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Association

PSYCHIATRIC NEWS

inside

PERIODICALS: TIME-SENSITIVE MATERIALS

FDA Panel Wants Warnings On ADHD Medications

An unexpected recommendation to add a black-box warning to the labels of all stimulant medications used for ADHD proves to FDA staffers that you can never predict what an advisory committee will do.

BY JIM ROSACK

A panel of Food and Drug Administration (FDA) advisors last month voted 8 to 7 (with one abstention) to endorse a recommendation for a black-box warning regarding cardiovascular adverse events on the labels of all stimulant medications used to treat attention-deficit/hyperactivity disorder (ADHD). Several advisors said they voted for the warning not because they were particularly worried about safety issues relating to the potential of increased risk of heart attack, stroke, and sudden death, but because they were alarmed about the recent sharp rise in the number of prescriptions for the medications written for both children and adults.

During a public meeting on February 9, FDA officials told members of the Drug Safety and Risk Management Advisory Committee that data show that between 1999 and 2003, 78 million prescriptions were written for ADHD medications for children under 18, and 14 million were written for adults. In contrast, in the 12-year period from 1992 to 2004, 190 million prescriptions for ADHD medications were written for children and adults.

Agency safety reviewers then detailed the very rare reports of deaths and serious cardiovascular events the FDA has received. The stated intent of the meeting was to discuss how to study possible causality of such a rare event. However, the discussion soon turned to a surprise recommendation for new warnings on the drugs' labels—something the FDA was not even considering.

"I want to cause people's hands to tremble a little bit before they write that prescription" for an ADHD medication, said Cleveland Clinic cardiologist Steven Nissen, M.D., a consultant to the advisory committee. Indeed, it was Nissen who suggested the committee consider endorsing a black-box warning because he saw a need "to slow the growth of utilization."

Nissen and committee member Curt Furberg, M.D., a professor of public health

please see ***FDA*** *on page 36*

What's Your Part D Experience?

APA's Office of Healthcare Systems and Financing (OHSF) is monitoring how Medicare's new prescription drug benefit, known as Medicare Part D, is working for you and your patients. OHSF wants to pinpoint problems as soon as possible so they can be brought quickly to the attention of the Centers for Medicare and Medicaid Services and remedies sought. Your experiences are vital to letting OHSF know how Part D is really working. Share your comments by calling APA's PartD Line at (866) 882-6227 or sending them by e-mail to partd@psych.org.

Medicaid Patients Suffer Most From Part D Transition Problems

Many problems encountered in the first days of the new Medicare program are likely to recur when patients who had enough medication on on January 1 enter the system when those prescriptions run out.

BY MARK MORAN

Enormous problems continue to plague the new Medicare Part D prescription drug program, despite temporary relief provided by states that have intervened to pay the costs for dual eligibles and other beneficiaries moving into the program.

Irvin (Sam) Muszynski, J.D., director of APA's Office of Healthcare Systems and Financing, said that his office is continuing to receive reports through the Part D monitoring system it established regarding serious problems with enrollment of patients in the program, including inappropriate copayment requirements, failure to ensure continuity of care for dual-eligible beneficiaries transitioning from drug coverage under state Medicaid plans, and inappropriate utilization review requirements.

Moreover, Muszynski and clinicians who spoke with *Psychiatric News* said that many problems encountered in the first days of the new program are likely to reappear when countless patients who had received refill medications prior to December 31, 2005, enter the system when those prescriptions run out.

In a statement submitted to the Senate Finance Committee last month, APA said that widespread problems persist as the new Part D program is being implemented.

"Many of these problems concern the transition of Medicaid/Medicare dual eligibles to Part D plans, and states have spent millions of dollars covering the medication costs of these beneficiaries on an emergency basis. Common problems include inaccurate enrollment data, excessive charges for deductibles and copayments, drug plans failing to provide a temporary transition supply to beneficiaries stabilized on drugs, and ineffective use of the fallback drug plan [by which the government had assured beneficiaries that they would receive necessary medications if they showed up at the pharmacy with identification of their dual eligibility in Medicaid/Medicare].

"As a result, thousands of Part D beneficiaries are unable to access their medications," APA informed the committee.

APA also submitted the following recommendations:

please see ***Part D*** *on page 41*

APA's 2006 annual meeting is being held May 20 to 25 in Toronto. See page 26 for more information.

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APA Opposes WHO Proposal To Tighten Buprenorphine Controls

A proposed change in the way the World Health Organizaton and United Nations categorize buprenorphine could have significant impact on the drug's domestic availability.

BY JIM ROSACK

A proposed change in the way buprenorphine is listed internationally as a controlled substance could result in a rescheduling of the medication under the Controlled Substances Act in the United States.

The proposed change would likely result in buprenorphine being classified as a Schedule II controlled substance rather than a Schedule III substance, as it is now. That seemingly innocuous change "could lead to the elimination of office-based buprenorphine therapy for opioid addiction and severely restrict treatment access for patients," according to APA comments submitted to the U.S. Food and Drug Administration (FDA) on December 13, 2005.

The FDA had invited submission of comments on the potential international rescheduling of nine substances, including buprenorphine. That solicitation was a result of an October 2005 notification from the World Health Organization (WHO) asking member states for input on the use of the nine substances in individual member countries and the impact of proposed international scheduling.

In collaboration with the United Nations, the WHO provides expertise in updating the list of drugs of abuse under the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances. The WHO provides advice and guidance on psychotropic and narcotic substances in accordance with WHO's mandate under international treaties.

Three international drug control treaties now provide the legal basis for the international prevention of drug abuse.

The WHO undertakes medical and scientific review of psychotropic and narcotic substances before the United Nations Commission on Narcotic Drugs makes decisions on the control status of these substances.

Since 1949, through its Expert Committee on Drug Dependence, the WHO has reviewed more than 400 substances. Between 1948, when the WHO was established, and 1999, the number of narcotic drugs under international control increased from 18 to 118, and the number of psychotropic substances from 32 to 111.

With regard to buprenorphine, the WHO requested input on the impact of transferring the drug from its current listing on Schedule III of the Convention on Psychotropic Substances, 1971, to Schedule I of the Single Convention on Narcotic Drugs, 1961—a move that could place more restrictive international controls on the use of buprenorphine.

Specifically, WHO asked, "do you think that [buprenorphine's] availability for medical use will be affected? If yes, how do you think the transfer will impact its medical availablility?"

APA stated in its comments that the proposed change could have a "chilling effect on access to buprenorphine, to the extent that international drug scheduling influences individual countries' choices of how to control buprenorphine."

Given the influence of the international scheduling of substances, "the likely result of international rescheduling would be reduced access to buprenorphine for legitimate medical purposes. There is a potential for such a scheduling change to affect domestic drug classification of buprenorphine from [the U.S. Controlled Substances Act] Schedule III to Schedule II, which could lead to the elimination of office-based buprenorphine therapy and severely restrict treatment access for patients."

More information on the WHO's input on international control of narcotics and psychotropic drugs is posted at <www.who.int/medicines/areas/quality_safety/psycotrop_narcotics_intro/en/>. ■

Lifers in Toronto

The Lifers of APA will show those attending APA's 2006 annual meeting in Toronto that closing in on or reaching retirement can signal a beginning, not an end, to a career as a psychiatrist. The Lifers group plans a busy schedule of events during the week of the meeting, beginning on Friday, May 20, at 5:30 p.m., when the Assembly Lifers Caucus will meet in Confederation 3 Room at the Royal York Hotel. On Tuesday, May 23, the Lifers will hold its annual business meeting and forum at 7:30 a.m. in the York Room of the Royal York Hotel. Breakfast is included. That will be followed at 11 a.m. by the workshop "Integrating Evidence-Based Psychiatry with Clinical Intelligence" in Room 707, Level 700, Toronto Convention Centre, South. That evening, the group's reception will be held in the British Columbia Room at the Royal York Hotel from 7 p.m. to 9 p.m. All APA members are invited to the Lifers' events except for the Assembly caucus meeting.

More information is available by contacting Barbara Matos at bmatos@psych.org. ■

APA RESOURCES

- **APA and the APA Answer Center:** (888) 35-PSYCH in the U.S. and Canada; in other countries: (703) 907-3700. The Answer Center is open Monday through Friday, 8:30 a.m. to 6 p.m. Eastern time. All APA departments and staff may be reached through the Answer Center.
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Psychosocial Treatment: We Owe It to Our Patients

BY STEVEN SHARFSTEIN, M.D.

In my presidential response speech at last year's annual meeting in Atlanta, I decried the fact that for psychiatry the biopsychosocial model has become the "bio-bio-bio model." This comment received an impressive reaction from the audience at the time, indicating that they shared my concern. More significantly, I received correspondence, e-mails, and phone calls with similar sentiments and suggestions for change. Psychiatry has, for what I would argue more for economic reasons than anything else, focused on the psychopharmacological to the detriment of the psychosocial aspects of care.

As most of the care of patients with schizophrenia takes place in community-based settings, their treatment must include much more than expert psychopharmacology. Most psychiatrists with whom I've talked agree in principle with the approaches for which there is an evidence base, but few actually use them or prescribe their use. What do we know about what works? We know that family interventions work, but that they should be of at least nine months in duration. These interventions should include illness education, crisis intervention, emotional support for family members, and training in how to cope with illness symptoms. Family interventions help with the family's needs and with the prevention of relapse on the part of the ill family member. We know that supportive employment works, including individualized job development, rapid job placement, and ongoing job support, along with the integration of vocational and mental health services.

We also know that systems of care serving patients with schizophrenia should include a program of Assertive Community Treatment (ACT). ACT is a highly structured intervention that focuses on those patients at high risk for repeated hospitalization, those who have difficulty remaining in traditional services, or those who have become recently homeless. Key elements of ACT include a multidisciplinary team, including a psychiatrist, a shared caseload among team members, direct service provision by all team members, a high frequency of patient contact, a low staff-to-patient ratio, and outreach to patients in the community.

We know that those persons with deficits in social skills or activities of daily living should be offered skills training. We also know that patients with residual psychotic symptoms who are receiving adequate pharmacotherapy should also be offered cognitive-behavioral psychotherapy. The key elements of this psychotherapy include a shared understanding of the illness between the patient and the therapist, identification of target symptoms, and development of specific cognitive and behavioral strategies to cope with these symptoms.

Despite everything we know, however, many, if not most, of our patients do not receive these services. Joyce West, Ph.D., and colleagues, writing in the March *Psychiatric Services*, examined the treatment of 151 patients with schizophrenia from APA's practice research network and found that 69 percent of patients received some psychosocial treatment, but none of the unemployed patients received vocational services in the past 30 days, only 28 percent were receiving cognitive-behavioral-oriented therapy, and only 14 percent were receiving skills training. The authors noted that the conformance with psychosocial treatment recommendations was much lower than conformance with psychopharmacologic treatment recommendations.

Why is this so?

Tony Lehman, M.D., chair of psychiatry at the University of Maryland, asked this question in the *Schizophrenia Bulletin* in 2000. "If these [psychosocial] interventions are so great, why don't more clinicians use them?"

Lehman noted that clinicians have a natural resistance to change. He also commented that although these are evidence-based treatments, it's unclear which of these interventions are essential or best, how they should be phased in during the course of illness, and how specific interventions should be tailored to meet individual needs. But most critically, we have found that in contrast with market forces on the use of new medications, there is no profit in implementing new psychosocial interventions. Psychiatrists cannot make money for providing or prescribing state-of-the-art psychosocial services to their patients. Marketing of the new medications for our patients is a phenomenon that impacts on the daily lives of every psychiatrist. There are few product champions to market psychosocial treatment.

Dr. Lehman in the *Schizophrenia Bulletin* article concludes in an admonition to psychiatrists: "Are we off the hook? I would argue that we are not. Enough evidence exists that we are not using the knowledge we have to maximize patient outcomes by delivering programs that combine good pharmacological and psychosocial treatment for persons with schizophrenia. We did not wait for the perfect pill before proceeding to use the best that we had. . . . We should not wait for the perfect psychosocial treatment before applying the best that we have, either. In absence of strong profit motives for psychosocial treatments, we are only likely to move in this direction if we commit to accountability; establish clear, albeit imperfect standards of care; . . .and base reimbursements on these standards. . . ."

It's clear that we can do better for our patients and their families. Psychiatry must take the lead in advocating for these interventions in all of the treatment settings in which we work with and treat patients with schizophrenia. We need to ensure that these interventions are more fully implemented across the country. Bio-bio-bio is not enough. We owe our patients no less than to recommend and promote the use of the psychosocial interventions that have been demonstrated to be beneficial for this devastating disorder. ■

Assisted-Suicide Ruling Grants Patient Autonomy

The Supreme Court's decision upholding Oregon's assisted-suicide law may have some benefits for physicians and patients, according to psychiatrists on both sides of the assisted-suicide debate.

BY RICH DALY

Although the Supreme Court's decision in favor of the Oregon assisted suicide law removed obstacles for the relatively small number of patients who seek a physician's help to end their lives, some psychiatrists see its impact as much more profound.

The Supreme Court ruled 6-3 on January 17 that the Bush administration could not use a federal drug law to prosecute doctors under Oregon's one-of-a-kind physician-assisted suicide law. The Bush administration tried to prosecute Oregon doctors who prescribed overdoses to help terminally ill patients die. The ruling said federal authority to regulate aspects of medical practice does not override the 1997 Oregon law.

Adopted by Oregon voters in 1994 and reaffirmed in 1997, Oregon's Death With Dignity Act has allowed physicians to help end the lives of more than 200 seriously ill people in that state. The law lays out specific procedures for physicians to prescribe lethal doses of federally regulated medications to help mentally competent, terminally ill patients end their lives.

Former Attorney General John Ashcroft announced in November 2001 that doctors who prescribed lethal doses of drugs to assist a suicide could lose their federal licenses to prescribe all "controlled substances." Because it would be difficult for physicians to practice medicine without such a license, a physician, a pharmacist, several terminally ill patients, and the state of Oregon sued to block enforcement of the new rule (*Psychiatric News*, June 7, 2002).

Implications for Pain Management

Timothy Quill, M.D., a supporter of the Oregon law and a professor of medicine and psychiatry at the University of Rochester, said the rejection of a federal challenge to the Oregon law was critical to support pain management and palliative care nationwide. In addition to upholding the Oregon law, the decision blocks any role for federal drug agents in deciding what a physician's intentions were when prescribing medication at the end of a patient's life.

"Frequently, we use very large doses of medications to control symptoms—usually with patients tolerating quite well," said Quill. "But if you are inexperienced and you start to second guess these issues, there could be a lot of mischief and fear in the medical community, and people would have been even more reluctant to prescribe than they already are."

William Breitbart, M.D., a professor of psychiatry at Weill Medical College of Cornell University who studies end-of-life care, said he is very concerned about misperception of the Supreme Court ruling as an endorsement of physician-assisted suicide by those "who are depressed or in distress or despair that could be ameliorated by appropriate interventions." But the decision also was positive, he said, because it bars federal authorities from prosecuting physicians for how they treat terminally ill patients.

"My main concern is that patients who are terminally ill not have a limitation or restriction on their physician's ability to prescribe opioids to control pain," Breitbart said. "For someone who is terminally ill and receives opioids to control the pain and eventually dies, who is to determine whether the patient died because you prescribed opioid drugs? If determination of that is up to someone else who is not a physician, then that puts you as a physician in a very vulnerable position."

His research has led Breitbart (*Psychiatric News*, January 5, 2001), an attending psychiatrist at the Psychiatry Service at Memorial Sloan Kettering Cancer Center, to believe that the vast majority of dying patients can have their symptoms ameliorated through mechanisms other than death, and the relatively small number of terminal Oregon patients who have opted for physician suicide seems to support that.

Data Show Well-Designed Program

Quill said that the small numbers of patients opting for physician-assisted suicide in the Oregon program, which requires repeated patient requests and a second physician's concurrence before a terminal dose is prescribed, shows the program is well-designed. But more importantly, the program allows larger numbers of patients to have frank discussions with their physicians about end-of-life care. The Oregon law requires careful documentation, and those suspected of mental illness are referred to a psychiatrist or mental health professional for evaluation. The program's guidelines, Quill said, achieve a good balance between safety and invasiveness.

"In Oregon you can have that conversation out in the open. You can reassure people that you will be responsive, and it is much more variable than how that conversation goes in the rest of the country," Quill said.

Neither APA nor the Oregon Psychiatric Association has an official position on physician-assisted suicide.

Program Seems Abuse Free

Research conducted on the Oregon program, Breitbart said, shows it is conducted without abuses found in the Netherlands, where physicians assisted in the suicides of noncompetent and nonterminal patients. He does caution that research indicates that most patients who request a hastened death suffer from psychiatric issues, such as depression and existential distress like hopelessness and loss of meaning.

"There is a role for psychiatrists and mental health professionals to help deal with those issues that lead to the despair that would lead someone to request assisted suicide or to express the desire for a hastened death," Breitbart said.

He said he hopes the decision will move the focus from the less than 1 percent who receive physician-assisted suicide to the 20 percent of dying patients who experience despair or depression that leads them to express a desire for a hastened death. More attention to and research on this larger group of patients can lead to new and better treatments, such as meaning-centered psychotherapy and dignity-preserving interventions.

> **"My main concern is that patients who are terminally ill not have a limitation or restriction on their physician's ability to prescribe opioids to control pain."**

Breitbart said he was impressed by how many people say they weigh the option of physician-assisted suicide but don't act on it.

"That is probably important psychologically in that they are able to not feel trapped for the last weeks or months of their lives," he said.

Congress may still act to bar physician-assisted suicide, because the majority opinion in *Gonzales v. Oregon* did not block such laws. A unanimous 1997 Supreme Court ruling found that there is no constitutional right to die. That decision left room for states to set their own rules.

The majority and dissenting opinions in* Gonzales v. Oregon *are posted at <www.law.cornell.edu/supct/html/04-623.ZS.html>. Information on Oregon's Death With Dignity Act is posted at <http://egov.oregon.gov/DHS/ph/pas/faqs.shtml>. ■

Assisted-Suicide Law Has Strict Criteria

Oregon's Death With Dignity Act is implemented on an individual basis by qualified patients and physicians through the following steps:

- The patient makes two oral requests to the attending physician separated by at least 15 days.
- The patient provides a written request to the attending physician, signed in the presence of two witnesses.
- The attending physician and a consulting physician must confirm the patient's diagnosis and prognosis.
- The attending physician and a consulting physician determine whether the patient is capable of making and communicating health care decisions for himself or herself.
- The patient must be referred for psychological exam if either physician believes the patient's judgment is impaired by a psychiatric or psychological disorder.
- The attending physician must inform the patient of feasible alternatives to assisted suicide including comfort care, hospice care, and pain control.
- The attending physician must request that the patient notify his or her next-of-kin of the prescription request. A patient can rescind a request at any time and in any manner.

Advocate for Your Patients And Profession

A reception for all supporters of APA*PAC*, APA's political action committee, will be held during APA's 2006 annual meeting in Toronto on Saturday, May 20, at the Royal York Hotel in Toronto. If you are not among that number yet, then please join your colleagues in supporting the PAC by going to its Web site at <www.psych.org/members/apapac/index.cfm>.

Also during your stay in Toronto, stop by the APA*PAC* suite at the Royal York and help make APA*PAC* an integral part of APA's campaign to educate Congress about the needs of the profession and your patients.

APA*PAC* provides APA members with a direct opportunity to support the election of federal candidates who will best advocate for psychiatry's interest in Congress. In this election year, psychiatry will face crucial challenges in Congress, and it is essential that we have the opportunity to meet with and inform key legislators deciding a host of issues that will affect your practice. Among them:

- Opposing expansion of prescribing privileges to nonphysicians on the federal level; such privileges are being sought within the Indian Health Services program.
- Preventing arbitrary exclusion of the full range of psychotropic medications under Medicaid and the new Medicare Part D prescription drug benefit.
- Supporting efforts to block scheduled cuts in Medicare payments.
- Opposing draconian cuts to Medicaid programs.
- Repealing the ban on benzodiazepine coverage under Medicare Part D.
- Stopping marriage and family therapists and mental health counselors from stretching Medicare finances to cover independent reimbursement of their services, while Medicare beneficiaries continue to face 50 percent coinsurance payments for all mental health services.
- Ending insurance discrimination against people with mental illness.

Your PAC support enables APA to continue to increase education and lobbying efforts to key legislators on these and other issues that confront our practice and patients.

*More information about APA*PAC *is posted in the "Members Corner" section of APA's Web site at <www.psych.org/members/apapac/index.cfm> and is also available from Jason Pray by by e-mail at jpray@psych.org or by phone at (703) 907-8581.*

Become an APA Fellow!

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Still working to solve the problem of unresolved depression?

residual symptoms

sadness
low energy
anxiety

relapse

recurrence

IMPORTANT TREATMENT CONSIDERATIONS

Suicidality in Children and Adolescents

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

Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with Major Depressive Disorder (MDD), obsessive-compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4,400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving anti-depressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

- **EFFEXOR XR is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs). EFFEXOR XR should not be used in combination with an MAOI or within at least 14 days of discontinuing treatment with an MAOI; at least 7 days should be allowed after stopping EFFEXOR XR before starting an MAOI.**

- Adult and pediatric patients with MDD can experience worsening of their depression and/or the emergence of suicidal ideation and behavior, whether or not they are taking antidepressants. **Patients treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of drug therapy,**

Break the cycle with EFFEXOR XR

EFFEXOR XR is proven to help prevent new episodes of depression up to 1 year.[1]

or at the time of increases or decreases in dose. Anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania have been reported and may represent precursors to emerging suicidality. Stopping or modifying therapy should be considered especially when symptoms are severe, abrupt in onset, or not part of presenting symptoms.

- Treatment with venlafaxine is associated with sustained increases in blood pressure (BP) in some patients. Postmarketing cases of elevated BP requiring immediate treatment have been reported. Pre-existing hypertension should be controlled. Regular BP monitoring is recommended.
- Abrupt discontinuation or dose reduction has been associated with discontinuation symptoms. Patients should be counseled on possible discontinuation symptoms and monitored while discontinuing the drug; the dose should be tapered gradually. See the Precautions section of the Prescribing Information.
- The most common adverse events reported in EFFEXOR XR short-term placebo-controlled MDD, generalized anxiety disorder (GAD), social anxiety disorder (SAD), and/or panic disorder (PD) trials (incidence ≥10% and ≥2x that of placebo) were anorexia, asthenia, constipation, dizziness, dry mouth, ejaculation problems, impotence, insomnia, nausea, nervousness, somnolence, and sweating.

Please see brief summary of Prescribing Information on adjacent page.

Reference: 1. Effexor XR® (venlafaxine HCl) Extended-Release and Effexor Immediate-Release Prescribing Information, Wyeth Pharmaceuticals Inc.

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BRIEF SUMMARY. See package insert for full prescribing information.

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CONTRAINDICATIONS: Hypersensitivity to venlafaxine hydrochloride or to any excipients in the formulation. Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs). **WARNINGS: Clinical Worsening and Suicide Risk—** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with MDD and other psychiatric disorders. It is unknown whether the suicidality risk in pediatric patients extends to longer-term use, i.e., beyond several months. It is also unknown whether the suicidality risk extends to adults. **All pediatric patients being treated with antidepressants for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Adults with MDD or comorbid depression in the setting of other psychiatric illness being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.** 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 and other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see **PRECAUTIONS** and **DOSAGE AND ADMINISTRATION). Families and caregivers of pediatric patients being treated with antidepressants for MDD 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 Effexor XR should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose. Families and caregivers of adults being treated for depression should be similarly advised. **Screening Patients for Bipolar Disorder:** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed 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. Prior to initiating antidepressant treatment, patients with depressive symptoms should be 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. Effexor XR is not approved for use in treating bipolar depression. **Potential for Interaction with MAOIs—Adverse reactions, some serious, have been reported in patients who recently discontinued an MAOI and started on venlafaxine, or who recently discontinued venlafaxine prior to initiation of an MAOI. These reactions included tremor, myoclonus, diaphoresis, nausea, vomiting, flushing, dizziness, hyperthermia with features resembling neuroleptic malignant syndrome, seizures, and death. Effexor XR should not be used in combination with an MAOI, or within at least 14 days of discontinuing treatment with an MAOI. At least 7 days should be allowed after stopping venlafaxine before starting an MAOI. Sustained Hypertension**—Venlafaxine is associated with sustained increases in blood pressure (BP) in some patients. Postmarketing cases of elevated BP requiring immediate treatment have been reported. Pre-existing hypertension should be controlled. Regular monitoring of BP is recommended. For patients experiencing sustained increase in BP, consider either dose reduction or discontinuation. **PRECAUTIONS**: **General**—***Discontinuation of Treatment with Effexor XR.*** Abrupt discontinuation or dose reduction of venlafaxine at various doses is associated with new symptoms, the frequency of which increased with increased dose level and longer duration of treatment. Symptoms include agitation, anorexia, anxiety, confusion, coordination impaired, diarrhea, dizziness, dry mouth, dysphoric mood, emotional lability, fasciculation, fatigue, headaches, hypomania, insomnia, irritability, lethargy, nausea, nervousness, nightmares, seizures, sensory disturbances (e.g., paresthesias such as electric shock sensations), somnolence, sweating, tinnitus, tremor, vertigo, and vomiting. Monitor patients when discontinuing treatment. A gradual reduction in the dose rather than abrupt cessation is recommended. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, consider resuming the previously prescribed dose. Subsequently, continue decreasing the dose at a more gradual rate. ***Insomnia and Nervousness***: Treatment-emergent insomnia and nervousness have been reported. In Phase 3 trials, insomnia led to drug discontinuation in 1% of both depressed patients and Panic Disorder (PD) patients and in 3% of both Generalized Anxiety Disorder (GAD) and Social Anxiety Disorder (SAD) patients. Nervousness led to drug discontinuation in 0.9% of depressed patients, in 2% of GAD patients, and in 0% of SAD and PD patients. ***Changes in Weight***: ***Adult Patients***: In short-term MDD trials, 7% of Effexor XR patients had ≥5% loss of body weight and 0.1% discontinued for weight loss. In 6-month GAD studies, 3% of Effexor XR patients had ≥7% loss of body weight, and 0.3% discontinued for weight loss in 8-week studies. In 12-week SAD trials, 3% of Effexor XR patients had ≥7% loss of body weight and no patients discontinued for weight loss. In 12-week PD trials, 3% of Effexor XR patients had ≥7% loss of body weight, and no patients discontinued for weight loss. The safety and efficacy of venlafaxine in combination with weight loss agents, including phentermine, have not been established. Coadministration of Effexor XR and weight loss agents is not recommended. Effexor XR is not indicated for weight loss alone or in combination with other products. ***Pediatric Patients***: Weight loss was seen in patients aged 6-17 receiving Effexor XR. More Effexor XR patients than placebo patients experienced weight loss of at least 3.5% in both MDD and GAD studies (18% vs. 3.6%; *P*<0.001). Weight loss was not limited to patients with treatment-emergent anorexia (decreased appetite). Children and adolescents in a 6-month study had increases in weight less than expected based on data from age- and sex-matched peers. The difference between observed and expected weight gain was larger for children <12 years old than for adolescents >12 years old. ***Changes in Height***: ***Pediatric Patients***: In 8-week GAD studies, Effexor XR patients aged 6-17 grew an average of 0.3 cm (n=122), while placebo patients grew an average of 1.0 cm (n=132); *P*=0.041. This difference in height increase was most notable in patients <12. In 8-week MDD studies, Effexor XR patients grew an average of 0.8 cm (n=146), while placebo patients grew an average of 0.7 cm (n=147). In a 6-month study, children and adolescents had height increases less than expected based on data from age- and sex-matched peers. The difference between observed and expected growth rates was larger for children <12 years old than for adolescents >12 years old. ***Changes in Appetite***: ***Adult Patients***: Treatment-emergent anorexia was more commonly reported for Effexor XR (8%) than placebo (4%) patients in MDD studies. The discontinuation rate for anorexia was 1.0% in MDD studies. Treatment-emergent anorexia was more commonly reported for Effexor XR (8%) than placebo (2%) patients in GAD studies. The discontinuation rate for anorexia was 0.9% for up to 8 weeks in GAD studies. Treatment-emergent anorexia was more commonly reported for Effexor XR (20%) than placebo (2%) patients in SAD studies. The discontinuation rate for anorexia was 0.4% for up to 12 weeks in SAD studies. Treatment-emergent anorexia was more commonly reported for Effexor XR (8%) than placebo (3%) patients in PD studies. The discontinuation rate for anorexia was 0.4% for Effexor XR patients in 12-week PD studies. ***Pediatric Patients***: Decreased appetite was seen in pediatric patients receiving Effexor XR. In GAD and MDD trials, 10% of Effexor XR patients aged 6-17 for up to 8 weeks and 3% of placebo patients had treatment-emergent anorexia. None of the patients receiving Effexor XR discontinued for anorexia or weight loss. ***Activation of Mania/Hypomania***: Mania or hypomania has occurred during short-term depression and PD studies. As with all drugs effective in the treatment of MDD, Effexor XR should be used cautiously in patients with a history of mania. ***Hyponatremia***: Hyponatremia and/or the syndrome of inappropriate antidiuretic hormone secretion (SIADH) may occur with venlafaxine. Consider this in patients who are volume-depleted, elderly, or taking diuretics. ***Mydriasis***: Mydriasis has been reported; monitor patients with raised intraocular pressure or at risk of acute narrow-angle glaucoma (angle-closure glaucoma). ***Seizures***: In all premarketing depression trials with Effexor, seizures were reported in 0.3% of venlafaxine patients. Use cautiously in patients with a history of seizures. Discontinue in any patient who develops seizures. ***Abnormal Bleeding***: Abnormal bleeding (most commonly ecchymosis) has been reported. ***Serum Cholesterol Elevation***: Clinically relevant increases in serum cholesterol were seen in 5.3% of venlafaxine patients and 0.0% of placebo patients treated for at least 3 months in trials. Consider measurement of serum cholesterol levels during long-term treatment. ***Use in Patients With Concomitant Illness***: Use Effexor XR cautiously in patients with diseases or conditions that could affect hemodynamic responses or metabolism. Venlafaxine has not been evaluated in patients with recent history of MI or unstable heart disease. Increases in QT interval (QTc) have been reported in clinical studies. Exercise caution in patients whose underlying medical conditions might be compromised by increases in heart rate. In patients with renal impairment or cirrhosis of the liver, the clearances of venlafaxine and its active metabolites were decreased, prolonging the elimination half-lives. A lower dose may be necessary; use with caution in such patients. **Information for Patients**—Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Effexor XR and should counsel them in its appropriate use. A patient *Medication Guide About Using Antidepressants in Children and Teenagers* is available for Effexor XR. 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 available at www.effexorxr.com or in the approved prescribing information. Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking Effexor XR. **Clinical Worsening and Suicide Risk:** Patients, their families, and their caregivers should be encouraged to be alert to the emergence of symptoms listed in **WARNINGS: Clinical Worsening and Suicide Risk**, especially those seen early during antidepressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to observe for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication. Caution patients about operating hazardous machinery, including automobiles, until they are reasonably sure that venlafaxine does not adversely affect their abilities. Tell patients to avoid alcohol while taking Effexor XR and to notify their physician 1) if they become pregnant or intend to become pregnant during therapy, or if they are nursing; 2) about other prescription or over-the-counter drugs, including herbal preparations, they are taking or plan to take; 3) if they develop a rash, hives, or related allergic phenomena. **Laboratory Tests**—No specific laboratory tests are recommended. **Drug Interactions**— ***Alcohol***: A single dose of ethanol had no effect on the pharmacokinetics (PK) of venlafaxine or O-desmethylvenlafaxine (ODV), and venlafaxine did not exaggerate the psychomotor and psychometric effects induced by ethanol. ***Cimetidine***: Use caution when administering venlafaxine with cimetidine to patients with pre-existing hypertension or hepatic dysfunction, and the elderly. ***Diazepam***: A single dose of diazepam did not appear to affect the PK of either venlafaxine or ODV. Venlafaxine did not have any effect on the PK of diazepam or its active metabolite, desmethyldiazepam, or affect the psychomotor and psychometric effects induced by diazepam. ***Haloperidol***: Venlafaxine decreased total oral-dose clearance of haloperidol, resulting in a 70% increase in haloperidol AUC. The haloperidol C_{max} increased 88%, but the haloperidol elimination half-life was unchanged. ***Lithium***: A single dose of lithium did not appear to affect the PK of either venlafaxine or ODV. Venlafaxine had no effect on the PK of lithium. ***Drugs Highly Bound to Plasma Proteins***: Venlafaxine is not highly bound to plasma proteins; coadministration of Effexor XR with a highly protein-bound drug should not cause increased free concentrations of the other drug. ***Drugs That Inhibit Cytochrome P450 Isoenzymes***: CYP2D6 Inhibitors: Venlafaxine is metabolized to its active metabolite, ODV, by CYP2D6. Drugs inhibiting this isoenzyme have the potential to increase plasma concentrations of venlafaxine and decrease concentrations of ODV. No dosage adjustment is required when venlafaxine is coadministered with a CYP2D6 inhibitor. Concomitant use of venlafaxine with drug treatment(s) that potentially inhibits both CYP2D6 and CYP3A4, the primary metabolizing enzymes for venlafaxine, has not been studied. Use caution if therapy includes venlafaxine and any agent(s) that produces simultaneous inhibition of these two enzyme systems. ***Drugs Metabolized by Cytochrome P450 Isoenzymes***: Venlafaxine is a relatively weak inhibitor of CYP2D6. Venlafaxine did not inhibit CYP1A2 and CYP3A4, CYP2C9 (in vitro), or CYP2C19. ***Imipramine***: Venlafaxine did not affect the PK of imipramine and 2-OH-imipramine. However, desipramine AUC, C_{max} and C_{min} increased by ~35% in the presence of venlafaxine. The 2-OH-desipramine AUCs increased by 2.5-4.5 fold. Imipramine did not affect the PK of venlafaxine and ODV. ***Risperidone***: Venlafaxine slightly inhibited the CYP2D6-mediated metabolism of risperidone to its active metabolite, 9-hydroxyrisperidone, resulting in a ~32% increase in risperidone AUC. Venlafaxine coadministration did not significantly alter the PK profile of the total active moiety (risperidone plus 9-hydroxyrisperidone). **CYP3A4**: Venlafaxine did not inhibit CYP3A4 in vitro and in vivo. ***Indinavir***: In a study of 9 healthy volunteers, venlafaxine administration resulted in a 28% decrease in the AUC of a single dose of indinavir and a 36% decrease in indinavir C_{max}. Indinavir did not affect the PK of venlafaxine and ODV. **CYP1A2**: Venlafaxine did not inhibit CYP1A2 in vitro and in vivo. **CYP2C9**: Venlafaxine did not inhibit CYP2C9 in vitro. In vivo, venlafaxine 75 mg by mouth every 12 hours did not alter the PK of a single 550-mg dose of tolbutamide or the CYP2C9-mediated formation of 4-hydroxy-tolbutamide. **CYP2C19**: Venlafaxine did not inhibit the metabolism of diazepam, which is partially metabolized by CYP2C19 (see *Diazepam* above). ***MAOIs***: See **CONTRAINDICATIONS** and **WARNINGS**. ***CNS-Active Drugs***: Use caution with concomitant use of venlafaxine and other CNS-active drugs. Based on its mechanism of action and the potential for serotonin syndrome, use caution when coadministering venlafaxine with other drugs affecting the serotonergic neurotransmitter systems, such as triptans, serotonin reuptake inhibitors, or lithium. ***Electroconvulsive Therapy (ECT)***: There are no clinical data establishing the benefit of ECT combined with Effexor XR treatment. **Carcinogenesis, Mutagenesis, Impairment of Fertility**—***Carcinogenesis***: There was no increase in tumors in mice and rats given up to 1.7 times the maximum recommended human dose (MRHD) on a mg/m² basis. ***Mutagenesis***: Venlafaxine and ODV were not mutagenic in the Ames reverse mutation assay in Salmonella bacteria or the CHO/HGPRT mammalian cell forward gene mutation assay. Venlafaxine was not clastogenic in several assays. ODV elicited a clastogenic response in the in vivo chromosomal aberration assay in rat bone marrow. ***Impairment of Fertility***: No effects on reproduction or fertility in rats were noted at oral doses of up to 2 times the MRHD on a mg/m² basis. **Pregnancy**—***Teratogenic Effects***—***Pregnancy Category C***. Reproduction studies in rats given 2.5 times, and rabbits given 4 times the MRHD (mg/m² basis) revealed no malformations in offspring. However, in rats given 2.5 times the MRHD, there was a decrease in pup weight, an increase in stillborn pups, and an increase in pup deaths during the first 5 days of lactation when dosing began during pregnancy and continued until weaning. There are no adequate and well-controlled studies in pregnant women; use Effexor XR during pregnancy only if clearly needed. ***Nonteratogenic Effects***. Neonates exposed to Effexor XR late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Complications can arise immediately upon delivery. Reports include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. This is consistent with a direct toxic effect of SNRIs or a drug discontinuation syndrome. In some cases, it is consistent with serotonin syndrome. When treating a pregnant woman with Effexor XR during the third trimester, carefully consider the potential risks and benefits of treatment and consider tapering Effexor XR in the third trimester. **Labor, Delivery, Nursing**—The effect on labor and delivery in humans is unknown. Venlafaxine and ODV have been reported to be excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Effexor XR, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to 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**). No studies have adequately assessed the impact of Effexor XR on growth, development, and maturation of children and adolescents. Studies suggest Effexor XR may adversely affect weight and height (see **PRECAUTIONS-General**, *Changes in Height* and *Changes in Weight*). Should the decision be made to treat a pediatric patient with Effexor XR, regular monitoring of weight and height is recommended during treatment, particularly if long term. The safety of Effexor XR for pediatric patients has not been assessed for chronic treatment >6 months. In studies in patients aged 6-17, blood pressure and cholesterol increases considered to be clinically relevant were similar to that observed in adult patients. The precautions for adults apply to pediatric patients. **Geriatric Use**—No overall differences in effectiveness or safety were observed between geriatric and younger patients. Greater sensitivity of some older individuals cannot be ruled out. Hyponatremia and SIADH have been reported, usually in the elderly. **ADVERSE REACTIONS**: ***Associated with Discontinuation of Treatment***—The most common events leading to discontinuation in MDD, GAD, SAD, and PD trials included nausea, anorexia, anxiety, impotence, dry mouth, dizziness, insomnia, somnolence, hypertension, diarrhea, paresthesia, tremor, abnormal (mostly blurred) vision, abnormal (mostly delayed) ejaculation, asthenia, vomiting, nervousness, headache, vasodilatation, thinking abnormal, decreased libido, and sweating. ***Commonly Observed Adverse Events in Controlled Clinical Trials for MDD, GAD, SAD, and PD***—Body as a Whole: asthenia, headache, flu syndrome, accidental injury, abdominal pain. Cardiovascular: vasodilatation, hypertension, palpitation. Digestive: nausea, constipation, anorexia, vomiting, flatulence, diarrhea, eructation. Metabolic/Nutritional: weight loss. Nervous System: dizziness, somnolence, insomnia, dry mouth, nervousness, abnormal dreams, tremor, depression, hypertonia, paresthesia, libido decreased, agitation, anxiety, twitching. Respiratory System: pharyngitis, yawn, sinusitis. Skin: sweating. Special Senses: abnormal vision. Urogenital System: abnormal ejaculation, impotence, orgasmic dysfunction (including anorgasmia) in females. ***Vital Sign Changes***: Effexor XR was associated with a mean increase in pulse rate of about 2 beats/min in depression and GAD trials and a mean increase in pulse rate of 4 beats/min in SAD trials. (See **WARNINGS-Sustained Hypertension**). ***Laboratory Changes***: Clinically relevant increases in serum cholesterol were noted in Effexor XR clinical trials. Increases were duration dependent over the study period and tended to be greater with higher doses. ***Other Events Observed During the Premarketing Evaluation of Effexor and Effexor XR***—N=6,670. "Frequent"=events occurring in at least 1/100 patients; "infrequent"=1/100 to 1/1000 patients; "rare"=fewer than 1/1000 patients. **Body as a whole** - Frequent: chest pain substernal, chills, fever, neck pain; Infrequent: face edema, intentional injury, malaise, moniliasis, neck rigidity, pelvic pain, photosensitivity reaction, suicide attempt, withdrawal syndrome; Rare: appendicitis, bacteremia, carcinoma, cellulitis. **Cardiovascular system** - Frequent: migraine, postural hypotension, tachycardia; Infrequent: angina pectoris, arrhythmia, extrasystoles, hypotension, peripheral vascular disorder (mainly cold feet and/or cold hands), syncope, thrombophlebitis; Rare: aortic aneurysm, arteritis, first-degree atrioventricular block, bigeminy, bundle branch block, capillary fragility, cerebral ischemia, coronary artery disease, congestive heart failure, heart arrest, hematoma, cardiovascular disorder (mitral valve and circulatory disturbance), mucocutaneous hemorrhage, myocardial infarct, pallor, sinus arrhythmia. **Digestive system** - Frequent: increased appetite; Infrequent: bruxism, colitis, dysphagia, tongue edema, esophagitis, gastritis, gastroenteritis, gastrointestinal ulcer, gingivitis, glossitis, rectal hemorrhage, hemorrhoids, melena, oral moniliasis, stomatitis, mouth ulceration; Rare: abdominal distension, biliary pain, cheilitis, cholecystitis, cholelithiasis, esophageal spasms, duodenitis, hematemesis, gastroesophageal reflux disease, gastrointestinal hemorrhage, gum hemorrhage, hepatitis, ileitis, jaundice, intestinal obstruction, liver tenderness, parotitis, periodontitis, proctitis, rectal disorder, salivary gland enlargement, increased salivation, soft stools, tongue discoloration. **Endocrine system** - Rare: galactorrhoea, goiter, hyperthyroidism, hypothyroidism, thyroid nodule, thyroiditis. **Hemic and lymphatic system** - Frequent: ecchymosis; Infrequent: anemia, leukocytosis, leukopenia, lymphadenopathy, thrombocythemia; Rare: basophilia, bleeding time increased, cyanosis, eosinophilia, lymphocytosis, multiple myeloma, purpura, thrombocytopenia. **Metabolic and nutritional** - Frequent: edema, weight gain; Infrequent: alkaline phosphatase increased, dehydration, hypercholesteremia, hyperglycemia, hyperlipemia, hypoglycemia, hypokalemia, SGOT increased, SGPT increased, thirst; Rare: alcohol intolerance, bilirubinemia, BUN increased, creatinine increased, diabetes mellitus, glycosuria, gout, healing abnormal, hemochromatosis, hypercalcinuria, hyperkalemia, hyperphosphatemia, hyperuricemia, hypocholesteremia, hyponatremia, hypophosphatemia, hypoproteinemia, uremia. **Musculoskeletal system** - Frequent: arthralgia; Infrequent: arthritis, arthrosis, bone spurs, bursitis, leg cramps, myasthenia, tenosynovitis; Rare: bone pain, pathological fracture, muscle cramp, muscle spasms, musculoskeletal stiffness, myopathy, osteoporosis, osteosclerosis, plantar fasciitis, rheumatoid arthritis, tendon rupture. **Nervous system** - Frequent: amnesia, confusion, depersonalization, hypesthesia, thinking abnormal, trismus, vertigo; Infrequent: akathisia, apathy, ataxia, circumoral paresthesia, CNS stimulation, emotional lability, euphoria, hallucinations, hostility, hyperesthesia, hyperkinesia, hypotonia, incoordination, manic reaction, myoclonus, neuralgia, neuropathy, psychosis, seizure, abnormal speech, stupor, suicidal ideation; Rare: abnormal/changed behavior, adjustment disorder, akinesia, alcohol abuse, aphasia, bradykinesia, buccoglossal syndrome, cerebrovascular accident, feeling drunk, loss of consciousness, delusions, dementia, dystonia, energy increased, facial paralysis, abnormal gait, Guillain-Barré syndrome, homicidal ideation, hyperchlorhydria, hypokinesia, hysteria, impulse control difficulties, libido increased, motion sickness, neuritis, nystagmus, paranoid reaction, paresis, psychotic depression, reflexes decreased, reflexes increased, torticollis. **Respiratory system** - Frequent: cough increased, dyspnea; Infrequent: asthma, chest congestion, epistaxis, hyperventilation, laryngismus, laryngitis, pneumonia, voice alteration; Rare: atelectasis, hemoptysis, hypoventilation, hypoxia, larynx edema, pleurisy, pulmonary embolus, sleep apnea. **Skin and appendages** - Frequent: pruritus; Infrequent: acne, alopecia, contact dermatitis, dry skin, eczema, maculopapular rash, psoriasis, urticaria; Rare: brittle nails, erythema nodosum, exfoliative dermatitis, lichenoid dermatitis, hair discoloration, skin discoloration, furunculosis, hirsutism, leukoderma, miliaria, petechial rash, pruritic rash, pustular rash, vesiculobullous rash, seborrhea, skin atrophy, skin hypertrophy, skin striae, sweating decreased. **Special senses** - Frequent: abnormality of accommodation, mydriasis, taste perversion; Infrequent: conjunctivitis, diplopia, dry eyes, eye pain, hyperacusis, otitis media, parosmia, photophobia, taste loss, visual field defect; Rare: blepharitis, cataract, chromatopsia, conjunctival edema, corneal lesion, deafness, exophthalmos, eye hemorrhage, glaucoma, retinal hemorrhage, subconjunctival hemorrhage, keratitis, labyrinthitis, miosis, papilledema, decreased pupillary reflex, otitis externa, scleritis, uveitis. **Urogenital system** - Frequent: prostatic disorder (prostatitis, enlarged prostate, and prostate irritability), urination impaired; Infrequent: albuminuria, amenorrhea, breast pain, cystitis, dysuria, hematuria, kidney calculus, kidney pain, leukorrhea, menorrhagia, metrorrhagia, nocturia, polyuria, pyuria, urinary incontinence, urinary retention, urinary urgency, vaginal hemorrhage, vaginitis; Rare: abortion, anuria, balanitis, bladder pain, breast discharge, breast engorgement, breast enlargement, endometriosis, female lactation, fibrocystic breast, calcium crystalluria, cervicitis, orchitis, ovarian cyst, prolonged erection, gynecomastia (male), hypomenorrhea, kidney function abnormal, mastitis, menopause, pyelonephritis, oliguria, salpingitis, urolithiasis, uterine hemorrhage, uterine spasm, vaginal dryness. **Postmarketing Reports**: agranulocytosis, anaphylaxis, aplastic anemia, catatonia, congenital anomalies, CPK increased, deep vein thrombophlebitis, delirium, EKG abnormalities such as QT prolongation; cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia, ventricular extrasystoles, and rare reports of ventricular fibrillation and ventricular tachycardia, including torsades de pointes; epidermal necrosis/Stevens-Johnson syndrome, erythema multiforme, extrapyramidal symptoms (including dyskinesia and tardive dyskinesia), angle-closure glaucoma, hemorrhage (including eye and gastrointestinal bleeding), hepatic events (including GGT elevation; abnormalities of unspecified liver function tests; liver damage, necrosis, or failure; and fatty liver), involuntary movements, LDH increased, neuroleptic malignant syndrome-like events (including a case of a 10-year-old who may have been taking methylphenidate, was treated and recovered), neutropenia, night sweats, pancreatitis, pancytopenia, panic, prolactin increased, pulmonary eosinophilia, renal failure, rhabdomyolysis, serotonin syndrome, shock-like electrical sensations or tinnitus (in some cases, subsequent to the discontinuation of venlafaxine or tapering of dose), and SIADH (usually in the elderly). Elevated clozapine levels that were temporally associated with adverse events, including seizures, have been reported following the addition of venlafaxine. Increases in prothrombin time, partial thromboplastin time, or INR have been reported when venlafaxine was given to patients on warfarin therapy. **DRUG ABUSE AND DEPENDENCE**: Effexor XR is not a controlled substance. Evaluate patients carefully for history of drug abuse and observe such patients closely for signs of misuse or abuse. **OVERDOSAGE**: Electrocardiogram changes (e.g., prolongation of QT interval, bundle branch block, QRS prolongation), sinus and ventricular tachycardia, bradycardia, hypotension, altered level of consciousness (ranging from somnolence to coma), rhabdomyolysis, seizures, vertigo, liver necrosis, and death have been reported. Treatment should consist of those general measures employed in the management of overdosage with any antidepressant. Ensure an adequate airway, oxygenation and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients. Activated charcoal should be administered. Due to the large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. No specific antidotes for venlafaxine are known. In managing overdosage, consider the possibility of multiple drug involvement. Consider contacting a poison control center for additional information on the treatment of overdose. Telephone numbers for certified poison control centers are listed in the Physicians' Desk Reference® (PDR). **DOSAGE AND ADMINISTRATION**: Consult full prescribing information for dosing instructions. **Switching Patients to or From an MAOI**—At least 14 days should elapse between discontinuation of an MAOI and initiation of therapy with Effexor XR. At least 7 days should be allowed after stopping Effexor XR before starting an MAOI (see **CONTRAINDICATIONS** and **WARNINGS**). This brief summary is based on Effexor XR Prescribing Information W10404C019, revised November 2005.

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Iraq Tackles Daunting Task Of Rebuilding MH System

Iraqis and the international mental health community are working to train mental health care providers within the country and rebuild its mental health services.

BY AARON LEVIN

Iraq's attempts to rebuild its mental health services, allowed to grow moribund under the former regime, are complicated by low staffing levels, need for more up-to-date training, and erratic funding, said psychiatrists and others familiar with conditions in the country.

Mental health care and facilities had deteriorated since he left Iraq in 1979, said Najaf-born psychiatrist Sabah Sadik, M.D.,who returned late in 2003 after more than 20 years in the United Kingdom. Largely cut off from the rest of the world, psychiatric thinking had remained stagnant over that same time. Care was generally provided either in private practice or as tertiary care in the country's single, large mental hospital, said Sadik, now medical director for the West Kent National Health service in the United Kingdom and national advisor for mental health at the Iraqi Ministry of Health.

Photo courtesy of Heartland Alliance

Representatives from the Heartland Alliance, a Chicago-based nonprofit, train community mental health workers in northern Iraq on treating victims of torture who have posttraumatic stress disorder. The course required interpreters for two different Kurdish dialects.

There are an estimated 80 to 100 psychiatrists in Iraq, but some of them may have left since the U.S. invasion. There are also few trained nonphysician mental health workers, something that both the U.S. government and some nonprofits are trying to change.

The ministry has declared mental health a priority and has looked at best practices around the world as models for a new Iraqi mental health system, said Sadik, speaking at a news briefing recently in Washington, D.C.

"We are trying to integrate mental health into primary care, build mental health units into general hospitals, close the main mental hospital, and introduce a mental health reform law," he said. "We are trying to introduce the concept of community mental health services in primary care and the use of the tertiary centers for consultation or brief hospitalization."

Care System Long Neglected

Many psychiatrists and mental health professionals had left the country during the Saddam Hussein regime, which had neglected the health care system and intimidated Iraqi professionals as a means of social control, added Baghdad native Husam Alathari, M.D., a clinical instructor in psychiatry and behavioral sciences at George Washington University in Washington, D.C. Since 2004, he has consulted with the Ministry of Health on substance abuse treatment and training health professionals.

"The fall of the Hussein regime gives us an opportunity to look at different models and systems of mental health care," said Alathari.

Stigma about chronic mental illness remains a problem, but people seem more open to seeking help, said Alathari. The common practice of arranged marriages means that people are wary of taking on the burden of a mentally ill relative, although strong family bonds serve as a countervailing source of support, explained Winnie Mitchell, international officer at the Substance Abuse and Mental Health Services Administration (SAMHSA) in a separate interview.

Planning meetings have been held outside the country, most recently in Amman, Jordan, last March, with assistance from the World Health Organization, SAMHSA, Britain's Royal College of Psychiatrists, U.S. military physicians and others. Security conditions remain too dangerous to hold such meetings within Iraq yet.

Besides their ostensible purpose to plan a new mental health system, the meetings have another value, said Mitchell. During the Saddam regime, merely speaking up could be dangerous. The planning meetings allowed the Iraqi participants to establish an unprecedented level of personal trust, aided by role-playing in work groups. Sadik and SAMHSA Administrator Charles Curie, M.A., jointly presented a talk on leadership and team building.

"In the old days, people just waited to be told what to do," said Mitchell. "Now, once they get over that, things just take off."

Challenges Are Formidable

Much ground remains to be made up, even after several planning meetings held outside Iraq, cautioned Karen Babich, Ph.D., director of global mental health programs at the National Institute of Mental Health, in an interview. Iraqis will need more exposure to current community care models and to contemporary clinical practice, she said. For instance, the physician-centered approach to care that formerly prevailed may be broadened to include nurses, psychologists, social workers, or pharmacists.

Photo courtesy of Heartland Alliance

Iraqi social workers in northern Iraq study jail monitoring techniques and procedures under the auspices of the Heartland Alliance.

To that end, professionals have left the country for brief training courses in the United States, Britain, and elsewhere. Last year, 10 Iraqi psychiatrists trained for three months at Sadik's West Kent site in Britain, and 30 primary care physicians studied psychiatric concepts in a program in the Persian Gulf state of Bahrain.

Another planning meeting is scheduled for March 25 to 30, in Cairo, at which further integration of mental health with primary care and ways to deal with substance abuse will be considered.

Alcohol, Drug Use on Rise

Prescription drugs looted at the time of Saddam's fall represent one source of abusable drugs, especially anxiolytics. Alcohol abuse appears more common than in most other Middle Eastern countries, said Sadik.

A drug-control law is before the Iraqi cabinet, said Alathari, who expressed concern for potential abuse of illicit drugs. Iraq's geographic position and the chaos of the insurgency may place the country on opium and heroin trafficking routes and bring attendant problems. The prior regime claimed there was no drug abuse in Iraq, so current treatment is limited to detoxification and not rehabilitation or prevention, according to a SAMHSA report.

"There is a great need for training Iraqi doctors and for public education about these questions," said Alathari. Heartland Alliance, a Chicago-based nonprofit, has planned a training session in northern Iraq on substance abuse in June.

Updating the system is further complicated by the distribution of health professionals within Iraq. Psychiatrists are concentrated in the large cities, while some rural provinces have none. Often, younger, less-experienced doctors are assigned to the countryside, and little mental health infrastructure exists in most of the country, according to Scott Portman, director of international programs for Heartland Alliance. His organization now trains mental health workers to treat victims of torture.

"Our funding is specifically for torture treatment," said Portman in an e-mail interview from Suleimaniya in northern Iraq. "However, we are training the health care workers more broadly, as . . . it is unethical to assist someone with PTSD but turn away someone with major depression."

The students in this program are 200 medical assistants in rural hospitals and clinics in northern and southern Iraq, areas relatively safer than the center of the country.

In the Iraqi health model, medical assistants are considered better trained than nurses and do preliminary triage and referral. They receive two years of formal education at a medical technical institute, but there is no mental health concentration in their program, unlike specialized training in radiology, surgery, nursing, or pharmacology, said Portman.

The newly trained mental health workers are learning to provide psychosocial services, medication management, and family and community education and to help sensitize other health ministry staff to mental health, mental illness, and psychological trauma, he said. Heartland Alliance's goal is to place these workers in the 10 safest of Iraq's 18 provinces.

"The second phase of our program, if we are lucky enough to keep getting funding, is to create a special mental health worker track in the medical assistant technical colleges," he said.

The project also provides primary care physicians with a practical psychiatric refresher opportunity to help them identify and treat PTSD and major depression or other mood disorders and to recognize and refer severe mental illness cases to psychiatrists in the cities.

"We train physicians to improve their ability to interact with patients who are often traumatized and help the physicians supervise and understand the role of mental health paraprofessionals," said Portman. "Physicians are highly educated and generally Western in outlook—we try to train them to be more tolerant of traditional rural Iraqi cultures and ideas regarding mental health and to reach out in their communities to build alliances with religious leaders, schools, police, and others."

Elsewhere, a Swedish nongovernmental organization (NGO) is providing therapy services in Northern Iraq, an Italian NGO offers psychosocial services to children in Baghdad, and a Slovakian organization provides family support programs in Baghdad.

However Portman fears that U.S. budget cuts may prevent Heartland Alliance from continuing its work.

"A project like this requires a few years to be really successful," he said. "The State Department's Bureau of Democracy, Human Rights, and Labor funded it for the first year, but the administration is cutting human rights funding for Iraq."

The current State department budget for these programs is $11.575 million but the Department has not yet made funding decisions for the coming fiscal year, said State Department spokesman Justin Higgins. "There's still very much a need and we are working with NGOs and our coalition partners to provide these services." ■

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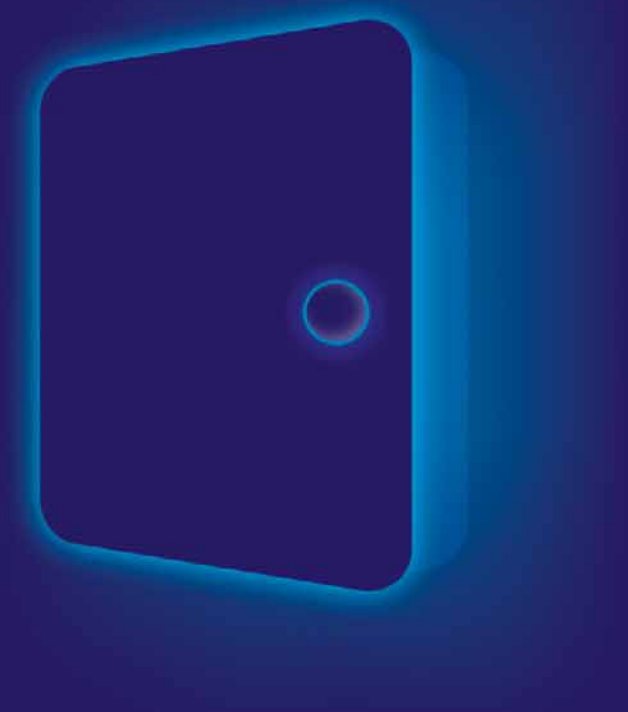

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Few Teens Turn to Adults To Help Mentally Ill Friend

Half of surveyed adolescents say that if they had a friend with mental illness, they would offer emotional support, while others would suggest that the friend use alcohol or drugs to cope.

BY EVE BENDER

Though a majority of adolescents in one Australian study would offer emotional support to a peer with mental illness, only about 1 in 4 would engage an adult to help when concerned about a friend's mental health.

In addition, 1 in 5 students would either take no action to help a friend with mental illness or would make harmful recommendations to the friend, according to a report published in the January *Australian and New Zealand Journal of Psychiatry*.

Researchers at the University of Melbourne's Orygen Research Centre surveyed 1,137 students aged 11 to 17 in schools throughout Southern Australia and the Australian Capital Territory. The schools and students were not randomly selected.

Students were presented with two written vignettes, each featuring an adolescent exhibiting symptoms of mental illness, and asked to address what actions they would take if the peer was a friend they wished to help.

In one of the vignettes, 16-year-old "Mark" displays symptoms of conduct disorder. He rarely comes to class and often frequents the mall, where he plays video games with friends. Mark has been in trouble for firesetting, vandalism, and theft. Though Mark's parents and teachers have tried to discipline him, "it does not work as he does not seem to care what anyone thinks," according to the vignette.

In the other vignette, "Jenny" is a 16-year-old who has been feeling unusually sad for the past month. In addition, she has lost weight due to poor appetite, has trouble concentrating and making decisions, and has lost interest in playing guitar, which "she has always loved."

Overall, in response to both vignettes, more than half of the respondents (53 percent) would offer emotional support to the person in the vignette or would seek further information about the situation from a trusted adult or through the Internet.

Just 23 percent indicated that they would enlist the help of a trusted adult, such as a school counselor.

About 20 percent of the adolescents surveyed would take no steps in helping the peer or expressed a desire to help but would have done so in an inappropriate way. For instance, according to the report, "a number of respondents wrote that they would purchase marijuana or alcohol for the distressed friend." The authors surmised that "in some cases, this was probably a joke, but in other cases it was likely that the respondent considered the use of recreational drugs to be an effective coping mechanism in times of stress."

Others encompassed in the 20 percent indicated that they would take violent action against the person in the vignette. Threats of violence may have been attempts at "misguided humor" on the part of some respondents, according to the authors, but for others, "the use of violence when trying to intervene with someone who is known for violence might seem appropriate."

Other inappropriate responses included threats to "withhold friendship" if the person's behavior did not change.

Another 3.5 percent of respondents listed steps that researchers characterized as "positive social support" but also listed an inappropriate step that didn't involve drugs, alcohol, or violence.

When researchers analyzed the responses by gender, they found that the girls were more likely than the boys to seek an adult's help when concerned about a friend's mental health.

According to lead author Claire Kelley, Ph.D., this may be because "girls more than boys recognize the seriousness of emotional problems" and the potential to develop into mental illness later in life. In contrast, "boys may find it easier to slowly extricate themselves from a friendship that is becoming complicated by emotional problems," she told *Psychiatric News*.

Kelley is the Hugh Lydiard Research Fellow at the Orygen Research Centre.

One other noteworthy finding was that the girls responding to the depression vignette were more likely to offer positive social support (67.8 percent compared with 51.8 percent for conduct disorder), while those responding to the conduct-disorder vignette were more likely to enlist an adult's help (35 percent compared with 21 percent for the depression vignette).

Kelley speculated that "an overt behavioral program is more likely to be frightening to girls, especially if there have been previous episodes of violence by the person," which prompts them to either steer clear" of that person or to "ensure safety by involving adults from the outset."

Stigmatizing attitudes that are prevalent within society or a lack of knowledge about mental illness may play some role in the inappropriate modes of "help" suggested by some of the youngsters. "Many people do not understand that mental illnesses can be effectively treated or that people with mental disorders are not 'crazy' or dangerous," she said.

Mental health education in schools should "include skills for offering help and encouraging peers to seek help," the authors concluded.

An abstract of "Adolescents' Responses to Peers With Depression or Conduct Disorder" is posted at <www.blackwell-synergy.com/action/showMultipleAbstracts>. ■

Police Learn Better Response To People With Mental Illness

The paradigm of standard police procedure has changed as police officers stop looking at some people with mental illness as "suspects" and began to consider them "customers."

BY RICH DALY

Long known as "curbside counselors" because of their front-line-role in dealing with crises involving mentally ill individuals, police are now educated to back up the nickname. A growing number of police departments nationwide have adopted a new approach to interact more effectively and more safely with people with mental illness.

Under the program, known as Crisis Intervention Teams (CITs), communities train individual volunteer officers to know how mental illness manifests and best practices for dealing with those with mental illness in the field. Another arm of the program designates continuously available facilities where mental health professionals always accept police detainees with signs of mental illness. The final but critical aspect of the CIT program is to form partnerships with the mental health community so health professionals and those with mental illness can learn how the police operate and provide feedback on ways to improve the program.

Although the programs vary somewhat in different localities, program participants and researchers said in interviews with *Psychiatric News* and in published studies that the CIT program appears highly effective and among the best options for police departments looking to better handle situations involving people with mental illness.

"We're convinced that by providing additional skills to the officers, they have been able to de-escalate situations that in the past they might have not been so successful with," said Mark Munetz, M.D., chief clinical officer of the Summit County (Ohio) Alcohol, Drug Addiction, and Mental Health Services Board. Thus, individuals who are brought "to our emergency psychiatric facility are in better shape; they are calmer and often more willing to accept help. So it is a terrific program."

Origins of New Response

The CIT program began in Memphis, where police were looking for a better response to calls concerning people who displayed severe emotional disturbances than arresting and incarcerating them.

In 1988 the Memphis Police Department began working with the local chapter of the National Alliance on Mental Illness (NAMI) and two local universities to organize and implement the first CIT program and train officers.

The program now includes about 225 voluntary officers who have had 40 hours of special training from mental health professionals and psychiatrists, family advocates, and consumer groups. The training, like many CIT programs, includes instruction on the basics of psychiatry and psychology and de-stigmatizing mental illness, understanding the symptoms of these conditions, explaining the mechanics of the local mental health system, and learning de-escalation techniques. A part of the de-escalation mindset is the practice of referring to individuals as "customers" instead of "suspects" or "detainees."

"This is probably the most challenging because it is helping officers—within the framework of their own safety and the public safety—learn how to talk more effectively to people in a mental health crisis," said Munetz, who runs training for an Akron, Ohio, CIT program. "In their regular training they are generally taught to take command and be in charge, and a lot of what we teach is being lower key, more patient, and more soothing in their approach."

The number of officers trained—a common CIT guideline is 25 percent of the force—allows some CIT officers to be available regardless of the day or time of an emergency call requiring CIT help.

Having a designated mental health facility to receive people whom CIT officers detail for erratic or disruptive behavior was critical for police to accept the program because it allows them to return to their patrols as quickly as a simple arrest would.

The Memphis program has since spread to police departments throughout Tennessee and in several other states, including Ohio, Texas, North Carolina, Iowa, Oregon, New Mexico, and Washington.

In Ohio the Department of Mental Health developed a coordinating "center of excellence" to promote CIT and other jail-diversion efforts, which has led to more than 1,200 volunteer officers' receiving training since May 2000, according to Munetz, a professor and acting chair of the Department of Psychiatry at the Northeastern Ohio Universities College of Medicine in Rootstown, Ohio.

Effective for Police and Patients?

Although no national study has yet been completed on CIT programs, several limited studies have found them effective and superior to other law enforcement approaches for dealing with individuals with mental illness.

A comparison of the leading police approaches to better handle people with mental illness found CIT programs were superior in having fewer arrests of those who displayed mental illness and a higher likelihood that they would be taken for treatment. The study, in the May 2000 APA journal *Psychiatric Services*, compared the outcomes of the Memphis CIT program with those of the civilian counselor teams who work with police in Birmingham, Ala., and the Knoxville, Tenn., mobile crisis units of specially trained officers.

The study found only the CIT model included a dedicated crisis triage center with a policy of not refusing police cases, which was at least partially responsible for CIT's much greater response to "mental disturbance" calls. The small number of personnel in the Birmingham and Knoxville programs resulted in those units' frequent unavailability to respond to mental disturbance calls.

The study found that CIT officers were less likely to arrest someone in a "special-

please see ***Police*** *on page 25*

Residency Program Combines Child, General Psychiatry

The integration of child and general psychiatry early in training allows for teaching a more holistic approach to psychiatry that views mental health and illness across a person's lifespan.

BY MARK MORAN

At the University of Colorado Health Sciences Center (UCHSC), a psychiatry resident interested in treating children and adolescents won't have to wait three years to do so.

That's because the residency there is initiating an "integrated" training program, combining child and general psychiatry training in one five-year program.

The program is designed to expose interested residents early—and throughout their training—to children and to childhood psychopathology and to inculcate a "lifespan" approach to understanding mental health and psychopathology.

Photo courtesy of the University of Colorado at Denver

Randy Ross, M.D.: "Most people who are interested in treating children go into pediatrics."

Residency program associate director Randy Ross, M.D., told *Psychiatric News* that the new integrated program will begin in July and is part of a nationwide effort to address the severe shortage of child psychiatrists.

"We have bought into the philosophy that part of the problem with attracting people who are interested in being a psychiatrist and in treating children is that in a traditional training program they have to forego seeing kids for three years while they complete their general psychiatry training before going into the child program," Ross said.

Leaders in child psychiatry and education agree that a steep impediment to recruiting quality students into child programs is built into the structure of traditional residency training. By the time residents finish general training, many who might have made excellent child psychiatrists are eager to begin practice, have grown weary of training and the associated debts, or have simply changed their minds and their career direction.

"From the perspective of adult psychiatry as well as of child psychiatry, there is a real need for more child psychiatrists," said David Goldberg, M.D., former president of the American Association of Directors of Psychiatric Residency Training. "The big problem is that there are a lot of incoming residents who say they want child training but change their mind for one reason or another.

"I have experienced that many times," he continued. "Maybe 30 percent of applicants say they are interested in child training, but by the time they finish adult training, they change their mind."

Ross noted that the drop-off is especially pronounced for women residents who are likely to be planning families by the time they have completed general training and for that reason may be particularly averse to starting another rigorous, expensive residency.

So the logic behind an integrated program is this: medical students with an interest in children will be more attracted to training that exposes them to children's mental health issues and psychopathology early, than to a program that requires them to defer such exposure until adult training is completed

"We believe it is critical to let people choose child psychiatry training as an option coming right of medical school," Ross said. "That doesn't mean that we don't think that the general psychiatry training is important to being a child psychiatrist—it's critical—and we know there is a reason why child psychiatry is a subspecialty of adult psychiatry. But we want people to be able to identify as a child psychiatrist early in their training."

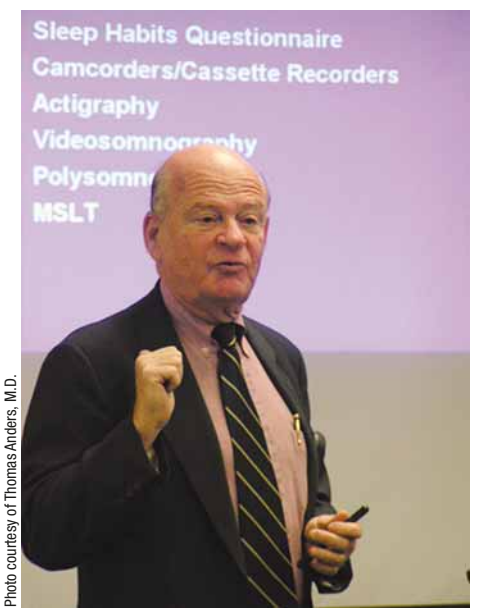

Photo courtesy of Thomas Anders, M.D.

Thomas Anders, M.D.: "Now we have regulatory concurrence that integrated training is feasible. We are left with how to implement this."

Funding Can Be Obstacle

The concept is not without obstacles, however. Most prominent is the fact that adult residency programs are typically paid for by the service obligations of trainees; if a resident cannot cover the adult inpatient service because he or she is covering the child service, the program has lost funding for one of its trainees.

"Psychiatry training has become very service dominated," Ross said. "The people who are paying the bills want more and more accountability. So it's something we talk about—-how to balance educational needs against one another. It's a constant negotiation."

Goldberg said he believes that integrated training, though it offers a number of advantages, is likely to remain the exception. "I don't think this is going to become the norm throughout the country," he said. "I think this is only suitable for large programs that really have the flexibility to bring another track into the residency and have enough slots in the adult program that they can forfeit one."

Another challenge for directors of integrated programs is the maintenance of class cohesion, he said. "Administratively, it's a lot more difficult," Goldberg said. "It involves a lot of collaboration between the adult and child programs. That's a good thing, but it's time consuming and will add more work to an already very full plate for training directors."

Thomas Anders, M.D., president of the American Academy of Child and Adolescent Psychiatry (AACAP), acknowledged those obstacles, but reported that recently the Residency Review Committee for Psychiatry made the adult training requirements more flexible so that integrated child training could begin in the first year.

"Now we have regulatory concurrence that integrated training is feasible," Anders said. "We are left with how to implement this."

Teaches More Holistic Approach

In the new program at UCHSC, Ross said, a resident in the first year learns both adult and child neurology; in the second year of training residents see both child and adult inpatients; and in the third and fourth years they are taught outpatient skills for treating children and adults. The fifth year of training includes advanced clinical electives focused on working with other health care providers such as pediatricians and psychologists.

Ross said that the integration of child and general psychiatry early in training allows for teaching a more holistic approach to psychiatry that views mental health and illness across a person's lifespan—a philosophy that already predominates at UCHSC.

Research Training Included

Ross said his program already has evidence that integrated training can work. In 2004 the department began a six-year program incorporating child and general training along with training in clinical research.

Integration of clinical research skills into child psychiatry training has been championed by James Leckman, M.D., director of research at the Child Study Center at Yale University School of Medicine, and by agencies such as the National Institute of Mental Health and the Institute of Medicine.

"Everything is working," Ross said of the program. "People who want to do child training and learn clinical research are getting an identity as child psychiatrists early."

Integrated training programs like the one at UCHSC are one component of a multidimensional strategy adopted by AACAP to address the shortage of child psychiatrists.

The strategy, outlined in a 2002 "Call to Action" issued by then AACAP President Marilyn Benoit, M.D., entails development of flexible training programs that offer "multiple portals" for entry into the field. It also involves creation of an attractive image of child psychiatry and efforts to increase child psychiatrists' reimbursement rates and funding for residents and training programs.

Anders told *Psychiatric News* that the concept of integrated training grew out of the experience with "triple-board" residency programs, which beginning in the 1980s sought to provide residents training in pediatrics, child psychiatry, and general psychiatry.

"The triple board was an attempt to attract to child psychiatry those who might have chosen pediatrics or adult psychiatry and to create a new kind of child and adolescent psychiatrist who was much more medically and biologically trained and could collaborate with colleagues in pediatrics," he said.

Few institutions, however, have embraced the triple-board model; as of 2004, 10 such programs existed. But Anders said the triple-board program had taken its lead from an earlier model, developed in the 1970s at the University of Pittsburgh by Peter Henderson, M.D., that combined child and adult training "from day one."

Since that time, approximately 11 institutions have adopted something like the Pittsburgh model of integrated training. While they may vary in the specific way in which they configure training requirements, all share in common the principle of exposing residents early and continuously to children and childhood pathology.

Anders believes it is a model that has potential to grow in a way that the triple-board programs have not. "We would like to popularize integrated training to enhance the early and continued exposure of residents to children and childhood psychopathology," he said.

So severe is the shortage of child and adolescent psychiatrists that some change in the structure of training itself appears necessary to open the gates of the field. Anders and Ross also agreed that a critical problem is the nearly complete lack of exposure to child psychiatrists or child psychiatry in medical school.

Begin Exposure in Medical School

"Most people who are interested in treating children go into pediatrics," Ross said. "If we are going to recruit people into child psychiatry, it is critical that we expose medical students to the field, so that they know that child psychiatry exists, what it is, and that programs are available.

"The programs that are most successful in recruiting people into child psychiatry are putting huge efforts into programs aimed at exposing students to the field in medical school," he said.

More information on child psychiatry training and AACAP's 2002 "Strategic Work Force Plan" is posted at <www.aacap.org/training/index.htm>. ■

HIV Study Stipend for Minority Students

Minority medical students can receive a stipend for a fourth-year elective in HIV psychiatry. This rotation will provide intensive training in HIV mental health including neuropsychiatry, a clinical and/or research experience, and participation in APA's Committee on AIDS. This program is intended to identify minority medical students and those who have primary interests in services related to HIV/AIDS and substance abuse and its relationship to the mental health or psychological well-being of ethnic minorities. Program details and application forms are posted at <www.psych.org/aids>. The deadline for submission is March 31.

More information is available from Diane Pennessi in the Office of HIV Psychiatry by phone at (703) 907-8668 or by e-mail at dpennessi@psych.org. ■

Cocaine Addicts Benefit From Treatment Combination

Bupropion enables cocaine-dependent subjects receiving methadone to enjoy the rewards they earn for abstaining from drug use.

BY EVE BENDER

Combining bupropion with behavioral therapy that reinforces a drug-free lifestyle may significantly reduce cocaine use in those in a methadone-maintenance program, according to Yale University researchers.

The combination of treatments worked better than either alone, according to findings published in the February *Archives of General Psychiatry*.

Researchers recruited 106 people who met *DSM* criteria for opiate and cocaine dependence through ads in a New Haven, Conn., community paper and assessed them from September 2001 to November 2003.

The article noted that combined opioid and cocaine use is not uncommon and that some studies have even shown that cocaine use increases in some people who begin receiving methadone for the treatment of opiate addiction.

Study subjects were randomized to receive one of four treatments for 25 weeks. A nurse administered methadone to each of the participants for the duration of the study. An initial dose of 30 mg was increased to a target dose of 60 mg by the end of the first week of the study.

The first group received "contingency management" and bupropion, and the second received contingency management and placebo.

Those randomized to contingency management received vouchers for submitting cocaine- and opiate-free urine samples three times a week. For example, the vouchers could be exchanged for a gift card to Wal-Mart and clothes or be used toward a down payment on a car or a rent payment.

Each time subjects submitted a clean urine sample, they received a $3 voucher. This amount increased by $1 for each subsequent clean urine sample to a maximum of $15 per sample. Neither of the latter two groups received the contingency management.

In addition, those in the contingency management groups also received vouchers for completing steps that were meant to help them remain drug free, such as attending meetings of 12-step programs or working toward the completion of a General Educational Development equivalency exam.

The other subjects were randomized to either the third or fourth group. The former received vouchers with an increasing dollar amount for each urine sample submitted, no matter what the results, plus a placebo pill, while those in the latter group received vouchers under the same conditions, along with bupropion.

The two groups assigned to receive bupropion took an initial dose of 75 mg a day, with the dose increased to the target dose of 300 mg a day by the end of the second week.

James Poling, Ph.D., the study's lead investigator, found that in the group assigned to contingency management plus bupropion, the proportion of cocaine-positive urine samples decreased significantly between the third and 15th week of the study ($p<.001$) and remained low for the remainder of the 25-week study.

In contrast, the groups that received vouchers and bupropion or vouchers and placebo showed no significant reduction in cocaine use.

Poling, an assistant professor of psychiatry at Yale, told *Psychiatric News* that because "there is currently no effective medication for the treatment of cocaine abuse," it is excellent news that when combined with contingency management, bupropion helps to reduce cocaine use.

Thomas Kosten, M.D., who obtained a grant from the National Institute on Drug Abuse to conduct the study, explained why bupropion and contingency management may work so well together.

Kosten is a professor of psychiatry and medicine at Yale and deputy chief of psychiatry at the VA Connecticut Healthcare System.

Chronic cocaine use disrupts a person's ability to experience the pleasure he or she would normally experience upon redeeming the reward vouchers, he explained, because repeated cocaine use leads to a marked reduction in dopamine receptors. "The neurobiology of this reduction in pleasure. . . occurs through an abnormally low level of stimulation of the dopamine reinforcement pathways."

> **"It is excellent news that when combined with contingency management, bupropion helps to reduce cocaine use."**

Bupropion combined with this behavioral therapy "were synergistic due to the ability of bupropion to help subjects experience the pleasure of successful and rewarded drug abstinence," he said.

In acknowledging that drug-treatment programs in many community settings don't have the money to implement contingency management rewards on the scale of this study, Poling mentioned research by Nancy Petry, Ph.D., of the University of Connecticut Health Center, who has found that low-cost contingency management can also be effective in reducing drug addiction.

Poling said that future research should explore the issue of whether bupropion and contingency management can successfully reduce cocaine use beyond the 25-week study period and whether contingency management can be paired with another behavioral intervention, such as cognitive-behavioral therapy, for lasting effects.

An abstract of "Six-Month Trial of Bupropion With Contingency Management With Cocaine Dependence in a Methadone-Maintained Population" is posted at <http://archpsyc.ama-assn.org/cgi/content/abstract/63/2/219>. ■

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Several Factors Critical In Ability to Handle Crises

Several qualities, behaviors, and skills can arm people to deal with misfortune. Because of their calming effects, the SSRI antidepressants and whiffs of neuropeptide-Y might also help.

BY JOAN AREHART-TREICHEL

Twenty-six years ago, a New Jersey couple announced to their mothers that they were moving to New Zealand. The husband's mother was devastated by the news and died a few months later. The wife's mother, however, said, "Oh, that's interesting. I look forward to visiting you there!" And that is precisely what she has done. Her most recent visit was at age 80.

Could this true story illustrate how some people, when faced with a traumatic situation, buckle under, whereas others not only survive but thrive? Possibly, because finding "opportunity in difficult situations" is a major characteristic of resilient people, a resilience researcher reported at a recent meeting of the American Psychoanalytic Association in New York City.

Yet looking for a "silver lining" in storm clouds is not the only attribute or behavior of resilient people, the researcher — Steven Southwick, M.D., a professor of psychiatry at Yale University — emphasized. There are a number of others as well. Notably:

- **Having a moral compass.** "In traumatic situations, there are always difficult choices," Southwick explained. "I have never met a posttraumatic stress disorder patient who did not have a lot of guilt" because he or she believed that they had not done enough to help others affected by the trauma. Resilient individuals, in contrast, are convinced that they took the right course of action in a difficult situation. For instance, he said, an American prisoner of war survived four years in solitary confinement because he believed deeply in what he had done, that he had made the right choices.
- **Religious faith.** There was a woman who was raped, then thrown into a river. Yet she managed to swim to shore and survive. Her religious faith is what saved her, she told Southwick.
- **Meditation.** Meditation has been used for thousands of years to calm the mind, said Southwick. "It is extremely powerful. . . . It helps us face whatever comes our way calmly and courageously."
- **Acceptance.** "Acceptance is a very important survival mechanism," Southwick asserted. Once people accept the implications of a crisis, they can test whether they have the power to change them.
- **Social support.** Friends can help an individual deal with trauma, even if that individual is especially susceptible to stress due to genetic factors. In one study of subjects with a particular version of the serotonin transporter known to make people vulnerable to stress, subjects functioned better if they had social supports on which they could rely.
- **Exercise.** Exercise can promote not just physical resilience but psychological resilience, it appears. When rats increased their physical exercise, it triggered nerve growth in the hippocampus—a brain region not only crucial for memory but also bombarded by stress hormones.
- **Coping skills.** There are numerous skills that people can acquire to help them deal with adversity. For example, Southwick reported, a special-forces soldier learned how to handle different types of weapons, parachute from a plane, speak several foreign languages, pick locks, and master other tasks that could benefit him in a life-or-death situation. As a result, the soldier was confident that, if dropped into the Amazon Jungle, or some other remote area on earth, he would not only survive but find his way home within a week.

Joan Arehart-Treichel

Steven Southwick, M.D.: "Psychiatrists are good at assessing psychopathology, but not very good at assessing people's strengths."

In addition to the qualities, behaviors, and skills that can help people successfully cope with crises, some medications may help as well, Southwick pointed out.

For instance, animals placed on SSRI antidepressants were found to handle stress better than animals not placed on them. One of the reasons may be that the SSRIs, like physical exercise, promote nerve growth in the hippocampus.

The most abundant neuropeptide in the brain—neuropeptide-Y—is known to have a calming effect. Further, soldiers who are more resilient make a lot of it, whereas individuals with posttraumatic stress disorder make very little, Southwick and his colleagues have learned. So they are planning to conduct a study to see if a nasal-spray form of neuropeptide-Y might increase people's ability to cope with stress. ■

Consciousness Continues To Baffle Psychoanalysts

Former President Bill Clinton used to tell the public that he "felt their pain." He may have been right—literally. Empathy has been shown to activate a brain region involved in feeling pain.

BY JOAN AREHART-TREICHEL

A large part of a psychiatrist's day is spent navigating the world of emotions, feelings, and consciousness. Yet what is actually known about these ephemeral mental states?

During the past two decades quite a bit has been learned about emotions, something about feelings, yet very little about consciousness, two sessions at a recent meeting of the American Psychoanalytic Association in New York City suggested.

One session was conducted by Antonio Damasio, M.D., a professor of neuroscience and psychology at the University of Southern California. The other session included Damasio and Arnold Modell, M.D., a professor of psychiatry at Harvard Medical School.

Emotions, Damasio explained, are essentially automatic reactions to a stimulus in the world or in one's mind. Sometimes people's brains respond with a particular emotion because of evolution—for instance, a dark form or a loud noise can provoke fear.

Yet other times, people learn to react emotionally. For example, one individual may be emotionally moved by a Chopin piano concerto, whereas another person may not. Moreover, emotions can be grouped into three tiers—background emotions such as enthusiasm; primary emotions such as fear, anger, and sadness; and social emotions such as compassion.

Scientists have identified specific areas of the brain that trigger emotions, Damasio noted. The amygdala, ventromedial prefrontal cortex, anterior cingulate cortex, anterior insula, and basal ganglia are some of the regions that are known to be involved.

Researchers have also found out that specific brain areas are involved in processing specific emotions. For example, the ventromedial prefrontal cortex is involved in the manufacture of social emotions. About a dozen brain structures are implicated in sparking fear. Also, investigators have discovered some of the changes that occur in the brain as a result of emotions. For instance, regardless of whether they are positive or negative, emotions can influence attention or working memory, and while a small emotional response can enhance attention or memory, a large response can impair them.

Feelings Are Not Emotions

As for feelings, Damasio added, they are not the same as emotions, but are rather composite perceptions about things, situations, or people. For example, a person might say, "I'm not feeling very well today" or "I just don't feel that that house is the right one for us." In fact, an individual can have a feeling about an emotion he or she has experienced. Also, "You have parts of the brain that lead to emotional states and parts of the brain that lead to feelings about these states," and the two may be different. A case in point: A fMRI study showed that when subjects experienced the emotion of sadness, certain brain areas became activated, yet when they formed a feeling about their sadness, other brain domains were aroused.

In contrast, some brain areas may be involved in processing both emotions and feelings, Damasio suggested. Take the insula. In a recent experiment, a skin wound was inflicted on subjects while their partners looked on. The brain activity of both the subjects and their partners was monitored before, during, and after the wound infliction. Results revealed that the insula in both the subjects' and partners' brains became activated right after the wound was inflicted. In other words, as the subjects felt pain in reaction to the wound, their partners "felt" their pain as well—in other words, experienced the emotion of compassion.

Also, feelings have both a mental and physical component, Damasio pointed out. For example, during combat and while in a great state of fear, a soldier can become wounded, yet not feel any pain. "We have this way of fooling ourselves about the body," Damasio said.

Consciousness: The Great Unknown

Finally, when it comes to consciousness, which *Webster's New Collegiate Dictionary* defines as "the quality or state of being aware, especially of something within oneself," a few glimmerings of knowledge been obtained. For example,"emotions and feelings are obligate presences in consciousness," Damasio declared. "I think I am on solid ground in saying that." Nonetheless, a vast number of questions about consciousness still lack answers.

For instance, what is the evolutionary value of consciousness? No one is sure, but Damasio speculates that one of its values is that "it can help you deal with situations that are unpredictable," and one way by which it can do so is by "allowing you to manipulate images in a process of thought." Yet another value of consciousness, Modell believes, is that it benefits "approach behavior." In other words, he explained, people can engage in avoidance behaviors without being conscious of it, yet they need consciousness to engage in approach behaviors—say, selecting a mate.

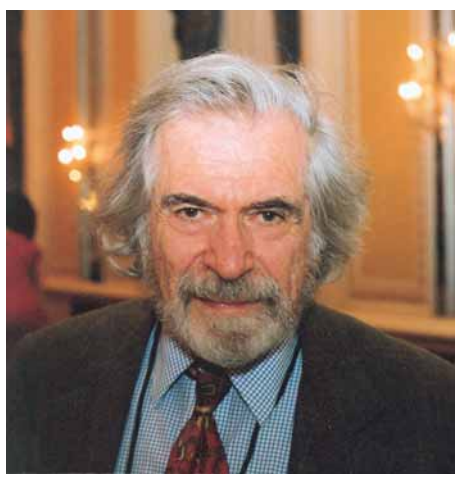
Are patients in a coma conscious? No one knows, but Damasio thinks not. Consciousness, he explained, includes not only brain activity but a sense of self. So even though stimulation can activate parts of the brain of comatose patients, they probably do not have a sense of self.

When people talk in their sleep, are they conscious? Probably to some degree, Damasio speculated, because consciousness seems to be necessary for speaking. And the same holds for sleepwalking, he reasoned. "But I'm not sure," he confessed. "All I know about consciousness and sleepwalking comes from Lady MacBeth."

And how about people who assume more than one personality? Do they have more than one consciousness? Damasio believes not because he has never heard of anyone simultaneously engaging in multiple personalities. Yet an analyst in the audience challenged his conclusion: "I have worked with patients who have exhibited more than one personality at one time." ■

Photos: Joan Arehart-Treichel

Antonio Damasio, M.D.: Consciousness "can help you deal with situations that are unpredictable."



Arnold Modell, M.D. "Consciousness benefits not avoidance behavior but approach behavior."

Don't Make Assumptions About Patients' Culture, Analysts Advised

When patients identify with two or more cultures, they may experience a mild dissociative process and thus need help integrating their different selves.

BY JOAN AREHART-TREICHEL

Not long ago, Kerry Sulkowicz, M.D., a New York City psychoanalyst who consults to businesses, received a request for help from a business executive in another country. Sulkowicz told the executive that he was open to helping him, but admitted that he had never been to the country in question. "No problem," the executive replied. "In fact, it's good that you've never been to my country because you can bring some fresh perspective with you."

This interplay, which Sulkowicz cited at a recent meeting of the American Psychoanalytic Association in New York City, illustrates the fact that when a therapist and a patient do not share the same culture, it does not invariably lead to disappointing results.

In fact, other examples of cultural mismatches between therapist and patient leading to successful outcomes were cited at a session on culture and psychotherapy at the meeting. For example, S. Kalman Kolansky, M.D., an Alexandria, Va., psychiatrist, reported that over the years a number of non-Jewish patients have sought him out because of his "Jewishness," his "otherness."

And along the same lines, when therapist and patient come from the same culture, it does not invariably lead to a positive outcome, session participants stated. For instance, some Hassidic Jewish patients have made it clear to Kolansky that they consider their Jewishness superior to his. And as Carmela Perez, Ph.D., a New York City psychologist said, even though she comes from Guatemala, some Hispanic patients do not regard her favorably because they consider their country of origin in competition with hers.

Carmela Perez, Ph.D., says that some patients think their home country is superior to hers.

So, to optimize the therapist-patient relationship from a cultural vantage, session participants offered some suggestions. Among them:

- First, think about what culture means. It doesn't invariably mean country of origin, current nationality, race, religion, or other obvious demographic factors, Susan Bodnar, Ph.D., an adjunct professor of clinical psychology at Columbia University Teachers College, pointed out. It can also designate micro-cultures within larger cultural landscapes—say, business executives who go drinking together.
- "Each of us has to think carefully about what our cultural contexts are," Boston psychiatrist Michael Caplan, M.D., advised, because therapists' cultural identi-

please see ***Culture*** *on page 16*

Photos: Joan Arehart-Treichel

S. Kalman Kolansky, M.D., is sometimes sought out by non-Jewish patients because of his "Jewishness."

Advocates Condemn Cuts In Federal Health Spending

At long last, Congress approves the final 2006 budget, which includes massive Medicare and Medicaid cuts and a drop in most federal mental health programs and grants.

BY RICH DALY

Congress approved a federal budget in early February that included the first cuts to entitlement programs such as Medicare and Medicaid since 1997.

The delayed vote on the budget, projected to save $39 billion over five years and $99 billion over a decade, was forced after Senate Democrats made small changes to the bill the House passed in December before adjourning.

The measure cuts about 0.3 percent of federal spending over five years but will only slightly dent the federal budget deficit. The cuts sparked opposition from mental health advocates and others, who charged Republicans with slashing necessary spending on programs that help the poor and aged to partially offset tax cuts for the wealthy. Critics of the measure also will point to provisions they say give breaks to the pharmaceutical and insurance industries at the expense of Medicare and Medicaid beneficiaries

The measure cuts about $6.4 billion from Medicare and $4.8 billion from Medicaid.

Physicians Get Some Help

The law includes a one-year freeze on Medicare physician payment rates at the 2005 levels, which averted a scheduled 4.4 percent reduction and will cost $7.3 billion annually. APA lobbied to block the planned cut and instead provide a two-year 1 percent rate increase.

"We're delighted with the efforts of Congress to address the health professional payment issue because we saw that as a potential access barrier itself by creating a significant disincentive for Medicare patients," said Nicholas Meyers, director of APA's Department of Government Relations (DGR).

The measure dropped provisions from the earlier Senate version to establish new Medicare value-based purchasing programs, which track and reward good clinical performance for physicians and other Medicare providers. Nonetheless, the Centers for Medicare and Medicaid Services (CMS) will continue implementation of its Physician Voluntary Reporting Program (PVRP), under which physicians voluntarily send information to CMS about the quality of care they provide to beneficiaries, which APA leaders worry may later develop into a mandatory quality-reporting program. APA strongly opposes the CMS program.

The measure also dropped earlier language allowing marriage and family therapists and mental health counselors to bill Medicare independently for their services. The APA-led opposition to expanded coverage for these providers argued that "scarce resources should be spent first on addressing the discriminatory 50 percent coinsurance requirement for all mental health services," according to Meyers.

Medicaid Beneficiaries to Pay More

The measure allows states to impose new copayments on Medicaid beneficiaries with incomes above the federal poverty line and provides states with considerable flexibility in redesigning their Medicaid programs. Copayments could apply to both services and medications. APA opposed these changes along with the rest of the mental health community.

"We are extremely cognizant of the impact of this, particularly on the poor and disabled, and we are deeply concerned," said Meyers.

It includes controversial Medicaid "asset transfer" language that would make it harder for seniors to qualify for Medicaid coverage of their nursing home care if they have transferred any assets to children or grandchildren.

The law includes an APA-supported provision to allow low-income working parents of disabled children to buy into Medicaid, even if their income exceeds the federal poverty level.

The bill dropped an APA-supported provision for oversight requirements for states that seek to use restrictive formulary policies for atypical antipsychotic and antidepressant drugs.

The cost-sharing provisions could save about $1.9 billion over five years, a figure that jumps to $9.7 billion when projected 10 years out, according to Congressional Budget Office estimates.

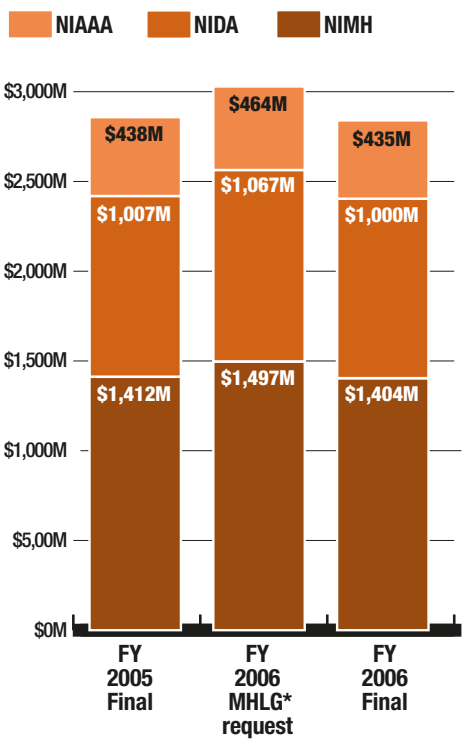
Substantial Medicare Savings Projected

The Medicare cuts came from a wide variety of sources, although significant savings came from lower payments for some imaging services, spending on which has

please see ***Spending*** *on page 34*

MH Funding at NIH

Fiscal 2006 budget for NIH fell to less than the previous year, following a 1 percent across-the-board cut of the federal budget.



* MHLG = Mental Health Liaison Group
Source: National Mental Health Association, December 27, 2005

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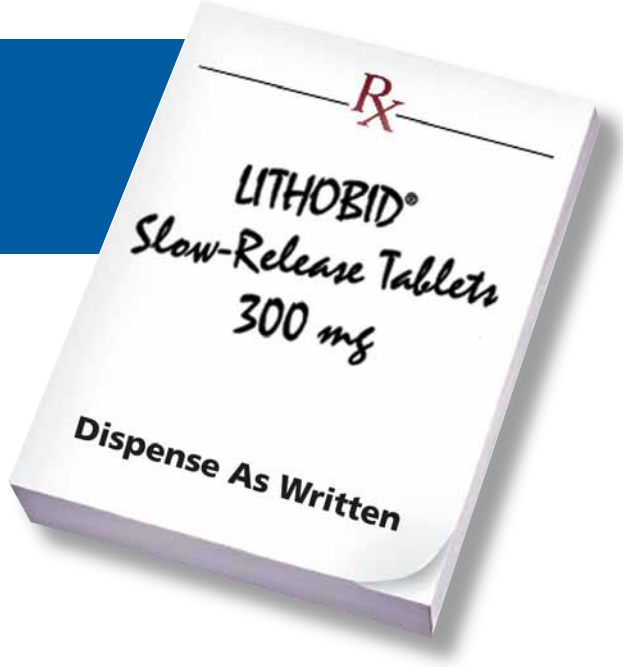

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States Get More Flexibility To Cut Medicaid Programs

As states begin to grapple with how to implement recently approved Medicaid cuts, mental health advocates are preparing to fight for the least disruptive version of the cuts possible.

BY RICH DALY

Congress's approval in February of cuts of about $6.9 billion from Medicaid will require implementation by all 50 states. Mental health advocates hope to use state legislation to minimize the impact of those cuts.

The National Mental Health Association (NMHA) said the groundswell of opposition mounted by mental health advocates can have a long-term impact by focusing on state restructuring of Medicaid through benefit-reductions and greater cost-sharing.

"Advocates are well positioned to remind state legislators of the depth and breadth of opposition to such cuts and of the potential electoral consequences of taking that step," according to an NMHA statement. "Advocates can take pride in the intensity of the fight and the dividends those efforts can have in preventing full implementation of Medicaid cuts at the state level."

Rachel Klein, deputy direct of Health Policy at Families USA, told attendees at that group's recent annual meeting that advocates have an opportunity to impact the cuts at the state level because some cuts are mandatory while others are optional.

States may increase copayments substantially and impose new premiums on many beneficiaries, including some children. The Congressional Budget Office (CBO) estimates these copayment and premium increases would reduce Medicaid expenditures by $1.9 billion over five years and $9.9 billion over 10 years.

Nearly 80 percent of the savings from increases in copayments is expected to come from decreased use of medical services, rather than from collection of increased copayments, according to the CBO.

For the first time, states may allow providers to deny needed services to beneficiaries who cannot make the higher copayments. Previously, Medicaid beneficiaries who could not make required copayments remained financially responsible to the provider but were not denied the needed service or prescription drug.

Another new option for states is joining as one of 10 demonstration states to offer Health Opportunity Accounts. The program offers Medicaid recipients the option of choosing coverage similar to health savings accounts. Klein said the option has dubious benefits because participants first have to pay the deductible before their benefits are activated, which can be up to 110 percent of the $2,500 adult account.

The law also funds a program to allow Medicaid coverage for disabled children whose families are not eligible for the program and is projected to cost $1.4 billion over five years.

In describing his state's implementation of a program to insure all of the children in Illinois, Gov. Rod Blagojevich (D) said the challenge was to find cost savings in Medicaid. Some funding came from the use of primary care case managers to better manage chronic illnesses. He also cautioned legislators to not lose sight of the individual in their effort to save money.

"Budgeting is not just about making revenue match spending. It is a moral process," Blagojevich said.

Further information about the Medicaid cuts are available through the Center on Budget and Policy Priorities at <www.cbpp.org/1-29-06health.htm>. ■

Culture

continued from page 13

fications can influence how they view and interact with patients. For example, Bodnar thinks of herself as a Pennsylvania coalminer's granddaughter who grew up in the Philippines and who then became an anthropologist and is now "a well-educated Jewish psychoanalyst living and working on Manhattan's Upper West Side."

- Determining the cultures with which patients identify can help clinicians better understand their psychological difficulties. For instance, if there is a large gap between how they were raised and what was expected of them, and what they are doing with their present life, it might be a source of their problems, Bodnar said. And one clue to the culture that bilingual or multilingual patients identify with, Perez noted, is the language they prefer to use in therapy.
- When people emigrate from one country to another, it can lead to their becoming confused about who they are and which culture they are a part of. The same is true about patients who identify with two or more cultures because their parents are of different nationalities or because they have lived in different cultures, Bodnar added. In a sense, she said, a "mild dissociative process is what happens when multiple culture identities crash against each other. . . ." Thus, the therapist may need to help them integrate their disparate selves.
- Becoming better informed about various cultures is one way to maximize the potential for successful therapy. ■

Are your patients still caught in the cycle of unresolved panic disorder?

IMPORTANT TREATMENT CONSIDERATIONS

Suicidality in Children and Adolescents

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

Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with Major Depressive Disorder (MDD), obsessive-compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4,400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

- **EFFEXOR XR is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs). EFFEXOR XR should not be used in combination with an MAOI or within at least 14 days of discontinuing treatment with an MAOI; at least 7 days should be allowed after stopping EFFEXOR XR before starting an MAOI.**
- Adult and pediatric patients with MDD can experience worsening of their depression and/or the emergence of suicidal ideation and behavior, whether or not they are taking antidepressants. **Patients treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of drug therapy,**

Please see brief summary of Prescribing Information on adjacent page.

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or at the time of increases or decreases in dose. Anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania have been reported and may represent precursors to emerging suicidality. Stopping or modifying therapy should be considered especially when symptoms are severe, abrupt in onset, or not part of presenting symptoms.

- Treatment with venlafaxine is associated with sustained increases in blood pressure (BP) in some patients. Postmarketing cases of elevated BP requiring immediate treatment have been reported. Pre-existing hypertension should be controlled. Regular BP monitoring is recommended.
- Abrupt discontinuation or dose reduction has been associated with discontinuation symptoms. Patients should be counseled on possible discontinuation symptoms and monitored while discontinuing the drug; the dose should be tapered gradually. See the Precautions section of the Prescribing Information.
- The most common adverse events reported in EFFEXOR XR short-term placebo-controlled MDD, generalized anxiety disorder (GAD), social anxiety disorder (SAD), and/or panic disorder (PD) trials (incidence ≥10% and ≥2x that of placebo) were anorexia, asthenia, constipation, dizziness, dry mouth, ejaculation problems, impotence, insomnia, nausea, nervousness, somnolence, and sweating.

* Panic-free was defined as free from full-symptom panic attacks (ie, panic attacks with 4 or more *DSM-IV®* symptoms).

† Two double-blind, 12-week, placebo-controlled studies in adult patients diagnosed with panic disorder. Patients received fixed doses of 75 (n=158) or 150 (n=159) mg/day in one study and 75 (n=156) or 225 (n=160) mg/day in the other.

‡ Relapse was defined as having 2 or more full-symptom panic attacks per week for 2 consecutive weeks.

§ The cumulative probability of remaining relapse-free at 6 months was 76% with EFFEXOR XR.

Reference: 1. Data on file, Wyeth Pharmaceuticals Inc.

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BRIEF SUMMARY. See package insert for full prescribing information.

Suicidality in Children and Adolescents

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Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with Major Depressive Disorder (MDD), obsessive-compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4,400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

CONTRAINDICATIONS: Hypersensitivity to venlafaxine hydrochloride or to any excipients in the formulation. Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs). **WARNINGS: Clinical Worsening and Suicide Risk—** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. There has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients. Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with MDD and other psychiatric disorders. It is unknown whether the suicidality risk in pediatric patients extends to longer-term use, i.e., beyond several months. It is also unknown whether the suicidality risk extends to adults. **All pediatric patients being treated with antidepressants for any indication should be observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Adults with MDD or comorbid depression in the setting of other psychiatric illness being treated with antidepressants should be observed similarly for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.** 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 and other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see **PRECAUTIONS** and **DOSAGE AND ADMINISTRATION**). **Families and caregivers of pediatric patients being treated with antidepressants for MDD 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 Effexor XR should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose. Families and caregivers of adults being treated for depression should be similarly advised. **Screening Patients for Bipolar Disorder:** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed 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. Prior to initiating antidepressant treatment, patients with depressive symptoms should be 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. Effexor XR is not approved for use in treating bipolar depression. **Potential for Interaction with MAOIs—Adverse reactions, some serious, have been reported in patients who recently discontinued an MAOI and started on venlafaxine, or who recently discontinued venlafaxine prior to initiation of an MAOI. These reactions included tremor, myoclonus, diaphoresis, nausea, vomiting, flushing, dizziness, hyperthermia with features resembling neuroleptic malignant syndrome, seizures, and death. Effexor XR should not be used in combination with an MAOI, or within at least 14 days of discontinuing treatment with an MAOI. At least 7 days should be allowed after stopping venlafaxine before starting an MAOI. Sustained Hypertension**—Venlafaxine is associated with sustained increases in blood pressure (BP) in some patients. Postmarketing cases of elevated BP requiring immediate treatment have been reported. Pre-existing hypertension should be controlled. Regular monitoring of BP is recommended. For patients experiencing sustained increase in BP, consider either dose reduction or discontinuation. **PRECAUTIONS**: **General**—***Discontinuation of Treatment with Effexor XR.*** Abrupt discontinuation or dose reduction of venlafaxine at various doses is associated with new symptoms, the frequency of which increased with increased dose level and longer duration of treatment. Symptoms include agitation, anorexia, anxiety, confusion, coordination impaired, diarrhea, dizziness, dry mouth, dysphoric mood, emotional lability, fasciculation, fatigue, headaches, hypomania, insomnia, irritability, lethargy, nausea, nervousness, nightmares, seizures, sensory disturbances (e.g., paresthesias such as electric shock sensations), somnolence, sweating, tinnitus, tremor, vertigo, and vomiting. Monitor patients when discontinuing treatment. A gradual reduction in the dose rather than abrupt cessation is recommended. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, consider resuming the previously prescribed dose. Subsequently, continue decreasing the dose at a more gradual rate. ***Insomnia and Nervousness***: Treatment-emergent insomnia and nervousness have been reported. In Phase 3 trials, insomnia led to drug discontinuation in 1% of both depressed patients and Panic Disorder (PD) patients and in 3% of both Generalized Anxiety Disorder (GAD) and Social Anxiety Disorder (SAD) patients. Nervousness led to drug discontinuation in 0.9% of depressed patients, in 2% of GAD patients, and in 0% of SAD and PD patients. ***Changes in Weight***: ***Adult Patients***: In short-term MDD trials, 7% of Effexor XR patients had ≥5% loss of body weight and 0.1% discontinued for weight loss. In 6-month GAD studies, 3% of Effexor XR patients had ≥7% loss of body weight, and 0.3% discontinued for weight loss in 8-week studies. In 12-week SAD trials, 3% of Effexor XR patients had ≥7% loss of body weight and no patients discontinued for weight loss. In 12-week PD trials, 3% of Effexor XR patients had ≥7% loss of body weight, and no patients discontinued for weight loss. The safety and efficacy of venlafaxine in combination with weight loss agents, including phentermine, have not been established. Coadministration of Effexor XR and weight loss agents is not recommended. Effexor XR is not indicated for weight loss alone or in combination with other products. ***Pediatric Patients***: Weight loss was seen in patients aged 6-17 receiving Effexor XR. More Effexor XR patients than placebo patients experienced weight loss of at least 3.5% in both MDD and GAD studies (18% vs. 3.6%; $P<0.001$). Weight loss was not limited to patients with treatment-emergent anorexia (decreased appetite). Children and adolescents in a 6-month study had increases in weight less than expected based on data from age- and sex-matched peers. The difference between observed and expected weight gain was larger for children <12 years old than for adolescents >12 years old. ***Changes in Height***: ***Pediatric Patients***: In 8-week GAD studies, Effexor XR patients aged 6-17 grew an average of 0.3 cm (n=122), while placebo patients grew an average of 1.0 cm (n=132); $P=0.041$. This difference in height increase was most notable in patients <12. In 8-week MDD studies, Effexor XR patients grew an average of 0.8 cm (n=146), while placebo patients grew an average of 0.7 cm (n=147). In a 6-month study, children and adolescents had height increases less than expected based on data from age- and sex-matched peers. The difference between observed and expected growth rates was larger for children <12 years old than for adolescents >12 years old. ***Changes in Appetite***: ***Adult Patients***: Treatment-emergent anorexia was more commonly reported for Effexor XR (8%) than placebo (4%) patients in MDD studies. The discontinuation rate for anorexia was 1.0% in MDD studies. Treatment-emergent anorexia was more commonly reported for Effexor XR (8%) than placebo (2%) patients in GAD studies. The discontinuation rate for anorexia was 0.9% for up to 8 weeks in GAD studies. Treatment-emergent anorexia was more commonly reported for Effexor XR (20%) than placebo (2%) patients in SAD studies. The discontinuation rate for anorexia was 0.4% for up to 12 weeks in SAD studies. Treatment-emergent anorexia was more commonly reported for Effexor XR (8%) than placebo (3%) patients in PD studies. The discontinuation rate for anorexia was 0.4% for Effexor XR patients in 12-week PD studies. ***Pediatric Patients***: Decreased appetite was seen in pediatric patients receiving Effexor XR. In GAD and MDD trials, 10% of Effexor XR patients aged 6-17 for up to 8 weeks and 3% of placebo patients had treatment-emergent anorexia. None of the patients receiving Effexor XR discontinued for anorexia or weight loss. ***Activation of Mania/Hypomania***: Mania or hypomania has occurred during short-term depression and PD studies. As with all drugs effective in the treatment of MDD, Effexor XR should be used cautiously in patients with a history of mania. ***Hyponatremia***: Hyponatremia and/or the syndrome of inappropriate antidiuretic hormone secretion (SIADH) may occur with venlafaxine. Consider this in patients who are volume-depleted, elderly, or taking diuretics. ***Mydriasis***: Mydriasis has been reported; monitor patients with raised intraocular pressure or at risk of acute narrow-angle glaucoma (angle-closure glaucoma). ***Seizures***: In all premarketing depression trials with Effexor, seizures were reported in 0.3% of venlafaxine patients. Use cautiously in patients with a history of seizures. Discontinue in any patient who develops seizures. ***Abnormal Bleeding***: Abnormal bleeding (most commonly ecchymosis) has been reported. ***Serum Cholesterol Elevation***: Clinically relevant increases in serum cholesterol were seen in 5.3% of venlafaxine patients and 0.0% of placebo patients treated for at least 3 months in trials. Consider measurement of serum cholesterol levels during long-term treatment. ***Use in Patients With Concomitant Illness***: Use Effexor XR cautiously in patients with diseases or conditions that could affect hemodynamic responses or metabolism. Venlafaxine has not been evaluated in patients with recent history of MI or unstable heart disease. Increases in QT interval (QTc) have been reported in clinical studies. Exercise caution in patients whose underlying medical conditions might be compromised by increases in heart rate. In patients with renal impairment or cirrhosis of the liver, the clearances of venlafaxine and its active metabolites were decreased, prolonging the elimination half-lives. A lower dose may be necessary; use with caution in such patients. **Information for Patients**—Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Effexor XR and should counsel them in its appropriate use. A patient *Medication Guide About Using Antidepressants in Children and Teenagers* is available for Effexor XR. 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 available at www.effexorxr.com or in the approved prescribing information. Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking Effexor XR. **Clinical Worsening and Suicide Risk:** Patients, their families, and their caregivers should be encouraged to be alert to the emergence of symptoms listed in **WARNINGS: Clinical Worsening and Suicide Risk**, especially those seen early during antidepressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to observe for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication. Caution patients about operating hazardous machinery, including automobiles, until they are reasonably sure that venlafaxine does not adversely affect their abilities. Tell patients to avoid alcohol while taking Effexor XR and to notify their physician 1) if they become pregnant or intend to become pregnant during therapy, or if they are nursing; 2) about other prescription or over-the-counter drugs, including herbal preparations, they are taking or plan to take; 3) if they develop a rash, hives, or related allergic phenomena. **Laboratory Tests**—No specific laboratory tests are recommended. **Drug Interactions**— ***Alcohol***: A single dose of ethanol had no effect on the pharmacokinetics (PK) of venlafaxine or O-desmethylvenlafaxine (ODV), and venlafaxine did not exaggerate the psychomotor and psychometric effects induced by ethanol. ***Cimetidine***: Use caution when administering venlafaxine with cimetidine to patients with pre-existing hypertension or hepatic dysfunction, and the elderly. ***Diazepam***: A single dose of diazepam did not appear to affect the PK of either venlafaxine or ODV. Venlafaxine did not have any effect on the PK of diazepam or its active metabolite, desmethyldiazepam, or affect the psychomotor and psychometric effects induced by diazepam. ***Haloperidol***: Venlafaxine decreased total oral-dose clearance of haloperidol, resulting in a 70% increase in haloperidol AUC. The haloperidol C_{max} increased 88%, but the haloperidol elimination half-life was unchanged. ***Lithium***: A single dose of lithium did not appear to affect the PK of either venlafaxine or ODV. Venlafaxine had no effect on the PK of lithium. ***Drugs Highly Bound to Plasma Proteins***: Venlafaxine is not highly bound to plasma proteins; coadministration of Effexor XR with a highly protein-bound drug should not cause increased free concentrations of the other drug. ***Drugs That Inhibit Cytochrome P450 Isoenzymes***: CYP2D6 Inhibitors: Venlafaxine is metabolized to its active metabolite, ODV, by CYP2D6. Drugs inhibiting this isoenzyme have the potential to increase plasma concentrations of venlafaxine and decrease concentrations of ODV. No dosage adjustment is required when venlafaxine is coadministered with a CYP2D6 inhibitor. Concomitant use of venlafaxine with drug treatment(s) that potentially inhibits both CYP2D6 and CYP3A4, the primary metabolizing enzymes for venlafaxine, has not been studied. Use caution if therapy includes venlafaxine and any agent(s) that produces simultaneous inhibition of these two enzyme systems. ***Drugs Metabolized by Cytochrome P450 Isoenzymes***: Venlafaxine is a relatively weak inhibitor of CYP2D6. Venlafaxine did not inhibit CYP1A2 and CYP3A4, CYP2C9 (in vitro), or CYP2C19. ***Imipramine***: Venlafaxine did not affect the PK of imipramine and 2-OH-imipramine. However, desipramine AUC, C_{max} and C_{min} increased by ~35% in the presence of venlafaxine. The 2-OH-desipramine AUCs increased by 2.5-4.5 fold. Imipramine did not affect the PK of venlafaxine and ODV. ***Risperidone***: Venlafaxine slightly inhibited the CYP2D6-mediated metabolism of risperidone to its active metabolite, 9-hydroxyrisperidone, resulting in a ~32% increase in risperidone AUC. Venlafaxine coadministration did not significantly alter the PK profile of the total active moiety (risperidone plus 9-hydroxyrisperidone). **CYP3A4**: Venlafaxine did not inhibit CYP3A4 in vitro and in vivo. ***Indinavir***: In a study of 9 healthy volunteers, venlafaxine administration resulted in a 28% decrease in the AUC of a single dose of indinavir and a 36% decrease in indinavir C_{max}. Indinavir did not affect the PK of venlafaxine and ODV. **CYP1A2**: Venlafaxine did not inhibit CYP1A2 in vitro and in vivo. **CYP2C9**: Venlafaxine did not inhibit CYP2C9 in vitro. In vivo, venlafaxine 75 mg by mouth every 12 hours did not alter the PK of a single 550-mg dose of tolbutamide or the CYP2C9-mediated formation of 4-hydroxy-tolbutamide. **CYP2C19**: Venlafaxine did not inhibit the metabolism of diazepam, which is partially metabolized by CYP2C19 (see *Diazepam* above). ***MAOIs***: See **CONTRAINDICATIONS** and **WARNINGS**. ***CNS-Active Drugs***: Use caution with concomitant use of venlafaxine and other CNS-active drugs. Based on its mechanism of action and the potential for serotonin syndrome, use caution when coadministering venlafaxine with other drugs affecting the serotonergic neurotransmitter systems, such as triptans, serotonin reuptake inhibitors, or lithium. ***Electroconvulsive Therapy (ECT)***: There are no clinical data establishing the benefit of ECT combined with Effexor XR treatment. **Carcinogenesis, Mutagenesis, Impairment of Fertility**—***Carcinogenesis***: There was no increase in tumors in mice and rats given up to 1.7 times the maximum recommended human dose (MRHD) on a mg/m² basis. ***Mutagenesis***: Venlafaxine and ODV were not mutagenic in the Ames reverse mutation assay in Salmonella bacteria or the CHO/HGPRT mammalian cell forward gene mutation assay. Venlafaxine was not clastogenic in several assays. ODV elicited a clastogenic response in the in vivo chromosomal aberration assay in rat bone marrow. ***Impairment of Fertility***: No effects on reproduction or fertility in rats were noted at oral doses of up to 2 times the MRHD on a mg/m² basis. **Pregnancy**—***Teratogenic Effects***—***Pregnancy Category C***. Reproduction studies in rats given 2.5 times, and rabbits given 4 times the MRHD (mg/m² basis) revealed no malformations in offspring. However, in rats given 2.5 times the MRHD, there was a decrease in pup weight, an increase in stillborn pups, and an increase in pup deaths during the first 5 days of lactation when dosing began during pregnancy and continued until weaning. There are no adequate and well-controlled studies in pregnant women; use Effexor XR during pregnancy only if clearly needed. ***Nonteratogenic Effects***. Neonates exposed to Effexor XR late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Complications can arise immediately upon delivery. Reports include respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. This is consistent with a direct toxic effect of SNRIs or a drug discontinuation syndrome. In some cases, it is consistent with serotonin syndrome. When treating a pregnant woman with Effexor XR during the third trimester, carefully consider the potential risks and benefits of treatment and consider tapering Effexor XR in the third trimester. **Labor, Delivery, Nursing**—The effect on labor and delivery in humans is unknown. Venlafaxine and ODV have been reported to be excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Effexor XR, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to 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**). No studies have adequately assessed the impact of Effexor XR on growth, development, and maturation of children and adolescents. Studies suggest Effexor XR may adversely affect weight and height (see **PRECAUTIONS-General**, *Changes in Height* and *Changes in Weight*). Should the decision be made to treat a pediatric patient with Effexor XR, regular monitoring of weight and height is recommended during treatment, particularly if long term. The safety of Effexor XR for pediatric patients has not been assessed for chronic treatment >6 months. In studies in patients aged 6-17, blood pressure and cholesterol increases considered to be clinically relevant were similar to that observed in adult patients. The precautions for adults apply to pediatric patients. **Geriatric Use**—No overall differences in effectiveness or safety were observed between geriatric and younger patients. Greater sensitivity of some older individuals cannot be ruled out. Hyponatremia and SIADH have been reported, usually in the elderly. **ADVERSE REACTIONS**: ***Associated with Discontinuation of Treatment***—The most common events leading to discontinuation in MDD, GAD, SAD, and PD trials included nausea, anorexia, anxiety, impotence, dry mouth, dizziness, insomnia, somnolence, hypertension, diarrhea, paresthesia, tremor, abnormal (mostly blurred) vision, abnormal (mostly delayed) ejaculation, asthenia, vomiting, nervousness, headache, vasodilatation, thinking abnormal, decreased libido, and sweating. ***Commonly Observed Adverse Events in Controlled Clinical Trials for MDD, GAD, SAD, and PD***—Body as a Whole: asthenia, headache, flu syndrome, accidental injury, abdominal pain. Cardiovascular: vasodilatation, hypertension, palpitation. Digestive: nausea, constipation, anorexia, vomiting, flatulence, diarrhea, eructation. Metabolic/Nutritional: weight loss. Nervous System: dizziness, somnolence, insomnia, dry mouth, nervousness, abnormal dreams, tremor, depression, hypertonia, paresthesia, libido decreased, agitation, anxiety, twitching. Respiratory System: pharyngitis, yawn, sinusitis. Skin: sweating. Special Senses: abnormal vision. Urogenital System: abnormal ejaculation, impotence, orgasmic dysfunction (including anorgasmia) in females. ***Vital Sign Changes***: Effexor XR was associated with a mean increase in pulse rate of about 2 beats/min in depression and GAD trials and a mean increase in pulse rate of 4 beats/min in SAD trials. (See **WARNINGS-Sustained Hypertension**). ***Laboratory Changes***: Clinically relevant increases in serum cholesterol were noted in Effexor XR clinical trials. Increases were duration dependent over the study period and tended to be greater with higher doses. ***Other Events Observed During the Premarketing Evaluation of Effexor and Effexor XR***—N=6,670. "Frequent"=events occurring in at least 1/100 patients; "infrequent"=1/100 to 1/1000 patients; "rare"=fewer than 1/1000 patients. **Body as a whole** - Frequent: chest pain substernal, chills, fever, neck pain; Infrequent: face edema, intentional injury, malaise, moniliasis, neck rigidity, pelvic pain, photosensitivity reaction, suicide attempt, withdrawal syndrome; Rare: appendicitis, bacteremia, carcinoma, cellulitis. **Cardiovascular system** - Frequent: migraine, postural hypotension, tachycardia; Infrequent: angina pectoris, arrhythmia, extrasystoles, hypotension, peripheral vascular disorder (mainly cold feet and/or cold hands), syncope, thrombophlebitis; Rare: aortic aneurysm, arteritis, first-degree atrioventricular block, bigeminy, bundle branch block, capillary fragility, cerebral ischemia, coronary artery disease, congestive heart failure, heart arrest, hematoma, cardiovascular disorder (mitral valve and circulatory disturbance), mucocutaneous hemorrhage, myocardial infarct, pallor, sinus arrhythmia. **Digestive system** - Frequent: increased appetite; Infrequent: bruxism, colitis, dysphagia, tongue edema, esophagitis, gastritis, gastroenteritis, gastrointestinal ulcer, gingivitis, glossitis, rectal hemorrhage, hemorrhoids, melena, oral moniliasis, stomatitis, mouth ulceration; Rare: abdominal distension, biliary pain, cheilitis, cholecystitis, cholelithiasis, esophageal spasms, duodenitis, hematemesis, gastroesophageal reflux disease, gastrointestinal hemorrhage, gum hemorrhage, hepatitis, ileitis, jaundice, intestinal obstruction, liver tenderness, parotitis, periodontitis, proctitis, rectal disorder, salivary gland enlargement, increased salivation, soft stools, tongue discoloration. **Endocrine system** - Rare: galactorrhoea, goiter, hyperthyroidism, hypothyroidism, thyroid nodule, thyroiditis. **Hemic and lymphatic system** - Frequent: ecchymosis; Infrequent: anemia, leukocytosis, leukopenia, lymphadenopathy, thrombocythemia; Rare: basophilia, bleeding time increased, cyanosis, eosinophilia, lymphocytosis, multiple myeloma, purpura, thrombocytopenia. **Metabolic and nutritional** - Frequent: edema, weight gain; Infrequent: alkaline phosphatase increased, dehydration, hypercholesteremia, hyperglycemia, hyperlipemia, hypoglycemia, hypokalemia, SGOT increased, SGPT increased, thirst; Rare: alcohol intolerance, bilirubinemia, BUN increased, creatinine increased, diabetes mellitus, glycosuria, gout, healing abnormal, hemochromatosis, hypercalcinuria, hyperkalemia, hyperphosphatemia, hyperuricemia, hypocholesteremia, hyponatremia, hypophosphatemia, hypoproteinemia, uremia. **Musculoskeletal system** - Frequent: arthralgia; Infrequent: arthritis, arthrosis, bone spurs, bursitis, leg cramps, myasthenia, tenosynovitis; Rare: bone pain, pathological fracture, muscle cramp, muscle spasms, musculoskeletal stiffness, myopathy, osteoporosis, osteosclerosis, plantar fasciitis, rheumatoid arthritis, tendon rupture. **Nervous system** - Frequent: amnesia, confusion, depersonalization, hypesthesia, thinking abnormal, trismus, vertigo; Infrequent: akathisia, apathy, ataxia, circumoral paresthesia, CNS stimulation, emotional lability, euphoria, hallucinations, hostility, hyperesthesia, hyperkinesia, hypotonia, incoordination, manic reaction, myoclonus, neuralgia, neuropathy, psychosis, seizure, abnormal speech, stupor, suicidal ideation; Rare: abnormal/changed behavior, adjustment disorder, akinesia, alcohol abuse, aphasia, bradykinesia, buccoglossal syndrome, cerebrovascular accident, feeling drunk, loss of consciousness, delusions, dementia, dystonia, energy increased, facial paralysis, abnormal gait, Guillain-Barré syndrome, homicidal ideation, hyperchlorhydria, hypokinesia, hysteria, impulse control difficulties, libido increased, motion sickness, neuritis, nystagmus, paranoid reaction, paresis, psychotic depression, reflexes decreased, reflexes increased, torticollis. **Respiratory system** - Frequent: cough increased, dyspnea; Infrequent: asthma, chest congestion, epistaxis, hyperventilation, laryngismus, laryngitis, pneumonia, voice alteration; Rare: atelectasis, hemoptysis, hypoventilation, hypoxia, larynx edema, pleurisy, pulmonary embolus, sleep apnea. **Skin and appendages** - Frequent: pruritus; Infrequent: acne, alopecia, contact dermatitis, dry skin, eczema, maculopapular rash, psoriasis, urticaria; Rare: brittle nails, erythema nodosum, exfoliative dermatitis, lichenoid dermatitis, hair discoloration, skin discoloration, furunculosis, hirsutism, leukoderma, miliaria, petechial rash, pruritic rash, pustular rash, vesiculobullous rash, seborrhea, skin atrophy, skin hypertrophy, skin striae, sweating decreased. **Special senses** - Frequent: abnormality of accommodation, mydriasis, taste perversion; Infrequent: conjunctivitis, diplopia, dry eyes, eye pain, hyperacusis, otitis media, parosmia, photophobia, taste loss, visual field defect; Rare: blepharitis, cataract, chromatopsia, conjunctival edema, corneal lesion, deafness, exophthalmos, eye hemorrhage, glaucoma, retinal hemorrhage, subconjunctival hemorrhage, keratitis, labyrinthitis, miosis, papilledema, decreased pupillary reflex, otitis externa, scleritis, uveitis. **Urogenital system** - Frequent: prostatic disorder (prostatitis, enlarged prostate, and prostate irritability), urination impaired; Infrequent: albuminuria, amenorrhea, breast pain, cystitis, dysuria, hematuria, kidney calculus, kidney pain, leukorrhea, menorrhagia, metrorrhagia, nocturia, polyuria, pyuria, urinary incontinence, urinary retention, urinary urgency, vaginal hemorrhage, vaginitis; Rare: abortion, anuria, balanitis, bladder pain, breast discharge, breast engorgement, breast enlargement, endometriosis, female lactation, fibrocystic breast, calcium crystalluria, cervicitis, orchitis, ovarian cyst, prolonged erection, gynecomastia (male), hypomenorrhea, kidney function abnormal, mastitis, menopause, pyelonephritis, oliguria, salpingitis, urolithiasis, uterine hemorrhage, uterine spasm, vaginal dryness. **Postmarketing Reports**: agranulocytosis, anaphylaxis, aplastic anemia, catatonia, congenital anomalies, CPK increased, deep vein thrombophlebitis, delirium, EKG abnormalities such as QT prolongation; cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia, ventricular extrasystoles, and rare reports of ventricular fibrillation and ventricular tachycardia, including torsades de pointes; epidermal necrosis/Stevens-Johnson syndrome, erythema multiforme, extrapyramidal symptoms (including dyskinesia and tardive dyskinesia), angle-closure glaucoma, hemorrhage (including eye and gastrointestinal bleeding), hepatic events (including GGT elevation; abnormalities of unspecified liver function tests; liver damage, necrosis, or failure; and fatty liver), involuntary movements, LDH increased, neuroleptic malignant syndrome-like events (including a case of a 10-year-old who may have been taking methylphenidate, was treated and recovered), neutropenia, night sweats, pancreatitis, pancytopenia, panic, prolactin increased, pulmonary eosinophilia, renal failure, rhabdomyolysis, serotonin syndrome, shock-like electrical sensations or tinnitus (in some cases, subsequent to the discontinuation of venlafaxine or tapering of dose), and SIADH (usually in the elderly). Elevated clozapine levels that were temporally associated with adverse events, including seizures, have been reported following the addition of venlafaxine. Increases in prothrombin time, partial thromboplastin time, or INR have been reported when venlafaxine was given to patients on warfarin therapy. **DRUG ABUSE AND DEPENDENCE**: Effexor XR is not a controlled substance. Evaluate patients carefully for history of drug abuse and observe such patients closely for signs of misuse or abuse. **OVERDOSAGE**: Electrocardiogram changes (e.g., prolongation of QT interval, bundle branch block, QRS prolongation), sinus and ventricular tachycardia, bradycardia, hypotension, altered level of consciousness (ranging from somnolence to coma), rhabdomyolysis, seizures, vertigo, liver necrosis, and death have been reported. Treatment should consist of those general measures employed in the management of overdosage with any antidepressant. Ensure an adequate airway, oxygenation and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients. Activated charcoal should be administered. Due to the large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. No specific antidotes for venlafaxine are known. In managing overdosage, consider the possibility of multiple drug involvement. Consider contacting a poison control center for additional information on the treatment of overdose. Telephone numbers for certified poison control centers are listed in the Physicians' Desk Reference® (PDR). **DOSAGE AND ADMINISTRATION**: Consult full prescribing information for dosing instructions. **Switching Patients to or From an MAOI**—At least 14 days should elapse between discontinuation of an MAOI and initiation of therapy with Effexor XR. At least 7 days should be allowed after stopping Effexor XR before starting an MAOI (see **CONTRAINDICATIONS** and **WARNINGS**). This brief summary is based on Effexor XR Prescribing Information W10404C019, revised November 2005.

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Psychiatrists Proactive in Scope-of-Practice Battles

Although legislation in nine states to expand psychologists' scope of practice to include drug prescribing moved little last year, district branches and APA see emerging bills as a continuing threat.

BY RICH DALY

As legislation to grant prescribing privileges to psychologists has proliferated in recent years, state psychiatric organizations have sought greater support from other state and national groups, including APA, to fight such bills.

APA has stepped up its effort to curb such scope-of-practice expansions following the approval in recent years of laws in New Mexico and Louisiana to allow psychologists to prescribe drugs. APA has reached out to other national organizations to help bolster the efforts of district branches and state associations, which are seen as the front line in efforts to fend off such legislation.

"We are not alone in psychiatry with our concerns over the safety of patients when more and more groups of nonphysician health care providers want to expand their practices beyond their training and education," said James H. Scully Jr., M.D., APA medical director and CEO. "Our members have been intensely concerned about nonphysicians such as psychologists practicing medicine without adequate education and the risks that poses to patients."

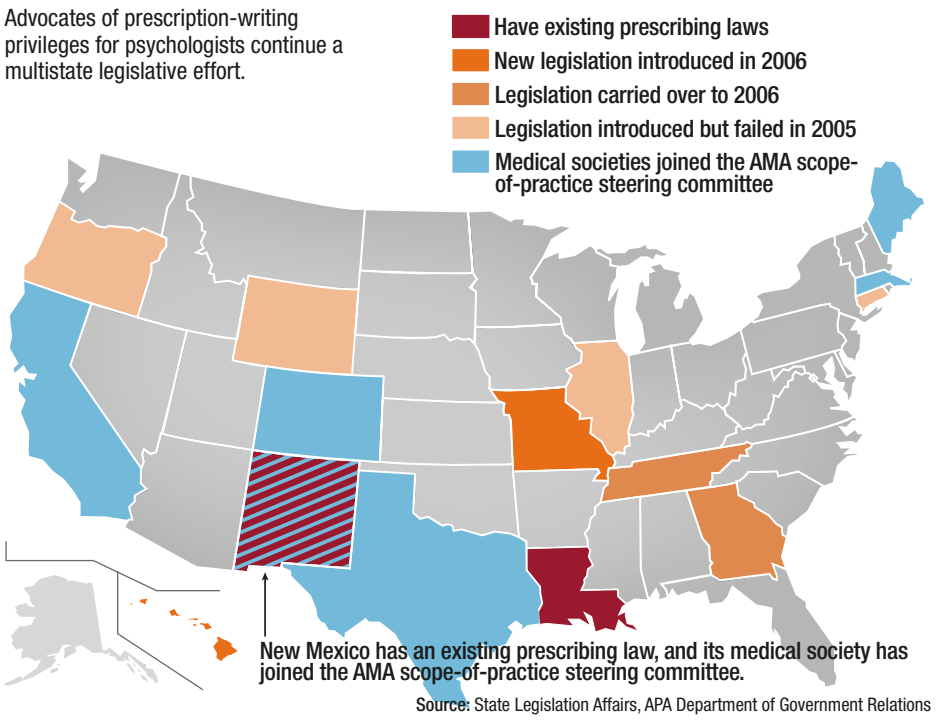
APA's efforts have included increased financial assistance to state groups, advice for district branches on resisting such legislation, and formation of a partnership with the AMA and other specialty societies.

The increased effort was based in part on the proliferation of such bills, which appeared in nine states in 2005. Only legislation in Hawaii and New Mexico—which sought to expand existing psychologist prescription-writing privileges—advanced at all, but bills were offered in Wyoming, Connecticut, Oregon, Tennessee, Georgia, Missouri, and Illinois.

APA's efforts may soon be tested in several states where bills already have been introduced in the 2006 legislative session.

The State of Prescribing Legislation

Advocates of prescription-writing privileges for psychologists continue a multistate legislative effort.



Source: State Legislation Affairs, APA Department of Government Relations

Missouri

A bill (HB 1447) sponsored by state Rep. Dennis Wood (R) would create the classification of licensed prescribing psychologist under the State Committee of Psychologists. The bill would authorize psychologists to write prescriptions for Schedule II psychotropic medicine "or any other psychological treatment or laboratory test as it relates to the practice of psychology."

The bill would require candidates to have one year of supervision with at least 100 patients consistent with "supervision-preceptorship" models recommended by the American Psychological Association and 300 hours of didactic educational training, and to pass an exam testing their competency.

The bill would require psychologists to form a collaborative practice agreement with a licensed physician for one year to expose them to diagnosis and treatment of medical problems.

The legislation, which did not advance when introduced last year, is not expected to gain much support this year, according to Jill Watson, interim executive director of the Western Missouri Psychiatric Society. She credits APA with helping the district branch stay informed about developments on the issue in other states. APA's message to state groups to form stronger partnerships with their better-funded and more connected state medical societies has already been realized in Missouri, where the state medical society undertakes all of the lobbying against the psychologist prescription bill.

Watson said she hopes to get the society's membership more focused on the issue and to take a more active role in lobbying against the bill.

Georgia

The Georgia Psychiatric Physicians Association (GPPA) is facing the reintroduction of a psychologist prescribing bill introduced at the end of last year's legislative session, said Lasa Joiner, the association's executive director and lobbyist.

The bill (HB 923), sponsored by state Rep. Clay Cox (R), would authorize "health service provider psychologists" who meet continuing education requirements to prescribe drugs in certain circumstances.

No movement appears likely on the bill, but Joiner said the GPPA is watching that the legislation is not attached to scope-of-practice bills for other allied health professionals that are advancing in the legislature.

The legislation's authors justify it on concerns that psychiatrists are insufficiently dispersed throughout the state to allow timely visits by patients requiring a psychiatric medication. The bill sponsor, who owns a private probation company, said the legislation may help patients such as his clients who live in rural areas. Joiner said he will likely find psychologists are no better distributed around the state.

A better option might be the approval of another bill to allow advanced-practice nurses—such as nurse practitioners—to prescribe under a protocol with a physician, Joiner said. Georgia is the only state that does not allow advanced-practice nurses to write a prescription, though they are allowed to call in a prescription over the phone.

In recent years GPPA has received APA grants to help fund its lobbying effort when hotly contested bills affecting mental health care have arisen. The group also benefits from the Georgia Medical Association's grassroots lobbying campaign, which draws on a pool of more than 6,000 patient-advocates and physicians to pressure legislators.

Their lobbying focus is to help legislators understand the risks and complexities of prescribing medications instead of setting up a choice between psychologists and psychiatrists.

Tennessee

Legislation in Tennessee (HB 479 and SB 723) would give prescriptive authority to psychologists certified by a board of examiners in psychology. It also would require training and education standards set by the board, which would include a psychiatrist representative.

The legislation advanced out of a House subcommittee for the first time last year, said Greg Kyser, M.D., chair of the Legislative Committee of the Tennessee Psychiatric Association (TPA). He credited support from the Tennessee Medical Association and the local branch of the National Alliance on Mental Illness for stopping the bill's progress. An emergency lobbying grant from APA also was critical.

please see ***Scope of Practice*** *on page 34*

AMA Forms Coalition to Thwart Non-M.D. Practice Expansion

Members of a new medical partnership plan to share expertise and resources in turning the tide against expansions in nonphysician health professionals' scope of practice.

BY RICH DALY

In an effort to marshal the medical community's resources against the growing threat of expanding scope of practice for allied health professionals, the AMA has formed a national partnership to confront such initiatives nationwide.

The AMA Scope of Practice Steering Committee, formed at the urging of APA, will coordinate research to help medical specialty societies and state medical associations fight expansions in nonmedical scope of practice and improve information sharing among those groups.

The strength of the approach lies in the breadth of its membership, which will feed information on local legislative developments into the partnership so all of the members will know what legislative strategies allied health professionals are using nationally, according to Michael Maves, M.D., executive vice president and CEO of the AMA.

The committee will use $25,000 annual contributions from its initial members to fund research that helps refute the key arguments allied health professionals use to advance their measures in state legislatures. Initial research will accumulate national data on differences in training and education between physicians and other medical professionals and track the geographic distribution of such professions. Advocates of scope-of-practice expansion often mitigate differences between allied health professionals and physicians and claim such legislation is needed to improve health care access in areas underserved by physicians.

The partnership also will fund campaigns to stop scope-of-practice legislation in states where such bills appear likely to advance.

Issues surrounding prescriptive authority will be a major focus for the partnership, which was formed in part at the urging of APA Medical Director James H. Scully Jr., M.D. APA has helped lead physicians into the scope-of-practice fight following the enactment of laws in Louisiana and New Mexico that allow psychologists to write prescriptions.

"These are issues that go beyond any one specialty," Scully said. Every medical specialty has concerns with a group of allied health professionals seeking privileges generally reserved for physicians.

The group will undertake projects focusing on the identification of what constitutes adequate training and establish relationships with all of the state medical boards and associations, Scully said. That coordination will help clarify the message to state legislators that scope-of-practice concerns are not turf issues for one or another specialty but are concerns of the profession of medicine.

Although the partnership aims to expand to all 50 states, its initial state medical society members are from Massachusetts, Colorado, Texas, California, New Mexico, and Maine. It also includes six medical specialty societies: APA, American Society of Plastic Surgeons, American Academy of Otolaryngology–Head and Neck Surgery, American Academy of Ophthalmology, American Academy of Orthopedic Surgeons, and American Society of Anesthesiologists. ■

APA Works on Many Fronts For Members, Patients

BY EUGENE D. CASSEL, J.D.

Throughout the year, *Psychiatric News* provides regular and comprehensive coverage of APA's many advocacy activities in both the public and private sector, including government relations, public affairs, business initiatives, and psychiatric practice. I applaud that coverage and want to highlight some of our activities from 2005 and our plans for 2006 as part of our efforts to provide you with more information on how APA is working on your behalf.

Eugene Cassel, J.D., is special counsel and director of APA's Division of Advocacy.

As you may recall, the Division of Advocacy is composed of the Department of Government Relations, the Office of Healthcare Systems and Financing, and the Office of Communications and Public Affairs. Many—if not most—of our activities are a result of group efforts, not only within the division but also through communication and participation with APA's components, leadership, and other staff and divisions including, of course, our medical director and CEO, James H. Scully Jr., M.D.

A major initiative in 2005 was the "Healthy Minds, Healthy Lives" public information campaign that led our efforts to reduce the stigma associated with mental illness and put a new and positive face on mental health and psychiatry. Implemented by the Office of Communications and Public Affairs, the campaign provided both electronic and written communications to the public, as well as useful information for our members and our district branches/state associations (DB/SAs). We launched our consumer Web site, <www.HealthyMinds.org>; developed a new series of "Let's Talk Facts" brochures and fact sheets, which are available in English and Spanish; created a new public service announcement; and posted ParentsMedGuide.org in English and Spanish to assist parents who are concerned about their children's mental health, specifically depression.

As a first-time endeavor, we produced a video on the Mental Illness Awareness Week Congressional Symposium, cosponsored by APA and NAMI, to help raise awareness in Congress of posttraumatic stress disorder suffered by returning soldiers and survivors of natural disasters such as Hurricane Katrina.

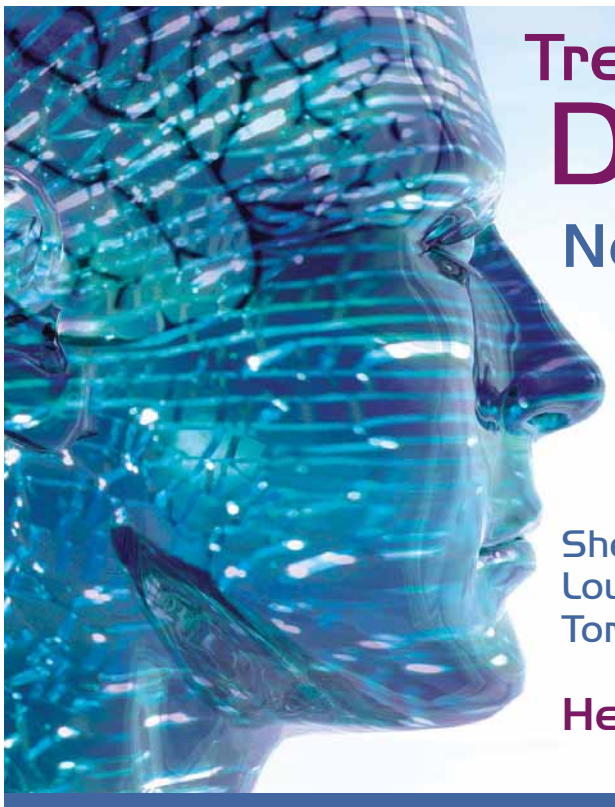
This year we are launching our second year of the "Healthy Minds, Healthy Lives" campaign, which remains very timely, given the increase in media and public attention to mental illnesses and psychiatry over the past year. In addition to our key messages, the public has had to sort through many perspectives on mental health from a range of sources including celebrities, the media, physicians, government officials, and mental health providers, to name a few. To ensure that APA continues to understand which messages are most meaningful to the public, as part of the 2006 campaign, we will conduct new consumer research to help gauge public understanding of mental disorders and psychiatry. From this research, we will be able to provide our members and the public with information to help counter misinformation about psychiatric illnesses and treatment. Other important aspects of our Healthy Minds campaign will include an array of national and local media and advertising placements and several new "Let's Talk Facts" brochures, with topics ranging from obsessive-compulsive disorder and substance use disorders to mental health in various minority communities.

Implementation of Medicare Part D, the new Medicare prescription drug benefit, has been beset by significant problems in enrollment and communications between the Centers for Medicare and Medicaid Services (CMS), the health plans, and pharmacies, resulting in reports of patients not receiving their medications. APA, partnering with the National Mental Health Association, National Alliance on Mental Illness, American Association for Geriatric Psychiatry, American Association of Community Psychiatrists, National Association of State Mental Health Program Directors, National Council for Community Behavioral Health Care, and Treatment Effectiveness Now, has developed a Web site at <www.MentalHealthPartD.org> to assist our members, patients, families, and providers in transitioning to Part D.

APA and other partners met with CMS numerous times in 2005 detailing our concerns focusing on the Medicare/Medicaid (dual-eligible) patient population, drug formularies and administrative processes. We have increased our activities this year as implementation has hit some major snags. We have established an ongoing relationship with CMS staff through meetings, e-mails, and phone calls, sometimes on a daily basis, in an effort to resolve issues. APA has broadened its efforts including meeting with members of Congress and working with the AMA and national medical specialty societies to urge strongly that the problems be fixed.

We have also provided APA DB/SAs with letters and articles detailing the new Part D program and issues that might arise for physicians and continue to hold a weekly

please see ***APA Works*** *on page 20*



Treatment-Resistant Depression: New Data, New Approaches

Saturday, May 20, 2006

Dinner 5:30–6:00 PM

Scientific Program 6:00–9:00 PM

Sheraton Centre Toronto Hotel
Lower Concourse Grand Ballroom
Toronto, Ontario, Canada

Held at the APA 2006 Annual Meeting

Agenda

6:00 PM **Introduction**
David L. Dunner, MD—Chairman
University of Washington School of Medicine

6:05 **Definitions and Clinical Characteristics of Treatment-Resistant Depression**
David L. Dunner, MD

6:30 **Treatment Resistance and Genes: The Biology vs. Pharmacology Enigma**
Francisco A. Moreno, MD • University of Arizona College of Medicine

6:55 **Positron Emission Tomography of Chronic Vagus Nerve Stimulation for Severe Treatment-Resistant Depression**
Jose V. Pardo, MD • University of Minnesota Medical School

7:20 **Augmentation Strategies for Patients With Difficult-to-Treat Major Depressive Disorder**
Alicia Ruelaz, MD • Cedars-Sinai Health System

7:45 **Brain Stimulation Therapies for Treatment-Resistant Depression**
Linda L. Carpenter, MD • Brown Medical School

8:10 **Panel Discussion and Q&A Session**

9:00 **Conclusion**

The American Psychiatric Association (APA) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The APA designates this educational activity for a maximum of 3 *AMA PRA Category 1 Credits*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Attendees must be registered for the APA Annual Meeting to attend this symposium. Seating is limited and will be based on a first-come, first-served basis. For more information about the meeting, please visit the APA website at www.psych.org or contact the APA toll free at 1-888-357-7924 (within the US or Canada) or 703-907-7300.

Statement of Need

This symposium will present new findings regarding treatment-resistant depression (TRD). About half of all patients who are treated for depression either do not respond to therapy or do not achieve a full remission of symptoms. Persistence of depression in these patients results in continued impairment in psychosocial function and increases the likelihood of medical morbidity and suicide mortality. In this symposium, there will be a discussion of the definition of TRD, its clinical, neuroradiological, and familial characteristics, psychotherapeutic and psychopharmacologic treatment strategies, and the use of physical therapies to enhance response. Novel treatments undergoing research in this population will be presented. Patients with TRD pose considerable problems for clinicians involved in their care. Presentations from this symposium will be aimed at providing rational and systematic approaches for clinicians to improve outcomes in patients with TRD.

Educational Objectives

At the conclusion of this program, the participants should be better able to

- Assess the therapeutic approach to treating patients with treatment-resistant depression (TRD)
- Identify the complexities of a diagnosis of TRD
- Recognize the "naturalistic" treatment outcome of TRD
- Identify brain metabolic correlates of TRD and describe the effects of chronic vagus nerve stimulation (VNS) on brain metabolism in TRD
- Define the role of genetics in depressive disorders
- Describe genetic and environmental influences in the biology of depression and treatment resistance
- Evaluate the strengths and weaknesses of the existing acute treatment data investigating the efficacy of augmentation treatment for difficult-to-treat major depressive disorder
- Utilize efficacy data for established and investigational central neuromodulatory treatments for TRD, including electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), magnetic seizure therapy (MST), and vagus nerve stimulation (VNS) therapy

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Supported by an educational grant from Cyberonics

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In schizophrenia…

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- Significant control achieved between 15 and 30 minutes* after injection[1,3]
- Proven advantages over haloperidol IM
  - twice the improvement as measured on the BPRS[4†]
  - significantly lower incidence of movement disorders[2‡]
- Smooth transition, with continued improvement, from IM to oral therapy[2,4]
- May be used concomitantly with benzodiazepines

*In 2 pivotal studies vs control, significance was achieved at 15 minutes (with 10 mg dose) and 30 minutes (with 20 mg dose), respectively.

†In a 7-day, open-label IM-to-oral transition study.

‡In a 6-week, open-label IM-to-oral transition study.

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*and **Injection** (ziprasidone mesylate)*

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

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

In fixed-dose, pivotal studies, the most commonly observed adverse events associated with the use of GEODON for Injection (incidence ≥5%) and observed at a rate in the higher GEODON dose groups (10 mg, 20 mg) of at least twice that of the lowest GEODON dose group (2 mg control) were somnolence (20%), headache (13%), and nausea (12%).

Please see brief summary of prescribing information on adjacent page.

APA Works

continued from page 18

conference call with DB/SA executive staff to provide regular updates and to hear how the implementation is going in the various states. Please share your experience with Part D—the good, the bad, and the ugly—through APA's Medicare Part D Help Line at (866) 882-6227 or by e-mail at partd@psych.org (see box on page 1). We want to hear from you.

Our Medicare Part D efforts have been led by the Office for Healthcare Systems and Financing. Other initiatives this year include continuing high-quality and responsive membership service through the managed care help line, providing key technical assistance and advocacy on CPT coding and practice management, as well as reaching out and working with the business community addressing employee mental health. Our business outreach also includes our renewed cosponsorship of the Second World Congress Leadership Summit scheduled for May.

The first session of the 109th Congress was challenging for APA and the rest of medicine, as advocacy goals for our patients and the profession were buffeted by budget deficit actions by Congress directed at Medicaid and Medicare. The budget deficit conference agreement passed by the Senate and the House and signed by President Bush includes reductions in Medicare and Medicaid spending of roughly $40 billion over the next five years.

The conference agreement grants the states the flexibility to redesign their Medicaid program and impose copayments and is certainly of concern to APA and many other mental health advocacy organizations. APA strongly opposed these Medicaid reductions (see page 16).

Despite strong interest by some members of Congress in the inclusion of pay-for-performance legislation for physicians in the provisions of the conference agreement, such language was successfully not included. Instead of permitting a 4.4 percent decrease in the Medicare fee schedule, which APA and all of medicine strongly opposed, the conferees agreed to a one-year freeze. A provision permitting marriage and family therapists to bill Medicare independently was successfully removed.

Your DGR staff was successful in having legislation passed by Congress and signed by President Bush that removes the 30-patient group-practice limit on buprenorphine treatment. Implementation of this law will significantly increase access to these treatments.

For 2006, the second session of the 109th Congress, we will be seeking passage of legislation to phase out Medicare's discriminatory 50 percent outpatient coinsurance, mental health parity legislation, legislation to eliminate the statutory ban on Medicare coverage of benzodiazepines, psychiatry workforce legislation, increased NIH and VA funding, legislation protecting patient privacy, Medicaid improvements, and many other important initiatives.

To further these activities, APA will be convening major events on Capitol Hill, such as the Advocacy Day Conference and the Academic Consortium, designed for APA members and partners to meet with their members of Congress and staff and advocate for the above-noted priorities. Participants at these events will receive health policy briefings and instruction to sharpen their lobbying skills.

Throughout 2005, APA continued to provide important financial and staff support to our DB/SAs in states facing strong challenges from psychologists to win prescribing authority by legislative fiat. Despite the 2005 implementation of prescribing laws in New Mexico and Louisiana, no new laws were approved, and psychologist-prescribing bills were defeated in Hawaii, Wyoming, Oregon, Connecticut, Missouri, and Illinois. New Mexico defeated legislation to expand the psychologist prescribing formulary, and New Hampshire defeated legislation to establish an independent board of psychology, seen as a precursor to a prescribing bill. Without question, there will be additional legislative challenges in 2006. Bills have already been introduced in Hawaii and Missouri and carried over from 2005 in Georgia and Tennessee (see page 17).

I want to acknowledge the important role of our APA*PAC* in providing support for our Congressional activities. In 2005 our membership has grown by nearly 250 members, to a total of 1,693 members, and our PAC member contributions increased significantly! APA*PAC* hosted or cohosted events for 64 members of Congress, and our members in their home districts had many opportunities to meet and discuss psychiatry's issues with their House and Senate members.

I want to offer my thanks to our many APA members who participate and support our APA*PAC*.

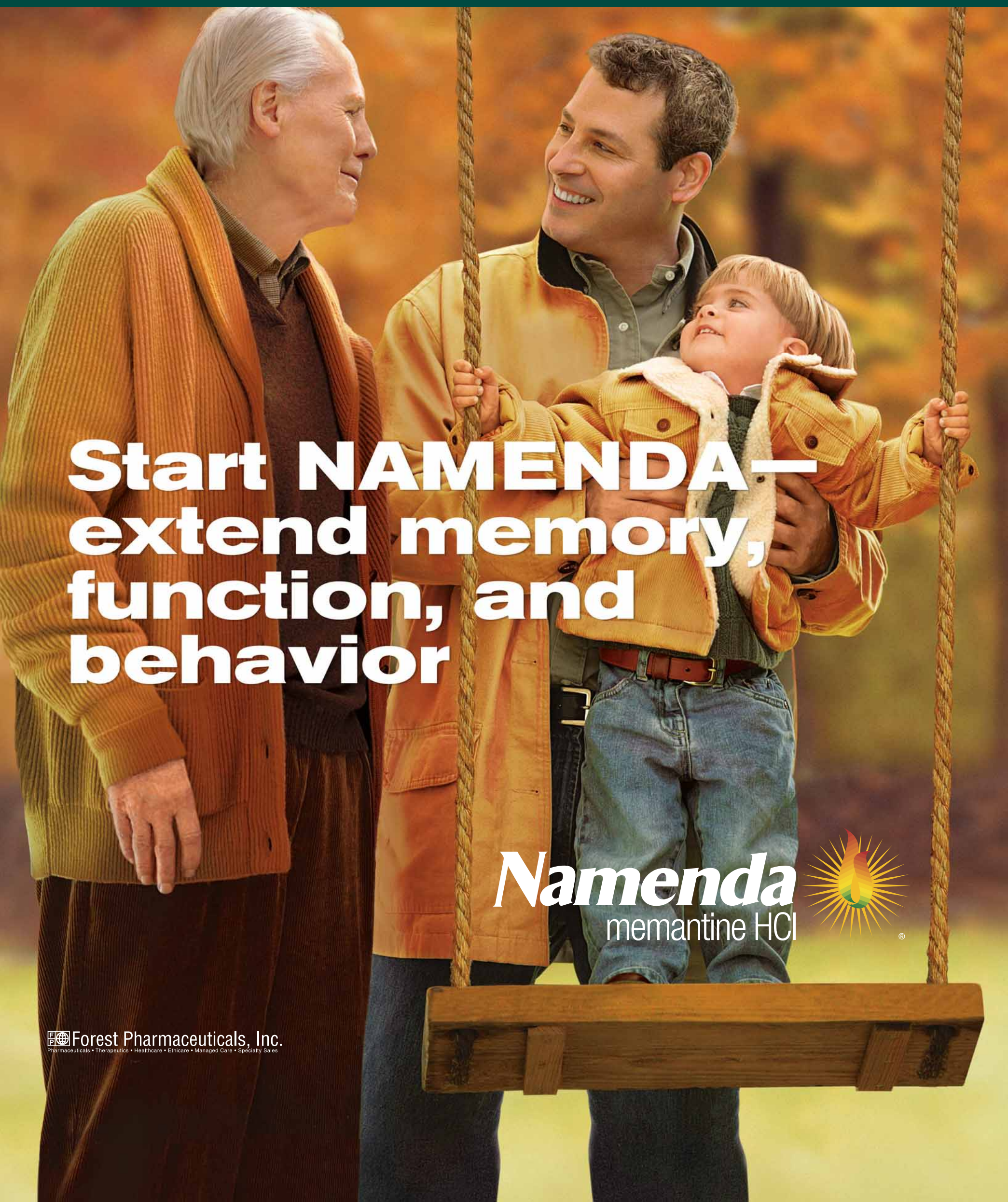
As you can see, the Division of Advocacy has a full complement of activities and programs under way on your behalf. We plan to communicate our efforts on a regular basis through *Psychiatric News*, APA's *Member Update* newsetter, Government Relations Action Alerts, and member broadcast e-mails.

In all that we do, our ultimate goal is to support your ability to provide the best possible care to your patients. I am very hopeful that our advocacy efforts in 2006 will build positively upon our now solid foundation, and we invite your comments on how we can best communicate with you and continue to add value to your profession, practice, and patient success. ■

Erratum

It was incorrectly reported in the January 20 issue that the methylphenidate skin patch was deemed approvable by an FDA panel for the treatment of attention-deficit/hyperactivity disorder in adults as well as children aged 6 to 12. In fact, approval was sought and obtained for use only in children aged 6 to 12. The patch was developed by Noven Pharmaceuticals and will be marketed jointly by Noven and Shire Pharmaceuticals under the trade name Daytrana. ■

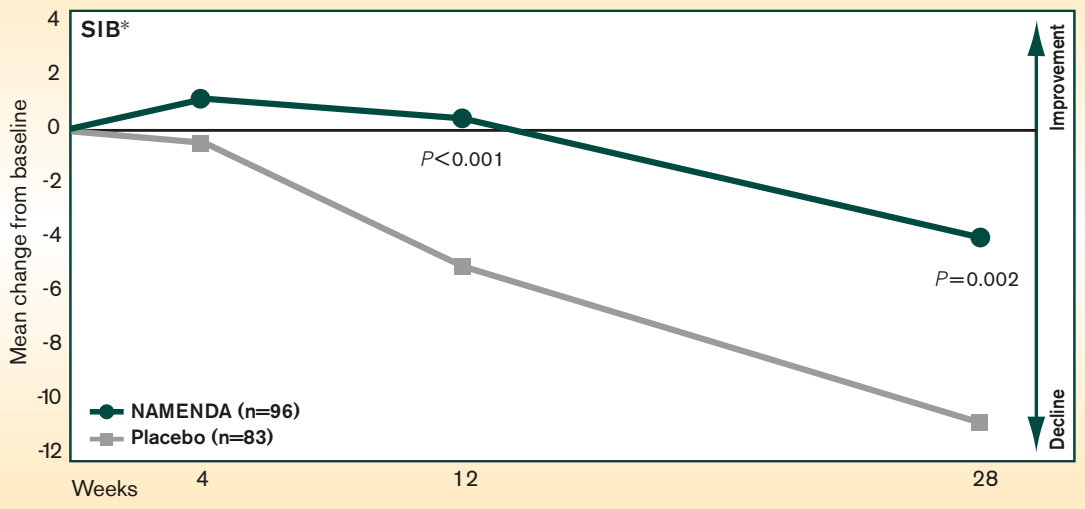
At the first sign of moderate Alzheimer's disease



Extend cognition with NAMENDA

First-line—for newly diagnosed moderate or severe patients and those who do not tolerate AChEIs

Significantly superior cognitive benefits vs placebo[1,2]



Results from a randomized, multicenter, double-blind, parallel-group, placebo-controlled U.S. study investigating the efficacy and safety of NAMENDA in 175 outpatients with moderate to severe Alzheimer's disease (AD). Results shown are from observed cases (OC) analysis. Patients received treatment with NAMENDA (10 mg BID) or placebo BID for 28 weeks.[1]

*SIB=Severe Impairment Battery. Evaluates cognitive performance in moderate to severe AD. It is a 40-item scale that assesses attention, language, praxis, visuospatial ability, construction, memory, orientation, orienting to name, and social interaction. The test is scored from 0 (greatest impairment) to 100.[3]

† Separate placebo-controlled cost analysis.

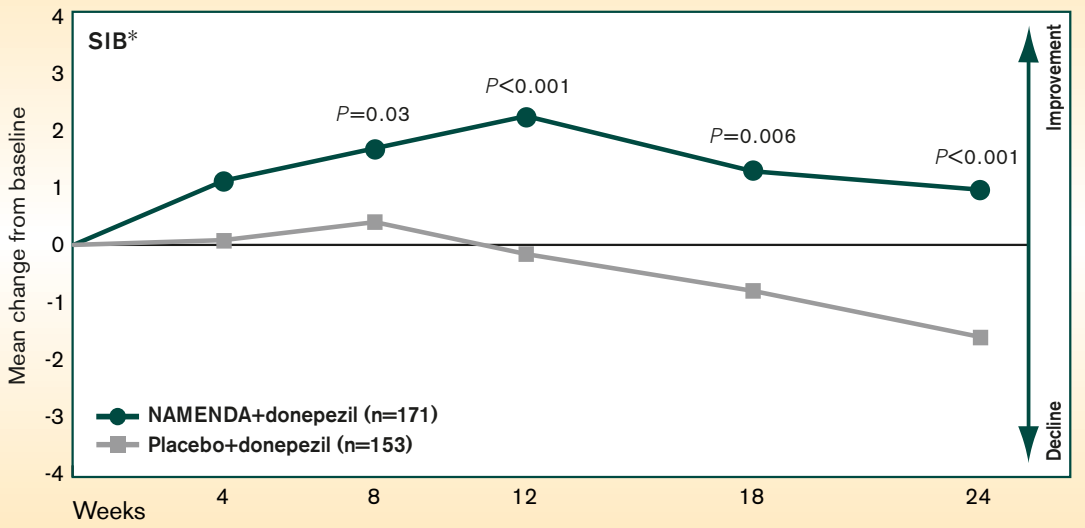
- NAMENDA provided a significantly superior effect on cognition vs placebo over the first 28 weeks of the study period (P=0.002)[1]

NAMENDA significantly:

- ***Reduced monthly caregiving time by 46 hours*** *(P=0.02)*
- ***Reduced monthly costs by $824*** *(P=0.03)*[4†]

In combination—for patients taking AChEIs

Improved cognitive benefits with NAMENDA+donepezil[5]



Results from a randomized, multicenter, double-blind, parallel-group, placebo-controlled U.S. study investigating the efficacy of NAMENDA plus donepezil in patients with moderate to severe AD. Results shown are from OC analysis. The study involved 404 outpatients ≥50 years of age with a Mini-Mental State Examination (MMSE) score of 5 to 14 points. Patients were randomized to treatment with NAMENDA (10 mg BID) or placebo added to a stable regimen of donepezil (5 mg-10 mg/day) for 24 weeks.[5]

‡ Donepezil therapy could have been 6 months or longer.

§ Alzheimer's Disease Cooperative Study Activities of Daily Living$_{19}$ (ADCS-ADL$_{19}$) Inventory. Autonomy subscale included: using a telephone, watching television, traveling, and being left alone; higher-level functions subscale included: conversing, finding belongings, obtaining a beverage, and turning a light off.[2]

- NAMENDA in combination with donepezil significantly improved and sustained cognitive performance above baseline for 6 months vs progressive decline seen with donepezil+placebo (P<0.001)[5‡]

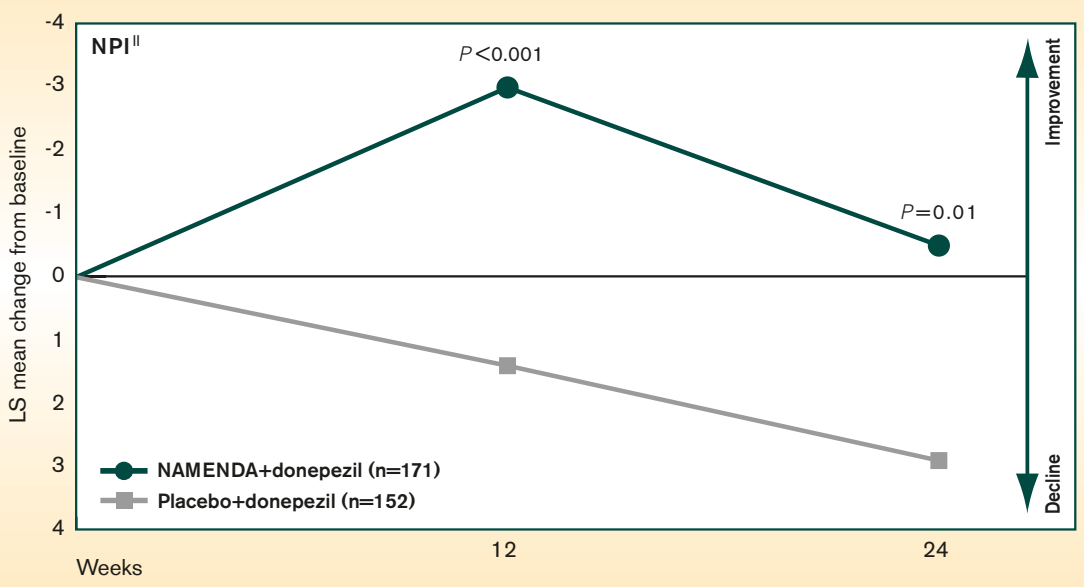
NAMENDA-treated patients also maintained significantly more autonomy and higher-level functioning than patients taking donepezil+placebo (P<0.05)[2]

- Autonomy and higher-level function are subscales derived from the ADCS-ADL$_{19}$[§]

Improve behavioral symptoms

In combination—for patients taking AChEIs

NAMENDA+donepezil sustains behavior above baseline[5,6]



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‖ NPI=Neuropsychiatric Inventory. The NPI is designed to assess behavioral disturbances occurring in patients with Alzheimer's disease or other dementias. It is particularly relevant because it is based on scripted questions administered to caregivers.[7]

- As measured by caregivers, NAMENDA+donepezil significantly improved behavioral function for 6 months compared with the progressive decline seen with patients taking donepezil+placebo (P=0.01)[5,6]

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

References: 1. 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.** Data on file. Forest Laboratories, Inc. **3.** Saxton J, McGonigle KL, Swihart A, Boller F. The Severe Impairment Battery. Bury St Edmunds, England: Thames Valley Test Company; 1993. **4.** Wimo A, Winblad B, Stöffler A, Wirth Y, Möbius HJ. Resource utilisation and cost analysis of memantine in patients with moderate to severe Alzheimer's disease. *Pharmacoeconomics.* 2003;21:327-340. **5.** 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. **6.** Cummings JL, Schneider E, Tariot PN, Graham SM, for the Memantine Study Group. Effect of memantine on behavioral outcomes in moderate to severe Alzheimer's disease. Poster presented at: Annual Meeting of the American College of Neuropsychopharmacology; December 12-16, 2004; San Juan, Puerto Rico. **7.** Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. *Neurology.* 1994;44:2308-2314.

AChEIs=acetylcholinesterase inhibitors.

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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^2 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^2 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^2 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^2 basis).
Slight maternal toxicity, decreased pup weights and an increased incidence of non-ossified cervical vertebrae were seen at an oral dose of 18 mg/kg/day in a study in which rats were given oral memantine beginning pre-mating and continuing through the postpartum period. Slight maternal toxicity and decreased pup weights were also seen at this dose in a study in which rats were treated from day 15 of gestation through the post-partum period. The no-effect dose for these effects was 6 mg/kg, which is 3 times the MRHD on a mg/m^2 basis.
There are no adequate and well-controlled studies of memantine in pregnant women. Memantine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

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

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

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

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

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

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

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

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

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

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

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

Other Adverse Events Observed During Clinical Trials
Namenda has been administered to approximately 1350 patients with dementia, of whom more than 1200 received the maximum recommended dose of 20 mg/day. Patients received Namenda treatment for periods of up to 884 days, with 862 patients receiving at least 24 weeks of treatment and 387 patients receiving 48 weeks or more of treatment.
Treatment emergent signs and symptoms that occurred during 8 controlled clinical trials and 4 open-label trials were recorded as adverse events by the clinical investigators using terminology of their own choosing. To provide an overall estimate of the proportion of individuals having similar types of events, the events were grouped into a smaller number of standardized categories using WHO terminology, and event frequencies were calculated across all studies.
All adverse events occurring in at least two patients are included, except for those already listed in Table 1, WHO terms too general to be informative, minor symptoms or events unlikely to be drug-caused, e.g., because they are common in the study population. Events are classified by body system and listed using the following definitions: frequent adverse events - those occurring in at least 1/100 patients; infrequent adverse events - those occurring in 1/100 to 1/1000 patients. These adverse events are not necessarily related to Namenda treatment and in most cases were observed at a similar frequency in placebo-treated patients in the controlled studies.

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

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

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

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

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

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

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

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

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

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

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

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

ANIMAL TOXICOLOGY
Memantine induced neuronal lesions (vacuolation and necrosis) in the multipolar and pyramidal cells in cortical layers III and IV of the posterior cingulate and retrosplenial neocortices in rats, similar to those which are known to occur in rodents administered other NMDA receptor antagonists. Lesions were seen after a single dose of memantine. In a study in which rats were given daily oral doses of memantine for 14 days, the no-effect dose for neuronal necrosis was 6 times the maximum recommended human dose on a mg/m^2 basis. The potential for induction of central neuronal vacuolation and necrosis by NMDA receptor antagonists in humans is unknown.

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

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

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

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Rev. 07/05

A Psychiatric Pioneer Remembered

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

Time erases memories, memories of people who have made great accomplishments during their lifetimes. One such person was Marion Edwina Kenworthy, M.D. At a time when women physicians occupied subservient places in medicine and psychiatry, she found ways to use her knowledge, skills, and personality to improve the world. She was the first woman vice president of APA (1965-66); the first woman president of the American Psychoanalytic Association (1958-59), American Academy of Child Psychiatry (1959-61), and Group for the Advancement of Psychiatry (1959-60); the recipient of the APA Agnes Purcell McGavin Award for astounding contribution to child psychiatry (1971); recipient of honorary degrees from the Women's Medical College in Philadelphia (doctor of medical science, 1968) and Columbia University (doctor of science, 1973). She was a pioneer in teaching psychiatry in social work.

Kenworthy was born in Hamden, Mass. She received a medical degree from Tufts in 1913. She then spent three years at the Garden State Hospital and three years at Foxboro State Hospital, both in Massachusetts. She also spent time at the Boston Psychopathic Hospital and the Judge Baker Guidance Clinic.

In 1919 Kenworthy moved to New York City, serving as an assistant at the Vanderbilt Clinic and Neurology Institute. In 1921 she underwent a training analysis with Otto Rank. That year she affiliated with the Bureau of Child Guidance, soon becoming its director. She also began to teach psychiatry at the New York School of Social Work (soon to become part of Columbia University). She taught psychiatry to hundreds of social workers until 1956, when she retired to become professor emerita. At her retirement, the Marion E. Kenworthy Professorial Chair in Psychiatry was established at the School of Social Work in her honor.

Kenworthy's activities were manifold, especially in serving on boards of directors and on committees. She was active with the National Association for Mental Health, N.Y. State Charities Aid Association, National Conference of Social Workers, Wiltwyck School for Boys (which she helped establish), the Menninger Foundation board, and others. She was a charter member of the American Orthopsychiatric Association, a life fellow of the New York Academy of Medicine, and an associate member of the World Federation for Mental Health. She worked with the Children's Court in New York.

During World War II, Kenworthy helped establish Selective Service criteria, was appointed to the National Civilian Advisory Committee for the Women's Army Corps, helped to provide the impetus for mental hygiene clinics in the military, and promoted the status of social work. She provided consultation to the U.S. Public Health Service from 1946 to 1950.

Kenworthy collected books. She donated 50 books of rare quality (16th- to 19th-century publications) and 65 pamphlets, mainly from the 19th century, to APA.

On September 9, 1988, APA dedicated the Marion E. Kenworthy Learning Center in the Library in its headquarters at the time in Washington, D.C. A conference room named in her honor and furnished with audiovisual equipment for learning and research is now a part of APA's new headquarters in Arlington, Va. The Kenworthy donation has been integrated with the rare-book collection in APA's library.

Viola Bernard, M.D., Kenworthy's friend and colleague, wrote of her: "[S]he was a compassionate, generous, and gifted clinician, teacher, and administrator. . . . Her way of living her life has made an immense difference. . . in the lives of many people. . . . She gave of her wisdom, hard work, and organizational ability. . . ." ■

professional news

Police

continued from page 8

ized response" case (2 percent) than either the civilian counselor team (13 percent) or the mobile-crisis units (5 percent). CIT resulted in 75 percent of individuals in such cases being taken to a treatment location, while that happened for only 20 percent of the Birmingham cases and 42 percent of the Knoxville cases.

In comparison, more than 3,000 individuals have been processed by CIT officers in the Akron program since May 2000, with about 75 percent transported for treatment and 6 percent arrested, Munetz said.

"What I have found in my research and field work is that none of the programs is as extensive at CIT," said Bonnie Sultan, CIT technical assistance coordinator for NAMI. "There are some other options available, but CIT is the gold standard."

Sultan is conducting the first national study of CIT programs with the Council of State Governments and the Police Excellence Research Forum. Her study will identify the number of CIT programs, the number of jail-diversion programs, the number of individuals who are involved in each program, the types of training and personnel used, and funding sources. The results will be released in April.

Meanwhile, the number of CIT programs is expected to increase. One sign of that expected growth: The CIT programs' first national conference in 2005 had more than 700 attendees, when organizers expected only about 250.

Information about the Memphis CIT program is posted at <www.cityofmemphis.org/printcontent.aspx?modid=2005&modtitle=Memphis+Police+Crisis+Intervention+Team>, and the program comparison study is posted at <http://mhlp.fmhi.usf.edu/Training/lei/Originals/Major%20Models-Psych%20Serv.pdf>. ■

Another Residency Program Joins APA's 100% Club

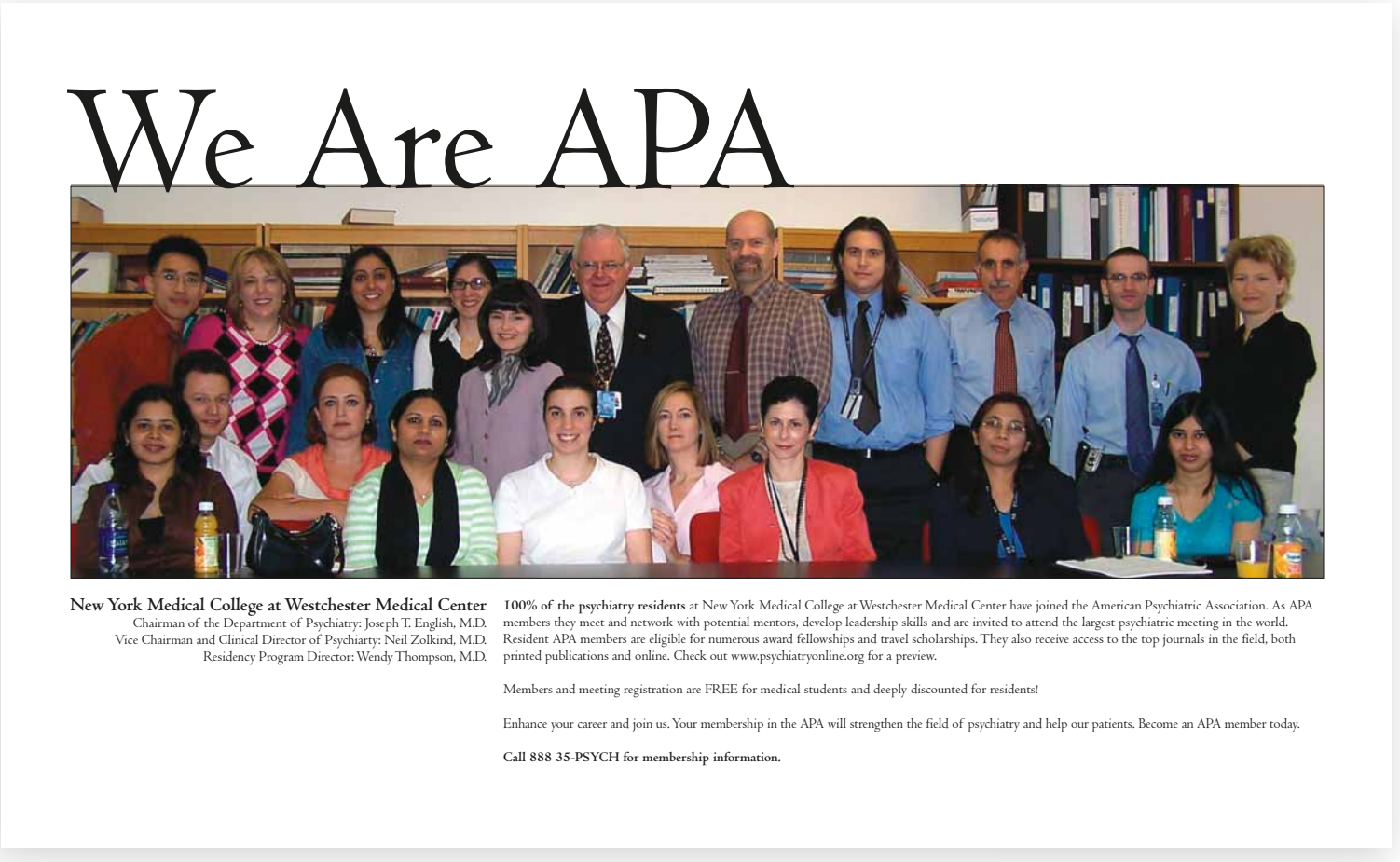
The child and adolescent psychiatry residency program at New York Medical College at Westchester Medical Center in Valhalla, N.Y., is the latest residency program to have all of its psychiatry residents become members of APA.

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

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

"APA is at the forefront of American psychiatry, dealing with the many exciting opportunities as well as challenges facing psychiatrists," commented Wendy Thompson, M.D., director of residency training and undergraduate medical education at the Westchester Medical Center. "Drs. Joseph English and Neil Zolkind and I are pleased that all of our residents have become APA members at this early point in their careers, as this will help them keep abreast of ongoing developments in the field and hopefully spur them to increased participation in APA and district branches."

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. ■



Top row, from left: Gene Lui, D.O., Diane Dekeyser, M.D., Reba Bindra, M.D., Natalie Lara, M.D., Martha Gamboa, M.D., Joseph T. English, M.D. (psychiatry department chair), Harold Berkheimer, M.D., Greg Fernandez, M.D., Neil Zolkind, M.D. (vice chair and clinical director of psychiatry), Denis Drubetskiy, M.D., Olga Bendinger, M.D. Bottow Row, from left: Eran Feit, M.D., Neha Khurana, M.D., Etel Leybovich, M.D., Mahpara Kahn, M.D., Eleanor Spumberg, D.O., Mari Cherie Bertoni, M.D., Residency Program Director Wendy Thompson, M.D., Kaiser Sultana, M.D., Preeti Mathur, M.D.

Small Towns, Big Falls: Lots to See Outside Toronto

From beautiful lakes and wineries to golf courses and Niagara Falls, travelers to Toronto have many incentives to sample the nearby pleasures of Ontario.

BY AARON LEVIN

Visitors to Toronto may be wise to budget a few extra days for visiting the small towns and beautiful countryside lying an hour or two outside the city. The province of Ontario offers everything from world-renowned theater festivals to lakeside getaways to the continent's most famous destination, Niagara Falls.

An hour north and east of Toronto along Route 11 lies Orillia, the small town fictionalized as "Mariposa" by beloved Canadian author Stephen Leacock in his short story cycle "Sunshine Sketches of a Little Town." Farther north are the 19th-century towns of Gravenhurst, Port Carling, and Huntsville in the Muskoka Lakes region, once accessible only by boat, now bases to explore a region filled with natural beauty. Resorts in the area offer attractive settings and challenging courses for golfers.

East of the city along Route 401 are Cobourg and Port Hope, a restored Victorian town. Both offer pleasant restaurants and opportunities for antique hunting.

Many regional points of interest lie west of Toronto. The next major city is Hamilton, an hour away by car or the Lakeshore line of the GO train service from Union Station. Hamilton features the Royal Botanical Gardens, with events at the annual Lilac Festival scheduled for the weekends before and after APA's annual meeting. The Lilac Dell contains the world's largest collection of lilacs, as well as 100,000 tulips, 250,000 iris blooms, 3,000 rose bushes, a 30-kilometre trail system, and four nature sanctuaries. Hamilton is also home to McMaster University, best known to physicians as a primary source for the evidence-based-medicine movement.

Beyond Hamilton, visitors can travel along the Ontario Wine Route. More than 20 wineries offer tours and tastings for visitors. For traveling gourmets, several wineries also offer full-service restaurants. The well-signposted Ontario Wine Route follows less-trafficked secondary roads between Hamilton and Niagara-on-the-Lake through towns like Grimsby, Beamsville, Vineland, Jordan, and St. Catharine's. The vineyards lie between Lake Ontario and the protective slope of the Niagara Escarpment.

Farther along lies Niagara-on-the-Lake, whose early 19th-century architecture provides the setting for the Shaw Festival. The festival presents the works of George Bernard Shaw and his contemporaries, and since Shaw lived from 1856 to 1950, "contemporary" covers a lot of theatrical ground. During the APA meeting, the festival will present five plays in repertory. The town is also home to many restaurants and boutiques along Queen Street.

Theater lovers may also look to Stratford, two hours northwest of Toronto by car and home of the Shakespeare Festival. The festival presents the works of the master and other great playwrights on four stages. Matinees every day except Monday make day trips feasible from Toronto. Visitors may want to stay longer, though, since the town is equally renowned for its restaurants, whose chefs make excellent use of the local agricultural bounty.

Also northwest of Toronto lies Mennonite country. St. Jacob's holds its market days on Thursdays and Saturdays, while Fergus and Elora, on a deep gorge along the Grand River, are home to fine food and numerous craft breweries.

Straddling the U.S-Canadian border, Niagara Falls has been a destination for honeymooners and other tourists for over a century and a half, yet it still has the power to impress the most jaded traveler. There may be higher waterfalls in the world, but they tend to be in remote jungles, with intermittent water flow.

Ontario's Wine Route encompasses more than 20 wineries.

"Niagara Falls is a grand, natural spectacle, easily accessible, and the water flows pretty constantly in any season," said Sherman Zavitz, the Canadian city's official historian and a former teacher who now guides visitors around the town.

Niagara Falls is 80 miles from Toronto. It became a tourist destination in the 1820s, but the advent of the railroad in the mid-19th century made access easier from major Canadian and U.S. cities. Soon the falls were the place to go for honeymoons for the next century. Even now Zavitz said he'll be leading a tour group, and older people occasionally sidle up and recount how they came as honeymooners half a century ago.

The Journey Behind the Falls attraction, located in the Canadian Horseshoe Falls.

"Niagara Falls is a place set apart from the ordinary," he said. "Maybe that's why it became the place to go at an extraordinary moment in life, when people were poised between the single and married states."

Visitors to the falls can approach from either the United States or Canada, but the Canadian side of the Niagara River offers better overall views of the two cascades. Maid-of-the-Mist tour boats leave from either side, chugging upriver to get close to both the American Falls and the Horseshoe (Canadian) Falls. Crew members hand each passenger a plastic rain poncho because spray from the falling water amounts to a light rainstorm as the boats draw near.

Niagara Falls has always attracted some people whose fascination with the deep gorge and rushing water crosses beyond the limits of tourism.

"I wanted to do something no one else had ever done and make some money honestly and quickly," said Annie Taylor, who was the first to go over Niagara Falls in a barrel, in 1901. She was certainly the first, said Zavitz, but she never made much money off the feat in those pre-Oprah days. Officially, 17 people (including Taylor) have tried their luck at going over Niagara Falls in a barrel, and a dozen survived.

Seven-year-old Roger Woodward may have been the luckiest person to make the trip. He did it accidentally, wearing only a bathing suit and a life jacket after his boat capsized five miles upstream.

Yet another group is attracted to the falls for the same reason they are drawn to the Golden Gate Bridge. People contemplating suicide may be mesmerized by the flow of water and the surrounding heights, said Zavitz, sharing the tale of a young bride of an elderly millionaire who leaped 250 feet to her doom from a cable car in 1934.

Not everyone has been impressed by the watery display. After a visit, Oscar Wilde observed, "Niagara Falls is simply a vast unnecessary amount of water going the wrong way and then falling over unnecessary rocks. The wonder would be if the water did not fall."

When tourist traffic slacked off in the early 1990s, the town and provincial elders built a casino. Some residents worried about crime and the loss of the family atmosphere, but there were no drawbacks to interfere with the success of gambling, said Zavitz. In 2004 a second casino, costing $1 billion, opened with a view of the falls that is probably wasted on most gamblers. The two casinos have sparked development of hotels and residences.

Beyond Toronto

Golfing in the Muskoka Lakes region: www.golfinmuskoka.com

Niagara Falls tour and hotel information: www.niagarafallslive.com. (See Niagara Falls live through the site's Webcam.)

Royal Botanical Gardens: www.rbg.ca/

Ontario Wine Route: www.winetour.ca/ontario-wine-route.htm

Shaw Festival 2006: www.shawfest.com/2006/web/

Stratford Festival: www.stratfordfestival.ca/index.cfm

Village of St. Jacobs and Ontario's Mennonite Heritage: www.magiccarpetjournals.com/St_Jacobs.htm

There's more to the Niagara region than the falls, however. Two thousand species of butterflies flit about the nearby Niagara Parks Butterfly Conservancy. Several battles in the War of 1812 were fought nearby, at Lundy's Lane in the town and at Acton on Lake Ontario. ■

How to Register

There are two easy ways for APA members to register for APA's 2006 annual meeting:

• Go to APA's Web site at www.psych.org, click on "2006 APA Annual Meeting," and select "Online Registration for Members." You will be asked to log into "Members Corner." Also, reserve your hotel room by clicking on "Reservations for Members."

• Fill out the forms in the 2006 Annual Meeting Advance Registration Information packet and submit them by mail or fax. If you have not yet received your packet, call the APA Answer Center at (888) 35-PSYCH; from outside the U.S. and Canada, call (703) 907-3800.

The deadline for course enrollment and advance registration is April 21.

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AMA Statement: Albert Einstein College of Medicine designates this educational activity for a maximum of 25 *AMA PRA Category 1 Credit(s)™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

LOS ANGELES
The Westin Hotel at the Los Angeles Airport
5400 West Century Boulevard, Los Angeles, CA 90045
Friday, September 8 to Sunday, September 10, 2006
7:45 AM – 5:00 PM

NEW YORK
The Graduate Center, Concourse Level
City University of New York (CUNY)
365 Fifth Avenue (Between 34th and 35th Streets), New York, NY 10016
Friday, October 6 to Sunday, October 8, 2006
8:15 AM – 5:15 PM

PSYCHIATRY FOR PSYCHIATRISTS
Andrea J. Weiss, MD and David Myland Kaufman, MD

This two-day course will be a pre-test that will complement standard psychiatry review courses and complete the review in Clinical Neurology for Psychiatrists. In this course, an expert group of faculty who are experienced and well-informed about modern psychiatry and test-taking strategies will present essential information through a series of test-type questions and subsequent discussions directly with the audience.

AMA Statement: Albert Einstein College of Medicine designates this educational activity for a maximum of 14 *AMA PRA Category 1 Credit(s)™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

LOS ANGELES
The Westin Hotel at the Los Angeles Airport
Monday, September 11 to Tuesday, September 12, 2006
7:45 AM – 5:00 PM

NEW YORK
The Graduate Center, Concourse Level
City University of New York (CUNY)
Monday, October 9 to Tuesday, October 10, 2006
8:15 AM – 5:15 PM

FOR MORE INFORMATION

- **Web site** Course Information or To Register: www.cnfp.org
- **Write:** CCME, 3301 Bainbridge Avenue, Bronx, NY 10467
- **E-mail:** cme@montefiore.org
- **Call:** 718-920-6674 • **Fax:** 718-798-2336

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Clinical Neurology for Psychiatrists	☐ Sept. 8-10 (Fri-Sun)	☐ Oct. 6-8 (Fri-Sun)
Psychiatry: Pre-Test	☐ Sept. 11-12 (Mon-Tues)	☐ Oct. 9-10 (Mon-Tues)
Recert Course (New York only)	Not Available	☐ June 16-17 (Fri-Sat)

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Clinical Neurology (Course)	☐ $975.00	☐ $850.00
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Pathological Gambling Symptoms Respond to Addiction Drug

A drug used to treat addiction has been found to counter pathological gambling. This discovery bolsters the argument that pathological gambling is, at least in part, an addiction illness.

BY JOAN AREHART-TREICHEL

In 2001 Suck Won Kim, M.D., a professor of psychiatry at the University of Minnesota, published results of a trial exploring the possible value of treating pathological gambling with the opiate antagonist naltrexone. Naltrexone was found to be superior to a placebo in countering symptoms of the disorder. However, the medication caused liver enzyme problems in subjects who took over-the-counter pain medications at the same time.

Subsequently, Kim helped other pathological-gambling investigators design a study to learn whether the opiate antagonist nalmefene, which is related to naltrexone but purportedly safer, might also counter symptoms of pathological gambling. "Results are quite promising," lead investigator Jon Grant, M.D., J.D., an associate professor of psychiatry at the University of Minnesota, recently said (*Psychiatric News*, March 18, 2005).

The results of this study are published in the February *American Journal of Psychiatry*.

The study took place at 15 outpatient treatment centers throughout the United States. Subjects were recruited via newspaper ads and medical referrals. The researchers ended up with 207 individuals who met criteria for a *DSM-IV* pathological gambling disorder.

The 207 subjects were then randomized to receive, over a 16-week period, 25 mg daily of nalmefene, 50 mg daily of nalmefene, 100 mg daily of nalmefene, or a placebo.

The primary outcome measure was the Yale-Brown Obsessive-Compulsive Scale Modified for Pathological Gambling, which is used to rate gambling thoughts, urges, and behaviors within the previous week. Subjects were assessed with it throughout the study. For overall treatment response, subjects with a Clinical Global Improvement score of "much improved" or "very much improved" at the last available evaluation point were considered responders.

Fifty-nine percent of the 25 mg nalmefene group; 48 percent of the 50 mg nalmefene group; 42 percent of the 100 mg nalmefene group, and 34 percent of the placebo group were found to be responders (see chart).

Why the 100 mg and 50 mg nalmefene groups did not respond as well as the 25 mg nalmefene group is not clear. However, it may be because these higher doses caused more intolerable side effects.

So it looks as if nalmefene can reduce gambling symptoms in a number of pathological gamblers and that the ideal dose for doing so might be 25 mg a day, since this dose appeared to be quite effective while producing few adverse effects.

However, optimal dosing and titration can be determined only from further research, Grant and his colleagues pointed out in their report. The same is true for determining the optimal length of treatment.

"It is possible that a longer course of therapy could result in continued and even greater reduction in gambling symptoms," they speculated.

Grant and his colleagues are currently conducting another study of nalmefene in pathological gamblers, he told *Psychiatric News*. This one is taking place at 20 different sites. Because it has obtained rights to nalmefene, Somaxon Pharmaceuticals in San Diego is also launching several trials of nalmefene to treat pathological gambling, Grant said.

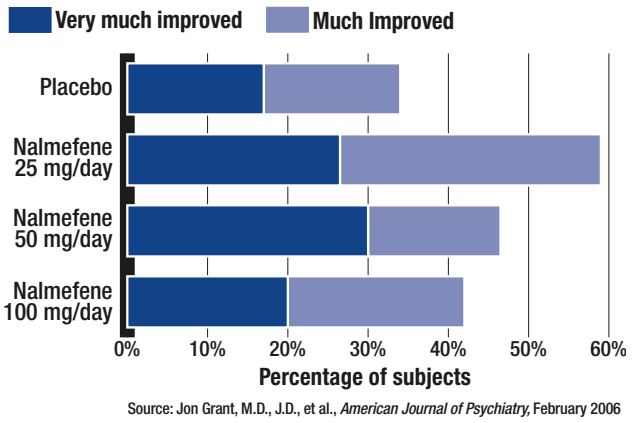
Meanwhile, the results achieved from the just-published study illustrate that "psychiatry is finally gaining rational treatments for its illnesses, treatments based on demonstrated brain mechanisms," Carol Tamminga, M.D., and Eric Nestler, M.D., Ph.D., wrote in an accompanying editorial. They are professors of psychiatry and neuroscience at the University of Texas Southwestern Medical Center.

In other words, they explained, the study was based on the hypothesis that pathological gambling is an addiction disorder and that a drug known to counter addiction could thwart pathological gambling as well.

"Multicenter Investigation of the Opioid Antagonist Nalmefene in the Treatment of Pathological Gambling" is posted at <http://ajp.psychiatryonline> under the February issue. ■

Less Is More?

Among 206 subjects who met *DSM-IV* criteria for pathological gambling, the greatest number showed some improvement on the lowest dose tested of nalmefene.



Source: Jon Grant, M.D., J.D., et al., *American Journal of Psychiatry*, February 2006

NARSAD Honors Groundbreaking Advances in MH Research

Once again, NARSAD awards scientists who have made outstanding contributions to the understanding, treatment, and prevention of various mental illnesses.

BY JOAN AREHART-TREICHEL

Seven scientists were lauded for their outstanding achievements in psychiatric research by the National Alliance for Research on Schizophrenia and Depression (NARSAD) at its recent awards dinner in New York City.

• **Lieber Prize for Schizophrenia Research** was presented to David Lewis, M.D., a professor of psychiatry at the University of Pittsburgh, for his work in furthering the understanding of the origins and functional changes of schizophrenia. He was the first to apply DNA micro-array technology successfully to the study of the disease.

• **Falcone Prize for Affective Disorders Research** was presented to Jan Fawcett, M.D., a professor of psychiatry at the University of New Mexico, and Alan Schatzberg, M.D., chair of psychiatry at

please see ***NARSAD Awards*** *on page 34*

Photo courtesy of NARSAD

Constance E. Lieber, president of NARSAD, poses with (from left) Herbert Pardes, M.D., president of NARSAD's Scientific Council; David A. Lewis, M.D., Jan A. Fawcett, M.D., Bruce S. McEwen, Ph.D., Allan L. Reiss, M.D., Linda M. Brzustowicz, M.D., Alan F. Schatzberg, M.D., and Takanori Hashimoto, M.D., Ph.D.

Antidepressants Show Promise In Pain Management

In 2004 the FDA approved an SNRI antidepressant expressly for the treatment of diabetic peripheral neuropathy. This watershed event suggests that the SNRIs may be able to combat some other kinds of pain as well.

BY JOAN AREHART-TREICHEL

Psychiatrists have long been interested in pain and pain treatment because pain and depression, as well as pain and anxiety, often go hand in hand. This interest grew during the latter half of the 20th century with the discovery that the tricyclic antidepressants could counter various types of pain. Yet psychiatrists' interest in pain and pain treatment waned somewhat during the 1980s and early 1990s, when it became clear that the SSRI antidepressants were not as effective in treating pain as the tricyclics were.

In 1997, however, a new class of antidepressants made its debut on the American market—the combined selective serotonin-norepinephrine reuptake inhibitors (SNRIs). These drugs act on both serotonin and norepinephrine, as the tricyclic antidepressants do, but without the latter's side effects. Specifically, the Food and Drug Administration (FDA) approved the SNRI venlafaxine in 1997 for the treatment of depression, and in 2004 approved the SNRI duloxetine not just for depression, but also for peripheral nerve pain in diabetics. Duloxetine, in fact, is the first drug approved to treat this condition, and it appears to be the first psychotropic drug that the FDA had approved for treating pain of any kind.

These developments have once again ignited psychiatrists' interest in pain and pain management. They have also set the stage for this question: Could the SNRI antidepressants counter other kinds of pain besides peripheral neuropathy in diabetics? Preliminary research findings suggest that the answer is yes.

SNRIs Effective in Fibromyalgia

"Fibromyalgia is a funny disorder," Jordan Karp, M.D., a physician investigator at the University of Pittsburgh's John A. Hartford Center of Excellence in Geriatric Psychiatry, explained during a recent interview. "When joints and nerves and muscles from fibromyalgia patients are biopsied, there is no pain pathology. These are patients who hold onto pain in their brains differently from other folks; they don't let go of the pain they experience. So it is really a problem of central pain processing rather than of neuropathic pain, musculoskeletal pain, or visceral pain."

Nonetheless, there is ample evidence that the SNRIs can combat such pain. For example, Leslie Arnold, M.D., an associate professor of psychiatry at the University of Cincinnati, and colleagues conducted a 12-week trial to assess the efficacy and safety of duloxetine in countering fibromyalgia in individuals with or without current major depressive disorder.

About a fourth of the 354 women subjects had a current major depressive disorder. The subjects were randomly placed in three groups: one group received 60 mg of duloxetine daily, the second group received 60 mg twice daily, and the third group received a placebo. The researchers used the Brief Pain Inventory to assess subjects' pain both at the start and end of the study.

The researchers found that 55 percent of the subjects who had received 60 mg of duloxetine daily and 54 percent of the subjects who had received 120 mg of duloxetine daily were treatment responders—that is, they had experienced at least a 30 percent reduction in pain during the study—compared with a third of subjects receiving a placebo. Moreover, duloxetine was found to be well tolerated.

Thus, duloxetine appears to be both "effective and safe in the treatment of fibromyalgia in female patients with or without major depressive disorder," Arnold and her group concluded in their report, which is in press with the journal *Pain*.

Eli Lilly and Co., the manufacturer of duloxetine, is also researching the drug's potential for countering fibromyalgia pain, Tamara Hull, a senior communications associate at Lilly, told *Psychiatric News*. The company announced in December 2005 that its duloxetine-fibromyalgia research has now entered phase III testing.

Yet another SNRI antidepressant—milnacipran—is being developed for the treatment of fibromyalgia by Cypress Bioscience Inc. in San Diego. As Sabrina Johnson, chief financial officer of Cypress Bioscience, informed *Psychiatric News*, its first phase III trial pitting milnacipran against fibromyalgia pain did not reach statistical significance, but it was close to it, so the company is now conducting two more phase III trials to explore the drug's potential in countering fibromyalgia pain.

Currently, there are no FDA-approved treatments for fibromyalgia. Thus, if an SNRI antidepressant were to be approved by the FDA for such treatment, Arnold pointed out, it "would increase therapeutic options for patients, potentially reducing the morbidity associated with fibromyalgia, and improve clinician awareness and recognition of fibromyalgia."

SNRIs Take on Migraines

The SNRIs may also have the capacity to prevent migraine headaches, a Turkish study reported in the February 2005 *Journal of Head and Face Pain* suggests.

Suleyman Ozyalcin, M.D., an associate professor of anesthesiology at Istanbul University, and colleagues conducted what appears to be the first randomized, double-blind, placebo-controlled trial to determine

whether the SNRI venlafaxine might be able to prevent migraines. Sixty subjects who were prone to migraine headaches without aura were randomly assigned to receive 75 mg daily of venlafaxine, 150 mg daily of venlafaxine, or a placebo for two months. The frequency of migraines they experienced during that period were monitored. The group receiving 150 mg daily of venlafaxine experienced significantly fewer migraines than did the placebo group.

Back Pain Studied

The SNRIs' potential for countering back pain is likewise being explored. The Department of Veterans Affairs launched a study in June 2005 to determine whether venlafaxine counters chronic neuropathic pain following spinal-cord injury. Although a number of medications have been used to treat such pain, no drug has been consistently helpful.

Craig Nelson, M.D., director of geriatric psychiatry at the University of California at San Francisco, and colleagues conducted a study on 90 subjects aged 55 years or older who had a major depressive disorder to determine whether duloxetine could combat not just depression, but also associated pain symptoms. As they reported in the March 2005 *American Journal of Geriatric Psychiatry*, "60 mg daily of duloxetine was significantly better than a placebo in not just countering depression, but in reducing pain, including back pain."

Karp and his coworkers will soon conduct a trial to explore novel approaches to treating older adults who have both depression and chronic back pain. The approaches will consist of combining social interventions—say, help from a partner or friend—with medications, and one of the medications that will be tested is an SNRI antidepressant.

Other Possible Uses Suggested

The SNRI antidepressants might be able to quell neuropathic pain arising from a number of sources, Rollin Gallagher, M.D., a psychiatrist and director of the Center for Pain Medicine Research and Policy at the University of Pennsylvania, speculated in an interview. For instance, they might be effective against neuropathic pain due to a herniated disc, radiation and chemotherapy treatment, toxic exposure, or postherpetic neuralgia.

The SNRI antidepressants might also be able to counter tension headaches and the pain of irritable bowel syndrome, Johnson suggested. In fact, she added, the types of pain that the SNRIs are capable of subduing may well be the same types of pains that the tricyclic antidepressants counter since the SNRIs and some of the tricyclics have similar norepinephrine-serotonin reuptake profiles.

To really harness the SNRIs' pain-fighting abilities, of course, scientists need to better understand how they work in this domain. And fortunately here, too, some research is taking place. For example, the analgesic and antidepressant effects of the SNRIs were thought to be inseparable, meaning that if a patient received an analgesic effect, it was because of the antidepressant effect. However, David Fishbain, M.D., a professor of psychiatry at the University of Miami, has now found that the two effects are entirely separate, and, as he told *Psychiatric News*, "the analgesic effect actually occurs before the antidepressant effect." He has submitted these findings to the journal *Pain*.

While the ultimate pain-fighting potential of the SNRIs is not known, the clinical implications could be substantial.

"The SNRIs will have an important role in the management of chronic pain disorders," Arnold predicted. "Both serotonin and norepinephrine are involved in the regulation of pain perception through the descending pain inhibitory pathways. The SNRIs, by increasing serotonin, and norepinephrine-mediated neurotransmission, might enhance pain inhibition."

"I've seen in patients with diabetic peripheral neuropathy and in some fibromyalgia patients both duloxetine and venlafaxine being helpful," said Karp. "I certainly think they have a role to play in pain management, particularly for patients with diabetes and fibromyalgia."

"I think the recent publications about the SNRIs will increase interest among psychiatrists, especially those treating older patients and medically ill patients, in the treatment of pain occurring in depression," Nelson said.

"The treatment of pain is not a one-medication treatment; it is using medications that affect a number of different parts of the pain-perception system," Gallagher explained. "So the SNRI antidepressants will probably have a growing role in this treatment." ■

Applications Invited

Applications are now being invited for the George Washington Institute for Spirituality and Health (GWish) Spirituality and Medicine Curricular Awards for Medical and Osteopathic Schools and Residency Training Programs in Psychiatry and Primary Care.

The awards, given by GWish, are funded by the John Templeton Foundation. The Medical School Curricular Awards are for $50,000 over four years. The Residency Training Awards for Primary Care and Psychiatry are for $30,000 over three years.

The GWish Spirituality and Medicine Curricular Awards program criteria now include an emphasis on institutional changes that incorporate the lessons learned in the classroom; evaluation methods to provide program outcomes data; and a research component to assist GWish to collect scientifically valid data on the role of spirituality in medical practice.

The application deadline is April 1. Application instructions and additional information are posted at <www.gwish.org>. Award-winning courses will begin in the 2006-2007 academic year.

More information is available from Michele Zwolinski at (202) 496-6411 or bcsmaz@gwumc.edu. ■

'Treat to Remission' Is Message of STEP-BD Study

Despite modern evidence-based treatment, bipolar disorder remains a highly recurrent, predominantly depressive illness. Nonetheless, the goal of treatment should be full recovery, not just symptom reduction.

BY JIM ROSACK

The first of many analyses to come from the National Institute of Mental Health's (NIMH) Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) provides much-needed, long-term data on the potential for recovery from manic and depressive episodes and predictors of relapse into subsequent mood episodes.

"In spite of really optimized treatment with guideline-based pharmacotherapy, combined with psychoeducation provided by clinicians specifically trained in the management of bipolar disorder, nearly half of our patients suffered a recurrence within two years," said Roy Perlis, M.D., an assistant professor of psychiatry at Harvard Medical School and one of several STEP-BD investigators at Massachusetts General Hospital in Boston. Perlis and his co-investigators published their report in the February *American Journal of Psychiatry*.

"I think [these data] indicate the severity [of bipolar disorder] overall, and while we have some wonderful, newer treatments and some very effective older treatments," Perlis told *Psychiatric News*, "we still have a lot of work to do."

STEP-BD is the largest national research program aimed at determining the best treatment practices for bipolar disorder. Begun in 1998 and concluded in September 2005, researchers treated 4,360 patients with bipolar disorder (I, II, or NOS) who were followed long term to determine the most effective treatment or combination of treatments to combat depressive and manic episodes and to prevent relapse.

"We also found that one of the strongest predictors of recurrence in our sample was the presence of residual mood symptoms following recovery," Perlis said. "Even when patients were largely well, if they continued to be somewhat symptomatic, they were more likely to have a relapse. In short, those residual symptoms matter."

For the predictors of recurrence analysis, Perlis and his team looked at a subset of the full patient sample, focusing on 1,469 patients who had at least two years of participation in the STEP-BD program. The researchers found that slightly more than half (858 patients, or 58 percent) of this group achieved recovery, defined as having no more than two symptoms of the disorder for a period of at least eight weeks during the two-year follow-up period.

Within that two-year window, nearly half of those who achieved recovery (416 patients, or 48.5 percent) relapsed; almost twice as many patients who relapsed suffered a depressive episode (298 patients, or 34.7 percent) than those relapsing to a manic, hypomanic, or mixed episode (118 patients, or 13.8 percent).

Perlis and his co-authors concluded in their article that "taken together, these results demonstrate that mood episodes in bipolar disorder, and particularly depressive episodes, are prevalent and likely to recur in spite of guideline-based treatments."

Patients in STEP-BD, they noted, "received evidence-based care from specialized clinicians with training in the use of standardized assessments, combination pharmacotherapy, and psychosocial treatments where appropriate. In addition, participants received at minimum a core psychosocial educational intervention."

As such, the co-authors wrote, "the finding that nearly half of the study participants nonetheless suffered at least one recurrence during follow-up highlights the need for development of new interventions [for] bipolar disorder."

"I think [the importance of residual symptoms] parallels the major depression literature, where we've come to see that full remission is really the goal of treatment," Perlis told *Psychiatric News*. "Improvement is great, but remission is really critical. I think [these results] suggest that we need to take the same kind of focus in bipolar disorder—which many clinicians already do—and that is to treat to remission, not simply recovery. It emphasizes the importance of those residual symptoms and their association with risk of recurrence."

Interestingly, somewhat different factors appeared to be associated with relapse to a depressive episode versus relapse to a manic/hypomanic/mixed episode (see chart). For example, a current substance use disorder increased the risk of manic relapse, but not depressive relapse, while a current anxiety diagnosis was associated with increased risk of a depressive relapse but not manic relapse.

The STEP-BD protocols were intended to represent an effectiveness study, and patients in the STEP-BD's Standard Care Pathway could receive any intervention believed to be clinically indicated by their clinician. In addition to rigorous guidelines for monitoring the progress of individual patients, clinicians adhered to pharmacotherapy guidelines based on published treatment guidelines (APA's revised Practice Guideline for the Treatment of Patients With Bipolar Disorder, the Expert Consensus Guideline Series: Medication Treatment of Bipolar Disorder, and the Department of Veterans Affairs' Clinical Practice Guidelines for Bipolar Disorder).

STEP-BD also incorporated a "core psychosocial intervention." All patients received a workbook and videotape describing the intervention, which emphasized alliance-building and provided techniques for recognizing and managing stress, negative thought patterns, problems in interpersonal interactions, and sleep disturbances.

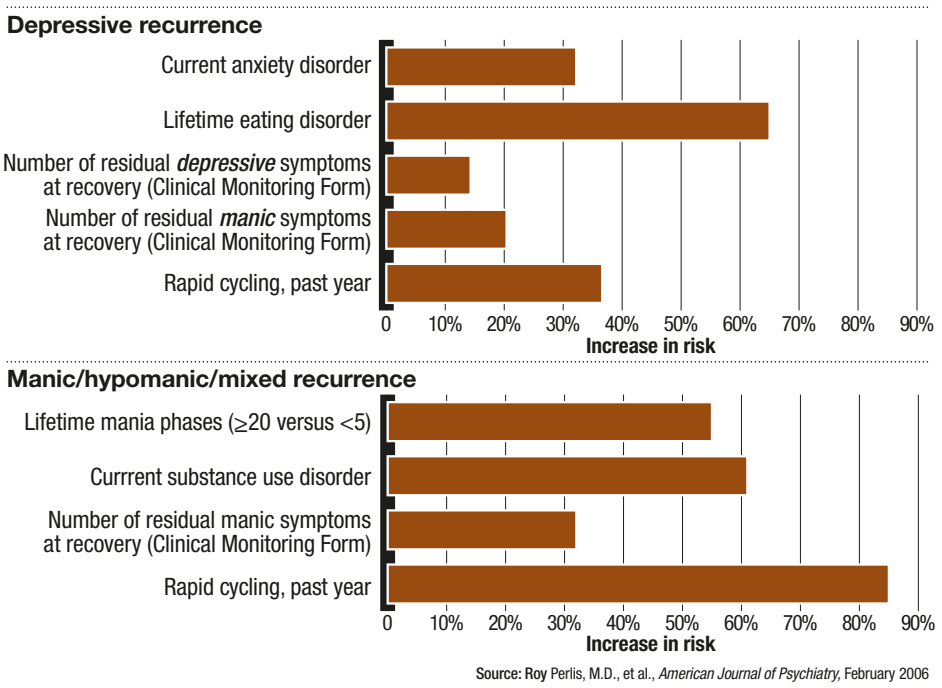
Perlis expressed some level of discomfort with the STEP-BD protocols being described as "state of the art."

"We didn't do anything that can't be done by any physician in the community," Perlis explained, "and that was an important principle [in designing the study]—we wanted this to very specifically be generalizable across the country." Perlis also emphasized that "there will be much more to come from STEP-BD that will focus more on specific treatment questions. There are several studies embedded within the larger STEP-BD design looking more closely at psychosocial interventions and providing a head-to-head comparison of different pharmacotherapies."

"Predictors of Recurrence in Bipolar Disorder: Primary Outcomes From the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD)" is posted at <http://ajp.psychiatryonline.org/cgi/content/abstract/163/2/217>. ■

Predicting Bipolar Recurrence

Of the 4,360 bipolar subjects in STEP-BD, researchers followed a subset of 1,469 who had been in the study for at least two years. The factors associated with an increased risk of relapse to a depressive episode were somewhat different from those associated with an increased risk of relapse to a manic episode.



Source: Roy Perlis, M.D., et al., *American Journal of Psychiatry*, February 2006

Anticonvulsant Studied as Adjunct To Bipolar Disorder Treatment

A small, randomized head-to-head comparison within STEP-BD provides intriguing, albeit inconclusive, results regarding add-on medications for resistant depression.

BY JIM ROSACK

One of the first waves of results from the National Institute of Mental Health's (NIMH) Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) suggests that the anticonvulsant/mood stabilizer lamotrigine (Lamictal) may have added value in treating patients with bipolar disorder for resistant depression.

A three-way head-to-head comparison of lamotrigine, risperidone (Risperdal), and inositol as adjunct pharmacotherapy in the treatment of bipolar depression in patients who have not adequately responded to appropriate pharmacotherapy is believed to be the first trial of any medication for treatment-resistant bipolar depression. The results of the small trial appear in the February *American Journal of Psychiatry*.

"This study was designed back in 1999, and it was felt then that we really didn't know a lot about bipolar depression in general or about treatment-resistant depression in particular," said lead author Andrew Nierenberg, M.D., an associate professor of psychiatry at Harvard Medical School and Massachusetts General Hospital.

STEP-BD was designed to include two randomized, controlled trials, one looking at the treatment of acute depression (results of which should be published in the next year) and this "smaller study of refractory depression," Nierenberg told *Psychiatric News*.

At that time, lamotrigine had yet to be approved by the FDA for maintenance treatment of bipolar I disorder. An anticonvulsant/mood stabilizer, lamotrigine is currently indicated to "delay the time to occurrence of mood episodes (depression, mania, hypomania, mixed episodes) in patients treated for acute mood episodes with standard therapy."

While the efficacy of lamotrigine has not been established for the acute treatment of mood episodes, a growing body of evidence indicates that the drug may be particularly useful in treating depressive episodes associated with bipolar disorder.

Nierenberg and his STEP-BD co-investigators looked at a subset of 66 of the nearly 4,500 patients enrolled in the larger study (see article above). Participants in the head-to-head trial were patients with bipolar I or II and were in a current major depressive episode that was not responsive to a combination of adequate doses of established mood stabilizers plus at least one antidepressant.

Patients were randomly assigned to open-label treatment with lamotrigine, inositol, or risperidone for up to 16 weeks in addition to their existing mood stabilizer and antidepressant therapy. The primary outcome measure was the rate of recovery, with recovery defined as "no more than two symptoms meeting *DSM-IV* threshold criteria for a mood episode and no significant symptoms present for eight weeks."

Nierenberg and his colleagues found no statistically significant differences between the rates of recovery of any two drugs compared (lamotrigine versus risperidone, lamotrigine versus inositol, and inositol versus risperidone). Nierenberg told *Psychiatric*

please see ***Anticonvulsant*** *on facing page*

Lithium Often Takes Backseat To Other Bipolar Therapies

Despite the evidence base, lithium is still reserved for the sickest patients with bipolar disorder.

BY JIM ROSACK

Patients with bipolar disorder who exhibit suicidal ideation are more likely to be prescribed antidepressants and second-generation antipsychotics (SGA) than lithium, despite lithium's reputation for an antisuicide effect.

Data published in the December 2005 *Psychiatric Services* by the team running the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) indicates that lithium appears to be "reserved for those patients with more severe illness characteristics." The report provides a snapshot of current medications taken by the first 1,000 patients who entered the STEP-BD study, which was funded by the National Institute of Mental Health (NIMH).

For many years lithium has been thought to exert an antisuicide effect, with some researchers reporting that in patients with bipolar disorder, lithium is associated with up to a six- to eightfold reduction in the risk of suicide attempt or completion compared with placebo. Other researchers reported that suicide completion was 2.7 times more likely to occur in patients with bipolar disorder on divalproex compared with those on lithium.

Yet these earlier studies did not control for other medications taken concomitantly or for severity of illness at baseline relative to prescription choice. In addition, "little is known about the antisuicidal benefits of other new agents for bipolar disorder, particularly the second-generation antipsychotics."

STEP-BD investigators, led by Gary Sachs, M.D., a professor of psychiatry at Massachusetts General Hospital and Harvard University, enrolled nearly 5,000 patients aged 15 and older with bipolar disorder I, II, or NOS, or cyclothymia, at 11 academic research centers across the U.S. The researchers' goal of the current report was to provide "a description of community-based pharmacotherapy treatments relative to suicidal ideation" in the first 1,000 patients to enter the study. The study group was assessed between November 1999 and April 2001 to determine "prevalence of prescriptions for mood stabilizers, second-generation antipsychotics, and antidepressants and the clinical features of patients who received these different classes of medications."

A battery of assessments was administered to each patient, yielding demographic details, past and current signs and symptoms of mental illness, and past and current treatments.

At baseline, 605 of 998 patients were euthymic (61 percent), 58 (6 percent) were manic or hypomanic, 87 (9 percent) were mixed or cycling, and 248 (25 percent) were depressed (two patients did not complete the entire baseline assessment).

Among the 998 patients, 211 (21 percent) exhibited signs of suicidal ideation. Suicidal ideation was significantly more common among persons who were experiencing depressive (49 percent) or mixed episodes (47 percent) than those who were manic or hypomanic (9 percent) or euthymic (7 percent).

Sachs and his coauthors reported that 362 (36 percent) patients were taking lithium at baseline, and 349 (35 percent) were taking divalproex. Of the 270 patients (27 percent) who were taking an antipsychotic, nearly all (264) were taking an SGA. Of those taking an SGA, about two-thirds were also taking either lithium or divalproex.

The number of patients taking an antidepressant was 418 (42 percent); 346 (83 percent) were taking one antidepressant, while 72 (17 percent) were taking at least two antidepressants at the beginning of the study.

Finally, Sachs and his colleagues reported that "rates of suicidal ideation were similar between patients who were taking any lithium and those who were not. Rates of suicidal ideation were also not statistically significantly different between those taking divalproex and those who didn't take divalproex. However, the mean number of prescribed medicines for patients with suicidal thoughts was higher than for those without suicidal thoughts.

"Our findings suggest," Sachs and his colleagues wrote, "that after use of other medications and baseline severity indices were controlled for (such as severity of illness and history of suicide attempts), psychiatrists may be more likely to prescribe lithium for suicidal patients with bipolar disorder."

"Suicidal Ideation and Pharmacotherapy Among STEP-BD Patients" is posted at <http://ps.psychiatryonline.org/cgi/content/full/56/12/1534>. ■

Anticonvulsant

continued from facing page

News this is likely due to the small number of patients in each comparison. For example, in the comparison of lamotrigine and inositol, only six patients were taking lamotrigine compared with 11 patients taking inositol. The number of patients in the other two paired comparisons were similar (15 on lamotrigine and 16 on inositol; 13 on risperidone and eight on inositol).

However, using the same rigorous definition of sustained response for eight weeks, secondary outcomes—in which all patients taking lamotrigine (n=21), inositol (n=23), and risperidone (n=22) were considered—recovery rates were different between the three groups. The overall recovery rates were 23.8 percent for those taking lamotrigine, 17.4 percent for those taking inositol, and 4.6 percent for those taking risperidone; these medications were taken in addition to the patients' existing pharmacotherapy.

"This study suggests, but by no means proves, that risperidone didn't look particularly helpful," Nierenberg told *Psychiatric News*. "However, that would have to be looked at much more closely in a larger study. Perhaps there was a role for inositol, and perhaps there was really a role for lamotrigine."

"Treatment-Resistant Bipolar Depression: A STEP-BD Equipoise Randomized Effectiveness Trial of Antidepressant Augmentation With Lamotrigine, Inositol, or Risperidone" is posted at <http://ajp.psychiatryonline.org/cgi/content/full/163/2/210>. ■

Scope of Practice

continued from page 17

The bill's chances may have faced a setback because one of its former sponsors in the state Senate resigned last year amid a corruption sting by the Tennessee Bureau of Investigation.

In challenging the legislation, Kyser's group focused criticism on the bill's approach to psychologist training, whether it is via a Florida correspondence course or a program at Fairleigh Dickinson University in New Jersey. The TPA is especially wary of programs that appear to inflate training hours or are overseen by general practitioners instead of psychiatrists.

"We try to point out the shortcomings of these programs," Kyser said.

Hawaii

The Hawaii legislation (HB 539) would authorize "trained and supervised medical psychologists working in federally qualified health centers or other licensed health clinics located in federally designated medically underserved areas" to prescribe psychotropic medications. The prescriptive authority would sunset in 2013. The bill would require psychopharmacological training from an institution of higher learning approved by the state psychology board. It also would require a one-year supervised practicum involving 400 hours treating at least 100 patients with mental disorders. The practicum would be supervised by a "licensed health care provider who is experienced in the provision of psychopharmacotherapy."

The bill would require psychologist supervision by a "prescribing mental health professional" for two years and then allow candidates to apply for a prescription certificate to prescribe independently. They could not prescribe narcotics. The board of psychology would adopt rules to implement the prescribing rules.

Reintroduced from last year, the bill has not yet advanced. However, the Hawaii Psychiatric Medical Association has received assistance from APA to prepare for the legislation, said Paula Johnson, deputy director for state affairs in APA's Department of Government Relations. The fight has been a long one in Hawaii, where psychologist prescription legislation was first introduced in 1984.

New Mexico

Although there was no legislation introduced in the already concluded 2006 New Mexico legislative session, a bill to expand the 2003 psychologist prescription law advanced in 2005 and is expected again next year, according to the Psychiatric Medical Association of New Mexico (PMANM).

George Greer, M.D., legislative representative for PMANM, said the legislation would expand psychologists' prescribing privileges from those medications that treat mental disorders to those that treat "mental, emotional, behavioral, or cognitive disorders or those that manage the side effects of such drugs."

The PMANM has received grants from APA to combat psychologist prescribing legislation and fights such legislation through the New Mexico Medical Society, which coordinates combined lobbying by every medical specialty against every scope-of-practice expansion, Greer said.

The support of the statewide group is critical, according to Greer, because it brings more physicians and resources to bear on the issue.

A similar approach is underway nationally, with the AMA unveiling a national partnership of six national medical specialty societies, including APA, and six state medical groups.

"If you get a group of state medical society CEOs and a group of specialty society CEOs together, this issue comes out near the top in terms of problems that they are facing and areas where they need to collaborate and help one another," said Michael Maves, M.D., AMA's executive vice president and CEO.

Information on psychologist-prescribing legislation is posted for Missouri at <www.house.mo.gov/bills061/bills/hb1447.htm>; Georgia at <www.legis.state.ga.us/legis/2005_06/sum/hb923.htm>; Tennessee at <www.legislature.state.tn.us/bills/currentga/BILL/HB0479.pdf>; Hawaii at <www.capitol.hawaii.gov/site1/docs/getstatus2.asp?billno=HB539>; and New Mexico at <http://legis.state.nm.us/lcs/_session.asp?chamber=H&type=++&number=463&year=05>. ■

Spending

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grown faster than any other service in recent years.

Lawmakers also found $6.5 billion in savings through a Bush administration plan to give higher Medicare payments to insurers that cover sicker patients and lower payments to plans that enroll healthier beneficiaries.

The measure kept alive a fund included in the 2003 prescription drug law designed to encourage preferred provider organizations to participate in Medicare. An earlier version aimed to eliminate the fund, and save $5.4 billion over five years.

The measure also provides medical relief to hurricane victims and expands some programs, including one for disabled children.

Congress approved a Department of Health and Human Services budget in December 2005 that includes a 1 percent across-the-board cut, except for veterans programs, from Fiscal 2005 levels. The measure included an additional $30 million from the earlier version of the spending bill toward implementation of the new Medicare prescription drug program.

The National Institutes of Health (NIH) received its smallest percentage increase since 1970. The Center for Mental Health Services (CMHS) was cut by $8 million.

"We knew that was coming, and Congress had to use that to trim the budget and trim spending," said Lizbet Boroughs, deputy director of APA's DGR. "However, when you are talking about cutting $220 million out of an agency like NIH, that is significant."

Among the practical implications of such cuts is the decision of the Substance Abuse and Mental Health Services Administration (SAMHSA) to reduce the amount it can offer its grant recipients. For instance, instead of funding 85 percent of a grant application, the agency might be able to pay only 82 percent or 83 percent of an application.

There have been no specific agency statements about what trade-offs they will make to meet the lower budget limit. The cut is also expected to trim the rate at which the NIH approves new research grants from the 2005 rate of 22 percent to an expected rate of 19.5 percent. Similar impacts are expected at SAMHSA and CMS.

Congress also moved to shore up mental health services for veterans by designating $2.2 billion of the $22.5 billion Department of Veterans Affairs medical services budget for mental health care.

"The language is very clear, and Congress was very emphatic, but now it is up to advocacy groups to hold the VA accountable," Boroughs said about the mental health funding designation.

The measure also instructs the VA to come up with a plan to establish Posttraumatic Stress Disorder Clinical Teams at every medical center in part because of concern that large numbers of soldiers returning from Iraq and Afghanistan are suffering from the disorder. ■

letters to the editor

Better Way to Supervise

The use of audiotaped treatment sessions for supervision of psychiatric trainees was described in the October 21, 2005, issue by Dr. Tomar Levin. He pointed out how much is lost or distorted in the description of treatment when supervisors meet with trainees at some time after the session in question was held. While the time invested in listening to audiotapes more than doubles the time for the supervisor, at least a close replica of what actually transpired in the treatment session becomes available for scrutiny and discussion.

However, there is yet a better way to conduct supervision, one that I have used to good advantage for over 30 years. I meet with the patient and the trainee together—with the patient's permission. As the session unfolds, the trainee employs his/her skills for me to observe directly, including the subtleties of nonverbal communication, relating, timing, and reciprocity. In addition, I am able to demonstrate interviewing and therapeutic techniques, as the educational process dictates. The trainee is prepared for this spontaneous interplay, benefiting from the positive feedback that is contingent upon his/her emerging competencies as well as from my professional modeling. The learning experience is reinforced by approximately 15 minutes of debriefing after the session ends. This pedagogical method is used for diagnostic evaluations and individual, family, and group treatment.

This is the traditional "bedside" or "clinic" rounding that has been a keystone of teaching in all medical specialties for 100 years—except for psychiatry. The inexplicable failure of psychiatry to use the most effective teaching technique has been yet another nail in the coffin of psychiatry's credibility with our colleagues in medicine, surgery, and primary care. A false curtain drawn around confidentiality and solipsistic self-disclosure in the psychoanalytic tradition has led to psychiatry's indirect and watered down modes of teaching.

In three decades of teaching buttressed by principles of learning, there have been fewer than a handful of patients who have been uncomfortable with the spontaneity of this direct teaching; most feel that they are benefiting from two physicians' experiences and expertise, give permission, and cooperate fully. Residents and other trainees respond with enthusiasm to this competency-based approach to teaching.

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Los Angeles, Calif.

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

NARSAD Awards

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Stanford University. Fawcett was recognized for his lifelong contributions to the understanding and treatment of bipolar disorder and suicide prevention. Schatzberg was honored for his work with the stress hormone cortisol and the neurotransmitter dopamine and its metabolites related to psychotic depression, which has led to novel treatment approaches.

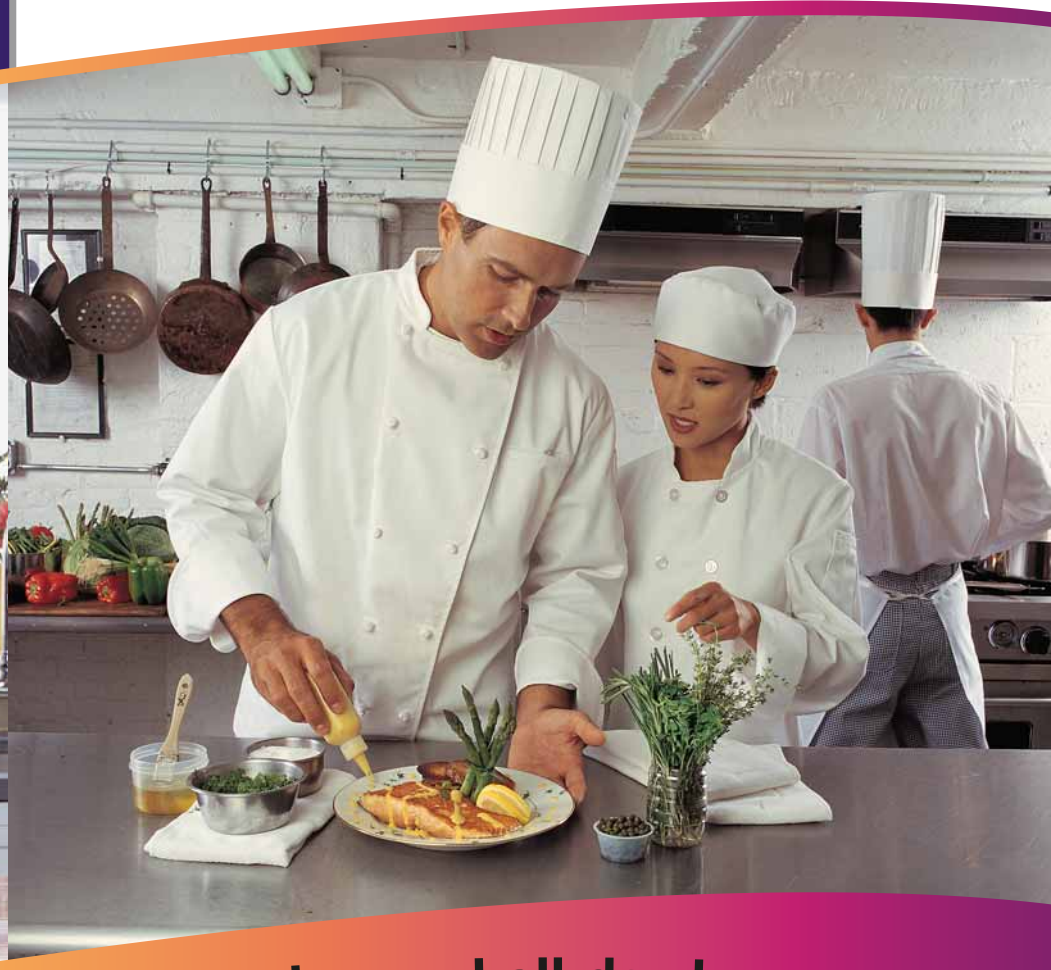
• **Ruane Prize for Child and Adolescent Psychiatric Research** went to Allan Reiss, M.D., a professor of psychiatry at Stanford University. With an exceptional technical expertise in deep brain structure imaging, he has specialized in studies of children with neurodevelopmental and neurogenetic disorders.

• **Goldman-Rakic Prize for Cognitive Neuroscience** was presented to Bruce McEwen, Ph.D., head of the laboratory of neuroendocrinology at Rockefeller University. His work has contributed greatly to the understanding of stress and stress hormones in a range of disorders, including depression, posttraumatic stress disorder, and the early stages of dementia.

• **Sidney R. Baer Jr. Prize** for a promising young investigator was given to Takanori Hashimoto, M.D., Ph.D., a research assistant professor of psychiatry at the University of Pittsburgh. Hashimoto is investigating mechanisms that contribute to alterations in inhibitory neurons in the prefrontal cortex of subjects with schizophrenia, which account for some of the behavior changes associated with the illness.

• **Staglin Family Music Festival Schizophrenia Research Award,** which is designated for an outstanding scientist under the age of 45, went to Linda Brzustowicz, M.D., a professor of genetics at Rutgers University. She was recognized for her pioneering work in psychiatric genetics, having identified one of a handful of genes currently thought to be related to schizophrenia. ■

#1 Prescribed Brand of ADULT ADHD Medication*



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The most common adverse events in clinical studies of ADDERALL XR included: *pediatric*–loss of appetite, insomnia, abdominal pain, and emotional lability; *adolescent*–loss of appetite, insomnia, abdominal pain, and weight loss; *adult*–dry mouth, loss of appetite, insomnia, headache, and weight loss.

The effectiveness of ADDERALL XR for long-term use has not been systematically evaluated in controlled trials. As with other psychostimulants indicated for ADHD, there is a potential for exacerbating motor and phonic tics and Tourette's syndrome. A side effect seen with the amphetamine class is psychosis. Caution also should be exercised in patients with a history of psychosis.

Abuse of amphetamines may lead to dependence. Misuse of amphetamine may cause sudden death and serious cardiovascular adverse events. These events have also been reported rarely with amphetamine use. ADDERALL XR generally should not be used in those with structural cardiac abnormalities. ADDERALL XR is contraindicated in patients with symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism and glaucoma, known hypersensitivity to this class of compounds, agitated states, history of drug abuse, or current or recent use of MAO inhibitors. ADDERALL XR should be prescribed with close physician supervision.

Please see references and Brief Summary of Prescribing Information on adjacent page.

*IMS Dataview, October 2005.

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FDA

continued from page 1

sciences at Wake Forest University School of Medicine, told fellow committee members they were especially concerned about the recent sharp increase in prescriptions to adults. If the drugs are associated with rare cardiovascular adverse events, Nissen and Furberg reasoned, the danger would be more marked in adults in whom the incidence of underlying heart disease is significantly higher than in children.

APA President Steven Sharfstein, M.D., however, characterized that stance as "unsupported by clear evidence at this time." In a statement released the evening of the advisory panel meeting, APA expressed concern about the process by which the FDA panel, charged with recommending how to study potential adverse events, instead "abruptly recommended" that the agency issue new black-box warnings.

In the APA statement, Sharfstein said, "FDA is to be commended for responding to reports about possible increased risk of hypertension, heart attacks, and strokes associated with the use of these medications by embarking on such a detailed study." He emphasized, however, that the FDA panel "took action that even some panel members acknowledged was beyond the scope of their mission."

APA, Sharfstein said, believes any regulatory actions the FDA takes "should be based on scientific evidence and the welfare of patients who currently use the medications."

It was FDA data on utilization that seemed to fuel Nissen's arguments. FDA staff medical reviewer Andrew Mossholder, M.D., had noted that FDA data estimate that about 2.5 million children and 1.5 million adults are now taking stimulant medications during any 30-day period, presumably mostly for ADHD.

"When you have that kind of exposure to drugs that are suspicious, it creates a major public health concern," Nissen said. Nissen said the committee should consider not just potential signals of risk, but also much broader issues including the effects of pharmaceutical industry marketing and direct-to-consumer advertising that have fueled the significant increase in stimulant prescriptions.

Concerns over the efficacy and safety of medications to treat ADHD, as well as questions about the validity of the disorder itself, have been around for many years. Yet last summer a different FDA advisory panel studied postmarketing adverse-event reports for some ADHD medications and noted what it described as a "concerning trend." That panel, the Pediatric Advisory Committee, will revisit that discussion at another meeting later this month.

At the February 9 meeting, FDA staff medical reviewer Kate Gelperin, M.D., told advisory panel members that between 1992 and 2004, the agency's MedWatch adverse-event reporting system logged 27 reports of deaths of children younger than 18 and 12 reports of deaths of adults that the agency had determined were "possibly linked" to ADHD medications. Most reports involved adults and children with underlying structural heart disease who suffered sudden cardiac death, presumably due to arrhythmias. Stimulants are known to increase heart rate as well as blood pressure and could lower the threshold for cardiac arrhythmias as well.

Gelperin said those 39 reports were a subset of the 81 MedWatch reports of deaths in patients taking at least one stimulant medication. However, she said, most of the reports involved multiple medications and other possible causes of deaths and so were discounted. Gelperin also warned that the 39 death reports in her analysis were not definitively tied to an ADHD medication, but "are simply associated." The FDA received an additional 54 reports of serious, nonfatal, cardiovascular events, Gelperin added, including reports of heart attacks and strokes in both children and adults between 1999 and 2003.

Still, she said, "the reports were substantially below background rates" that would be expected in the general population. Gelperin warned, though, that reporting to the MedWatch system is notoriously incomplete and therefore assumptions made on MedWatch reports are inherently inaccurate.

Fellow FDA safety reviewer David Graham, M.D., noted that the agency would not have asked the committee to discuss the adverse-event reports and ways to study possible associations between ADHD medications and the rare adverse events without some level of concern within the agency itself.

Committee member Arthur Levin, M.P.H., who is director of the Center for Medical Consumers in New York City, noted that patients—and in the case of children, their parents—have a false sense of security in assuming that stimulants are safe.

"For us to sit around and talk about it and for us to not make a very strong warning about the uncertainty of these drugs and their possible risks would be unethical," Levin concluded.

Yet it was that very uncertainty that underscored FDA officials' restraint.

"We still believe that what you tell people should reflect the available data, even if you are a little more inclined to act in the face of uncertainty," said Robert Temple, M.D., director of FDA's Office of Medical Policy, at a press briefing following the advisory committee meeting. "We didn't find the sudden-death data very persuasive."

Temple added that FDA officials do not "usually write black boxes about something that there isn't some evidence for—some pretty decent evidence for—but I don't think we've reached our conclusions about that yet."

Temple and FDA's Thomas Laughren, M.D., director of the Division of Psychiatric Drug Products, said that the agency will wait until the March 22 meeting of the Pediatric Advisory Committee before moving ahead with any new warnings. That panel of pediatric specialists, Laughren said, "is going to be enhanced by a number of child psychiatrists, who have a lot more direct experience in dealing with ADHD. We believe it's important for a committee that has some direct knowledge and experience with the condition to also weigh in on this issue."

The FDA's briefing materials from the February 9 meeting of the Drug Safety and Risk Management Advisory Committee are posted at <www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4202_00_TOC.htm>. ■

Lilly

Important Safety Information for ZYPREXA® (olanzapine)

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

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

Cerebrovascular adverse events (CVAE), including stroke, in elderly patients with dementia—Cerebrovascular adverse events (eg, stroke, transient ischemic attack), including fatalities, were reported in trials of ZYPREXA in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of CVAE in patients treated with ZYPREXA compared to patients treated with placebo. ZYPREXA is not approved for the treatment of elderly patients with dementia-related psychosis.

Hyperglycemia and diabetes mellitus—Hyperglycemia, in some cases associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including ZYPREXA. All patients taking atypicals should be monitored for symptoms of hyperglycemia. Persons with diabetes who are started on atypicals should be monitored regularly for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Patients who develop symptoms of hyperglycemia during treatment should undergo fasting blood glucose testing.

Neuroleptic malignant syndrome (NMS)—As with all antipsychotic medications, a rare condition known as NMS has been reported with olanzapine. If signs and symptoms appear, immediate discontinuation is recommended.

Tardive dyskinesia (TD)—As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of TD. If its signs and symptoms appear, discontinuation should be considered.

Orthostatic hypotension—In premarketing schizophrenia trials, some patients taking ZYPREXA may have experienced orthostatic hypotension associated with dizziness, tachycardia, and, in some cases, syncope (15/2500, 0.6%).

Seizures—Occurred infrequently in premarketing clinical trials (22/2500, 0.9%). ZYPREXA should be used cautiously in patients with a history of seizures or with conditions that lower the seizure threshold.

Effect on prolactin—Modest elevations of prolactin were seen with ZYPREXA in acute-phase schizophrenia trials (incidence 34% vs 13% with placebo), although mean changes from baseline to endpoint were not statistically significantly different between olanzapine and placebo. Some patients may have persisting modest prolactin elevations.

Transient, asymptomatic elevations of hepatic transaminase—In placebo-controlled schizophrenia trials, clinically significant ALT (SGPT) elevations (≥3 times the upper limit of the normal range) were observed in 2% (6/243) of patients exposed to ZYPREXA compared to none (0/115) of the placebo patients. None of these patients developed jaundice. Periodic assessment of transaminases is recommended in patients with significant hepatic disease.

Special populations, elderly—Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Olanzapine should be used with caution in patients at risk for aspiration pneumonia. In 5 studies in elderly patients with dementia-related psychosis, adverse events reported more commonly with olanzapine than with placebo were falls, somnolence, peripheral edema, abnormal gait, urinary incontinence, lethargy, increased weight, asthenia, pyrexia, pneumonia, dry mouth, and visual hallucinations. Olanzapine should be used with caution in elderly patients with dementia. Olanzapine is not approved for treatment of patients with dementia-related psychosis.

Drug interactions—Coadministration of diazepam or ethanol with ZYPREXA may potentiate orthostatic hypotension. Lower doses of ZYPREXA should be considered in patients receiving concomitant therapy with fluvoxamine.

Medication dispensing and prescribing errors have occurred between ZYPREXA® (olanzapine) and Zyrtec® (cetirizine HCl). These errors could result in unnecessary adverse events or potential relapse in patients suffering from schizophrenia or bipolar disorder. To reduce the potential for dispensing errors, please write ZYPREXA clearly.

The most common treatment-emergent adverse events associated with ZYPREXA (vs placebo) in 6-week acute-phase schizophrenia trials were somnolence (26% vs 15%), dizziness (11% vs 4%), weight gain (6% vs 1%), personality disorder (COSTART term for nonaggressive objectionable behavior; 8% vs 4%), constipation (9% vs 3%), akathisia (5% vs 1%), and postural hypotension (5% vs 2%).

The most common treatment-emergent adverse events associated with ZYPREXA (vs placebo) in 3- and 4-week bipolar mania trials were somnolence (35% vs 13%), dry mouth (22% vs 7%), dizziness (18% vs 6%), asthenia (15% vs 6%), constipation (11% vs 5%), dyspepsia (11% vs 5%), increased appetite (6% vs 3%), and tremor (6% vs 3%).

ZYPREXA®
Olanzapine

I have bipolar disorder.
But I won't let it have me.

If I have to fight it the rest of my life,
with the help of my doctor, and my family,
and my friends, I will do it.

Because I am the most important
thing in her world, and being her
mother is the most important
thing in mine.

ZYPREXA is approved for the treatment of schizophrenia, for acute bipolar mania, and for maintenance treatment in bipolar disorder.

For important safety information, including boxed warning, see adjacent pages and Brief Summary of Prescribing Information.

Lilly

ZYPREXA® (Olanzapine Tablets)
ZYPREXA® ZYDIS® (Olanzapine Orally Disintegrating Tablets)
ZYPREXA® IntraMuscular (Olanzapine for Injection)
Brief Summary: Please consult package insert for complete prescribing information.

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

INDICATIONS AND USAGE: ZYPREXA and ZYPREXA Zydis are indicated for short- and long-term treatment of schizophrenia, for acute manic and mixed episodes of bipolar I disorder, and for maintenance treatment in bipolar disorder. The use of ZYPREXA for extended periods should be periodically re-evaluated as to the long-term usefulness of the drug for the individual patient. ZYPREXA IntraMuscular is indicated for treatment of agitation associated with schizophrenia and bipolar I mania.

CONTRAINDICATIONS: Known hypersensitivity to olanzapine.

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. ZYPREXA is not approved for the treatment of patients with dementia-related psychosis (*see* BOX WARNING).

In placebo-controlled clinical trials of elderly patients with dementia-related psychosis, the incidence of death in olanzapine-treated patients (3.5%) was significantly greater than placebo-treated patients (1.5%).

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia—Cerebrovascular adverse events (eg, stroke, transient ischemic attack), including fatalities, were reported in patients in trials of olanzapine in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with olanzapine compared to patients treated with placebo. Olanzapine is not approved for the treatment of patients with dementia-related psychosis.

Hyperglycemia and Diabetes Mellitus—Hyperglycemia, in some cases associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including olanzapine. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Patients diagnosed with diabetes who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes who are starting treatment with atypicals should have fasting blood glucose (FBG) testing at baseline and periodically during treatment. Any patient treated with atypicals should be monitored for symptoms of hyperglycemia. Patients who develop symptoms of hyperglycemia during treatment with atypicals should undergo FBG testing.

Neuroleptic Malignant Syndrome (NMS)—Potentially fatal NMS has been reported in association with administration of antipsychotic drugs, including olanzapine. See complete prescribing information for information on management of NMS. Patients requiring antipsychotic drug treatment after recovery from NMS should be carefully monitored since recurrences have been reported.

Tardive Dyskinesia (TD)—Potentially irreversible TD may develop in patients treated with antipsychotic drugs. Although the prevalence of TD appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients are more likely to develop the syndrome. If signs and symptoms of TD appear, consider drug discontinuation.

PRECAUTIONS: Hemodynamic Effects—Olanzapine may induce orthostatic hypotension associated with dizziness; tachycardia; and in some patients, syncope. Hypotension, bradycardia with/without hypotension, tachycardia, and syncope were also reported during the clinical trials with intramuscular olanzapine for injection. Incidence of syncope was 0.6%, 15/2500 with oral olanzapine in phase 2-3 trials and 0.3%, 2/722 with intramuscular olanzapine for injection in clinical trials. Three normal volunteers in phase 1 studies with intramuscular olanzapine experienced hypotension, bradycardia, and sinus pauses of up to 6 seconds that spontaneously resolved (in 2 cases the events occurred on intramuscular olanzapine, and in 1 case, on oral olanzapine). The risk for this sequence of events may be greater in nonpsychiatric patients compared to psychiatric patients who are possibly more adapted to certain effects of psychotropic drugs. Patients should remain recumbent if drowsy or dizzy after injection with intramuscular olanzapine for injection until examination has indicated they are not experiencing postural hypotension, bradycardia, and/or hypoventilation. Olanzapine should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemia, heart failure, or conduction abnormalities), cerebrovascular disease, and conditions which would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications) where the occurrence of syncope, or hypotension and/or bradycardia might put them at increased medical risk. Caution is necessary in patients receiving treatment with other drugs having effects that can induce hypotension, bradycardia, respiratory or CNS depression (*see* Drug Interactions). Concomitant administration of intramuscular olanzapine and parenteral benzodiazepine has not been studied and is not recommended. If such combination treatment is considered, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended.

Seizures—During premarketing testing, seizures occurred in 0.9% (22/2500) of olanzapine-treated patients, regardless of causality. Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold.

Hyperprolactinemia—Like other drugs that antagonize dopamine D2 receptors, olanzapine elevates prolactin levels; a modest elevation persists during chronic administration. Tissue culture experiments indicate that approximately one third of human breast cancers are prolactin dependent in vitro. However, neither clinical nor epidemiologic studies have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is inconclusive.

Transaminase Elevations—In placebo-controlled studies, clinically significant ALT (SGPT) elevations (≥3 times the upper limit of normal) were observed in 2% (6/243) of patients exposed to olanzapine compared to no (0/115) placebo patients. None of these patients experienced jaundice. Among about 2400 patients with baseline SGPT ≤90 IU/L, 2% (50/2381) had asymptomatic SGPT elevations to >200 IU/L. Most were transient changes that tended to normalize while olanzapine treatment was continued. Among 2500 patients in oral olanzapine trials, about 1% (23/2500) discontinued treatment due to transaminase increases. Exercise caution in patients who have signs and symptoms of hepatic impairment; preexisting conditions associated with limited hepatic functional reserve; or concomitant treatment with potentially hepatotoxic drugs (*see* Laboratory Tests, below).

Potential for Cognitive and Motor Impairment—Somnolence was a commonly reported, dose-related adverse event in premarketing trials (olanzapine 26% vs placebo 15%). Somnolence led to discontinuation in 0.4% (9/2500) of patients in the oral premarketing database.

Body Temperature Regulation—Use appropriate care when prescribing olanzapine for patients who will be experiencing conditions that may contribute to an elevation in core body temperature.

Dysphagia—Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's disease. Olanzapine and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia.

Suicide—The possibility of a suicide attempt is inherent in schizophrenia and in bipolar disorder, and close supervision of high-risk patients should accompany drug therapy. Prescriptions for olanzapine should be written for the smallest quantity of tablets consistent with good patient management.

Use in Patients with Concomitant Illnesses—Olanzapine should be used with caution in patients with clinically significant prostatic hypertrophy, narrow angle glaucoma, or a history of paralytic ileus.

In 5 placebo-controlled studies in elderly patients with dementia-related psychosis (n=1184), these treatment-emergent adverse events were reported with olanzapine at an incidence of ≥2% and significantly greater than with placebo: falls, somnolence, peripheral edema, abnormal gait, urinary incontinence, lethargy, increased weight, asthenia, pyrexia, pneumonia, dry mouth, visual hallucinations. Discontinuation due to adverse events was significantly greater with olanzapine than placebo (13% vs 7%). Elderly patients with dementia-related psychosis treated with olanzapine are at an increased risk of death compared to placebo. Olanzapine is not approved for treatment of patients with dementia-related psychosis. If the prescriber elects to treat this patient population, vigilance should be exercised (*see* BOX WARNING *and* WARNINGS).

Because of the risk of orthostatic hypotension with olanzapine, use caution in cardiac patients (*see* Hemodynamic Effects).

Information for Patients—See full prescribing information for information to discuss with patients taking olanzapine.

Laboratory Tests—Periodic assessment of transaminases is recommended in patients with significant hepatic disease.

Drug Interactions—Use caution when olanzapine is taken in combination with other centrally acting drugs and alcohol. Olanzapine may enhance the effects of certain antihypertensive agents. Olanzapine may antagonize the effects of levodopa and dopamine agonists. Agents that induce CYP1A2 or glucuronyl transferase enzymes (e.g., omeprazole, rifampin) may cause an increase in olanzapine clearance. Inhibitors of CYP1A2 could potentially inhibit olanzapine clearance. Although olanzapine is metabolized by multiple enzyme systems, induction or inhibition of a single enzyme may appreciably alter olanzapine clearance. A dosage adjustment may need to be considered with specific drugs.

Activated charcoal (1 g) reduced the C_{max} and AUC of oral olanzapine by about 60%. Single doses of cimetidine (800 mg) or aluminum- and magnesium-containing antacids did not affect the oral bioavailability of olanzapine. Carbamazepine (200 mg bid) causes an approximately 50% increase in the clearance of olanzapine. Higher daily doses of carbamazepine may cause an even greater increase in olanzapine clearance. Neither ethanol (45 mg/70 kg single dose) nor warfarin (20 mg single dose) had an effect on olanzapine pharmacokinetics. Fluoxetine at 60 mg (single or multiple doses) causes a small increase in the C_{max} of olanzapine and a small decrease in olanzapine clearance; however, the impact of this factor is small in comparison to the overall variability between individuals, and dose modification is not routinely recommended. Fluvoxamine decreases the clearance of olanzapine; lower doses of olanzapine should be considered in patients receiving fluvoxamine concomitantly. In vitro data suggest that a clinically significant pharmacokinetic interaction between olanzapine and valproate is unlikely.

Olanzapine is unlikely to cause clinically important drug interactions mediated by the enzymes CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A. Single doses of olanzapine did not affect the pharmacokinetics of imipramine/desipramine or warfarin. Multiple doses of olanzapine did not influence the kinetics of diazepam/N-desmethyldiazepam, lithium, ethanol, or biperiden. However, coadministration of either diazepam or ethanol potentiated the orthostatic hypotension observed with olanzapine. Multiple doses of olanzapine did not affect the pharmacokinetics of theophylline or its metabolites. Co-administration of intramuscular lorazepam and intramuscular olanzapine for injection added to the somnolence observed with either drug alone (*see* Hemodynamic Effects).

Carcinogenesis, Mutagenesis, Impairment of Fertility—The incidence of liver hemangiomas and hemangiosarcomas in female mice was significantly increased in one carcinogenicity study at 2 times the maximum human daily oral dose (MHDOD) but not in another study at 2-5 times the MHDOD (mg/m^2 basis). In this study there was a high incidence of early mortalities in males in the 30/20 mg/kg/d group. The incidence of mammary gland adenomas and adenocarcinomas was significantly increased in female mice and rats given olanzapine at 0.5 and 2 times the MHDOD respectively (mg/m^2 basis). In other studies, serum prolactin measurements of olanzapine showed elevations up to 4-fold in rats at the same doses used in the carcinogenicity studies. The relevance for human risk of the finding of prolactin mediated endocrine tumors in rodents is unknown. No evidence of mutagenic potential for olanzapine has been found.

In rats, fertility (females) and mating performance (males and females) were affected at doses 1.5-11 times the MHDOD (mg/m^2 basis). Diestrous was prolonged and estrous delayed at 0.6 times the MHDOD (mg/m^2 basis); therefore, olanzapine may produce a delay in ovulation.

Pregnancy Category C—There are no adequate and well-controlled studies in pregnant women. Olanzapine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery, Nursing Mothers—Parturition in rats was not affected by olanzapine; its effect on labor and delivery in humans is unknown. In a study in lactating, healthy women, olanzapine was excreted in breast milk. Mean infant dose at steady state was estimated to be 1.8% of the maternal dose. It is recommended that women receiving olanzapine should not breast-feed.

Use in Pediatric and Geriatric Patients—Safety and effectiveness in pediatric patients have not been established. In premarketing clinical trials in patients with schizophrenia, there was no indication of any different tolerability of olanzapine in the elderly compared to younger patients. Studies in elderly patients with dementia-related psychosis have suggested there may be a different tolerability profile in these patients. Elderly patients with dementia-related psychosis treated with olanzapine are at an increased risk of death compared to placebo. Olanzapine is not approved for treatment of patients with dementia-related psychosis. If the prescriber elects to treat these patients, vigilance should be exercised. Consider a lower starting dose for any geriatric patient in the presence of factors that might decrease pharmacokinetic clearance or increase the pharmacodynamic response to olanzapine (*see* BOX WARNING, WARNINGS, *and* PRECAUTIONS).

ADVERSE REACTIONS: The following findings are based on a clinical trial database consisting of 8661 patients with approximately 4165 patient-years of exposure to oral olanzapine and 722 patients with exposure to intramuscular olanzapine for injection, including patients with schizophrenia, bipolar mania, or Alzheimer's disease (oral olanzapine trials) and patients with agitation associated with schizophrenia, bipolar I disorder (manic or mixed episodes), or dementia (intramuscular olanzapine for injection trials). See the full prescribing information for details on these trials. Certain portions of the discussion below relating to dose-dependent adverse events, vital sign changes, weight gain, laboratory changes, and ECG changes are derived from studies in patients with schizophrenia and have not been duplicated for bipolar mania or agitation; however, this information is also generally applicable to bipolar mania and agitation.

Associated with Discontinuation—Overall there was no difference in discontinuations due to adverse events in placebo-controlled oral olanzapine trials (olanzapine vs placebo: schizophrenia, 5% vs 6%; bipolar mania monotherapy, 2% vs 2%; bipolar mania cotherapy, 11% [olanzapine plus lithium or valproate] vs 2% [lithium or valproate alone]); or in placebo-controlled intramuscular olanzapine for injection trials (olanzapine for injection, 0.4%; placebo 0%). Discontinuations in oral schizophrenia trials due to increases in SGPT were considered to be drug related (olanzapine 2% vs placebo 0%; *see* PRECAUTIONS).

Commonly Observed Adverse Events—In 6-week, placebo-controlled, premarketing schizophrenia trials, the most common treatment-emergent adverse events associated with oral olanzapine (incidence ≥5% and olanzapine incidence at least twice that for placebo) were: postural hypotension, constipation, weight gain, dizziness, personality disorder (COSTART term for nonaggressive objectionable behavior), and akathisia. In 3- and 4-week placebo-controlled bipolar mania monotherapy trials, the most common treatment-emergent adverse events associated with oral olanzapine were: asthenia, dry mouth, constipation, dyspepsia, increased appetite, somnolence, dizziness, and tremor. In short-term bipolar mania combination therapy trials, the most common treatment-emergent adverse events observed with olanzapine plus lithium or valproate were dry mouth, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, and paresthesia. In 24-hour placebo-controlled trials of intramuscular olanzapine for injection for agitation associated with schizophrenia or bipolar mania, somnolence was the one adverse event observed at an incidence of ≥5% and at least twice that for placebo (olanzapine for injection 6%, placebo 3%).

Adverse Events with an Incidence ≥2% in Oral Monotherapy Trials—The following treatment-emergent events were reported at an incidence of ≥2% with oral olanzapine (doses ≥2.5 mg/d), and at a greater incidence with olanzapine than with placebo in short-term placebo-controlled trials (olanzapine N=532, placebo N=294): ***Body as a Whole***—accidental injury, asthenia, fever, back pain, chest pain; ***Cardiovascular***—postural hypotension, tachycardia, hypertension; ***Digestive***—dry mouth, constipation, dyspepsia, vomiting, increased appetite; ***Hemic and Lymphatic***—ecchymosis; ***Metabolic and Nutritional***—weight gain, peripheral edema; ***Musculoskeletal***—extremity pain (other than joint), joint pain; ***Nervous System***—somnolence, insomnia, dizziness, abnormal gait, tremor, akathisia, hypertonia, articulation impairment; ***Respiratory***—rhinitis, cough increased, pharyngitis; ***Special Senses***—amblyopia; ***Urogenital***—urinary incontinence, urinary tract infection.

Adverse Events with an Incidence ≥2% in Oral Combination Therapy Trials—The following treatment-emergent events were reported at an incidence of ≥2% with oral olanzapine (doses ≥5 mg/d) plus lithium or valproate (N=229), and at a greater incidence than with placebo plus lithium or valproate (N=115) in short-term placebo-controlled trials: ***Body as a Whole***—asthenia, back pain, accidental injury, chest pain; ***Cardiovascular***—hypertension; ***Digestive***—dry mouth, increased appetite, thirst, constipation, increased salivation; ***Metabolic and Nutritional***—weight gain, peripheral edema, edema; ***Nervous System***—somnolence, tremor, depression, dizziness, speech disorder, amnesia, paresthesia, apathy, confusion, euphoria, incoordination; ***Respiratory***—pharyngitis, dyspnea; ***Skin and Appendages***—sweating, acne, dry skin; ***Special Senses***—amblyopia, abnormal vision; ***Urogenital***—dysmenorrhea, vaginitis.

Adverse Events with an Incidence ≥1% in Intramuscular Trials—The following treatment-emergent adverse events were reported at an incidence of ≥1% with intramuscular olanzapine for injection (2.5 -10 mg/injection) and at incidence greater than placebo in short-term, placebo-controlled trials in agitated patients with schizophrenia or bipolar mania: ***Body as a Whole***—asthenia; ***Cardiovascular***—hypotension, postural hypotension; ***Nervous System***—somnolence, dizziness, tremor.

Dose Dependency of Adverse Events in Short-Term, Placebo-Controlled Trials—*Extrapyramidal Symptoms*—In an acute-phase controlled clinical trial in schizophrenia, there was no significant difference in ratings scales incidence between any dose of oral olanzapine (5+2.5, 10+2.5, or 15+2.5 mg/d) and placebo for parkinsonism (Simpson-Angus Scale total score >3) or akathisia (Barnes Akathisia global score ≥2). In the same trial, only akathisia events (spontaneously reported COSTART terms akathisia and hyperkinesia) showed a statistically significantly greater adverse events incidence with the 2 higher doses of olanzapine than with placebo. The incidence of patients reporting any extrapyramidal event was significantly greater than placebo only with the highest dose of oral olanzapine (15+2.5 mg/d). In controlled clinical trials of intramuscular olanzapine for injection, there were no statistically significant differences from placebo in occurrence of any treatment-emergent extrapyramidal symptoms, assessed by either rating scales incidence or spontaneously reported adverse events.

Other Adverse Events—Dose-relatedness of adverse events was assessed using data from a clinical trial involving 3 fixed oral dosage ranges compared with placebo. The following treatment-emergent events showed a statistically significant trend: asthenia, dry mouth, nausea, somnolence, tremor.

Vital Sign Changes—Oral olanzapine was associated with orthostatic hypotension and tachycardia in clinical trials. Intramuscular olanzapine for injection was associated with bradycardia, hypotension, and tachycardia in clinical trials (*see* PRECAUTIONS).

Weight Gain—In placebo-controlled 6-week schizophrenia studies, weight gain was reported in 5.6% of oral olanzapine patients (average 2.8-kg gain) compared to 0.8% of placebo patients (average 0.4-kg loss); 29% of olanzapine patients gained >7% of their baseline weight, compared to 3% of placebo patients. During continuation therapy (238 median days of exposure), 56% of patients met the criterion for having gained >7% of their baseline weight. Average gain during long-term therapy was 5.4 kg.

Laboratory Changes—Olanzapine is associated with asymptomatic increases in SGPT, SGOT, and GGT and with increases in serum prolactin and CPK (*see* PRECAUTIONS). Asymptomatic elevation of eosinophils was reported in 0.3% of olanzapine patients in premarketing trials. There was no indication of a risk of clinically significant neutropenia associated with olanzapine in the premarketing database.

In clinical trials among olanzapine-treated patients with baseline random triglyceride levels of <150 mg/dL (N=659), 0.5% experienced triglyceride levels of ≥500 mg/dL anytime during the trials. In these same trials, olanzapine-treated patients (N=1185) had a mean triglyceride increase of 20 mg/dL from a mean baseline of 175 mg/dL. In placebo-controlled trials, olanzapine-treated patients with baseline random cholesterol levels of <200 mg/dL (N=1034) experienced cholesterol levels of ≥240 mg/dL anytime during the trials more often than placebo-treated patients (N=602; 3.6% vs 2.2% respectively). In these same trials, olanzapine-treated patients (N=2528) had a mean increase of 0.4 mg/dL in cholesterol from a mean baseline of 203 mg/dL, which was significantly different compared to placebo-treated patients (N=1415) with a mean decrease of 4.6 mg/dL from a mean baseline of 203 mg/dL.

ECG Changes—Analyses of pooled placebo-controlled trials revealed no statistically significant olanzapine/placebo differences in incidence of potentially important changes in ECG parameters, including QT, QTc, and PR intervals. Olanzapine was associated with a mean increase in heart rate of 2.4 BPM compared to no change among placebo patients.

Other Adverse Events Observed During Clinical Trials—The following treatment-emergent events were reported with oral olanzapine at multiple doses ≥1 mg/d in clinical trials (8661patients, 4165 patient-years of exposure). This list may not include events previously listed elsewhere in labeling, those events for which a drug cause was remote, those terms which were so general as to be uninformative, and those events reported only once or twice which did not have a substantial probability of being acutely life-threatening. *Frequent* events occurred in ≥1/100 patients; *infrequent* events occurred in 1/100 to 1/1000 patients; *rare* events occurred in <1/1000 patients. ***Body as a Whole***—*Frequent:* dental pain, flu syndrome; *Infrequent:* abdomen enlarged, chills, face edema, intentional injury, malaise, moniliasis, neck pain, neck rigidity, pelvic pain, photosensitivity reaction, suicide attempt; *Rare:* chills and fever, hangover effect, sudden death. ***Cardiovascular***—*Frequent:* hypotension; *Infrequent:* atrial fibrillation, bradycardia, cerebrovascular accident, congestive heart failure, heart arrest, hemorrhage, migraine, pallor, palpitation, vasodilatation, ventricular extrasystoles; *Rare:* arteritis, heart failure, pulmonary embolus. ***Digestive***—*Frequent:* flatulence, increased salivation, thirst; *Infrequent:* dysphagia, esophagitis, fecal impaction, fecal incontinence, gastritis, gastroenteritis, gingivitis, hepatitis, melena, mouth ulceration, nausea and vomiting, oral moniliasis, periodontal abscess, rectal hemorrhage, stomatitis, tongue edema, tooth caries; *Rare:* aphthous stomatitis, enteritis, eructation, esophageal ulcer, glossitis, ileus, intestinal obstruction, liver fatty deposit, tongue discoloration. ***Endocrine***—*Infrequent:* diabetes mellitus; *Rare:* diabetic acidosis, goiter. ***Hemic and Lymphatic***—*Infrequent:* anemia, cyanosis, leukocytosis, leukopenia, lymphadenopathy, thrombocytopenia; *Rare:* normocytic anemia, thrombocythemia. ***Metabolic and Nutritional***—*Infrequent:* acidosis, alkaline phosphatase increased, bilirubinemia, dehydration, hypercholesteremia, hyperglycemia, hyperlipemia, hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, lower extremity edema, upper extremity edema; *Rare:* gout, hyperkalemia, hypernatremia, hypoproteinemia, ketosis, water intoxication. ***Musculoskeletal***—*Frequent:* joint stiffness, twitching; *Infrequent:* arthritis, arthrosis, leg cramps, myasthenia; *Rare:* bone pain, bursitis, myopathy, osteoporosis, rheumatoid arthritis. ***Nervous System***—*Frequent:* abnormal dreams, amnesia, delusions, emotional lability, euphoria, manic reaction, paresthesia, schizophrenic reaction; *Infrequent:* akinesia, alcohol misuse, antisocial reaction, ataxia, CNS stimulation, cogwheel rigidity, delirium, dementia, depersonalization, dysarthria, facial paralysis, hypesthesia, hypokinesia, hypotonia, incoordination, libido decreased, libido increased, obsessive compulsive symptoms, phobias, somatization, stimulant misuse, stupor, stuttering, tardive dyskinesia, vertigo, withdrawal syndrome; *Rare:* circumoral paresthesia, coma, encephalopathy, neuralgia, neuropathy, nystagmus, paralysis, subarachnoid hemorrhage, tobacco misuse. ***Respiratory***—*Frequent:* dyspnea; *Infrequent:* apnea, asthma, epistaxis, hemoptysis, hyperventilation, hypoxia, laryngitis, voice alteration; *Rare:* atelectasis, hiccup, hypoventilation, lung edema, stridor. ***Skin and Appendages***—*Frequent:* sweating; *Infrequent:* alopecia, contact dermatitis, dry skin, eczema, maculopapular rash, pruritus, seborrhea, skin discoloration, skin ulcer, urticaria, vesiculobullous rash; *Rare:* hirsutism, pustular rash. ***Special Senses***—*Frequent:* conjunctivitis; *Infrequent:* abnormality of accommodation, blepharitis, cataract, deafness, diplopia, dry eyes, ear pain, eye hemorrhage, eye inflammation, eye pain, ocular muscle abnormality, taste perversion, tinnitus; *Rare:* corneal lesion, glaucoma, keratoconjunctivitis, macular hypopigmentation, miosis, mydriasis, pigment deposits lens. ***Urogenital***—*Frequent:* vaginitis*; *Infrequent:* abnormal ejaculation,* amenorrhea,* breast pain, cystitis, decreased menstruation,* dysuria, female lactation,* glycosuria, gynecomastia, hematuria, impotence,* increased menstruation,* menorrhagia,* metrorrhagia,* polyuria, premenstrual syndrome,* pyuria, urinary frequency, urinary retention, urinary urgency, urination impaired, uterine fibroids enlarged,* vaginal hemorrhage*; *Rare:* albuminuria, breast enlargement, mastitis, oliguria. (*Adjusted for gender.)

The following treatment-emergent events were reported with intramuscular olanzapine for injection at one or more doses ≥2.5 mg/injection in clinical trials (722 patients). This list may not include events previously listed elsewhere in labeling, those events for which a drug cause was remote, those terms which were so general as to be uninformative, and those events reported only once or twice which did not have a substantial probability of being acutely life-threatening. ***Body as a Whole***—*Frequent:* injection site pain; *Infrequent:* abdominal pain, fever. ***Cardiovascular***—*Infrequent:* AV block, heart block, syncope. ***Digestive***—*Infrequent:* diarrhea, nausea. ***Hemic and Lymphatic***—*Infrequent:* anemia. ***Metabolic and Nutritional***—*Infrequent:* creatine phosphokinase increased, dehydration, hyperkalemia. ***Musculoskeletal***—*Infrequent:* twitching. ***Nervous System***—*Infrequent:* abnormal gait, akathisia, articulation impairment, confusion, emotional lability. ***Skin and Appendages***—*Infrequent:* sweating.

Postintroduction Reports—Reported since market introduction and temporally (not necessarily causally) related to olanzapine therapy: allergic reaction (eg, anaphylactoid reaction, angioedema, pruritus or urticaria), diabetic coma, pancreatitis, priapism, rhabdomyolysis, and venous thromboembolic events (including pulmonary embolism and deep venous thrombosis). Random cholesterol levels of ≥240 mg/dL and random triglyceride levels of ≥1000 mg/dL have been rarely reported.

DRUG ABUSE AND DEPENDENCE: Olanzapine is not a controlled substance.

Literature revised September 30, 2005

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Part D

continued from page 1

• Require the Centers for Medicare and Medicaid Services (CMS) to report on drug plan progress in implementing effective transition policies.
• Request that CMS restate its guidance to drug plans, directing them to have formularies that allow access to important classes of drugs (including antipsychotics and antidepressants) beyond the initial transition period.
• Ask CMS to monitor drug plans' exceptions and appeals process.
• Pass legislation requiring coverage of drugs for substance abuse and of benzodiazepines and barbiturates.
• Establish a CMS advisory board to identify persistent short-term problems and long-term correctives.

Meanwhile, the pervasive problems with the Part D rollout have been the subject of reports in the popular press, but there are no formal data on how the program is actually affecting patients and clinicians. For that reason, the American Psychiatric Institute for Research and Education (APIRE) is undertaking a large, national study to assess issues around continuity of care for individuals with mental illness receiving medications under the new program (see article below).

"Medicare Part D is the single most significant mental health policy initiative to have been undertaken in the last decade," said Darrel Regier, M.D., M.P.H., director of APIRE and APA's Division of Research. "We think it would be extremely helpful to have a sense of how this is actually impacting our patients and practitioners. The only way of systematically assessing the strengths and weaknesses of the new program is a survey that would get a representative sample of the experiences our patients are having."

Utilization Review Causing Problems

Clinically inappropriate utilization review (UR) requirements by prescription drug plans (PDPs) appear to be the most pervasive—but by no means the only—complaint. In some cases, it appears that UR requirements have been backed up by CMS in defiance of the agency's stated transition policies requiring continuity of medications for people moving from Medicaid into the new program.

Muszynski described the case of one clinician seeking prior authorization to prescribe Zyprexa for a patient previously stabilized on that drug. The clinician was told by a physician reviewer to treat the patient with Clozaril—despite the potential problems associated with that drug and the requirements for regular blood testing.

"In some cases it appears that CMS is just not serious about its own transition policies," Muszynski said. "Another serious concern we are having is that the exceptions and appeals process is one sided and in disarray."

In many parts of the country, states have stepped in to assume the costs of prescription drugs for dual eligibles who have not been able to receive necessary medications in a timely fashion (*Psychiatric News*, February 3).

That appears to have provided at least temporary relief for what Massachusetts psychiatrist Andrea Stone, M.D., had described as "pandemonium" in the first weeks of January. But she told *Psychiatric News* that problems persist, and some are likely to recur since states are providing only temporary coverage.

"When Mass Health stepped in [to assume costs of medications for beneficiaries unable to receive them] there was an immediate improvement in the overall situation," she said. "At this point most people are getting their medications through their Medicare plans, but sporadic problems exist. A patient was told by her insurer that all of her medications would require prior authorization. In fact, none did. Another patient cannot get her ID number, which means she can't get her meds. She was on the telephone for three hours one Friday without resolution of the problem, Stone noted.

Some of the actions taken by PDPs have bordered on the bizarre. Stone reported a denial for medication in which the patient was asked to provide two unique peer-reviewed journal articles to support the request.

"This is a patient who has been taking the refused medication for at least eight years and is in the best psychiatric shape of her life," Stone said. "The letter said that she or her representative could appeal, but did not provide information on how to do that except to say that it had to be done within 60 days."

Some PDPs Ignore Rules

Jeffrey Geller, M.D., director of public psychiatry at the University of Massachusetts Medical School and a treating clinician at the Carson Center, pointed out that the CMS transition policy, designed to ensure that patients who are stabilized on a particular medication prior to January 1 continue to receive those meds without interruption, has not been adhered to by PDPs.

"This has not been the case even for oral medications, much less depot medications, including antipsychotic and antidepressant medications," Geller reported.

Moreover, every company has a different form for prior authorization, requiring significant paperwork from clinicians, yet none appears to allow for the override of a denial on the basis of prior stabilization. "Not one of the forms indicates prior stabilization on the medication will justify an override," he said.

In Pennsylvania, problems of enrollment in the new program, stemming from inadequate communication, continue to plague continuity of care.

"We weren't clear what PDPs were going to be operating in Pennsylvania until very late in the game," psychiatrist Mary Diamond, M.D., medical director for the state's Office of Mental Health and Substance Abuse, told *Psychiatric News*. "When we did finally get the PDPs arranged it was a great challenge to get our state-hospital population enrolled. Medicare didn't realize that our seriously mentally ill patients couldn't enroll themselves and didn't have the ability to get the right plans.

"My greatest disappointment has been that many people in the community didn't know about these systems," she said. "Medicare chose to notify pharmacies through their national organizations, but we have a substantial number of independent pharmacies."

In Washington, D.C., leaders in both parties have acknowledged serious problems with the new Medicare program's roll out. But Democratic leaders are calling for legislative fixes to the problems, while Republicans argue that most of the problems can be fixed administratively.

The Hill, a Capitol Hill newspaper, published a number of opinion pieces by leaders in both parties addressing the problems in the Medicare prescription drug program.

"There were some unacceptable problems, but as the problems are resolved I'm confident beneficiaries will agree the new benefit will bring them better health security in the long run," wrote Charles Grassley (R-Iowa), chair of the Senate Finance Committee, who helped champion passage of the program.

But Grassley took a swipe at Democrats calling for new legislation to fix problems with the program. "Some senators who aren't on the [finance] committee—mostly those with partisan political motives—are pushing for legislation to change the benefit in the name of fixing the problems. But the problems so far don't lend themselves to a legislative fix. The issues with computer systems and long wait times on phone lines are better addressed administratively."

Sen. John Kerry (D-Mass.) was one of those calling for new legislation in his column in *The Hill*.

"In some states, as many as 20 percent of elderly Medicaid recipients have seen their coverage denied," he wrote. "Already overburdened states are being forced to pick up the tab for the White House's incompetence, to the tune of hundreds of millions of dollars. Insurance and pharmaceutical companies are no doubt thrilled with their profits, but this latest Bush boondoggle is a real-life nightmare for state budgets and, worse, for millions of seniors just looking to fill a needed prescription."

APA members can contact the Part D monitoring system by e-mail at partd@psych.org or by phone at (866) 882-6227. APA is continuing to post information about the program at <www.mentalhealthpartd.org>. APA's testimony to the Senate Committee on Finance on implementation of the new Medicare drug benefit is posted at <www.psych.org/members/download.cfm?file=1013>. ■

APA Undertakes Nationwide Study Of Medicare Part D Impact

APA will obtain data on how the new Medicare Part D prescription benefit is affecting psychiatric patients in terms of medication-management issues and their impact on patients' illnesses.

BY MARK MORAN

APA wants to get hard data on what so far have been anecdotal reports about the Medicare prescription drug program's tumultuous beginning.

The American Psychiatric Institute on Research and Education (APIRE) is undertaking a national survey of psychiatrists to assess problems with continuity of care for psychiatric dual-eligible patients—those who until January 1 were covered by both Medicaid and Medicare—in the new Part D prescription drug program.

APIRE is also undertaking a parallel, 10-state study of medication access and continuity for psychiatric patients with only Medicaid insurance.

The overall goal is to monitor psychiatrists' practices with respect to the psychopharmacologic management of Medicaid and dual-eligible Medicaid and Medicare patients with mental and addictive illnesses, including:

• Assessing access to medications and the extent of disruptions in medication continuity,
• Characterizing adverse consequences that may result from unintended medication disruptions (e.g., symptom relapse or exacerbation, hospitalizations, increased functional impairment, homelessness, and injury to self or others),
• Evaluating the administrative functioning and requirements of the new programs for clinicians and their staffs,
• Identifying specific prescription drug plans (PDPs) or management mechanisms that appear to be functioning well or poorly to inform the development and implementation of future Medicare Part D PDPs.

"The transition to Medicare Part D has been quite rocky," said APA President Steven Sharfstein, M.D. "We need to know what the impact is on our patients' access to essential treatment. This study will help see to what extent disruptions in care have led to poor outcomes for our patients. "

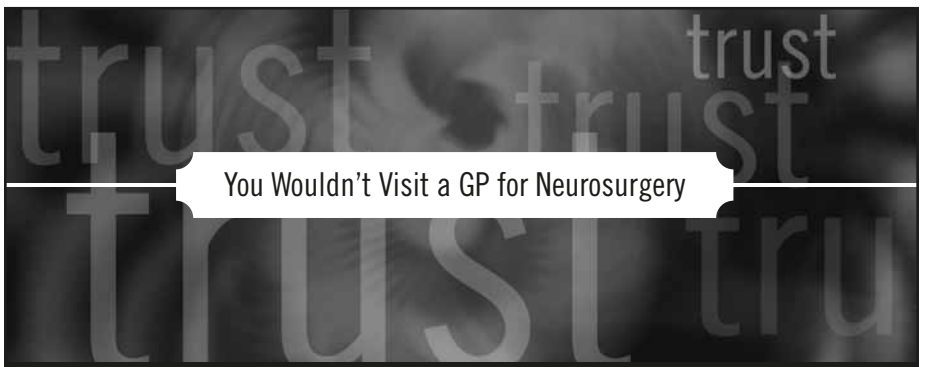
The survey will be an observational evaluation tracking patient and clinician experiences with medication continuity and access, throughout the implementation of Medicare Part D. Data collection will consist of three cross-sectional assessments conducted during the first nine months of Medicare Part D to capture effects of possible changes in PDP practices over time.

Key design issues of the Medicaid and Medicare PDPs in different states or regions will be assessed over time. This would include examining the relationship between medication continuity and key plan features such as preferred drug/formulary lists, prior authorization, "step therapy" or "fail-first" protocols, other management protocols such as automatically switching to generics, prohibiting benzodiazepines and off-label use of medications, dosing or number of medication limits, or time limits on transitioning patients to new medications.

The study focuses on two primary groups: dual-eligible patients and patients with Medicaid only. Some key patient outcome indicators include

• Rates of problems accessing specific medications for new and continuing patients, including access to refills and "emergency" supplies, benzodiazepines, and off-label uses of medications,
• Rates of clinically undesired medication switches or discontinuations,
• Rates of symptom relapse or exacerbation,
• Rates of hospitalizations, emergency room visits, and crisis mental health care,
• Rates of injury to self or others,
• Changes in housing status,
• Changes in work and social functioning,
• Changes in medication adherence and side effects.

Some key psychiatrist/practice outcome indicators would include administrative time spent by clinicians and their office staff in facilitating transition to the new Medicare Part D PDP plans and specific PDP prescription management and program administration features and their perceived impact—both positive and negative—on medication continuity and quality of care. ■



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Please send letter of interest and C.V. to:

Robert A. Zucker, Ph.D.
Director, Substance Abuse Section
University of Michigan Addiction Research Center
2025 Traverwood, Suite A
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ABOUT THE DEPARTMENT OF PSYCHIATRY

The Department of Psychiatry is located near the southern shore of Lake Erie where the University district includes the affordable and historic neighborhoods of Shaker Heights, University Heights, and Cleveland Heights, an outstanding public school system, a world class orchestra, and abundant recreational activities. University Hospitals of Cleveland and Case Western Reserve are Affirmative Action/Equal Opportunity Employers. Women and minorities are strongly encouraged to apply. The University is an equal-opportunity/affirmative action employer. Visit us on the web at www.case.edu/med/psychiatry.

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pam.klaus@heartland-health.com
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St. John's Clinic is seeking energetic board certified/eligible Adult Psychiatrists to join their well-established, busy Psychiatry Department, in lovely Springfield, Missouri. Inpatient and outpatient practice with large referral base. Enjoy call of 1:4. The inpatient unit is conveniently located close to the physician office building. The department is part of St. John's Clinic, a progressive and growing multi-specialty clinic of 470+ physicians in an integrated health care delivery system. For more information about St. John's Health System, please visit **www.stjohns.com**. St. John's was recently ranked #1 in patient satisfaction by Press Ganey.

Position offers a competitive salary guarantee. In addition, there is bonus potential and a full array of benefits including health, dental, vision, life and disability insurance, malpractice, CME, vacation, retirement, and relocation.

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For more information, contact:

Angie Farris, Director
St. John's Clinic
1965 S. Fremont, Suite 320
Springfield, MO 65804
Phone: (877) 880-6650
Fax: (888) 290-8300
afarris@sprg.mercy.net

In Pursuit of Excellence...

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CASE
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Associate Director, Bipolar Disorders Research Center
Department of Psychiatry
University Hospitals of Cleveland/Case School of Medicine

The Bipolar Disorders Research Center at Case Western Reserve University/University Hospitals of Cleveland (CWRU/UHC) is inviting applications for the position of Associate Director. The scientific theme of the Center is interventions and services research designed to improve clinical outcomes in underserved populations, including those with rapid cycling, dual diagnosis presentations, forensic complications, adults and older adults, and more recently, 'deployment mental health'. The main goal of this position is to facilitate the growth of the center through strong operational oversight of Federally-funded research. Applicants must have an MD or a PhD and extensive experience with NIMH-funded research projects. University Hospitals of Cleveland and Case Western Reserve are Affirmative Action/Equal Opportunity Employers. Women and minorities are strongly encouraged to apply.

Interested individuals should forward their CV to Joseph. Calabrese@uhhs.com or call 216/844-2865.

www.case.edu/med/psychiatry

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CASE
CASE WESTERN RESERVE UNIVERSITY

GERIATRIC PSYCHIATRIST
Department of Psychiatry
University Hospitals of Cleveland/Case School of Medicine

Several open rank, full-time faculty positions in Geropsychiatry are available in either the tenure or nontenure track at Case Western Reserve University/University Hospitals Health System. Positions involve a combination of administrative leadership, teaching, clinical care, and consultation. Salary support for development of the faculty members own areas of research leading to independent support is available. Please send Inquiries to: Lindsey Dozanti, Faculty Recruitment, Department of Psychiatry, 11100 Euclid Avenue, Cleveland, OH 44106. Fax inquiries to 216-844-3851 or Email Lindsey.Dozanti@uhhs.com.

ABOUT THE DEPARTMENT OF PSYCHIATRY
The Department of Psychiatry is located near the southern shore of Lake Erie where the University district includes the affordable and historic neighborhoods of Shaker Heights, University Heights, and Cleveland Heights, an outstanding public school system, a world class orchestra, and abundant recreational activities. University Hospitals of Cleveland and Case Western Reserve are Affirmative Action/Equal Opportunity Employers. Women and minorities are strongly encouraged to apply. The University is an equal-opportunity/affirmative action employer. Visit us on the web at www.case.edu/med/psychiatry.

SCOTT & WHITE

College of Medicine
The Texas A&M University System Health Science Center

Associate Chair
Department of Psychiatry
TEXAS A & M UNIVERSITY SYSTEMS COLLEGE OF MEDICINE
SCOTT & WHITE CLINIC, HOSPITAL, AND HEALTH PLAN
CENTRAL TEXAS VETERANS' HEALTH CARE SYSTEM

Scott & White Clinic and Hospital, and Texas A&M University Systems Health Science Center College of Medicine, Temple, TX is seeking a Clinical/Academic psychiatrist to lead, manage, and expand an established and therapeutic, clinical department as the Associate Chair of the Department of Psychiatry. Candidates should be recognized leaders in psychiatry with demonstrated superior clinical, administrative, and leadership skills. This position involves clinical care of adults, in both inpatient and outpatient settings, with broad responsibility for teaching medical students and psychiatry residents. Interest and experience in teaching is required, and interest in research is desirable. Teamwork and collegial interactions are emphasized within the Department and across specialties and departments. Close working relationships with colleagues in other departments, especially in primary care regional clinics, are emphasized.

Scott & White Clinic, a 500+ physician directed multi-specialty group practice, is part of the Scott & White integrated healthcare system which includes the 465 bed tertiary Scott & White Memorial Hospital, and the a 185,000 member Scott & White Health Plan. Scott &White is the primary teaching campus of the Texas A&M University Systems Health Science Center College of Medicine.

Temple is located 60 miles north of Austin on Interstate 35. The community is an ideal setting for families, outdoor recreation, with easy access to major metropolitan areas in Texas. Salary and benefits are competitive, including 20 days of annual leave and 15 days of CME leave with a stipend for travel.

For more information, please contact: **Paul Golden, Physician Recruitment, Scott and White Clinic, 2401 S. 31st St., Temple, TX 76508. (800) 725-3627 Fax to 254-724-4974, e-mail drrpfg@swmail.sw.org** Scott & White is an equal opportunity employer. For more information on Scott & White, please visit our web site at: www.sw.org. For Texas A&M www.tamhsc.edu

FLORIDA

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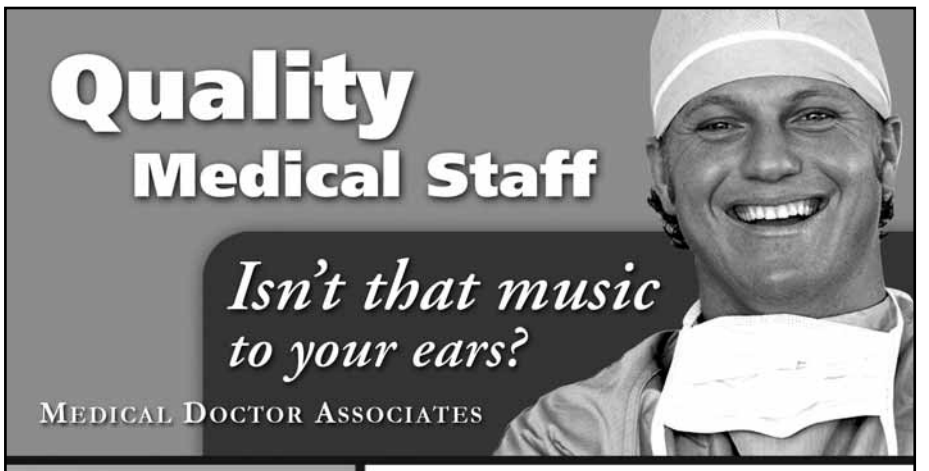
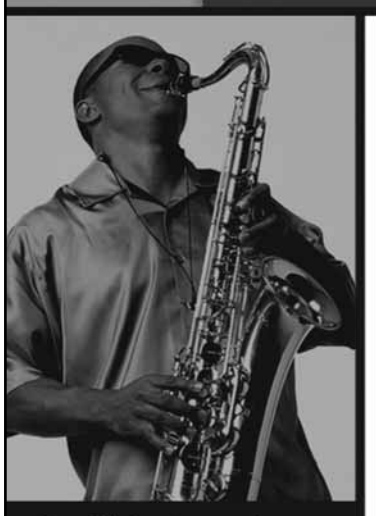
STATE OF FLORIDA





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Dartmouth Medical School
Child Psychiatry Section Chief

The Department of Psychiatry is seeking a Professor or Associate Professor of Psychiatry to lead the Child and Adolescent Psychiatry Section. The successful candidate will be a board certified child and adolescent psychiatrist who has demonstrated skills as an academic/clinical leader.

The Child Section Chief role will include conceptualizing and developing clinical services, promoting and facilitating research at all clinical sites, and supporting the teaching and training functions of the section. The Child Section Chief will recruit, mentor, and support high-quality child-focused faculty members. The Child Section Chief will work as part of Dartmouth-Hitchcock's children's hospital (ChaD) to develop a sustainable model of pediatric mental health services for the region. The ideal candidate will also either be directly engaged in research or have experience nurturing research in child psychiatry.

Please send Curriculum vitae and three letters of reference to:

William C. Torrey, M.D., Chair, Search Committee
Dartmouth-Hitchcock Medical Center
Department of Psychiatry,
One Medical Center Drive
Lebanon, NH 03756
e-mail: William.C.Torrey@Dartmouth.EDU
FAX: 603-650-9478

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ASSISTANT PROFESSOR
(or rank commensurate with exp)

INTERNATIONAL CENTER ON RESPONSES TO CATASTROPHES

DEPARTMENT OF PSYCHIATRY

The UIC Department of Psychiatry is seeking a full-time tenure or non-tenure assistant for an appointment in the International Center on Responses to Catastrophes (ICORC). ICORC's primary mission is to promote multidisciplinary research and scholarship that will contribute to improved helping efforts for those affected by catastrophes.

Applicants must have a PhD or MD, experience in international fieldwork, and in research in writing. We seek a person committed to an academic career in the field of catastrophes and global health. Person would be expected to participate in several existing projects concerning refugees, migration, and HIV/AIDS prevention, and to develop and seek funding for new research projects.

Qualified candidates should send a letter of interest and CV by March 31, 2006 to: Prof. Stevan Weine, MD, c/o Ena Casas, UIC department of Psychiatry (M/C 912), 1601 w. Taylor St., Room 554, Chicago, IL 60612. or Fax to 312-413-1228.

UIC is and AA/EOE.

POST-DOCTORAL RESEARCH FELLOWSHIP IN CHILD PSYCHIATRY
UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

A post-doctoral research fellowship position is available in our clinical research program focusing on the following areas: the longitudinal study of the characteristics, course, risk factors, psychobiology (including functional magnetic resonance imaging) and treatment of childhood/adolescent affective and anxiety disorders, autism, attention deficit, disruptive disorders and eating disorders.

Our Advanced Center for Interventions and Services Research for Early-Onset Mood and Anxiety Disorders and three program projects (in the Psychobiology of Affective & Anxiety Disorders, Behavior Genetics of Affective/Anxiety Disorders, and the Neurobiology of Autism) provide the opportunity to work and study with some of the country's leading clinical researchers. Potential mentors include:

- David Axelson, M.D. – *Bipolar Disorder*
- Boris Birmaher, M.D. – *Mood & Anxiety Disorders*
- David Brent, M.D.– *Mood & Anxiety Disorders and Suicidal Behavior*
- Oscar Bukstein, M.D., M.P.H. – *Adolescent Substance Abuse*
- Jack Cornelius, M.D., M.P.H. – *Alcohol Use Disorders and Depression*
- Bernie Devlin, Ph.D. – *Psychiatric Genetics*
- Ben Handen, Ph.D. – *Psychosocial and Pharmacological Treatment of Children with Developmental Disorders*
- Walter Kaye, M.D. – *Eating Disorders*
- David Kolko, Ph.D. – *Conduct Disorders*
- Rolf Loeber, Ph.D. – *Conduct Disorders*
- Beatriz Luna, Ph.D. – *fMRI*
- Nancy Minshew, M.D. – *Autism*
- Brooke Molina, Ph.D. – *ADHD*
- James Perel, Ph.D. – *Psychopharmacology*
- Harold Pincus, M.D. – *Health Services Research*
- Neal Ryan, M.D. – *Mood & Anxiety Disorder*

We seek individuals either with an M.D. who have completed an accredited residency program in general and/or child psychiatry or a Ph.D. in psychology (clinical /quantitative) from an APA-accredited program with a broad-based intellectual background, evident potential for academic/psychiatric research, and ability to think creatively. Must have clinical experience in psychiatric inpatient/outpatient and/or pediatric setting, familiarity with psychiatric nosology and interest in basic or applied research in developmental psychopathology. A high proportion of our graduates have received external funding.

Please submit vita and three letters of recommendation to:

David A. Brent, M.D.
Professor of Psychiatry, Pediatrics and Epidemiology
University of Pittsburgh School of Medicine
Western Psychiatric Institute and Clinic
3811 O'Hara Street, BT 313
Pittsburgh, PA 15213
Email: brentda@upmc.edu
FAX: (412) 246-5344

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Issue	Deadline (Friday, 2 p.m. E.T.)
April 7	March 24
April 21	April 7

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PHOENIX - GENERAL ADULT, FORENSIC AND ADOLESCENT PSYCHIATRISTS

Come to the beautiful and sunny southwest! Arizona State Hospital in Phoenix is recruiting for full-time board certified/qualified psychiatrists at our 338 bed JCAHO accredited hospital, including 160 beds-adult civil, 162 beds-forensic, and 16 beds-adolescent.

Phoenix offers a rich variety of cultural, sporting and recreational opportunities. The state of Arizona offers a diversity of climates and recreational opportunities all within a few hours of the sixth largest city in the U.S.

Salary is negotiable with an excellent fringe benefit package and additional compensation for Officer-of-the-Day duty. Bilingual Spanish applicants are encouraged to apply. Arizona state license required for process of application. Open until filled. Apply via e-mail to Jerry L. Dennis, MD @ dennisj@azdhs.gov.

Arizona State Hospital
2500 East Van Buren Street
Phoenix, Arizona 85008
www.azdhs.gov/azsh

The Arizona Department of Health Services is an Equal Opportunity Employer and Provides a Tobacco-Free Campus (hospital patients excepted).

Assistant Professor, Clinical Psychiatry University of Arizona (Kino)

The University of Arizona's Department of Psychiatry is offering a full-time academic appointment for an Adult Psychiatrist at the Assistant Professor level to join a progressive and growing academic department located in the beautiful southwest. 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 position, and to apply, go to http://www.uacareertrack.com and reference job #33731. If you have questions, please contact Lesley Bailey, Assistant to the Head of the Department of Psychiatry, 1501 N. Campbell Ave., P. O. Box 245002, Tucson, AZ 85724-5002, lbailey@email.arizona.edu or 520-626-8021. Review of applications is ongoing until position is filled.

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

Maricopa County Government - Correctional Health Services, Department of Psychiatry has immediate full time positions for general and forensic psychiatrist(s). Candidates must be Board Certified or eligible in Psychiatry and have current credentials to practice in the State of Arizona. We offer a competitive salary and excellent benefits package. For more complete information about the position(s) and to apply, please visit our web site at www.maricopa.gov/jobs

UNIVERSITY OF ARIZONA CAMPUS HEALTH SERVICE PSYCHIATRIST

Progressive, accredited clinic serving 35,000 grad and undergrad students looking to fill a 1.00 FTE position in our counseling section with one full time or two half time psychiatrists. Full time position covers 8-5 M-F. On-call not req'd.

Min reqs: MD/DO degree from accredited school of medicine/osteopathic medicine; completed residency in psychiatry; board cert/ eligible in psychiatry; current DEA #; will need AZ St. Bd. of Med. & Osteo Examiners license.

Benefits inc 1 mo vacation; retirement plan; health, dental & life insurance programs partial premium paid; tuition reduction for qualified family members, etc. Salary $96K-$106K

Must apply online citing job #34451 at www.uacareertrack.com

PSYCHIATRIST

West Yavapai Guidance Clinic, a non-profit organization with a 40-year history of providing quality service to the Prescott Arizona area, has openings for adult and child and adolescent psychiatrists to augment its current staff of five psychiatrists. The clinic is experiencing rapid growth and presently has 220 employees who provide inpatient and outpatient behavioral health services. We offer a competitive salary, excellent employer-paid benefits, a 401k plan, generous paid time off, 10 paid holidays, paid CME days and allowance, and a relocation and/or hire-on bonus. Positions eligible for National Health Services Corp loan and scholarship programs. Prescott, 96 miles north of Phoenix, is Arizona's quaint mile-high city bordered by the Prescott National Forest offering four seasons of mild weather with year round outdoor activities. Please contact: Human Resources, 642 Dameron Drive, Prescott, AZ 86301. Phone: 928-445-5211, Fax: 928-445-6542, e-mail: wygc.org. EOE.

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UC DAVIS SCHOOL OF MEDICINE DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

Assistant Health Sciences Clinical Professor. The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting an Assistant Health Sciences Clinical Professor for the Child Psychiatry Division. The position is in the clinician/teaching series and the faculty member will be a teaching attending in the department's child psychiatry outpatient settings and/or inpatient unit to provide clinical services to patients eligible for care through the University or through the County of Sacramento. Third year medical students and child psychiatry residents rotate through this site; consequently, experience in teaching and supervision of both groups is highly desirable. The successful candidate should be licensed in the State of California and board certified in general psychiatry and child and adolescent psychiatry, and have an interest in psychiatric education and training.

The successful candidate will be able to teach in formal settings, seminars, and case conferences, and provide group and individual supervision of clinical cases. The incumbent will provide clinical teaching for child and general psychiatry residents, psychology fellows and medical students.

For full consideration, applications must be received by June 30, 2006. Interested candidates should email a curriculum vitae and letter of interest in response to Position #3830 to Robert Hendren, D.O., Professor of Psychiatry at rlhendren@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/

PSYCHIATRIST OPPORTUNITY

Merced County Department of Mental Health offers an excellent opening for BE/BC General/Adult/Child Psychiatrists to join our multidisciplinary team offering extensive outpatient, inpatient, and crisis intervention services. Bilingual/Multicultural background are encouraged to apply. Competitive salaries from $143,496 - $174,720 plus full benefits. 5% differential for Jail sites and Board Certification. 10% differential for Inpatient. On-Call is optional offering additional earnings. Contract positions are also available.

Merced County offers the convenience of being ideally located within 1-2 hours commute to the central coast. San Francisco Bay area. Yosemite National Park, and ski resorts. Merced County is the site of the 10th UC Campus. FAX CV to Dr. Daisy Ilano at 209-725-3775 or phone 209-381-6877.

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Psychiatrist Opportunities

Are you tired of managing overhead expenses or are you finishing residency and looking for a stable opportunity to practice your clinical skills? We at the Riverside County Department of Mental Health are looking for qualified psychiatrists. The department operates an inpatient facility as well as out patient clinics in multiple locations. We serve people of all ages and are staffed by knowledgeable and supportive personnel.

Our salary is very competitive. Per-diem positions include liability insurance as well as a 401(a) pension plan. **Hours are flexible with no on-call**. Full-time employment may be offered on a case by case basis.

Riverside County is one of the fastest growing counties in coveted Southern California with numerous choices of both active and leisure lifestyles along with more affordable housing and an easy reverse commute from surrounding areas.

Interested? Please call Dr. Raja at (951) 358-4610 and send resume (CV) by email to rschulte @co.riverside.ca.us or by mail to:

County of Riverside
Attn: Ryan Schulte
4095 County Circle Drive
P.O. Box 7549
Riverside, CA 92513-7549

For additional information you may visit our website at www.rc-hr.com.

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Atascadero State Hospital now pays board certified psychiatrists $159,000, plus a generous year-end retention bonus. Atascadero is the nation's premier center for the treatment of forensically committed mentally ill patients. Our hospital is a teaching site affiliated with the University of California, accredited by JCAHO, and recipient of the prestigious Codman Award. All of our psychiatrists are board eligible and most are board certified. Many of our psychiatrists have forensic subspecialty boards.
We are located midway between San Francisco and Los Angeles on the scenic central California Coast, south of Big Sur. We offer a spectacularly beautiful environment in San Luis Obispo County with temperate climate, beaches, world class wineries, cultural activities, golfing, sailing, riding, clean air, and excellent schools through the University level.
Our benefit package is valued at an additional 30%, which includes retirement plans (including safety retirement), health plans, professional liability coverage, paid holidays, educational leave, and generous annual leave. On-call duty is compensated hour for hour over and above the base salary. Applicants must hold a current California license, or have pending application with the Medical Board of California.
For a prompt and confidential review, send CV to Jeanne Garcia, M.D., P. O. Box 7001, Atascadero, CA 93423-7001; (805) 468-2005 or fax (805) 468-2138; or e-mail us at jgarcia@dmhash.state.ca.us. We are an equal opportunity employer.

COALINGA STATE HOSPITAL

Get in on the ground floor!

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

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

This is an opportunity for a psychiatrist interested in being on the forefront to explore the sexually violent predator and forensic fields within a leading national organization. Not only is Coalinga State Hospital's salary package competitive, we offer job security, flexible work schedules, and an excellent California State benefit package, including paid leave, medical insurance, and CalPERS Retirement.

Staff Psychiatrist (Safety)* $162,792 - $172,572
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If you are interest in discussing any of our psychiatric positions, please contact: Stephen Wyman, M.D., at (559) 935-4079, or Erica Weinstein, M.D., at (559) 935-4343, or E-mail SWyman@csh.dmh.ca.gov or EWeinstein@csh.dmh.ca.gov. For more information, visit our website at www.dmh.ca.gov/Statehospitals/Coalinga. CSH is an equal opportunity employer.

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Or call 805-568-2800

COLORADO

Colorado State Hospital needs two psychiatrists by July 1, 2006; one with forensic interest and one with civil interest. Forty-hour week and half time proposals considered. University of Colorado medical appointments with good benefits. Four-day workweek option. If interested, please call Jerra Harr, Recruitment Coordinator @ (719) 546-4637 or fax CV to (719) 546-4484.

CONNECTICUT

GENERAL PSYCHIATRY—
CENTRAL CONNECTICUT

Opportunity for BC/BE psychiatrist to join well established two-person successful adult psychiatric private practice. Practice is affiliated with Bristol Hospital, a leading community hospital offering a comprehensive mental health continuum, including both inpatient and outpatient settings. Our central Connecticut location offers a wide range of upscale suburban living options, including first-rate schools, many desirable cultural activities, and easy accessibility to NY and Boston. We offer a benefits package and salary. To learn more about this opportunity, call toll-free, Christine Bourbeau in the recruitment office at 800-892-3846 or fax your CV to 860-585-3086. EOE. Email address: **cbourbeau@brishosp.chime.org**

SOUTHEAST CT: Child Psychiatrist - Directorship position - new adolescent residential treatment program. Program development & clinical care responsibilities. Competitive salary & benefits. Contact Joy Lankswert @ **866-227-5415** or email **joy.lankswert@uhsinc.com**

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

Capitol Suburb. Facility seeks leaders to be Medical Director of Mental Health & addiction programs on their inpatient and outpatient units. 170-180K + bene. Academic appt available. Call Susan Springer @ 800.575.2880 x 315 **sspringer@medsourceconsultants.com.**

University of Connecticut
Health Center

CORRECTIONAL MANAGED HEALTH CARE

Seeking board certified and board eligible psychiatrists to provide care to patients in the Connecticut Department of Correction. Opportunities include patient care, research, teaching, and leadership in both an academic and public health care setting. Opportunities exist throughout the state. Exciting employment, excellent state benefits, regular working hours, and competitive salaries. Please contact Noreen Logan, Human Resources, for information and an application at (860) 679-7691 or e-mail at logan@uchc.edu.

AA/EEO M/F/PWD/V

PSYCHIATRIST:

The University of Connecticut at Storrs, Counseling and Mental Health Service is seeking a licensed/Board certified psychiatrist for a part-time, twelve-month position, as part of a multidisciplinary team. Experience with diverse college age population, crisis intervention, on call duties and psychopharmacologic/evaluation services required. This is an UCPEA, UCP XII position. Excellent benefits. Salary commensurate with experience. Send cover letter, vitae and the names of 3 references to: Ellen Seader, LCSW, Director, Counseling & Mental Health Service, University of Connecticut, Unit 2011, Storrs, CT 06269-2011. We encourage applications from under-represented groups, including minorities, women and people with disabilities (Search #06S13)

Inpatient Staff Psychiatrist

Hall-Brooke Behavioral Health Services
Westport, CT

Hall-Brooke Behavioral Health Services is recruiting a full-time adult psychiatrist to join an expanding inpatient service at our Westport, CT campus. Our beautiful 76-bed hospital has general adult, addiction, child/adolescent, and women's services. As a member of St. Vincent's Health Services in Bridgeport, CT, our affiliation with the Columbia University Department of Psychiatry in New York offers opportunities for career development. Responsibilities include daily (Monday-Friday) management of acute inpatients, with minimal weekend and on-call requirements. Job responsibilities may be tailored to suit specific skill areas or interests.

For confidential consideration, please submit CV and cover letter, including salary requirements to: George Catalano, Director of Human Resources, Hall-Brooke Behavioral Health Services, 47 Long Lots Road, Westport, CT 06880, Phone: (203) 221-8812, Fax: (203) 341-9461, email: **HallBrookeHR@svhs-ct.org**. EOE

PSYCHIATRIST AND APRN: Full time (40hrs/wk) for progressive community mental health center with on site partial hospital. Exquisite area along the Thames River. Provide medication management for dually diagnosed in a multidisciplinary team environment. Excellent salary and benefits, 40/hour workweek M-F, flextime, no call, weekends or holidays, Bi-lingual helpful. Faculty appointment at UCONN or Yale possible for qualified, interested candidates. CT license necessary. Send resume in confidence to Kathleen Degen, M.D., Medical Director, Sound Community Services, Inc., 165 State St.-Ste. 200, New London, CT 06320. Tel: (860) 443-0036. Fax: (860) 443-4284. Email: kathleen.degen@SCSCT.org. EOE

DELAWARE

NEWARK/WILMINGTON: Child Psychiatrist. Fulltime position for partial hospital & inpatient services. Active, supportive multidisciplinary setting. Limited call. Salary & benefits. **Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com**

Deadlines:
April 7 issue - March 24
April 21 issue - April 7

DISTRICT OF COLUMBIA

The Department of Psychiatry and Behavioral Sciences at the George Washington University Medical Faculty Associates, an independent non-profit clinical practice affiliated with The George Washington University, is seeking a psychiatrist for a full-time academic appointment at the rank of instructor or assistant professor beginning July 2006. This clinician-educator position in the adult outpatient division requires expertise in the evaluation and treatment of mood and anxiety disorders. The applicant must be license eligible in the District of Columbia and be Board Certified or Board Eligible in General Psychiatry. Academic rank and salary will be commensurate with qualifications. Review of applications will begin March 17, 2006 and continue until the position is filled. Please send letter of interest and CV to Jeffrey S. Akman, MD, Chair, Department of Psychiatry and Behavioral Sciences, 2150 Pennsylvania Avenue, NW, Washington, DC 20037. Tel. 202-741-2880; fax 202-741-2891. The George Washington Medical Faculty Associates is an Equal Opportunity/Affirmative Action Employer.

FLORIDA

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.

Located along South Florida's east coast just minutes from the Atlantic Ocean, CARF accredited community mental health center is seeking a part-time/full-time inpatient and outpatient psychiatrists to provide comprehensive psychiatric care to children and adults. Must be Board Certified (or eligible). Excellent salary and benefits package, great staff and a lovely coastal community. Seeking applications directly from candidates. (No recruitment firms please!) Send/Fax CV: HR, New Horizons, 4500 W. Midway Rd., Ft. Pierce, FL 34981 FAX (772) 468-5606 EOE/ADA/DFWP www.nhtcinc.org

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PSYCHIATRIST NEEDED to work side by side with other correctional health care professionals in North & Central **Florida** prisons. Great schedules and excellent State of Florida benefits. Must have Florida license prior to hire. For further information contact: Sharon McKinnie, R.N. @ 850-922-6645 or mckinnie.sharon @mail.dc.state.fl.us

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PANAMA CITY - Adult board certified or board eligible psychiatrist to join staff of comprehensive community mental health center. Salary range is: $176,000 - $183,000. Beautiful area of the country. Apply through our website www.lifemanagementcenter.org or send CV to: **Peter Hampton, Ph.D., Executive Director, Life Management Center of Northwest Florida, 525 E. 15th St., Panama City FL 32405**, EOE/DFWP. Pre-hire drug screen required.

Selling satellite office in wonderful Ft. Lauderdale area. Ripe for expansion - one half managed care. Good terms. I'm too busy running my other offices. Serious inquiries only. Leave contact phone number at 954-583-2629.

GEORGIA

ATLANTA: General or Addiction Psychiatrist. Intensive outpatient program - multidisciplinary setting. Ideal candidate is BC with special interest & proven skills in treating patients with substance abuse and psychiatric disorders. **Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com**

ILLINOIS

CHICAGO SUBURBS! Numerous positions available at integrated hospital system! Opportunities include: 1) Child and Adolescent Psychiatrist 2) Addictions psychiatrist 3) Eating disorder psychiatrist 4) Neuro-Psychiatrist. All opportunities are **extremely lucrative** with a competitive base salary, full benefits, & **bonus incentives!** For more info, call Carrley Ward @ 800-735-8261 ext 219, fax your CV to 703-995-0647, or e-mail: cward@medsourceconsultants .com

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Suburbs of St. Louis! Opportunity for a staff psychiatrist! 37 ½ hour workweek and **NO CALL!** No managed care environment! Competitive compensation package and outstanding benefits package offered! For more info, call Sarah McGlinnen @ 800.735.8261 ext 216, fax your CV to 703.995.0647 or e-mail: smcglinnen @medsourceconsultants.com.

PSYCHIATRIST NEEDED!

A well established and very busy private practice, located in the Chicago area is looking to hire a full time or part time psychiatrist. Work includes hospitals, outpatients and nursing homes. Compensation package is very attractive and negotiable. For more information please call Kathy at our office between 8am and 4pm 1-312-565-2251.

Chicago - Outpatient Child and Adolescent Psychiatrist. The Feinberg School of Medicine, Northwestern University and the Children's Memorial Hospital are seeking a child psychiatrist for primarily outpatient and consultation services. Join an exciting, growing, multidisciplinary child and adolescent psychiatry division at Children's Memorial Hospital! Full-time faculty position at the instructor or assistant professor level. Rank and salary commensurate with qualifications and experience. Clinical experience (especially pediatric hospital-based), ABPN certification or eligibility in child and adolescent psychiatry, experience and excellence in teaching and an interest in clinical research required. Training in Pediatrics is a plus. Start-up support available for research pilot funding. Northwestern University and the Children's Memorial Medical Group are Equal Opportunity Employers. Women and minorities are encouraged to apply. Hiring is contingent upon eligibility to work in the United States and eligibility for licensure in Illinois. Start date July 2006. Applications will be evaluated as received. Send CV with letter describing clinical and academic interests to Mina Dulcan, MD, Department of Psychiatry, Box #10, Children's Memorial Hospital, 2300 Children's Plaza, Chicago, IL 60614. Fax: 773/880-4066. E-mail: m-dulcan@northwestern.edu.

IOWA

Dynamic, highly regarded private non-profit multidisciplinary mental health clinic less than one hour from Des Moines seeks psychiatrist or ARNP with RX priveleges interested in working with clients of all ages. Position primarily involves outpatient medication management, but C/L work at local hospital possible as well as many other interesting opportunities. Would be affiliated with a variety of highly competent clinicians. Well supported by local medical community. Minimal on-call responsibilities (telephone back-up). Limited academic affiliation possible. Very flexible position that could be tailored to individual's needs. Very attractive benefit package. J-1 and loan repayment programs available. Send CV to Diane Baker at Center Associates, 9 North 4th Ave., Marshalltown, IA, 50158. Fax: 641-753-2171. dbaker@centerassoc.com

LOUISIANA

IMMEDIATE OPENING FOR PSYCHIATRISTS -
J-1 Visa holders qualify - Attractive salary w/benefits. Other candidates - Guaranteed net income or attractive salary w/benefits. Board Certified or board eligible. Louisiana license required.

Please respond to Box P-469, Psychiatric News Classifieds, American Psychiatric Publishing, Inc., 1000 Wilson Blvd., Suite 1825, Arlington, VA 22209

MAINE

Sweetser
YOUR PARTNER IN BEHAVIORAL HEALTH

Are you looking for a life of harmony? One that achieves a true balance?
At Sweetser it is a reality!

As a Child & Adolescent Psychiatrist for Maine's largest non-profit child welfare / mental health facility you can achieve true balance. This outpatient position will allow you to work with an amazing team developing, implementing, and overseeing a treatment plan for each of your clients that will encompass a wide range of services. All the while keeping you closely connected to each client. Sweetser's highly skilled staff of Crisis clinicians eliminates the need for inpatient work, providing you with more of that personal and/or family time we all yearn for.

The state of Maine also offers a great balance! Here you will find beautiful change of seasons, each presenting new and exciting recreational activities. Cultural activities are also abound from amazing art galleries to renowned theater groups. Maine has bustling cities full of shopping and nightlife, as well as an incredible countryside with farmers markets and talented craftsmen.

Sweetser is as dedicated to its employees and their families as they are to their clients. For the security of you and your family, Sweetser offers a competitive salary and a wide range of benefits, inclusive of generous retirement programs.

If you are a licensed Child & Adolescent Psychiatrist with the appropriate board certifications and want to achieve "True Balance", check out our website at www.sweetser.org or submit letter and C.V. to Sweetser Human Resources, 50 Moody St., Saco, ME 04072, Fax (207) 294-4420, or jobs@sweetser.org (text files only). Please state referral source.

Maine's First Magnet Hospital and the World's First Free-Standing Psychiatric Magnet Hospital Seeking Adult and Child/Adolescent Psychiatrists

We are seeking BC/BE psychiatrists for both our adult and child/adolescent inpatient and outpatient programs. Acadia Hospital is a thriving, non-profit, private community-based hospital offering acute psychiatric care for adults and children, as well as chemical dependency programs. One of the only two private psychiatric hospitals in Maine. The Acadia Hospital offers physicians clinical practice in a highly collaborative, multi-disciplinary setting. Competitive salary and benefit package. Send resume to: Vice President of Medical Affairs, The Acadia Hospital, P.O. Box 422, Bangor ME 04402-0422. **www.acadiahospital.org**

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.

Your resource for life.
MaineGeneral Health

Augusta & Waterville, ME

The MaineGeneral Medical Center is recruiting for **two adult psychiatrists** in Augusta. One psychiatrist will serve as Medical Director for the intensive outpatient service and provide outpatient services. The other will serve as a hospital-based psychiatrist working with two other psychiatrists to cover an 18 bed inpatient service and provide consultation to primary care and specialty clinicians. These two psychiatrists will join three other psychiatrists and a psychologist on the Augusta campus, and five psychiatrists and one psychologist on the Waterville campus. We emphasize team work to provide quality care to our patients and psychiatric support for a comprehensive behavioral health system.

We offer a competitive salary with a full benefits package, including paid leave, time off for CME and an educational allowance. On-call is approximately one in six at each campus.

Our mission in behavioral health: *"We help people build healthy relationships and satisfying lives."*

Contact:

David G. Folks, M.D.
Chief of Psychiatry and Medical Director
MaineGeneral Medical Center
6 East Chestnut Street
Augusta, ME 04330
Phone: 207-626-1278
Email: david.folks@mainegeneral.org

MARYLAND

Psychiatrist

Springfield Hospital Center - a 405 bed psychiatric in patient facility, operated by The Maryland State Mental Hygiene Administration seeks Maryland licensed Psychiatrists. Our rural 400 acre campus is located 22 miles west of Baltimore and convenient to Washington, DC. via routes 70 & 29. We offer full time and part time positions with comprehensive benefits, which include 27 days of paid leave, medical coverage and access to Maryland State Employees Pension at retirement. Additionally, Contractual day/night positions available. Both Board & Non-Board Certified physicians will be considered. Salary for these positions is negotiable. Please send CV to: Jonathan Book, M.D., Clinical Dir, SHC, 6655 Sykesville Rd. Sykesville, Maryland 21784. For questions call 410-970-7006 or email Jbook@dhmh.state.md.us. EOE

Psychiatrist

Pathways, Inc., the longest operating multi-service mental health agency in St. Mary's County, located on Maryland's western shore of the Chesapeake Bay, is seeking a licensed, board certified/board eligible Psychiatrist for the position of Medical Director.

St. Mary's County has been designated as an underserved area for mental health professionals so applicants with foreign visas are welcome. Assistance with moving expenses and student loan payments consistent with the underserved area designation for this county are possible. Additional benefits include a competitive wage, medical, dental, disability, and malpractice insurance, paid leave and no on-call requirement.

This position will require a minimum effort of twenty-eight (28) hours per week and a targeted start date of July 2006. Salary and other terms are negotiable. If interested please submit your C.V. and letter of interest to: Jack Dent, Administrative Officer, Pathways, Inc., P.O. Box 129, Hollywood, MD 20636, 301-373-3065 ext. 208, Fax 301-373-3265, e-mail: jdent@pathwaysinc.org

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MPB Group, Inc.-OMHC in Columbia, MD seeks **MD licensed Child/Adolescent Psychiatrists** for contractual day/evening to help meet our rising needs. Send CV to: Dr. Brewer, CEO, via fax to 301-829-7714 or email maggy@mpbhealth.com. Questions? 410-562-7677 www.mpbhealth.com

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PSYCHIATRIST. Full-Time Medical Director Position for minority owned practice in Baltimore, MD. Excellent salary & benefits package. Ownership potential in fabulous psychiatric practice. Contact John Fisher at 410.779.3102 or fax 410.230.2687.

PSYCHIATRIST PT for fast-paced growing Geriatric Behavioral Health Practice to provide consultation services in LTC setting in Maryland. Background in medical/neurological basis for psychiatric symptoms desirable. Fax cover letter and resume to CGS, 410-832-5783, Attn.: Dr. Fitting.

Clifton T. Perkins Hospital Center, a JCAHO-accredited institution and Maryland's only maximum security forensic hospital, is seeking candidates for the position of staff psychiatrist. Candidates with forensic interest or experience would be especially well-suited. Responsibilities include the provision of high quality psychiatric care on an inpatient unit in a state-of-the-art forensic facility. Additional opportunities include evaluations of dangerousness, competency to stand trial, and criminal responsibility.

Join a vibrant medical staff with expertise in care of the seriously mentally ill within a forensic setting. Faculty appointments are available at University of Maryland and Johns Hopkins, if eligible. The hospital is centrally located 20 minutes from Baltimore, 35 minutes from DC, and 20 minutes from Annapolis. Competitive salary with excellent benefits, flexible working hours, and the opportunity for paid overnight call.

Interested candidates should contact C. Dennis Barton, Jr., MD, MBA, at 410-724-3078 or P.O. Box 1000, 8450 Dorsey Run Road, Jessup, MD 20794 (BartonD@dhmh.state.md.us.)

MASSACHUSETTS

Part/Full Time Psychiatrist
Tri-City Mental Health Center, one of the area's largest providers of community mental health services minutes north of Boston, is looking for PT/FT psychiatrists to provide Outpatient services with flexible hours. No evening or weekend calls. Multiple positions are available immediately to BC/BE Psychiatrists with special interests in Gen. Adult Psych., positions also working with Geriatric, Subst. Abuse and Chronic Mentally Ill Services. We work in a supportive multi-disciplinary structure with an excellent team of Clinicians and support staff. Visit our web site tcmhc.org. Contact Medical Director rgreiger@tcmhc.org, or Fax 617 387-1089

CAMBRIDGE: Psychiatry Positions

Positions available at Cambridge Health Alliance Department of Psychiatry, Harvard Medical School. Full and part time opportunities in adult services. 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. Inpatient, geriatric psychiatry, and consultation-liaison service positions are available. Academic appointment, as determined by the criteria of Harvard Medical School, is anticipated.

Qualifications: BE/BC, 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. Interest and experience with dual diagnosis and/or substance use disorders preferred. 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).

CORRECTIONAL & FORENSIC PSYCHIATRY

The University of Massachusetts Medical School seeks psychiatrists for its innovative and multidisciplinary correctional mental health program, which provides services at several locations throughout the state. We offer generous, newly enhanced salaries, excellent benefits, regular hours without call responsibilities, and a faculty appointment with the University of Massachusetts Medical School. Send letter of interest and curriculum vitae to: Kenneth Appelbaum, MD, University of Massachusetts Medical School, Health & Criminal Justice Programs, 1 Research Drive, Suite 120C, Westborough, MA 01581; Kenneth.Appelbaum@umassmed.edu; Phone: 508-475-3236; Fax: 508-475-3258. UMMS is an equal opportunity employer.

CENTRAL MASSACHUSETTS - UMass Memorial Medical Center, Department of Psychiatry is seeking a psychiatrist for our affiliated hospital Health Alliance, in Fitchburg, Massachusetts. The position involves primarily inpatient and partial hospital responsibilities. Academic opportunities and faculty rank commensurate with experience and interests. Candidates must be BE/BC in Psychiatry. Applicants should send letter of interest and CV to Alan Brown, MD, Vice Chairman for Clinical Services, Department of Psychiatry, UMass Memorial, 55 Lake Avenue North, Worcester, MA 01655 or e-mail BrownA01@ummhc.org AA/EOE

WORCESTER - Director of Outpatient Psychiatry Service
Excellent opportunity for outstanding clinical psychiatrist at large multidisciplinary university hospital clinic. Position involves supervisory, teaching and direct care responsibilities, with opportunities for research. Faculty rank commensurate with experience. Applicants should send letter of interest and CV to Alan Brown, MD, Vice Chairman for Clinical Services, Department of Psychiatry, UMass Memorial, 55 Lake Avenue North, Worcester, MA 01655 or e-mail BrownA01@ummhc.org AA/EOE

BOSTON areas
BROOKLINE - General Psychiatrist - new 20 bed adult intermediate services unit.
JAMAICA PLAIN - Child Psychiatrist for program serving a predominant Latino patient population. **General or Child Psychiatrist** - inpatient & partial services. Work with adult & some adolescents.
LOWELL - Child Psychiatrist for Inpatient & Partial program - multidisciplinary acute services setting.
Positions offer very competitive salary/benefits package. **NO CALL. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com**

CENTRAL MASSACHUSETTS - UMass Memorial Medical Center, Department of Psychiatry seeks a Psychiatrist for our Geriatric Psychiatry Inpatient Unit at Clinton Hospital. Clinical care on a 20-bed unit that serves as an important referral site for the region. Psychiatry and Family Practice resident, medical student teaching occurs on-site. Opportunities for collaboration and teaching at Worcester Campus. Competitive compensation with complete benefit package. Faculty rank commensurate with experience. Candidates should be BC/BE in general psychiatry. Added qualifications in Geriatric Psychiatry and/or previous experience working with geriatric patients is preferred. Applicants should send letter of interest and CV to Tatyana Shteinlukht, MD, Medical Director, Geri/Psych Unit, Clinton Hospital, 201 Highland Street, Clinton, MA 01510 or e-mail Shteinlt@ummhc.org AA/EOE

Child and/or Adult Psychiatrist to join busy, large, established private psychiatric group practice. Work consists of outpatient psychiatric treatment, both psychotherapy and psychopharmacology, and some hospital consultations. A lot of flexibility in terms of job and schedule. Please send C.V. to Paul Menitoff, M.D., Greater Lowell Psychiatric Associates, LLC 9 Acton Road Suite 25 Chelmsford, MA 01824.

CONSULTATION-LIAISON PSYCHIATRIST

Mount Auburn Hospital, affiliated with Harvard Medical School, is seeking a full-time consultation-liaison psychiatrist. This clinical position involves working closely with our medical and surgical services, including residents in our internal medicine residency program. Academic appointment, salary package. Please send CV to: Joseph D'Afflitti, M.D., Chair, Department of Psychiatry, 330 Mount Auburn Street, Cambridge, MA 02138; tel: 617 499-5008; email: jdafflit@mah.harvard.edu.

Staff Psychiatrist
For Work In Public Sector Community Mental Health Centers

North Suffolk Mental Health Association is a dedicated provider of comprehensive, community-based services to individuals confronting mental health and other daily challenges. We currently have a Staff Psychiatrist position, benefit eligible, available immediately. Job entails performance of Psychopharmacologic Evaluations and ongoing medication management. Psychiatrist will participate in multi-disciplinary treatment teams at full-service, public sector Outpatient clinics located throughout the Greater Boston, MA area. Additional duties include leadership role at multidisciplinary staff meetings, consultation to the Substance Abuse Team, and supervision of a PGYIII Resident on Community Rotation. Pay commensurate with credentials and experience. MGH/Harvard appointment possible with appropriate credentials. NSMHA offers a comprehensive benefits package including competitive salaries, medical / dental insurance and generous paid time off. Interested candidates should send cover letter and C.V. to **North Suffolk Mental Health Association, Attn: Recruiter, 301 Broadway, Chelsea, MA 02150; Fax: 617-889-4635; E-mail: gethired@northsuffolk.org EOE**

Commonwealth of Massachusetts
Department of Mental Health
Metro Boston Area

Part-Time Public Sector
Inpatient Psychiatrist
Unique opportunity at Lemuel Shattuck Hospital Metro Boston Mental Health Units for a 1/2 time inpatient psychiatrist. MBMHU provides continuing care to DMH patients within a Boston JCAHO certified urban public health teaching general hospital. Join an expert group of colleagues in Boston. Teaching and mentoring opportunities and academic appointment at Tufts or Harvard potentially available. No weekend or night call. No managed care. Contact Amy Lisser, MD at amy.lisser@dmh.state.ma.us or 617-971-3177.

The Massachusetts Department of Mental Health is an AA/EEO employer.

Southbridge Harrington Memorial Hospital seeking a part-time psychiatrist for the G.B. Wells Center, its large friendly community mental health center serving south Worcester County from Brimfield to Sturbridge to Oxford. Competitive salary. Separate on call position available. HMH is not subsidiary of UMass. Call/write Zamir Nestelbaum, M.D., G.B. Wells Center, 29 Pine Street, Southbridge, MA 01550 (508) 765-9167

MISSOURI

Provide psychiatric services to long-term inpatients. No acute unit, no ER. Modern facility with electronic medical record, dictated progress notes. Salary range up to $165,000 depending on experience. Moving expenses, student loan repayment available. Benefits and malpractice coverage provided by employer. Small city community, one hour from Kansas City, half hour from major airport. Medical school affiliation. Pharmacy residency program on site. Training site for Certified Forensic Examiners.

James B. Reynolds, M.D.
Medical Director
(816)387-2501

MONTANA

ST. PATRICK HOSPITAL & HEALTH SCIENCES CENTER

PSYCHIATRIC HOSPITALIST

MISSOULA, MONTANA

St. Patrick Hospital, located in Missoula, Montana, is home to the International Heart Institute of Montana and the Montana Neuroscience Institute Foundation. We are a 213-bed, acute care, JCAHO accredited, Sister's of Providence, regional referral center for W. Montana and N. Idaho. Missoula is home to the University of Montana and offers an abundance of beauty & recreational opportunities. Close to Glacier and Yellowstone National Parks, you can live and recreate in beautiful country and work for a stable and well-respected hospital. We currently have a full-time Psychiatric Hospitalist opportunity for our co-occurring 26-bed inpatient unit. The co-occurring unit consists of 60-70% psychiatric patients and 30-40% addiction patients including acute detoxification. Position will also include call.

****We offer a competitive wage & benefit package.**

For a Big Sky Welcome!!
Contact: Jan Van Fossen
Vanfoss@saintpatrick.org
Human Resources Department
St. Patrick Hospital
P.O. Box 4587
Missoula, MT 59806
1-800-325-7271 ext#5627
Job line: 406-329-5885
Fax: 406-329-5856
www.saintpatrick.org

BIG OPPORTUNITY UNDER THE BIG SKY

BE/BC PSYCHIATRIST, MONTANA - You've earned it. Things are different here. The Great Falls Clinic seeks a BE/BC Psychiatrist to join the Neurosciences Department of a rapidly expanding 125-physician multi-specialty group. Successful candidates will have strong skills in both adult and geriatric psychiatry as well as a medical management approach to patient care.

Great Falls is a warm and safe community perfect for a physician interested in making a home for themselves and/or their family. Access to world-class recreational venues, outdoor activities, scenic vistas and regional culture are right outside your practice door. This opportunity does not qualify as a J-1 waiver site. For more information about this wonderful opportunity, contact Kate Bogue, Physician Recruitment Coordinator at (406) 771-3332 or kate.bogue@gfclinic.com. You may also visit our website at www.gfclinic.com

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Enjoy an extraordinary outdoor lifestyle in a beautiful western Montana university town. Several opportunities currently available for motivated psychiatrists. *Outpatient practice* opportunities with an established, well-managed neurobehavioral group for a psychiatrist with an interest in general adult psychiatry; subspecialty interest(s) a plus. Group includes four psychiatrists, two clinical psychologists, two neuropsychologists and two neurologists. Busy practice, with both inpatient and outpatient opportunities is very quickly anticipated from both internal and regional referrals. Remuneration is production-based with start-up financing assistance available. *Psychiatric hospitalist* opportunity in association with a 213 bed, acute care, JCAHO, regional referral center. Patient population includes inpatient mental health and addiction treatment. Missoula, Montana offers an extraordinary lifestyle and is the home of the University of Montana and the Montana Neuroscience Institute Foundation. Research opportunities exist in collaboration with the Neuroscience Institute, including PET and fMRI capabilities. View the Northern Rockies from your office window, fly fish the Clark's Fork River 6 blocks away during lunch, or ski 20 minutes from the office during winter. For more information direct CV and inquiries to: Psychiatry, PO Box 8169, Missoula MT 59807, e-mail to AmyS@mtneuro.com or call Amy Shoales, Practice Mgr at (406) 327-3371. Visit our web site at montanaminds.com.

NEVADA

The University of Nevada School of Medicine, Department of Family Medicine, is seeking candidates for a full-time, administrative faculty position as a clinical physician at the Mojave Adult, Child and Family Services (MACFS) clinics in Reno. Duties include: Clinical service in outpatient community psychiatry; evaluation and treatment of patients at MACFS outpatient clinics in collaboration with Medical Director in utilization review/quality assurance. For complete position description and requirements, contact: Search Chair/Coordinator, (Jim Parcells, C.O.O./Pam Soucy, HR Director, 702-968-5071) or view at http://jobs.unr.edu/professional. For full consideration, please apply by April 15, 2006.

The University of Nevada School of Medicine, Department of Family Medicine, is seeking candidates for a full-time, administrative faculty position as a clinical physician at the Mojave Adult, Child and Family Services (MACFS) clinics in Las Vegas. Duties include: Clinical service in outpatient community psychiatry; evaluation and treatment of patients at MACFS outpatient clinics in collaboration with Medical Director in utilization review/quality assurance. For complete position description and requirements, contact: Search Chair/Coordinator, (Jim Parcells, C.O.O./Pam Soucy, HR Director 702-968-5071) or view at http://jobs.unr.edu /professional. For full consideration, please apply by April 15, 2006.

Southern Nevada Adult Mental Health Services (SNAMHS); Las Vegas, NV JCAHO accredited; Active Resident training; System expanding; Hiring BE/BC psychiatrists October 2005; hospital and outpatient. New Acute Hospital opens May 2006. Limited call responsibilities; Relocation assistance; Salary up to $163,000; Good Benefit and Retirement packages. No State income tax.
Contact David A. Rosin, MD; 6161, W. Charleston Blvd, Las Vegas, NV, 89146 mddirect @snamhs.nv.gov or psmith@snamhs.nv.gov; Phone 702-486-6050

Northern Nevada Adult Mental Health Services; JCAHO accredited State Facility; Hiring BE/BC psychiatrists FY 2006; hospital and outpatient positions. Active Resident training; Possible University Medical School Affiliation; Relocation assistance; Salary up to $166,000; Excellent Benefit and Retirement packages. No State income tax

Contact:
Dr. Harold Cook PhD, Agency Administrator
775-688-2015
Dr. Ira Pauly MD
775-688-2015
NNAMHS
480 Galletti Way
Sparks, Nevada 89431-5578
775-688-2011
775-688-2052 (fax)

NEW JERSEY

Wish to purchase fee for service practices in the Morristown, Overlook and St. Barnabas Hospital service areas. Contact Alpha Behavioral Care at (908) 273-0800.

If you are a child or adult board certified psychiatrist looking to grow in a private practice that is not dependent on managed care, call us at 908.273.0800 and fax CV to 908.273.0815. We have a growing private practice in Summit, NJ, an affluent suburban community.

New Jersey Psychiatrists - Rapidly expanding behavioral health organization has immediate positions available in Newark and Cranford locations. Seeking adult and child Psychiatrists for partial hospitalization and outpatient services. Spanish speaking a plus. Full and part-time positions available. Excellent employment package including competitive salary, benefits and malpractice insurance. Fax CV to (732) 212-0061 or e-mail hr@ppenet.com.

Psychiatrist - well established, for profit outpatient mental health practice has immediate opening for experienced adult, adolescent and/or child psychiatrist. Fee for service cliental, private practice model within comprehensive multidisciplinary group of highly qualified clinicians. Fax CV to (856) 985-8148 or call (856) 983-3866 ext. 3018.

GREAT OPPORTUNITY
CHILD & ADOLESCENT PSYCHIATRIST

Exciting opportunity for a BC/BE child & adolescent psychiatrist to join a thriving private outpatient Child Therapy Center in an upscale suburban area of Northwestern New Jersey, just one hour from NYC. Position is part time, with opportunity for growth, if desired. Position involves providing clinical evaluations and treatment in a supportive, colleaguial atmosphere. Exciting growth. Excellent compensation. Fax CV to (973)898-9305 or e-mail to gllach@optonline.net.

Fantastic opportunity in Northern New Jersey over looking the Manhattan skyline. The position is 100% OUTPATIENT with a reasonable 1 in 4 call. The patient ratio is a mix 70% adult and 30% child/adolescent. Bi-lingual Spanish is preferred. Contact Matt Brewster @ 800 575-2880 x 311

NEW MEXICO

Presbyterian Medical Services is a non-profit integrated healthcare network with JCHO accreditation providing medical, dental, behavioral health, children's services and supportive living services to the multi-cultural people of New Mexico. We are seeking a **Psychiatrist** who will see clients of all ages to work in our Farmington clinic. Excellent benefits. Sign-on bonus offered. For more information contact Diane Kramer at (800) 477-7633; fax (505) 954-4414; diane_kramer@pmsnet.org; P.O. Box 2267, Santa Fe, NM 87504. EOE.

NEW YORK CITY & AREA

On-Call Psychiatrist
St. Vincent's Hospital Westchester has per diem positions available for BC/BE psychiatrists in our evaluation and admitting service. Choice of day, evening, or nighttime hours. NYS license required. Competitive hourly rate, excellent work environment. Fax CV to: Dean Harlam, M.D., at (914) 925-5158, or phone (914) 925-5310, St. Vincent's Hospital Westchester, 275 North Street, Harrison, New York 10528. EOE.

PSYCHIATRIST
Outpatient

The highly regarded Pederson-Krag Center offers a F/T position in our Smithtown and Wyandanch Mental Health Clinics. Flexible schedule; competitive salary. Excellent benefits. Send CV to: **Roger Kallhovd, M.D., Pederson-Krag Center, 55 Horizon Drive, Huntington, N.Y. 11743**
Or fax to 631-920-8165. EOE/AA

PSYCHIATRISTS

Lutheran HealthCare, a sweeping system of inpatient and ambulatory services across Southwest Brooklyn, is seeking NYS licensed psychiatrists for a variety of positions in its expanding Department of Psychiatry.

Ambulatory Care Psychiatrists-Full-time openings are tailored for psychiatrists with expertise in psychopharmacology, but also multidisciplinary team participation, staff supervision and teaching. General adult and child/adolescent positions available, including special interest areas in HIV behavioral health, treatment of child/family victims of trauma, and substance abuse treatment. Bilingual Spanish, Chinese, or Arabic strongly desirable. Psychiatrists will offer treatment in facilities that have a Federal Mental Health HPSA (Health Profession Shortage Area) designation for loan repayment purposes.

Moonlighting Psychiatrists-Opportunities available on inpatient ED/CL/Detox services for a variety of shifts 24/7.

We are conveniently located for travel from all of NYC Boro's. For consideration, please email: ghartman@lmcmc.com, fax (718) 630-8594, or send your CV to: Grace Hartman, Department of Psychiatry, Lutheran Medical Center, Suite 2-45, 150 55th Street, Brooklyn, NY, 11220. EOE/AA/M/F/D/V

LUTHERAN HEALTHCARE

Affluent NYC Suburbs! Hospital looking to fill numerous inpatient positions. **Prestigious tertiary care facility** has opportunities for **teaching and research**. Opportunity to make additional money by moonlighting & additional call coverage. Enjoy the security of a competitive salary with outstanding benefits! For more info on this or any of our other nationwide positions, call Ariana Sanjabi @ 800-735-8261 ext 214, fax your CV to 703-995-0647 or e-mail: asanjabi@medsourceconsultants.com.

NEW YORK STATE

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 140 bed adult inpatient facility and **CHILD/ADOLESCENT PSYCHIATRISTS** for its Child/Adolescent Behavioral Health Center (outpatient only, no inpatient, no call). Abundant on-site CME. Salaried, permanent positions with excellent New York State benefits.

Submit CV to: Personnel Office
Greater Binghamton Health Center
425 Robinson St., Binghamton, NY 13904
Fax: (607) 773-4117. EOE/AAE

Excellent opportunity for BC/BE Psychiatrist in Central New York. Fast paced environment. Dedicated Psychiatry ER at St. Joseph's Hospital Health Center in Syracuse, NY. Full or Part-Time, 8-hour shifts. No beeper call. Excellent salary/benefits incl. malpractice, CME, health, 401(k). Contact: Joseph Gross - phone: (315) 448-2783; fax: (315) 703-2198; e-mail: Joseph.Gross@sjhsyr.org.

P/T CHILD/ADOLESCENT PSYCHIATRIST WANTED. Outpatient position with leading LI Children and Family Mental Health Agency. Fax Resume: HR-(516)626-8403.

Psychiatrists Needed

Comprehensive Neuroscience, Inc., a national clinical research organization specializing in CNS research is seeking part-time, board certified psychiatrists to assist in conducting clinical trials for our sites in Northern New Jersey, Washington, DC, Northern Virginia, Chicago, IL and Southern California (LA area). Position responsible for acting as sub-investigator for outpatient studies with various CNS investigational compounds.

E-mail resume to hr@cnsmail.com or fax to 914-997-4024. EOE

Practice In The Perfect Place: Saratoga Springs, NY
Saratoga Hospital seeks a BC/BE psychiatrist to provide care as part of a multi-disciplinary care team on a 16-bed adult inpatient unit.

This is a part time position that would require 4-5 weeks of full time work annually to cover Director's vacation and continuing education time. The flexibility exists to combine this position with an outpatient position at the attached outpatient community mental health center for a physician desiring more than part time. Call sharing responsibilities are reasonable. Compensation for this position is competitive.

Located a half hour from Albany, and less than three hours from NYC, Montreal and Boston, Saratoga Springs offers lovely neighborhoods and a downtown with fine restaurants and specialty shops. The city is known for world-class entertainment including thoroughbred racing and the Saratoga Performing Arts Center. Nearby mountains, lakes and rivers beckon outdoor enthusiasts for year-round recreation.

For more information, contact: Denise Romand, Medical Staff/Practice Liaison. Phone: (518)583-8465 FAX: (518)580-2605 E-mail: docfind@saratogacare.org View Saratoga Hospital's website at: www.saratogacare.org See our community at: www.saratoga.org

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NORTHERN WESTCHESTER, NEW YORK - Therapy practice, well established in the community, managed care friendly, seeking both child/adolescent and adult psychiatrists. Salaried position. Part time hours to begin. Growing practice with many opportunities for creative involvement. Please fax resume to L. Innes, MD @ (914) 242-5152

NORTH CAROLINA

SENIOR FACULTY POSITION

The University of North Carolina School of Medicine is seeking a senior psychiatrist at the Associate or Full Professor level (fixed-term) for the position of Clinical Director for a new, modern public psychiatric facility which is under construction in nearby Butner, North Carolina. This 432 bed hospital will provide psychiatric services for the central region of the state, and will include vibrant academic, teaching, and research programs in partnership with both the UNC School of Medicine and Duke University Medical Center. The Clinical Director will be responsible for medical leadership and the planning and organization of clinical, research and teaching functions. Candidates must have an M.D. from an accredited university, be Board Certified/Eligible, and able to obtain medical licensure in North Carolina. A strong track record of administrative leadership in a public academic setting is highly desirable.

Candidates should submit a letter of application, current CV, and the names and contact information of three professional references to: David Rubinow, M.D., Meymandi Professor and Chair of Psychiatry, Campus Box #7160, University of North Carolina School of Medicine, Chapel Hill, NC 27599-7160. UNC is an Equal Opportunity/ADA Employer.

PSYCHIATRISTS ($124,620 - $179,068)

John Umstead Hospital, a state psychiatric hospital located in Butner, NC seeks psychiatrist for the Adult Admissions and Alcohol & Drug Abuse Treatment units. Convenient to Raleigh/Durham/Chapel Hill and has close ties with Duke University and UNC-Chapel Hill. Competitive salary and benefits package. Requires graduation from an accredited medical school, completion of an accredited psychiatric residency, and board certification or eligibility. Selected employees may qualify for the education loan repayment program authorized by Section 332 of the Public Health Service Act. Send state application (PD-107) and/or vitae to JUH, Human Resources Office, 1003 12th St., Butner, NC 27509 or contact Dr. Lou Ann Crume, Clinical Director at 919-575-7233. FAX 919-575-7550. EEO/AA Employer

Coastal North Carolina Residential Treatment Center seeks BC/BE child or general psychiatrist with child experience for Clinical Director of a 46 bed RTC. This employed position offers generous base salary, great benefits and a lucrative performance bonus. For info call S. Wiltgen, CEO at (910) 577-1400 or email sarah.wiltgen@psysolutions.com

NORTH DAKOTA

MeritCare Health System of Fargo, ND is seeking an Adult Psychiatrist to join its 32-member multi-disciplinary Psychiatry Department. Faculty appointment and teaching of psychiatry residents is available through University of North Dakota School of Medicine. MeritCare is an integrated 384-physician multi-specialty group practice, 583-bed Level II tertiary/trauma hospital with 26 primary care clinic sites in two states. Sister cities, Fargo, ND and Moorhead, MN are a tri-college community of 200,000 located near the heart of Minnesota's lake country. Fargo-Moorhead offers excellent educational systems, recreation and sporting activities as well as a variety of entertainment and cultural events. This is an excellent opportunity with a competitive compensation and benefits package being offered. Drug-free workplace. AA/EOE. This is not a designated HPSA site.

To apply send CV to:

Jill Gilleshammer, Physician Recruiter
MeritCare Health System
P O Box MC
Fargo, North Dakota 58122
Phone: (800) 437-4010, ext. 280-4851
Email: Jill.Gilleshammer@meritcare.com

OHIO

Cincinnati! 100% Outpatient work, with absolutely no call. Full or part-time work available. Practice with 4 other competent psychiatrists in a pleasant community health care setting. Salaried position w/benefits. Call Ken Pruchnicki @ 800-575-2880 x319
kpruchnicki@medsourceconsultants.com

OREGON

Psychiatrist
Summit Research Network
(Oregon)

We are seeking a board certified Psychiatrist who is comfortable working in a team environment as a Sub-investigator/Principal Investigator at our clinical research site in Portland, Oregon.

We are looking for someone to work a minimum 20-24 hours per week with opportunity to increase to Fulltime. Position offers competitive salary based on experience & credentials and excellent benefit package.

Submit inquiries and CV to: Marsha Wellnitz,
Summit Research Network,
2701 NW Vaughn St., Ste. 350,
Portland, OR 97210
or email mwellnitz@summitnetwork.com

PENNSYLVANIA

LEHIGH VALLEY HOSPITAL (LVH) in Allentown, PA seeks 7th Consultation/Liaison psychiatrist to join salaried group. Focus on med/surg, ob/gyn, oncology, cardiology, trauma and burn. Job is 50% C/L and 50% outpatient. LVH is an 800-bed hospital with a Level 1 trauma center, regional burn center, 3,300 births, transplant program and 10 residency programs (no psychiatry). Competitive salary and excellent benefits, including paid medical malpractice insurance. Teaching (medical student rotation) and clinical research available. Faculty appointment at Penn State/Hershey. Allentown is in the Lehigh Valley, 60 miles north of Philadelphia and 90 miles west of NYC. Email CV to Ralph A. Primelo, Chief, Section of C/L Psychiatry, c/o Pamela.Adams@lvh.com. Fax 610-402-7014. Phone (610) 402-7008.

The Penn State Milton S. Hershey Medical Center, the university hospital for Penn State University College of Medicine, is currently recruiting a board certified/eligible psychiatrist for the Behavioral Health Division of the Department of Psychiatry. The successful candidate would be involved in outpatient services with a heavy emphasis on program based consult liaison. Responsibilities would include development and participation in multidisciplinary programs including transplant services, bariatric surgery, and diabetes with opportunities for further growth and expansion over time. Other responsibilities include resident and medical student supervision and teaching. Faculty appointment will be at a level commensurate with experience.

Successful candidates must be board certified/board eligible in Psychiatry.

Penn State Milton S. Hershey Medical Center is committed to affirmative action, equal opportunity and the diversity of its workforce.

Candidates with interest and skills in this area should send their curriculum vitae and a cover letter referring to position #11965 to:

CONTACT:
Steven Sinderman, M.D.
Director, Behavioral Health Services
Penn State Milton S. Hershey Medical Center
Department of Psychiatry HP16
22 Northeast Dr.
Hershey, PA 17033
Fax 717-531-6250 or email scs194@psu.edu.

SOUTH CENTRAL PENNSYLVANIA — BE/BC Psychiatrist needed to join thriving psychiatry department at Chambersburg Hospital. Position flexible based upon physician preference. Excellent salary with bonus program and outstanding benefits package. Local colleges and universities. Family-oriented lifestyle with very affordable housing and abundant outdoor and cultural activities yet an easy drive to Harrisburg, Baltimore or DC. Email CV to mroyce@summithealth.org Mail CV to Marie Royce, Director of Physician Relations, Summit Health, 112 N. 7th Street, Chambersburg, PA 17201. Call 1-800-758-8835. Fax 717-267-7769. Visit us at www.summithealth.org

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Outstanding Private Practice - Seeking BC/BE psychiatrist for successful, established private group practice in southeastern Pennsylvania's Lehigh Valley. Great earning potential, option to teach and do clinical research. In and outpatient responsibilities, weekend call is 1 in 6. Beautiful suburban area 1 hour from Philadelphia, 1.5 hours from NYC. Email CV to Dr. Paul Gross at pkgmd@yahoo.com, Fax to (610) 820-3835.

PSYCHIATRISTS... BE/BC exellent salary, benefits, no billing, upscale working environment, Inpatient or Outpatient. Full time and Part time available. Pennsylvania locations send CV bp@pennhurstmedical.com or fax to 610-524-0952 **Pennhurst Medical Group, P.C.** Some LT also!

City of Brotherly Love!
Position open in Philadelphia for an Adult Psychiatrist for outpatient work. 37 1/2 work week. Can become a permanent position. APA endorsed Occurrence Malpractice with excellent pay. Other positions nationwide including NYC locums positions available. Contact Linda Tripp-Graziani @ 800-575-2880 ext 323, fax your CV to 203-324-0555 or e-mail: ltripp@medsourceconsultants.com

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Outpatient Child/Adolescent and Adult Psychiatrists: Positions available in the scenic Laurel Highlands of Southwestern Pennsylvania (60 minutes SE of Pittsburgh/3 hours NW of to D.C.). Join team of seven psychiatrists in a progressive community-based behavioral health program. Full-time and part-time positions available in a comprehensive outpatient service. Treatment provided in concert with a team of professional counselors and certified psychiatric nurses. Crisis Intervention team provides 24/7 on-call coverage. Competitive salary and excellent benefit package. **J-1/H-1 positions available**. Please forward CV to: Brian Eberts, M.D., Medical Director, Chestnut Ridge Counseling Services, Inc., 100 New Salem Road, Uniontown, PA 15401 FAX: 724 437-6415 EMAIL: beberts@crcsi.org

Philadelphia: Drexel University College of Medicine's Dept of Psychiatry seeks to fill a FT position for a Community Psychiatrist, specializing in Child & Adolescent Psychiatry. The position is based in a community mental health ctr and will involve a substantial commitment for providing direct care to patients. Candidate needs to be board certified or eligible in general psychiatry and have completed an accredited child & adolescent psychiatry training program. Must be licensed in PA. Position must be filled by April 30 '06. The Drexel University College of Medicine is an affirmative action/equal opportunity employer. Women and minority candidates are encouraged to apply. Send CV Department of Psychiatry, Attn: Mr. David Logan, PO Box 45358, Philadelphia, Pa. 19124-8358.

STATE COLLEGE area: The Meadows Psychiatric Center provides behavioral health services to varied patient populations - inpatient, partial hospitalization & outpatient. Rewarding practice opportunities work with multidisciplinary treatment teams in all services.
SHIPPENSBURG: General and Geriatric Psychiatrists - existing & new programs. Directorship positions.
Very competitive salary, bonus potential & full benefits. Interested candidates contact **Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com**

Quarterback your own youth championship team! Immediate need in downtown Pittsburgh for a child & adolescent medical director. Inpatient duties within this new med facility. Med Supervision, competitive salary + bene. Call Dave Featherston @ 800-575-2880 x314
dfeatherston@medsourceconsultants.com

SEEKING ADULT PSYCHIATRIST - Because of departmental growth, the Department of Psychiatry at 800-bed Lehigh Valley Hospital (LVH) has gotten approval to add another adult psychiatrist. Join the 14-member salaried psychiatry group that provides a continuum of care from emergency evaluation to intensive care, partial hospital and outpatient follow-up, homecare and skilled nursing facility consultation. The general hospital-based inpatient psychiatric division has 52 adult and 13 adolescent beds. Faculty appointment at Penn State/Hershey is offered along with a very competitive salary, excellent benefits that include paid medical malpractice and paid health insurance for self and family. Lehigh Valley Hospital is located in Pennsylvania, 60 miles north of Philadelphia and 90 miles west of NYC, in one of the fastest growing areas on the Atlantic Seaboard. For more information, call 610-402-7013. Email CV to Pamela.Adams@lvh.com or fax to 610-402-7014.

SEEKING 3rd C&A PSYCHIATRIST FOR SALARIED POSITION - Lehigh Valley Hospital has recently signed a second child and adolescent psychiatrist and now seeks a third to join its well-established salaried group of mental health professionals. The position responsibilities include outpatient work and shared call coverage of the 13-bed adolescent inpatient unit. Enjoy a call schedule of 1:7 shared with four adult psychiatrists and two C&A psychiatrists. Opportunity to teach and do clinical research. Academic appointment at Penn State/Hershey is offered. The Lehigh Valley is 90 miles west of NYC and 60 miles north of Philadelphia. The suburban area offers safe neighborhoods with very good public schools, 10 colleges and universities and many year-round recreational and cultural activities. Email CVs to Pamela.Adams @LVH.com or fax to 610-402-7014. Phone 610-402-7008.

TENNESSEE

EAST TENNESSEE STATE UNIVERSITY
JAMES H. QUILLEN COLLEGE OF MEDICINE
DEPARTMENT OF PSYCHIATRY & BEHAVIORAL SCIENCES

CHILD PSYCHIATRIST

Full-time position available for Child Psychiatrist. 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. Telephone inquiries should be made at (423)439-2235 or e-mail at lovedayc@etsu.edu. AA/EOE.

TEXAS

Geriatric Psychiatrist for busy private practice. Outpatient, research, drive to nursing homes and assisted livings. Competitive salary and benefits. Send CV to SASH at JWinston@austin.rr.com or fax to 512-476-0195.

Assistant Professor

The Department of Psychiatry and Behavioral Sciences at the University of Texas Medical Branch in Galveston is seeking an Assistant Professor.

Responsibilities include inpatient care, outpatient clinics, resident supervision and teaching. Research opportunities are available. Successful candidates must be board certified/board eligible in Psychiatry.

Candidates with interest and skills in this area should send a curriculum vitae and cover letter to: **Robert M.A. Hirschfeld, M.D., The University of Texas Medical Branch, Department of Psychiatry and Behavioral Sciences, 301 University Boulevard, Galveston, TX 77555-0188**.

The University of Texas Medical Branch is an equal opportunity, affirmative action institution which proudly values diversity. Candidates of all backgrounds are encouraged to apply.

Nacogdoches and Livingston - The Burke Center, a multi-site, JCAHO accredited community mental health center, currently has a full time Adult Psychiatrist position available in Nacogdoches, and a full time Child Psychiatrist (or General Psychiatrist with child experience) position available in Livingston to see a mix of child and adult patients. Physician Assistants and Advanced Nurse Practitioners will be considered as well. Both positions are outpatient only, 40 hour weeks, with no on call. Enjoy a comfortable lifestyle in the beautiful, pineywoods/lakes area of East Texas. Recreational opportunities abound in national forests nearby. Houston less than 2 hours away; Dallas 3 hours; major state university nearby. Excellent benefits and competitive salary. Please send CV to Mark Janes, M.D., Medical Director, Burke Center, 4101 S. Medford Drive, Lufkin, TX 75901. Fax: (936) 634-8601. Email: markj@burke-center.org. Check out the details on our website: www.burke-center.org.

AMARILLO: Private Practice group seeking associate/partner. Inpatient & outpatient care with diverse patient population. Community need & great income potential.
MCALLEN: Child Psychiatrists for combination inpatient/outpatient private practice.
SAN ANGELO: General or Geriatric Psychiatrist. Must Established practice - will offer employment.
Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

Greater Dallas Metro Area! Single specialty group seeks a Child or Adult Psychiatrist to work with children through adult patients. Mix of I/P & O/P. Weekend rounding 1 in 8. 1st year $165K + bonus; **2nd year make $200K+!** Call **Karen Brennan at 800-575-2880 x307**. E-mail to kbrennan@medsourceconsultants.com.

North Texas State Hospital

North Texas State Hospital is a preeminent psychiatric facility located in North Central Texas with campuses in Vernon and Wichita Falls. Psychiatrist in our organization have the opportunity for a professionally stimulating practice that genuinely makes a difference in these patients' lives, while at the same time affording themselves a rich quality of life in an area with a comparatively low cost of living. The Vernon Campus serves as the only adult Maximum Security facility and adolescent forensic program in the Texas Department of State Health Services and the Wichita Falls campus is a multi-faceted general psychiatric facility serving north central and west Texas. Populations served include: forensic, substance abuse, adult, child, adolescent, geriatric, and developmentally disabled. If you are looking for a challenging and rewarding position with an excellent salary, employment security, outstanding benefits* and opportunities for professional growth, we invite you to visit our progressive, modern facility at North Texas State Hospital. **No state income tax, paid sick leave, paid vacation, paid time off for CME, 12-14 paid holidays per year, retirement plan, additional pay available if on call is provided, and much more.*

Contact **Thomas R. Mareth, M.D.**
for more information.
Phone: (940) 552-4150
Fax: (940) 553-2530
thomas.mareth@dshs.state.tx.us
North Texas State Hospital-P.O. Box 2231-Vernon, Texas 76385
North Texas State Hospital is an Equal Opportunity/Drug Free Workplace
Not a Healthcare Shortage Opportunity

Bluebonnet Trails Community MHMR Center currently has a full time opening for staff Psychiatrist to serve our adult population the Guadalupe County (Seguin, TX), Caldwell County, (Luling, TX) and Gonzales County, (Gonzales, TX). Counties are beautifully located in central Texas, close to Austin and San Antonio. Please send CV to Vicky Hall, Mental Health Director, at vicky.hall@bluebonnetmhmr.org, fax (512.244.8401), or visit our website at www.bluebonnetmhmr.org

UTAH

LICENSED PSYCHIATRIST- Bear River Mental Health Services, Inc., serving northern Utah. Duties: medical assessments; medication management; coordination of medical care with PCP's; hospital rotation; psychiatric emergency consultation. Team model of service delivery. Must maintain hospital privileges. Computer literacy. Specialty in child/adolescent psychiatry preferred but not required. Salary negotiable. Competitive benefits. Potential for student loan repayment program. EOE. Send resume and cover letter to: **HR Dept., Bear River Mental Health Services, Inc., 90 E. 200 N., Logan, UT, 84321; Email: sharons@brmh.com**

WASHINGTON

BC/BE PSYCHIATRIST
Seeking a BC/BE Psychiatrist with an interest in geriatrics (*fellowship training a plus*), to join a *colloborative* practice **affiliated with a comprehensive medical center. Mostly outpatient with some inpatient. Competitive base salary guarantee, good benefits plus potential additional compensation for productivity**. Located just 20 minutes from downtown Seattle and the shores of Puget Sound. This area is consistently rated as one of the best places to live. For more information send CV to Gail Mumma, gmumma@HighlineMedical.org or Fax to 206-242-4625 or Call: (206)431-0785

GENERAL PSYCHIATRIST
LONGVIEW, WASHINGTON

Northwest Permanente, P.C., has an excellent practice opportunity for a board certified general psychiatrist at our medical office in Longview-Kelso, Washington, a picturesque, family-oriented community of 65,000 people situated near the beautiful Columbia River, 45 miles north of Portland, Oregon. A full range of professional services are provided to Kaiser Permanente's 38,000 plan members in the area. Our new associate will join a seven-member mental health department, which is part of our multidisciplinary staff of over 130 mental health professionals throughout Kaiser Permanente's Northwest Region.

Experience in medication consultation, crisis intervention, and all treatment modalities required. The position includes direct clinical work with outpatients and requires compatibility with physicians in primary care setting. Ours is a collegial and professionally stimulating practice in one of the most successful managed care programs in the country. We offer a competitive salary and benefit package which includes two comprehensive pension plans, paid professional liability and sabbatical leave.

Please forward CV to P.N. Parmenter, Recruitment Manager, Northwest Permanente, P.C., 500 NE Multnomah, Suite 100, Portland OR 97232-2099. Phone: (800) 813-3763 or e-mail: nw.perm.careers@kp.org; or visit our web site at: http://physiciancareers.kp.org. No J1 opportunities available. We are an equal opportunity employer and value diversity within our organization.

Live in the beautiful Wine Country Of Southeast Washington State.

Opportunity for Board Eligible Psychiatrist with WA State License. Up to full time Contractor position with staff placement possible at later date if desired. Inpatient and Outpatient care at Washington State Penitentiary

Contact: Michael Wall 509.526.6436
mbwall@DOC1.WA.GOV

Starbucks, Anyone - Great Location! There is an immediate need for an Adult Psychiatrist to provide locum tenens coverage on an inpatient unit. This a 40 hour a week position. APA endorsed Occurrence malpractice, Travel, lodging, rental car and excellent pay are provided. Contact Gene Itoh @ 800.735.8261 ext. 223, fax your CV to 703.995-0647 or E-mail: gitoh@medsourceconsultants.com for this or any or our nationwide locum tenens opportunities.

Pacific Northwest - Inpatient and Outpatient Psychiatrists

Highline West Seattle Mental Health/West Seattle Psychiatric Hospital is a large community mental health agency located in the Emerald city of Seattle. We have FT positions available in our psychiatric hospital and PT in our outpatient mental health center. Seattle offers a full, contemporary urban experience, with excellent schools and culture, surrounded by incredible mountains and outdoor recreation. Our salary is competitive; benefits include all the standard insurances, CME, approx. 1 month leave, etc. Please contact Jeff Skolnick, MD-Chief Medical Officer 206-933-7127 or JeffS@Highline.Org

WEST VIRGINIA

MEDICAL DIRECTOR/PSYCHIATRIST

Westbrook Health Services, a community based, not for profit, behavioral health center located in the Mid-Ohio Valley is recruiting a **Medical Director/Psychiatrist**. Rich on heritage...long on beauty! Reach your peak with a great place to work and a beautiful place to live! Work with a well trained and supportive staff.

This is a unique and special opportunity. Metro area of 125,000. A great place to raise a family. Good schools, including colleges and a university, and a very low crime rate. Practice where you are wanted and appreciated. For details, call or send your CV to:

Director, Human Resources
Westbrook Health Services
2121 Seventh Street
Parkersburg, WV 26101
(304) 485-1721 Ext. 145 FAX: (304) 422-0908
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WISCONSIN

SPECTACULAR OPPORTUNITY
FOR INPATIENT MEDICAL DIRECTOR

Gundersen Lutheran, a multidisciplinary 400 member group practice in La Crosse, WI, is seeking an experienced BC/BE Psychiatrist to perform the functions of the Medical Director of an existing Inpatient Unit and to develop a day hospital program.

This candidate will join 9 general and 4 child psychiatrists, 7 psychologists and more than 40 therapists in providing outpatient/inpatient care for a broad range of clinical disorders.

Psychiatric outpatient care is offered on our main campus and at several sites in the Gundersen Lutheran healthcare system. Inpatient care is provided in a 27-bed unit, which is adjacent to the medical center. Call will be 1:12.

Located in a city of 52,000 with a metropolitan area of 120,000 and a service delivery area of more than 500,000, Gundersen Lutheran provides the opportunity to practice metropolitan-scale medicine in a context of small town character and comforts. Nationally recognized schools, three universities, safe neighborhoods, affordable housing and extensive recreational and cultural activities make La Crosse, on the Mississippi River, an outstanding place to live and work. Our compensation package, pension plan and continuing education opportunities are exceptional.

Interested candidates are invited to call Gale Kreibich, Medical Staff Development, Gundersen Lutheran, at 1-800-362-9567, ext. 56863, 1900 South Ave., La Crosse, WI, 54601, or e-mail grkreibi@gundluth.org

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For additional information please contact Rita Puttkammer, Administrative Assistant at (608) 372-1631, E-mail: Rita.Puttkammer@va.gov. Interested candidates should mail or fax CV to:

VA Medical Center
Mental Health Service Line
500 E. Veterans Street
Tomah, WI 54660
Fax: (608) 372-1224
EOE/AA Employer Random Pre-employment Drug Screen

CHILD-ADOLESCENT/ADULT PSYCHIATRIST - LA CROSSE, WI

Board certified/eligible child-adolescent psychiatrist needed to join the Psychiatry Department/Behavioral Health Program at Franciscan Skemp Healthcare-Mayo Health System in La Crosse, WI. At least 50% of the position will be devoted to outpatient child-adolescent psychiatry patients. Remainder of the practice will be a mix of inpatient and outpatient adult psychiatry. Position will include sharing in the general Psychiatry call schedule with five adult psychiatrists. Competitive salary & comprehensive benefits. Franciscan Skemp Healthcare, part of Mayo Health System, is a multispecialty group/healthcare network with 200+ providers, serving a primary care population of 240,000 in WI, MN & IA. La Crosse, city of 52,000 with metro area of 120,000, located on the scenic Upper Mississippi River, offers an ideal family environment with unlimited, four-season recreational & cultural activities. Excellent schools, including two universities and technical college.

Contact Bonnie Guenther or Mike Hesch, Physician Services
Franciscan Skemp Healthcare-
Mayo Health System
700 West Avenue South, La Crosse, WI 54601
800-269-1986 / fax 608-791-9898
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To apply please send a cover letter, CV and names of three references to:

Hassen Al-Amin, MD, Associate Professor and Acting Chairman
Department of Psychiatry, American University of Beirut
P.O.Box 11-0236 / Department of Psychiatry
Riad El-Solh / Beirut 1107 2020, Lebanon

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PSYCHIATRY RESEARCH FELLOWSHIP at the Zucker Hillside Hospital/North Shore Long Island Jewish Medical Center, Glen Oaks, NY, starting July 1, 2006. This 2-year fellowship, under the direction of John Kane, MD is designed for Board Certified/ Board Eligible Psychiatrists who seek advanced training in biomedical, neuroscience, and behavioral neuroscience research. Fellows work closely with senior faculty on existing studies in schizophrenia, bipolar and unipolar mood disorders, and dementia. Projects may encompass psychiatric genetics/pharmacogenetics, neuroimaging (fMRI, DTI, PET), psychopharmacology (e.g., clinical trials, challenge assays), neuroendocrinology, neurochemistry, neurocognition, prodromal/first episode studies, electrophysiology (ERPs), phenomenology and assessment, and outcome (e.g., functional disability, suicide). Fellows develop independent lines of investigation and are encouraged to publish and pursue funding in preparation for careers in academic medicine. Applicants should send a CV and letter outlining their interests to: Serge Sevy, MD., The Zucker Hillside Hospital, 75-59 263rd Street, Glen Oaks, NY 11004; ssevy@lij.edu. Minority applicants are encouraged to apply.

PUBLIC PSYCHIATRY FELLOWSHIP
CMHC - YALE

The Connecticut Mental Health Center - Yale University School of Medicine is offering a one-year Fellowship in Public Psychiatry beginning July 2006. CMHC is a major site for training, research and clinical service within the Yale and State systems. As a state-funded, academic, urban mental health center it provides a unique setting for psychiatrists to obtain advanced training as they pursue careers as leaders in the field. Fellows will spend 50% time in seminars, supervision, and administrative/policy meetings of CMHC and the CT Dept. of Mental Health and Addiction Services; and 50% effort providing direct clinical service and/or consultation within public mental health settings in New Haven. Candidates must be eligible for board certification and CT licensure. Minority applicants are encouraged to apply. For further information contact Jeanne Steiner, D.O. Medical Director, CMHC - Yale Univ., 34 Park St New Haven, CT 06519 or Jeanne.Steiner@yale.edu.

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A Psychosomatic Medicine fellowship position is available at the University of Michigan, Department of Psychiatry. The one-year fellowship program (PGY-5) provides a broad-based clinical experience, with a strong multidisciplinary emphasis, and opportunities to achieve skills in research, education and administration, in an extraordinarily rich academic environment, with no night or weekend on-call. Supervision is provided by full-time attendings with board certification in Psychosomatic Medicine. The fellowship begins on July 1, 2006. Excellent salary and benefits. Candidates must have completed an approved residency in Psychiatry.

Applications will be accepted through April 14, 2006. Please email/mail/fax CV to Michelle Riba, MD, Co-Director, Psychosomatic Medicine Services, Department of Psychiatry, University of Michigan Health System, 1500 E. Medical Center Drive, Room F6236 MCHC, Ann Arbor, MI, 48109-0295. Tel: (734) 764-6879; FAX: (734) 936-1130; web: http://www.med.umich.edu/psych/education, Email: gacioch@umich.edu .

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BRIEF SUMMARY. See package insert for full prescribing information.

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

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

CONTRAINDICATIONS — ***QT Prolongation:*** Because of GEODON's dose-related prolongation of the QT interval and the known association of fatal arrhythmias with QT prolongation by some other drugs, GEODON is contraindicated in patients with a known history of QT prolongation (including congenital long QT syndrome), with recent acute myocardial infarction, or with uncompensated heart failure (see **WARNINGS**). Pharmacokinetic/pharmacodynamic studies between GEODON and other drugs that prolong the QT interval have not been performed. An additive effect of GEODON and other drugs that prolong the QT interval cannot be excluded. Therefore, GEODON should not be given with dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol, or tacrolimus. GEODON is also contraindicated with drugs that have demonstrated QT prolongation as one of their pharmacodynamic effects and have this effect described in the full prescribing information as a contraindication or a boxed or bolded warning (see **WARNINGS**). GEODON is contraindicated in individuals with a known hypersensitivity to the product. **WARNINGS—Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. GEODON (ziprasidone) is not approved for the treatment of patients with dementia-related psychosis (see Boxed Warning).** ***QT Prolongation and Risk of Sudden Death:*** **GEODON use should be avoided in combination with other drugs that are known to prolong the QT_c interval. Additionally, clinicians should be alert to the identification of other drugs that have been consistently observed to prolong the QT_c interval. Such drugs should not be prescribed with GEODON. A study directly comparing the QT/QT_c-prolonging effect of GEODON with several other drugs effective in the treatment of schizophrenia was conducted in patient volunteers. The mean increase in QT_c from baseline for GEODON ranged from approximately 9 to 14 msec greater than for four of the comparator drugs (risperidone, olanzapine, quetiapine, and haloperidol), but was approximately 14 msec less than the prolongation observed for thioridazine. In this study, the effect of GEODON on QT_c length was not augmented by the presence of a metabolic inhibitor (ketoconazole 200 mg bid). In placebo-controlled trials, GEODON increased the QT_c interval compared to placebo by approximately 10 msec at the highest recommended daily dose of 160 mg. In clinical trials the electrocardiograms of 2/2988 (0.06%) GEODON patients and 1/440 (0.23%) placebo patients revealed QT_c intervals exceeding the potentially clinically relevant threshold of 500 msec. In the GEODON patients, neither case suggested a role of GEODON. Some drugs that prolong the QT/QT_c interval have been associated with the occurrence of torsade de pointes and with sudden unexplained death. The relationship of QT prolongation to torsade de pointes is clearest for larger increases (20 msec and greater) but it is possible that smaller QT/QT_c prolongations may also increase risk, or increase it in susceptible individuals, such as those with hypokalemia, hypomagnesemia, or genetic predisposition. Although torsade de pointes has not been observed in association with the use of GEODON at recommended doses in premarketing studies, experience is too limited to rule out an increased risk. A study evaluating the QT/QT_c prolonging effect of intramuscular GEODON, with intramuscular haloperidol as a control, was conducted in patient volunteers. In the trial, ECGs were obtained at the time of maximum plasma concentration following two injections of GEODON (20 mg then 30 mg) or haloperidol (7.5 mg then 10 mg) given four hours apart. Note that a 30 mg dose of intramuscular GEODON is 50% higher than the recommended therapeutic dose. The mean change in QT_c from baseline was calculated for each drug using a sample-based correction that removes the effect of heart rate on the QT interval. The mean increase in QT_c from baseline for GEODON was 4.6 msec following the first injection and 12.8 msec following the second injection. The mean increase in QT_c from baseline for haloperidol was 6.0 msec following the first injection and 14.7 msec following the second injection. In this study, no patient had a QT_c interval exceeding 500 msec. As with other antipsychotic drugs and placebo, sudden unexplained deaths have been reported in patients taking GEODON at recommended doses. The premarketing experience for GEODON did not reveal an excess of mortality for GEODON compared to other antipsychotic drugs or placebo, but the extent of exposure was limited, especially for the drugs used as active controls and placebo. Nevertheless, GEODON's larger prolongation of QT_c length compared to several other antipsychotic drugs raises the possibility that the risk of sudden death may be greater for GEODON than for other available drugs for treating schizophrenia. This possibility needs to be considered in deciding among alternative drug products. Certain circumstances may increase the risk of the occurrence of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QT_c interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QT_c interval; and (4) presence of congenital prolongation of the QT interval. GEODON should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias (see CONTRAINDICATIONS, and see** ***Drug Interactions*** **under PRECAUTIONS). It is recommended that patients being considered for GEODON treatment who are at risk for significant electrolyte disturbances, hypokalemia in particular, have baseline serum potassium and magnesium measurements. Hypokalemia (and/or hypomagnesemia) may increase the risk of QT prolongation and arrhythmia. Hypokalemia may result from diuretic therapy, diarrhea, and other causes. Patients with low serum potassium and/or magnesium should be repleted with those electrolytes before proceeding with treatment. It is essential to periodically monitor serum electrolytes in patients for whom diuretic therapy is introduced during GEODON treatment. Persistently prolonged QT_c intervals may also increase the risk of further prolongation and arrhythmia, but it is not clear that routine screening ECG measures are effective in detecting such patients. Rather, GEODON should be avoided in patients with histories of significant cardiovascular illness, eg, QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. GEODON should be discontinued in patients who are found to have persistent QT_c measurements >500 msec.** ***Neuroleptic Malignant Syndrome (NMS):*** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported. ***Tardive Dyskinesia (TD):*** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients undergoing treatment with antipsychotic drugs. Although the prevalence of TD appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop TD. If signs and symptoms of TD appear in a patient on GEODON, drug discontinuation should be considered. ***Hyperglycemia and Diabetes Mellitus:*** Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON, and it is not known if GEODON is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia. **PRECAUTIONS —** ***General:*** Rash: In premarketing trials, about 5% of GEODON patients developed rash and/or urticaria, with discontinuation of treatment in about one-sixth of these cases. The occurrence of rash was dose related, although the finding might also be explained by longer exposure in higher-dose patients. Several patients with rash had signs and symptoms of associated systemic illness, e.g., elevated WBCs. Most patients improved promptly upon treatment with antihistamines or steroids and/or upon discontinuation of GEODON, and all patients were reported to recover completely. Upon appearance of rash for which an alternative etiology cannot be identified, GEODON should be discontinued. Orthostatic Hypotension: GEODON may induce orthostatic hypotension associated with dizziness, tachycardia, and, in some patients, syncope, especially during the initial dose-titration period, probably reflecting its α_1-adrenergic antagonist properties. Syncope was reported in 0.6% of GEODON patients. GEODON should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Seizures: In clinical trials, seizures occurred in 0.4% of GEODON patients. There were confounding factors that may have contributed to seizures in many of these cases. As with other antipsychotic drugs, GEODON should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older. Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia, and GEODON and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. **(See also Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis)**. Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, GEODON elevates prolactin levels in humans. Tissue culture experiments indicate that approximately one third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time. Potential for Cognitive and Motor Impairment: Somnolence was a commonly reported adverse event in GEODON patients. In the 4- and 6-week placebo-controlled trials, somnolence was reported in 14% of GEODON patients vs 7% of placebo patients. Somnolence led to discontinuation in 0.3% of patients in short-term clinical trials. Since GEODON has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about performing activities requiring mental alertness, such as operating a motor vehicle (including automobiles) or operating hazardous machinery until they are reasonably certain that GEODON therapy does not affect them adversely. Priapism: One case of priapism was reported in the premarketing database. Body Temperature Regulation: Although not reported with GEODON in premarketing trials, disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Suicide: The possibility of a suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. GEODON prescriptions should be written for the smallest quantity of capsules consistent with good patient management to reduce overdose risk. Use in Patients with Concomitant Illness: Clinical experience with GEODON in patients with certain concomitant systemic illnesses is limited. GEODON has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies. Because of the risk of QT_c prolongation and orthostatic hypotension with GEODON, caution should be observed in cardiac patients (see ***QT Prolongation and Risk of Sudden Death*** in **WARNINGS** and Orthostatic Hypotension in **PRECAUTIONS**). ***Information for Patients:*** To ensure safe and effective use of GEODON, the information and instructions in the *Patient Information Section* should be discussed with patients. ***Laboratory Tests:*** Patients being considered for GEODON treatment who are at risk of significant electrolyte disturbances should have baseline serum potassium and magnesium measurements. Low serum potassium and magnesium should be repleted before treatment. Patients who are started on diuretics during GEODON therapy need periodic monitoring of serum potassium and magnesium. Discontinue GEODON in patients who are found to have persistent QT_c measurements >500 msec (see **WARNINGS**). ***Drug Interactions:*** (1) GEODON should not be used with any drug that prolongs the QT interval. (2) Given the primary CNS effects of GEODON, caution should be used when it is taken in combination with other centrally acting drugs. (3) Because of its potential for inducing hypotension, GEODON may enhance the effects of certain antihypertensive agents. (4) GEODON may antagonize the effects of levodopa and dopamine agonists. Effect of Other Drugs on GEODON: *Carbamazepine,* 200 mg bid for 21 days, resulted in a decrease of approximately 35% in the AUC of GEODON. *Ketoconazole*, a potent inhibitor of CYP3A4, 400 mg qd for 5 days, increased the AUC and C_{max} of GEODON by about 35%-40%. *Cimetidine,* 800 mg qd for 2 days, did not affect GEODON pharmacokinetics. Coadministration of 30 mL of *Maalox* did not affect GEODON pharmacokinetics. Population pharmacokinetic analysis of schizophrenic patients in controlled clinical trials has not revealed any clinically significant pharmacokinetic interactions with benztropine, propranolol, or lorazepam. Effect of GEODON on Other Drugs: In vitro studies revealed little potential for GEODON to interfere with the metabolism of drugs cleared primarily by CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4, and little potential for drug interactions with GEODON due to displacement. GEODON 40 mg bid administered concomitantly with *lithium* 450 mg bid for 7 days did not affect the steady-state level or renal clearance of lithium. GEODON 20 mg bid did not affect the pharmacokinetics of concomitantly administered *oral contraceptives*, ethinyl estradiol (0.03 mg) and levonorgestrel (0.15 mg). Consistent with in vitro results, a study in normal healthy volunteers showed that GEODON did not alter the metabolism of *dextromethorphan*, a CYP2D6 model substrate, to its major metabolite, dextrorphan. There was no statistically significant change in the urinary dextromethorphan/dextrorphan ratio. ***Carcinogenesis, Mutagenesis, Impairment of Fertility:*** Lifetime carcinogenicity studies were conducted with GEODON in Long Evans rats and CD-1 mice. In male mice, there was no increase in incidence of tumors relative to controls. In female mice there were dose-related increases in the incidences of pituitary gland adenoma and carcinoma, and mammary gland adenocarcinoma at all doses tested. Increases in serum prolactin were observed in a 1-month dietary study in female, but not male, mice. GEODON had no effect on serum 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/m² basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m² basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m² basis). The fertility of female rats was reduced. ***Pregnancy—Pregnancy Category C:*** There are no adequate and well-controlled studies in pregnant women. GEODON should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. ***Labor and Delivery:*** The effect of GEODON on labor and delivery in humans is unknown. ***Nursing Mothers:*** It is not known whether, and if so in what amount, GEODON or its metabolites are excreted in human milk. It is recommended that women receiving GEODON should not breast feed. ***Pediatric Use:*** The safety and effectiveness of GEODON in pediatric patients have not been established. ***Geriatric Use:*** Of the approximately 4500 patients treated with GEODON in clinical studies, 2.4% (109) were 65 years of age or over. In general, there was no indication of any different tolerability for GEODON or of reduced clearance of GEODON in the elderly compared to younger adults. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to GEODON, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients. **ADVERSE REACTIONS —** ***Adverse Findings Observed in Short-term, Placebo-Controlled Trials:*** The following findings are based on the short-term placebo-controlled premarketing trials for schizophrenia (a pool of two 6-week, and two 4-week fixed-dose trials) and bipolar mania (a pool of two 3-week flexible-dose trials) in which GEODON was administered in doses ranging from 10 to 200 mg/day. ***Adverse Events Associated with Discontinuation:*** Schizophrenia: Approximately 4.1% (29/702) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 2.2% (6/273) on placebo. The most common event associated with dropout was rash, including 7 dropouts for rash among GEODON patients (1%) compared to no placebo patients (see **PRECAUTIONS**). Bipolar Mania: Approximately 6.5% (18/279) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 3.7% (5/136) on placebo. The most common events associated with dropout in the GEODON-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash and vomiting, with 2 dropouts for each of these events among GEODON patients (1%) compared to one placebo patient each for dystonia and rash (1%) and no placebo patients for the remaining adverse events. ***Adverse Events at an Incidence ≥5% and at Least Twice the Rate of Placebo:*** The most commonly observed adverse events associated with GEODON in schizophrenia trials were somnolence (14%) and respiratory tract infection (8%). The most commonly observed adverse events associated with the use of GEODON in bipolar mania trials were somnolence (31%), extrapyramidal symptoms (31%), dizziness (16%), akathisia (10%), abnormal vision (6%), asthenia (6%), and vomiting (5%). The following list enumerates the treatment-emergent adverse events that occurred during acute therapy, including only those events that occurred in 2% of GEODON patients and at a greater incidence than in placebo. Schizophrenia: Body as a Whole—asthenia, accidental injury, chest pain. Cardiovascular—tachycardia. Digestive—nausea, constipation, dyspepsia, diarrhea, dry mouth, anorexia. Nervous—extrapyramidal symptoms, somnolence, akathisia, dizziness. Respiratory—respiratory tract infection, rhinitis, cough increased. Skin and Appendages—rash, fungal dermatitis. Special Senses—abnormal vision. Bipolar Mania: Body as a Whole—headache, asthenia, accidental injury. Cardiovascular—hypertension. Digestive—nausea, diarrhea, dry mouth, vomiting, increased salivation, tongue edema, dysphagia. Musculoskeletal—myalgia. Nervous—somnolence, extrapyramidal symptoms, dizziness, akathisia, anxiety, hypesthesia, speech disorder. Respiratory—pharyngitis, dyspnea. Skin and Appendages—fungal dermatitis. Special Senses—abnormal vision. ***Dose Dependency:*** An analysis for dose response in the schizophrenia trials revealed an apparent relation of adverse event to dose for the following: asthenia, postural hypotension, anorexia, dry mouth, increased salivation, arthralgia, anxiety, dizziness, dystonia, hypertonia, somnolence, tremor, rhinitis, rash, and abnormal vision. ***Extrapyramidal Symptoms (EPS):*** The incidence of reported EPS for GEODON patients in the short-term, placebo-controlled schizophrenia trials was 14% vs 8% for placebo. Objectively collected data from those trials on the Simpson-Angus Rating Scale and the Barnes Akathisia Scale did not generally show a difference between GEODON and placebo. ***Vital Sign Changes:*** GEODON is associated with orthostatic hypotension (see **PRECAUTIONS**). ***Weight Gain:*** In short-term schizophrenia trials, the proportions of patients meeting a weight gain criterion of ≥7% of body weight were compared, revealing a statistically significantly greater incidence of weight gain for GEODON patients (10%) vs placebo patients (4%). A median weight gain of 0.5 kg was observed in GEODON patients vs 0.0 kg in placebo patients. Weight gain was reported as an adverse event in 0.4% of both GEODON and placebo patients. During long-term therapy with GEODON, a categorization of patients at baseline on the basis of body mass index (BMI) showed the greatest mean weight gain and the highest incidence of clinically significant weight gain (>7% of body weight) in patients with a low BMI (<23) compared to normal (23-27) or overweight (>27) patients.There was a mean weight gain of 1.4 kg for patients with a "low" baseline BMI, 0.0 kg for patients with a "normal" BMI, and a 1.3 kg mean weight loss for patients with a "high" BMI. ***ECG Changes:*** GEODON is associated with an increase in the QT_c interval (see **WARNINGS**). In schizophrenia trials, GEODON was associated with a mean increase in heart rate of 1.4 beats per minute compared to a 0.2 beats per minute decrease among placebo patients. ***Other Adverse Events Observed During the Premarketing Evaluation of GEODON:*** Frequent adverse events are those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. Schizophrenia: Body as a Whole—*Frequent:* abdominal pain, flu syndrome, fever, accidental fall, face edema, chills, photosensitivity reaction, flank pain, hypothermia, motor vehicle accident. Cardiovascular System—*Frequent:* tachycardia, hypertension, postural hypotension; *Infrequent:* bradycardia, angina pectoris, atrial fibrillation; *Rare:* first-degree AV block, bundle branch block, phlebitis, pulmonary embolus, cardiomegaly, cerebral infarct, cerebrovascular accident, deep thrombophlebitis, myocarditis, thrombophlebitis. Digestive System—*Frequent:* anorexia, vomiting; *Infrequent:* rectal hemorrhage, dysphagia, tongue edema; *Rare:* gum hemorrhage, jaundice, fecal impaction, gamma glutamyl transpeptidase increased, hematemesis, cholestatic jaundice, hepatitis, hepatomegaly, leukoplakia of mouth, fatty liver deposit, melena. Endocrine—*Rare:* hypothyroidism, hyperthyroidism, thyroiditis. Hemic and Lymphatic System—*Infrequent:* anemia, ecchymosis, leukocytosis, leukopenia, eosinophilia, lymphadenopathy; *Rare:* thrombocytopenia, hypochromic anemia, lymphocytosis, monocytosis, basophilia, lymphedema, polycythemia, thrombocythemia. Metabolic and Nutritional Disorders—*Infrequent:* thirst, transaminase increased, peripheral edema, hyperglycemia, creatine phosphokinase increased, alkaline phosphatase increased, hypercholesteremia, dehydration, lactic dehydrogenase increased, albuminuria, hypokalemia; *Rare:* BUN increased, creatinine increased, hyperlipemia, hypocholesteremia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hyperchloremia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. Musculoskeletal System—*Frequent:* myalgia; *Infrequent:* tenosynovitis; *Rare:* myopathy. Nervous System—*Frequent:* agitation, extrapyramidal syndrome, tremor, dystonia, hypertonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, hypesthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, buccoglossal syndrome, choreoathetosis, diplopia, incoordination, neuropathy; *Infrequent:* paralysis; *Rare:* myoclonus, nystagmus, torticollis, circumoral paresthesia, opisthotonos, reflexes increased, trismus. Respiratory System—*Frequent:* dyspnea; *Infrequent:* pneumonia, epistaxis; *Rare:* hemoptysis, laryngismus. Skin and Appendages—*Infrequent:* maculopapular rash, urticaria, alopecia, eczema, exfoliative dermatitis, contact dermatitis, vesiculobullous rash. Special Senses—*Frequent:* fungal dermatitis; *Infrequent:* conjunctivitis, dry eyes, tinnitus, blepharitis, cataract, photophobia; *Rare:* eye hemorrhage, visual field defect, keratitis, keratoconjunctivitis. Urogenital System—*Infrequent:* impotence, abnormal ejaculation, amenorrhea, hematuria, menorrhagia, female lactation, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; *Rare:* gynecomastia, vaginal hemorrhage, nocturia, oliguria, female sexual dysfunction, uterine hemorrhage. **Adverse Finding Observed in Trials of Intramuscular GEODON:** In these studies, the most commonly observed adverse events associated with the use of intramuscular GEODON (≥5%) and observed at a rate on intramuscular GEODON (in the higher dose groups) at least twice that of the lowest intramuscular GEODON group were headache (13%), nausea (12%), and somnolence (20%). **Adverse Events at an Incidence >1% in Short-Term Fixed-Dose Intramuscular Trials:** The following list enumerates the treatment-emergent adverse events that occurred in ≥1% of GEODON patients (in the higher dose groups) and at least twice that of the lowest intramuscular GEODON group. Body as a Whole—headache, injection site pain, asthenia, abdominal pain, flu syndrome, back pain. Cardiovascular—postural hypotension, hypertension, bradycardia, vasodilation. Digestive—nausea, rectal hemorrhage, diarrhea, vomiting, dyspepsia, anorexia, constipation, tooth disorder, dry mouth. Nervous—dizziness, anxiety, insomnia, somnolence, akathisia, agitation, extrapyramidal syndrome, hypertonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. Respiratory—rhinitis. Skin and Appendages—furunculosis, sweating. Urogenital—dysmenorrhea, priapism. **DRUG ABUSE AND DEPENDENCE—** ***Controlled Substance Class:*** GEODON is not a controlled substance. **OVERDOSAGE**—In premarketing trials in over 5400 patients, accidental or intentional overdosage of GEODON was documented in 10 patients. All patients survived without sequelae. In the patient taking the largest confirmed amount (3240 mg), the only symptoms reported were minimal sedation, slurring of speech, and transitory hypertension (BP 200/75).

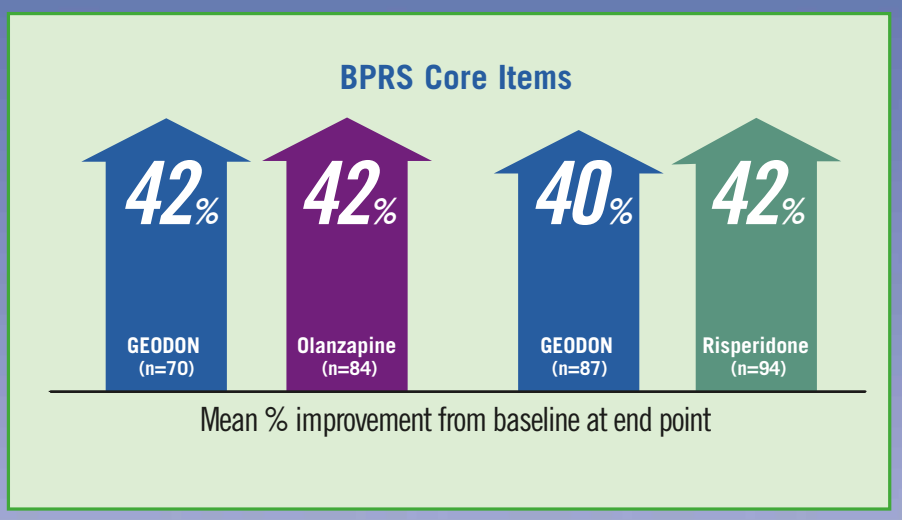
References: 1. Data on file. Pfizer Inc., New York, NY. **2.** Simpson GM, Glick ID, Weiden PJ, Romano SJ, Siu CO. Randomized, controlled, double-blind multicenter comparison of the efficacy and tolerability of ziprasidone and olanzapine in acutely ill inpatients with schizophrenia or schizoaffective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

Revised May 2005

Treat schizophrenia with the body in mind

COMPARABLE EFFICACY

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

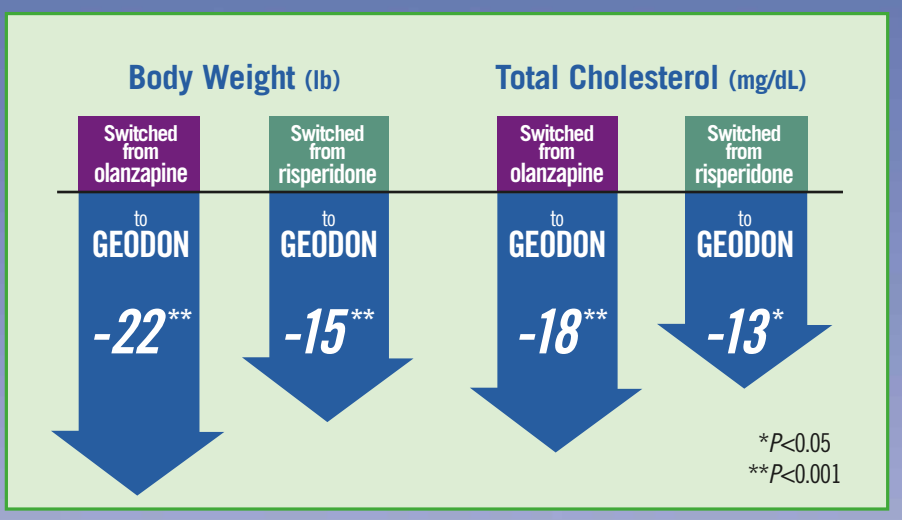


A 6-week, double-blind, randomized study of GEODON vs olanzapine and an 8-week, double-blind, randomized study of GEODON vs risperidone.

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

WITHOUT COMPROMISING METABOLIC PARAMETERS

Significant results in switch studies[1,5]



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

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

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

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

GEODON®
(ziprasidone HCl) Oral Capsules

GEODON is indicated for the treatment of schizophrenia and of acute manic or mixed episodes associated with bipolar disorder.

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

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

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

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

Please see brief summary of prescribing information on adjacent page.

Pfizer NEUROSCIENCE