictions, child and women's mental health and psychopharmacology. VCU is a large urban university with robust health science campus and 750-bed university hospital. Richmond, the State Capital, has moderate climate and rich mix of history with modern facilities, excellent suburban housing, public/private schools. See comparative cost of living via Internet at [www.coli.org/](http://www.coli.org/). Send CV to Bela Sood, MD, c/o Marie Baker-Roach, VCU, Box 980710, Richmond VA 23298. Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Women, minorities, and persons with disabilities are encouraged to apply.



### Psychiatrist - Multiple Opportunities Available Carilion Clinic - Virginia

Carilion Clinic in Roanoke, VA has an opening for a full-time BE/BC adult Psychiatrist at Carilion Roanoke Memorial Hospital, an 843-bed academic/tertiary referral center in with 32 acute adult psychiatric beds. Responsibilities include outpatient clinical services for the Department of Psychiatry and Behavioral Medicine, along with teaching medical students and supervising residents in psychiatry. In collaboration with Virginia Tech, Carilion Clinic is establishing its own allopathic medical school opening Fall 2010 with a problem-based learning curriculum. Call 1:10.

Carilion New River Valley Medical Center in Christiansburg, VA has an opening for a full-time BE/BC adult Psychiatrist at Saint Albans Behavioral Health, located at 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 Virginia Tech in nearby Blacksburg. Call 1:7.

*Weekend positions also available in Roanoke and Christiansburg locations.* See new patients, do consults and round on 75% of patients over course of two 16-hour weekend shifts (Saturday/Sunday). One weekend off per quarter. Work an additional 2 hours per week with Chair of Psychiatry on projects and qualify for full-time benefits.

Positions include a competitive base salary augmented with a substantial bonus for quality, plus additional compensation for meeting productivity targets and comprehensive benefits package, including relocation. For more information or to submit your CV and cover letter for consideration, contact:

Rhonda B. Creger, Senior Consultant,  
Professional Staffing  
Carilion Clinic  
800-856-5206 or [rhondac@carilion.com](mailto:rhondac@carilion.com)  
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## 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 [MultiCareHealthSystemProviderServices@providerservices@multicare.org](mailto:MultiCareHealthSystemProviderServices@providerservices@multicare.org) or fax your CV to 866-264-2818.

Refer to opportunity #534-645

### Puyallup, WA - Psychiatry ARNP

The growing community of Puyallup, Washington is seeking a psychiatric ARNP to provide psychiatric evaluations and psychiatric medication management to individuals receiving counseling services at Good Samaritan Behavioral Healthcare. Experience and expertise working with children and adolescents is essential although there is the opportunity to work with clients of all ages. Located 40 minutes south of Seattle and 30 minutes from an international airport, Puyallup and the surrounding communities provide a broad range of educational and cultural activities for all ages. Nestled between the Cascade Mountains and the shores of Puget Sound, the region's year round temperate climate affords outdoor enthusiasts endless recreational opportunities. 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 call 800-621-0301 or email your CV to [blazenewtrails@multicare.org](mailto:blazenewtrails@multicare.org) or fax your CV to 866-264-2818.

Refer to Opportunity #566-739

### MultiCare is a Drug Free Workplace

**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 up to \$158,304 DOQ. 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](mailto:JONESNL2@DSHS.WA.GOV).

**The University of Washington and Harborview Medical Center (HMC)** in Seattle, WA is accepting applications for a full-time geriatric psychiatrist (MD degree) at the rank of Instructor or Assistant Professor. This position is 1.0 FTE and will work half time doing hospital consultation work with a large team consisting of another psychiatrist, psychologist, nurse and social worker. The other half time will be spent working in geriatric outpatient services. The position will also be responsible for teaching residents and medical students. Start date January 1, 2008. **Please send application and CV to Peter Roy-Byrne MD, Chief Psychiatry, Harborview Medical Center 325 9th Ave. Box 359911, Seattle, WA 98104.** The UW is building a culturally diverse faculty and strongly encourages applications from females and minority candidates. The UW is and EOE/AA employer. University of Washington faculty engage in teaching, research, and service.

## Puyallup, WA - Psychiatry

The growing community of Puyallup, Washington is seeking a BC/BE psychiatrist to provide psychiatric evaluations and psychiatric medication management services to individuals receiving counseling services at Good Samaritan Behavioral Healthcare. Experience and expertise working with children and adolescents is essential although there is the opportunity to work with clients of all ages. Located 40 minutes south of Seattle and 30 minutes from an international airport, Puyallup and the surrounding communities provide a broad range of educational and cultural activities for all ages. Nestled between the Cascade Mountains and the shores of Puget Sound, the region's year round temperate climate affords outdoor enthusiasts endless recreational opportunities. 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 call 800-621-0301 or email your CV to [blazenewtrails@multicare.org](mailto:blazenewtrails@multicare.org) or fax your CV to 866-264-2818.

Refer to Opportunity ID #565-739

### MultiCare is a Drug-Free Workplace

## WISCONSIN

### Adult Psychiatrists

### Child and Adolescent Psychiatrists

The University of Wisconsin Department of Psychiatry is seeking BC/BE Child and Adolescent Psychiatrists and BC/BE Adult Psychiatrists to join our expanding clinical and research programs. Primary responsibilities include outpatient or inpatient clinical care, supervision of residents, and teaching of medical students and residents. Administrative and research experience is highly valued. Candidates will also have the opportunity to participate in collaborative and independent research within a Department nationally recognized for excellence in developmental and emotions research.

Please send letter of interest and your CV to:

Jeff Charlson  
Department Administrator  
University of Wisconsin School of Medicine  
and Public Health  
Department of Psychiatry  
6001 Research Park Boulevard  
Madison, WI 53719  
or via email to [jtcharls@wisc.edu](mailto:jtcharls@wisc.edu)

**Madison, WI** - noted as "U.S. Best City", two years, seeks a BC/BE child psychiatrist. *Capitol Associates*, well-recognized for more than 20 years, is Madison's largest, independent, licensed mental health clinic and is dedicated to comprehensive inpatient/outpatient care. CA boasts 14 mental health professionals, including 2 psychiatrists. A university town surrounded by many lakes, Madison has abundant recreational activities, high educational standards and support for the arts. Please consider joining our caring, energetic team. Capitol Associates, LLC, Attention: Johna Gerasch, PhD (Managing Partner), 440 Science Dr., Suite 200, Madison, WI 53711. (608) 238-5176, ext. 314.

## WYOMING

**WYOMING: General Psychiatrist.** Position duties include covering Inpatient and Outpatient services in a private hospital setting. Salary, benefits and bonus. Join a great staff & stable physician team. Contact Joy Lankswert @ 866-227-5415 or email [joy.lankswert@uhsinc.com](mailto:joy.lankswert@uhsinc.com)

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## Fellowships

**RESEARCH FELLOWSHIPS IN GERIATRIC PSYCHIATRY:** Department of Psychiatry, Columbia University, College of Physicians and Surgeons-New York State Psychiatric Institute. This is a two to three year NIMH sponsored program to prepare promising M.D.'s and Ph.D.'s for a career as an independent clinical investigator. Training includes work with a mentor and courses in statistics, research design, translational research, ethics and grant writing. Open to M.D.'s and Ph.D.'s. Position available for July 1, 2008. **Deadline for receipt of application: December 15, 2007.** Applicants should send a resume and/or request an application/brochure from the director of the fellowships: Contact: Steven P. Roose, M.D., NYS Psychiatric Institute, 1051 Riverside Drive, Unit 98, New York, NY 10032: Tel: (212) 543-5749: Fax: (212) 543-5607: E-mail: [Spr2@columbia.edu](mailto:Spr2@columbia.edu). Columbia University is an Affirmative Action/Equal Employment Opportunity Employer especially interested in recruiting minorities and women.

### RESEARCH FELLOWSHIPS BASIC AND CLINICAL STUDIES ON PSYCHIATRIC DISORDERS

Department of Psychiatry, Columbia University (New York State Psychiatric Institute & Creedmoor Psychiatric Center), through NIMH support, offers two to three year post-residency fellowships starting July 2008 in research on affective, anxiety, eating, schizophrenia, and other psychiatric disorders, training in research techniques including brain imaging, genetics, animal studies, epidemiology and clinical trials. These fellowships train psychiatrists for grant submissions and independent research. The stipend is approximately \$83,500.00 for those who have completed residency training. **Deadline for receipt of application: November 30, 2007.** Applicants should send a resume and/or request an application/brochure from: Steven P. Roose, M.D., NYS Psychiatric Institute, 1051 Riverside Drive, Unit 98, New York, NY 10032: Tel: (212) 543-5749: Fax: (212) 543-5607: E-mail: [Spr2@columbia.edu](mailto:Spr2@columbia.edu). Columbia University is an AA/EEO employer especially interested in recruiting minorities and women.

### 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](mailto:czeanah@tulane.edu). Tulane is strongly committed to policies of non-discrimination and affirmative action in student admission and in employment.

### Psychiatry Fellowships

Virginia Commonwealth University, Department of Psychiatry is offering ACGME fellowships in Geriatrics, Psychosomatics and Forensics. Competitive salary and allowances. Fellowships offer broad-based training in inpatient/outpatient settings, focusing on acute and chronic disease, consultation services, private evaluations, seminars, research and teaching experiences. Applicants must demonstrate good communication skills, and have completed approved residency in psychiatry. J-1 applicants eligible. Applications should be sent to Joel Silverman, MD, Chairman, c/o Marie Baker-Roach, Department of Psychiatry, Box 980710, Richmond, VA 23298-0710. Virginia Commonwealth University is Equal Opportunity/Affirmative Action employer and encourages applications from women, minorities, and persons with disabilities.



**PSYCHOSOMATIC MEDICINE  
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This ACGME-accredited one-year fellowship has positions available at the PGY-V level or above, starting July 1, 2008, as well as PGY-IV chief resident positions (PGY-IV training would not qualify for subspecialty certification). The program offers training in inpatient and outpatient consultation-liaison psychiatry at Yale New Haven Hospital and at the VA Connecticut Healthcare System, with multiple specialty electives. An Equal Opportunity employer. Please contact Paul Desan, MD, PhD, Yale New Haven Hospital, 20 York St CB2039, New Haven, CT 06504, paul.desan@yale.edu, (203) 785-2618.

**University of Rochester  
Geriatric Psychiatry Fellowship**

**DESCRIPTION:** The University of Rochester Geriatric Psychiatry Program offers one-year PGY-5 clinical fellowships in Geriatric Psychiatry. Ours is an ACGME accredited program, successful completion of which makes graduates eligible for the ABPN subspecialty examination in geriatric psychiatry. The fellowship offers training in the care of older patients in a variety of inpatient, long-term care, outpatient, consultation, and palliative care settings. Supervised clinical experiences are complemented by a didactic program, elective offerings, and opportunities to develop individual scholarly and research interests. In addition to the breadth of our clinical programs and patient populations, we have a large cadre of experienced and nationally recognized clinicians, teachers, and researchers serving on our faculty. We pride ourselves on providing a stimulating, rewarding educational experience in a supportive and nurturing environment.

**CONTACT:** For more information please contact Jeffrey M. Lyness, M.D., Director, Geriatric Psychiatry Fellowship, Department of Psychiatry, University of Rochester Medical Center, 300 Crittenden Boulevard, Rochester, NY 14642-8409 (Phone 585-275-6741; Fax 585-273-1082; E-Mail Jeffrey\_Lyness@urmc.rochester.edu) Website: www.urmc.rochester.edu/smd/psych/educ\_train/fellowship/geriatrics/index.cfm

The University of Rochester is an equal opportunity/affirmative action employer. Applications from women and minority groups are encouraged.

**Geriatric Psychiatry Fellowship with Emphasis  
on Integrated Consultation-Liaison Psychiatry**

Stony Brook University's Department of Psychiatry and Behavioral Science announces the availability of an innovative ACGME-accredited geriatric psychiatry fellowship position starting July 2008 with the option for special emphasis on consultation-liaison psychiatry. With eight board-certified geriatric psychiatrists on the faculty, the geriatric psychiatry fellow will have dedicated experiences in geriatric inpatient, long-term care, outpatient, ECT, and consultation-liaison psychiatry at both the University Hospital as well as several community settings. Located within the new Stony Brook Division of Medical and Geriatric Psychiatry, fellows in geriatric psychiatry will participate in a clinical milieu emphasizing understanding the psychiatric aspects of medical conditions along with the medical aspects of psychiatric conditions. Fellows have the unusual opportunity through collaborative consultation-liaison work to develop added clinical expertise and professional relationship skills working closely with trainees and faculty in geriatric medicine, neurology, and family medicine. To apply for the position send by U.S. mail, fax (631) 444-7534, or e-mail [steven.cole@stonybrook.edu](mailto:steven.cole@stonybrook.edu) your letter of interest, your CV, and three letters of reference to Steven Cole, M.D., Head, Division of Medical and Geriatric Psychiatry Health Sciences Center, 10th Floor, Room 042, Stony Brook NY 11794-8101. Equal opportunity/affirmative action employer. Visit [www.stonybrook.edu/jobs](http://www.stonybrook.edu/jobs) for employment information.

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**Department of Health and Human Services  
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National Institute of Mental Health  
(Position Available)**

The National Institute of Mental Health (NIMH), a major research component of the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS), offers a full-time Clinical Fellow position for a PGY-4 or PGY-5 physician at one of the premier research sites in the U.S., the 300 acre Bethesda campus of the NIH, near Washington D.C. which houses state-of-the-art facilities dedicated to research. The strong scientific environment and outstanding equipment resources at NIH make this a unique opportunity for an outstanding scientist/physician. The position is open to MD's trained in psychiatry or neurology and will be hired as Clinical Fellows. The candidates' function would be to assist in the management of an 11-bed inpatient facility dedicated to schizophrenia research at the Clinical Research Center in Bethesda, Maryland, and to participate in outpatient clinical duties related to clinical research. The candidate will be part of a multidisciplinary clinical team who participates in the clinical care of patients. The clinical fellow may also choose to participate in a multidisciplinary research team that uses molecular biological, genetic and neuroimaging tools to map genetic and neurochemical mechanisms associated with normal higher cognitive function as well as dysfunction in neuropsychiatric illnesses such as schizophrenia. In addition to their clinical work, there is opportunity for outstanding candidates to develop their own research projects within the Branch. Possible areas of concentration include 1) Functional MRI and spectroscopic studies assessing neurofunctional and neurochemical substrates of higher cognitive function, particularly as regards working memory and frontal lobe function, 2) Positron Emission Tomography studies, 3) Pharmacogenetic studies involving phase II drug trials based on genotype. For imaging research studies familiarity with computational and statistical methods for neuroimaging confers an advantage but is not absolutely required. Competitive stipends depend on level of experience. Letter of interest outlining experience and research goals, CV, and three recommendation letters sent to: Daniel R. Weinberger, M.D., NIH, Building 10, Rm. 4S235; 9000 Rockville Pike; Bethesda MD 20892-1365 USA. Phone: (301) 402-7564; FAX: (301) 480-7795. Weinberd@mail.nih.gov. This position is subject to a background investigation.

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The building is handicapped accessible and has a large parking lot in the rear. There is room for an additional building on the expansive lot. The office is located across the street from 2 major pharmacies and is in very close proximity to several other medical offices and a regional hospital. The office is currently fully staffed with a Child Psychiatrist, 4 therapists and 2 part time APRN's. For more information visit the office website at [www.sbhccf.com](http://www.sbhccf.com). Forward inquiries to E-mail : [aalmai@optonline.net](mailto:aalmai@optonline.net) or call phone (860)485-3700.

**Tucson, AZ \*Practice for Sale\***

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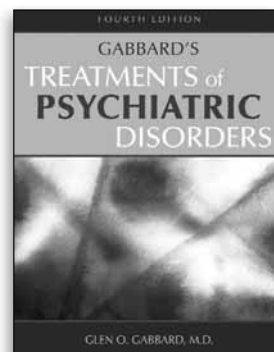
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**Brief Summary:** Consult the package insert for complete prescribing information.

**WARNING**

Suicidality and Antidepressant Drugs—Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Cymbalta or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and 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.

**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. **Monamine 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 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. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment.

Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older.

The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk of differences (drug vs placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1.

Table 1	
Age Range	Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated
	Increases Compared to Placebo
<18	14 additional cases
18-24	5 additional cases
	Decreases Compared to Placebo
25-64	1 fewer case
≥65	6 fewer cases

No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide.

It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression.

**All patients being treated with antidepressants for any indication should be monitored appropriately and 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.**

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 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.

**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 (duloxetine) 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 duloxetine. Following abrupt discontinuation in placebo-controlled clinical trials, the following symptoms occurred at a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; nightmares; insomnia; diarrhea; anxiety; hyperhidrosis; and vertigo.

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<sub>1c</sub> (HbA<sub>1c</sub>) 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<sub>1c</sub> 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<sub>max</sub> 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.

**Monamine Oxidase Inhibitors**—See CONTRAINDICATIONS and WARNINGS.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**—**Carcinogenesis**—Duloxetine was administered in the diet to mice and rats for 2 years. In female mice receiving duloxetine at 140 mg/kg/day (11 times the maximum recommended human dose [MRHD, 60 mg/day] and 6 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis), there was an increased incidence of hepatocellular adenomas and carcinomas. The no-effect dose was 50 mg/kg/day (4 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis). Tumor incidence was not increased in male mice receiving duloxetine at doses up to 100 mg/kg/day (8 times the MRHD and 4 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis). In rats, dietary doses of duloxetine up to 27 mg/kg/day in females (4 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis) and up to 36 mg/kg/day in males (6 times the MRHD and 3 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis) did not increase the incidence of tumors. **Mutagenesis**—Duloxetine was not mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) and was not clastogenic in an *in vivo* chromosomal aberration test in mouse bone marrow cells. Additionally, duloxetine was not genotoxic in an *in vitro* mammalian forward gene mutation assay in mouse lymphoma cells or in an *in vitro* unscheduled DNA synthesis (UDS) assay in primary rat hepatocytes, and did not induce sister chromatid exchange in Chinese hamster bone marrow *in vivo*. **Impairment of Fertility**—Duloxetine administered orally to either male or female rats prior to and throughout mating at daily doses up to 45 mg/kg/day (7 times the maximum recommended human dose of 60 mg/day and 4 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis) did not alter mating or fertility.

**Pregnancy**—**Pregnancy Category C**—In animal reproduction studies, duloxetine has been shown to have adverse effects on embryo/fetal and postnatal development. When duloxetine was administered orally to pregnant rats and rabbits during the period of organogenesis, there was no evidence of teratogenicity at doses up to 45 mg/kg/day (7 times the maximum recommended human dose [MRHD, 60 mg/day] and 4 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis, in rats; 15 times the MRHD and 7 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis in rabbits). However, fetal weights were decreased at this dose, with a no-effect dose of 10 mg/kg/day (2 times the MRHD and ~1 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis in rats; 3 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m<sup>2</sup> basis in rabbits). When duloxetine was administered orally to pregnant rats throughout gestation and lactation, the survival of pups to 1 day postpartum and pup body weights at birth and during the lactation period were decreased at a dose of 30 mg/kg/day (5 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m<sup>2</sup> 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, Monamine 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 flashes; **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; dry mouth; constipation; dizziness; 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; **Upper abdominal pain, dyspepsia**; **General Disorders and Administration Site Conditions**—fatigue; **Metabolism and Nutrition Disorders**—appetite decreased; **Nervous System Disorders**—dizziness, somnolence, tremor, paresthesia; **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 flashes.

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, headache, 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





**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.<sup>1a-c,2\*</sup> Cymbalta also offers high rates of remission, so patients can feel more like themselves again.<sup>1d†</sup> To learn more about treating beyond the obvious, visit [www.insidecymbalta.com](http://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<sub>17</sub> Total Score, Maier Subscale, Psychic Anxiety, and Visual Analog Scale. Full antidepressant response may take 4-6 weeks.

MMRM=Mixed-effects Models Repeated Measures analysis

† Remission=HAM-D<sub>17</sub> Total Score  $\leq 7$ , 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.

treat beyond the obvious

  
**Cymbalta**<sup>®</sup> DELAYED  
duloxetine HCl RELEASE  
CAPSULES

### **Important Safety Information**

- **Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children, adolescents, and young adults with major depressive disorder (MDD) and other psychiatric disorders.**
- **Patients of all ages started on therapy should be monitored appropriately and 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 patients being treated with an antidepressant for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially within the first few months of treatment and when changing 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 ( $\text{CrCl} < 30 \text{ mL/min}$ ).

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  $\text{HbA}_{1c}$  in both the Cymbalta (0.5%) and routine care groups (0.2%) was noted.

Most common adverse events ( $\geq 5\%$  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.

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