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PSYCHIATRIC NEWS

inside

Job-Related Variations Found In Rescue Workers' PTSD Rates

A study published on the sixth anniversary of 9/11 reports that the prevalence rate of current probable PTSD among nearly 29,000 workers at the World Trade Center averages 12.4 percent.

BY AARON LEVIN

Training and experience go a long way in reducing the aftereffects of traumatic stress, according to a study of thousands of workers who toiled at the World Trade Center site in Manhattan in the nine months following the September 11, 2001, terror attacks.

Two to three years after the event, police officers had the lowest prevalence of posttraumatic stress disorder (PTSD) among the eight occupational groups represented among the workers, wrote Megan Perrin, M.P.H., of the Nathan S. Kline Institute for Psychiatric Research in Orangeburg, N.Y., and colleagues in the September *American Journal of Psychiatry*. The researchers used both the PTSD Checklist–Civilian Version and *DSM-IV* diagnostic criteria to evaluate PTSD.

The prevalence of current probable PTSD among the 28,962 workers enrolled in the World Trade Center Health Registry averaged 12.4 percent. Police officers showed a rate of 6.2 percent, while firefighters, emergency medical or disaster personnel, and other employees of government agencies were twice as likely to have PTSD (see chart on page 28).

Construction or engineering crew members (17.8 percent) and unaffiliated volunteers (21.2 percent) recorded the highest rates of PTSD. The latter category included people such as clergy, white-collar workers, and others who reported occupations not directly related to rescue and recovery work.

Probability of PTSD rose for all occupations other than police as the time they worked on the site increased. Not surprisingly, probabilities were higher for those who began work in the first week after the attack than among those who started after September 18.

Stepping outside of one's usual job boundaries added measurable stress, too,

please see ***PTSD*** *on page 23*

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A firefighter walks up the ramp from the site of the World Trade Center after paying his respects at a 2004 memorial on the third anniversary of the September 11, 2001, attacks. Two to three years after the attacks, firefighters were found to be twice as likely to have current probable posttraumatic stress disorder as police.

Impact of Label Warnings Felt Beyond Target Groups

While the black-box warning of suicide risk appearing on antidepressant labels applies primarily to youngsters, diagnosis and treatment for adult depression are also affected.

BY JUN YAN

From 2003 to 2005, the U.S. Food and Drug Administration (FDA) released a series of public-health advisories and required a black-box warning be added to the labeling information of antidepressants regarding increased risk of suicidality in pediatric patients. These much publicized alerts, aimed primarily at pediatric depression treatment, appear to have led to a spillover effect on the diagnosis and treatment of adults with depression, according to a study in the August *American Journal of Psychiatry*.

The various public health advisories and alerts since October 2003 issued by the FDA contained broad warnings and admitted a lack of conclusive evidence on the suicide risks in adult patients using antidepressants. This past May the black-box warning was expanded to young adults aged 19 to 24 and wording pointing out the benefits of antidepressants was added (see page 28). These changes occurred after the time frame of the current study.

The rate of diagnosis of new depressive episodes saw a decreasing trend in the two years after October 2003, when the FDA issued its initial public health advisory on antidepressant risks. The percentage of antidepressant prescriptions filled after diagnosed episodes also declined signifi-

please see ***Warnings*** *on page 28*

Come to *New Orleans*

It's not too late to register for APA's 2007 Institute on Psychiatric Services, being held October 11 to 14 at the New Orleans Marriott. The deadline to receive the discounted APA group rate for housing at the Marriott is September 20. The meeting promises to have particular meaning for community psychiatry this year: Taking advantage of the New Orleans location, APA has planned a special track of sessions called "OMNA on Tour in the Gulf Coast." See page 19 for information on the track and registration.

Contents

Features

Volume 42
Number 17
September 7, 2007

Departments

Newspaper of the American Psychiatric Association **PSYCHIATRIC news**

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APA Urges Vigilance as Public Gains Access to Physician Data

APA recommends that members check their National Provider Identifier data and correct any inaccuracies. Edits may be made at any time.

BY MARK MORAN

Ready or not, the National Provider Identifier (NPI) is here, and with its arrival anyone may be able to access information about physicians and health plans that was previously not available in one place.

At press time the Centers for Medicare and Medicaid Services (CMS) was expected to begin disseminating data early next month via the Internet to the public about health care providers and plans with an NPI as part of the National Plan and Provider Enumeration System (NPPES).

Data will be available in two forms: a query-only database, known as the NPI Registry, and a downloadable file. The NPI Registry is expected to go live on September 4, and the downloadable file should be available about one week later.

NPIs are unique identification numbers to be used in all electronic administrative and financial transactions with payers; it was mandated as part of the Health Insurance Portability and Accountability Act (HIPAA).

Most psychiatrists and other physicians must have and use an NPI, but even those who do not use electronic transactions and are not covered by HIPAA are advised to have an identifier; for instance, patients may need to have a physician's NPI when they file their own insurance claims, and physicians are required to have an NPI should they decide to opt out of Medicare.

The date of the public access had been pushed back several times, and APA, the AMA, and other physician groups have opposed the government's plan for making the information available to the general public.

APA is recommending that members check the data for accuracy and edit data that are inaccurate; edits to the NPI information can be made at any time, according to APA's Office of Healthcare Systems and Financing.

In comments submitted to CMS this summer, APA Medical Director James H. Scully Jr., M.D., noted that while some information can be deleted, much of it cannot.

Scully wrote in the comments, "The information required on the NPI application that CMS can disclose and that cannot be deleted by the provider is [the] provider's first, middle, and last names with prefixes and suffixes (or organization names); credentials; IRS employer identification number (EIN) (for organizations); full business location and mailing addresses and phone and fax numbers; date, state, country of birth; NPI number; primary health care provider taxonomy code to identify specialties; provider gender code; provider license number and provider license number state code; provider enumeration date with last update; NPI deactivation reason code and date and NPI reactivation date; and authorized official's full name, authorized official title or position, and telephone number (for organizations)."

In addition, Scully urged the agency to delay disseminating the physician information.

"After waiting over two years to publish this policy strategy, a little more time could be afforded to consider the ramifications of this policy and to ensure privacy

please see ***Data*** *on page 9*

Nominations Invited

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

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

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

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Reports of Our Death Have Been Greatly Exaggerated

BY CAROLYN ROBINOWITZ, M.D.


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In the almost 40 years since I finished residency, there have been several predictions of the death of psychiatry. Late in the 20th century, two psychiatrists—E. Fuller Torrey, M.D., and Thomas Detre, M.D., envisaged our becoming neurologists, based on the growth of neuroscience and the limits they perceived psychotherapy had in treating mental illness. This reductionistic forecast has not come to fruition. Even as research has led to a tremendous increase in neuroscience, research also has demonstrated the importance of psychotherapies in patient care, and we have come to a greater awareness of the crucial role of psychiatric physicians in providing care.

Now, we are informed of a similar prediction from a past president of the American Psychological Association. It is tempting to speculate on his motivation or how he came to this determination, but neither matters since his prediction is so far from reality at a time when our profession continues to grow immensely in its science base, stature, and effectiveness.

Public understanding of mental disorders and psychiatry's role in providing care has never been so high. Our partnerships with national advocacy organizations such as the National Alliance on Mental Illness and Mental Health America, as well as the contributions of celebrities who have spoken openly about their illness and the success of their treatment, have helped reduce stigma, fear, and blame and have united professionals, patients, families, and the public in support of research and access to nondiscriminatory care.

Federal lawmakers view us positively. The public agrees that good mental health is as important as good physical health, and research consistently has demonstrated their connections. There is broad recognition that mental disorders are real medical disorders that can be treated effectively without breaking the bank, as demonstrated by numerous health services research studies. Even the business community has recognized that good care for its employees is not only the right thing to do, but that it enhances productivity and provides benefits that far offset the cost of care. (I will discuss our extensive efforts with the business community in a future column.) And attacks on psychiatric care, motivated by emotion and prejudice, have been successfully fended off with science and data.

Our relationships with our colleagues in the rest of medicine, through the AMA and medical specialty organizations, are extremely positive and have included their support on key issues such as insurance parity and legislation to remove the Medicare discriminatory copayment for psychiatric care. Psychiatrists are highly valued leaders in medical centers where they serve as presidents and deans; research in academic departments of psychiatry is funded and flourishing, ranging from studies of psychotherapies to cellular biology. We are welcomed in our medical communities.

With the diminution of reductionistic approaches to care, psychiatrists have a more sophisticated integration of psychotherapy and psychopharmacology. When senior psychoanalysts such as Glen Gabbard, M.D., discuss treatment, they may include not only psychodynamics, but also behavioral genetics and adaptation over the life cycle, biological markers and pharmacogenomics, as well as the use of medications. PET scans demonstrate the impact of psychotherapy, mirroring changes in behavior and mood. Although many results of neuroscience research may not yet be applicable in everyday practice, this work demonstrates the importance of a biopsychosocial approach both in patients with psychiatric disorders only and those with other medical disorders as well.

With these advances come challenges to psychiatry residency training, as faculty must address the ever-expanding knowledge base, new systems and venues of care, and the associated economics, while ensuring time for the skill development so vital to good treatment. As we define and measure competencies in residency, we must also consider ways to ensure growth, maturation, and continued integration of scientific developments. My interactions with residents during my travels as president, as well as observation of residents serving on APA components and in the Assembly, add to my optimism about the strong future of psychiatry. Nonetheless, our continued success depends on hard-nosed and nondefensive examination of our professional function, as well as the education and training of the residents who represent our future. To that end, our Board approved a new committee on graduate education, which has just begun its deliberations.

Psychiatry's health is strong. Spread the word. Work for our future. ■

APA Wants To Help!

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

Federal Government Eases Medicaid Citizenship Rules

Changes to the Medicaid citizenship requirements come in response to comments from a wide range of organizations, including APA and other physician groups.

BY RICH DALY

The final rule listing proof-of-citizenship requirements for Medicaid eligibility was released in July by the Centers for Medicare and Medicaid Services (CMS). The rule has loosened the much-maligned requirements in the interim rule that had been in effect since last July.

The changes reflected in the final rule came in response to more than 1,400 public comments—including those from APA. It was published in the July 13 *Federal Register* and went into effect that same day.

The rule stemmed from the Deficit Reduction Act of 2005 (DRA), which required states to verify the identity and prove citizenship of current or potential Medicaid beneficiaries. The restrictions aimed to prevent undocumented immigrants from falsely claiming to be citizens and receiving benefits. Until passage of the DRA, Medicaid applicants in most states needed only to "self-attest" to U.S. citizenship under penalty of perjury (*Psychiatric News*, September 15, 2006). Documentation was required only from those whose citizenship status was in doubt.

The interim rule had exempted beneficiaries who received Medicare and Supplemental Security Income, because they had already met documentation requirements. The final rule expands this exemption to include people eligible for Social Security Disability Insurance.

Also exempted are children receiving adoption assistance or foster-care payments. In making that change, CMS responded to concerns from many, including APA, that children in foster care may have a hard time documenting citizenship and thus may not be able to obtain needed health care coverage under Medicaid. Foster children, APA pointed out, may be even more likely to need mental health care than other beneficiaries.

Also, as required by the Tax Relief and Health Care Act of 2006, the responsibility to verify the citizenship or immigration status of children in foster care who receive Medicaid benefits rests with the states instead of foster parents.

The final rule includes a CMS policy change that extends Medicaid benefits for up to the first year of life to a newborn whose mother was receiving Medicaid on the date of the child's birth, regardless of the mother's immigration status.

The final rule also expands the list of documents to prove citizenship status and identity beyond such documents as a U.S. passport, naturalization certificate, or certificate of U.S. citizenship. The newly approved documents include religious records filed in the United States within three months of a child's birth, as well as some school records. The Roll of Alaska Natives also was approved as evidence of citizenship.

In recent months, two independent reports have found that Medicaid's citizenship documentation requirements under the interim rule led to citizens' losing Medicaid coverage without the government's achieving the savings sought.

The Government Accountability Office (GAO) found that eligible citizens faced barriers to access when applying for Medicaid coverage under the interim rule documentation requirements. Data from 22 of 44 states studied by the GAO showed a decline in eligible citizens' Medicaid enrollment and delays in obtaining coverage.

Another report, conducted by the majority staff of the House Committee on Oversight and Government Reform, investigated nine states and found that for every $100 spent to administer the documentation requirements, the federal government saved only 14 cents.

"By way of comparison, for every $100 the Office of the Inspector General of the Department of Health and Human Services expends to investigate waste, fraud, and abuse, the federal government recovers nearly $1,300," committee chair Rep. Henry Waxman (D-Calif.), wrote in the report.

Acting CMS Administrator Leslie Norwalk said in a July 3 press release that the final rule ensures that Medicaid dollars are "spent effectively on those who are qualified for coverage." Norwalk resigned on July 20.

Further loosening of the citizenship requirements may come through reauthorization of the State Children's Health Insurance Program (SCHIP), which also is subject to the requirements. Legislation under consideration in the House (HR 3162) and Senate (S 1893) would extend SCHIP eligibility through Medicaid to all newborns within their first year of life, regardless of the mother's immigration status (see article below). Further, both SCHIP reauthorization bills would give states the option of returning to pre-DRA citizenship-documentation requirements—including parental testaments to their children's U.S. citizenship under penalty of perjury—for children, with the requirement that the state conduct audits to demonstrate compliance. Opponents said this option ultimately would allow states to set the criteria for citizenship determinations.

The Senate SCHIP reauthorization bill would further reduce administrative barriers to enrollment by encouraging states to standardize their enrollment procedures and eliminate the requirement for face-to-face interviews to complete enrollment.

CMS's final rule on Medicaid citizenship requirements is posted at <http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-3291.pdf>. ■

Many With Mental Illness Could Benefit From Changes to SCHIP

Included in the House-passed State Children's Health Insurance Program (SCHIP) expansion is the long-sought APA goal of nondiscriminatory Medicare reimbursement for outpatient mental health care.

BY RICH DALY

The House and Senate have passed large expansions in the leading federal health care program for children, known as the State Children's Health Insurance Program (SCHIP).

The measures vary in several ways, including differing provisions related to mental health care. At press time Congressional leaders planned to begin conference committee discussions to reconcile the differences this month.

Without reauthorization, SCHIP will expire on September 30. Nonetheless, the legislation faces another serious obstacle: President Bush has threatened to veto it because of the high cost and large expansion of a government-run program.

Among the provisions that have drawn cost-related criticism from opponents of the legislation is a House-passed component mandating an end to Medicare's discriminatory payment requirements for outpatient mental health services.

The House narrowly approved SCHIP reauthorization legislation (HR 3162) over Republican opposition that was based largely on the cost of the $47-billion expansion over five years, which would be financed largely by a tobacco-tax increase and cuts for managed care companies in Medicare.

The Senate, where the legislation (S 1893) has strong bipartisan support, approved a less-aggressive $35 billion expansion. Bush had proposed a $5 billion expansion of SCHIP over five years.

The bills would insure 5 million more children, in addition to the 6 million children already covered. Under the expansion, children in the program would gain coverage for dental and mental health care.

The House bill also includes $19 billion over five years to prevent scheduled cuts to physician reimbursements under Medicare. The Senate bill does not address this issue, thus it will be up to a joint conference committee to resolve the difference.

Opponents of the House bill—mainly Republicans—criticized it as the first step toward nationalized health care and said it would reduce access to Medicare and imperil seniors. The Medicare criticism was based on a provision that would reduce insurance reimbursements under Medicare Advantage plans to the level provided under standard Medicare.

Among several mental health gains in the bill was inclusion of APA's long-sought equalization of reimbursements for outpatient mental health services with those for other medical illnesses. The 50 percent coinsurance that Medicare beneficiaries have had to pay for outpatient mental health services would drop to the 20 percent coinsurance charged for all other Part B services beginning in 2008.

"By any measure, the repeal of the 50 percent coinsurance would be a huge win for patients and for APA members, a testament to the emphasis on 'pro-patient' priorities of the Board of Trustees and vindication for 20 years for relentless lobbying by staff in that time period," said Nicholas Meyers, director of APA's Department of Government Relations.

The Medicare copayment change would affect a significant number of nonelderly Medicare beneficiaries who have a disability and qualify through the Social Security Disability Insurance (SSDI) program. As many as 40 percent of SSDI beneficiaries have a mental disorder and must pay the higher cost for outpatient mental health services, according to a 1999 report by the Consortium for Citizens With Disabilities Housing Task Force.

The House-passed version, known as the Children's Health and Medicare Protection (CHAMP) Act, includes legislation APA helped develop to cover benzodiazepines under Medicare Part D and to establish new protections for access to critical psychiatric medications. The measure would lift the benzodiazepine exclusion in 2013, due to cost concerns; however, APA is lobbying to move that date closer.

The CHAMP Act also includes a temporary 5 percent increase in Medicare payments for psychotherapy services. The increase aims to offset previous payment reductions that disproportionately affected psychotherapy due to the way federal officials assign value to different medical services.

The Senate bill does not include any major Medicare provisions—such as parity—but it does provide mental health parity benefits for children enrolled in SCHIP plans. The parity provisions would prohibit discriminatory limits on mental health care in SCHIP plans by mandating that the same financial requirements and treatment limitations that apply to mental health or substance abuse services apply to other medical services.

House and Senate supporters of the measures face a challenge to produce legislation that can be approved in both chambers and withstand a presidential veto.

Negotiators must decide whether to keep the Medicare provisions and SCHIP expansion linked. APA and the AMA have lobbied for the physician-payment change, and a majority of Congress seems to agree that the cut must be averted. However, the expensive plan to reverse the physician payment cuts—estimated at $101 billion over 10 years, according to Congressional Budget Office—will require either steep cuts in other areas or additional taxes.

The text of the SCHIP reauthorization bills can be accessed at <http://thomas.loc.gov> by searching on the bill numbers, HR 3162 and S 1893. ■

State Medicaid Reforms Place More Responsibility on Patients

West Virginia and Alabama have implemented very different approaches to trying to control the rising costs of Medicaid. Mental health advocates are especially concerned about West Virginia's experiment.

BY RICH DALY

A small number of West Virginia's Medicaid-eligible population has enrolled in a new pilot program that has drawn criticism from mental health advocates for placing unreasonable demands on people with mental illness.

The pilot program, called Mountain Health Choices, operates in three counties and is designed to encourage healthy lifestyles. Enrollees are eligible to receive enhanced benefits in exchange for signing contracts that pledge they will pursue healthy behaviors, such as regular physician visits and use of necessary medications. The program offers options to help beneficiaries maintain a healthy lifestyle through weight management, cardiac rehabilitation, and nutrition-education programs.

The goal of the program is to improve state residents' overall health and reduce Medicaid's long-term costs. However, among 2,236 eligible residents, only 64 adults and 216 children had enrolled by July, according to the state Medicaid agency.

State Medicaid officials expect that as more beneficiaries learn about the program, the number of residents enrolled will increase.

The new program was made possible by the Deficit Reduction Act of 2005 (DRA), which President Bush signed into law early last year. The law gives state Medicaid officials greater latitude to amend their programs to increase cost sharing and premiums or to reduce benefits. Prior to the DRA, states seeking such sweeping alterations to their programs had to go through a public review process and be approved for a waiver by the secretary of Health and Human Services.

Several states that amended their programs under the DRA, such as West Virginia, Kentucky, and Florida, have come under criticism from mental health advocates for changes that placed a heavier program compliance burden on beneficiaries with mental illness than they are often able to meet. For example, continued access to Medicaid mental health and substance abuse benefits under West Virginia's enhanced package is based on compliance factors such as taking medication as directed and keeping all medical appointments. Beneficiaries with mental health and substance abuse problems may have difficulty complying with such requirements (*Psychiatric News*, June 2, 2006).

West Virginia Medicaid officials used their authority under the DRA to implement a Medicaid amendment in 2006 to create an "enhanced" program. The program's redesign included a choice of two benefit packages: a basic plan based on the current Medicaid service package and an enhanced plan for those who sign and adhere to a compliance agreement, which includes benefits not traditionally offered under Medicaid.

In a major change from the standard Medicaid program, the new plan limits access to chemical dependency and mental health services to those who choose the enhanced package. Access to those services is

please see ***Medicaid*** *on page 29*

Rep. Carolyn Maloney (D-N.Y., center) stands with **Jose Vito, M.D.,** and **Vivian Pender, M.D.,** at a recent event in New York. Vito is a member of APA*PAC's* Member-in-Training Advisory Group and chair of the Assembly Committee of Members-in-Training. Pender is a member of the APA*PAC* Board of Directors and a New York County District Branch Assembly representative. The visit with Maloney is part of an ongoing program at APA—through APA*PAC*—in which APA members educate federal legislators and policymakers about mental health and physician issues.

Psychiatrist Steers Ailing Institutions Down Path to Better Health

An Irish-born psychiatrist is adept at taking psychiatric hospitals and departments of psychiatry in disarray and turning them around. He thinks it may be because "when I see opportunities, I run with them."

BY JOAN AREHART-TREICHEL

Not long ago, Peter Buckley, M.D., hopped into his black Volkswagen convertible and drove a visitor across the campus of the Medical College of Georgia to show off the Department of Psychiatry's new digs.

Buckley said that he considered the new building "a very important part of my own journey, my story." Indeed, it is a tale of a psychiatrist leaving the wet, cool climate of Dublin, Ireland, and ending up in the small American city of Augusta, Ga., replete with sunshine, sultry temperatures, and the scent of magnolias.

Buckley was born in Dublin in 1962 and did his medical studies and psychiatric training at University College Dublin. In 1991, at age 29, he was doing a schizophrenia research fellowship in Dublin when, as he put it, "serendipity played in." He had the opportunity to attend a schizophrenia research meeting in Tucson, Ariz., that was organized by Charles Schulz, M.D., at the time chair of psychiatry at Case Western Reserve University in Cleveland. His contact with Schulz and other American psychiatrists led to his applying for a faculty position at Case Western, which, he said, "was just brimming with intellectual excitement, as Dr. Schulz and Dr. Herbert Meltzer had brought together stellar schizophrenia investigators from all over the world."

But then he faced the challenge of obtaining a visa to work in the United States, a challenge he met successfully. And in 1992 he and his wife moved to the United States.

"From the beginning, it confirmed itself as a great opportunity," said Buckley. He ran an outpatient program, got involved in several research projects with Meltzer, and received a start-up grant from the National Alliance for Research in Schizophrenia and Affective Disorders.

Then in 1994, opportunity knocked again. Michael Hogan, Ph.D., was commissioner of Ohio's Department of Mental Health (and later headed up the President's New Freedom Commission on Mental Health). Hogan believed that Ohio's public mental health system could profit from a strong relationship with Case Western University School of Medicine. He also believed that Buckley could facilitate that relationship. So Buckley was offered the job of medical director of a state psychiatric hospital in Cleveland.

"It was a really terrific opportunity in administrative experience at a relatively junior stage of my career, and I was very fortunate to have the support of Drs. Hogan and Schulz," he said.

The hospital was under a state mandate to improve its care and facilities. Buckley helped it do so. By 1998, the hospital was voted the best psychiatric hospital in Ohio by the National Alliance on Mental Illness. Also between 1994 and 1998, Buckley became medical director of two more state psychiatric hospitals in the Cleveland area and rose to the rank of professor and vice chair of psychiatry at Case Western.

Credit: Joan Arehart-Treichel

Although Peter Buckley, M.D., finds recruiting national talent to a small Southern city challenging, Augusta does have its amenities—for example, beautiful homes such as the one above. "Augusta is also a fantastic city to raise children in," Buckley says.

Serendipity Surfaces

In 1999 serendipity was again about to touch Buckley. The Medical College of Georgia advertised that it needed someone to head its Department of Psychiatry. Buckley was interested in the position for two reasons. One was that the dean of the medical college, Darryl Kirch, M.D., had been a schizophrenia researcher and could serve as a mentor. The other reason was that the Department of Psychiatry faculty and staff had been demoralized by a scandal involving a previous chair, who had been convicted of fraud and subsequently imprisoned. Buckley reasoned that since he had helped turn around a bad situation in Ohio, he might be able to do the same in Georgia.

In 2000 he and his wife moved to Augusta. Not long after, however, something unexpected happened. The position of chair of psychiatry at University College Dublin opened, and Buckley was invited to interview for it. "When I got on the plane to move to the United States," he said, "I never dreamt I would have a shot at such a position. Also, it was my alma mater and such a great honor!"

Not only did he interview for the position, but he was offered it, so he and his wife had to decide whether to stay in the United States or return to Ireland.

For various reasons they decided to stay. As Buckley put it, "We had taken this journey together, and it was working for us. Also by now my wife and I had become American citizens and we had two American boys. And this astounding opportunity in Ireland was eclipsed by the even more astounding opportunities in academic psychiatry that lay in America. For example, since the United States is a vastly larger country than Ireland, the possibilities for collaboration in schizophrenia research and funding for schizophrenia research are much greater here."

So with the decision made, Buckley turned his attention to the Department of Psychiatry at the Medical College of Georgia.

First, he said, the college "decided that it needed to put some muscle behind psychiatry now that it was going to have a new chair. I found that very gratifying and an indication that I had made the right career choice. It could have been a wrong one if the medical college and hospital hadn't stepped up so well together to support us." Also, he said, department faculty and staff were delighted to finally have a new chair and were "positive and encouraging."

Focus Turns to Residents

After that, he and his colleagues set about recruiting good residents "because on a daily basis the residents are so much the face of the department." And although the department had not traditionally filled its national match, it started to do so. "Filling the match," he explained, "was from my viewpoint not only a very important statement of how the department was doing, but a building block—in other words, if you filled the match one year, chances were you would fill it the next. And we have now filled the match six years in a row."

Then he and his colleagues reached out to medical students at the Medical College of Georgia to convince them that if they wanted to go into psychiatry, they could do their training there as opposed to moving elsewhere. And again they experienced success. "When you are doing a better job in the training of residents, and your clinical services are running better, then the environment for teaching medical students becomes better as well," he explained. "All boats rise with the same tide."

Moreover, under his leadership, the Department of Psychiatry formed partnerships with the medical college's neuroscience community, the Georgia Department of Mental Health, and the Carter Center. "The Carter Center," he said, "has turned out to be a wonderful promoter of the liaisons for our department, especially between us and the Georgia Department of Mental Health."

In 2004 Buckley received APA's Psychiatric Administration and Management Award for his success in turning the state psychiatric hospital in Cleveland and the

please see ***Buckley*** *on facing page*

Recruitment Challenges

Credit: Joan Arehart-Treichel

Peter Buckley, M.D.: "[R]eaching out is very important for a smaller department like ours."

Psychiatric News asked Peter Buckley, M.D., what several of his biggest challenges are in running the Department of Psychiatry at the Medical College of Georgia. "Recruitment is always a challenge," he replied. One recruitment difficulty "is that in a small department such as ours, where you have limited resources, you have to be careful of how you spend those resources. By that I mean, there is so much talent from which to recruit—for instance, someone who is an expert in anxiety disorders rather than an expert in schizophrenia."

He continued, "It is also an ongoing challenge nowadays to keep a department afloat financially. This is a crucial part of our job because, as they say, 'No margin, no mission.' But with the help of the faculty and staff within my department, we've managed to turn a deficit around and have been in the black for five years now.

"And recruiting national talent to a Southern city as small as Augusta can be challenging," Buckley added. "But it is actually a fantastic city to live in and raise children in."

Does Buckley have any lessons he might share with the chairs of other psychiatry departments? "In our jobs," he replied, "we are often torn in loyalty because we wear multiple hats and have numerous bosses. But the most important thing, I think, is to maintain a strong alliance with one's medical school and hospital.

"I also think that reaching out is very important for a smaller department like ours. It may be relevant to large departments of psychiatry as well. For example, we are working with the public mental health system in Georgia, with the Emory University Department of Psychiatry, which has been like a big sister to us, and with the departments of psychiatry in Columbia and Charleston, South Carolina, which have collaborated with us on some research projects."

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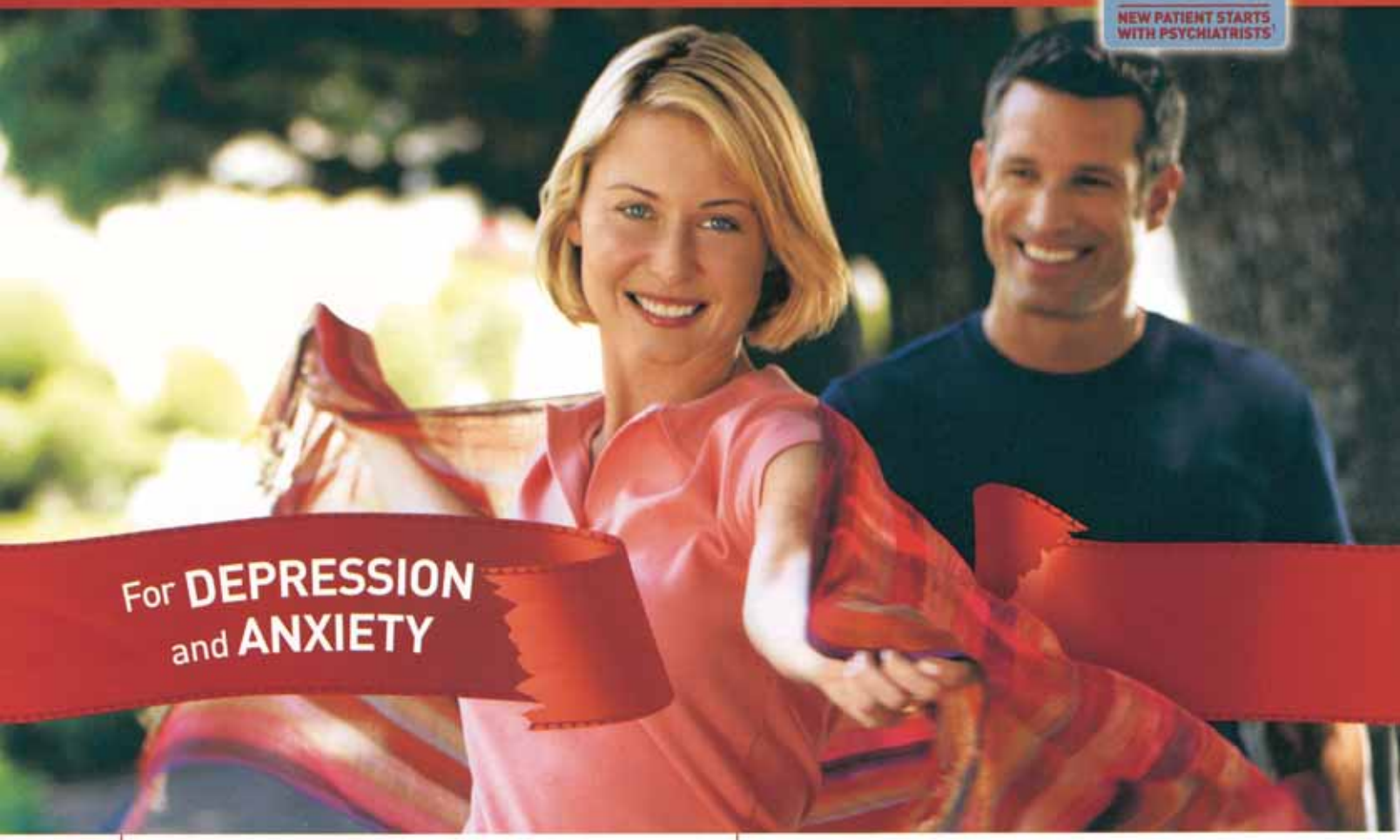

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IMPORTANT SAFETY INFORMATION - Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Antidepressants increased the risk of suicidality (suicidal thinking and behavior) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of antidepressants in children, adolescents or young adults must balance the risk to clinical need. Patients of all ages started on antidepressant therapy should be closely monitored and observed for clinical worsening, suicidality or unusual changes in behavior, especially at the beginning of therapy or at the time of dose changes. This risk may persist until significant remission occurs. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients.

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

References: 1. Verispan Weekly VONA Data (Retail Only). Twenty-four-week rolling average. September 2006. **2.** Sadock BJ, Sadock VA. *Kaplan and Sadock's Synopsis of Psychiatry: Behavioral Sciences/Clinical Psychiatry.* 9th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2003:552. **3.** LEXAPRO (package insert). St Louis, Mo: Forest Pharmaceuticals, Inc.; 2007.

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

Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Lexapro or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use)

CONTRAINDICATIONS Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated (see **WARNINGS**). Concomitant use in patients taking pimozide is contraindicated (see **Drug Interactions – Pimozide and Celexa**). Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Lexapro. **WARNINGS WARNINGS-Clinical Worsening and Suicide Risk Clinical Worsening and Suicide Risk** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs. placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in **Table 1. TABLE 1: Age Range and Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated:** Drug-Related Increases; <18 (14 additional cases); 18-24 (5 additional cases); Drug-Related Decreases; 25-64 (1 fewer case); ≥65 (6 fewer cases). No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide. It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression. **All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.** The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms (see PRECAUTIONS and DOSAGE AND ADMINISTRATION—Discontinuation of Treatment with Lexapro, for a description of the risks of discontinuation of Lexapro). **Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers.** Prescriptions for Lexapro should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. **Screening Patients for Bipolar Disorder:** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Lexapro is not approved for use in treating bipolar depression. **Potential for Interaction with Monoamine Oxidase Inhibitors In patients receiving serotonin reuptake inhibitor drugs in combination with a monoamine oxidase inhibitor (MAOI), there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Furthermore, limited animal data on the effects of combined use of SSRIs and MAOIs suggest that these drugs may act synergistically to elevate blood pressure and evoke behavioral excitation. Therefore, it is recommended that Lexapro should not be used in combination with an MAOI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days should be allowed after stopping Lexapro before starting an MAOI. Serotonin syndrome has been reported in two patients who were concomitantly receiving linezolid, an antibiotic which is a reversible non-selective MAOI.** ***Serotonin Syndrome:*** The development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including Lexapro treatment, particularly with concomitant use of serotonergic drugs (including triptans) and with drugs which impair metabolism of serotonin (including MAOIs). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The concomitant use of Lexapro with MAOIs intended to treat depression is contraindicated (see **CONTRAINDICATIONS** and **WARNINGS - Potential for Interaction with Monoamine Oxidase Inhibitors.**) If concomitant treatment of Lexapro with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **PRECAUTIONS - Drug Interactions**).The concomitant use of Lexapro with serotonin precursors (such as tryptophan) is not recommended (see **PRECAUTIONS - Drug Interactions**). **PRECAUTIONS General** Discontinuation of Treatment with Lexapro During marketing of Lexapro and other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with Lexapro. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (see **DOSAGE AND ADMINISTRATION**). Abnormal Bleeding Published case reports have documented the occurrence of bleeding episodes in patients treated with psychotropic drugs that interfere with serotonin reuptake. Subsequent epidemiological studies, both of the case-control and cohort design, have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding. In two studies, concurrent use of a nonsteroidal anti-inflammatory drug (NSAID) or aspirin potentiated the risk of bleeding (see **Drug Interactions**). Although these studies focused on upper gastrointestinal bleeding, there is reason to believe that bleeding at other sites may be similarly potentiated. Patients should be cautioned regarding the risk of bleeding associated with the concomitant use of Lexapro with NSAIDs, aspirin, or other drugs that affect coagulation. Hyponatremia Cases of hyponatremia and SIADH (syndrome of inappropriate antidiuretic hormone secretion) have been reported in association with Lexapro treatment. All patients with these events have recovered with discontinuation of escitalopram and/or medical intervention. Hyponatremia and SIADH have also been reported in association with other marketed drugs effective in the treatment of major depressive disorder. Activation of Mania/Hypomania In placebo-controlled trials of Lexapro in major depressive disorder, activation of mania/hypomania was reported in one (0.1%) of 715 patients treated with Lexapro and in none of the 592 patients treated with placebo. One additional case of hypomania has been reported in association with Lexapro treatment. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorders treated with racemic citalopram and other marketed drugs effective in the treatment of major depressive disorder. As with all drugs effective in the treatment of major depressive disorder, Lexapro should be used cautiously in patients with a history of mania. Seizures Although anticonvulsant effects of racemic citalopram have been observed in animal studies, Lexapro has not been systematically evaluated in patients with a seizure disorder. These patients were excluded from clinical studies during the product's premarketing testing. In clinical trials of Lexapro, cases of convulsion have been reported in association with Lexapro treatment. Like other drugs effective in the treatment of major depressive disorder, Lexapro should be introduced with care in patients with a history of seizure disorder. Interference with Cognitive and Motor Performance In a study in normal volunteers, Lexapro 10 mg/day did not produce impairment of intellectual function or psychomotor performance. Because any psychoactive drug may impair judgment, thinking, or motor skills, however, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro therapy does not affect their ability to engage in such activities. Use in Patients with Concomitant Illness Clinical experience with Lexapro in patients with certain concomitant systemic illnesses is limited. Caution is advisable in using Lexapro in patients with diseases or conditions that produce altered metabolism or hemodynamic responses. Lexapro has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were generally excluded from clinical studies during the product's premarketing testing. In subjects with hepatic impairment, clearance of racemic citalopram was decreased and plasma concentrations were increased. The recommended dose of Lexapro in hepatically impaired patients is 10 mg/day (see **DOSAGE AND ADMINISTRATION**). Because escitalopram is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Until adequate numbers of patients with severe renal impairment have been evaluated during chronic treatment with Lexapro, however, it should be used with caution in such patients (see **DOSAGE AND ADMINISTRATION**). **Information for Patients** Physicians are advised to discuss the following issues with patients for whom they prescribe Lexapro. Patients should be cautioned about the risk of serotonin syndrome with the concomitant use of Lexapro and triptans, tramadol or other serotonergic agents. In a study in normal volunteers, Lexapro 10 mg/day did not impair psychomotor performance. The effect of Lexapro on psychomotor coordination, judgment, or thinking has not been systematically examined in controlled studies. Because psychoactive drugs may impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro therapy does not affect their ability to engage in such activities. Patients should be told that, although Lexapro has not been shown in experiments with normal subjects to increase the mental and motor skill impairments caused by alcohol, the concomitant use of Lexapro and alcohol in depressed patients is not advised. Patients should be made aware that escitalopram is the active isomer of Celexa (citalopram hydrobromide) and that the two medications should not be taken concomitantly. Patients should be advised to inform their physician if they are taking, or plan to take, any prescription or over-the-counter drugs, as there is a potential for interactions. Patients should be cautioned about the concomitant use of Lexapro and NSAIDs, aspirin, or other drugs that affect coagulation since the combined use of psychotropic drugs that interfere with serotonin reuptake and these agents has been associated with an increased risk of bleeding. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. Patients should be advised to notify their physician if they are breastfeeding an infant. While patients may notice improvement with Lexapro therapy in 1 to 4 weeks, they should be advised to continue therapy as directed. Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Lexapro and should counsel them in its appropriate use. A patient Medication Guide about "Antidepressant Medicines, Depression and other Serious Mental Illness, and Suicidal Thoughts or Actions" is available for Lexapro. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking Lexapro. **Clinical Worsening and Suicide Risk:** Patients, their families, and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during anti-depressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to look for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication. **Laboratory Tests** There are no specific laboratory tests recommended. **Concomitant Administration with Racemic Citalopram** Citalopram - Since escitalopram is the active isomer of racemic citalopram (Celexa), the two agents should not be coadministered. **Drug Interactions Serotonergic Drugs:** Based on the mechanism of action of SNRIs and SSRIs including Lexapro, and the potential for serotonin syndrome, caution is advised when Lexapro is coadministered with other drugs that may affect the serotonergic neurotransmitter systems, such as triptans, linezolid (an antibiotic which is a reversible non-selective MAOI), lithium, tramadol, or St. John's Wort (see **WARNINGS-Serotonin Syndrome**). The concomitant use of Lexapro with other SSRIs, SNRIs or tryptophan is not recommended (see **PRECAUTIONS - Drug Interactions**). **Triptans:** There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of Lexapro with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **WARNINGS - Serotonin Syndrome**). CNS Drugs - Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs. Alcohol - Although Lexapro did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by patients taking Lexapro is not recommended. Monoamine Oxidase Inhibitors (MAOIs) - See **CONTRAINDICATIONS** and **WARNINGS**. **Drugs That Interfere With Hemostasis (NSAIDs, Aspirin, Warfarin, etc.)** Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of the case-control and cohort design that have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding have also shown that concurrent use of an NSAID or aspirin potentiated the risk of bleeding. Thus, patients should be cautioned about the use of such drugs concurrently with Lexapro. Cimetidine - In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of 400 mg/day cimetidine for 8 days resulted in an increase in citalopram AUC and C_{max} of 43% and 39%, respectively. The clinical significance of these findings is unknown. Digoxin - In subjects who had received 21 days of 40 mg/day racemic citalopram, combined administration of citalopram and digoxin (single dose of 1 mg) did not significantly affect the pharmacokinetics of either citalopram or digoxin. Lithium - Coadministration of racemic citalopram (40 mg/day for 10 days) and lithium (30 mmol/day for 5 days) had no significant effect on the pharmacokinetics of citalopram or lithium. Nevertheless, plasma lithium levels should be monitored with appropriate adjustment to the lithium dose in accordance with standard clinical practice. Because lithium may enhance the serotonergic effects of escitalopram, caution should be exercised when Lexapro and lithium are coadministered. Pimozide and Celexa - In a controlled study, a single dose of pimozide 2 mg co-administered with racemic citalopram 40 mg given once daily for 11 days was associated with a mean increase in QTc values of approximately 10 msec compared to pimozide given alone. Racemic citalopram did not alter the mean AUC or C_{max} of pimozide. The mechanism of this pharmacodynamic interaction is not known. Sumatriptan - There have been rare postmarketing reports describing patients with weakness, hyperreflexia, and incoordination following the use of an SSRI and sumatriptan. If concomitant treatment with sumatriptan and an SSRI (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram) is clinically warranted, appropriate observation of the patient is advised. Theophylline - Combined administration of racemic citalopram (40 mg/day for 21 days) and the CYP1A2 substrate theophylline (single dose of 300 mg) did not affect the pharmacokinetics of theophylline. The effect of theophylline on the pharmacokinetics of citalopram was not evaluated. Warfarin - Administration of 40 mg/day racemic citalopram for 21 days did not affect the pharmacokinetics of warfarin, a CYP3A4 substrate. Prothrombin time was increased by 5%, the clinical significance of which is unknown. Carbamazepine - Combined administration of racemic citalopram (40 mg/day for 14 days) and carbamazepine (titrated to 400 mg/day for 35 days) did not significantly affect the pharmacokinetics of carbamazepine, a CYP3A4 substrate. Although trough citalopram plasma levels were unaffected, given the enzyme-inducing properties of carbamazepine, the possibility that carbamazepine might increase the clearance of escitalopram should be considered if the two drugs are coadministered. Triazolam - Combined administration of racemic citalopram (titrated to 40 mg/day for 28 days) and the CYP3A4 substrate triazolam (single dose of 0.25 mg) did not significantly affect the pharmacokinetics of either citalopram or triazolam. Ketoconazole - Combined administration of racemic citalopram (40 mg) and ketoconazole (200 mg), a potent CYP3A4 inhibitor, decreased the C_{max} and AUC of ketoconazole by 21% and 10%, respectively, and did not significantly affect the pharmacokinetics of citalopram. Ritonavir - Combined administration of a single dose of ritonavir (600 mg), both a CYP3A4 substrate and a potent inhibitor of CYP3A4, and escitalopram (20 mg) did not affect the pharmacokinetics of either ritonavir or escitalopram. CYP3A4 and -2C19 Inhibitors - *In vitro* studies indicated that CYP3A4 and -2C19 are the primary enzymes involved in the metabolism of escitalopram. However, coadministration of escitalopram (20 mg) and ritonavir (600 mg), a potent inhibitor of CYP3A4, did not significantly affect the pharmacokinetics of escitalopram. Because escitalopram is metabolized by multiple enzyme systems, inhibition of a single enzyme may not appreciably decrease escitalopram clearance. Drugs Metabolized by Cytochrome P4502D6 - *In vitro* studies did not reveal an inhibitory effect of escitalopram on CYP2D6. In addition, steady state levels of racemic citalopram were not significantly different in poor metabolizers and extensive CYP2D6 metabolizers after multiple-dose administration of citalopram, suggesting that coadministration, with escitalopram, of a drug that inhibits CYP2D6, is unlikely to have clinically significant effects on escitalopram metabolism. However, there are limited *in vivo* data suggesting a modest CYP2D6 inhibitory effect for escitalopram, i.e., coadministration of escitalopram (20 mg/day for 21 days) with the tricyclic antidepressant desipramine (single dose of 50 mg), a substrate for CYP2D6, resulted in a 40% increase in C_{max} and a 100% increase in AUC of desipramine. The clinical significance of this finding is unknown. Nevertheless, caution is indicated in the coadministration of escitalopram and drugs metabolized by CYP2D6. Metoprolol - Administration of 20 mg/day Lexapro for 21 days in healthy volunteers resulted in a 50% increase in C_{max} and 82% increase in AUC of the beta-adrenergic blocker metoprolol (given in a single dose of 100 mg). Increased metoprolol plasma levels have been associated with decreased cardioselectivity. Coadministration of Lexapro and metoprolol had no clinically significant effects on blood pressure or heart rate. Electroconvulsive Therapy (ECT) - There are no clinical studies of the combined use of ECT and escitalopram. **Carcinogenesis, Mutagenesis, Impairment of Fertility** Carcinogenesis Racemic citalopram was administered in the diet to NMRI/BOM strain mice and COBS WI strain rats for 18 and 24 months, respectively. There was no evidence for carcinogenicity of racemic citalopram in mice receiving up to 240 mg/kg/day. There was an increased incidence of small intestine carcinoma in rats receiving 8 or 24 mg/kg/day racemic citalopram. A no-effect dose for this finding was not established. The relevance of these findings to humans is unknown. Mutagenesis Racemic citalopram was mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) in 2 of 5 bacterial strains (Salmonella TA98 and TA1537) in the absence of metabolic activation. It was clastogenic in the *in vitro* Chinese hamster lung cell assay for chromosomal aberrations in the presence and absence of metabolic activation. Racemic citalopram was not mutagenic in the *in vitro* mammalian forward gene mutation assay (HPRT) in mouse lymphoma cells or in a coupled *in vitro*/*in vivo* unscheduled DNA synthesis (UDS) assay in rat liver. It was not clastogenic in the *in vitro* chromosomal aberration assay in human lymphocytes or in two *in vivo* mouse micronucleus assays. Impairment of Fertility When racemic citalopram was administered orally to 16 male and 24 female rats prior to and throughout mating and gestation at doses of 32, 48, and 72 mg/kg/day, mating was decreased at all doses, and fertility was decreased at doses ≥ 32 mg/kg/day. Gestation duration was increased at 48 mg/kg/day. **Pregnancy** Pregnancy Category C In a rat embryo/fetal development study, oral administration of escitalopram (56, 112, or 150 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased fetal body weight and associated delays in ossification at the two higher doses (approximately ≥ 56 times the maximum recommended human dose [MRHD] of 20 mg/day on a body surface area [mg/m^2] basis). Maternal toxicity (clinical signs and decreased body weight gain and food consumption), mild at 56 mg/kg/day, was present at all dose levels. The developmental no-effect dose of 56 mg/kg/day is approximately 28 times the MRHD on a mg/m^2 basis. No teratogenicity was observed at any of the doses tested (as high as 75 times the MRHD on a mg/m^2 basis). When female rats were treated with escitalopram (6, 12, 24, or 48 mg/kg/day) during pregnancy and through weaning, slightly increased offspring mortality and growth retardation were noted at 48 mg/kg/day which is approximately 24 times the MRHD on a mg/m^2 basis. Slight maternal toxicity (clinical signs and decreased body weight gain and food consumption) was seen at this dose. Slightly increased offspring mortality was seen at 24 mg/kg/day. The no-effect dose was 12 mg/kg/day which is approximately 6 times the MRHD on a mg/m^2 basis. In animal reproduction studies, racemic citalopram has been shown to have adverse effects on embryo/fetal and postnatal development, including teratogenic effects, when administered at doses greater than human therapeutic doses. In two rat embryo/fetal development studies, oral administration of racemic citalopram (32, 56, or 112 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased embryo/fetal growth and survival and an increased incidence of fetal abnormalities (including cardiovascular and skeletal defects) at the high dose. This dose was also associated with maternal toxicity (clinical signs, decreased body weight gain). The developmental no-effect dose was 56 mg/kg/day. In a rabbit study, no adverse effects on embryo/fetal development were observed at doses of racemic citalopram of up to 16 mg/kg/day. Thus, teratogenic effects of racemic citalopram were observed at a maternally toxic dose in the rat and were not observed in the rabbit. When female rats were treated with racemic citalopram (4.8, 12.8, or 32 mg/kg/day) from late gestation through weaning, increased offspring mortality during the first 4 days after birth and persistent offspring growth retardation were observed at the highest dose. The no-effect dose was 12.8 mg/kg/day. Similar effects on offspring mortality and growth were seen when dams were treated throughout gestation and early lactation at doses ≥ 24 mg/kg/day. A no-effect dose was not determined in that study. There are no adequate and well-controlled studies in pregnant women; therefore, escitalopram should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Pregnancy-Nonteratogenic Effects** Neonates exposed to Lexapro and other SSRIs or SNRIs, late in the third trimester, have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome (see **WARNINGS**). Infants exposed to SSRIs in late pregnancy may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN). PPHN occurs in 1–2 per 1000 live births in the general population and is associated with substantial neonatal morbidity and mortality. In a retrospective, case-control study of 377 women whose infants were born with PPHN and 836 women whose infants were born healthy, the risk for developing PPHN was approximately six-fold higher for infants exposed to SSRIs after the 20th week of gestation compared to infants who had not been exposed to antidepressants during pregnancy. There is currently no corroborative evidence regarding the risk for PPHN following exposure to SSRIs in pregnancy; this is the first study that has investigated the potential risk. The study did not include enough cases with exposure to individual SSRIs to determine if all SSRIs posed similar levels of PPHN risk. When treating a pregnant woman with Lexapro during the third trimester, the physician should carefully consider both the potential risks and benefits of treatment (see **DOSAGE AND ADMINISTRATION**). Physicians should note that in a prospective longitudinal study of 201 women with a history of major depression who were euthymic at the beginning of pregnancy, women who discontinued antidepressant medication during pregnancy were more likely to experience a relapse of major depression than women who continued antidepressant medication. **Labor and Delivery** The effect of Lexapro on labor and delivery in humans is unknown. **Nursing Mothers** Racemic citalopram, like many other drugs, is excreted in human breast milk. There have been two reports of infants experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of citalopram by its mother and, in the second case, no follow-up information was available. The decision whether to continue or discontinue either nursing or Lexapro therapy should take into account the risks of citalopram exposure for the infant and the benefits of Lexapro treatment for the mother. **Pediatric Use** Safety and effectiveness in the pediatric population have not been established (see **BOX WARNING** and **WARNINGS—Clinical Worsening and Suicide Risk**). One placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients. Anyone considering the use of Lexapro in a child or adolescent must balance the potential risks with the clinical need. **Geriatric Use** Approximately 6% of the 1144 patients receiving escitalopram in controlled trials of Lexapro in major depressive disorder and GAD were 60 years of age or older; elderly patients in these trials received daily doses of Lexapro between 10 and 20 mg. The number of elderly patients in these trials was insufficient to adequately assess for possible differential efficacy and safety measures on the basis of age. Nevertheless, greater sensitivity of some elderly individuals to effects of Lexapro cannot be ruled out. In two pharmacokinetic studies, escitalopram half-life was increased by approximately 50% in elderly subjects as compared to young subjects and C_{max} was unchanged (see **CLINICAL PHARMACOLOGY**). 10 mg/day is the recommended dose for elderly patients (see **DOSAGE AND ADMINISTRATION**). Of 4422 patients in clinical studies of racemic citalopram, 1357 were 60 and over, 1034 were 65 and over, and 457 were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but again, greater sensitivity of some elderly individuals cannot be ruled out. **ADVERSE REACTIONS** Adverse event information for Lexapro was collected from 715 patients with major depressive disorder who were exposed to escitalopram and from 592 patients who were exposed to placebo in double-blind, placebo-controlled trials. An additional 284 patients with major depressive disorder were newly exposed to escitalopram in open-label trials. The adverse event information for Lexapro in patients with GAD was collected from 429 patients exposed to escitalopram and from 427 patients exposed to placebo in double-blind, placebo-controlled trials. Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tables and tabulations that follow, standard World Health Organization (WHO) terminology has been used to classify reported adverse events. The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. **Adverse Events Associated with Discontinuation of Treatment Major Depressive Disorder** Among the 715 depressed patients who received Lexapro in placebo-controlled trials, 6% discontinued treatment due to an adverse event, as compared to 2% of 592 patients receiving placebo. In two fixed-dose studies, the rate of discontinuation for adverse events in patients receiving 10 mg/day Lexapro was not significantly different from the rate of discontinuation for adverse events in patients receiving placebo. The rate of discontinuation for adverse events in patients assigned to a fixed dose of 20 mg/day Lexapro was 10%, which was significantly different from the rate of discontinuation for adverse events in patients receiving 10 mg/day Lexapro (4%) and placebo (3%). Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice that of placebo, were nausea (2%) and ejaculation disorder (2% of male patients). **Generalized Anxiety Disorder** Among the 429 GAD patients who received Lexapro 10-20 mg/day in placebo-controlled trials, 8% discontinued treatment due to an adverse event, as compared to 4% of 427 patients receiving placebo. Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice the placebo rate, were nausea (2%), insomnia (1%), and fatigue (1%). **Incidence of Adverse Events in Placebo-Controlled Clinical Trials Major Depressive Disorder Table 2** enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred among 715 depressed patients who received Lexapro at doses ranging from 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The prescriber should be aware that these figures can not be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and non-drug factors to the adverse event incidence rate in the population studied. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were insomnia, ejaculation disorder (primarily ejaculatory delay), nausea, sweating increased, fatigue, and somnolence (see **TABLE 2**). **TABLE 2: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Major Depressive Disorder* (Lexapro (N=715) and Placebo (N=592)): Autonomic Nervous System Disorders:** Dry Mouth (6% and 5%); Sweating Increased (5% and 2%). **Central & Peripheral Nervous System Disorders:** Dizziness (5% and 3%). **Gastrointestinal Disorders:** Nausea (15% and 7%); Diarrhea (8% and 5%); Constipation (3% and 1%); Indigestion (3% and 1%); Abdominal Pain (2% and 1%). **General:** Influenza-like Symptoms (5% and 4%); Fatigue (5% and 2%). **Psychiatric Disorders:** Insomnia (9% and 4%); Somnolence (6% and 2%); Appetite Decreased (3% and 1 %); Libido Decreased (3% and 1%). **Respiratory System Disorders:** Rhinitis (5% and 4%); Sinusitis (3% and 2%). **Urogenital:** Ejaculation Disorder[1,2] (9% and <1%); Impotence[2]

Drug's Cost Can Determine Availability, Court Says

A judge dismisses pharmaceutical companies' legal challenge to the British health care system's restrictions on Alzheimer's drug coverage.

BY JUN YAN

The maker of donepezil (Aricept), a medication used in the treatment of Alzheimer's disease, challenged the National Institute for Health and Clinical Excellence (NICE), which advises the state-run health systems in England and Wales on drug coverage, in court over the institute's restrictions on the product.

The court upheld the national agency's power to restrict insurance coverage of medications based on assessments of their cost-effectiveness.

The Japanese drug manufacturer Eisai, which shares the worldwide marketing of donepezil with Pfizer, brought a legal challenge against NICE over its guidance document that limits the use of the drug. In the guidance document, dated November 2006, NICE stated that the use of donepezil in patients with mild Alzheimer's was not cost-effective and thus recommended that the National Health Service (NHS) pay for the treatment for patients with Alzheimer's disease of moderate severity only (that is, those with a Mini-Mental State Examination score of between 10 to 20 points).

NICE, which was established in 1999, is responsible for systematic review of the safety, efficacy, and cost-effectiveness of drugs and medical devices. It provides guidance to the NHS in determining coverage for drugs and medical products. It is the cost-effectiveness assessment and recommendations that have sparked the dispute.

Eisai filed the lawsuit with support from Pfizer and the Alzheimer's Society, a patient-advocacy group. It argues that NICE's analyses underestimate the drug's benefits, especially the benefits for caregivers of Alzheimer's patients, and that the health-economics models used by NICE are flawed. This is the first time it has faced judicial review of its decisions.

In a ruling handed down on August 10, the judge affirmed that NICE can restrict access to medicines and rejected the plaintiffs' claims. It also ruled, however, that NICE had breached its duties by not offering specific guidance in testing the disease severity of patients with learning disabilities and those for whom English is not their first language, which might unfairly deny appropriate treatment for these patients.

The court's decision has direct implications for NHS coverage of two other Alzheimer's drugs, rivastigmine and galantamine, which are also restricted to use in patient with moderate Alzheimer's disease as recommended by the NICE guidelines. All three drugs are in the class of reversible anticholinesterase inhibitors. They have been shown to improve the symptoms of Alzheimer's disease, but there is no evidence to indicate that they reverse the course of the underlying dementia process, according to the labeling information approved by the U.S. Food and Drug Administration.

The case attracted international attention, because it could set a precedent for others to challenge government attempts to restrict or deny payment for medical treatments based on the economic "worth" of a drug's efficacy. The state-run health care systems in the United Kingdom have sought to stem the rapid growth of medical expenditure through NICE-recommended restrictions, an approach that other countries' national health systems are watching closely.

The pharmaceutical industry is increasingly seeking to stop government payers' cost-cutting efforts aimed at reducing health care spending. The Association of the British Pharmaceutical Industry has announced plans to challenge the legality of another NHS policy related to switching patients from brand-name drugs to cheaper generic substitutions, as reported by Reuters on July 4. In addition, the July 13 *Wall Street Journal* reported on a campaign in the United States by makers of epilepsy drugs to pass legislation making it more difficult to switch epilepsy patients to generic drugs.

The NICE guidance on Alzheimer's disease treatment is posted at <http://guidance.nice.org.uk/TA111/guidance/pdf/English>. ■

Buckley

continued from facing page

Department of Psychiatry at the Medical College of Georgia around (*Psychiatric News*, December 17, 2004).

But Buckley was only getting started. He launched the *Journal of Dual Diagnosis*. He set out to recruit psychiatrists with national reputations to join the department faculty. Department faculty also started participating in national cooperative and federal studies of schizophrenia.

Then a year ago, Buckley said to himself: "If peer support is as important to schizophrenia patients as it seems to be, then we should be giving our residents and medical students experience with it."

This idea led to a contract with the Georgia Department of Mental Health to try out the concept of recovery in an academic medical center. Specifically, a peer-support specialist, Gareth Fenley, joined the department staff. She is training residents on how peer support can be used to promote recovery from schizophrenia—something, Buckley said, that few other residency programs are offering. Buckley and his colleagues are also planning to conduct a study to determine exactly how effective peer support is in schizophrenia recovery.

The Medical College of Georgia has recognized Buckley's success and has renovated the only historic building on campus to the tune of $1 million and designated it as the Department of Psychiatry's new home. "It is a strategic, beautiful building, and we're very excited," Buckley said. "It is sort of a bricks-and-mortar yardstick that the department has done well."

Also, in addition to serving as chair of the Department of Psychiatry, Buckley has been promoted to the position of associate dean for faculty leadership and planning.

To what does 45-year-old Buckley attribute his professional success to date—luck of the Irish or some other factor? "I'm not sure," he chuckled. "America has been very good to me and to my family. I feel very fortunate, and people have been very kind. I am also most grateful for all the support and encouragement that my colleagues, both at the Medical College of Georgia and at other institutions across the country, have given me. But certainly when I see opportunities, I run with them. That is part of what I see as an immigrant to America—it's very rewarding when people seize opportunities." ■

Member Feedback Urgently Needed On APA Elections

By Maria T Lymberis, M.D.
Chair, APA Elections Committee

PROBLEM: The number of APA members voting in APA's 2007 national election reached a new low. Since the 1960s, the percentage of members casting ballots has been declining from a high of 59 percent in 1968 to the low of 28.8 percent in 2007. This decline has been steady and relentless, with a new low record characterizing each decade.

For a number of years now, the chronic decline in the number of APA members voting in our elections has been a major concern to the APA committees involved in the APA elections process (Elections and Tellers). Earlier this year the Board of Trustees directed the Elections Committee to study the problem and return with recommendations for improvement and correction.

The Elections Committee is examining all aspects of the APA elections process. We are asking for your participation in this effort. Please take a minute to provide us with your feedback on what you think will promote active member involvement and increase overall voter participation. Please send your responses to Chanda Brooks, staff liaison to the Elections Committee, by e-mail at cbrooks@psych.org or by fax at (703) 907-7852.

Military Deployment Stress Tied to Child-Abuse Increase

Children of U.S. Army soldiers face increased risk of maltreatment while a parent is deployed away from home.

BY AARON LEVIN

The rate of child maltreatment in families of enlisted soldiers was 42 percent higher when military spouses were off at war than when they were at home, according to a study covering all substantiated reports of child maltreatment among U.S. Army families worldwide between September 2001 and December 2004.

"The findings confirm the need for supportive and preventive services for Army families during times of deployment," wrote Deborah Gibbs, M.S.P.H., of the child and families program at RTI International in Research Triangle Park, N.C., and colleagues in the August 1 *Journal of the American Medical Association*. The U.S. Army Medical Research and Materiel Command provided funding for the study.

The study linked Army human-resource data with information from the Army Central Registry on confirmed incidents of child maltreatment or spousal abuse reported by Army medical, social-service, educational, and law-enforcement personnel. Overall, there are 1.1 million children younger than age 18 in U.S. military families. During the 40 months covered by the study, 1,858 parents in 1,771 families of enlisted soldiers neglected or abused their children, in a total of 3,334 incidents involving 2,968 children. Of those, 942 incidents occurred during deployments.

Among the families excluded from the study because of likely differences in families' experiences of deployment and small sample size were 156 families in which the soldier and civilian parent were not married.

During deployments, rates of child maltreatment rose for female civilian parents but not for male civilians, and rates were greater for non-Hispanic whites than for blacks or Hispanics, said the researchers. Children between the ages of 2 and 12 were more likely to be mistreated during deployment than those younger or older.

Female civilian parents were twice as likely to abuse a child physically and almost four times more likely to neglect a child when male soldiers were deployed than at other times, said Gibbs and colleagues. Sexual abuse rates remained almost the same.

"We see here the classic profile of child neglect," Gibbs told *Psychiatric News*. "Parents who are suffering from depression and need help the most are the least likely to seek help or accept services."

The researchers found similar increases in maltreatment rates in both lower and higher (sergeant or above) enlisted pay grades.

The study did not measure initial rates of maltreatment, only the difference between families who were dealing with deployment and those who were not.

Both single and multiple deployments affected child maltreatment rates, but more than one deployment did not appear to be associated with worse rates of maltreatment beyond those seen in families with soldiers deployed once.

That may suggest some resiliency, if validated by future research, said Stephen Cozza, M.D., associate director of the Center for Traumatic Stress and a professor of psychiatry at the Uniformed Services University of the Health Sciences in Bethesda, Md., in an interview.

"This is the first piece of data-driven analysis I've seen that looks at the effects of multiple deployments," he said. "However, based upon the statistical measures used, we cannot draw any conclusions about the relative change in risk of child maltreatment between families in which a single or multiple deployment has occurred. Many variables could be impacting these results."

Not only deployment but the increased pressures of training and other operations in shorthanded units during wartime also create stresses for families, said Cozza.

The late-2004 cutoff of Gibbs's study should prompt caution regarding the impact of multiple deployments, said Joyce Raezer, M.A., chief operating officer of the National Military Families Association.

"I suspect that at that time, increased deployments, extended tours of duty in Iraq, and diminished time at home had not yet had a major effect on Army units, as they do now," said Raezer, in an interview. "From every measure I have, things are more difficult for families now than in 2004."

Gibbs's study supports findings of an earlier study of child maltreatment rates in military families in Texas. That study found that while maltreatment rates were historically lower in military households than in comparable civilian families from 2000 to 2002, they began to rise as war approached and commenced, wrote E. Danielle Rentz, Ph.D., and colleagues (including Gibbs) in the May 15 *American Journal of Epidemiology*. Rentz was then in the Department of Epidemiology at the University of North Carolina, Chapel Hill, and is now an epidemic intelligence service officer with the Cen-

please see ***Child Abuse*** *on page 10*

Stay-at-Home Spouses of Deployed Troops At Increased Risk for Maltreating Children

Non-Hispanic, white wives of U.S. Army soldiers sent to war were more likely than other spouses to neglect or mistreat their children while their spouses were away, according to a new, Army-funded study.

	Incidents during deployment (n=942)		Incidents during nondeployment (n=2,392)	
Severity of maltreatment	**No.**	**%**	**No.**	**%**
Moderate or severe	638	67.7%	1421	59.4%
Mild	304	32.3%	971	40.6%
Type of maltreatment				
Neglect	761	80.8%	1407	58.8%
Physical abuse	97	10.3%	451	18.9%
Emotional abuse	28	3.0%	340	14.2%
Sexual abuse	18	1.9%	60	2.5%
Characteristics of offenders				
Civilian				
Female	783	83.1%	832	34.8%
Male	54	5.7%	155	6.5%
Soldier				
Female	7	0.7%	107	4.5%
Male	98	10.4%	1298	54.3%
Race/ethnicity				
Non-Hispanic white	629	69.2%	1227	53.3%
Black or Hispanic	280	30.8%	1076	46.7%
Soldier deployments				
Number of deployments				
1	693	73.6%	1852	77.4%
≥2	249	26.4%	540	22.6%

Sources: Deborah Gibbs, et al, *Journal of the American Medical Association,* August 1, 2007

VA Hopes Hotline Will Reverse Rise in Veterans' Suicides

A new suicide-prevention hotline for military veterans allows real-time use of electronic health records to guide referrals.

BY AARON LEVIN

Veterans in crisis can now call a toll-free suicide-prevention hotline for help at any time.

The hotline, at (800) 273-8255, is operated by the Department of Veterans Affairs and staffed 24 hours a day with mental health professionals who can refer callers to one of more than 120 VA crisis centers closest to them. Service in Spanish can be obtained at (888) 628-9454.

The hotline went into effect following several publicized cases in which young veterans of the Iraq war committed suicide after having difficulty accessing services at VA hospitals, according to their families.

The hotline operates nationwide and is based in a VA hospital in Canandaigua, N.Y. Nurses, social workers, or psychologists serve as staff, Gerald Cross, M.D., principal deputy assistant secretary for health at the VA, told *Psychiatric News*.

"They are able to pull up electronic health records, look at the veteran's history, make notes, and make referrals directly," said Cross. The staff members can link with suicide-prevention coordinators at VA facilities to coordinate the response to each caller.

The system began operating in July with VA staff working in cooperation with an existing Substance Abuse and Mental Health Administration (SAMHSA) hotline. The system shifted to Canandaigua in August, but arrangements have been made to direct any momentary overload to the SAMHSA system, if needed.

In the first weeks of operation, the system was handling about 60 calls a day, including some from persons who were neither veterans nor their family members.

"Part of the training will include how to handle nonveterans or to enroll veterans not yet in the VA system," said Antoinette Zeiss, Ph.D., deputy chief consultant of the VA's office of mental health services, in an interview. "If they have not signed up with the VA before they call, we can arrange for them to be met and enrolled."

The VA has taken other steps recently to cut suicide rates among veterans. Every VA facility now has a suicide-prevention coordinator and held a suicide-prevention awareness day on March 1.

The VA deserves good marks for trying to get help to suicidal veterans, said Michael O'Rourke, assistant director for veterans' health policy at the Veterans of Foreign Wars. "I hope it works well as usage rises, but I'm still concerned about referrals in remote areas."

So are people like Pat Rowe Kerr, state veterans ombudsman for Missouri.

"People aren't going to drive four hours to Kansas City before they commit suicide," Kerr told *Psychiatric News*. "The VA needs to connect with all available community-based resources so they are geographically relevant."

However, the VA has made provision for helping callers from rural areas, said Janet Kemp R.N., Ph.D., National Suicide Prevention Coordinator at the Canandiagua VA Medical Center, in an e-mail interview.

"We can make arrangements through the nearest VA to have callers seen urgently at a community facility, a nearby VA community-based clinic, or at a Vet Center," she said. "If it is an emergency situation, we will and have contacted the local rescue organization to send immediate help and stay on the line until help arrives. We then work with the local VA to arrange for follow-up where it is easiest for the veteran. Our goal is to get the veteran immediate help if needed from the best possible source."

The VA's mental health Web site is <ww.mentalhealth.va.gov>. ■

Much Room for Improvement In PTSD Care, Report States

A presidential commission says that better care for wounded troops, improved coordination between the Pentagon and the VA health systems, and a more patient-centered focus are needed.

BY AARON LEVIN

"The Departments of Defense and Veterans Affairs must rapidly improve prevention, diagnosis, and treatment of both posttraumatic stress disorder and traumatic brain injury," said a presidential commission on the care of wounded service members. "The VA should provide care for any veteran of the Afghanistan and Iraq conflicts who has PTSD, and both departments must work aggressively to reduce the stigma of PTSD."

The President's Commission on Care for America's Returning Wounded Warriors was co-chaired by former Sen. Bob Dole, a wounded World War II veteran, and Donna Shalala, president of the University of Miami and former secretary of Health and Human Services. The commission was established in the wake of revelations by the *Washington Post* of poor treatment and bureaucratic delays at Walter Reed Army Medical Center earlier this year. Dole and Shalala discussed the commission's report to the president, titled "Serve, Support, Simplify," at a news conference on July 25.

Only six of the 35 steps suggested by the panel require congressional action, said the commissioners. The others could be implemented by action within either or both of the cabinet departments.

The commission also recommended more support for the families of wounded veterans, better coordination of information between the two departments, a restructuring of disability and compensation systems, and comprehensive recovery plans for each patient.

The commission noted that while the VA had experience treating combat-related PTSD, "knowledge generated through research and clinical experience is not systematically disseminated to all DoD and VA providers of care."

"Laudable" efforts to prevent or diagnose psychological symptoms have overextended the capacity of both uniformed and VA mental health personnel, they said. Professionals in the armed services have been leaving at the end of their enlistments, and not enough new personnel have been entering the services, especially the Army. Attrition of Army psychologists increased 55 percent between 2004 and 2006, for instance. VA hospitals in isolated areas are also having a hard time recruiting professionals, a problem worsened by shortages in the civilian sector as well.

The commission echoed the findings and recommendations of other investigations and task forces, many of which seem to have gone "nowhere," according to an interview on National Public Radio with Harry Walters, who is a a former assistant secretary of the Army and served on one of those commissions.

Like the Department of Defense's recent mental health task force (*Psychiatric News*, June 15), the Dole-Shalala commission called for reducing stigma about mental health within the armed services. Many troops who spoke to the commission said they feared that reporting psychological symptoms would harm their careers or delay their return home.

More than 2,700 service members have sustained a traumatic brain injury preventing a return to duty within 72 hours, according to the commission. The Department of Defense and the VA should work together to disseminate or develop practice guidelines for traumatic brain injury and PTSD to all providers and train military leaders, medical personnel, troops, and family members to understand these conditions.

The commission also recommended development of "a patient-centered recovery plan for every seriously injured service member."

Furthermore, each patient should be assigned a trained recovery coordinator to serve as an advocate to move the patient through the military and VA medical systems and to serve as a point of contact for families. The commission said that 20 to 30 coordinators would be needed to deal with the approximately 3,100 troops seriously wounded so far in Iraq and Afghanistan.

Finally, the commission recommended creation of a personal Web page to let each service member track benefits and confidential health records and make appointments. Current online information is "disparate, confusing, and cumbersome," said the commission, and would benefit by a unified approach from both the Department of Defense and the VA.

Further information about the President's Commission on Care for America's Returning Wounded Warriors is accessible at <www.pccww.gov>. The commission's report, "Serve, Support, Simplify," and reports from its subcommittees can also be accessed at this site. ■

Data

continued from page 2

protections and enforcement," Scully said. "CMS should also promulgate regulations that specifically prohibit any commercial use for any of these data, such as reselling them or using them for direct marketing."

APA members having problems or questions regarding the NPI can contact the Managed Care Helpline at (800) 343-4671.

Information about the NPI is posted at <www.cms.hhs.gov/NationalProvIdentStand>. Physicians can apply for an NPI at no charge at <https://nppes.cms.hhs.ngov> or by calling (800) 465-3203 to request a paper application. ■

Two-Way Street Crucial To Fostering Recovery

A group of community psychiatrists discusses the importance of promoting patient recovery and suggests ways in which psychiatrists can help patients lead more meaningful lives.

BY EVE BENDER

Although psychiatrists may face barriers such as limited time or lack of training about recovery principles in their quest to help patients recover from serious mental illness, they can empower themselves—much in the same way they empower their patients—to overcome these barriers.

This was the hopeful message from a consensus conference held in Philadelphia in January 2006, the outcome of which appeared in a report in the August *Psychiatric Services*.

At the meeting, 24 community psychiatrists convened to discuss the barriers to recovery they have encountered in practice and consider ways to promote recovery in their patients.

Three major consensus points they reached involved the need to enhance psychiatrists' knowledge of recovery, the need to redefine their roles in ways that support their efforts to promote recovery, and the need to invest in recovery-oriented training throughout their careers.

One of the problems identified by psychiatrists at the meeting was that they had only a vague sense of the principles of recovery and that "those providing clinical supervisions or working day to day with patients had little training and too few opportunities to learn about recovery and its implications for their work," their report stated.

The meeting participants also believed that too few public mental health programs emphasize the tenets of recovery—empowerment, employment, and education—so that psychiatrists do not always know where to refer patients for help in these areas.

According to Mark Salzer, Ph.D., one of the article authors and an assistant professor of psychiatry at the University of Pennsylvania, psychiatrists at the meeting had a sense that there were few recovery guidelines available for them to use in their daily work with patients.

Another problem identified was that they have limited time to work with patients and perceive little opportunity for more in-depth interactions with patients. According to Salzer, they remarked that psychiatry's leaders have not done enough to "promote the importance of recovery within the field," and he noted that current reimbursement systems do not support recovery.

In addition, participants noted that there were no standardized methods of assessing the effectiveness in achievement of recovery-oriented goals.

Some of the problems identified stem from a lack of funding in the public mental health system and from injustices such as stigma toward people with psychiatric problems.

Psychiatrists at the meeting voiced a need for "more substantial funding for a wide range of rehabilitation programs that respond to recovery-oriented goals."

They suggested a number of ways to overcome the problems they identified and thus help patients lead more meaningful lives. They recommended that psychiatrists be systematically educated on the principles of recovery, for instance, and that the field develop best-practice guidelines that emphasize a range of approaches to support patients' progress toward recovery (see box).

Psychiatrist Anita Everett, M.D., helped organize the meeting and participated in the discussions. "It is critical that all psychiatrists in community practice fully understand the value of working with consumers from a recovery paradigm," she told *Psychiatric News*. "Preparing psychiatrists to be well-equipped to work in contemporary mental health centers is essential for our profession to thrive."

Everett is section director for community and general psychiatry at Johns Hopkins School of Medicine in Baltimore.

She noted that psychiatrists have moved from a more "custodial-care era" to one in which there is increased emphasis on community integration and consumers' participation in their own wellness and recovery.

The tools already available to psychiatrists include new medications that are better tolerated than medications in decades past and a more sophisticated knowledge of effective psychosocial rehabilitation and support services, Everett said.

"My favorite shorthand for recovery," she said, "is the Home Depot tag line, 'You can do it. We can help!' "

An abstract of "Barriers to Recovery and Recommendations for Change: The Pennsylvania Consensus Conference on Psychiatry's Role" is posted at <www.psychservices.psychiatryonline.org/cgi/content/abstract/58/8/1119>. ■

Promoting Recovery: Recommendations for Psychiatrists

Community psychiatrists who convened in Philadelphia last year at the Pennsylvania Consensus Conference were charged with identifying barriers they experienced in promoting recovery in their patients (see article at left). But for each barrier they identified, they also had at least one recommendation for psychiatrists and others involved in the public mental health system on ways to overcome those barriers and help patients lead more meaningful lives. The following are a summary of those recommendations:

- Establish more standardized training on the principles of recovery for medical students, residents, and practicing psychiatrists.
- Expose psychiatry residents and practicing psychiatrists more consistently to patients who have achieved recovery.
- Redefine the role of community psychiatrists to emphasize their importance in supporting recovery to ensure that they have more time to spend with patients working on recovery issues and reintegrating them into the community.
- Contribute to the development of best-practice guidelines that describe a range of approaches that support recovery goals.
- Specify recovery-oriented outcomes within federal, state, and local mental health systems to ensure that psychiatrists focus on practical recovery-oriented goals.
- Continue to establish partnerships with consumer mental health advocates and groups to further policies that support recovery-oriented systems of care.
- Transform the public mental health system to emphasize recovery and principles of integrated community care.
- Advocate for increased funding for a wide range of services in community settings for people with serious mental illness.
- Lead community education campaigns to highlight the discrimination and stigma encountered by those with serious mental illness.
- Advocate for elimination of discriminatory policies such as zoning exclusions and custody arrangements that penalize people with mental illness and for increased public funding for services that help to eliminate stigma-based policies.

Child Abuse

continued from page 8

ters for Disease Control and Prevention in Atlanta.

Rentz and colleagues looked at files from the National Child Abuse and Neglect Data System (NCANDS) for the state of Texas, which was chosen because it had a large military population and the most complete information on the military family status of child victims. They compared 1,399 children in military families with 146,583 in civilian families. Child maltreatment included physical abuse, sexual abuse, emotional abuse, and neglect.

Rates of maltreatment in civilian families remained stable throughout the study period, January 2000 to June 2003, said Rentz. Military families had lower rates than among civilians until the last six months of 2002. However, as service members were deployed to war zones in late 2002 and early 2003, rates of maltreatment in military families rose above those of civilian families.

The child maltreatment rate in military families after October 2002 was double the rate before that time, while civilian rates remained the same.

Arguments can be made in both directions for risk and protective factors when comparing civilian and military populations. On the one hand, military families face stresses like repeated relocations, separations caused by deployments, and a dangerous work environment. On the other hand, troops must meet educational, psychological, and physical health standards upon enlistment. They receive housing, health care, and both formal and informal family psychosocial support. Drug and severe alcohol abuse is not tolerated.

The threshold for tolerating child maltreatment is probably lower in military settings, but those thresholds haven't changed, said Cozza, and he believes the rate is indeed going up.

"These studies indicate the need for more scientific understanding of the impact of deployment on families and children," said Cozza.

Raezer agreed. "We're doing a good job capturing what's happening with deployed service members, but not as good a job with their families," she said. "There should be more research because there's a lot we don't know."

Better outreach, increased resources, and more effective services would help families left behind during a spouse's tour of duty, said Gibbs. The Army does have the Family Advocacy Program, family readiness support groups, and family assistance centers to help. The service has also instructed all primary care providers to ask patients about deployment in the family, screen for depression, and refer if needed, she said.

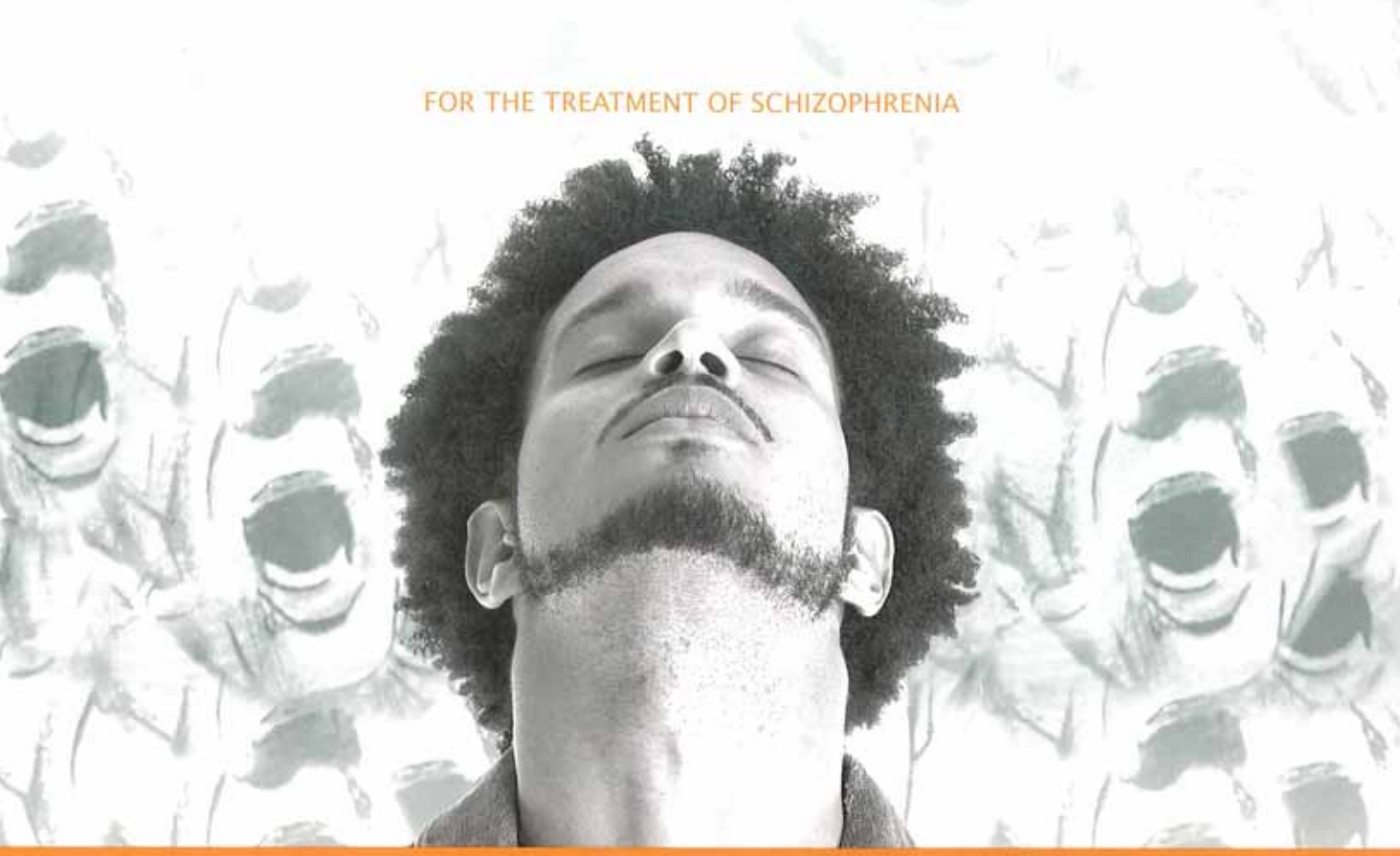
"The Army is doing more now to help than in 2002, but it's still not enough," said Raezer. "Nobody's doing enough. We need ongoing research and ongoing support."

However, further studies on this dataset depend on Congressional funding, which has not yet been authorized.

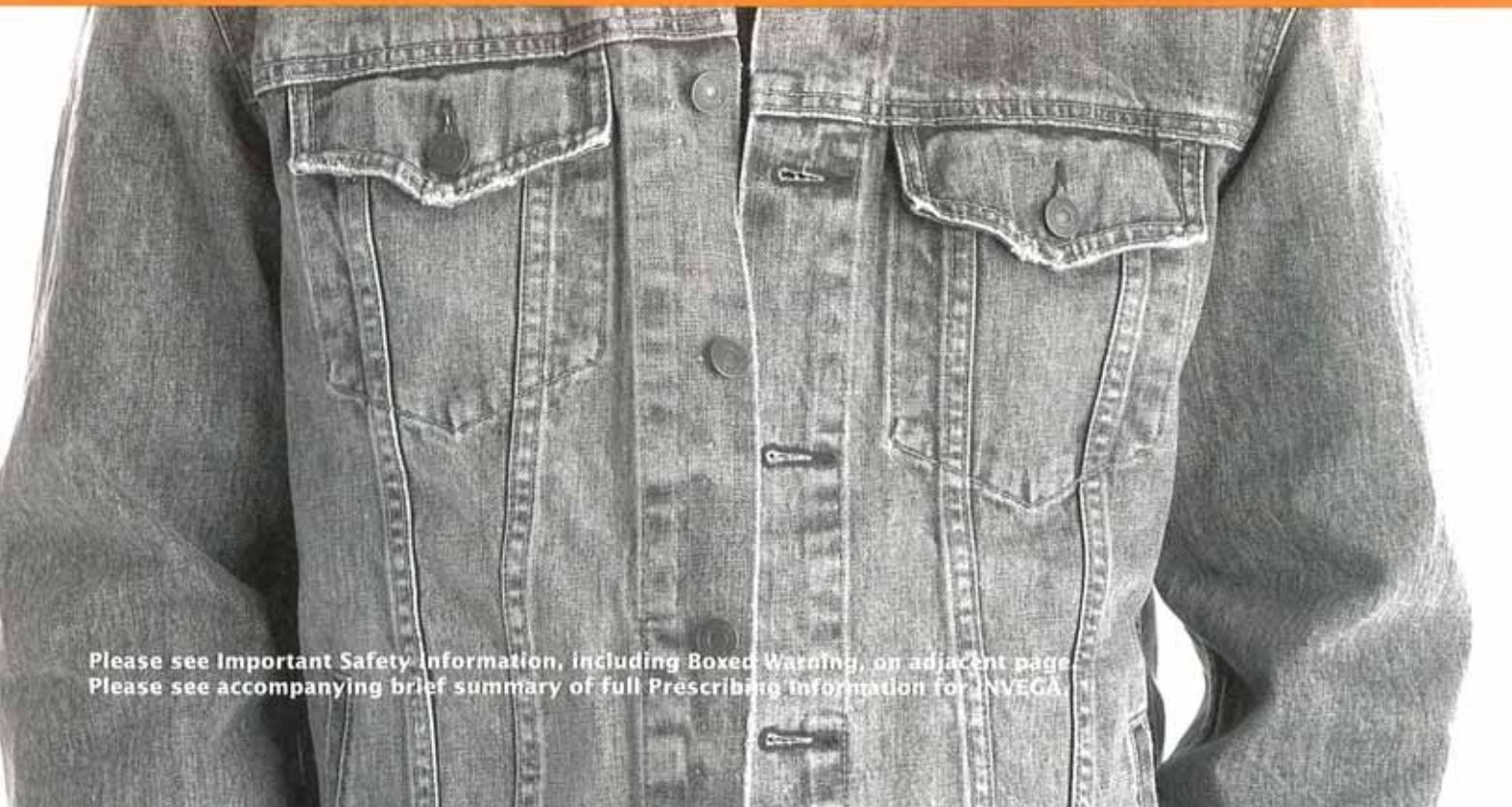
"Given the increased deployment tempo and casualties, I would really like to know what is happening," said Gibbs.

An abstract of "Child Maltreatment in Enlisted Soldiers' Families During Combat-Related Deployments" is posted at <http://jama.ama-assn.org/cgi/content/abstract/298/5/528>. ■

FOR THE TREATMENT OF SCHIZOPHRENIA



He Needs Powerful Efficacy for His Mind
But What Will It Do to His Body?



Please see Important Safety Information, including Boxed Warning, on adjacent page.
Please see accompanying brief summary of full Prescribing Information for INVEGA.

IN THE TREATMENT OF SCHIZOPHRENIA

Powerful Efficacy for the Mind

- Every dose proven to effectively control symptoms in every acute pivotal trial (6 weeks)[1]
- Demonstrated efficacy over the longer term by delaying time to relapse[2]
- The first antipsychotic to measure efficacy by improvements in personal and social performance[3]

EXPERIENCE THE

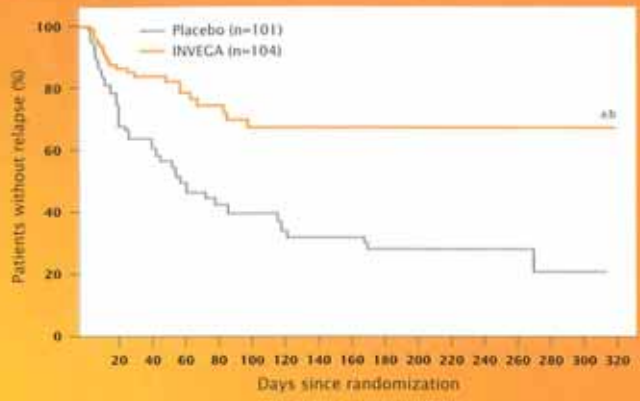
Proven Safety and Tolerability for the Body

- Weight gain comparable with placebo in 6-week clinical trials
- EPS rates comparable with placebo in 6-week trials with the recommended 6-mg dose*
- Adverse event type and severity in a longer-term trial were similar to those seen in 6-week pivotal trials

*Total EPS-related adverse events at the 9-mg and 12-mg doses were 25% and 26%, respectively, versus 11% for placebo.

Janssen L.P.

TIME TO RELAPSE[2]
(KAPLAN-MEIER PLOT OF TIME)



[a]$P<0.001$ vs placebo.
[b]Percentage of patients without recurrence at 11 months is projected.

From Kramer et al.[2]
Results from a placebo-controlled study that included a 14-week run-in and stabilization phase, during which patients received INVEGA (3 mg to 15 mg) once daily until they were deemed stable, followed by a double-blind phase in which patients were maintained on a stable dose of INVEGA or given placebo for up to 11 months. The average dose of INVEGA was 10.8 mg (average 24 weeks). The trial was ended at a predetermined interim analysis due to occurrence of a total number of relapses between the 2 groups (mean duration of therapy with INVEGA and placebo was 74 days and 56 days, respectively).[1,2]

BENEFITS OF INVEGA

WEIGHT CHANGE FROM BASELINE WITH INVEGA[1,2]

Short term (6 weeks)[c,d]

3-mg and 6-mg doses	1.3 lb
9-mg dose	2.2 lb
12-mg dose	2.4 lb
Placebo	−0.9 lb

Longer term (24 weeks)[d,e]

Data on file[1] and adapted from Kramer et al.[2]
[c]Pooled results from three 6-week pivotal trials.
[d]The proportion of patients gaining ≥7% of body weight with INVEGA was 7% (3 mg), 6% (6 mg), 9% (9 mg), and 9% (12 mg) versus 5% (placebo) in 6-week trials, and 20% (average 10.8 mg) versus 12% (placebo) in a longer-term, flexible-dose trial.
[e]Results from a longer-term trial of up to 11 months (average 24 weeks that includes a 14-week run-in and stabilization phase). The average dose of INVEGA was 10.8 mg.

Please see Important Safety Information, including Boxed Warning, on adjacent page.
Please see accompanying brief summary of full Prescribing Information for INVEGA.

INVEGA™
PALIPERIDONE
Extended-Release Tablets
STRENGTH FOR THE WHOLE PERSON

INVEGA™

(paliperidone)
Extended-Release Tablets

BEFORE PRESCRIBING, PLEASE CONSULT COMPLETE PRESCRIBING INFORMATION OF WHICH THE FOLLOWING IS A BRIEF SUMMARY

Rx only

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

INDICATIONS AND USAGE: INVEGA™ (paliperidone) Extended-Release Tablets is indicated for the acute and maintenance treatment of schizophrenia.

CONTRAINDICATIONS: INVEGA™ (paliperidone) is contraindicated in patients with a known hypersensitivity to paliperidone, risperidone, or to any components in the INVEGA™ formulation.

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

PRECAUTIONS

General: Orthostatic Hypotension and Syncope: Paliperidone can induce orthostatic hypotension and syncope in some patients because of its alpha-blocking activity. In pooled results of the three placebo-controlled, 6-week, fixed-dose trials, syncope was reported in 0.8% (7/850) of subjects treated with INVEGA™ (3, 6, 9, 12 mg) compared to 0.3% (1/355) of subjects treated with placebo. INVEGA™ should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of myocardial infarction or ischemia, conduction abnormalities), cerebrovascular disease, or conditions that predispose the patient to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Monitoring of orthostatic vital signs should be considered in patients who are vulnerable to hypotension. **Seizures:** Like other antipsychotic drugs, INVEGA™ should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold. **Hyperprolactinemia:** Like other drugs that antagonize dopamine D_2 receptors, paliperidone elevates prolactin levels and the elevation persists during chronic administration. Paliperidone has a prolactin-elevating effect similar to that seen with risperidone, a drug that is associated with higher levels of prolactin than other antipsychotic drugs. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. An increase in the incidence of pituitary gland, mammary gland, and pancreatic islet cell neoplasia (mammary adenocarcinomas, pituitary and pancreatic adenomas) was observed in the risperidone carcinogenicity studies conducted in mice and rats (see PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility). Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans, but the available evidence is too limited to be conclusive. **Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's dementia. INVEGA™ and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. **Suicide:** The possibility of suicide attempt is inherent in psychotic illnesses, and close supervision of high-risk patients should accompany drug therapy. **Potential for Cognitive and Motor Impairment:** Somnolence and sedation were reported in subjects treated with INVEGA™ (see ADVERSE REACTIONS). Antipsychotics, including INVEGA™, have the potential to impair judgment, thinking, or motor skills. Patients should be cautioned about performing activities requiring mental alertness, such as operating hazardous machinery or operating a motor vehicle, until they are reasonably certain that paliperidone therapy does not adversely affect them. **Priapism:** No cases of priapism have been reported in clinical trials with INVEGA™. **Thrombotic Thrombocytopenia Purpura (TTP):** No cases of TTP were observed during clinical studies with paliperidone. Although cases of TTP have been reported in association with risperidone administration, the relationship to risperidone therapy is unknown. **Body Temperature Regulation:** Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing INVEGA™ to patients who will be experiencing conditions which may contribute to an elevation in core body temperature. **Antiemetic Effect:** An antiemetic effect was observed in preclinical studies with paliperidone. This effect, if it occurs in humans, may mask the signs and symptoms of overdosage with certain drugs or of conditions such as intestinal obstruction, Reye's syndrome, and brain tumor. **Use in Patients with Concomitant Illness:** Clinical experience with INVEGA™ in patients with certain concomitant illnesses is limited (see CLINICAL PHARMACOLOGY: Pharmacokinetics: Special Populations: Hepatic Impairment and Renal Impairment in full PI). Patients with Parkinson's Disease or Dementia with Lewy Bodies are reported to have an increased sensitivity to antipsychotic medication. Manifestations of this increased sensitivity include confusion, obtundation, postural instability with frequent falls, extrapyramidal symptoms, and clinical features consistent with the neuroleptic malignant syndrome. INVEGA™ has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical trials. Because of the risk of orthostatic hypotension with INVEGA™, caution should be observed in patients with known cardiovascular disease (see PRECAUTIONS: General: Orthostatic Hypotension and Syncope). **Information for Patients:** Physicians are advised to discuss the following issues with patients for whom they prescribe INVEGA™. **Orthostatic Hypotension:** Patients should be advised that there is risk of orthostatic hypotension, particularly at the time of initiating treatment, re-initiating treatment, or increasing the dose. **Interference With Cognitive and Motor Performance:** As INVEGA™ has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that INVEGA™ therapy does not affect them adversely. **Pregnancy:** Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with INVEGA™. **Nursing:** Patients should be advised not to breast-feed an infant if they are taking INVEGA™. **Concomitant Medication:** Patients should be advised to inform their physicians if they are taking, or plan to take, any prescription or over-the-counter drugs, as there is a potential for interactions. **Alcohol:** Patients should be advised to avoid alcohol while taking INVEGA™. **Heat Exposure and Dehydration:** Patients should be advised regarding appropriate care in avoiding overheating and dehydration. **Administration:** Patients should be informed that INVEGA™ should be swallowed whole with the aid of liquids. Tablets should not be chewed, divided, or crushed. The medication is contained within a nonabsorbable shell designed to release the drug at a controlled rate. The tablet shell, along with insoluble core components, is eliminated from the body; patients should not be concerned if they occasionally notice something that looks like a tablet in their stool. **Drug Interactions: Potential for INVEGA™ to Affect Other Drugs** – Paliperidone is not expected to cause clinically important pharmacokinetic interactions with drugs that are metabolized by cytochrome P450 isozymes. *In vitro* studies in human liver microsomes showed that paliperidone does not substantially inhibit the metabolism of drugs metabolized by cytochrome P450 isozymes, including CYP1A2, CYP2A6, CYP2C8/9/10, CYP2D6, CYP2E1, CYP3A4, and CYP3A5. Therefore, paliperidone is not expected to inhibit clearance of drugs that are metabolized by these metabolic pathways in a clinically relevant manner. Paliperidone is also not expected to have enzyme inducing properties. At therapeutic concentrations, paliperidone did not inhibit P-glycoprotein. Paliperidone is therefore not expected to inhibit P-glycoprotein-mediated transport of other drugs in a clinically relevant manner. Given the primary CNS effects of paliperidone (see ADVERSE REACTIONS), INVEGA™ should be used with caution in combination with other centrally acting drugs and alcohol. Paliperidone may antagonize the effect of levodopa and other dopamine agonists. Because of its potential for inducing orthostatic hypotension, an additive effect may be observed when INVEGA™ is administered with other therapeutic agents that have this potential (see PRECAUTIONS: General: Orthostatic Hypotension and Syncope). **Potential for Other Drugs to Affect INVEGA™** – Paliperidone is not a substrate of CYP1A2, CYP2A6, CYP2C9, and CYP2C19, so that an interaction with inhibitors or inducers of these isozymes is unlikely. While *in vitro* studies indicate that CYP2D6 and CYP3A4 may be minimally involved in paliperidone metabolism, *in vivo* studies do not show decreased elimination by these isozymes and they contribute to only a small fraction of total body clearance. **Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis:** Carcinogenicity studies of paliperidone have not been performed. Carcinogenicity studies of risperidone, which is extensively converted to paliperidone in rats, mice, and humans, were conducted in Swiss albino mice and Wistar rats. Risperidone was administered in the diet at daily doses of 0.63, 2.5, and 10 mg/kg for 18 months to mice and for 25 months to rats. A maximum tolerated dose was not achieved in male mice. There were statistically significant increases in pituitary gland adenomas, endocrine pancreas adenomas, and mammary gland adenocarcinomas. The no-effect dose for these tumors was less than or equal to the maximum

INVEGA™ (paliperidone) extended-release tablets is indicated for the acute and maintenance treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION FOR INVEGA

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks) in these 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. INVEGA™ (paliperidone) is not approved for the treatment of patients with Dementia-Related Psychosis.

Commonly observed adverse events: The most commonly observed adverse events, occurring at an incidence of ≥5% and at least 2 times placebo, were akathisia and extrapyramidal disorder.

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

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

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

Hyperglycemia and Diabetes: Hyperglycemia, some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics (APS). Patients starting treatment with APS who have or are at risk for diabetes should undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing.

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

Cerebrovascular Adverse Events (CAEs): CAEs, including fatalities, have been reported in elderly patients with dementia-related psychosis taking atypical antipsychotics in clinical trials. INVEGA is not approved for treating these patients.

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

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, INVEGA elevates prolactin levels and the elevation persists during chronic administration.

Suicide: The possibility of suicide attempt is inherent in psychotic illnesses and close supervision of high-risk patients should accompany drug therapy.

Orthostatic Hypotension: INVEGA may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose-titration period. Monitoring should be considered in patients for whom this may be of concern. INVEGA should be used with caution in patients with known cardiovascular disease, and conditions that would predispose patients to hypotension.

Potential for Cognitive and Motor Impairment: INVEGA has the potential to impair judgment, thinking, or motor skills. Caregivers and patients should use caution until they are reasonably certain that INVEGA does not affect them adversely.

Maintenance Treatment: Physicians who elect to use INVEGA for extended periods should periodically re-evaluate the long-term risks and benefits of the drug for the individual patient.

References: 1. Data on file. Janssen, L.P., Titusville, NJ. **2.** Kramer M, Simpson G, Maciulis V, et al. Paliperidone extended-release tablets for prevention of symptom recurrence in patients with schizophrenia: a randomized, double-blind, placebo-controlled study. *J Clin Psychopharmacol.* 2007;27(1):6-14. **3.** Kane J, Canas F, Kramer M, et al. Treatment of schizophrenia with paliperidone extended-release tablets: a 6-week placebo-controlled trial. *Schizophr Res.* 2007;90:147-161.

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

recommended human dose of risperidone on a mg/m^2 basis (see risperidone package insert). An increase in mammary, pituitary, and endocrine pancreas neoplasms has been found in rodents after chronic administration of other antipsychotic drugs and is considered to be mediated by prolonged dopamine D_2 antagonism and hyperprolactinemia. The relevance of these tumor findings in rodents in terms of human risk is unknown (see PRECAUTIONS: General: Hyperprolactinemia). **Mutagenesis:** No evidence of genotoxic potential for paliperidone was found in the Ames reverse mutation test, the mouse lymphoma assay, or the *in vivo* rat micronucleus test. **Impairment of Fertility:** In a study of fertility, the percentage of treated female rats that became pregnant was not affected at oral doses of paliperidone of up to 2.5 mg/kg/day. However, pre- and post-implantation loss was increased, and the number of live embryos was slightly decreased, at 2.5 mg/kg, a dose that also caused slight maternal toxicity. These parameters were not affected at a dose of 0.63 mg/kg, which is half of the maximum recommended human dose on a mg/m^2 basis. The fertility of male rats was not affected at oral doses of paliperidone of up to 2.5 mg/kg/day, although sperm count and sperm viability studies were not conducted with paliperidone. In a subchronic study in Beagle dogs with risperidone, which is extensively converted to paliperidone in dogs and humans, all doses tested (0.31-5.0 mg/kg) resulted in decreases in serum testosterone and in sperm motility and concentration. Serum testosterone and sperm parameters partially recovered, but remained decreased after the last observation (two months after treatment was discontinued). **Pregnancy: Pregnancy Category C:** In studies in rats and rabbits in which paliperidone was given orally during the period of organogenesis, there were no increases in fetal abnormalities up to the highest doses tested (10 mg/kg/day in rats and 5 mg/kg/day in rabbits, which are 8 times the maximum recommended human dose on a mg/m^2 basis). In rat reproduction studies with risperidone, which is extensively converted to paliperidone in rats and humans, increases in pup deaths were seen at oral doses which are less than the maximum recommended human dose of risperidone on a mg/m^2 basis (see risperidone package insert). Use of first generation antipsychotic drugs during the last trimester of pregnancy has been associated with extrapyramidal symptoms in the neonate. These symptoms are usually self-limited. It is not known whether paliperidone, when taken near the end of pregnancy, will lead to similar neonatal signs and symptoms. There are no adequate and well controlled studies of INVEGA™ in pregnant women. INVEGA™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Labor and Delivery:** The effect of INVEGA™ on labor and delivery in humans is unknown. **Nursing Mothers:** In animal studies with paliperidone and in human studies with risperidone, paliperidone was excreted in the milk. Therefore, women receiving INVEGA™ should not breast-feed infants. **Pediatric Use:** Safety and effectiveness of INVEGA™ in patients < 18 years of age have not been established. **Geriatric Use:** The safety, tolerability, and efficacy of INVEGA™ were evaluated in a 6-week placebo-controlled study of 114 elderly subjects with schizophrenia (65 years of age and older, of whom 21 were 75 years of age and older). In this study, subjects received flexible doses of INVEGA™ (3 to 12 mg once daily). In addition, a small number of subjects 65 years of age and older were included in the 6-week placebo-controlled studies in which adult schizophrenic subjects received fixed doses of INVEGA™ (3 to 15 mg once daily, see CLINICAL PHARMACOLOGY: Clinical Trials in full PI). Overall, of the total number of subjects in clinical studies of INVEGA™ (n = 1796), including those who received INVEGA™ or placebo, 125 (7.0%) were 65 years of age and older and 22 (1.2%) were 75 years of age and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in response between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. This drug is known to be substantially excreted by the kidney and clearance is decreased in patients with moderate to severe renal impairment (see CLINICAL PHARMACOLOGY: Pharmacokinetics: Special Populations: Renal Impairment in full PI), who should be given reduced doses. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (see DOSAGE AND ADMINISTRATION: Dosing in Special Populations in full PI).

ADVERSE REACTIONS

The information below is derived from a clinical trial database for INVEGA™ consisting of 2720 patients and/or normal subjects exposed to one or more doses of INVEGA™ for the treatment of schizophrenia. Of these 2720 patients, 2054 were patients who received INVEGA™ while participating in multiple dose, effectiveness trials. The conditions and duration of treatment with INVEGA™ varied greatly and included (in overlapping categories) open-label and double-blind phases of studies, inpatients and outpatients, fixed-dose and flexible-dose studies, and short-term and longer-term exposure. Adverse events were assessed by collecting adverse events and performing physical examinations, vital signs, weights, laboratory analyses and ECGs. Adverse events during exposure were obtained by general inquiry and recorded by clinical investigators using their own terminology. Consequently, to provide a meaningful estimate of the proportion of individuals experiencing adverse events, events were grouped in standardized categories using MedDRA terminology. The stated frequencies of adverse events represent the proportions of individuals who experienced a treatment-emergent adverse event of the type listed. An event was considered treatment emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. The information presented in these sections was derived from pooled data from the three placebo-controlled, 6-week, fixed-dose studies based on subjects with schizophrenia who received INVEGA™ at daily doses within the recommended range of 3 to 12 mg (n = 850). Additional safety information from the placebo-controlled phase of the long-term maintenance study, in which subjects received INVEGA™ at daily doses within the range of 3 to 15 mg (n = 104), is also included. **Adverse Events Observed in Short-Term, Placebo-Controlled Trials of Subjects with Schizophrenia** The information presented in these sections were derived from pooled data from the three placebo-controlled, 6-week, fixed-dose studies based on subjects with schizophrenia who received INVEGA™ at daily doses within the recommended range of 3 to 12 mg (n = 850). Adverse Events Occurring at an Incidence of 2% or More Among INVEGA™-Treated Patients with Schizophrenia and More Frequent on Drug than Placebo Table 1 enumerates the pooled incidences of treatment-emergent adverse events that were spontaneously reported in the three placebo-controlled, 6-week, fixed-dose studies, listing those events that occurred in 2% or more of subjects treated with INVEGA™ in any of the dose groups, and for which the incidence in INVEGA™-treated subjects in any of the dose groups was greater than the incidence in subjects treated with placebo. **Treatment-Emergent Adverse Events in Short-Term, Fixed-Dose, Placebo-Controlled Trials in Adult Subjects with Schizophrenia.* Body System or Organ Class** (Dictionary-derived Term) Percentage of Patients Reporting Event INVEGA™ Placebo (N=355) first, INVEGA™ dosage once daily 3 mg (N=127) second, 6 mg N=235) third, 9 mg (N=246) fourth, 12 mg (N=242) fifth, **Percentage of subjects with adverse events** 66, 72, 66, 70, 76; **Cardiac disorders:** Atrioventricular block first degree 1, 2, 0, 2, 1; Bundle branch block 2, 3, 1, 3, <1; Sinus arrhythmia 0, 2, 1, 1, <1; Tachycardia 7, 14, 12, 12, 14; **Eye disorders:** Vision blurred 1, 1, <1, 0, 2; **Gastrointestinal disorders:** Abdominal pain upper 1, 1, 3, 2, 2; Dry mouth 1, 2, 3, 1, 3; Dyspepsia 4, 2, 3, 2, 5; Nausea 5, 6, 4, 4, 4; Salivary hypersecretion <1, 0, <1, 1, 4; **General disorders**: Asthenia 1, 2, <1, 2, 2; Fatigue 1, 2, 1, 2, 2; Pyrexia 1, 1, <1, 2, 2; **Investigations:** Blood insulin increased 1, 2, 1, 1, <1; Blood pressure increased 1, 2, <1, <1, 1; Electrocardiogram QT corrected interval prolonged 3, 3, 4, 3, 5; Electrocardiogram T wave abnormal 1, 2, 1, 2, 1; **Musculoskeletal and connective tissue disorders**: Back pain 1, 1, 1, 1, 2; Pain in extremity 1, 0, 1, 0, 2; **Nervous system disorders**: Akathisia 4, 4, 3, 8, 10; Dizziness 4, 6, 5, 4, 5; Dystonia 1, 1, 1, 5, 4; Extrapyramidal disorder 2, 5, 2, 7, 7; Headache 12, 11, 12, 14, 14; Hypertonia 1, 2, 1, 4, 3; Parkinsonism 0, 0, <1, 2, 1; Somnolence 7, 6, 9, 10, 11; Tremor 3, 3, 3, 4, 3; **Psychiatric disorders**: Anxiety 8, 9, 7, 6, 5; **Respiratory, thoracic and mediastinal disorders**: Cough 1, 3, 2, 3, 2; **Vascular disorders**: Orthostatic hypotension 1, 2, 1, 2, 4; *Table includes adverse events that were reported in 2% or more of subjects in any of the INVEGA™ dose groups and which occurred at greater incidence than in the placebo group. Data are pooled from three studies; one included once-daily INVEGA™ doses of 3 and 9 mg, the second study included 6, 9, and 12 mg, and the third study included 6 and 12 mg (see CLINICAL PHARMACOLOGY: Clinical Trials in full PI). Events for which the INVEGA™ incidence was equal to or less than placebo are not listed in the table, but included the following: constipation, diarrhea, vomiting, nasopharyngitis, agitation, and insomnia. **Dose-Related Adverse Events in Clinical Trials:** Based on the pooled data from the three placebo-controlled, 6-week, fixed-dose studies, adverse events that occurred with a greater than 2% incidence in the subjects treated with INVEGA™, the incidences of the following adverse events increased with dose: somnolence, orthostatic hypotension, salivary hypersecretion, akathisia, dystonia, extrapyramidal disorder, hypertonia and Parkinsonism. For most of these, the increased incidence was seen primarily at the 12 mg, and in some cases the 9 mg dose. **Common and Drug-Related Adverse Events in Clinical Trials** In the pooled data from three placebo-controlled, 6-week, fixed-dose studies, adverse events reported in 5% or more of subjects treated with INVEGA™ and at least twice the placebo rate for at least one dose included: akathisia and extrapyramidal disorder. **Extrapyramidal Symptoms (EPS) in Clinical Trials:** Pooled data from the three placebo-controlled, 6-week, fixed-dose studies provided information regarding treatment-emergent EPS. Several methods were used to measure EPS: (1) the Simpson-Angus global score (mean change from baseline) which broadly evaluates Parkinsonism, (2) the Barnes Akathisia Rating Scale global clinical rating score (mean change from baseline) which evaluates akathisia, (3) use of anticholinergic medications to treat emergent EPS, and (4) incidence of spontaneous reports of EPS. For the Simpson-Angus Scale, spontaneous EPS reports and use of anticholinergic medications, there was a dose-related increase observed for the 9 mg and 12 mg doses. There was no difference observed between placebo and INVEGA™ 3 mg and 6 mg doses for any of these EPS measures. **Percentage of Patients INVEGA™** Placebo (N=355) first, INVEGA™ dosage once daily 3 mg (N=127) second, 6 mg N=235) third, 9 mg (N=246) fourth, 12 mg (N=242) fifth, **EPS Group:** Parkinsonism [a] 9, 11, 3, 15, 14; Akathisia [b] 6, 6, 4, 7, 9; Use of anticholinergic medications [c] 10, 10, 9, 22, 22; [a]: For Parkinsonism, percent of patients with Simpson-Angus global score > 0.3 (Global score defined as total sum of items score divided by the number of items). [b]: For Akathisia, percent of patients with Barnes Akathisia Rating Scale global score ≥ 2. [c]: Percent of patients who received anticholinergic medications to treat emergent EPS. **Percentage of Patients INVEGA™** Placebo (N=355) first, INVEGA™ dosage once daily 3 mg (N=127) second, 6 mg N=235) third, 9 mg (N=246) fourth, 12 mg (N=242) fifth, **EPS Group**: Overall percentage of patients with EPS-related AE 11.0, 12.6, 10.2, 25.2, 26.0; Dyskinesia 3.4, 4.7, 2.6, 7.7, 8.7; Dystonia 1.1, 0.8, 1.3, 5.3, 4.5; Hyperkinesia 3.9, 3.9, 3.0, 8.1, 9.9; Parkinsonism 2.3, 3.1, 2.6, 7.3, 6.2; Tremor 3.4, 3.1, 2.6, 4.5, 3.3: Dyskinesia group includes: Dyskinesia, Extrapyramidal disorder, Muscle twitching, Tardive dyskinesia Dystonia group includes: Dystonia, Muscle spasms, Oculogyration, Trismus. Hyperkinesia group includes: Akathisia, Hyperkinesia. Parkinsonism group includes: Bradykinesia, Cogwheel rigidity, Drooling, Hypertonia, Hypokinesia, Muscle rigidity, Musculoskeletal stiffness, Parkinsonism. Tremor group includes: Tremor. **Adverse Events Associated with Discontinuation of Treatment in Controlled Clinical Studies:** Based on the pooled data from the three placebo-controlled, 6-week, fixed dose studies, there was no difference in the incidence of discontinuation due to adverse events between INVEGA™-treated (5%) and placebo-treated (5%) subjects. The types of adverse events that led to discontinuation were similar for the INVEGA™-and placebo-treated subjects, except for Nervous System Disorders events which were more common among INVEGA™-treated subjects than placebo-treated subjects (2% and 0%, respectively), and Psychiatric Disorders events which were more common among placebo-treated subjects than INVEGA™-treated subjects (3% and 1%, respectively). **Demographic Differences in Adverse Reactions in Clinical Trials:** An examination of population subgroups in the three placebo-controlled, 6-week, fixed-dose studies did not reveal any evidence of differences in safety on the basis of age, gender or race (see PRECAUTIONS: Geriatric Use). **Laboratory Test Abnormalities in Clinical Trials:** In the pooled data from the three placebo-controlled, 6-week, fixed-dose studies, between-group comparisons revealed no medically important differences between INVEGA™ and placebo in the proportions of subjects experiencing potentially clinically significant changes in routine hematology, urinalysis, or serum chemistry, including mean changes from baseline in fasting glucose, insulin, c-peptide, triglyceride, HDL, LDL, and total cholesterol measurements. Similarly, there were no differences between INVEGA™ and placebo in the incidence of discontinuations due to changes in hematology, urinalysis, or serum chemistry. However, INVEGA™ was associated with increases in serum prolactin (see PRECAUTIONS: General: Hyperprolactinemia). **Weight Gain in Clinical Trials:** In the pooled data from the three placebo-controlled, 6-week, fixed-dose studies, the proportions of subjects having a weight gain of ≥ 7% of body weight were similar for INVEGA™ 3 mg and 6 mg (7% and 6%, respectively) and placebo (5%), but there was a higher incidence of weight gain for INVEGA™ 9 mg and 12 mg (9% and 9%, respectively). **Other Events Observed During the Premarketing Evaluation of INVEGA™:** The following list contains all serious and non-serious treatment-emergent adverse events reported at any time by individuals taking INVEGA™ during any phase of a trial within the premarketing database (n = 2720), except (1) those listed in Table 1 above or elsewhere in labeling, (2) those for which a causal relationship to INVEGA™ use was considered remote, and (3) those occurring in only one subject treated with INVEGA™ and that were not acutely life-threatening. Events are classified within body system categories using the following definitions: *very frequent* adverse events are defined as those occurring on one or more occasions in at least 1/10 subjects, *frequent* adverse events are defined as those occurring on one or more occasions in at least 1/100 subjects, *infrequent* adverse events are those occurring on one or more occasions in 1/100 to 1/1000 subjects, and *rare* events are those occurring on one or more occasions in less than 1/1000 subjects. **Blood and Lymphatic System Disorders:** *rare*: thrombocytopenia; **Cardiac Disorders:** *frequent*: palpitations; *infrequent*: bradycardia; **Gastrointestinal Disorders:** *frequent:* abdominal pain; *infrequent*: swollen tongue; **General Disorders:** *infrequent*: edema; **Immune Disorder:** *rare*: anaphylactic reaction; **Nervous System Disorders:** *rare*: coordination abnormal; **Psychiatric Disorders:** *infrequent*: confusional state; **Respiratory, Thoracic and Mediastinal Disorders:** *frequent*: dyspnea; *rare*: pulmonary embolus; **Vascular Disorders:** *rare*: ischemia, venous thrombosis; The safety of INVEGA™ was also evaluated in a long-term trial designed to assess the maintenance of effect with INVEGA™ in adults with schizophrenia (see CLINICAL PHARMACOLOGY: Clinical Trials in full PI). In general, adverse event types, frequencies, and severities during the initial 14-week open-label phase of this study were comparable to those observed in the 6-week, placebo-controlled, fixed-dose studies. Adverse events reported during the long-term double-blind phase of this study were similar in type and severity to those observed in the initial 14-week open-label phase. **Adverse Events Reported With Risperidone**; Paliperidone is the major active metabolite of risperidone. Adverse events reported with risperidone can be found in the ADVERSE REACTIONS section of the risperidone package insert.

DRUG ABUSE AND DEPENDENCE

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

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

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Janssen

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PSYCHIATRIC PRACTICE & MANAGED CARE
APA OFFICE OF HEALTHCARE SYSTEMS AND FINANCING

SSA Disability Applicants Require Rapid Response

Staff from the Social Security Administration's (SSA's) Office of Disability Programs met with APA staff this summer to ask for help in reassuring psychiatrists that complying with requests for medical information required for their patients' Social Security disability applications in no way violates confidentiality protections for patients' medical information as mandated by HIPAA (Health Insurance Portability and Accountability Act). Apparently SSA reviewers are often unable to process disability claims because physicians are reluctant to supply the information requested. This is the case even though the request for information is made on Form SSA-827, Authorization to Disclose Information to the Social Security Administration, which is signed by the patient.

When physicians fail to respond to requests for medical records, disability applicants encounter delays in being approved for and receiving the benefits to which they are entitled. Since close to 40 percent of all the disability claims received by SSA are based on mental impairments, it is especially important that psychiatrists understand how the process works and what is required of them. SSA recognizes the special concerns psychiatrists have about the confidentiality of patients' treatment records and has asked for APA's assistance in providing information to psychiatrists so they can respond to requests for medical information without hesitation. So here are the facts:

Although Social Security Disability Insurance (SSDI) is a federal program, the application process is conducted by state disability offices. This duality may account for some confusion, because the request-for-records letter from the state may not make it clear that the information requested is needed for an SSDI determination.

Generally, a patient who wants to apply for disability fills out an application at the local Social Security office. As part of this process the applicant is asked to provide contact information for all of the medical professionals who can furnish information related to the disability claim. The applicant also is asked to fill out the SSA-827 form mentioned above, which is good for one year. This is a legal document that ensures that patient confidentiality is honored. The state disability office sends this form and a request for information about the applicant to the medical professionals listed by the applicant. Sometimes a form is filled out for each medical professional listed by the applicant, but it is just as likely that the request for records will include only a copy of the form filled out by the applicant, which includes all the listed medical professionals. Either form is legal.

If you receive a letter requesting a patient's medical records that includes a form SSA-827, it is important to understand that it has been sent to you at the patient's request. Your patient has identified you as a medical professional who has information that can help him or her obtain the disability benefits applied for. The application cannot be processed until the requested medical information is received.

If you prefer to send a report on the patient's condition rather than a copy of the patient's medical record, all the specific information SSA needs to determine the validity of the patient's claim is listed online at <www.ssa.gov/disability/professionals/greenbook/ce-adult.htm>. Just scroll down until you get to the heading "Mental Disorders."

SSA reviewers are not interested in your psychotherapy notes; they are interested only in the patient's medical record. Under HIPAA, psychotherapy notes must be kept separate from the rest of the patient's medical record and are defined as "notes. . . documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session." Psychotherapy notes do not include medication prescription and monitoring, therapy session start and stop times, modalities and frequency of treatment, results of clinical tests, and summaries of diagnosis, functional status, the treatment plan, symptoms, progress to date, or prognosis.

If your psychotherapy notes are enmeshed with the rest of the patient's medical record, you are permitted to release them as well or you may redact the "psychotherapy note" portions before you send the medical record to the reviewers. SSA will not redisclose the medical records it receives to other entities or individuals without the applicant's prior written consent, except in the limited manner permitted by federal law and regulations.

More information about requests for patient records to support disability claims is posted at <www.socialsecurity.gov/disability/professionals>. ■

Psychiatric Practice & Managed Care (PP&MC) provides news and updates on practice management issues to APA members. PP&MC is printed bimonthly in *Psychiatric News* and is posted in PDF format under "Psychiatric Practice" on APA's Web site.

Do You Need Two National Provider Identifier Numbers?

If you have incorporated your practice—even if you are a solo provider—you need to have two national provider identifiers (NPIs) to bill Medicare appropriately: one for you, the physician who provided the care the claim is for, and one for the corporation under which you bill. The Type I NPI, for individuals, must be listed on form CMS 1500 (08-05 version) in box 24j ("Rendering Provider ID #"). The Type II NPI, for incorporated organizations, must be listed in box 33a, under "Billing Provider Info & Ph #."

If your practice is a sole proprietorship rather than a corporation, you need to use only the Type I NPI, which can be listed in both box 24j and 33a on the 1500 form.

The use of NPIs began for most health entities on May 23. ■

Medicare Fees May Decrease Again In 2008 Unless Congress Acts

As those of you who see Medicare patients are well aware, in 2007 Medicare fees for psychiatry codes fell an average of about 7 percent. This occurred despite the fact that Congress voted to use the 2006 conversion factor to calculate Medicare fees.

Unfortunately, the Medicare program must maintain "budget neutrality," and since payments for more than 300 procedure codes (including the frequently used evaluation and management [E/M] codes) increased for 2007 following the mandated five-year review of work values by the AMA/Specialty Society Relative Value Update Committee (RUC), CMS determined that a corresponding decrease in the work values for all *CPT* codes was required to compensate for this.

For 2008 the RUC has called for an average 32 percent boost in the payments for anesthesiology codes, as well as for increases in some other codes. To compensate, for the 2008 fee schedule CMS has proposed to increase the negative budget adjuster for work values from last year's 10.1 percent to 11.8 percent. This means there will be a drop in work values across the board of 1.7 percent.

APA, along with the AMA and other medical specialty societies, has been lobbying Congress long and hard to stanch the decline in Medicare physician fees. All groups advocate spreading any budget-neutrality adjustment across all relative value units instead of just making an adjustment to the work values. This is especially important for psychiatry, since work values for psychiatry codes account for as much as 75 percent of the codes' values.

The recently passed bill by the House of Representatives to reauthorize the State Children's Health Insurance Program (see page 4) includes a provision for a slight increase in Medicare physician fees, but the Senate version does not.

As it stands now, even if Congress acts to eliminate the overall 9.9 percent cut to the fee-schedule conversion factor that is mandated by the law (as it has done for the past several years), there will still be a decrease in fees created by the change in work values that was necessitated by the increase in value of the anesthesiology and other codes. ■

From the Help Line Database: How to Terminate Treatment

APA's Managed Care Help Line frequently receives calls from members asking about what steps they must take to terminate their treatment relationship with a patient appropriately and limit liability risk.

Though the reasons may vary regarding why the patient's treatment is being terminated—the patient has failed to follow treatment instructions, the psychiatrist believes another therapist could provide better treatment, the psychiatrist is no longer in the patient's treatment network, the psychiatrist is retiring, or the psychiatrist believes the patient no longer requires treatment—the steps that must be taken are the same to ensure that there will be no potential liability for having abandoned the patient.

- It is ***never*** appropriate to sever a treatment relationship when a patient is in an emergency situation unless the patient agrees to see another clinician or is hospitalized.
- Give the patient reasonable notice and time to find a new therapist. This means a minimum of 30 days.
- Assist the patient in the process of finding a new therapist.
- Provide records and information as requested by a new therapist.

The psychiatrist should send a letter to the patient explaining the reason for the termination even if the psychiatrist provides the patient with this information in person or on the phone. The letter should offer assistance in finding a new therapist if continuing therapy is indicated.

Complete information about ending a relationship with a patient and a template for a termination letter is posted on APA's Web site at <www.psych.org/members/download.cfm?file=1693>.

If you have any questions about terminating patient relationships, call the Managed Care Help Line at (800) 343-4671. ■

When Mass Tragedy Struck, MH Responders Were Ready

To provide her local community with support after the deadliest mass shooting in U.S. history, a mental health professional calls on a cadre of trained volunteers to address the mental health needs of those affected.

BY EVE BENDER

When the first shots rang out on the Virginia Tech campus in Blacksburg on April 16, one phone call to the New River Valley Community Disaster Response Coalition (CDRC) launched a carefully synchronized plan that would ultimately extend much-needed support to thousands of people whose lives were affected by the shootings.

"People have a hard time believing that a disaster will ever affect them," said Dorinda Miller, Ph.D., in an interview with *Psychiatric News*.

Miller, along with several others, created the CDRC in 2002 with funds from the American Psychiatric Foundation. The goal was to meet the mental health needs of people affected by disaster in the New River Valley, an area that encompasses four mountainous counties and includes Blacksburg, Va., home of Virginia Tech.

When the deadliest mass shooting in U.S. history took place in the quiet college town, Miller, together with an entire community of trained volunteers, was ready to spring into action.

Miller noted that the genesis of the New River Valley CDRC began with the 9/11 terrorist attacks.

At the time, she was providing mental health relief services at the Pentagon with the Red Cross and said she realized that there was no way one agency could hope to meet the disaster mental health needs of an entire community and that she would need to form partnerships with other agencies in the New River Valley, where she ran A-Kee Inc., a nonprofit organization dedicated to providing the community with disaster-relief mental health services and education.

Her goal was to develop a program that would provide consistent disaster mental health training to local mental health clinicians and community members and forge partnerships with local emergency and rescue teams.

Credit: Kent Miller

Community Disaster Response Coalition President Dorinda Miller, Ph.D., disseminates information about disaster mental health services offered by her organization at a fair in Blacksburg, Va.

Miller worked with colleagues Amy Forsyth-Stephens,M.S.W., and Harvey Barker, Ph.D., the head of the New River Valley Community Services Center, a mental health agency, to develop a disaster mental health protocol.

In doing so, she sought guidance from local county emergency coordinators and the emergency planner for Virginia Tech. She then began recruiting volunteers to train them to provide disaster mental health services by using a curriculum she developed.

The daylong training, according to Miller, educates volunteers about crisis-intervention techniques, good-listening techniques, symptoms indicating an individual needs to be referred to a mental health clinician in the community, confidentiality of victims and family members, and ways to take care of themselves under stressful situations. Trainees also learn about how disasters affect certain populations, such as children, the elderly, and people with various types of disabilities.

Training typically takes place three or four times a year and is free, according to Miller.

Most Trainees are Laypeople

Miller's approach, she noted, focuses on resilience and empowerment and is not meant to probe victims about the trauma they have endured. "We want to keep people functioning," she noted.

About one-third of the CDRC trainees are licensed and nonlicensed mental health professionals from the community. Many work with the New River Valley Community Services Center, which provides mental health services to the community, including substance abuse workers, emergency service workers, case managers, and residential support personnel. Two-thirds of CDRC trainees are laypeople—hairdressers, retired seniors, students, business people, clergy, and teenagers.

All of the CDRC volunteers take the same course in disaster mental health because "they are all novices in terms of disaster operations," Miller said.

Community Liaisons Established

One of the most important aspects of the CDRC is its partnerships with various community organizations, including the local branch of the Red Cross, hospitals, hospices, emergency medical technicians, clergy, schools, fire/rescue squads, and police. "We teach them about what we do and how they can use us," Miller said.

Prior to the Virginia Tech shootings, volunteers with the CDRC responded mostly to floods and fires.

The CDRC serves to supplement New River Valley Community Services, which is designated as the lead agency in disaster mental health, as well as the local branch of the Red Cross. By the time of the Virginia Tech shootings in April, the capacities of the CDRC volunteers were ready to be put to the test.

"With the bulk of the shootings over in 45 minutes," noted Forsyth-Stephens, director of the New River Valley Mental

please see ***Responders*** *on page 23*

Minn. Psychiatrists Reach Out After Fatal Bridge Collapse

Psychiatrists' offer to help after a bridge fell into the Mississippi River may be overshadowed by the "group therapy" of a community's common shock and grief.

BY AARON LEVIN

The collapse of the I-35W bridge over the Mississippi River in downtown Minneapolis on August 1 reverberated emotionally throughout the Twin Cities, psychiatrist Alan Radke, M.D., told *Psychiatric News*.

"Everybody knows the bridge and has traveled over it, so the impact was communitywide," said Radke, medical director for the Minnesota Department of Human Services' State Operated Services and chair of the Minnesota Psychiatric Society's Disaster Preparedness Committee.

Radke is no exception. He lives nearby and had ridden his bicycle to work every day on roads running beneath the span. His son-in-law was driving toward the bridge at 6:05 p.m. that Wednesday and watched it buckle, but he was able to drive safely off the last exit ramp.

©Marie Park Foss/epa/Corbis

The Minnesota Psychiatric Society is coordinating its long-term response to the I-35W bridge collapse with the Red Cross, focusing on first responders and alerting parents and teachers about symptoms among children, said society disaster chair Alan Radke, M.D.

Chance probably prevented even more deaths than the 13 reported as of late August. About 100 cars were on the bridge as it went down, but police, firefighters, and the public responded immediately to help survivors, said Radke. Red Cross headquarters were within walking distance of the disaster, which helped that organization take the lead in providing rescue services and services to survivors and families.

"We thought of ourselves as complementing that response, so coordination with the Red Cross was important," he said. "We expect our role in the longer term will be largely educational, preparing parents and teachers to be alert for behavioral symptoms among children as school starts, and becoming a resource for first responders—through the Red Cross—if needed."

The Minnesota Psychiatric Society (MPS) issued a press release expressing sympathy to the families and friends of the victims of the bridge collapse and pointing out possible psychological effects on victims and other citizens.

"Affected individuals may have various stress reactions that present psychological as well as physical symptoms," said the release. "If you feel anxious, angry, or sad, you are not alone. Talk to friends, family, or peers who likely are experiencing the same feelings."

Radke asked MPS members, by e-mail the next day through the chapter's executive director, to be available to the public for help if requested.

As the event became the region's center of attention, however, he saw that processing death and destruction was more an impromptu form of communitywide group therapy than anything directed by mental health professionals.

please see ***Bridge*** *on page 28*

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Researchers in Hunt for Key To Preventing Schizophrenia

As the science has progressed, identification of at-risk individuals has advanced beyond targeting those on the very cusp of psychosis to those who are even earlier in the developmental process of schizophrenia.

BY MARK MORAN

Preventing Psychosis

THIS IS PART ONE OF A TWO-PART SERIES ON PREVENTION OF SCHIZOPHRENIA, FOCUSING ON THE WORK OF STAFF AND CLIENTS AT THE PRIME CLINIC IN TORONTO.

"I knew from the beginning there was something wrong with me."

Call him "Sam." He is a patient—or a "client," since he doesn't yet have a diagnosis—at a clinic whose purpose is not to cure him of illness, but to prevent it from happening. At 19, he looks and dresses like any of the thousands of young people at the nearby University of Toronto—jeans, T-shirt, and sneakers. There is little about him that marks him as a young man at risk for a severe mental illness; a slight nervousness maybe, as if he were watching his words or watching himself, fearful of slipping up.

On the surface, his story as he describes it is not so out of the ordinary either—a breakup with a girlfriend, spending a lot of time by himself, a sudden drop in his grades. But he also described an anomalous physical ailment, a sense of being paralyzed in his sleep.

"And then I began to feel that people were looking at me," he said. "Like, if I was on a street corner in a crowd and I saw someone staring at me, I thought they might be watching me."

"Sam" is a client at the PRIME (Prevention Through Risk Identification, Management and Education) Clinic in downtown Toronto, at the Centre for Addiction and Mental Health (CAMH). He agreed to share his story with *Psychiatric News* anonymously.

CAMH is affiliated with the University of Toronto and is Canada's leading addiction and mental health teaching hospital. Following referral by a college counselor and a lengthy battery of standardized psychological and neuropsychological tests—including the Scale of Prodromal Symptoms (SOPS), Positive and Negative Syndrome Scale (PANSS), Calgary Depression in Schizophrenia Scale (CDSS), and the Schizophrenia Predictive Instrument-Adult Version—he was found to be a risk for psychosis.

Staff at PRIME say the specificity of Sam's thoughts about who he believed was watching him and why—along with other symptoms—convinced them that he was on the verge of conversion to psychosis.

Now, he comes periodically to the clinic to talk to therapists and to psychometric "raters" who assess his progress (or his deterioration). And as a subject in a multicenter study looking at the efficacy of alternative methods for preventing or delaying the onset of schizophrenia, Sam is a participant in unique public-health initiative that is on a far frontier of schizophrenia research.

Credit: Mark Moran

Whether they go on to develop psychosis or not, individuals who arrive at the PRIME Clinic in Toronto typically come of their own accord with serious psychological and emotional problems. "These people are help-seeking individuals who merit some kind of treatment in any case," says Jean Addington, Ph.D.

"Individuals who come to us say, 'A change has come over me, and I can't explain what it is,' " PRIME Clinic psychiatrist Irvin Epstein, M.D., told *Psychiatric News*. "They are starting to feel that the whole world is strange to them, they don't feel right about themselves, they feel awkward in company or in school, and they are starting to lack focus and direction. They describe being anxious, but they don't know why, and they sense they are starting to lose their emotional connections to others."

Today there is a growing scientific confidence in the validity of the "prodrome," the prepsychotic signs and symptoms that schizophrenia researchers believe precede an acute psychotic episode. As the science has progressed, identification of at-risk individuals has advanced beyond targeting those on the very cusp of psychosis to those who are even earlier in the developmental process of schizophrenia.

"The field is starting to mature," Epstein said. "We are out of the period of infancy and uncertainty, and we now have a better idea of whom we should be targeting and what the symptoms are. Originally we were catching people on the verge of psychosis. These were people who didn't require a professional to appreciate that they were at risk of psychosis. In essence, what we were doing was trying to identify and to limit the extent of the inevitable psychosis.

"Now we are getting people who have a subjective sense that something in their world is changing, and it is really transforming the scope of what we are trying to accomplish from improving the outcome to really preventing the onset of a first episode."

Better Predictive Model Sought

Yet prevention of schizophrenia remains an effort on the cutting edge of research and clinical practice and still has significant obstacles to overcome.

"Currently we have a set of criteria for the prodrome [see table], and if people meet these criteria, we know that approximately 20 percent to 30 percent will go on to develop schizophrenia," said lead investigator at PRIME, Jean Addington, Ph.D. "That's good, and it's much better than if you simply follow those at genetic high risk. But it's not good enough to be treating people with medication. For our next step we really need to improve our predictive model."

An important step toward that goal was taken with the publication of the May *Schizophrenia Bulletin* in which aggregated data on 888 at-risk and comparison subjects at eight sites participating in the North American Prodrome Longitudinal Study (NAPLS) were published. The NAPLS study is believed to be the world's largest sample of prospectively followed subjects at risk for schizophrenia.

Addington told *Psychiatric News* that the database provides an opportunity to explore fundamental questions related to prodromal psychosis, including descriptive phenomenology of currently accepted diagnostic criteria, conversion rates over a 30-month period, predictors of onset of psychosis and functional disability, and the impact of early treatment on the course of prodromal symptoms.

The eight sites in NAPLS, each of which is looking at different aspects of the prodrome and prevention, are the PRIME Clinic at the University of Toronto, Zucker Hillside Hospital in New York City, University of California at San Diego, Emory University, University of California at Los Angeles, University of North Carolina, Yale University, and Harvard University.

Prevention and False Positives

Prevention in any field presents ethical and methodological difficulties that treatment research does not: How is success measured when "success" is defined as the absence of disease? And what are the implications of doing an intervention with individuals for a severe disorder that they may not go on to develop?

Prevention of severe mental illness, with the stigma that surrounds that label, only compounds the problem.

"If you want to try to do prevention, you have to start intervening with people before they have developed the full illness," said Scott Woods, M.D., principal investigator in the Enhancing the Prospective Prediction of Psychosis study at Yale University. "You have to essentially

please see ***Preventing*** *on page 29*

How Do You Diagnose Prodromal Syndromes?

Below are prospective diagnostic criteria for three schizophrenia prodromes that predict onset of psychosis in the near future. The criteria, developed by Scott Woods, M.D., and Thomas McGlashan, M.D., of Yale University School of Medicine, are used by prevention researchers at PRIME Clinic in Toronto. The four sets of criteria describe three prodromal syndromes and the threshold for frank psychosis.

Prodromal Syndromes	Diagnostic Criteria
I. Attenuated Positive Symptom Syndrome (APSS)	1. Abnormal unusual thought content, suspiciousness, grandiosity, perceptual abnormalities, and/or organization of communication that is below the threshold of frank psychosis. AND 2. These symptoms have begun or worsened in past year. AND 3. These symptoms occur at least once per week for last month. AND 4. Psychosis ruled out.
II. Brief Intermittent Psychosis Syndrome (BIPS)	1. Frankly psychotic unusual thought content, suspiciousness, grandiosity, perceptual abnormalities, and/or organization of communication. BUT 2. These symptoms have begun in the past three months. AND 3. The symptoms occur currently at least several minutes per day at least once per month. AND 4. Psychosis ruled out.
III. Genetic Risk + Recent Deterioration (G/D)	1. First-degree relative with history of any psychotic disorder. OR 2. Schizotypal personality disorder in patient. AND 3. Substantial functional decline in the past year. AND 4. Psychosis ruled out.
Rule Out Psychosis	1. Frankly psychotic unusual thought content, suspiciousness, grandiosity, perceptual abnormalities, and/or organization of communication. AND 2a. Symptoms are disorganizing or dangerous. OR 2b. Symptoms occur more than one hour per day more than four times per week in the past month.

Source: Scott Woods, M.D., Thomas McGlashan, M.D., Special Issues in Psychosis: Early Detection and Early Intervention. In B.J. Sadock and V.A. Sadock (eds), *Comprehensive Textbook of Psychiatry (eighth edition),* Lippincott, Williams & Wilkins, 2005

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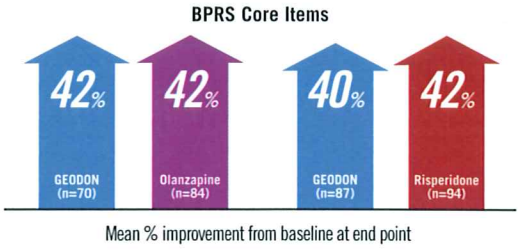

A 6-week, double-blind, randomized study of GEODON vs olanzapine and an 8-week, double-blind, randomized study of GEODON vs risperidone.

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

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

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

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

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

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

CHOOSE GEODON® (ziprasidone HCl) Oral Capsules

GEODON is indicated for the treatment of acute manic or mixed episodes associated with bipolar disorder and for the treatment of schizophrenia.

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

GEODON is contraindicated in patients with a known history of QT prolongation, recent acute myocardial infarction, or uncompensated heart failure, and should not be used with other QT-prolonging drugs. GEODON has a greater capacity to prolong the QT_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.

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

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

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

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

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

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

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

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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 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/m^2 basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m^2 basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m^2 basis). The fertility of female rats was reduced. ***Pregnancy—Pregnancy Category C:*** There are no adequate and well-controlled studies in pregnant women. GEODON should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. ***Labor and Delivery:*** The effect of GEODON on labor and delivery in humans is unknown. ***Nursing Mothers:*** It is not known whether, and if so in what amount, GEODON or its metabolites are excreted in human milk. It is recommended that women receiving GEODON should not breast feed. ***Pediatric Use:*** The safety and effectiveness of GEODON in pediatric patients have not been established. ***Geriatric Use:*** Of the approximately 4500 patients treated with GEODON in clinical studies, 2.4% (109) were 65 years of age or over. In general, there was no indication of any different tolerability for GEODON or of reduced clearance of GEODON in the elderly compared to younger adults. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to GEODON, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients. **ADVERSE REACTIONS — *Adverse Findings Observed in Short-term, Placebo-Controlled Trials:*** The following findings are based on the short-term placebo-controlled premarketing trials for schizophrenia (a pool of two 6-week, and two 4-week fixed-dose trials) and bipolar mania (a pool of two 3-week flexible-dose trials) in which GEODON was administered in doses ranging from 10 to 200 mg/day. ***Adverse Events Associated with Discontinuation:*** Schizophrenia: Approximately 4.1% (29/702) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 2.2% (6/273) on placebo. The most common event associated with dropout was rash, including 7 dropouts for rash among GEODON patients (1%) compared to no placebo patients (see **PRECAUTIONS**). Bipolar Mania: Approximately 6.5% (18/279) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 3.7% (5/136) on placebo. The most common events associated with dropout in the GEODON-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash and vomiting, with 2 dropouts for each of these events among GEODON patients (1%) compared to one placebo patient each for dystonia and rash (1%) and no placebo patients for the remaining adverse events. ***Adverse Events at an Incidence ≥5% and at Least Twice the Rate of Placebo:*** The most commonly observed adverse events associated with GEODON in schizophrenia trials were somnolence (14%) and respiratory tract infection (8%). The most commonly observed adverse events associated with the use of GEODON in bipolar mania trials were somnolence (31%), extrapyramidal symptoms (31%), dizziness (16%), akathisia (10%), abnormal vision (6%), asthenia (6%), and vomiting (5%). The following list enumerates the treatment-emergent adverse events that occurred during acute therapy, including only those events that occurred in 2% of GEODON patients and at a greater incidence than in placebo. Schizophrenia: Body as a Whole—asthenia, accidental injury, chest pain. Cardiovascular—tachycardia. Digestive—nausea, constipation, dyspepsia, diarrhea, dry mouth, anorexia. Nervous—extrapyramidal symptoms, somnolence, akathisia, dizziness. Respiratory—respiratory tract infection, rhinitis, cough increased. Skin and Appendages—rash, fungal dermatitis. Special Senses—abnormal vision. Bipolar Mania: Body as a Whole—headache, asthenia, accidental injury. Cardiovascular—hypertension. Digestive—nausea, diarrhea, dry mouth, vomiting, increased salivation, tongue edema, dysphagia. Musculoskeletal—myalgia. Nervous—somnolence, extrapyramidal symptoms, dizziness, akathisia, anxiety, hypesthesia, speech disorder. Respiratory—pharyngitis, dyspnea. Skin and Appendages—fungal dermatitis. Special Senses—abnormal vision. ***Dose Dependency:*** An analysis for dose response in the schizophrenia trials revealed an apparent relation of adverse event to dose for the following: asthenia, postural hypotension, anorexia, dry mouth, increased salivation, arthralgia, anxiety, dizziness, dystonia, hypertonia, somnolence, tremor, rhinitis, rash, and abnormal vision. ***Extrapyramidal Symptoms (EPS):*** The incidence of reported EPS for GEODON patients in the short-term, placebo-controlled schizophrenia trials was 14% vs 8% for placebo. Objectively collected data from those trials on the Simpson-Angus Rating Scale and the Barnes Akathisia Scale did not generally show a difference between GEODON and placebo. ***Vital Sign Changes:*** GEODON is associated with orthostatic hypotension (see **PRECAUTIONS**). ***Weight Gain:*** In short-term schizophrenia trials, the proportions of patients meeting a weight gain criterion of ≥7% of body weight were compared, revealing a statistically significantly greater incidence of weight gain for GEODON patients (10%) vs placebo patients (4%). A median weight gain of 0.5 kg was observed in GEODON patients vs 0.0 kg in placebo patients. Weight gain was reported as an adverse event in 0.4% of both GEODON and placebo patients. During long-term therapy with GEODON, a categorization of patients at baseline on the basis of body mass index (BMI) showed the greatest mean weight gain and the highest incidence of clinically significant weight gain (>7% of body weight) in patients with a low BMI (<23) compared to normal (23-27) or overweight (>27) patients. There was a mean weight gain of 1.4 kg for patients with a "low" baseline BMI, 0.0 kg for patients with a "normal" BMI, and a 1.3 kg mean weight loss for patients with a "high" BMI. ***ECG Changes:*** GEODON is associated with an increase in the QT_c interval (see **WARNINGS**). In schizophrenia trials, GEODON was associated with a mean increase in heart rate of 1.4 beats per minute compared to a 0.2 beats per minute decrease among placebo patients. ***Other Adverse Events Observed During the Premarketing Evaluation of GEODON:*** Frequent adverse events are those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. Schizophrenia: Body as a Whole — *Frequent:* abdominal pain, flu syndrome, fever, accidental fall, face edema, chills, photosensitivity reaction, flank pain, hypothermia, motor vehicle accident. Cardiovascular System — *Frequent:* tachycardia, hypertension, postural hypotension; *Infrequent:* bradycardia, angina pectoris, atrial fibrillation; *Rare:* first-degree AV block, bundle branch block, phlebitis, pulmonary embolus, cardiomegaly, cerebral infarct, cerebrovascular accident, deep thrombophlebitis, myocarditis, thrombophlebitis. Digestive System — *Frequent:* anorexia, vomiting; *Infrequent:* rectal hemorrhage, dysphagia, tongue edema; *Rare:* gum hemorrhage, jaundice, fecal impaction, gamma glutamyl transpeptidase increased, hematemesis, cholestatic jaundice, hepatitis, hepatomegaly, leukoplakia of mouth, fatty liver deposit, melena. Endocrine — *Rare:* hypothyroidism, hyperthyroidism, thyroiditis. Hemic and Lymphatic System — *Infrequent:* anemia, ecchymosis, leukocytosis, leukopenia, eosinophilia, lymphadenopathy; *Rare:* thrombocytopenia, hypochromic anemia, lymphocytosis, monocytosis, basophilia, lymphedema, polycythemia, thrombocythemia. Metabolic and Nutritional Disorders — *Infrequent:* thirst, transaminase increased, peripheral edema, hyperglycemia, creatine phosphokinase increased, alkaline phosphatase increased, hypercholesteremia, dehydration, lactic dehydrogenase increased, albuminuria, hypokalemia; *Rare:* BUN increased, creatinine increased, hyperlipemia, hypocholesteremia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hyperchloremia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. Musculoskeletal System — *Frequent:* myalgia; *Infrequent:* tenosynovitis; *Rare:* myopathy. Nervous System — *Frequent:* agitation, extrapyramidal syndrome, tremor, dystonia, hypertonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, hypesthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, buccoglossal syndrome, choreoathetosis, diplopia, incoordination, neuropathy; *Infrequent:* paralysis; *Rare:* myoclonus, nystagmus, torticollis, circumoral paresthesia, opisthotonos, reflexes increased, trismus. Respiratory System — *Frequent:* dyspnea; *Infrequent:* pneumonia, epistaxis; *Rare:* hemoptysis, laryngismus. Skin and Appendages — *Infrequent:* maculopapular rash, urticaria, alopecia, eczema, exfoliative dermatitis, contact dermatitis, vesiculobullous rash. Special Senses — *Frequent:* fungal dermatitis; *Infrequent:* conjunctivitis, dry eyes, tinnitus, blepharitis, cataract, photophobia; *Rare:* eye hemorrhage, visual field defect, keratitis, keratoconjunctivitis. Urogenital System — *Infrequent:* impotence, abnormal ejaculation, amenorrhea, hematuria, menorrhagia, female lactation, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; *Rare:* gynecomastia, vaginal hemorrhage, nocturia, oliguria, female sexual dysfunction, uterine hemorrhage. **Adverse Finding Observed in Trials of Intramuscular GEODON:** In these studies, the most commonly observed adverse events associated with the use of intramuscular GEODON (≥5%) and observed at a rate on intramuscular GEODON (in the higher dose groups) at least twice that of the lowest intramuscular GEODON group were headache (13%), nausea (12%), and somnolence (20%). **Adverse Events at an Incidence >1% in Short-Term Fixed-Dose Intramuscular Trials:** The following list enumerates the treatment-emergent adverse events that occurred in ≥1% of GEODON patients (in the higher dose groups) and at least twice that of the lowest intramuscular GEODON group. Body as a Whole — headache, injection site pain, asthenia, abdominal pain, flu syndrome, back pain. Cardiovascular — postural hypotension, hypertension, bradycardia, vasodilation. Digestive — nausea, rectal hemorrhage, diarrhea, vomiting, dyspepsia, anorexia, constipation, tooth disorder, dry mouth. Nervous — dizziness, anxiety, insomnia, somnolence, akathisia, agitation, extrapyramidal syndrome, hypertonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. Respiratory — rhinitis. Skin and Appendages — furunculosis, sweating. Urogenital — dysmenorrhea, priapism. **DRUG ABUSE AND DEPENDENCE — *Controlled Substance Class:*** GEODON is not a controlled substance. **OVERDOSAGE** — In premarketing trials in over 5400 patients, accidental or intentional overdosage of GEODON was documented in 10 patients. All patients survived without sequelae. In the patient taking the largest confirmed amount (3240 mg), the only symptoms reported were minimal sedation, slurring of speech, and transitory hypertension (BP 200/95).

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

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When Schizophrenia Develops Early, Impairment Often More Severe

Forty-five percent of youth with schizophrenia and 54 percent with schizoaffective disorder have been hospitalized for their disorder. Twenty-five percent of children with early-onset schizophrenia spectrum disorders have a history of aggression or legal problems.

BY MARK MORAN

Youth with schizophrenia spectrum disorders have symptom profiles similar to, but more severe than, adults with schizophrenia.

A multicenter study of children with schizophrenia, schizoaffective disorder, and schizophreniform disorder revealed that they have very significant social and functional impairment and are liable to have had a range of psychiatric diagnoses prior to being diagnosed with a schizophrenia spectrum disorder.

Lead author Jean Frazier, M.D., told *Psychiatric News* that the study, which is reported in the August *Journal of the American Academy of Child and Adolescent Psychiatry*, provides the largest formal study of the demographic and clinical characteristics of this rare cohort of patients. Schizophrenia onset prior to age 18 occurs in approximately 0.5 percent of adolescents; very early onset (prior to age 13) occurs in 0.002 percent (or 2 per 100,000).

She said the severity of impairment revealed by the study confirms long-held clinical impressions.

"Our youths showed more impairment than what is described in the literature on adults with schizophrenia," Frazier said. "They had significantly worse symptoms and greater functional and social impairment."

These impairments included social, academic, and behavioral problems in school; a history of aggression and legal problems; prior hospitalizations; and a history of suicide attempts.

Frazier said that early-onset schizophrenia spectrum disorders (EOSS) in children share clinical features with other psychiatric disorders; that is, many of the children in the study had received previous diagnoses such as ADHD, major depression, and bipolar disorder and had been prescribed multiple psychotropic medications.

"The study highlights the need for a thorough evaluation by a clinician well trained in early identification of early-onset schizophrenia due to the challenges of making an accurate diagnosis."

Early Diagnosis Means Early Treatment

Frazier also noted that the data from this study, combined with the use of structured rating instruments, can help clinicians identify those children with EOSS disorder. "A systematic approach to diagnosis and treatment should lead to more timely initiation of appropriate treatment and improved outcome," Frazier told *Psychiatric News*.

She is director of the child and adolescent neuropsychiatric research program and director of child psychopharmacology, as well as co-director of the Center for Child and Adolescent Development at Cambridge Health Alliance at Harvard Medical School.

In the study, "Treatment of Early-Onset Schizophrenia Spectrum Disorders," 119 youth with schizophrenia, schizoaffective disorder, or schizophreniform disorder were recruited at four academic sites—the University of Washington, Case Western Reserve University School of Medicine, University of North Carolina School of Medicine, and Cambridge Heath Alliance at Harvard Medical School.

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

Subjects had to be aged 8 to 19 and had to score at least "moderate" on one or more of the key psychosis items of the Positive and Negative Syndrome Scale (PANSS) or the Brief Psychiatric Rating Scale for Children (BPRS-C). The structured Clinical Interview for *DSM-IV*, Childhood Diagnoses (KID-SCID) was used to exclude other diagnoses, and children with active substance abuse were excluded.

The EOSS diagnosis was made by a board-certified or board-eligible child and adolescent psychiatrist at each site based on clinical interview, a review of records, and the KID-SCID. The mean age at enrollment was 13.

Here are some key findings from the study:

- The majority of subjects had IQ scores that were average or below average. Most of the participants resided with their families, 4 percent were hospitalized at the time of the study, 10 percent lived with extended family, and 7 percent lived in a group home or residential care.
- The most common lifetime diagnoses before study entry were ADHD (28 percent), mood disorders (25 percent), anxiety disorders (19 percent), and conduct and oppositional defiant disorders (16 percent). Many subjects had previous medication therapies, including antipsychotics (50 percent), antidepressants (42 percent), stimulants (32 percent), and mood stabilizers (21 percent).
- Forty-five percent of subjects with schizophrenia and 54 percent with schizoaffective disorder had at least one previous hospitalization.
- Twenty-five percent of those with EOSS disorder had a history of aggression or legal problems, and 15 percent had a history of suicide attempts.

Frazier noted that one goal of the study was to compare characteristics of children with schizophrenia with those of children who have schizoaffective disorder. She and colleagues found that functional and social impairments were similar in both groups, though youth with schizophrenia had significantly poorer rapport as measured by the PANSS; children with schizoaffective disorder reported significantly more depressive symptoms on the BPRS-C.

"Early identification of these children is important, but it appears to be less important to distinguish schizophrenia from schizoaffective disorder due to the fact that they are so similar," she said.

Among the most striking findings from the study, Frazier said, was the severity of impairment compared with adults with schizophrenia. To compare the symptom and functional profiles of the EOSS sample with those of adults suffering from the illness, Frazier and colleagues used PubMed to search for studies of adults with first-episode schizophrenia published within the past 10 years that included ratings on the PANSS, Clinical Global Impression-Severity (CGI-S), or Children's Global Assessment Scale.

They found that youth with EOSS had significantly worse overall ratings on the PANSS and on the CGI-S than reported in the literature on adults.

Frazier noted that forthcoming results from the same study will report the efficacy of treatment of youngsters with the antipsychotics olanzapine and risperidone.

"This is important because we typically base prescriptive practice on treatment studies done in adult populations," she said. "Yet these studies typically fall short because kids are not small adults, and they respond differently to medication.

"Not only do youth with schizophrenia spectrum disorders benefit from medication but they also benefit from psychoeducation, educational support, vocational training, family and psychotherapeutic interventions, and substance abuse treatment," Frazier said.

Development Can Complicate Diagnosis

In addition to the fact that children with EOSS can have symptoms of other psychiatric illnesses, the relative rarity of the disorder may cause clinicians to think of more common diagnoses before considering EOSS. Moreover, some of the prominent symptoms these children display—such as social withdrawal and inattention—can be nonspecific to EOSS.

In addition, there are developmental factors that complicate the diagnosis of EOSS. For instance, children are normally expected to have a rich fantasy life, but youth with EOSS have thought content that goes well beyond what is normally expected, Frazier said.

She said that children with EOSS display a gradual progression that begins in infancy with a broad spectrum of nonspecific dysfunction. By preschool, there is likely to be concern on the part of parents and teachers that something is wrong, and by school age these children will display social, behavioral and attentional impairments.

"As they grow a little older, they develop psychosis," Frazier said. She cited a March 2002 report in *JAACAP* describing a diagnostic pathway to early-onset schizophrenia that typically began with a diagnosis of ADHD, then bipolar disorder, and finally schizophrenia.

Frazier noted that in that sample it was only child psychiatrists who made the distinguishing diagnosis of early-onset schizophrenia. "The important thing about our study is that it should heighten awareness that these children do exist," she said. "Clinicians generally understand that you can have schizophrenia prior to the age of 18, but education on how to look for it and assess it is important."

An abstract of "Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS): Demographic and Clinical Characteristics" is posted at <www.jaacap.com/pt/re/jaacap/abstract.00004583-200708000-00009.htm>. ■

Child Behavior Problems May Signal Pathway to Violence in Schizophrenia

Researchers identify a subpopulation of patients with schizophrenia whose risk for violence is linked to early antisocial tendencies rather than to their psychosis.

BY JUN YAN

New analyses of violent behavior in patients with schizophrenia have traced propensity for violent behavior in certain patients to childhood conduct problems before psychotic symptoms emerged.

A study published June 30 in the online version of *Law and Human Behavior* by Jeffrey Swanson, Ph.D., an associate professor of the Department of Psychiatry and Behavioral Sciences at Duke University, and colleagues suggests a pathway to violent behavior in schizophrenia linked to a developmental pattern of early antisocial characteristics.

The authors reviewed data on 1,445 adult schizophrenia patients from the Clinical Antipsychotic Trials for Intervention Effectiveness (CATIE) study and looked for associations between their history of childhood conduct problems and prevalence of violent behavior within the six months before study screening.

The definition of violent behavior included both minor (simple battery without injury or weapon use) and serious violence (assault using a lethal weapon or resulting in injury, any threat with a lethal weapon in hand, or any sexual assault). History of childhood conduct problems before age 15 was defined as positive response to at least two of the six questions designed to assess defiant antisocial characteristics in children.

The rate of violence within the preceding six months was 28.2 percent among the 488 patients who had a history of childhood conduct problems. This was twice the rate of violence (14.4 percent) among the 956 patients without a history of childhood conduct problems (none or one positive response to the six assessment questions); the difference was statistically significant.

please see ***Violence*** *on page 29*

Ketamine's Antidepressant Effect Offers Drug-Development Target

Tinkering with glutaminergic receptors could open doors to new drugs that may provide immediate relief from depression.

BY JUN YAN

A new study in mice sheds light on why ketamine, an injectable drug used to induce anesthesia in surgery, has a rapid and sustained effect in treating depression.

Researchers are implicating receptors activated by the neurotransmitter glutamate in the drug's mechanism of action, a finding that may provide targets for combating depression.

All available antidepressants commonly take weeks to begin achieving results, but ketamine alleviates depressed mood almost immediately. Patients feel better within hours after receiving an intravenous infusion of ketamine, according to Carlos Zarate and colleagues at the National Institute of Mental Health (NIMH). Their randomized, placebo-controlled, crossover trial was published in the August 2006 *Archives of General Psychiatry*. One day after receiving an intravenous infusion of ketamine hydrochloride (0.5 mg/kg), 71 percent of the 17 patients with treatment-resistant major depression met the response criteria, and 29 percent reached remission; none taking placebo met the response or remission criteria at this time point.

In a new study published online on July 23 in *Biological Psychiatry*, the same group of NIMH researchers presented biochemical evidence to support the role of N-methyl d-aspartate (NMDA) receptors and alpha-amino-3-hydroxy-5 methylisoxazole-4-propionic acid (AMPA) receptors in facilitating the antidepressant effect of ketamine. Both are receptors that, bound by the neurotransmitter glutamate, regulate the flow of ions across the cellular membrane and the electrical potentials inside and outside the neuron.

The researchers simulated depressive behavior in mice and studied the changes after injecting the "depressed" mice with ketamine. As seen previously in humans, a single injection of ketamine effectively countered the artificially induced "depression" in mice. The effect became apparent as fast as 30 minutes after injection and remained apparent two weeks later. The control mice treated with saline or imipramine did not exhibit residual antidepressant effect when they were retested after two weeks.

To confirm that NMDA receptors are involved in this process, the mice were injected with two other chemicals. One is an NMDA antagonist like ketamine; the other selectively binds to a subunit in the NMDA receptor. Both chemicals exerted antidepressant effects similar to ketamine with a shorter duration.

The authors speculated that the antidepressant effect of blocking NMDA receptors is carried out through subsequent activation of AMPA receptors relative to NMDA receptors. The findings supported this hypothesis. Giving mice an AMPA receptor antagonist blocked the antidepressant effect of ketamine, suggesting that AMPA-receptor activation is downstream to NMDA antagonism in the mood-alteration process.

"After the positive results from the clinical trial of ketamine [from the 2006 study], we decided to use the mouse depression model to study how the NMDA and AMPA interaction figures into ketamine's rapid effect on depression," said Husseini Manji, M.D., a co-author of the new study and the 2006 human study and director of the Mood and Anxiety Disorders Program at NIMH, in an interview with *Psychiatric News*. "Ketamine is probably not going to be useful for treatment because of its psychotomimetic side effects. So we are interested in a specific NMDA receptor subunit called NR2B. It can help us narrow the molecular target and develop drugs with similar therapeutic effects as ketamine, but hopefully without the psychotomimetic, dissociative side effects."

The labeling information for ketamine lists the side effects as primarily central nervous system reactions ranging from pleasant dreamlike states and vivid imagery to hallucinations and delirium, sometimes accompanied by confusion, excitement, and irrational behavior. Ketamine may also cause increased blood pressure and stimulation of the cardiovascular system and carry some risk of dependence and abuse.

In this study, the mice were given a drug called Ro25-6981 that specifically targets the NR2B subunit in NMDA receptors. The NR2B antagonist indeed reversed depressive behavior in mice, although the effect did not last as long as that of ketamine. Manji said that preliminary human studies of a particular NR2B antagonist so far have shown little psychotomimetic side effects.

The researchers suggested that adding AMPA agonists to low doses of NMDA antagonists could be a potential approach to treating depression. "One of the directions our research is taking is to look into whether modulating the AMPA receptors can sustain the antidepressant effect after it is 'jump-started' by ketamine," said Manji.

As a continuation of the NIMH ketamine clinical trial, riluzole, a modulator of glutamate release and AMPA receptors and FDA-approved for treating amyotrophic lateral sclerosis, is being given to patients with treatment-resistant depression who had responded to a single dose of ketamine. Another AMPA modulator and glutamate-release inhibitor, lamotrigine, FDA-approved for treating bipolar disorder, is also being studied in a clinical trial by researchers at Mt. Sinai School of Medicine in New York. Both studies are listed on the ClinicalTrials.gov Web site as ongoing. This study is funded by Mt. Sinai School of Medicine and the National Alliance for Research on Schizophrenia and Depression.

An abstract of "Cellular Mechanisms Underlying the Antidepressant Effects of Ketamine: Role of α-Amino-3-Hydroxy-5-Methylisoxazole-4-Propionic Acid Receptors" is posted at <http://journals.elsevierhealth.com/periodicals/bps/content/0600666abs>. ■

Modafinil May Be Useful Adjunct In Bipolar Depression Patients

Combined with a mood stabilizer, a narcolepsy drug improves depressive symptoms in patients with bipolar disorder in a placebo-controlled, six-week study.

BY JUN YAN

Approved by the U.S. Food and Drug Administration for promoting wakefulness in patients with narcolepsy, sleep apnea, and shift-work sleep disorder, modafinil (Provigil) is being tested in clinical trials for a variety of other indications ranging from unipolar depression to multiple sclerosis.

In a study published in the August *American Journal of Psychiatry*, modafinil showed favorable effectiveness as an add-on drug to mood stabilizers, compared with placebo, in patients with bipolar depression.

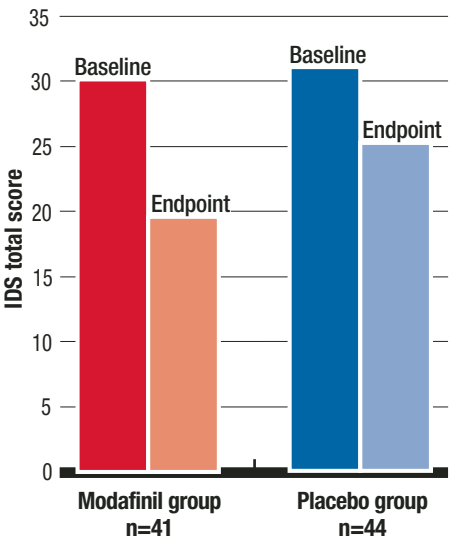
In this double-blind, placebo-controlled study, 85 patients were randomly assigned to either the modafinil (n=41) or placebo (n=44) group. The patients all had a diagnosis of bipolar disorder with depressive symptoms despite being on stable doses of mood stabilizers for at least two weeks before enrolling in the study. About half were also taking antidepressant drugs. The inclusion criteria required that patients have moderate depression, defined as a score of at least 16 on the Inventory of Depressive Symptoms–Clinician Rated (IDS) as an indication of inadequate response to their current treatment.

Patients were given one 100 mg tablet of modafinil or placebo daily for one week and titrated up to two tablets daily if necessary. Twelve and 15 patients dropped out of the modafinil and placebo groups, respectively, resulting in 58 patients completing the study.

At the end of six weeks, the reductions in the IDS score, four-item fatigue-and-energy subset of the IDS, and Clinical Global Impression–Bipolar Version scale (CGI-BP) depression severity item score in the modafinil group were significantly greater than the reductions in the placebo group. In the modafinil group, 44 percent of patients achieved a 50 percent or greater improvement in IDS score, significantly better than the placebo group, in which 23 percent achieved such response.

Adjunctive Modafinil Shows Some Benefit

After six weeks of treatment for bipolar depression, patients randomly assigned to adjunctive modafinil had a statistically significant (analysis of covariance, F=4.50, df=1, p=0.04) reduction in Inventory Depressive Symptoms (IDS) total score compared with patients assigned to placebo.



Source: Mark Frye, et al., *American Journal of Psychiatry*, August 2007

The remission rates (defined as an IDS score of less than 12 at the end of the study) were 39 percent and 18 percent in the modafinil and placebo groups, respectively, also statistically significant.

During the study period, six patients in the modafinil group and five in the placebo group experienced hypomania or mania, including one in each group who needed to be hospitalized for mania.

This study was funded by the Stanley Medical Research Institute, a supporting research organization under the Treatment Advocacy Center, which is a nonprofit organization based in Chevy Chase, Md. Cephalon Inc., the manufacturer of modafinil, provided the active drug and placebo and a grant for patient recruitment and advertisement. The researchers are affiliated with the departments of psychiatry at the University of California, Los Angeles; University of Texas Southwestern Medical Center; and Ludwig-Maximilians University, Munich, Germany. The study was conducted at these three academic centers.

In an accompanying editorial, R.H. Belmaker, M.D., of Ben-Gurion University of the Negev, Beer-Sheba Mental Health Center in Israel, said that "it is biologically plausible that modafinil might be useful in some cases of bipolar depression." He cautioned about the similar rates of mania-switching found in the modafinil and placebo groups, as the modafinil dose in the study was relatively low (mean dose 177 mg/day). The recommended dosage of modafinil for treating sleep disorders is 200 mg, according to the product labeling information.

An abstract of "A Placebo-Controlled Evaluation of Adjunctive Modafinil in the Treatment of Bipolar Depression" is posted at <http://ajp.psychiatryonline.org/cgi/content/abstract/164/8/1242>. ■

Therapy Helps Avert Depression When Vision Loss Imminent

A new intervention has been found in the short term to keep persons who are losing their vision from becoming depressed. It is also another indication that prevention may be coming of age in psychiatry.

BY JOAN AREHART-TREICHEL

Not surprisingly, when a person with age-related macular degeneration has already lost vision in one eye and starts to lose it in the other as well, he or she is at high risk for depression. However, a new therapy can prevent depression in such individuals, at least over the short term.

So reported Barry Rovner, M.D., a professor of psychiatry at Jefferson Hospital for Neuroscience in Philadelphia, and colleagues in the August *Archives of General Psychiatry*.

The new therapy is called problem-solving treatment (PST). The goal is to teach persons with age-related macular degeneration how to compensate for their poor vision and thereby make it possible for them to continue pursuing activities that are important to them.

Rovner and his colleagues explored the possible value of PST in preventing depression in 206 persons who had already lost vision in one eye due to age-related macular degeneration and who had recently been found to have the condition in their other eye as well. None of the subjects was depressed at the start of the study. Half the subjects were randomly assigned to usual care and the other half to PST.

Those assigned to PST received six therapy sessions over an eight-week period in their homes. During these sessions, they were asked to carefully define their visual challenges, to break them down into smaller, more manageable parts, and to brainstorm possible solutions. Solutions might be getting better lighting, reading large-print books, listening to books on tape, using magnifiers, using brightly colored tape to mark stove settings, enlisting the help of others, or being evaluated by a low-vision rehabilitation specialist. They were urged to pursue one or more of these solutions.

From the start of the study to six months later, Rovner and his colleagues followed subjects in both groups to determine whether any became depressed.

At the two-month follow-up, only 12 percent of the PST group had developed depression, compared with 23 percent of the control group—a significant difference. Moreover, the reason why the PST group had a lower level of depression appeared to be because PST helped them to stay engaged in life despite visual impairment.

This positive effect, however, was no longer evident at the six-month follow-up. Although Rovner and his colleagues were disappointed by this result, they were still heartened by the two-month finding. Furthermore, they believe that if booster PST sessions had been offered to PST subjects after the active-treatment phase, it might well have warded off depression for a longer period. "We are in the process of designing a study that will include booster sessions," Rovner told *Psychiatric News*.

Meanwhile, if persons with age-related macular degeneration want PST treatment, how can they get it? "Because mental health and eye care are not integrated, it is necessary to go through a mental health provider directly," Rovner said. "Most older people will not do that. A very reasonable alternative is to see a low-vision ophthalmologist or optometrist, some of whom work with occupational therapists. They can improve function using some of the strategies of PST and thereby possibly prevent depression. We're now preparing an intervention that would train occupational therapists, working with optometrists, to use PST to structure their interventions and directly deal with depressive symptoms."

Because it is relatively generic, PST could also be applied to prevent depression in individuals with other kinds of medical illnesses, Rovner and his colleagues suggested. In fact, one of them—Mark Hegel, Ph.D., of Dartmouth Medical Center—is using PST to try to prevent depression in women with breast cancer.

In an accompanying editorial, Charles Reynolds III, M.D., a professor of geriatric psychiatry at the University of Pittsburgh, and colleagues praised the study by Rovner and his team because "it breaks new ground." They noted that few clinical trials have been undertaken to determine whether depression can be prevented in middle-aged and older adults with medical illnesses.

The study by Rovner and his group is also another indication that prevention may finally be coming of age in psychiatry. During the past decade, for example, resilience has garnered increasing attention from psychiatric researchers, an Air Force suicide-prevention program has been found effective, a cognitive-behavioral intervention delivered via the Internet has been found capable of preventing eating disorders, and a phone intervention has kept primary-care patients on the brink of a clinical depression from developing one.

The study was funded by the National Institute of Mental Health, National Eye Institute, and Farber Institute for Neurosciences of Thomas Jefferson University.

An abstract of "Preventing Depression in Age-Related Macular Degeneration" is posted at <http://archpsyc.ama-assn.org/cgi/content/abstract/64/8/886>. ■

Long-Term Temperature Trends May Affect Suicide Rates

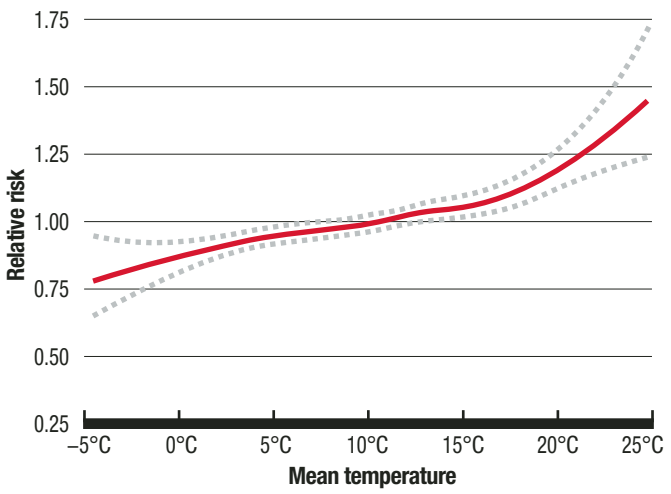
Researchers suggest possible causes of an apparent relationship in England and Wales between increased temperatures and suicide rates.

BY JOAN AREHART-TREICHEL

There is little doubt that hot weather can adversely affect people's health. During periods of sizzling temperatures, there is a surge in the hospital admissions of patients with heat-related conditions and deaths due to various causes. Severely mentally ill patients are at an even greater danger of dying during brutal temperatures than the general population is, according to a report in the August 1998 *Psychiatric Services*, by Nigel Bark, M.D., of the Bronx Psychiatric Center in the Bronx, N.Y.

As Temperatures Increase, So Do Suicide Deaths

Using data on daily suicide counts and temperature in England and Wales from 1993 to 2003, researchers found that the number of suicides increased as the temperature increased. The effect was especially pronounced for violent suicides. Broken lines indicate upper and lower limits of confidence interval.



Source: Lisa Page, M.D., et al., *British Journal of Psychiatry*, August 2007

Now it looks as though heat may have an impact on suicides as well, a study published in the August *British Journal of Psychiatry* has found. It was headed by Lisa Page, M.D., a clinical lecturer and National Institutes of Health research fellow at the Institute of Psychiatry at King's College London.

Page and her colleagues investigated whether there was any relationship from 1993 to 2003 between daily suicide counts in England and Wales and daily temperatures. They took various factors into account that might have skewed results, including year of death, month of death, day of the week, public holidays, and hours of daylight.

They found an association. Above 18 degrees Celsius (64 degrees Fahrenheit), there was strong evidence for a small but significant effect of increasing temperature on all suicides, but especially on violent ones. In fact, suicides increased by 42 percent during the July 29 to August 3, 1995, heat wave, compared with what was expected for that time of year. This 42 percent was well in excess of the 11 percent increase in all-cause mortality reported for the same period.

Concluded Page and her colleagues: "There is increased risk of suicide during hot weather. . . . This is the first time that death from suicide has been shown to be contributing to the known increase in all-cause mortality at higher temperatures."

The ways in which high temperatures might contribute to suicides remain to be determined, though. The neurotransmitter serotonin might be implicated, Page speculated during an interview, since "serotonin levels are known to vary cyclically around the year, with low levels in the summer months. Also, postmortem studies have shown that people who commit suicide are more likely to have low levels of central serotonin. . . . However, I know of no evidence to support the idea that serotonin levels respond quickly to increases in temperature, which is what would have to be the case for this to be a realistic explanation for our findings."

Nonetheless, Page and her colleagues believe that the putative impact of hot weather on suicidal behavior will become even greater as global warming continues.

"I am not sure that these results have huge implications for psychiatrists," Page admitted. "The effect of temperature on suicide is small when considering any one individual patient and when contrasted with traditional (individual level) risk factors such as male gender, previous self-harm, or major mental illness."

Nonetheless, she does believe that the results have public health implications and that countries' health-service plans for heat waves should perhaps address suicide prevention.

"Those with mental illness are highlighted as an at-risk group in England's heat-wave plan," she said, "although this is because of their increased susceptibility to heat stroke rather than for suicide prevention."

Interestingly, in charting the relationship between daily suicide counts and daily temperatures over the course of a decade, Page and her colleagues could not find any peak in suicides during the spring and summer months, as have a number of researchers in the past. One reason, she said, may be because "temperature has a short-term, that is, near-immediate, effect

please see ***Suicides*** *on page 29*

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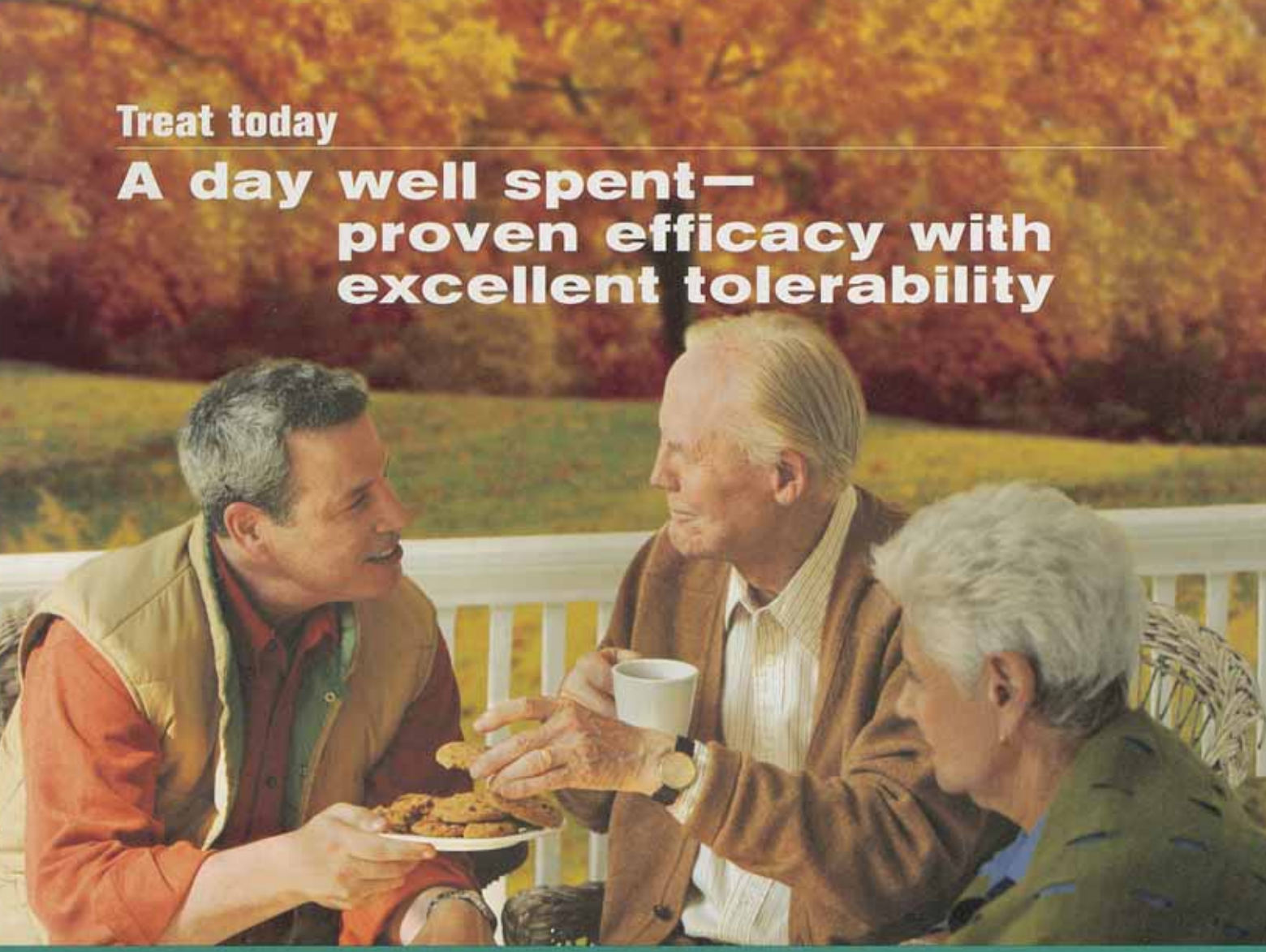

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References: 1. Reisberg B, Doody R, Stöffler A, Schmitt F, Ferris S, Möbius HJ, for the Memantine Study Group. Memantine in moderate-to-severe Alzheimer's disease. *N Engl J Med.* 2003;348:1333-1341. **2.** Tariot PN, Farlow MR, Grossberg GT, Graham SM, McDonald S, Gergel I, for the Memantine Study Group. Memantine treatment in patients with moderate to severe Alzheimer disease already receiving donepezil: a randomized controlled trial. *JAMA.* 2004;291:317-324. **3.** Cummings JL, Schneider E, Tariot PN, Graham SM, for the Memantine MEM-MD-02 Study Group. Behavioral effects of memantine in Alzheimer disease patients receiving donepezil treatment. *Neurology.* 2006;67:57-63. **4.** Data on file. Forest Laboratories, Inc. **5.** NAMENDA® (memantine HCl) Prescribing Information. Forest Pharmaceuticals, Inc., St Louis, Mo. **6.** Winblad B, Poritis N. Memantine in severe dementia: results of the 'M-BEST Study (Benefit and efficacy in severely demented patients during treatment with memantine). *Int J Geriatr Psychiatry.* 1999;14:135-146.

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

62-1009392 11/06

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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59th Institute on Psychiatric Services

OMNA Session Track To Focus on Gulf Coast

The APA Office of Minority and National Affairs (OMNA) will continue its traveling regional mental health disparities elimination program with a special track called "OMNA on Tour in the Gulf Coast: Eliminating Mental Health Disparities in Diverse and Underserved Populations." Since 2005 OMNA on Tour has visited Washington, D.C., the Delaware Valley, and the Midwest to raise awareness of the manifestations of mental health disparities across the nation and to stimulate collaboration within communities to achieve optimal mental health for ethnically and racially diverse populations.

OMNA has tailored this "conference within a conference" to the region in which the institute is being held, with a special focus on the underserved populations in the Gulf Coast region affected by hurricanes Katrina and Rita. Among the highlights of the track are presentations addressing the cultural diversity of the Gulf Coast and its impact on mental health, regional mental health responses to Hurricane Katrina, resilience in children and youth, underserved elderly populations post-Katrina, mental health needs of military personnel and veterans of color post-Katrina and Iraq, suicide in diverse populations, wellness strategies for recovery personnel, and mental health/faith community collaborative approaches.

Listed below is an abbreviated version of the "OMNA on Tour in the Gulf Coast" track. A special insert will be distributed at the institute to guide participants regarding the track's rich offerings.

THURSDAY, OCTOBER 11, 2007

Workshops

10 a.m.-11:30 a.m. OMNA on Tour in the Gulf Coast: APA Making an Impact on Disaster, Diversity, Disparities, and Cultural Competence

1:30 p.m.-3 p.m. Challenges in Meeting the Mental Health Needs of People Displaced Out of State

Recovery and Resiliency in Children: Comparison of Services After 9/11 and Katrina

3:30 p.m.-5 p.m. Root Shock: Understanding the Impact of Disaster and Displacement in the Gulf Coast States

When the Levees Broke: A Spike Lee Documentary

Innovative Program

1:30 p.m.-3 p.m. Regional Responses to Katrina: Planning for the Future

Symposium

2 p.m.-5 p.m. Understanding Diversity in the Gulf Coast: Providing Culturally Competent, Consumer-Centered, Recovery-Oriented Care Across the Age Spectrum

FRIDAY, OCTOBER 12, 2007

Workshops

8 a.m.-9:30 a.m. Mental Health Resiliency and Vulnerability Among Gay, Lesbian, Bisexual, and Transgender Populations

10 a.m.-11:30 a.m. Confronting Issues in Services to Military Populations: National Guard, Active Military, Soldiers of Color, and Service During Iraq

Operation Gumbo: Mixing Strategies to Foster Resilience in Youth Affected by Disaster

1:30 p.m.-3 p.m. Suicide in Diverse Populations Post-Disaster: Myth or Reality?

3:30 p.m.-5 p.m. The Storm Before the Storm: Corrections, Mental Health, and People of Color Innovative Program

Innovative Program

1:30 p.m.-3 p.m. Innovative Responses to Katrina

Symposium

2 p.m.-5 p.m. Addressing Wellness in Recovery Personnel and Their Families

Lecture

3:30 p.m.-5 p.m. Co-Occurring Disorders and Disparities
Rochelle Head-Dunham, M.D., Medical Director, Louisiana Office of Addictive Disorders

SATURDAY, OCTOBER 13, 2007

Workshops

8 a.m.-9:30 a.m. The Path Home for the Elderly: Underserved Elderly Populations of Post-Katrina Gulf Coast

10 a.m.-11:30 a.m. Mobilizing Resources to Eliminate Pre-Existing and Post-Disaster Health Disparities: The Regional Coordinating Center for Hurricane Response at Morehouse School of Medicine

1:30 p.m.-3 p.m. The Use of Telepsychiatry in the Post-Disaster Gulf Coast

3:30 p.m.-5 p.m. All Healers Mental Health Alliance: Bringing Hope and Help in Times of Disaster and All Hazards

Discussion Group

10 a.m.-11:30 a.m. The Emergence of Aftermath Psychiatry: A Paradigm Shift and Implications for Diverse and Underserved Populations

Lecture

10 a.m.-11:30 a.m. Risk Factors Are Not Predictive Factors Due to Protective Factors
Carl C. Bell, M.D., president and CEO, Community Mental Health Council, and professor of psychiatry and public health, University of Illinois at Chicago

Symposia

8:30 a.m.-11:30 a.m. Sanctity and Sanity in the Face of Disaster

2 p.m.-5 p.m. Research in Diverse and Underserved Populations in the South: Current Realities and Imperatives for the Future

IPS Offers Opportunities To Discuss Critical Issues

The Institute on Psychiatric Services has long been known as APA's "more intimate" meeting. As such, it allows participants more opportunities to interact with the experts, such as in discussion groups.

BY WESLEY SOWERS, M.D.

The 59th Institute on Psychiatric Services will be held October 11 to 14 in New Orleans on the theme "Recovery: Patients, Families, Communities." It goes without saying that New Orleans is a most appropriate venue to consider issues related to recovery. Although that community has made great strides toward regaining its past ambiance and vitality, much work remains to be done, and much assistance will continue to be needed. The symbolic import of this great city to the work of psychiatry will not be lost on participants during this institute.

One way that attendees can become involved in the content of the conference is through participation in the discussion group format. This format is perhaps self-explanatory, but a brief description may be helpful to those who have not previously participated in it. Each 90-minute discussion group focuses on a topic that is particularly timely or relevant to the provision of psychiatric care. A discussion leader with expertise in the topic provides brief background information and introduces questions or issues that might be considered in the discussion. The remainder of the session is unprogrammed, giving all participants an opportunity to enter the ensuing discourse.

This year's institute offers 17 discussion groups scattered throughout the four days of the meeting. Several of the groups are related to professional development and how psychiatrists can expand their influence. APA President Carolyn Robinowitz, M.D., will lead a discussion on "Advocacy: Who, What, Where, When, Why, and How?" APA President-elect Nada Stotland, M.D., will cover the topic "You Can Make the Media Work for You" in her group. APA Secretary-Treasurer Donna Norris, M.D., will facilitate a group discussion on "The Quest for Personal and Professional Balance."

A number of discussion groups on clinically oriented topics will be offered as well. "Rational Polypharmacy With Children and Adolescents: Is it Possible?" is one such offering and will be facilitated by Steve Jewel, M.D. David Mee-Lee, M.D., will lead a group discussion on "What They Didn't Teach You About Addiction Patients and How to Engage Them in Treatment." William McFarlane, M.D.'s topic is "Biosocial Treatment of Schizophrenia: Barriers and Promise." "Engaging Environments: Moving From Coercion Using Trauma Informed Care" will be led by Margaret Bennington-Davis, M.D.

Another common topic in discussion groups is social issues and the profession's relationship to them. Ken Thompson, M.D., will lead a discussion on working with special populations that are often underserved. Curtis Adams, M.D., will be leading a group with the intriguing title "Why Won't Bill Cosby Be Quiet? Class, Culture, and the Airing of Dirty Laundry." Other discussion groups include "Psychiatric Services in Post-Katrina New Orleans," led by Daniel Winstead, M.D.; "Doing Outreach: Art or Science?," led by Anthony Ng, M.D.; and "Is the Recovery Movement a True Human Rights Transformation?," led by Joel Feiner, M.D.

Finally, there will be a couple of sessions with special relevance to psychiatry residency training. Carol Bernstein, M.D., will lead a group on "Preparing for Residency," and Michael Garrett, M.D., will lead two related sessions: "For Educators: Experiential Exercises to Teach the Phenomenology of Psychoses" and "Experiential Exercises Linking Psychoses and Ordinary Mind."

All in all, the institute will clearly provide an impressive array of discussion topics to which participants can bring their own expertise and share their experiences. ■

©Carlos Barria/Reuters/Corbis

New Orleans residents stand on a levee in Orleans Parish during a candlelight ceremony dedicated to the victims and survivors of Hurricane Katrina, nearly a year after the hurricane struck.

Wesley Sowers, M.D., is a member of the Scientific Program Committee of the Institute on Psychiatric Services.

How to Register

- Online registration will remain open until October 5.
- You may still register by mail or by fax by using the registration form found in the preliminary program booklet or downloadable from <www.psych.org/edu/ann_mtgs/ips/07/preliminaryprogram/index.cfm>.
- On-site registration at the New Orleans Marriott begins on Thursday, October 11, at 7:30 a.m.

The deadline to reserve a hotel room at APA's special group rate is September 20. The cost of a single hotel room is $225. Call (800) 228-9290.

APA Honors Those Who Have Made a Difference

Through their work in clinical care, advocacy, or teaching, a group of professionals honored at APA's 2007 annual meeting in San Diego have made outstanding contributions to the field of mental health.

BY EVE BENDER

These are the honorees and the awards they received, as listed in the program book of APA's 51st Convocation of Distinguished Fellows:

William C. Menninger Memorial Convocation Lecture: *John Nash Jr., Ph.D.*, Nobel laureate and mathematician who was the subject of the Oscar-winning film "A Beautiful Mind."

Special Presidential Commendations: *Ezra Griffith, M.D.*, deputy chair for clinical affairs in the Department of Psychiatry at Yale University School of Medicine and a professor of psychiatry and African-American studies; *Sheldon Miller, M.D.*, medical director of Timberline Knolls, a residential treatment center in Chicago; *Ahmed Okasha, M.D.*, professor and director of the World Health Organization Collaborating Center for Training and Research in Mental Health at the Institute of Psychiatry at Ain Shams University in Cairo; *Melvin Sabshin*, M.D., APA medical director from 1974 to 1997; *Suzanne Vogel-Scibilia, M.D.*, president of the National Alliance on Mental Illness; *Lucy Ozarin, M.D., M.P.H.*, distinguished APA fellow for 61 years and frequent author and contributor of History Notes, a column that appears in *Psychiatric News*.

Distinguished Service Award: *James Scully Jr., M.D.*, APA medical director and CEO; *George Vaillant, M.D.*, a professor of psychiatry at Harvard Medical School.

Organizational Distinguished Service Award: *The John D. and Catherine T. MacArthur Foundation*, a private, independent institution dedicated to helping groups and individuals foster lasting improvement in the human condition.

APA/Lilly Resident Research Award: *Xingjia Cui, M.D., M.P.H.*, a PGY-4 psychiatry resident at the University of Rochester; *Daniel Eisenberg, M.D.*, a PGY-4 chief psychiatry resident at Albert Einstein College of Medicine's Beth Israel Medical Center; *Amir Garakani, M.D.*, a PGY-5 psychiatry fellow at Mount Sinai School of Medicine; *Roger Jou, M.D., M.P.H.*, a PGY-3 psychiatry resident at Yale University; *Manpreet Singh, M.D.*, a PGY-5 pediatrics, psychiatry, and child and adolescent psychiatry resident at the University of Cincinnati School of Medicine.

Human Rights Award: *Steven Sharfstein, M.D.*, president and CEO of the Sheppard Pratt Health System and clinical professor and vice chair of psychiatry at the University of Maryland and a past president of APA.

Blanche F. Ittleson Award for Research in Child Psychiatry: *Gabrielle Carlson, M.D.*, a professor of psychiatry and pediatrics and director of child and adolescent psychiatry at Stony Brook University School of Medicine.

APIRE/Kempf Fund Award for Research Development in Psychobiological Psychiatry (mentor): *James Meador-Woodruff, M.D.*, Herman E. Drummond Professor and Chair of the Department of Psychiatry of the University of Alabama at Birmingham and editor in chief of *Neuropsychopharmacology*.

APIRE/Kempf Fund Award for Research Development in Psychobiological Psychiatry (mentee): *Robert McCullumsmith, M.D., Ph.D.*, an assistant professor of psychiatry and behavioral neurobiology at the University of Alabama at Birmingham.

Agnes Purcell McGavin Award for Distinguished Career Achievement in Child and Adolescent Psychiatry: *James Harris Jr., M.D.*, professor of psychiatry at Johns Hopkins University.

Issac Ray Award: *Richard Rosner, M.D.*, medical director of the Forensic Psychiatry Clinic of Bellevue Hospital, clinical professor of psychiatry, and director of the forensic psychiatry residency program at New York University School of Medicine.

Jack Weinberg Memorial Award for Geriatric Psychiatry: *Hugh Hendrie, M.B., Ch.B, D.Sc.*, faculty of medicine at the University of Glasgow, a professor of psychiatry at Indiana University School of Medicine, and a research scientist at the Indiana University Center on Aging Research, Regenstrief Institute.

APA Administrative Psychiatry Award Lecture: *Jon Gudeman, M.D.*, director of the Center for Psychotherapy at Columbia-St. Mary's Hospital and a professor of psychiatry at the Medical College of Wisconsin.

APA Simon Bolivar Lecture: *Francisco Fernandez, M.D.*, director of the Institute for Research in Psychiatry and interim head of the Child Development Center at the University of South Florida.

APA John Fryer Award Lecture: *Lawrence Hartmann, M.D.*, APA past president and an assistant clinical professor of psychiatry at Harvard Medical School.

APA Solomon Carter Fuller Award Lecture: *David Henderson, M.D.*, an associate professor of psychiatry at Harvard Medical School, director of the Schizophrenia Diabetes and Weight Reduction Research Program at Massachusetts General Hospital, director of the clozapine program at the Erich Lindemann Mental Health Center, associate director of the Schizophrenia Clinical and Research Program, and associate director in the Division of International Psychiatry at Massachusetts General Hospital.

APA Alexander Gralnick, M.D., Award for Research in Schizophrenia: *William McFarlane, M.D.*, a professor of psychiatry at the University of Vermont and director of the Center for Psychiatric Research at Maine Medical Center and the Spring Harbor Hospital.

AAPL/APA Manfred S. Guttmacher Award Lecture: *Carl Malmquist, M.D.*, a professor of social psychiatry at the University of Minnesota.

APA Judd Marmor Award Lecture: *Nancy Andreasen, M.D., Ph.D.*, chair of psychiatry at the University of Iowa, director of the Iowa Neuroimaging Center and of the Mental Health Clinical Research Center at the University of Iowa, and editor in chief of the *American Journal of Psychiatry* from 1992 to 2005.

APA Adolf Meyer Award Lecture: *Jeffrey Lieberman, M.D.*, Lawrence E. Kolb professor and chair of psychiatry at Columbia University College of Physicians and Surgeons, director of the New York State Psychiatric Institute, Lieber Chair and director of the Lieber Center for Schizophrenia Research at Columbia University, and principal investigator of the Clinical Antipsychotic Trials of Intervention Effectiveness Research Program.

APA Oskar Pfister Award Lecture: *William Miller, Ph.D.*, emeritus distinguished professor of psychology and psychiatry at the University of New Mexico.

APA Award for Research in Psychiatry: *A. John Rush, M.D.*, professor of psychiatry and vice chair in the Department of Clinical Sciences at the University of Texas Southwestern Medical Center.

APA Kun-Po Soo Award Lecture: *J. David Kinzie, M.D.*, a professor of psychiatry at Oregon Health and Science University.

APA Alexandra Symonds Award Lecture: *Silvia Olarte, M.D.*, a clinical professor of psychiatry and director of the Psychoanalytic Institute at New York Medical College.

APA George Tarjan Award Lecture: *Nalini Juthani, M.D.*, a professor of clinical psychiatry at Albert Einstein College of Medicine and a member of the *Psychiatric News* Editorial Advisory Board.

APA/NIMH Vestermark Psychiatry Educator Award Lecture: *Stephen Scheiber, M.D.*, former executive vice president of the American Board of Psychiatry and Neurology.

APA/AACDP Research Mentorship Award: *Andrew Krystal, M.D.*, an associate professor in the Department of Psychiatry at Duke University Medical Center.

APA/AstraZeneca Young Minds in Psychiatry International Awards Program: *Zubin Bhagwagar, M.D., Ph.D.*, an assistant professor of psychiatry at Yale University and inpatient unit chief and director of the Bipolar Research Clinic at Yale's Clinical Neuroscience Research Unit; *Maristela Spanghero, M.D.*, a clinical researcher at the Psychiatric Neuroimaging Laboratory at the University of Sao Paulo in Brazil; *Carmine Pariante, M.D.*, senior lecturer and head of the Stress, Psychiatry, and Immunology Laboratory at the Institute of Psychiatry at King's College London; *Rakesh Karmacharya, M.D., Ph.D.*, a postdoctoral fellow at McLean Hospital; *Marcia Sant'Anna, M.D.*, a psychiatrist with the Mood Disorders Centre for Excellence in Vancouver; *Daniel Smith, M.D.*, a clinical lecturer in psychological medicine at Cardiff University.

APA/Merck & Co. Inc. Early Academic Career Research Award: *Andrew Pieper, M.D., Ph.D.*, an assistant professor of psychiatry at the University of Texas Southwestern Medical Center; *Scott Schobel, M.D.*, a fellow in schizophrenia research at Columbia University's Department of Psychiatry.

APIRE/Lilly Psychiatric Research Fellowship: *Tiffany Farchione, M.D.*, a PGY-5 fellow in child and adolescent psychiatry and chief resident of the research track at Western Psychiatric Institute and Clinic; *Christina Mangurian, M.D.*, chief resident at Columbia University's Department of Psychiatry.

APIRE/Wyeth M.D./Ph.D. Psychiatric Research Fellowship: *Christopher Pittenger, M.D., Ph.D.*, chief resident of the Neuroscience Research Training Program, co-director of the Yale OCD Research Clinic, and the McNeil research fellow.

Carol Davis Ethics Award: *D. Ray Freebury, M.D.*, a lecturer of psychoanalytic ethics at the Toronto Psychoanalytic Society; *L. Alan Wright, M.D.*, a private practitioner and chair of APA's Ethics Committee from 1996 to 2006.

Health Services Research Early Career Award: *Seth Himelhock, M.D.*, an assistant professor at the University of Maryland School of Medicine; *Grayson Norquist, M.D.*, professor and chair of the Department of Psychiatry and Human Behavior at the University of Mississippi Medical Center.

Jacob K. Javits Public Service Award: *Sen. Richard Codey (D-N.J.)*, New Jersey State Senate president and champion of those with mental disorders.

Frank J. Menolascino Award for Psychiatric Services for Persons With Mental Retardation/Developmental Disabilities: *Stephen Ruedrich, M.D.*, an associate professor of psychiatry at Case Western Reserve University School of Medicine and director of the Developmental Disabilities in Psychiatry Program at MetroHealth Medical Center.

Jeanne Spurlock, M.D., Minority Fellowship Achievement Award: *Yvonne Ferguson, M.D.*, a child psychiatrist at Sansum Medical Clinic and the head of the Disaster Mental Health Committee at Cottage Hospital's Department of Psychiatry. ■

TREAT ME LIKE ME...
so I can be who I want to be

Important Safety Information

- Daytrana should not be used in patients with allergy to methylphenidate or patch components; marked anxiety, tension and agitation; glaucoma; tics, diagnosis or a family history of Tourette's syndrome; seizures; or during or within 14 days after treatment with monoamine oxidase inhibitors (MAOIs).
- Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses in ADHD. Physicians should take a careful patient history, including family history, and physical exam to assess the presence of cardiac disease. Patients who report symptoms of cardiac disease such as exertional chest pain and unexplained syncope should be promptly evaluated. Use with caution in patients whose underlying medical condition might be affected by increases in blood pressure or heart rate.
- New psychosis, mania, aggression, growth suppression, and visual disturbances have been associated with the use of stimulants. Use with caution in patients with a history of: psychosis; EEG abnormalities; bipolar disorder; depression. Growth and hematologic monitoring is advised during prolonged treatment. Patients should avoid applying external heat to the Daytrana patch. Skin irritation or contact sensitization may occur.
- **Daytrana should be given cautiously to patients with a history of drug dependence and alcoholism. Chronic abuse can lead to marked tolerance and psychological dependence. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder.**
- Common adverse events reported by patients who received Daytrana in clinical trials were decreased appetite, insomnia, nausea, vomiting, decreased weight, tics, affect lability, and anorexia, consistent with adverse events commonly associated with the use of methylphenidate.

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

References: 1. Daytrana [package insert]. Wayne, Pa: Shire US Inc; 03/07. **2.** McGough JJ, Wigal SB, Abikoff H, et al. A randomized, double-blind, placebo-controlled, laboratory classroom assessment of methylphenidate transdermal system in children with ADHD. *J Atten Disord.* 2006;9:476-485.

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With Daytrana™ the methylphenidate patch

Every child is unique. And so are their schedules. Daytrana provides a novel way to treat ADHD on all their different days.

INDIVIDUALIZATION...

- The ability to personalize ADHD treatment according to daily needs by adding flexible wear time to dose titration[1]
- A way to treat from weekday to weekend

THE BENEFITS OF INDIVIDUALIZATION...

- Control through the 12-hour time point with the recommended 9-hour wear time,[1] to take them through school, homework, and family time
- Option of shorter wear time for parents who are concerned about the potential for late-day side effects[1]

Daytrana is indicated as an integral part of a comprehensive ADHD treatment program that may include other measures (psychological, educational, social). The efficacy of Daytrana was established in clinical trials in children aged 6 to 12 years.[1]

Daytrana™
(methylphenidate transdermal system)

ADHD Treatment That Sticks[2]

Building Confidence—and a Career

BY ABIGAIL DONOVAN, M.D.

Every July, medical students become new interns, interns become second-year residents, senior residents become fellows, and fellows become attendings.

The summer is a time of transition, a progression of the natural life cycle of hospitals, clinics, and residency programs. Each stage feeds naturally into the next, each phase of training builds upon the foundation of the previous ones.

I remember starting as a pediatrics intern five years ago. I was so nervous and unsure of myself as a doctor. I couldn't even dose Tylenol without looking it up, and I practiced running codes on pretend patients. Then, when I had become comfortable treating children with physical illness, I became a resident in adult psychiatry.

While I could treat sepsis in a 3-month-old infant, I was lost with the five men over 50 with schizophrenia whom I was supposed to be helping. Two years later, when I had finally grown comfortable treating adults with psychiatric illness, I became a first-year child psychiatry fellow. Many of the medications I used were the same ones I had used to treat adult patients, but in microscopic doses. My patients were so tiny, and their problems were so big. Their parents looked to me for answers and advice, but it was a long time before I felt competent to give them.

This past year, my first as a child psychiatry fellow, I spent most of my time in the outpatient clinic. I had gotten to know all of my patients and their families over the course of the year, and by June I felt comfortable with and confident in the treatment that I was providing them.

But July 1 came around much faster than I anticipated, and suddenly I was a second-year fellow, working on the inpatient unit. I was no longer comfortable or confident, but instead unsure and somewhat confused. I was starting over. Again.

It is exhausting to start over so many times. I feel a bit like Sisyphus, pushing the boulder up the mountain, only to have it roll back down, again and again. Every few years, as soon as I feel as though I actually know what I am doing, my professional identity shifts and becomes something different, something unfamiliar and foreign. This is not to say that it isn't exciting—it is actually thrilling to move from one level of training to the next, to feel more senior, even if only in title. I have to admit, I still get a little rush every time I say, "I am Dr. Donovan, a child psychiatry fellow."

Last weekend, I was "Dr. Donovan, child psychiatry fellow on call," covering three different hospitals. I was paged multiple times, by multiple people, all asking questions about small children. I amazed myself by actually having answers. It felt almost instinctual, the answers just came rolling out of my mouth before I could even stop to think about what I was saying. I was surprised to realize that my brain had been storing information I didn't know I had. I felt confident in my decisions and sure of myself as "the child psychiatry fellow on call."

As a child psychiatry fellow, I am asked to play many different roles—therapist, psychopharmacologist, pediatrician, parent guidance counselor. Now in the last year of my training, I can look back at each phase of internship, residency, and fellowship and understand how they all collectively prepared me for this career.

I can see how each shift in professional identity was necessary to give me the broad foundation I need to provide comprehensive treatment to children and their families. And I am thankful that I was pushed to continue growing as a doctor each year.

I understand now that as residents, we don't actually start over each July, not from the beginning. We retain the knowledge and skills we learn over time and build upon them. We assume new roles in July, a little big at first, but we grow into them quickly. The boulder doesn't actually roll back downhill; it is just a long hill to climb. ■

Abigail Donovan, M.D., is the member-in-training trustee.

The things that may describe a patient with bipolar mania…

Irritability
Elevated mood
Racing thoughts
Rapid speech

Concern about weight gain

…can obscure the person

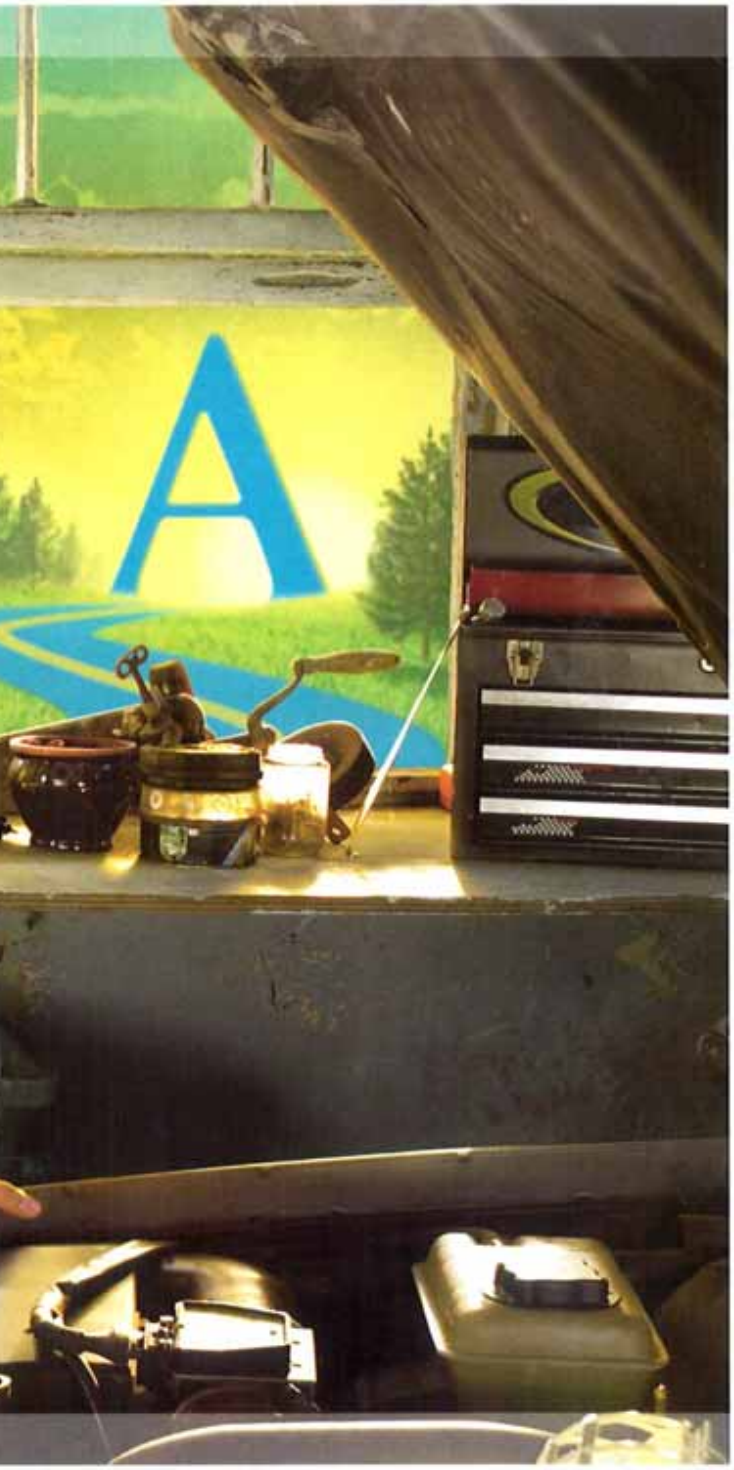
ABILIFY Helps Reveal

ABILIFY is indicated for the treatment of acute manic and mixed episodes associated with Bipolar I Disorder.

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). ABILIFY is not approved for the treatment of patients with dementia-related psychosis.

HELP ILLUMINATE

The Person Within.



Meet Jason, age 31. He is a patient with Bipolar I Disorder, but he is also a car enthusiast, brother, and friend. He's so much more than his illness.

Do you have someone like Jason in your practice?

ABILIFY significantly reduced manic symptoms, as measured by Y-MRS* Total Score, at primary endpoint (Day 21) in a 3-week, double-blind, placebo-controlled trial in patients with Bipolar I Disorder.[1]

In a 26-week Bipolar I Disorder maintenance trial, the mean change in weight was 0.5 kg for ABILIFY-treated patients compared to -1.7 kg for placebo-treated patients.

Some patients experienced significant weight gain. The percentage of patients meeting the weight gain criterion of ≥7% of baseline body weight was 13% for ABILIFY, 0% for placebo.[2]

*Young Mania Rating Scale.

Please see IMPORTANT SAFETY INFORMATION, including **Boxed WARNING**, on following page.

THE PERSON WITHIN

ABILIFY®
(aripiprazole)
TABLETS and ORAL SOLUTION 1 mg/mL

IMPORTANT SAFETY INFORMATION for ABILIFY

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). ABILIFY is not approved for the treatment of patients with dementia-related psychosis (see Boxed WARNING).

- **Neuroleptic malignant syndrome (NMS)**–As with all antipsychotic medications, a rare and potentially fatal condition known as NMS has been reported with ABILIFY. NMS can cause hyperpyrexia, muscle rigidity, diaphoresis, tachycardia, irregular pulse or blood pressure, cardiac dysrhythmia, and altered mental status. If signs and symptoms appear, immediate discontinuation is recommended
- **Tardive dyskinesia (TD)**–The risk of developing TD and the potential for it to become irreversible may increase as the duration of treatment and the total cumulative dose increase. Prescribing should be consistent with the need to minimize TD. If signs and symptoms appear, discontinuation should be considered since TD may remit, partially or completely
- **Cerebrovascular adverse events** (eg, stroke, transient ischemic attack), including fatalities, have been reported at an increased incidence in clinical trials of elderly patients with dementia-related psychosis treated with ABILIFY
- **Hyperglycemia and diabetes mellitus**–Hyperglycemia, in some cases associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including ABILIFY. Patients with diabetes should be monitored 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 should also undergo fasting blood glucose testing. There have been few reports of hyperglycemia with ABILIFY

Treatment-emergent adverse events reported with:

ABILIFY Oral

In short-term trials of patients with schizophrenia (up to 6 weeks) or bipolar disorder (up to 3 weeks), the following were reported at an incidence ≥10% and greater than placebo, respectively: headache (30% vs 25%), anxiety (20% vs 17%), insomnia (19% vs 14%), nausea (16% vs 12%), vomiting (12% vs 6%), dizziness (11% vs 8%), constipation (11% vs 7%), dyspepsia (10% vs 8%), and akathisia (10% vs 4%).

ABILIFY Injection

In short-term (24 hour) trials, the following were reported at an incidence ≥5% and greater than placebo, respectively: headache (12% vs 7%), nausea (9% vs 3%), dizziness (8% vs 5%), and somnolence (7% vs 4%).

ABILIFY for Bipolar I Disorder:

- Rapid control of agitation*
- Early† and sustained symptom control
- Low incidence of somnolence/sedation‡
- Low mean weight change in clinical trials
  - — In a 26-week Bipolar I Disorder maintenance trial, the mean change in weight was 0.5 kg for ABILIFY-treated patients compared to -1.7 kg for placebo-treated patients.

    Some patients experienced significant weight gain. The percentage of patients meeting the weight gain criterion of ≥7% of baseline body weight was 13% for ABILIFY, 0% for placebo.[2]

*With ABILIFY Injection at primary endpoint (2 hours). ABILIFY Injection is indicated for the treatment of agitation associated with Bipolar I Disorder.
†As early as Day 4 through study endpoint (Day 21).
‡ABILIFY 14%, placebo 7%.

Physicians who elect to use ABILIFY for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Like other antipsychotics, ABILIFY may have the potential to **impair judgment, thinking, or motor skills.** Patients should not drive or operate hazardous machinery until they are certain ABILIFY does not affect them adversely.

ABILIFY®
(aripiprazole)
TABLETS and ORAL SOLUTION 1 mg/mL

HELP ILLUMINATE THE PERSON WITHIN

Please see BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION, including **Boxed WARNING,** on adjacent pages.

References: 1. Sachs G, Sanchez R, Marcus R, et al. Aripiprazole in the treatment of acute manic or mixed episodes in patients with bipolar I disorder: a 3-week placebo-controlled study. *J Psychopharmacol.* 2006;20:536-546. 2. Keck PE Jr, Calabrese JR, McQuade RD, et al, for the Aripiprazole Study Group. A randomized, double-blind, placebo-controlled 26-week trial of aripiprazole in recently manic patients with bipolar I disorder. *J Clin Psychiatry.* 2006;67:626-637.

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ABILIFY® (aripiprazole) TABLETS
ABILIFY® (aripiprazole) ORAL SOLUTION
ABILIFY® DISCMELT™ (aripiprazole) Orally Disintegrating Tablets
ABILIFY® (aripiprazole) INJECTION FOR INTRAMUSCULAR USE ONLY

Rx only

BRIEF SUMMARY: PLEASE CONSULT PACKAGE INSERT FOR COMPLETE 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 (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. ABILIFY is not approved for the treatment of patients with dementia-related psychosis.

CONTRAINDICATIONS: Known hypersensitivity to aripiprazole

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. ABILIFY (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis (see Boxed WARNING).

Neuroleptic Malignant Syndrome (NMS): Potentially fatal NMS has been reported in association with administration of antipsychotic drugs, including ABILIFY. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. If signs and symptoms appear, immediate discontinuation is recommended (see **Full Prescribing Information for additional information on management of NMS**). Patients requiring antipsychotic drug treatment after recovery from NMS should be carefully monitored since recurrences of NMS 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. The risk of developing TD and the potential for it to become irreversible may increase as the duration of treatment and the total cumulative dose increase. Prescribing should be consistent with the need to minimize TD. If signs and symptoms appear, discontinuation should be considered since TD may remit, partially or completely. Antipsychotic treatment, itself, may suppress (or partially suppress) the signs and symptoms of the syndrome and, thereby, may possibly mask the underlying process. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. The need for continued treatment should be reassessed periodically.

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia-Related Psychosis: In placebo-controlled clinical studies (two flexible-dose and one fixed-dose study) of dementia-related psychosis, there was an increased incidence of cerebrovascular adverse events (eg, stroke, transient ischemic attack), including fatalities, in aripiprazole-treated patients. In the fixed-dose study, there was a statistically significant dose response relationship for cerebrovascular adverse events in patients treated with aripiprazole. ABILIFY is not approved for the treatment of patients with dementia-related psychosis. (See also **Boxed WARNING**, **WARNINGS** and **PRECAUTIONS** in **Full Prescribing Information**.)

Hyperglycemia and Diabetes Mellitus: Hyperglycemia, in some cases associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including ABILIFY. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus 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 should undergo baseline and periodic fasting blood glucose (FBG) testing. Any patient being treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia and those who develop symptoms of hyperglycemia should also undergo FBG testing.

PRECAUTIONS: General:

Orthostatic Hypotension: ABILIFY may be associated with orthostatic hypotension, perhaps due to its α_1-adrenergic receptor antagonism. The incidence of orthostatic hypotension-associated events from five short-term, placebo-controlled trials in schizophrenia (n=926) on oral ABILIFY included: orthostatic hypotension (1.9%), postural dizziness (0.8%), and syncope (0.6%). The incidence of orthostatic hypotension-associated events from short-term, placebo-controlled trials in bipolar mania (n=597) on oral ABILIFY included: orthostatic hypotension (0.7%), postural dizziness (0.5%), and syncope (0.3%). The incidence of orthostatic hypotension-associated events from short-term, placebo-controlled trials in agitation associated with schizophrenia or bipolar mania (n=501) on ABILIFY Injection included: orthostatic hypotension (0.6%), postural dizziness (0.2%), and syncope (0.4%). The incidence of a significant orthostatic change in blood pressure (defined as a decrease of at least 30 mmHg in systolic blood pressure when changing from a supine to standing position) for aripiprazole was not statistically different from placebo in trials in patients with schizophrenia, bipolar mania, or agitation associated with schizophrenia or bipolar mania. ABILIFY should be used with caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease, or conditions which would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). If parenteral benzodiazepine therapy is deemed necessary in addition to ABILIFY Injection treatment, patients should be monitored for excessive sedation and for orthostatic hypotension.

Seizures: In short-term trials, seizures/convulsions occurred in 0.1% (1/926) of oral aripiprazole-treated patients with schizophrenia, in 0.3% (2/597) of oral aripiprazole-treated patients with bipolar mania, and in 0.2% (1/501) of aripiprazole injection-treated patients with agitation associated with schizophrenia or bipolar mania. Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older.

Potential for Cognitive and Motor Impairment: Despite the relatively modest increased incidence of somnolence compared to placebo, ABILIFY, like other antipsychotics, may have the potential to impair judgment, thinking, or motor skills. In short-term trials, somnolence (including sedation) was reported in 10% of patients with schizophrenia on oral ABILIFY compared to 8% of patients on placebo; 14% of patients with bipolar mania on oral ABILIFY compared to 7% of patients on placebo; and in 9% of patients with agitation associated with schizophrenia or bipolar mania on ABILIFY Injection compared to 6% of patients on placebo. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that therapy with ABILIFY does not affect them adversely.

Body Temperature Regulation: Disruption of body temperature regulation has been attributed to antipsychotic agents. Use appropriate care when prescribing aripiprazole 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, including ABILIFY. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's disease. ABILIFY 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 psychotic illnesses and bipolar disorder, and close supervision of high-risk patients should accompany drug therapy. Prescriptions for ABILIFY should be written for the smallest quantity consistent with good patient management.

Use in Patients with Concomitant Illness: Clinical experience with ABILIFY in patients with certain concomitant systemic illnesses is limited. ABILIFY has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease.

In three, 10-week, placebo-controlled studies of aripiprazole in elderly patients with psychosis associated with Alzheimer's disease (n=938), the treatment-emergent adverse events that were reported at an incidence of ≥3% and aripiprazole incidence at least twice that for placebo were lethargy, somnolence (including sedation), incontinence (primarily, urinary incontinence), excessive salivation, and lightheadedness. ABILIFY is not approved for treatment of patients with dementia-related psychosis. If the prescriber elects to treat such patients with ABILIFY, vigilance should be exercised, particularly for the emergence of difficulty swallowing or excessive somnolence, which could predispose to accidental injury or aspiration (See **Boxed WARNING**, **WARNINGS** and **CLINICAL PHARMACOLOGY: Special Populations** in **Full Prescribing Information**.)

Information for Patients: Physicians are advised to discuss the following issues with patients for whom they prescribe ABILIFY (aripiprazole). See Full Prescribing Information for the complete information to discuss with patients taking ABILIFY:

Interference with Cognitive and Motor Performance: Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that ABILIFY does not affect them adversely.

Pregnancy: Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy with ABILIFY.

Nursing: Patients should be advised not to breast-feed an infant if they are taking ABILIFY.

Concomitant Medication: Patients should be advised to inform their physicians if they are taking, or plan to take, any prescription or over-the-counter drugs, since there is a potential for interactions.

Heat Exposure and Dehydration: Patients should be advised regarding appropriate care in avoiding overheating and dehydration.

Phenylketonurics: Phenylalanine is a component of aspartame. Each ABILIFY DISCMELT orally disintegrating tablet contains the following amounts: 10 mg - 1.12 mg phenylalanine and 15 mg - 1.68 mg phenylalanine.

Sugar Content: Patients should be advised that each mL of ABILIFY oral solution contains 400 mg of sucrose and 200 mg of fructose.

Drug Interactions: Use caution when ABILIFY is taken in combination with other centrally acting drugs and alcohol. ABILIFY may enhance the effect of certain antihypertensive agents. ABILIFY is unlikely to cause clinically important drug interactions mediated by the enzymes CYP1A1, CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, or CYP2E1 enzymes. *In vivo* studies using 10- to 30-mg/day doses of aripiprazole had no significant effect on metabolism by CYP2D6 (dextromethorphan), CYP2C9 (warfarin), CYP2C19 (omeprazole, warfarin), and CYP3A4 (dextromethorphan) substrates. No clinically significant effect of famotidine, valproate, or lithium was seen on the pharmacokinetics of aripiprazole.

Inducers of CYP3A4 (eg, carbamazepine) could cause an increase in aripiprazole clearance and lower blood levels. When a **CYP3A4** inducer is added to ABILIFY, the dose of ABILIFY should be doubled. Additional dose increases should be based on clinical evaluation. When the CYP3A4 inducer is withdrawn from combination therapy, the ABILIFY dose should be reduced.

Carbamazepine: Coadministration of carbamazepine (200 mg BID) with ABILIFY (30 mg QD) resulted in an approximate 70% decrease in C_{max} and AUC values of aripiprazole and its active metabolite, dehydro-aripiprazole.

Inhibitors of CYP3A4 (eg, ketoconazole) or **CYP2D6** (eg, quinidine, fluoxetine, or paroxetine) can inhibit the elimination of aripiprazole and cause increased blood levels. When a strong **CYP3A4** or **CYP2D6** inhibitor is added to ABILIFY, the dose of ABILIFY should be reduced to one-half of the usual dose. When the CYP3A4 or CYP2D6 inhibitor is withdrawn from the combination therapy, the ABILIFY dose should then be increased.

Ketoconazole: Coadministration of ketoconazole (200 mg/day for 14 days) with a 15-mg single dose of ABILIFY increased the AUC of aripiprazole and its active metabolite by 63% and 77%, respectively.

Quinidine: Coadministration of a 10-mg single dose of ABILIFY with quinidine (166 mg/day for 13 days) increased the AUC of aripiprazole by 112% but decreased the AUC of its active metabolite, dehydro-aripiprazole, by 35%.

Alcohol: There was no significant difference between aripiprazole coadministered with ethanol and placebo coadministered with ethanol on performance of gross motor skills or stimulus response in healthy subjects. As with most psychoactive medications, patients should be advised to avoid alcohol while taking ABILIFY.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis: Carcinogenicity studies were conducted in ICR mice and in Sprague-Dawley (SD) and F344 rats. Aripiprazole was administered for 2 years in the diet at doses of 1, 3, 10, and 30 mg/kg/day to ICR mice and at 10, 20, 40, 60 mg/kg/day (3 to 19 times the maximum recommended human dose [MRHD] based on mg/m^2) to SD rats and 1, 3, and 10 mg/kg/day to F344 rats (0.2 to 5 and 0.3 to 3 times the MRHD based on mg/m^2, respectively). In addition, SD rats were dosed orally for 2 years. Aripiprazole did not induce tumors in male mice or rats. In female mice, the incidences of pituitary gland adenomas and mammary gland adenocarcinomas and adenoacanthomas were increased at dietary doses of 3 to 30 mg/kg/day (0.1 to 0.9 times human exposure at MRHD based on AUC and 0.5 to 5 times the MRHD based on mg/m^2). In female rats, the incidence of mammary gland fibroadenomas was increased at a dietary dose of 10 mg/kg/day (0.1 times human exposure at MRHD based on AUC and 3 times the MRHD based on mg/m^2); and the incidences of adrenocortical carcinomas and combined adrenocortical adenomas/carcinomas were increased at an oral dose of 60 mg/kg/day (14 times human exposure at MRHD based on AUC and 19 times the MRHD based on mg/m^2). These findings are considered to be prolactin-mediated. Increases in serum prolactin were observed in a 13-week dietary study in female mice at doses used in the carcinogenicity study. Serum prolactin was not increased in a 4- and 13-week dietary study in female rats. The relevance for human risk of prolactin-mediated endocrine tumors in rodents is unknown. **Mutagenesis:** Aripiprazole and a metabolite (2,3-DCPP) were clastogenic in the *in vitro* chromosomal aberration assay in Chinese hamster lung (CHL) cells, with and without metabolic activation. The metabolite, 2,3-DCPP, produced increases in numerical aberrations in the *in vitro* assay in CHL cells in the absence of metabolic activation. A positive response was obtained in the *in vivo* micronucleus assay in mice; however, the response was shown to be due to a mechanism not considered relevant to humans. **Impairment of Fertility:** Female rats were treated with oral doses of 2, 6, and 20 mg/kg/day (0.6, 2, and 6 times the MRHD on an mg/m^2 basis) of aripiprazole from 2 weeks prior to mating through day 7 of gestation. Estrus cycle irregularities and increased corpora lutea were seen at all doses, but no impairment of fertility was seen. Increased pre-implantation loss was seen at 6 and 20 mg/kg, and decreased fetal weight was seen at 20 mg/kg. Male rats were treated with oral doses of 20, 40, and 60 mg/kg/day (6, 13, and 19 times the MRHD on an mg/m^2 basis) of aripiprazole from 9 weeks prior to mating through mating. Disturbances in spermatogenesis were seen at 60 mg/kg, and prostate atrophy was seen at 40 and 60 mg/kg, but no impairment of fertility was seen.

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Aripiprazole should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. In animal studies, aripiprazole demonstrated developmental toxicity, including possible teratogenic effects in rats and rabbits.

Labor and Delivery: The effect of aripiprazole on labor and delivery in humans is unknown.

Nursing Mothers: Aripiprazole was excreted in milk of rats during lactation. It is not known whether aripiprazole or its metabolites are excreted in human milk. It is recommended that women receiving aripiprazole should not breast-feed.

Pediatric Use: Safety and effectiveness in pediatric and adolescent patients have not been established.

Geriatric Use: Placebo-controlled studies of oral aripiprazole in schizophrenia or bipolar mania did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. There was no effect of age on the pharmacokinetics of a single 15-mg dose of aripiprazole. Aripiprazole clearance was decreased by 20% in elderly subjects (≥65 years) compared to younger adult subjects (18 to 64 years), but there was no detectable effect of age in the population pharmacokinetic analysis in schizophrenia patients. Studies of elderly patients with psychosis associated with Alzheimer's disease have suggested that there may be a different tolerability profile in this population compared to younger patients with schizophrenia. (See also **Boxed WARNING**, **WARNINGS** and **PRECAUTIONS** in **Full Prescribing Information**.)

ADVERSE REACTIONS

Aripiprazole has been evaluated for safety in 8456 patients who participated in multiple-dose, clinical trials in schizophrenia, bipolar mania, and dementia of the Alzheimer's type, and who had approximately 5635 patient-years of exposure to oral aripiprazole and 749 patients with exposure to aripiprazole injection. A total of 2442 patients were treated with oral aripiprazole for at least 180 days and 1667 patients treated with oral aripiprazole had at least 1 year of exposure.

Adverse Events Associated with Discontinuation of Treatment: Overall, there was little difference in the incidence of discontinuation due to adverse events in placebo-controlled oral aripiprazole trials (aripiprazole vs placebo: schizophrenia, 7% vs 9%; bipolar mania, 11% vs 9%; or in placebo-controlled intramuscular aripiprazole injection trials (aripiprazole injection, 0.8%; placebo 0.5%). The types of adverse events that led to discontinuation were similar between the oral aripiprazole and placebo-treated patients.

Commonly Observed Adverse Events: (≥5% incidence and at a rate at least twice the rate of placebo for ABILIFY vs placebo, respectively): In 4- to 6-week, placebo-controlled, schizophreenia trials (2 to 30 mg/day), the one commonly observed adverse event associated with the use of oral aripiprazole was: akathisia (8%, 4%). In 3-week, placebo-controlled, bipolar mania trials (15 or 30 mg/day), the most common adverse events associated with oral aripiprazole were: akathisia (15%, 3%), constipation (13%, 6%), sedation (8%, 3%), tremor (7%, 3%), restlessness (6%, 3%), extrapyramidal disorder (5%, 2%). In 24-hour placebo-controlled trials of intramuscular aripiprazole injection for agitation associated with schizophrenia or bipolar mania, nausea was the one adverse event observed (9%, 3%).

Adverse Events with an Incidence ≥2% in Oral Aripiprazole Trials: The following treatment-emergent

events were reported at an incidence of ≥2% with oral aripiprazole (doses ≥2 mg/d), and at a greater incidence with aripiprazole than with placebo in short-term placebo-controlled trials (aripiprazole N=1523, placebo N=849), respectively, were: headache (30%, 25%), anxiety (20%, 17%), insomnia (19%, 14%), nausea (16%, 12%), vomiting (12%, 6%), dizziness (11%, 8%), constipation (11%, 7%), dyspepsia (10%, 8%), akathisia (10%, 4%), sedation (7%, 4%), fatigue (6%, 5%), extrapyramidal disorder (6%, 4%), somnolence (5%, 4%), dry mouth (5%, 4%), arthralgia (5%, 4%), tremor (5%, 3%), restlessness (5%, 3%), pharyngolaryngeal pain (4%, 3%), pain in extremity (4%, 2%), cough (3%, 2%), nasal congestion (3%, 2%), abdominal discomfort (3%, 2%), stomach discomfort (3%, 2%), pain (3%, 2%), vision blurred (3%, 1%), salivary hypersecretion (2%, 1%), peripheral edema (2%, 1%), hypertension (including blood pressure increased) (2%, 1%). The following events were reported by patients treated with oral aripiprazole with an incidence equal to or less than placebo: diarrhea, toothache, upper abdominal pain, abdominal pain, musculoskeletal stiffness, back pain, myalgia, agitation, psychotic disorder, dysmenorrhea (percentage based on gender total), and rash.

Adverse Events with an Incidence ≥1% in Intramuscular Aripiprazole Injection Trials: The following treatment-emergent events were reported at an incidence ≥1% with intramuscular aripiprazole injection (doses ≥5.25 mg/day) and at incidence greater than placebo in 24-hour, placebo-controlled trials (aripiprazole injection N=501, placebo N=220) in agitated patients with schizophrenia or bipolar mania, respectively, include: headache (12%, 7%), nausea (9%, 3%), dizziness (8%, 5%), somnolence (7%, 4%), sedation (3%, 2%), vomiting (3%, 1%), fatigue (2%, 1%), tachycardia (2%, <1%), akathisia (2%, 0%), dyspepsia (1%, <1%), dry mouth (1%, <1%), blood pressure increased (1%, <1%), musculoskeletal stiffness (1%, <1%). The following events were reported by patients treated with aripiprazole injection with an incidence equal to or less than placebo: injection site pain, injection site burning, insomnia, agitation.

Dose-Related Adverse Events: Dose response relationships for the incidence of treatment-emergent adverse events were evaluated from four trials in patients with schizophrenia comparing various fixed doses (2, 5, 10, 15, 20, and 30 mg/day) of oral aripiprazole to placebo. The one adverse event to have a possible dose response relationship was somnotence (including sedation) which was most prominent at the 30 mg/day dose (placebo, 7.1%; 10 mg, 8.5%; 15 mg, 8.7%; 20 mg, 7.5%; 30 mg, 12.6%).

Extrapyramidal Symptoms: In the short-term, placebo-controlled trials of schizophrenia, the incidence of reported EPS-related events, excluding events related to akathisia was (oral aripiprazole 13%, placebo 12%) and the incidence of akathisia-related events was (oral aripiprazole 8%, placebo 4%). In the short-term, placebo-controlled trials in bipolar mania, the incidence of reported EPS-related events, excluding events related to akathisia was (oral aripiprazole 15%, placebo 8%) and the incidence of akathisia-related events was (oral aripiprazole 15%, placebo 4%). In the placebo-controlled trials in patients with agitation associated with schizophrenia or bipolar mania, the incidence of reported EPS-related events excluding events related to akathisia was (aripiprazole injection 2%, placebo 2%) and the incidence of akathisia-related events was (aripiprazole injection 2%, placebo 0%).

Laboratory Test Abnormalities: A between group comparison for 3- to 6-week, placebo-controlled trials revealed no medically important differences between the aripiprazole and placebo groups in the proportions of patients experiencing potentially clinically significant changes in routine serum chemistry, hematology, or urinalysis parameters. Similarly, there were no aripiprazole/placebo differences in the incidence of discontinuations for changes in serum chemistry, hematology, or urinalysis. In a long-term (26-week), placebo-controlled trial there were no medically important differences between the aripiprazole and placebo patients in the mean change from baseline in prolactin, fasting glucose, triglyceride, HDL, LDL, and total cholesterol measurements.

Weight Gain: In 4- to 6-week trials in schizophrenia, there was a slight difference in mean weight gain between aripiprazole and placebo patients (+0.7 kg vs. -0.05 kg, respectively), and also a difference in the proportion of patients meeting a weight gain criterion of ≥7% of body weight [aripiprazole (8%) compared to placebo (3%)]. In 3-week trials in mania, the mean weight gain for aripiprazole and placebo patients was 0.0 kg vs. -0.2 kg, respectively. The proportion of patients meeting a weight gain criterion of ≥7% of body weight was aripiprazole (3%) compared to placebo (2%). In a 26-week schizophrenia trial, weight change, respectively, for ABILIFY (aripiprazole)- and placebo-treated patients was -0.5 kg and -0.5 kg for those with BMI <23, -1.3 kg and -0.6 kg for those with BMI 23 to 27, and -2.1 kg and -1.5 kg for those with BMI >27. The percentage of ABILIFY- and placebo-treated patients, respectively, with ≥7% increase in baseline body weight was 6.8% and 3.7% for those with BMI <23, 5.1% and 4.2% for those with BMI 23 to 27, and 5.7% and 4.1% for those with BMI >27. In a 52-week schizophrenia trial, weight change for ABILIFY-treated patients was 2.6 kg for those with BMI <23, 1.4 kg for those with BMI 23 to 27, and -1.2 kg for those with BMI >27. The percentage of ABILIFY-treated patients with ≥7% increase in baseline body weight was 30% for those with BMI <23, 19% for those with BMI 23 to 27, and 8% for those with BMI >27.

ECG Changes: Pooled analysis of placebo-controlled trials in patients with schizophrenia or bipolar mania treated with oral aripiprazole or in patients with agitation associated with schizophrenia or bipolar mania treated with intramuscular aripiprazole injection, revealed no significant differences between aripiprazole and placebo of potentially important changes in ECG parameters. Oral aripiprazole was associated with a median increase in heart rate of 5 beats per minute compared to a 1 beat per minute increase among placebo patients.

Adverse Events in Long-Term, Double-Blind, Placebo-Controlled Trials

The adverse events reported in a 26-week, double-blind trial comparing oral ABILIFY and placebo in patients with schizophrenia or bipolar mania were generally consistent with those reported in the short-term, placebo-controlled trials, except for a higher incidence of tremor (ABILIFY 8% vs placebo 2%).

Other Adverse Events Observed During the Premarketing Evaluation of Oral Aripiprazole

The following adverse events were reported with oral aripiprazole at multiple doses ≥2 mg/day in clinical trials (8456 patients, 5365 patient-years of exposure). This list may not include events previously listed elsewhere in the labeling, those events for which a drug cause was remote, those terms which were so general as to be uninformative, and those events reported with an incidence of ≤0.05% and which did not have a substantial probability of being acutely life-threatening. *Frequent events* are those occurring in at least 1/100 patients; *infrequent events* are those occurring in 1/100 to 1/1000 patients; *rare events* are those occurring in fewer than 1/1000 patients. ***Blood and Lymphatic System Disorders:*** *Infrequent* - anaemia, lymphadenopathy, leukopenia (including agranulocytosis, neutropenia); *Rare* - leukocytosis, thrombocytopenia, idiopathic thrombocytopenic purpura, thrombocythaemia. ***Cardiac Disorders:*** *Frequent* - tachycardia (including ventricular, supraventricular, sinus); *Infrequent* - bradycardia, palpitations, cardiac failure (including congestive and acute), myocardial infarction, cardiac arrest, atrial fibrillation, atrioventricular block (including first degree and complete), extrasystoles (including ventricular and supraventricular), angina pectoris, cyanosis, bundle branch block (including left, right), myocardial ischaemia; *Rare* - atrial flutter, cardiomegaly, cardiomyopathy, cardiopulmonary failure. ***Ear and Labyrinth Disorders:*** *Infrequent* - ear pain, vertigo, tinnitus; *Rare* - deafness. ***Endocrine Disorders:*** *Infrequent* - hypothyroidism; *Rare* - goitre, hyperparathyroidism, hyperthyroidism. ***Eye Disorders:*** *Frequent* - conjunctivitis; *Infrequent* - eye redness, eye irritation, dry eye, blepharospasm, visual disturbance, eye pain, eye discharge, blepharitis, cataract, lacrimation increased; *Rare* - eyelid function disorder, oculogyration, eyelid oedema, photophobia, diplopia, eyelid ptosis, eye haemorrhage. ***Gastrointestinal Disorders:*** *Frequent* - loose stools; *Infrequent* - flatulence, dysphagia, gastroesophageal reflux disease, gastritis, haemorrhoids, abdominal distension, faecal incontinence, haematochezia, gingival pain, rectal haemorrhage, abdominal pain lower, oral pain, retching, faecaloma, gastrointestinal haemorrhage, ulcer (including gastric, duodenal, peptic), tooth fracture, gingivitis, lip dry; *Rare* - abdominal tenderness, chapped lips, periodontitis, aptyalism, gastrointestinal pain, hypoaesthesia oral, inguinal hernia, swollen tongue, colitis, haematemesis, hyperchlorhydria, irritable bowel syndrome, oesophagitis, faeces hard, gingival bleeding, glossodynia, mouth ulceration, reflux oesophagitis, cheilitis, intestinal obstruction, pancreatitis, eructation, gastric ulcer haemorrhage, melaena, glossitis, stomatitis. ***General Disorders and Administration Site Conditions:*** *Frequent* - asthenia, pyrexia, chest pain, gait disturbance; *Infrequent* - malaise, oedema, *influenza-like illness, chills*, general physical health deterioration, feeling jittery, mobility decreased, thirst, feeling cold, difficulty in walking, facial pain, sluggishness, condition aggravated; *Rare* - inflammation localized, swelling, energy increased, inflammation, abasia, xerosis, feeling hot, hyperthermia, hypothermia. ***Hepatobiliary Disorders:*** *Infrequent* - cholecystitis (including acute and chroeic); *Rare* - cholelithiasis, hepatitis. ***Immune System Disorders:*** *Infrequent* - hypersensitivity. ***Infections and Infestations:*** *Frequent* - respiratory tract infection (including upper and lower), pneumonia; *Infrequent* - cellulitis, dental caries, vaginitis, vaginal infection, cystitis, vaginal mycosis, eye infection, gastroenteritis, onychomycosis, vaginal candidiasis, otitis media, folliculitis, candidiasis, otitis externa, pyelonephritis, rash pustular; *Rare* - appendicitis, septic shock. ***Injury, Poisoning, and Procedural Complications:*** *Frequent* - fall, skin laceration, contusion, fracture; *Infrequent* - blister, scratch, joint sprain, burn, muscle strain, periorbital haematoma, arthropod bite/sting, head injury, sunburn; *Rare* - joint dislocation, alcohol poisoning, road traffic accident, self mutilation, eye penetration, injury asphyxiation, poisoning, heat exhaustion, heat stroke. ***Investigations:*** *Frequent* - weight decreased, blood creatine phosphokinase increased; *Infrequent* - blood glucose increased, heart rate increased, body temperature increased, alanine aminotransferase increased, blood cholesterol increased, white blood cell count increased, haemoglobin decreased, aspartame aminotransferase increased, blood urea increased, electrocardiogram ST segment abnormal (including depression, elevation), haematocrit decreased, hepatic enzyme increased, blood bilirubin increased, blood glucose decreased, blood creatinine increased, blood alkaline phosphatase increased, blood pressure decreased, blood potassium decreased, blood urine present, electrocardiogram QT corrected interval prolonged; *Rare* - transaminases increased, blood triglycerides increased, blood uric acid increased, cardiac murmur, eosinphil count increased, neutrophil count increased, platelet count increased, red blood cell count decreased, white blood cell count decreased, white blood cells urine positive, bacteria urine identified, blood lactate dehydrogenase increased, blood potassium increased, neutrophil count decreased, urine output decreased, blood creatine phosphokinase MB increased, ECG signs of myocardial ischemia, electrocardiogram T-wave inversion, heart rate decreased, tuberculin test positive, glucose urine present, glycosylated haemoglobin increased, glucose tolerance decreased, glycosylated haemoglobin decreased, muscle enzyme increased. ***Metabolism and Nutrition Disorders:*** *Frequent* - decreased appetite (including diet refusal, markedly reduced dietary intake), dehydration; *Infrequent* - anorexia, increased appetite, hypercholesterolaemia, hypokalaemia, hyperglycaemia, diabetes mellitus, hypoglycaemia, hyponatremia, diabetes mellitus non-insulin-dependent, hyperlipidaemia, obesity (including overweight), polydipsia; *Rare* - hypertriglyceridaemia, gout, hypernatraemia, weight fluctuation, diabetes mellitus inadequate control. ***Musculoskeletal and Connective Tissue Disorders:*** *Frequent* - musculoskeletal pain (including neck, jaw, chest wall, bone, buttock, groin, flank, musculoskeletal chest, pubic, and sacral), muscle rigidity, muscle cramp; *Infrequent* - muscle twitching, joint swelling, muscle spasms, muscle tightness, arthritis, osteoarthritis, muscular weakness, joint range of motion decreased, sensation of heaviness; *Rare* - tendonitis, osteoporosis, trismus, arthropathy, bursitis, exostosis, night cramps, coccydynia, joint contracture, localised osteoarthritis, osteopenia, rhabdomyolysis, costochondritis, rheumatoid arthritis, torticollis. ***Nervous System Disorders:*** *Frequent* - lethargy, dyskinesia; *Infrequent* - disturbance in attention, parkinsonism, dystonia, drooling, cogwheel rigidity, dysarthria, paraesthesia, hypoaesthesia, loss of consciousness (including depressed level of consciousness), hypersomnia, psychomotor hyperactivity, balance disorder, cerebrovascular accident, hypokinesia, tardive dyskinesia, memory impairment, amnesia, ataxia, dementia, hypotonia, burning sensation, dysgeusia, restless leg syndrome, hypertonia, Parkinson's disease, akinesia, dysphasia, transient ischaemic attack, facial palsy, hemiparesis, myoclonus, sciatica; *Rare* - bradykinesia, coordination abnormal, cognitive disorder, syncope vasovagal, carpal tunnel syndrome, hyporeflexia, intention tremor, muscle contractions involuntary, sleep apnea syndrome, dementia Alzheimer's type, epilepsy, hyperreflexia, mastication disorder, mental impairment, nerve compression, parkinsonian gait, tongue paralysis, aphasia, choreoathetosis, formication, masked facies, neuralgia, paresthesia oral, parkinsonian rest tremor, cerebral haemorrhage, dizziness exertional, hyperaesthesia, haemorrhage intracranial, ischaemic stroke, judgment impaired, subarachnoid haemorrhage. ***Psychiatric Disorders:*** *Frequent* - schizophrenia (including schizoaffective disorder), depression (including depressive symptom), hallucination (including auditory, visual, tactile, mixed, olfactory, and somatic), mood altered (including depressed, euphoric, elevated, and mood swings), paranoia, irritability, suicidal ideation, confusional state, aggression, mania, delusion (including persecutory, perception, somatic, and grandeur); *Infrequent* - tension, nervousness, nightmare, excitability, panic attack (including panic disorder, panic disorder with agoraphobia, and panic reaction), abnormal dreams, apathy, libido decreased, hostility, suicide attempt, bipolar disorder (including bipolar I), libido increased, anger, delirium, acute psychosis, disorientation, bruxism, hypomania, obsessive-compulsive disorder (including obsessive thoughts), mental status changes, crying, dysphoria, completed suicide, flat affect, impulsive behaviour; *Rare* - blunted affect, cognitive deterioration, logorrhea, psychomotor agitation, social avoidant behaviour, psychomotor retardation, suspiciousness, affect lability, anorgasmia, fear, homicidal ideation, tic, premature ejaculation, dysphemia, bradyphrenia, derealisation, depersonalisation. ***Renal and Urinary Disorders:*** *Infrequent* - pollakiuria, dysuria, haematuria, urinary retention, renal failure (including acute and chronic), urinary hesitation, enuresis, nephrolithiasis, micturition urgency, polyuria; *Rare* - nocturia, proteinuria, glycosuria, calculus urinary, azotaemia. ***Reproductive System and Breast Disorders:*** *Infrequent* - erectile dysfunction, vaginal discharge, amenorrhoea, vaginal haemorrhage, menstruation irregular, menorrhagia, premenstrual syndrome, testicular pain, genital pruritus female, ovarian cyst, benign prostatic hyperplasia, prostatitis; *Rare* - gynaecomastia, priapism (including spontaneous penile erection), breast pain, pelvic pain, epididymitis, galactorrhoea, uterine haemorrhage. ***Respiratory, Thoracic, and Mediastinal Disorders:*** *Frequent* - dyspnoea (including exertional); *Infrequent* - sinus congestion, rhinorrhoea, wheezing, epistaxis, asthma, hiccups, productive cough, chronic obstructive airways disease (including exacerbated), rhinitis allergic, pneumonia aspiration, pulmonary congestion, sinus pain, respiratory distress, dry throat, hoarseness; *Rare* - bronchopneumopathy, haemoptysis, respiratory arrest, sneezing, hypoxia, pulmonary embolism, pulmonary oedema (including acute), respiratory failure, brochospasm, nasal dryness, paranasal sinus hypersecretion, pharyngeal erythema, rhonchi, tonsillar hypertrophy, asphyxia, Mendelson's syndrome. ***Skin and Subcutaneous Tissue Disorders:*** *Infrequent* - hyperhydrosis, erythema, pruritis (including generalised), dry skin, decubitus ulcer, dermatitis (including allergic, seborrhoeic, acneiform, exfoliative, bullous, neurodermatitis), ecchymosis, skin ulcer, acne, eczema, hyperkeratosis, swelling face, skin discoloration, photosensitivity reaction, skin irritation, alopecia, rash maculopapular, cold sweat, scab, face oedema, dermal cyst, psoriasis, night sweats, rash erythematous; *Rare* - rash scaly, urticaria, rash maculopapular, rosacea, seborrhoea, periorbital oedema, rash vesicular. ***Vascular Disorders:*** *Frequent* - hypotension; *Infrequent* - hot flush (including flushing), haematoma, deep vein thrombosis, phlebitis; *Rare* - pallor, petechiae, varicose vein, circulatory collapse, haemorrhage, thrombophlebitis, shock.

Other Adverse Events Observed During the Premarketing Evaluation of Aripiprazole Injection

The following adverse events were reported with aripiprazole injection at doses ≥1 mg/day in clinical trials (749 patients). This list may not include events previously listed elsewhere in the labeling, those events for which a drug cause was remote, those terms which were so general as to be uninformative, and those events reported with an incidence of ≤0.05% and which did not have a substantial probability of being acutely life-threatening. *Frequent events* are those occurring in at least 1/100 patients; *infrequent events* are those occurring in 1/100 to 1/1000 patients; *rare events* are those occurring in fewer than 1/1000 patients. ***Ear and Labyrinth Disorders:*** *Infrequent* - hyperacusis. ***General Disorders and Administration Site Conditions:*** *Infrequent* - injection site stinging, abnormal feeling, injection site pruritus, injection site swelling, venipuncture site bruise. ***Infections and Infestations:*** *Infrequent* - bacteruria, urinary tract infection, urosepsis. ***Investigations:*** *Infrequent* - blood pressure abnormal, heart rate irregular, electrocardiogram T-wave abnormal. ***Psychiatric Disorders:*** *Infrequent* - intentional self-injury. ***Respiratory, Thoracic, and Mediastinal Disorders:*** *Infrequent* - pharyngolaryngeal pain, nasal congestion. ***Vascular Disorders:*** *Infrequent* - blood pressure fluctuation.

Postintroduction Reports: Reported since market introduction and temporally (not necessarily causally) related to aripiprazole therapy: allergic reaction (eg, anaphylactic reaction, angioedema, laryngospasm, oropharyngeal spasm, pruritis, or urticarial), grand mal seizure, and jaundice.

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

Abuse and Dependence: Aripiprazole has not been systematically studied in humans for its potential for abuse, tolerance, or physical dependence. While the clinical trials did not reveal any tendency for any drug-seeking behavior, it is not possible to predict on the basis of this limited experience the extent to which a CNS-active drug will be misused, diverted, and/or abused once marketed. Patients should be evaluated carefully for a history of drug abuse and closely observed for signs of ABILIFY (aripiprazole) misuse or abuse.

OVERDOSAGE: 76 cases of deliberate or accidental overdosage with oral ABILIFY alone or in combination with other substances were reported worldwide [44 cases with known outcome, 33 recovered without sequelae and one recovered with sequelae (mydriasis and feeling abnormal)]. Additionally, 10 of these cases were in children (age 12 and younger) involving oral aripiprazole ingestions up to 195 mg with no fatalities. The largest known acute ingestion was 1080 mg of oral aripiprazole (36 times maximum recommended daily dose) in a patient who fully recovered. Common adverse events (reported in at least 5% of all overdose cases) were vomiting, somnolence, and tremor. **For more information on symptoms of overdose, see Full Prescribing Information.**

Management of Overdosage: No specific information is available on the treatment of overdose with aripiprazole. An electrocardiogram should be obtained in case of overdosage and, if QTc interval prolongation is present, cardiac monitoring should be instituted. Otherwise, management of overdose should concentrate on supportive therapy, maintaining an adequate airway, oxygenation and ventilation, and management of symptoms. Close medical supervision and monitoring should continue until the patient recovers. ***Charcoal:*** In the event of an overdose of ABILIFY, an early charcoal administration may be useful in partially preventing the absorption of aripiprazole. Administration of 50 g of activated charcoal, one hour after a single 15-mg oral dose of aripiprazole, decreased the mean AUC and C_{max} of aripiprazole by 50%. ***Hemodialysis:*** Although there is no information on the effect of hemodialysis in treating an overdose with aripiprazole, hemodialysis is unlikely to be useful in overdose management since aripiprazole is highly bound to plasma proteins.

Tablets manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan or Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
Orally Disintegrating Tablets, Oral Solution and Injection manufactured by Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850 USA
Marketed by Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
US Patent Nos: 5,006,528; 6,977,257; and 7,115,587

Bristol-Myers Squibb Company
Princeton, NJ 08543 U.S.A.

Otsuka America Pharmaceutical, Inc.
Rockville, MD 20850 U.S.A.

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Based on FPI Revised October 2006

Responders

continued from page 12

Health Association, "the situation became a mental health disaster of epic proportions," she told *Psychiatric News*. "We are lucky that Dr. Miller is a member of our community and has been planning for just this kind of event since 9/11."

Forsyth-Stephens called on 50 mental health professionals working with the free clinic that operates under the auspices of the mental health association to supplement the cadre of mental health professionals trained by Miller.

The CDRC supports its disaster-relief activities primarily through consulting and training across Virginia and the rest of the country. Students from Edward Via College of Osteopathic Medicine and staff from several agencies who had received CDRC training also stepped forward to help.

Miller noted that there were also large numbers of "spontaneous" volunteers—well-intentioned people from around the country who showed up wanting to help in some way. "This was both a blessing and a burden," she noted.

In the hours after the shooting, CDRC, its partner agencies, and Virginia Tech staff established a staging center at the Virginia Tech Inn, where families gathered to await news of loved ones.

They also set up a respite center for law-enforcement personnel at the inn—a quiet space away from the activity where police could listen to music, contact family members, and get a massage.

During this time, CDRC volunteers worked closely with local clergy and mental health professionals from the Virginia Tech Cook Counseling Center, which was inundated with students who were still on campus. CDRC volunteers worked 24-hour shifts until the family staging area was closed at the end of that week.

In the days that followed, CDRC volunteers were posted at firehouses, police stations, coffee shops, and other businesses in Blacksburg, according to Miller.

Miller noted that attendance was nearly perfect when the school reopened. "Students showed up to support one another and their professors," she said.

While working in conjunction with Virginia Tech's student counseling center, Miller and her colleagues recruited more than 300 volunteers for Project Class Reentry a week after the shootings.

Chris Flynn, Ph.D., director of Virginia Tech's Cook Counseling Center, requested support teams' presence in each class where a student or faculty member had been injured or killed once classes reconvened. Teams were also assigned on the Drill Field, Squires Student Center, dining halls, and in downtown Blacksburg providing support and "compassionate loitering," Miller noted.

"We had walkie-talkies, vans shuttling between buildings, and a message center," said Forsyth-Stephens.

When graduation ceremonies began a couple of weeks later, Miller recalled, CDRC volunteers provided around-the-clock coverage with the families of injured and deceased students who were housed in a campus dorm.

Stephens said that the tasks performed by dozens of lay volunteers trained by Miller made it possible for mental health clinicians to reach out to students and faculty on campus.

"Having such a large group of laypeople who were ready to hit the ground running enabled us to pull together a massive mental health response," following the shooting, she noted.

Since graduation, Miller and the CDRC teams have appeared at local fairs and other community gatherings to disseminate information about the CDRC and to offer support to people affected by the shooting.

She noted that calls to the New River Valley Community Services Center have increased by 50 percent since the shooting. Most of the people are calling with concerns about mental health problems of a loved one, Miller noted.

"I think that right now, we are in a very difficult phase—people [who have been directly or indirectly impacted by the shootings] are disillusioned and angry. They realize that life will never be the same again, and they are exhausted."

It is Miller's hope that the CDRC will provide a model for other communities in the nation to follow so that they can galvanize local resources to respond to disasters.

"This is about teaching folks to help each other through rough times. People want to help, they just need to be prepared and trained before it hits their community.

Information about the New River Valley Community Disaster Response Coalition is posted at <nrvcdrc.org>. ■

PTSD

continued from page 1

wrote Perrin. PTSD risk increased for firefighters doing light construction work, for sanitation workers doing search and rescue work, and for police and emergency medical personnel fighting fires.

"Novelty does add a degree of stress," said emergency room psychiatrist Anthony Ng, M.D., who was medical director of Disaster Psychiatry Outreach in New York at the time of the terror attacks. He is also a member and former chair of APA's Committee on Psychiatric Dimensions of Disasters. "In simulations of job tasks, people show more stress if they're asked to do something different."

"Prior training or experience may protect against the psychological distress associated with disaster work," wrote Perrin, echoing results of previous research by others.

However, that did not explain all the disparity between the police and other first responders, she said. After Hurricane Katrina, for instance, the prevalence of PTSD among New Orleans police officers was 19 percent, close to the 22 percent reported for firefighters, although local conditions may have influenced those outcomes.

Another factor that may account for some of the difference is that police may underreport symptoms, fearing career repercussions, Perrin speculated. Or perhaps the police force may have more rigorous pre-employment screening that may produce more resilience than workers in other categories.

In addition, firefighters and paramedics, who lost 343 of their comrades when the towers collapsed, may well have identified with the lost victims or felt bereaved, adding to their psychological burden, she added. (Fires burned at the site for 99 days after the attacks.)

Police and firefighters also have different cultures and working styles, which may explain some variation in their response to stress, said Ng. Police officers rely on authority and force to do their job, while firefighters and medics rely on personality and persuasion, he said. That may increase the stress on their psychological resources.

"Cops work alone or with a partner, while firefighters work in groups and live together on the job," he suggested. "That might increase their camaraderie and the hurt they felt after September 11."

Other workers may not have received the organizational support, mental health services, or the public recognition that are available to police and firefighters, all of which may have increased their distress.

Interventions targeted at specific occupational groups who work at major disasters might alleviate the psychological burden that comes with their participation, wrote Perrin and colleagues. "Disaster preparedness training and shift rotations to enable a shorter duration of service at the site may reduce PTSD among workers and volunteers in future disasters."

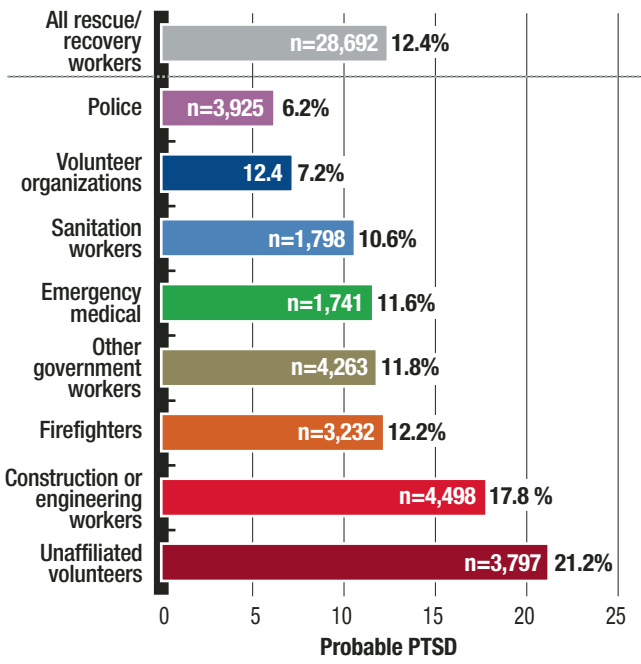
Preparation does provide some buffer for future events, agreed Ng.

"But that means ongoing training, not practicing once a year," he said. "You have to know what to expect and not be surprised, even when things are at their most chaotic."

"Differences in PTSD Prevalence and Associated Risk Factors Among World Trade Center Disaster Rescue and Recovery Workers" is posted at <ajp.psychiatryonline.org> under the September issue. ■

PTSD Prevalence Varies by Job At World Trade Center Cleanup

After time spent on the World Trade Center site, the chances of having PTSD two to three years after the September 11, 2001, terror attacks varied with workers' occupation and preparation for their tasks.



Probable PTSD is based on a both *DSM-IV* diagnostic criteria and the PTSD Checklist-Civilian Version cutoff score (≥44).

Source: Megan A. Perrin, M.P.H., et al., *American Journal of Psychiatry*, September 2007

letters to the editor

Bipolar Disorder: Default Diagnosis?

I read with interest the report of Blader and Carlson's study in the June 15 issue on the dramatic increase in the rates of children hospitalized with discharge diagnoses of bipolar disorder. They reported that since 1996 the rate of children discharged with the diagnosis of bipolar disorder has increased fivefold. The cause of this seems obscure. They suggested that upcoding (reporting a more pathological diagnosis to insurance companies to justify admission) might be at least partly to blame. In any case, I think most clinicians would agree that the diagnosis of bipolar disorder is currently being made significantly more frequently in children than in past years. This has occurred in spite of no change in *DSM* criteria for bipolar disorder. The implications of this in relation to our supposedly scientific diagnostic criteria are worth pondering.

It may be that we have only recently become adept at diagnosing bipolar disorder in children. David Axelson, M.D., is also quoted in this review (although he is not a co-author of the paper) as suggesting that the increased rate of bipolar discharge diagnoses may reflect frequent need for readmission among these children. If they are in and out of the hospital more often (because of chronic instability or difficulty in managing them), the number of discharged children carrying the bipolar diagnosis would go up.

If this claim is accurate, it may raise another concerning thought. In the September 1996 *American Journal of Psychiatry*, Drs. Sara Bolton and John Gunderson published a clinical case conference in which they presented a young woman who was diagnosed as bipolar. They claimed she was actually a borderline personality. They also suggested that the bipolar diagnosis resulted in the thrust of her treatment being primarily medication based,

please see ***Letters*** *on page 28*

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.

we can't wait.

Because I don't want to lose my son to the voices again.

The voices in his head are back.
I can't bear to see him like this.

He was doing so well on his own.
This will ruin everything.
It could send him back to the hospital.

We're fighting to get
things back under control.
But we need help now.

ZYPREXA®
Olanzapine

For resources to help you help your patients with schizophrenia, visit **www.ToolsForTheFight.com**

The labeling for ZYPREXA includes a boxed warning:

- 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 elderly patients with dementia-related psychosis.

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

For Important Safety Information, including boxed warning, see adjacent page and accompanying Brief Summary of Prescribing Information.

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 patients 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 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 and potentially fatal condition known as NMS has been reported with olanzapine. If signs and symptoms appear, immediate discontinuation is recommended. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

Tardive dyskinesia (TD)—As with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of TD. The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

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 event associated with ZYPREXA (vs placebo) in 6-week acute-phase schizophrenia trials was somnolence (26% vs 15%). Other common events were 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 event associated with ZYPREXA (vs placebo) in 3- and 4-week bipolar mania trials was somnolence (35% vs 13%). Other common events were 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%).

For complete safety profile, see the full Prescribing Information.

ZYPREXA is a registered trademark of Eli Lilly and Company.
Zyrtec is a registered trademark of UCB, SA.

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. Rare postmarketing reports of hepatitis have been received. Very rare cases of cholestatic or mixed liver injury have also been reported in the postmarketing period. 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 (eg, 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 Cmax 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 Cmax 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 this same clinical trial involving 3 fixed oral dosage ranges (5±2.5, 10±2.5, or 15±2.5 mg/d) compared with placebo. The following treatment-emergent events showed a statistically significant trend: asthenia, dry mouth, nausea, somnolence, tremor.

In an 8-week, randomized, double-blind study in patients with schizophrenia, schizophreniform disorder, or schizoaffective disorder comparing fixed doses of 10, 20, and 40 mg/d, statistically significant differences were seen between doses for the following: baseline to endpoint weight gain, 10 vs 40 mg/d; incidence of treatment-emergent prolactin elevations >24.2 ng/mL (female) or >18.77 ng/mL (male), 10 vs 40 mg/d and 20 vs 40 mg/d; fatigue, 10 vs 40 mg/d and 20 vs 40 mg/d; and dizziness, 20 vs 40 mg/d.

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 (8661 patients, 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, jaundice, neutropenia, 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 reported.

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

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Warnings

continued from page 1

cantly during the same period, suggesting undertreatment or lack of treatment for adult depression.

The study examined medical and pharmacy claims data from a nationwide database that included 47 million people who were covered in 85 managed-care plans. Based on the *ICD-9-CM* codes for the visits and on pharmacy data, more than 475,000 episodes of depression in about 400,000 adults (ages 19 to 89) were included in the analyses.

The researchers used monthly aggregate data and statistical regression to map the trends of depression diagnosis and antidepressant prescriptions from October 1998 to September 2005—two years after the initial FDA advisory.

New Diagnosis Rates Declined

Robert Valuck, Ph.D., an associate professor in the Department of Clinical Pharmacy at the University of Colorado at Denver, and colleagues found that the annual rates of diagnosed episodes of depression had been increasing steadily from 1999 to 2004, but dropped precipitously in 2005. If the increasing trend had continued, they predicted that the rate of depression diagnosis in 2005 would have been about 40 percent higher than the actual rate of diagnosis, a statistically significant difference.

Compared with the trend in the five years before the first FDA advisory, the number of new episodes of diagnosed depression dropped significantly faster in the two years after the advisory, accounting for a lower percentage of all depression episodes. In this study, new episodes of depression were defined as a diagnostic claim of depression for someone who had not had a depression diagnosis in the prior four months or any antidepressant prescription claims in the prior three months.

The authors examined the practice type of physicians who diagnosed depression. Before the advisory, nearly half of the depressive episodes were diagnosed by primary care physicians, and this share was growing at an annual rate of 5.4 percent. After the advisory, the absolute proportion of depressive episodes diagnosed by primary care physicians was more than half of all diagnosed episodes, but the trend was in fact reversed, declining at an annual rate of 2.86 percent, a statistically significant change. Thus, the FDA warning may have made primary care physicians more reluctant to diagnose depressive episodes.

The pattern of depression diagnosis among psychiatrists and mental health professionals did not significantly change after the advisory.

Fewer Patients Get Antidepressants

The authors also analyzed antidepressant prescription claims that were filled within 30 days of each diagnosed depression episode. In the five years before the FDA advisory in October 2003, an average of 53 percent of depressive episodes were accompanied by pharmacy claims for selective serotonin reuptake inhibitors (SSRIs), with a slightly growing trend over time. The percentage of episodes in which an SSRI prescription was filled declined sharply after the advisory, with an annualized decreasing rate of 13.15 percent. By September 2005, less than a quarter of all depressive episodes were accompanied by a filled prescription for an SSRI.

Tricyclic antidepressant prescriptions saw a milder decline. No other antidepressants saw significant increases. The percentage of depressive episodes with no accompanying antidepressant prescriptions filled grew at an annualized rate of 20.62 percent between October 2003 and September 2005.

The increasing number of patients not receiving antidepressant drug therapy did not appear to be getting other treatment, either. The researchers found no statistically significant change in the percentage of depressive episodes that were followed by at least one psychotherapy visit within 180 days. Similarly, no change was seen after the advisory in atypical antipsychotic or anxiolytic prescriptions within 30 days after depression diagnosis.

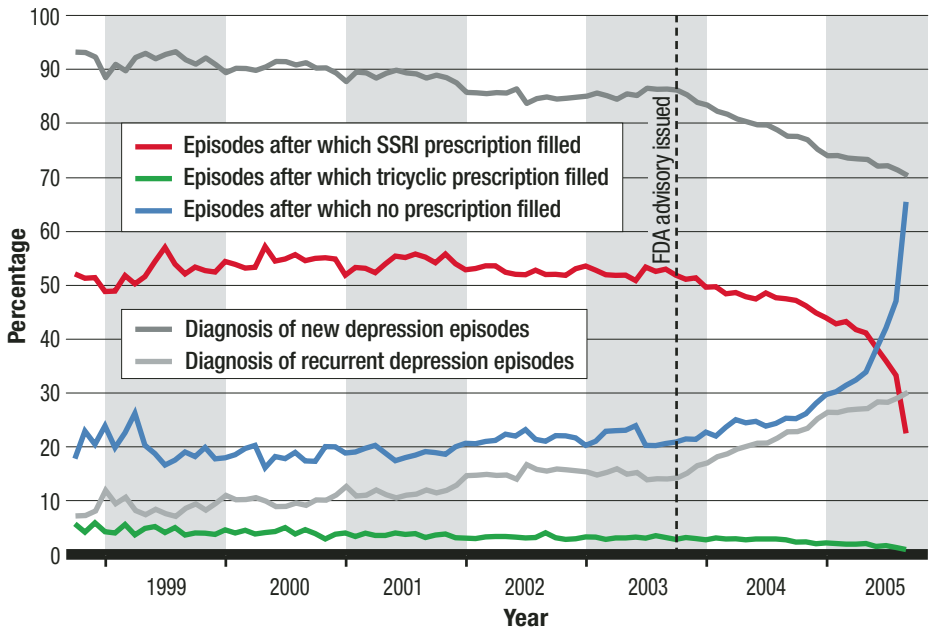
"The most alarming element in our findings was that rates of diagnosis of depression went down after the warnings came out," said Valuck. "It was not unexpected that rates of antidepressant prescribing would go down and that there could be compensatory increases in the use of other psychotropic medications and/or psychotherapy (although we didn't see any). But it was not expected that diagnosis rates would fall."

Similar decreasing trends in the diagnosis and treatment of depression in children and adolescents were detected in a study using the same managed-care-claims database and published in the June *American Journal of Psychiatry* (*Psychiatric News*, June 15).

The study "Spillover Effects on Treatment of Adult Depression in Primary Care After FDA Advisory on Risk of Pediatric Suicidality With SSRIs" is posted at <ajp.psychiatryonline.org/cgi/content/full/164/8/1198>. ■

Diagnosis, Drug Treatment for Depression Dropped Among Adults After FDA Warning

The percentage of newly diagnosed episodes of depression declined in the two years (October 2003 to September 2005) after the FDA released a Public Health Advisory on the increased suicide risk associated with pediatric antidepressant use. The percentage of depression episodes with an antidepressant prescription filled within 30 days also declined, while the percentage of episodes with no antidepressant prescription filled within 30 days rose sharply.



Source: Robert J. Valuck, Ph.D., et al., *American Journal of Psychiatry*, August 2007

FDA Timeline on Issuing Warnings

The following is a partial timeline of antidepressant-related meetings of and alerts issued by the U.S. Food and Drug Administration (FDA) in the past four years:

- **October 27, 2003:** The agency announces it will convene a special advisory committee, composed of members of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee, to examine the risk of suicidality associated with antidepressant use in pediatric and adolescent patients. A public-health advisory on this issue is distributed to all licensed U.S. physicians through the agency's MedWatch electronic notification system.
- **February 2, 2004:** The meeting of the Psychopharmacologic Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee is held.
- **March 22, 2004:** A Public Health Advisory urges clinicians to "carefully monitor patients on antidepressants for possible worsening of depression or suicidality" without making a distinction between the risks for children and adults.
- **October 14, 2004:** The FDA mandates a black-box warning on antidepressant drug labels to describe the increased risks of suicidality in children and adolescents.
- **June 30, 2005:** In a Public Health Advisory the FDA announces ongoing review of data on increased suicide risks associated with use of antidepressants and cautions that "adults being treated with antidepressant medications, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior."
- **May 2, 2007:** The FDA again revises wording about the risk of suicidality in product labels of antidepressants. While the warning is expanded to include young adults, the language for adults is changed to state that "short-term studies did not show an increase in the risk of suicidality with antidepressants compared with placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared with placebo in adults aged 65 and older."

letters to the editor

continued from page 23

which in turn resulted in deterioration in her condition. They argued that this diagnosis resulted in a sense of the patient's being out of control of her life and emotions and that this in turn resulted in significant regression.

It may be important for us to consider whether the many young people who in the past would have been diagnosed with various other disorders such as oppositional, conduct, or personality disorders and who are now being diagnosed as bipolar may not be experiencing the same problems described by Bolton and Gunderson (thus resulting in poor response to treatment and need for more frequent admissions).

Just to be clear, I am not suggesting that bipolar disorder does not occur in children. What I am suggesting is that when bipolar disorder becomes the default diagnosis for any child who is moody, difficult to manage, or stubborn, and when the primary mode of treatment becomes mood stabilizers, we might be missing, admittedly in some ways, harder-to-treat and manage family, environmental, and personality issues, and we also may be serving our patients poorly. The bipolar diagnosis needs to be made cautiously and after careful examination. If a "bipolar" child is not responding robustly to "treatment," it is imperative to reconsider the diagnosis.

VICTOR SCHWARTZ, M.D.
New York, N.Y.

community news

Bridge

continued from page 12

"People rely on friends, family, or church," said Radke. "Every conversation began with people asking, 'Where were you when it happened? Did you know anybody on the bridge or nearby?' "

While the number of dead and injured was low compared with disasters like Hurricane Katrina, the I-35W bridge collapse widely affected both local and national populations. News media around the country reported extensively on the health of bridges everywhere.

In Minnesota, the drawn-out process of recovering bodies has been a constant reminder of the event and may retrigger memories, said Anthony Ng, M.D., former chair of APA's Committee on the Psychiatric Dimensions of Disaster, in an interview. "Thousands of people could say, 'I travel that bridge all the time' and will be reminded of the collapse every time they detour through the city."

Aside from survivors and families of victims, people likely to be affected in the coming months may be those with preexisting mental illness or fear of heights, according to both Ng and Radke.

The Minnesota Psychiatric Society's response to the I-35W bridge collapse is posted at <www.mnpsychsoc.org/Bridge%20Collapse%20Response%208%202%2007.pdf>. ■

Medicaid

continued from page 5

based on compliance with a "member agreement," which requires actions such as taking medication as directed and keeping all medical appointments. Beneficiaries who do not adhere to the agreement are rolled back into the basic plan for 12 months, after which they can reapply for enhanced benefits.

More Access to MH Care Offered

Mental health advocates said placing the onus on beneficiaries with mental illness to manage their health care can be "unrealistic" in light of the seriousness of some of the illnesses from which they suffer and symptoms that can make it difficult for them to comply (*Psychiatric News*, September 1, 2006).

The limited enrollment in the new Medicaid program has led critics to say the first-in-the-nation approach will not meet the state's goals in improving overall health and reducing the long-term costs of Medicaid.

However, state Medicaid officials said they are satisfied with the progress of the program and plan to continue gradually rolling it out across the state. As more Medicaid recipients learn more about the enhanced benefits beyond the basic Medicaid plan—such as skilled nursing care—according to state officials, more are likely to enroll.

In West Virginia, about 288,000 residents are enrolled in Medicaid, which is the largest single item in the state budget, at $2.1 billion in state and federal funds.

Alabama Changes Medicaid Plan

The Centers for Medicare and Medicaid Services approved another state's Medicaid DRA amendment in July. Alabama is the first state to receive federal approval to allow self-directed personal assistance services as a feature of its Medicaid plan, eliminating the need for repeated waiver requests.

The new benefit will allow Alabama Medicaid enrollees to direct their personal care, homemaker, unskilled respite, and companion services. Alabama will allow participants to hire "legally liable" relatives to provide care and to use the funds budgeted for those services to pay for items that increase their independence or substitute for paid allied-health assistance. The state will also permit participants to receive some cash from the Medicaid program so that goods and professional services can be purchased directly.

"Alabama is the first to benefit from the federal law giving states an easier way to deliver better care by allowing Medicaid beneficiaries to have more control over the care they receive," said Mike Leavitt, secretary of the Department of Health and Human Services.

When beneficiaries direct their own care, federal officials said, research has found fewer unnecessary institutional placements, higher levels of beneficiary satisfaction, fewer unmet needs, less worker turnover, and a more efficient use of community services and supports.

Federal officials said several other states have expressed an interest in providing a similar option for their Medicaid populations.

Information on West Virginia's and Alabama's Medicaid programs is posted at <www.statehealthfacts.org/r/mfs.jsp>. ■

Preventing

continued from page 14

make a prediction, and whenever you make a prediction about the future, it's possible you could be wrong. It is simply not possible to have an aim of doing prevention and always be right—not in this field or any other field.

"It's an area that people are uncomfortable with, but it is inevitable that you will be giving the intervention to some people who will never need it," Woods continued. "We try to minimize the risk of stigmatization. We tell clients that we are not diagnosing a disease—we are diagnosing a risk. They may get worse and they may not.

"I like to turn the question on its head," Woods added. "Is there a risk of stigma if we don't identify people early? If we don't, and a person becomes fully schizophrenic, he or she may violate societal norms in a situation that can escalate into an emergency. Which is more stigmatizing?"

In Toronto, the location and appearance of the building where the PRIME Clinic is housed are deliberately contrived to be as work-a-day, as un-suggestive of a clinic treating pre-psychosis as possible. An old three-story Victorian house that stands unobtrusively near a corner of a busy intersection in the heart of Toronto's heavily trafficked university district, the building might be home to a group of trendy urban graduate students.

Also, although it is adjacent to the CAMH offices, no signage out front marks it as a prevention clinic. "You don't want to be inviting people to a schizophrenia program," Addington said. "People find that stigmatizing. So we've made it as informal as possible. People ring the doorbell to get in, and the idea is that you are just coming to a clinic to take care of these symptoms you don't feel you should be having."

She emphasized that the effort to prevent schizophrenia, while exciting, remains in the realm of clinical research until predictive criteria improve. She stressed that patients like Sam, whether they go on to develop psychosis or not, typically come to the PRIME Clinic of their own accord with serious psychological and emotional problems.

"These people are help-seeking individuals who merit some kind of treatment in any case," she said.

As a subject in the Access, Detection, and Psychological Treatments (ADAPT) study, Sam has been randomized into one of two treatment arms, receiving either cognitive-behavioral therapy (CBT) or a less-intensive treatment of regular monitoring of symptoms and supportive therapy.

Maria Haarmans, M.A., a therapist who has worked with Sam and others at PRIME Clinic, said that the hypothesis behind ADAPT is that "CBT will prevent or delay onset of psychosis" more effectively than monitoring.

"So many studies have shown how effective it is with mood disorders, but I've seen clinically that it also helps individuals who have anomalous experiences such as hearing voices," Haarmans said. "Part of why CBT works is that it helps the person to cope with these experiences by providing normalizing information that can 'de-catastrophize' the meaning of the experience."

If individuals in either treatment arm of the ADAPT study "convert" to psychosis, they can be quickly treated with antipsychotic medication and other treatments in the First Episode Psychosis Clinic at CAMH.

"We are able to get [these subjects] into treatment within hours of their having a psychotic episode," she said, noting that a significant body of research has shown that the earlier treatment begins, the better the prognosis.

For now, Sam is back in school and back in the swim of things as a 19-year-old. For a young man who has been told he is at risk for a devastating illness, one that carries severe stigma, Sam seems nonplussed, happy to have resumed his studies and a social life and grateful to have found PRIME Clinic.

"I get a lot of attention here," he said.

More information on the PRIME Clinic is posted at <www.camh.net/Care_Treatment/Program_Descriptions/Mental_Health_Programs/PRIME_Clinic/index.html>. ■

Violence

continued from page 15

CATIE was a national study of the cost-effectiveness of antipsychotic medications conducted from 2001 to 2004 at 56 sites across the United States and funded by the National Institute of Mental Health (*Psychiatric News*, April 6, March 16). The patients studied were adults aged 18 to 65 who met *DSM-IV* criteria for schizophrenia, were not experiencing the first episode of schizophrenia, and were treated with oral medications.

Additional analyses of the correlation between violence and childhood antisocial characteristics revealed risk-factor patterns associated with violence in the two patient groups.

In the patients with childhood conduct problems, for example, there was a statistically significant association between violence and substance use as well as a substance abuse or dependence disorder, but not between violence and positive psychotic symptomatology as measured by higher Positive and Negative Syndrome Scale positive scores. (Substance use, as opposed to abuse or dependence, refers to alcohol or illicit drug use that does not cause significant impairment, according to a study of CATIE data by the same researchers in the May 2006 *Archives of General Psychiatry*).

In the patients without childhood conduct problems, violence was statistically significantly associated with substance abuse or dependence disorder only and with positive psychotic symptomatology, but not with substance use. The two groups of patients did share several other risk factors also significantly associated with violence, including younger age, lack of substantial vocational activity, residing with family or other relatives, and recent involvement with the police.

The researchers discussed two theories that may explain the findings. First, the childhood antisocial tendency may be an early sign of an underlying pathology in a subgroup of schizophrenia patients prone to violence in adulthood. Or it may be that a subtype of patients has characteristics of comorbid antisocial personality disorder separate from psychosis.

"This study is an important contribution to the understanding of pathogenesis of violent behavior in schizophrenia patients. It is consistent with previous observations that violent patients with schizophrenia have high ratings on the psychopathy scale and that only about 20 percent of violent incidents in psychotic inpatients is directly attributable to positive symptoms," commented Jan Volavka, M.D., Ph.D., a professor emeritus of psychiatry and a research professor of psychiatry at New York University School of Medicine and the author of the book *Neurobiology of Violence*.

"The study indicates that much of the violence in schizophrenia is not directly related to psychosis. It is therefore not likely to respond to antipsychotic medication," Volavka said. Although treatment for violent behavior in this subpopulation is not well established, he pointed to previous studies that suggest long-term, cognitively based, behavioral treatment may be helpful to some schizophrenia patients with persistent violent behavior not directly related to psychotic symptoms.

An abstract of "Alternative Pathways to Violence in Persons With Schizophrenia: The Role of Childhood Antisocial Behavior Problems" is posted at <www.springerlink.com/content/c718739702076675/?p=0d39f6b1aa8847eab14d224ef6969fa1&pi=5>. ■

Suicides

continued from page 17

on suicide that may well not be reflected if monthly patterns are inspected."

Another possible explanation is that high temperatures do not play any role in the spring-summer suicide peak. A 2003 study found that the hours of bright sunlight a day, not temperature, explained the peak in suicides during Australia's spring and summer (*Psychiatric News*, June 20, 2003).

The study was funded by the U.S. National Institutes of Health, the Wellcome Trust, and the European Commission Directorate-General for Health and Consumer Protection for the EuroHEAT project.

An abstract of "Relationship Between Daily Suicide Counts and Temperature in England and Wales" is posted at <http://bjp.rcpsych.org/cgi/content/abstract/191/2/106>. ■

Application Deadline

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

More information is available from Crystal Garner at cgarner@psych.org or online at <www.psych.org/edu/cert-psych.cfm>. ■

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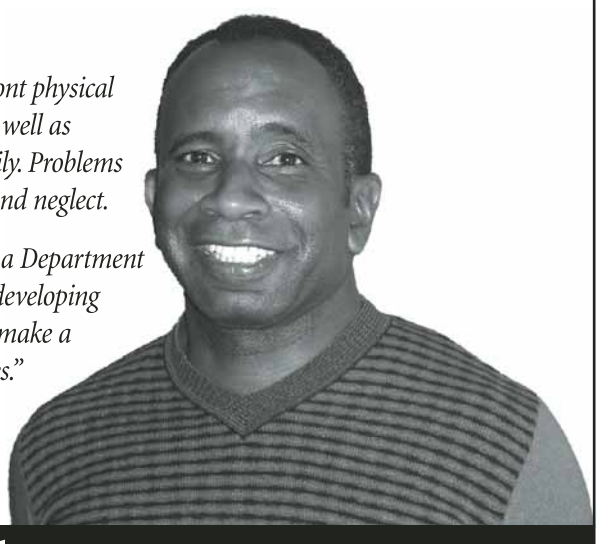

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CALIFORNIA DEPARTMENT OF Mental Health

Minority Research Training in Psychiatry

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

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

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

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

For more information,
Call: 1-800-852-1390 or 703-907-8622
E-mail: eguerra@psych.org
Write to PMRTP at the American Psychiatric Institute for Research and Education, 1000 Wilson Blvd, Ste. 1825
Arlington, VA 22209-3901

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Subject to random drug screening.
EOE

Broughton Hospital, which provides quality psychiatric care to the citizens of western North Carolina, is seeking psychiatrists to help expand and enhance its inpatient services. Generalists, sub-specialists, new graduates and recent retirees are all welcome to apply. In addition to adolescent, adult and geriatric services Broughton has recently opened a statewide psychiatric and substance abuse service for deaf citizens, and will open a forensic treatment unit covering the western half of the state in 2007.

Broughton is located in Morganton, NC in Burke County. Morganton has a vibrant downtown and is convenient by car to Hickory (20 minutes), Asheville (60 minutes), and the rest of the planet via Douglas Airport in Charlotte (85 minutes). Major league sports and some of the best hiking, skiing, trout fishing, and kayaking on the East Coast are just as close. Some staff reside on the shore of Lake James, just 20 minutes to the west. Burke County was voted as one of the 10 best places to raise a family by Reader's Digest.

Salary and benefits are competitive. Flexible or part-time schedules are negotiable. On-campus housing is available. Opportunities exist for additional income via paid call. The hospital has academic affiliation with a nationally known residency program. Broughton hosts medical students and voluntary participants in the clinical clerkship earn paid CME. Physicians here are eligible to apply for a State student loan repayment program.

Send CV and letter of interest to:
Sherrie Kappa
Broughton Hospital
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Morganton, NC 28655

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EOE

The Government of the District of Columbia, Department of Mental Health seeks a Supervisory Clinical Psychologist, Salary $82,424.00 - $106,202.00

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The incumbent is responsible for:

- **Provides leadership and professional supervision to all Psychology Department personnel and serves as a member of the Hospital Management Team.**
- **Makes major decisions affecting the basic content and character of Psychology Department operations, including what appropriate Psychology Department services should be provided for the patient population that includes Acute Psychiatric Care, Gero-psychiatric, Continuing Care, Medical Care, and Forensic services (pre-trial and post trial).**
- **Maintaining accreditation readiness for JCAHO, CMS, APA and other regulatory accrediting bodies.**
- **Collaborating with the Medical Staff office to assure timely credentialing and privileging of all SEH Psychologists.**
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This position requires one (1) year of specialized experience equivalent to the next lower grade level. Specialized experience is experience which has equipped the candidate with the particular knowledge, skills and abilities to successfully perform the duties of the position to be filled.

Candidates must have completed an American Psychological Association (APA) accredited doctoral program (Ph.D or Psy.D) in clinical or counseling psychology and an (APA) accredited clinical internship. Candidates must be a licensed Clinical Psychologist in the District of Columbia through the Department of Consumer and Regulatory Affairs.

To apply, please submit: current resume with salary history and cover letter and complete D.C. Government Employment Application Form (DC 2000). Send cover letter and resume to Clara Orino, Human Resources Specialist, DC Department of Mental Health, Division of Human Resources, 64 New York Ave, NE, 5th Floor, Washington, DC 20002, (202) 645-5979 or by facsimile to (202) 673-4386.

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Please contact Sandy Audsley at Sandra.Audsley@va.gov or 802-291-6285 to receive further information or to apply.

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Psychiatry

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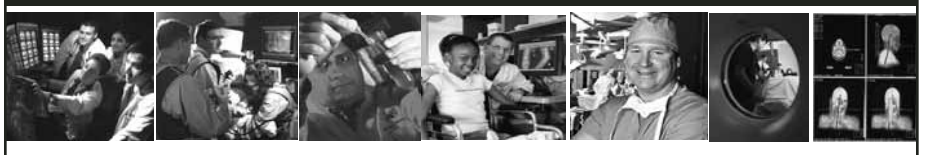

Adult and Child and Adolescent Psychiatrists & Psychologists
Scott & White/Texas A&M College of Medicine
Temple and College Station Clinics

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

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

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

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TEXAS A&M HEALTH SCIENCE CENTER
COLLEGE OF MEDICINE

New Hampshire Hospital Medical Director

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

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

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

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

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

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

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

ACADEMIC COMMUNITY PSYCHIATRIST

Washington Hospital Center Department of Psychiatry is a leader in providing full continuum of care for inpatient, outpatient, psychosomatic medicine and substance abuse treatment in the Washington DC Metropolitan area. The Outpatient Behavioral Health Services at Washington Hospital Center, seeks an academic psychiatrist to provide community psychiatric care, and have teaching responsibilities in community psychiatry.

Candidates must be board certified in general psychiatry and eligible for a District of Columbia medical license.

Qualified candidates should send a letter of interest and curriculum vitae to:

Karen M. Johnson, MD
Associate Chair & Director
Psychosomatic Services
Department of Psychiatry
Washington Hospital Center
110 Irving St., NW EB-3105
Washington D.C. 20010
Fax: (202) 877-7552
Email: Inga.L.Ricks@medstar.net

PSYCHIATRISTS

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

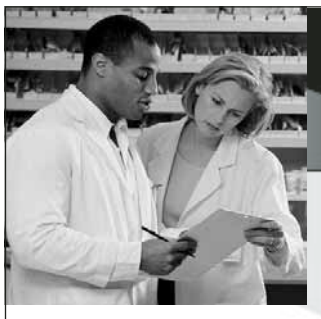
Applicants are required to have expertise in treatment of at least one of the following patient populations: the seriously mentally ill, PTSD or provision of mental health in primary care clinics.

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

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

Please Fax or send CV to:

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



Providence VA Medical Center

Psychiatrists

Two openings for outpatient Psychiatrists within our Posttraumatic Stress Disorders Clinical Team (PCT):

- The first position serves as the Medical Director of the PCT and is responsible for medical aspects of the program's care as well as provision of psychiatric outpatient services.
- The second position serves as a Staff Psychiatrist in the PTSD Clinic providing care to a caseload of veterans with traumatic stress disorders.

Both positions offer the opportunity to teach Brown Medical School students and psychiatry residents. The incumbent should be eligible for a clinical faculty appointment at Brown. A record of teaching and supervision of residents and other trainees preferred.

Candidates must possess a degree in medicine, a full unrestricted license, and be Board certified/eligible.

Qualified applicants should forward CV to:
Providence VA (05)
589 Atwells Ave.
Providence, RI 02909

or e-mail to:
providence.resume@med.va.gov

or fax to: **401-861-2396**.

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Arlington, Virginia 22209-3901
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DEADLINES: All new advertising copy, changes, and cancellations must be received *in writing* by Friday, 2 p.m. (E.T) two weeks prior to publication date. Publication dates are the first and third Fridays of every month. Specific deadline dates for upcoming issues are as follows:

Issue	Deadline (Friday, 2 p.m. E.T.)
October 5	September 21
October 19	October 5

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888-651-8367, ext. 35
www.PsychPros.com

ALABAMA

Mountain Lakes Behavioral Healthcare, located in beautiful northeast Alabama, has an excellent opportunity to practice general psychiatry in a community mental health center setting. We have an immediate full time opening in our Scottsboro Office in Jackson County (45 minutes from Huntsville). Looking for someone interested in a diversified caseload and varied work settings. Very good working conditions; eager, cooperative treatment team; competitive salary and benefits. Board certified or Board eligible. J-1; H1-B welcome. Contact: Jerome E. Johnson, email jjohnson@mlbhc.com; (256) 582-4240 ext. 106.

ALASKA

Fairbanks Memorial Hospital in Fairbanks, AK, is looking for a full-time, adult, inpatient Psychiatrist to join our exceptional team. We have a 20-bed inpatient unit, staffed with a Nurse Director, RNs, an LPN, CNAs, Psych Techs, Counselors, an OT, Social Workers and a Medical Director.

FMH is committed to continually upgrading the level of care in our close-knit community and invite you to join us. Come experience the Alaskan way of life, full of adventure and beauty, and work at a top-notch facility.

For more information, call 888.303.5402 or e-mail Suzan.Bast@bannerhealth.com. Check out our Web site at www.fmhdc.com.

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

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pn.psychiatryonline.org

ARIZONA

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

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

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

CALIFORNIA

Faculty Positions - UCSD

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

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GREATER BAY AREA - Modesto, California

General & Child Psychiatrists needed, for unique, stable County Mental Health system in a welcoming community. Serve both public & private sector patients, in both inpatient/outpatient settings that have been benchmarked for their quality. Possibilities for Resident teaching & consultation with a full range of providers. When patients require hospitalization, inpatient & outpatient staff work **TOGETHER** to optimize care. Stanislaus County is located only 1 1/2 hours from both San Francisco and Yosemite, enjoying the best of both worlds.

Excellent salary scale, with steps from $159K to $194K; **PLUS** full benefits; **PLUS** 5% additional for each of following: Inpatient, General Boards, Child Boards; **PLUS** extra for limited On-Call; **PLUS** Union-negotiated increases already set for next few years. Negotiable hourly contract also an option. Fax CV to Marshall Lewis, MD, 209-558-8641 or call 209-558-4639.

ADULT PSYCHIATRIST JOB OPPORTUNITIES

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

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

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

Central Coast: Unique private practice situation for well-qualified psychiatrist (or two). Solidly established small outpatient group in one of the nation's most desirable places to live seeks bc/be child or general psychiatrist to fill vacancy and another for planned expansion. Competitive reimbursement, great work environment, excellent benefits, opportunity for shared ownership. Submit CV, questions, contact info to Susan Lewis at cpc@cpcgroup.org.

The Perfect Position in Northern California!

I have an outstanding Adult Psychiatrist position that is available in one of California's fastest growing communities. It is located 45 minutes south of Sacramento with a population of over 260,000. The position is a highly sought after **Adult Psychiatrist employed outpatient opportunity with no call!** You can have a flexible schedule while you care for the full range of psychiatric cases. Work in an environment of collegiality with other highly trained Adult and C & A psychiatrists along with their superb team of therapists, social workers, nurses, and case managers. This is a perfect position to balance your personal and professional life! **Send your CV to Tina Wilkins at wilkinstina@earthlink.net; fax to 916-536-9281; call 1-888-229-9495.**

UCSF DEPARTMENT OF PSYCHIATRY SAN FRANCISCO GENERAL HOSPITAL

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

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

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

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

SHASTA COUNTY COMMUNITY MENTAL HEALTH

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

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Call Tarah Cronquist at 805-884-8098, or send resumes to tcronquist@sbcountyhr.org , **www.sbcountyjobs.com**

California Pacific Medical Center-San Francisco, A major not-for-profit, private teaching and tertiary care center located in the heart of San Francisco, is recruiting a BE/BC psychiatrist and clinical educator to join the faculty practice in the Department of Psychiatry.

Administrative and clinical duties include attending on a locked geriatric psychiatry inpatient unit, psychiatric consultation, supervision of psychiatry residents and leading a multidisciplinary team. Potential for individual growth includes developing an outpatient practice, participating in an active ECT program, teaching and supervising psychiatry residents.

This full time position includes competitive compensation and an excellent benefits package through the Physician Foundation at California Pacific Medical Center (PFCPMC), a multi-specialty medical group based at California Pacific Medical Center.

Please send curriculum vitae and inquiries to:

Arnaldo Moreno, M.D.
Department of Psychiatry
California Pacific Medical Center
2340 Clay Street 7th Floor
San Francisco, CA 94115

MorenoAX@sutterhealth.org
Phone: 415-600-7750
Fax: 415-600-7755

Research Psychiatrist Southern California

California Clinical Trials (CCT), a subsidiary of PAREXEL International, has full and part-time openings in Los Angeles for board eligible/certified psychiatrists with an interest in psychopharmacology research. Research experience is a plus.

Established over twenty years ago, CCT is one of the largest CNS research groups in the U.S., with a special emphasis on schizophrenia, sleep, and early drug development. We have a stellar reputation for quality, performance and innovation. CCT psychiatrists work as part of a research team comprised of clinical scientists and a highly trained research staff.

Research psychiatrists receive an excellent benefit package and competitive compensation commensurate with experience and qualifications. Candidates should be available to travel nationally to investigator meetings several times a year.

Interested candidates should e-mail their CV's to hrdept@cctrials.com or fax to 818-545-7044. EOE.

UC DAVIS SCHOOL OF MEDICINE DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

Associate Residency Program Director. The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting an Associate/Full Professor of Clinical Psychiatry to serve as Associate Residency Program Director of a growing general psychiatry residency program with 32 approved positions. The program is distinguished by excellence in 1) Clinical experiences in the academic, public sector, and private sector settings; 2) Innovative combined training program in psychiatry-family practice and psychiatry-internal medicine; 3) Specialized tracks in research and teaching for residents and a diverse patient population, residents and faculty. The academic series for this appointment is the teacher/clinician series. The faculty member is expected to engage in scholarly activities leading to publication of papers, book chapters and books. The individual selected will also supervise residents and treat patients in the department's outpatient clinic. The successful candidate should be board certified in general psychiatry, be eligible for a California Medical license, should have a passion for residency education and teaching and be committed to pursuing an academic career.

For full consideration, applications must be received by October 31, 2007. Position is open until filled, but no later than December 31, 2007. Interested candidates should email a curriculum vitae and letter of interest in response to Position # PY-01R-08 to Cecilia Mafnas, Academic Personnel Specialist at cecilia.mafnas@ucdmc.ucdavis.edu or UCDMC Department of Psychiatry and Behavioral Sciences, 2230 Stockton Blvd. Sacramento, CA 95817. In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

http://www.ucdmc.ucdavis.edu/psychiatry/

New Salaries Approved Great Psychiatrist Opportunities

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

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

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

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

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

Crownview Medical Group in beautiful and exclusive Coronado (San Diego) seeks a full time psychiatrist for its dynamic and growing practice which consists of inpatient, outpatient and very limited call. Competitive salary commensurate with experience or 75/25 split. Fax resume to (619)435-5401.

UC DAVIS SCHOOL OF MEDICINE DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

Luke and Grace Kim Endowed Professorship in Cultural Psychiatry. The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting an Associate/Full Professor of Clinical Psychiatry to be the holder of the Luke and Grace Kim Endowed Professorship in Cultural Psychiatry and Director of Cultural Psychiatry in the Department. The appointment is in the teacher/clinician series. The successful applicant is expected to engage in scholarly activities leading to the publication of peer-reviewed papers, book chapters, monographs and books. The candidate should have a well-established track record in cultural psychiatry as reflected in publications and grants from private foundations and state and federal agencies. A research background in cultural psychiatry and experience collaborating with other investigators to develop culturally-based research projects is highly desired. The candidate should have experience teaching medical students and residents about cultural psychiatry and other clinically-related topics. National prominence in the field of cultural psychiatry is desired. Experience in working in a community mental health setting with culturally diverse patient populations and with county and state governments in delivering culturally competent mental health services is also desired. The applicant should be board certified in general psychiatry and licensed or license-eligible to practice medicine in California.

The Department of Psychiatry and Behavioral Sciences has a multi-award winning Diversity Advisory Committee which has made major contributions to the teaching of diversity and cultural competence to medical students and residents. The Diversity Advisory Committee has 10-12 faculty members, three of whom have received awards from the UC Davis Chancellor for their outstanding achievements in promoting diversity throughout the UC Davis Community. The Department of Psychiatry has grown tremendously over the last decade with approximately 75 psychiatrists and psychologists, 350 employees and annual direct costs in research funding of approximately $10 million.

For full consideration, applications must be received by December 31, 2007. Position is open until filled, but no later than March 31, 2008. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-02R-08 to Cecilia Mafnas, Academic Personnel Specialist at cecilia.mafnas@ucdmc.ucdavis.edu or UCDMC Department of Psychiatry and Behavioral Sciences, 2230 Stockton Blvd. Sacramento, CA 95817. In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

http://www.ucdmc.ucdavis.edu/psychiatry/

The VA Long Beach Healthcare System currently has an opening for a part time board certified or board eligible psychiatrist to provide outpatient care at our community clinics located in Anaheim and Whittier/Santa Fe Springs. Three days a week will be spent at Whittier/Santa Fe Springs and 2 days a week in Anaheim. The ideal candidate would provide excellent clinical care and work well with other mental health professionals and primary care providers in the clinics. Competitive salary negotiable, depending on qualifications. There are ample benefits and recruitment incentives and assistance with re-payment of student loans are possible. The Veterans Administration is an Equal Opportunity Employer. **To find out more about this exciting opportunity contact: Larry Albers, MD, Chief of Mental Health at: larry.albers@va.gov (562-826-5758)**

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UC DAVIS SCHOOL OF MEDICINE
DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

Health Sciences Assistant/Associate Clinical Professor. The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting for a Health Sciences Assistant/Associate Clinical Professor in the clinician/teaching series to serve as teaching attending at the Mental Health Treatment Center located next to the UC Davis Medical Center in Sacramento. The Treatment Center has a crisis unit and a 100 bed inpatient unit that is staffed by UC Davis faculty, residents, and medical students. The Center also has three dually-trained medicine-psychiatry faculty and its own primary care physician on site. Experience in teaching and supervision of medical students, residents, and other mental health professional is highly desirable. The successful candidate should be board eligible or certified in general psychiatry, be in possession of a California Medical license, and have an interest in psychiatric education and training. The successful candidate will lecture in seminars and case conferences, and provide group and individual supervision of clinical cases. The incumbent will provide clinical teaching for general psychiatry residents, psychology fellows, medical students and other mental health professionals including timely and appropriate evaluation of trainee performance.

For full consideration, applications must be received by January 31, 2008. Position is open until filled, but no later than June 30, 2008. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-03R-08 to Cecilia Mafnas at Cecilia.mafnas@ucdmc.ucdavis.edu In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

http://www.ucdmc.ucdavis.edu/psychiatry/

The Department of Veterans Affairs Medical Center, Long Beach, California, is seeking a Board Certified/Board Eligible Psychiatrist to work with the Buprenorphine Treatment program for patients with opiate dependence. Knowledge of substance abuse is required. Psychiatrist (preferable ASAM or Addiction Psychiatry certified), will work in the development of buprenorphine treatment program for patients with opiate dependence. Requires knowledge of substance abuse and ability to prescribe Buprenorphine (Suboxone), detox and/ or maintain opiate addicted patients on outpatient basis using Suboxone. This is a new treatment program designed to reach veterans with Substance Use Disorder, specifically, opiate dependence, either singly or dually diagnosed with other mental health diagnoses Duties will include clinical assignments along with teaching and supervision of residents and students. Candidate must possess excellent skills, both clinical and administrative. There are ample benefits and recruitment incentives and assistance with re-payment of student loans are possible. The VA is an Equal Opportunity Employer. **To find out more about this exciting opportunity contact Larry Albers, MD, Chief of Mental Health at: larry.albers@va.gov (562-826-5758)**

COLORADO

General Psychiatrist - Immediate opening at Colorado State Hospital with good patient/staff ratio. 40-hour workweek with no required night or weekend work. Four day work week possible, providing time for limited private practice or other outpatient work. Position carries University of Colorado Medical School faculty appointment. Teaching medical student desirable. Please contact A.O. Singleton, III, M.D. @ (719) 546-4637 for more information.

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

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PSYCHIATRIC POSITIONS

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

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

ADULT OR GERIATRIC PSYCHIATRIST
(Interest in Geriatric Population)

We offer competitive salary and robust benefits package.

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

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

Pikes Peak Behavioral Health Group

Medical Director

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

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

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

CONNECTICUT

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

Part Time Out-Patient Adult/Adolescent Opportunity in Manchester, CT

Eastern Connecticut Health Network offers a 20-hour Psychiatric position working with adult and adolescent patients. Call 2-3 times per month with extra call compensation, no weekend call. Excellent colleagues, warm community hospital, with competitive salary and generous benefits including CME. Send CV or inquires to Dr. Stephen Alloy, 150 N. Main St., Manchester, CT 06040 or via email at salloy@echn.org.

SOUTHEAST CT: General or Child Psychiatrist - acute, residential & partial setting patient care settings. Salary & benefits. Opportunity for administrative title & duties. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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INCREDIBLE INPATIENT/OUTPATIENT PRACTICE OPPORTUNITY in an area nationally known as one of the MOST BEAUTIFUL residential communities in America! Located in the picturesque northwest corner of Connecticut, Sharon is an area with a great need for more psychiatrists. If being your own boss and the freedom of private practice is of interest, this is the perfect place to get established. Or if you have an outpatient practice already in the surrounding area, this would be a very lucrative addition to your current income. Exceptional prep schools, parks, and recreation. Contact Terry B. Good at Horizon Health, 866-865-7380; Fax: 804-684-5663; E-mail: terry.good@horizonhealth.cm. EOE

DELAWARE

DOVER: General Psychiatrist - Inpatient & Partial programs. Administrative/clinical title and duties an option. Great salary & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

FLORIDA

MIAMI AREA (Aventura, FL): PSYCHIATRIST, FT; FL LICENSE REQ'D; also hiring ARNP and/or P.A.; private practice (adoles/adult/geriatric pts); Office/SNF/IP; Excellent Salary & Benefits; **FAX CV** to Dusty: **305-935-1717** or **EMAIL:** aventuraoffices@bellsouth.net

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FT. MYERS/MERBOURNE/ORLANDO/DAYTONA/MIAMI/FORT LAUDERDALE/OCALA/GAINESVILLE - Psychiatrists needed for rapidly expanding Nursing Home Service. Great support. No call. Average Salary 210K + benefits. Part-time available. Some travel required. Must have FL Medicare & FL Medicaid provider #s. Call Mike at 866-936-5250.

STAFF PSYCHIATRIST / MEDICAL DIRECTOR - Daytona Beach - Miles of sandy beaches & excellent opportunities with flexible scheduling and limited on-call. Florida license required, clinical research preferred. Expanding medical staff with opportunities for professional growth in many areas. Excellent benefit package including professional liability insurance. For confidential consideration, please send or fax resume to Human Resources.

Act Corporation
1220 Willis Avenue
Daytona Beach, FL 32114
Fax (386) 236-3158
www.actcorp.org
Competitive $ & Benefits
DFWP/EOE/M/F/D/V/Equal Access

FACT Program Psychiatrist

Mental Health Resource Center, Inc. (MHRC) is seeking a **Psychiatrist** for its Adult Florida Assertive Community Treatment (FACT) Program in the Kissimmee area. Full-time (32 hours per week) salaried position with comprehensive benefits package. Opportunities for part-time work also available. Florida licensure and Board Eligibility/Certification required. To apply, contact Dr. Robert Sommers, President, RBHS, P. O. Box 19249, Jacksonville, FL 32245. e-mail: rbhspres@bellsouth.net. Fax: (904) 743-5109. Phone: (904) 743-1883, ext. 219.

Psychiatrist

Full-time position available in outpatient clinic of JCAHO accredited comprehensive community mental health center located in Jacksonville, FL. Position will also involve participation in on-call roster for inpatient services. (Other psychiatrist opportunities available periodically; please inquire.) Florida licensure and BE/BC required. Competitive salary with comprehensive benefits package. Contact Dr. Robert Sommers, President, RBHS, P. O. Box 19249, Jacksonville, FL 32245. e-mail: rbhspres@bellsouth.net. Fax: (904) 743-5109. Phone: (904) 743-1883, ext. 219.

Sunny Florida, just minutes from Ft. Lauderdale!!!! Live, work, and play next to 23 miles of beautiful beaches, performing arts centers, museums, shopping and the night life!!!! Excellent opportunity to join a private practice with partnership potential! For more information on this opportunity and others nationwide, Contact: Loree Frazitta @ 800-735-8261 ext 216, fax your CV to 703-995-0647, or e-mail: lfrazitta@medsourceconsultants.com.

Located along South Florida's east coast just minutes from the Atlantic Ocean, CARF accredited community mental health center is seeking a part-time/full-time inpatient and outpatient psychiatrists to provide comprehensive psychiatric care to adults. Must be Board Certified (or eligible). Excellent salary and benefits package, great staff and a lovely coastal community. Seeking applications directly from candidates. (No recruitment firms please!) Send/Fax CV: HR, New Horizons, 4500 W. Midway Rd., Ft. Pierce, FL 34981 FAX (772) 468-5606 EOE/AA/V/M/F/DFWP www.nhtcinc.org

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Good salary, incentives, and full benefits package for child and adolescent psychiatrist to join staff of seven psychiatrists at large hospital system. Excellent location near Tampa and Orlando. Call Jim Ault, St. John Associates at 800-737-2001 or email jault@stjohnjobs.com. www.stjohnjobs.com for opportunities nationwide.

New Port Richey - Fantastic Practice Opportunity in a Coastal Location - If being your own boss and having the freedom to set your own work schedule is what you've wanted, then please call me. This is an opportunity to open an inpatient and outpatient private practice (adult and geriatric) in the fifth fastest growing county in FL. Or if you have a practice already, adding our inpatient component to your income could be extremely lucrative. Call is 1 in 4. Please **call Terry B. Good at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

GEORGIA

Lakeside resort community near Atlanta! Hospital practice provides great salary and benefits. Inpatient and outpatient work. Call Jim Ault, St. John Associates at 800-737-2001 or email jault@stjohnjobs.com. www.stjohnjobs.com for opportunities nationwide.

ILLINOIS

PSYCHIATRIST EDUCATOR: Assist. Prof., Univ. of IL Coll. of Medicine at Peoria, Dept. of Psychiatry & Behav. Medicine is seeking a brd-cert./elig. PSYCHIATRIST to join a collegial community-based psychiatry department. Primary responsibilities include classroom/clinical teaching and outpt. clinical care. Applications accepted until position is filled. Reply to: Peter Alahi, M.D., Chair, Psychiatry Search Committee, Dept. of Psychiatry & Behav. Medicine, UIC College of Medicine at Peoria, 221 NE Glen Oak Ave., 7 West, Peoria, IL 61636; Phone (309) 671-2165; FAX (309) 671-8384 e-mail: palahi@uic.edu The University of Illinois is an AA/EO Employer.

INDIANA

Psychiatrists wanted

Midtown Community Mental Health Center, Indianapolis, IN is seeking several BC/BE Psychiatrists. Seeking one (1) outpatient psychiatrist to work with ACT Team as well as provide care for patients with SMI. Seeking one (1) psychiatrist to work in our Adult Outpatient services.

Need to be licensed to practice medicine in the state of Indiana. J-1 Visa applicants are welcome. Comparable salary and benefits package plus paid malpractice insurance.

Send CV to Steve Fekete, M.D., Medical Director, Midtown CMHC, 850 N. Meridian St., Indianapolis, IN 46204 or FAX: 317-554-2721. Telephone: 317-554-2703.

KANSAS

MEDICAL DIRECTOR
Valeo Behavioral Health Care, the leading provider of comprehensive mental health and substance abuse services for adults in Topeka, KS seeks a **Medical Director** to provide outpatient medical/psychiatric services to their consumers. This is an excellent opportunity for a Psychiatrist with strong clinical and interpersonal skills to provide leadership, clinical supervision, and clinical care in an Adult outpatient mental health setting. Valeo is licensed by the State of Kansas and nationally accredited by the Commission on the Accreditation of Rehabilitation Facilities (CARF). Valeo has served the behavioral health care needs of Shawnee County residents since 1967.

With cultural amenities to rival big cities, Topekans revel in numerous outdoor activities, excellent healthcare facilities, technologically advanced education, and a below-average cost of living. Topeka is located 50 miles east of Kansas City on Interstate I-70 and less than an hours drive to KCI airport.

The ideal candidate would be ABPN Board-certified or Board-eligible psychiatrists; MD or DO licensed by the State of Kansas; and have demonstrated interest in working with underserved and culturally diverse population with at least five years of administrative experience in a mental health setting. Compensation commensurate with experience; excellent benefit package.

Interested applicants submit a CV to Valeo Behavioral Health Care, Human Resources, 5401 SW 7th Street, Topeka, KS 66606 or fax it to 785 273-7489. For questions contact: Shawna Mercer, Human Resources, 785-273-2252 ext 5205 or email smercer@valeotopeka.org. Valeo is an EOE.

KENTUCKY

LOUISVILLE area: Medical Director & Child Psychiatrist positions. Inpatient/outpatient - adolescents & adults. Limited call - great salary & benefits. Will consider part-time or fulltime. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

LOUISIANA

CENTRAL LOUISIANA STATE HOSPITAL
CHILD AND ADOLESCENT PSYCHIATRIST

Central Hospital, a 132 bed Joint Commission approved psychiatric inpatient facility, and the Louisiana Office of Mental Health, seek a board eligible/certified child and adolescent psychiatrist to act as the medical director of a 16 bed adolescent inpatient unit. This psychiatrist will work with a dedicated and cohesive multi-disciplinary team providing a full range of integrated therapeutic services to patients aged 13 to 17 with emotional and behavioral disorders. We are looking for a solid clinician with strong leadership and communication skills. CLSH is located in the Pineville/Alexandria area of central Louisiana and is within driving distance to Lafayette (the heart of Cajun country), Baton Rouge, and New Orleans. Affordable housing, good schools, and a family oriented community make this area a wonderful place to live. Position is full time with some flexibility in the work schedule. Light call is on weekdays only and is primarily by phone. Salary range is competitive. A relocation stipend may be available. Benefits include annual/sick leave, retirement system with pension, life/health insurance, and tax sheltered savings program. Malpractice included. Academic appointment is potentially available to the appropriate candidate. Interested parties should forward a letter of interest and a c.v. in confidence to:

L. Lee Tynes, MD, PhD
Medical Director
Central LA State Hospital
PO Box 5031
Pineville, LA 71361-5031
ltynes@dhh.la.gov
telephone: 318-484-6203
EOE

The Louisiana Office of Mental Health is seeking psychiatrists to work across the state in a variety of positions. We have a unique mental health care delivery system that is transforming itself in a number of ways to better meet the needs of our citizens. With the challenges we are facing from the 2005 hurricane season, our system has had to be creative and responsive. Come be a part of the recovery of our beautiful state! Positions are available in urban and rural areas, inpatient and outpatient facilities, and forensic and civil settings; adult and child psychiatrists are needed. For more information, please contact Kathleen Crapanzano, M.D., Office of Mental Health Medical Director, 628 PO Box 4049, Baton Rouge, LA 70821-4049 or phone at 225-342-2550 or e-mail at kcrapanz@dhh.la.gov.

Ochsner™ Health System

BC/BE Psychiatrist

OCHSNER ST. ANNE GENERAL HOSPITAL is seeking:

- A BC/BE Psychiatrist for an employed position in Raceland, Louisiana
- Located 40 miles from New Orleans with a population of approximately 40,000
- Not-for-profit critical access hospital providing inpatient & outpatient services with high quality, cost-effective emergency, medical & surgical care
- Part of nationally renowned health system of 7 hospitals, 600+ member physician group, and 28 health centers
- Very competitive salary and benefits
- Family-oriented community with year-round outdoor activities
- Favorable malpractice environment in Louisiana
- J-1 visa candidates are welcome to apply
- Ochsner Health System is an equal opportunity employer.

Please email CVs to: profrecruiting@ochsner.org or call (800) 488-2240.
Ref# APSYN4.

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

MAINE

Dartmouth Faculty Psychiatrists

Dartmouth Medical School, Department of Psychiatry, in collaboration with the State of Maine Department of Health and Human Services, seeks faculty psychiatrists for the Riverview Psychiatric Center in Augusta, Maine. The Center is the flagship inpatient hospital serving central and southern Maine's system of public mental health care. A 92-bed, state of the art, replacement hospital opened in the Spring of 2004. Preference will be given to candidates with forensic training and/or experience. Maine licensure required. These are full-time Dartmouth faculty appointments with salary and rank commensurate with experience and academic accomplishments. Protected time for scholarly activities. Central and southern Maine offers exceptional opportunities to enhance your quality of life. We have safe communities, with very low crime, good schools and unparalleled four season recreational activities. Augusta is less than one hour from the Maine coast and closer to numerous crystal clear lakes and mountains. It is no wonder Maine is called "vacationland." Please send CV and three letters of reference to: **Alan I. Green, MD, Professor and Chair of Psychiatry, Dartmouth Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756**. Dartmouth Medical School is an EOE/AA Employer and encourages applications from women and members of minority groups.

MARYLAND

PSYCHIATRIST immediate contractual position for in-patient unit in Baltimore, MD. Daily rounds 10-12 patients, M-F, occ. weekend/holiday req. Board Elig/Cert. OPEN UNTIL FILLED. mmclaughlin@urbanbehavioralhealth.org or call Dr. Harini Balu at 410-362-3000 for addl info.

Psychiatrist

Springfield Hospital Center - a 405 bed psychiatric in patient facility, operated by The Maryland State Mental Hygiene Administration seeks Maryland licensed Psychiatrists. Our rural 400 acre campus is located 22 miles west of Baltimore and convenient to Washington, DC. via routes 70 & 29. We offer full time and part time positions with comprehensive benefits, which include 27 days of paid leave, medical coverage and access to Maryland State Employees Pension at retirement. Additionally, Contractual day/night positions available. Both Board & Non-Board Certified physicians will be considered. Salary for these positions is negotiable. Please send CV to: Jonathan Book, M.D., Clinical Dir, SHC, 6655 Sykesville Rd. Sykesville, Maryland 21784. For questions call 410-970-7006 or email Jbook@dhmh.state.md.us. EOE

PSYCHIATRIST PT for fast-paced growing Geriatric Behavioral Health Practice to provide consultation services in LTC setting in Maryland. Background in medical/neurological basis for psychiatric symptoms desirable. Fax cover letter and resume to CGS, 410-832-5783, Attn.: Dr. Fitting.

Faculty Position
Assistant Professor (Tenure Track)
Department of Psychiatry

The Department of Psychiatry at the Uniformed Services University of the Health Sciences, Bethesda, MD is seeking to fill an Assistant Professor, tenure-track, teaching and research position. The Department is comprised of twenty full-time faculty and has active research interests in the neurobiology and behavior of stress, PTSD, anxiety, depression, and substance abuse. The successful candidate will participate in and develop medical student and resident education, a research program and provide clinical care. Individuals who hold an M.D., have completed an approved psychiatric residency and are board eligible/certified are invited to apply. Send curriculum vitae, description of current and anticipated research interests and the names and addresses of four references to: Robert J. Ursano, M.D., Chairman, Department of Psychiatry, Uniformed Services University, 4301 Jones Bridge Road, Bethesda, MD 20814 (psychiatry@usuhs.mil). Review of applications is ongoing. The University is an affirmative action/equal opportunity employer.

PSYCHIATRIST: ADULT/CHILD Medication Eval. & Mgt. MD Bd Cert & 5 Yrs. Exp. Req'd. PT or FT Active Caseload Provided, Excellent Earning & Growth Potential. Large OutPt Multispecialty Grp Practice. Columbia Counseling Center. Fax Vita: 410-992-9921

PSYCHIATRIST immediate part-time contractual position for out-patient unit in Baltimore City. Board eligible/Certified
Open Until Filled
For Info 410-779-3102 or mmmclaughlin@urbanbehavioralhealth.org

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PT Psychiatrist-Well established, Pvt, Multi-Discipline Grp Practice in Montgomery County MD, has an immediate opening for BC adult/adolescent psychiatrist. 15-20 Hrs wkly. Flexible schedule. Team approach. Email CV apcadmin2@verizon.net or fax to 301-258-7482.

MASSACHUSETTS

CAMBRIDGE: Inpatient Unit Director/ Attending Psychiatrist

Position available at Cambridge Health Alliance Department of Psychiatry, Harvard Medical School. Full time inpatient unit Medical Director with clinical responsibility for a 9 patient team on an 18-bed teaching service. Clinical care is provided through a multidisciplinary team approach with psychiatrist leadership. The inpatient medical director will also oversee provision of care on the unit, lead quality initiatives on the unit, oversee teaching of residents, medical students and psychology interns, and demonstrate commitment to clinical excellence.

The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment to improving the health of our communities, coupled with a strong academic tradition, make this an ideal opportunity for candidates interested in caring for underserved populations in a rich clinical environment. We have strong adult and child residency training programs which provide opportunities for teaching. Academic appointment, as determined by the criteria of Harvard Medical School, is anticipated.

Qualifications: Board-certified, demonstrated commitment to public sector populations, strong clinical skills, strong leadership and management skills, team oriented, problem solver. Bilingual and/or bicultural abilities are desirable. Competitive compensation, excellent benefit package. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. **CV & letter to Derri Shtasel, MD, Dept. of Psychiatry, 1493 Cambridge Street, Cambridge, MA 02139. Fax 617-665-2521. Email: DShtasel@challiance.org** (email preferred).

CAMBRIDGE Health Alliance: Women's Health

Position available at Cambridge Health Alliance Department of Psychiatry, Harvard Medical School. Part time opportunity in Women's Health/outpatient C/L Psychiatry. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment to improving the health of our communities, coupled with a strong academic tradition, make this an ideal opportunity for candidates interested in caring for underserved populations in a rich clinical environment. We have strong adult and child residency training programs and a fellowship training program in Psychosomatic Medicine (C/L) which provide opportunities for teaching. Academic appointment, as determined by the criteria of Harvard Medical School, is anticipated.

Qualifications: BE/BC, demonstrated commitment to public sector populations, experience in women's mental health, strong clinical skills, excellent collaborator, problem solver. Bilingual and/or bicultural abilities and training in C/L Psychiatry are desirable. Competitive compensation, excellent benefit package. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. **CV & letter to Derri Shtasel, MD, Dept. of Psychiatry, 1493 Cambridge Street, Cambridge, MA 02139. Fax 617-665-2521. Email: DShtasel@challiance.org** (email preferred).

Inpatient Staff Psychiatrist
Bridgewater State Hospital

MHM Correctional Services, the nation's leader in correctional mental health, has recently contracted with the Massachusetts Department of Correction including Bridgewater State Hospital. Under new leadership, and with increased salaries and excellent benefits package, Bridgewater State Hospital offers a unique and challenging practice opportunity to qualified psychiatrists. Explore the benefits of working with MHM and the highly qualified psychiatry team at BSH. To apply or inquire, contact Dawn Sechrest: 866-604-2800 or email CV to: dsechrest@mhm-services.com

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Research Faculty Positions

University of Massachusetts Medical School

Department of Psychiatry

Worcester, MA

The University of Massachusetts Medical School Department of Psychiatry is recruiting for Research Faculty positions (full and part-time) to join our expanding Clinical & Translational Research team. Opportunities exist for leadership positions as well as researchers.

Candidates must have strong research background, experience, and interest in mentoring junior faculty. Areas of research interest include mental health services, primary care integration, program evaluation, addiction, psychosocial interventions, psychopharmacology, developmental disabilities, law and psychiatry, imaging, biostatistics, and trauma.

These positions are supported by a competitive salary and excellent benefits. To apply, please send CV and letter of interest to Douglas Ziedonis, MD, MPH, Chair, Department of Psychiatry, University of Massachusetts Medical School and UMass Memorial Health Care, 55 Lake Avenue North, Worcester MA 01655 or e-mail Denise Barrett at barrettd@ummhc.org AA/EOE

UMass Memorial Medical Center, Department of Psychiatry-is seeking a half-time Consultation-Liaison psychiatrist to provide services at its tertiary medical center and assist in training programs. Specialty training and/or research experience a plus. Full-time employment with other responsibilities may be available. Academic opportunities and rank commensurate with experience. Applicants should send letter of interest and CV to Alan Brown, MD, Vice Chairman for Clinical Services, Department of Psychiatry, UMMMC, 55 Lake Avenue North, Worcester, MA 01655 or e-mail BrownA01@ummhc.org AA/EOE

Boston North Shore: Northeast Hospital Corporation, a locally-based nonprofit medical and psychiatric system recently named one of the nation's top 100 integrated healthcare systems by Solucient, has opportunities for board certified or eligible psychiatrists at two of its facilities:

Beverly Hospital; inpatient or inpatient/C and L combination. Help take this general hospital psychiatry program to the next level! Two positions available, including Medical Director position for experienced psychiatrist with leadership skill; C/L fellowship training a plus. Salary is competitive with an excellent benefit package including generous time off and reimbursement for malpractice insurance and CME. Limited call, and lucrative coverage opportunities are available.

BayRidge Hospital: This well-established 62-bed psychiatric hospital located in Lynn, a teaching site for Boston University Medical School, has a full-time position for an inpatient psychiatrist. Work with an excellent and supportive staff in a friendly atmosphere. There is no required night call, but lucrative coverage opportunities are available. Salary is competitive with an excellent benefit package including generous time off, and reimbursement for malpractice insurance and CME.

Contact: Barry Ginsberg, M.D., Chief, Department of Psychiatry. Phone (781) 477-6965, Fax (781) 477-6967; email address: bginsber@nhs-healthlink.org

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BOSTON, BASEBALL, BEANTOWN! BOSTON PSYCHIATRY! Top Massachusetts hospital! Both inpatient and outpatient positions available. Great Staff & Atmosphere! Enjoy the security of a competitive salary with outstanding benefits! GO SOX! For more info on this position or other psychiatry positions in BOSTON, call Lindsay McCartney @ 800-735-8261 ext 213, fax your CV to 703-995-0647 or e-mail lmccartney@medsourceconsultants.com.

Inpatient psychiatrist position with unique group practice
BC/BE inpatient psychiatrist wanted to join a 10 psychiatrist group in Southeastern MA. Southern New England Physicians Associates (SNEPA) provides a collegial work atmosphere in an all physician/physician run group practice environment. Our group prides itself on facilitating members individual interest while providing high quality clinical services. This position will be well compensated and with partnership tract available.
CONTACT:
CV to Russell Pet, M.D or Duane Bishop, M.D.
101 Page St., New Bedford, MA 02740
Fax (508) 961-5931
Call (508) 961-5930 or
email c/o pepina@southcoast.org

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

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Full-time Psychiatrist (Inpatient, Domiciliary)

The ENRM VA Hospital in Bedford, MA is looking for a skilled full-time Psychiatrist who is very interested in inpatient team treatment, homelessness, teaching, and leadership to join our Psychiatry staff. The Psychiatrist will work approximately half-time leading an Acute Inpatient team and half-time providing psychiatric care to homeless veterans as part of the Domiciliary treatment team. In this role, the Psychiatrist will contribute direct clinical care, leadership to involved clinicians, teaching to psychiatric residents of Boston University and trainees of other professional schools, and involvement in a patient-centered system of mental health care. Occasional cross-covering with other psychiatric staff will be involved.
The Edith Nourse Rogers Memorial Veterans Hospital has a full spectrum of Mental Health treatment programs as well as a large Primary Care population. Our philosophy emphasizes patient empowerment and optimization of function. Our strong academic affiliation is with Boston University School of Medicine Division of Psychiatry, where a teaching appointment is possible. Our Psychiatry staff has low turnover and provides a welcoming collegial climate for learning and professional development. The low on-call duties and suburban location also make this position attractive. Salary and benefits are competitive, and the VA is an Equal Opportunity Employer.

US citizenship and verification of licensures is required. Applications received by COB September 28, 2007 will have first consideration.

Edith Nourse Rogers Memorial Veterans Hospital
Attn: Lawrence Herz, MD
Psychiatry Service
200 Springs Road
Bedford, MA 01730
Tel: (781) 687-2494
FAX: (781) 687-2428
Lawrence.herz@med.va.gov

Veterans who have served on active duty for a period of more than 180 consecutive days and were discharged or released from active duty under honorable conditions are encouraged to apply.

EEO Selected May Be Subject To Physical And Random Drug Testing
For other career opportunities in the VA New England Healthcare System, log onto:
www.vacareers.va.gov
Or: www.usajobs.gov

MICHIGAN

Geriatric Psychiatrist
Detroit Metro Area

Outstanding opportunity for a Gero-Psychiatrist to join thriving 12-bed adult and geropsych inpatient unit in the greater Detroit area. The unit runs an average daily census of 6-8, with an average length of stay of 8 days. Call schedule is 1:3 (weekends). Excellent income with relocation reimbursement available. Geropsych experience and Board Certification preferred. Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. EOE.

GRAND RAPIDS: General & Child Psychiatrists. Inpatient & outpatient - general & specialty programs. Great work environment & staff. Top salary & benefits. Contact Joy Lankswert @ 866-227-5415; email joy.lankswert@uhsinc.com

MINNESOTA

100% Outpatient Only Psychiatrist Opportunity in Southern Minnesota!

* Call will be 1 in 6 weeks. No Emergency Room Call. Interest in Child Psychiatry would be helpful, but not required. 2 year guaranteed salary of $160,000-180,000 + full benefits (based on experience) plus the opportunity to earn significantly more! Income is based on RVU's, not reduced Medicare, Medicaid or Insurance coverage!

* The community is a wonderful blend of charm, excellent schools and recreational opportunities have created a strong family oriented & safe community for a physician and their family. This beautiful college community of 12,000, was built around five large lakes (four of which are interconnected by canals: allowing boating to each). It features tree-lined boulevards, attractive established neighborhoods, waterfront homes and parks. Located less than a two hour drive from Minneapolis/St. Paul: allowing great weekend access to major shopping, cultural and sports activities. Also, less than one hour from a major university.

Debbie Tether at
800-690-8788 compass@up.net
Compass Healthcare Consultants, LLC

For additional information and pictures go to: www.GreatDocJobs.com

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In-patient/Out-patient Psychiatrist

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

ROCHESTER, MINNESOTA ADULT PSYCHIATRIST

Olmsted County Community Services Behavioral Health Unit seeks a Board Certified adult psychiatrist for their Assertive Community Treatment Team. This multi-disciplinary team serves 100 Serious and Persistently Mentally Ill Adults. 32 hours per week, 8:00 a.m. to 5:00 p.m. Annual salary range depending on experience $139K- 153K plus full benefits. No on call, no weekends, no holidays. Contact: Nancy Kolaas, 507-287-2243 or kolaas.nancy@co.olmsted.mn.us.

Minneapolis, MN. Beautiful Twin Cities! Many needs, take your pick! Medical Director, Adult, Child/Adolescent, Inpatient, or Outpatient!!! Salaries from the high hundreds to over 200K! Full benefits package, relocation, and sign on bonus! For more information on this opportunity and others nationwide, Contact: Ariana Sanjabi @ 800-735-8261 ext 214, fax your CV to 703-995-0647, or e-mail: asanjabi@medsourceconsultants.com.

MISSISSIPPI

BC/BE Psychiatrist

North Mississippi State Hospital (NMSH), a facility of the Department of Mental Health, is seeking a Board-certified or Board-eligible psychiatrist. NMSH is a 50-bed acute care psychiatric facility located in Tupelo, Mississippi. Treatment and services are prepared and carried out through an interdisciplinary approach by a team of professionals including psychiatrists, psychologists, medical doctors, nurse practitioners, nurses, social workers, and others. Qualifications include graduation from an accredited School of Medicine and a license to practice (or immediate eligibility for licensure) in the State of Mississippi. Competitive benefits offered by the State of Mississippi. Please send DV to: Johnny Anderson, Director of Human Resources, North Mississippi State Hospital, 1937 Briar Ridge Road, Tupelo, MS 38804, Phone 662.690.4222, FAX 662.690.5733; Email janderson@nmsh.state.ms.us.

Associate Medical Director
JACKSON AREA

Horizon Health seeks an Associate Medical Director for a 14-bed geriatric behavioral health program located in Brandon, Mississippi.

Associate Medical Director will be responsible for administrative duties, clinical direction, patient-care. Inpatient program would include admission, diagnosis, treatment, management, and discharge of patients.

Excellent Stipend offered with lucrative private practice potential.

Located 15 minutes from Jackson, Mississippi! For more information please contact Diane Odom, 972-420-4083, e-mail diane.odom@horizonhelath.com, fax 972-420-8233

MISSOURI

CHILD PSYCHIATRIST

A Board Certified, or Board Eligible Child Psychiatrist to provide psychiatric services to children, adolescents, and their families is being sought by Community Treatment, Inc. COMPREA is a comprehensive not for profit mental health and chemical abuse treatment center located a few minutes south of St. Louis, MO. This full time position requires proven ability to work as a member of a treatment team, monitor client care, and skills to document client contacts, interventions and medications of clients. Apply on line at www.comtrea.org or email resume to hrs@comtrea.org. E.O.E.

POPLAR BLUFF
GATEWAY TO THE OZARKS

Busy Group Practice seeks additional BC/BE psychiatrist to see adults & adolescents. Outpatient only Mon. - Fri. 8am - 5pm. **No Call**. Competitive salary with bonus incentive plus medical, dental, disability, life and malpractice insurance and an excellent retirement plan. **J-1s encouraged to apply**.
Located in the foothills of the Ozarks, Poplar Bluff serves a population of 150,000 and has a diversified economy, AAA-rated public schools, and low cost-of-living.
www.poplarbluffchamger.org
Additional info on our website: www.kneibertclinic.com Please call **Tom Warner: (573) 778-7175; or Email: twarner@kneibertclinic.com or mail CV to: 686 Lester St., Poplar Bluff, MO 63901.**

PSYCHIATRIST

Southwest Missouri Psychiatric Rehabilitation Center, a state run In-patient facility serving both acute and long-term clients, located in the scenic Ozarks of Southwest Missouri is seeking a half-time Psychiatrist. The position will have an active role as lead member of an interdisciplinary treatment setting dedicated to quality service. Minimum qualifications include: M.D. or D.O. with residency completion in psychiatry, board eligible or board certified, and licensed to practice in Missouri. The facility is located in a relaxed rural setting within a short driving distance of major metropolitan and lake resort areas. Salary and schedule negotiable.

Please forward Curriculum Vita to:
Human Resources, Southwest Missouri Rehabilitation Center,
1301 Industrial Parkway
East, El Dorado Springs, Missouri 64744,
Fax to 417-876-1004 or e-mail
james.stacy@dmh.mo.gov

The Missouri Department of Mental Health does not deny employment or services because of race, sex, creed, marital status, national origin, disability or age of applicants or employees.

MEDICAL DIRECTOR/EXECUTIVE VICE PRESIDENT

Community Treatment, Inc., a comprehensive not for profit mental health and chemical abuse treatment center located minutes south of St. Louis, MO, is seeking a Medical Director to carry out the purpose, policies and programs of their Medical Services Division. Will be involved in administration and management, facilitate program development, participate in community/public relations and perform direct psychiatric services. This full time position requires Board Certification, five years experience in psychiatric service delivery and three years supervisory experience. Apply on line at www.comtrea.org or email resume to hrs@comtrea.org. E.O.E.

Staff Psychiatrist
Jefferson City- MO State Capital!

A Staff Psychiatrist is needed for a 15-bed adult/geriatric psychiatric program in Jefferson City, Missouri.

In this position, the Psychiatrist will be responsible for a complete practice experience working on inpatient program, which would include admission, diagnosis, treatment, management, and discharge of patients.

For this position, an attractive salary, benefits, and relocation will be provided.

Jefferson City is the state capital of Missouri and the county seat of Cole County. Named after the third president of the United States, Jefferson City is in the Ozarks on the Missouri River near the geographic center of the state. Only 30 miles from Columbia, MO and 2 hrs from St. Louis, MO. For more information please contact Diane Odom, 972-420-4083, fax 972-420-8233, e-mail diane.odom@horizonhelath.com

MONTANA

PSYCHIATRIST-Seeking full-time board certified psychiatrist to fill staff position in VA Montana Healthcare System. Responsibilities include adult outpatient treatment with urgent care/walk-in service and inpatient consultation service in a facility where state-of-the-art medicine is practiced. Fort Harrison Hospital is located in Helena, the State Capital. Competitive salary, benefits and liability included. Additional information can be found at www.vacareers.va.gov. Fax curriculum vitae to 406-447-7916 or call at 406-447-7310 for additional information. EOE.

NEBRASKA

PSYCHIATRISTS

The VA Nebraska Western Iowa Health Care System is currently recruiting for psychiatrists at our Grand Island and Lincoln Divisions. Practitioners will have a unique opportunity to provide a full spectrum of mental health and substance use disorder services in collaboration with multidisciplinary team members and with an excellent support from Primary Care Practitioners.

Candidates are eligible for up to $38,000 in reimbursement of their medical school student loans under the Title 38 Education Debt Reduction Program, are eligible for a recruitment bonus and payment of relocation expenses.

Salary and rank are dependent upon education and experience, with regularly scheduled pay increases for tenure. We offer an excellent benefits package, including malpractice protection, health insurance at a very modest rate, life insurance, a pension plan with an opportunity for a tax-deferred savings plan, 26 days of annual paid vacation, 13 days of sick leave per year, plus 10 Federal holidays.

These positions are open to board eligible/ certified psychiatrists with a full, unrestricted license to practice in any state. Candidates must be US citizens.

If you are interested in working to positively influence the life of veterans for a set number of hours and a highly competitive wage with absolutely no hassles from Medicare, Medicaid or other third party payers -

Send or fax CV to Tami Franklin,
Human Resources at
Human Resources (05)
VA Medical Center
2201 N. Broadwell
Grand Island NE 68803
Fax 308-389-5183
Phone 308-389-5177

An Equal Opportunity Employer

Medical Director
Omaha, Nebraska!

DUE TO GROWTH, Horizon Health seeks a Medical Director for a NEW freestanding psychiatric hospital located in Omaha, Nebraska. Innovative 64-bed adult psychiatric hospital scheduled to open November of 2007.

Psychiatrist will be hired as Medical Director to oversee hospital program, which will provide sub-acute, acute, and crises intervention services. Medical Director will be responsible for administrative duties, clinical direction, and patient-care. Ideal candidate will have active Nebraska license, Board Certification and experience working in Community Mental Health, State Hospital, and Private Practice settings. Attractive compensation provided.

Please contact Diane Odom, 972-420-4083, Fax 972-420-8233, e-mail: diane.odom@horizonhealth.com

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THE 1ST CHOICE IN
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Adult and Child Psych 100% outpatient
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(800) 783-9152 FAX (270) 782-1055
www.fcspsy.com
admin@fcspsy.com

SOUTHERN NEVADA ADULT MENTAL HEALTH SERVICES

ADULT PSYCHIATRISTS: Southern Nevada Adult Mental Health Services, a JCAHO accredited State Agency, is recruiting BC/BE adult psychiatrists to join an integrated community mental health system of 50 psychiatrists and allied mental health providers in Las Vegas, NV. Area qualified for J1/H1 visa psychiatrists. Our practice is focused on the seriously mentally-ill and our philosophy is based on the community recovery model. In-patient and out-patient positions are available. Rawson-Neal is a 235 bed state-of-the-art facility which includes a 30-bed psychiatric observation unit. Community clinics offer walk-in, counseling, medication and pharmacy services. Treatment support programs include residential, case coordination and PACT/ACT teams. Specialized community services are available for co-occurring disorders, seniors, court diversion and more. Competitive salary, excellent benefits, limited on-call and malpractice make this an attractive opportunity. Teaching affiliation with the University of Nevada School of Medicine and relocation package are also available. Nevada has NO STATE INCOME TAX.

For additional information see our web site http://mhds.state.nv.us/sn/index.shtml.
Submit letter of interest and CV to
Jackie Arellano @ jarellano@snamhs.nv.gov

NEW HAMPSHIRE

PSYCHIATRIST
Portsmouth, NH

Beautiful Seacoast area with four seasons, 55 minutes from Boston. Expanding private, nonprofit community mental health center seeks two psychiatrists, one child and adolescent and one adult, to join a staff of seven psychiatrists, for outpatient care. Vibrant collegial atmosphere with competitive salary and excellent benefits package.

Interested candidates should send cover letter and C.V. to W.M. Hanna. M.D., Medical Director.

Seacoast Mental Health Center, Inc.
1145 Sagamore Avenue
Portsmouth, NH 03801
Fax: 603-433-5093

ADULT PSYCHIATRIST

Monadnock Family Services is a community mental health center offering assessment, counseling, support, education and referral services to children and adults of all ages. Position available with an innovative behavioral health agency with a 100-year history. Monadnock Family Services is a leader in area health and social services, alliances, and partnerships. Creative, innovative and supportive climate in the beautiful Monadnock region of N.H. - 90 miles from Boston; near many excellent recreational and cultural activities. MFS is seeking a 5-day per week general psychiatrist to work primarily with adult clients (including the geriatric population) with persistent mental illness for our community mental health center. The psychiatrist in this position works as a clinical leader in an interdisciplinary team consisting of various mental health professionals who provide services based in the recovery and evidence-based practice models of treatment. Candidate must be Board Certified or eligible in psychiatry, have current credentials to practice medicine in the US, and have a desire to work with individuals with severe and persistent mental illness. Competitive salary and fringe benefits with generous vacation leave, 11 paid holidays and sabbatical program. Infrequent on-call coverage required. *Our staff enjoys a generous benefit package, including health, dental, flexible-spending plan and company-provided LTD, AD&D and Life insurance and 3 weeks of vacation during the first year of employment.*
Please send resumes in confidence to: MONADNOCK FAMILY SERVICES ATTN: Human Resources, 17 93rd Street, Dept. PN, Keene, NH 03431 Or to Humanresources@mfs.org

NEW JERSEY

Child/Adol. or Adult Psychiatrists

Child/Adol. or Adult Psychiatrists - needed for growing multi-disciplinary group in affluent community in North/Central N.J. NO Managed Care! Please fax CV to (908) 598-2408.

Wish to purchase fee for service practices in the Overlook, Morristown, St. Barnabas service areas. Contact Alpha Behavioral Care at (908) 273-0800.

PSYCHIATRISTS
Earn up to $200K plus benefits

Get inside the criminal mind and make a difference. University Correctional HealthCare (UCHC), a branch of the University of Medicine and Dentistry of New Jersey (UMDNJ), currently has regular (full-time and part-time) and per diem openings for psychiatrists throughout the state. We are dedicated to providing excellent mental health and rehabilitative services to our patients.

As a psychiatrist, you will have the unique opportunity to work with interesting patients and stimulating colleagues within the New Jersey Department of Corrections' prisons. We offer a comprehensive benefits package and a salary of up to $200,000 depending upon location, board certification, and experience. You will work with a multidisciplinary team and a state-of-the-art medical record. With minimal call, flexible hours, no managed care, no insurance forms, and an emphasis upon treatment rather than paperwork, isn't it time you discovered the difference you can make with University Correctional HealthCare.

Please apply via our website at www.umdnj.edu/hrweb or e-mail our Medical Director, Rusty Reeves, M.D., at reevesdo@umdnj.edu. UMDNJ is an affirmative action/equal employment opportunity M/F/H/V and is a member of the University Health System of New Jersey.

NEW MEXICO

PRESBYTERIAN

Albuquerque, NM

PHS is New Mexico's largest private, non-profit integrated healthcare system.

The Behavior Medicine Program is a full-service psychiatry department with 2 adult and 1 child/adolescent inpatient units, a multidisciplinary outpatient department, intensive outpatient treatment, emergency and consultative programs.

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

This is a full time employed position with the 500+ provider Presbyterian Medical Group.

Competitive salary and benefit package, includes malpractice insurance and relocation allowance.

Additional information about PHS may be found at www.PHS.org
For MD benefits info click on tab for ´Careers´ and then from the left drop down menu under ´Careers´ chose ´Physicians´ and then ´Physician Benefits´.

Contact: Kay Kernaghan, Physician Recruiter, PHS
E-mail: kkernagh@phs.org
Phone: 1-866-757-5263

NEW YORK CITY & AREA

Catholic Charities Brooklyn & Queens-BFFY

Multi-service agency seeks qualified candidate for **PSYCHIATRIST FT OR PT** in outpatient services located in Brooklyn & Queens. Provide medication management & psychiatric treatment. Must have NYS Licensure/Certification, bilingual preferred, certification in child psych preferred, basic computer literacy a must. Email resume to: LLibby@ccbq.org or fax: 718-722-6217. EOE/AA

ASSOCIATE CLINICAL DIRECTOR
Manhattan Psychiatric Center, an OMH facility and NYU affiliate, is seeking a Board Certified Psychiatrist for the position of Associate Clinical Director (Psychiatrist 3). The applicant must have a license to practice in NYS, another state or Canada and 1 year post board certification experience. Preferred qualifications are 5 years post residency experience and have worked in a supervisory capacity.
The position involves responsibility for the supervision of staff psychiatrists, teaching of residents and medical students and opportunities for research.
Manhattan Psychiatric Center is a specialized facility for the treatment of the severe and persistent mentally ill with manualized programs for violence, diabetes and neurocognitive remediation.

Please fax resume to:
Samuel J. Langer, M.D., Chief of Psychiatry
646 672 6386
Manhattan Psychiatric Center
Wards Island, NY 10035
MPC is an equal opportunity employer

NEW YORK STATE

STAFF PSYCHIATRIST, SARATOGA SPRINGS, NY. Practice in the perfect place: Outpatient Psychiatry, Saratoga Springs, NY. **SALARY:** $156,267 plus excellent benefits. Optional on-call with Saratoga Hospital in-patient unit for additional compensation available. **QUALIFICATIONS:** License to practice medicine in New York State and Board eligibility to practice psychiatry. Applies psychiatric expertise to the planning, coordination and operation of the mental health and mental retardation services provided within Saratoga County. Submit resume to: William Baker, Personnel Director, 40 McMaster St., Ballston Spa, NY 12020, FAX (518) 884-4752 or email jobinfo@govt.co.saratoga.ny.us.

AA/EOE

GREATER BINGHAMTON HEALTH CENTER

ADULT PSYCHIATRISTS
and
CHILD/ADOLESCENT PSYCHIATRISTS

GBHC (JCAHO-Accredited New York State Office of Mental Health facility) is seeking full time; board certified/board eligible **ADULT PSYCHIATRISTS** for its adult inpatient facility and **CHILD/ADOLESCENT PSYCHIATRISTS** for its Child/Adolescent Behavioral Health Center. Abundant on-site CME. Salaried, permanent positions with excellent New York State benefits. No evening or weekend call required. Compensated optional call available. Enjoy the reasonable cost of living Central New York offers with easy access to NYC and other major cities.

Submit CV to:
Human Resources
Greater Binghamton Health Center
425 Robinson St., Binghamton, NY 13904
Fax: (607) 773-4117. EOE/AAE

Psychiatrist / Mental Health Nurse Practitioner

Psychiatric Services of Orange and Sullivan is seeking Psychiatry providers to join this successful Psychiatric practice in Chester, New York. The candidate should be interested in a full time private practice providing Psychiatric evaluations, follow-up visits and medication management. Scheduling is flexible, but a minimum of 40 hours of patient care is required per week. Hospital affiliations are optional. New York State licensor, board certification or eligibility in psychiatry are essential. The candidate should feel comfortable treating children and adolescents as well as adults and seniors. We offer a competitive compensation and benefit package. Interested parties should forward a letter of interest and a CV in confidence to the ludwigsengroup @frontiernet.net or fax to 845-858-4540.

NORTH CAROLINA

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER, SALISBURY, NC is seeking full time staff psychiatrists. Must be board eligible (within 2 years after residency graduation) or board certified, and must be eligible for a faculty appointment at Wake Forest University School of Medicine. Duties may include not only clinical assignments, but also teaching and supervision of residents and students. Research opportunities available. Opportunities in:

- General Inpatient and Outpatient Psychiatry
- Post Traumatic Stress Disorder Programs
- Iraq and Afghanistan Combat Veterans Services
- Buprenorphine Clinic
- Traumatic Brain Injury Services

Candidate must be U.S. citizen, and proficient in spoken and written English [(38 U.S.C. 7402 (d)]. Liberal benefits with 401K, 26 days paid vacation and paid federal holidays. Student loan repayment program available. Salisbury is a lovely, historic town in the Piedmont section of North Carolina, less than one hour from Winston-Salem and Charlotte and an easy drive to the Blue Ridge Parkway. Excellent cost of living and a rich cultural heritage.

Call for VA application form, and forward a current CV (addressing teaching responsibilities, if applicable) to: Janet Rasmussen, Human Resources Specialist (05C-JR), W.G. "Bill" Hefner VA Medical Center, 1601 Brenner Avenue, Salisbury, NC 28144. Phone (704) 638-9000, ext. 2880. May FAX to (704) 638-3322, or Email to Janet.Rasmussen@med.va.gov. EOE.

Psychiatrist (Assistant or Associate Professor): Department of Psychiatric Medicine at the Brody School of Medicine at East Carolina University is accepting applications for a full-time faculty position (Assistant or Associate Professor). The position offers an excellent blend of clinical care, teaching, and scholarly activities in this growing, multi-disciplinary, and collegial Department. Requirements include MD or equivalent degree, completion of accredited psychiatric residency training in psychiatry, and preferably board certification in Psychiatry. Salary and academic rank commensurate with experience and academic background. Located near many recreational areas, including the Atlantic Ocean coastal resorts, Greenville is a university town, rich in cultural activities with charm and an easy pace of life. Please send a letter of interest and a CV to: Dr. Diana J. Antonacci, Chair of Search Committee, Department of Psychiatric Medicine, the Brody School of Medicine, Room 4E-98A Brody Building, 600 Moye Blvd., Greenville, NC 27834, e-mail: antonaccid@ecu.edu or telephone 252-744-2660. East Carolina University is an AA/EO Employer.

CLOSE TO RALEIGH AND GREENVILLE - VERY LUCRATIVE COMPENSATION PACKAGE - Horizon Health seeks a Psychiatrist for a Medical Director position on a 34-bed adult unit and 16-bed CD unit in a very impressive general hospital in Rocky Mount. Offering a salary with benefits plus bonus plan or practice guarantee and stipend. Enjoy the wonderful climate and quality of life this lovely location offers-only 45 minutes from Raleigh and Greenville & an easy drive to the mountains or the beach. Please **call Terry B. Good at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

Make Your Match™ — PracticeMatch — Nash Health Care Systems ...building a healthier community — www.nhcs.org

"Make Your Match with PracticeMatch"
Nash Health Care Systems Ranked Among NC's Best Hospitals
Adult Psychiatry Position - Employed or Private You Decide
Various Employment Options Available
Compensation Commensurate with Experience
Comprehensive Benefits Include Paid Malpractice if Employed
Serve Only One Hospital
Country Club Setting
50 Bed In-Patient Facility
Service Area Over 400,000
EMR System
1:4 Call
"Nash Health Care Systems' work to deliver the best health care providers, technology, and techniques for our patients is the passion that drives us."
Contact: Amanda Patton, 800-489-1440 x6559
amanda.patton@practicematch.com
www.practicematch.com/nash

Make Your Match™ — PracticeMatch — Nash Health Care Systems ...building a healthier community — www.nhcs.org

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"Nash Health Care Systems' work to deliver the best health care providers, technology, and techniques for our patients is the passion that drives us."
Contact: Amanda Patton, 800-489-1440 x6559
amanda.patton@practicematch.com
www.practicematch.com/nash

Minutes from Charlotte, NC and easy access to Raleigh! Enjoy all the amenities of a metropolitan city! Well established hospital has 2 openings! 1. GERIATRIC psychiatrist needed to provide a mix of inpatient and outpatient 2. ADULT psychiatrist needed to provide all outpatient work. Very competitive salary and full benefits offered. Opportunity to take over a private practice is also possible. For more information on this opportunity or any of our other nationwide positions please contact Carrley Ward at 800-735-8261 x 219, fax your CV to 703-995-0647 or email cward@medsourceconsultants.com

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Private Practice Opportunities in North Carolina.

Carolina Partners in Mental HealthCare, PLLC is seeking BE/BC psychiatrists for our practices in Raleigh, Chapel Hill and Wake Forest, NC. Private outpatient practices, full partnership from day one - no investment required. FT, PT flexible. Carolina Partners has seven offices in Raleigh, Durham, Chapel Hill, Pittsboro and Wake Forest, North Carolina. Good opportunity to control your life and clinical practice, while making a good income! Contact Executive Director or send CV to: Carolina Partners in Mental HealthCare, 1502 W. Hwy 54, Suite 103, Durham, NC 27707. Phone 919-967-9567; Fax 801-729-9867; EMail carolinapartners@bellsouth.net.

Staff Psychiatrist - Convenient to Outer Banks, NC and Norfolk/VA Beach - Horizon Health has a very attractive salaried position with benefits in a general hospital located in an area that is becoming one of THE places to retire in NC. This position will be primarily outpatient with some inpatient. What could be better: low stress small town living with a wonderful climate and easy drive to the coast plus a very rewarding professional opportunity. Join two other psychiatrists making call 1 in 3. Please **call Terry B. Good at 1-866-865-7380**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. Or mail CV to: 1663 Denton Lane, Hayes, VA 23072.

OHIO

THE 1ST CHOICE IN PSYCHIATRIC RECRUITMENT
Cleveland
Adult Psychiatrist
For more information contact:
BOB TOTH
(800) 783-9152 FAX (270) 782-1055
www.fcspsy.com
admin@fcspsy.com

Psychiatrist needed to provide mental health care to residents of Cincinnati and surrounding area. Must have Ohio medical license or ability to obtain. Send CV and references to Melvin S. Gale, M.D., and Associates, 2123 Auburn Avenue, Suite 303, Cincinnati, OH 45219 or email to mgalemd@fuse.net.

Psychiatrist
Cleveland, Ohio

Outstanding opportunity for a Psychiatrist to join thriving private practice and also practice on a 10-bed geropsych inpatient unit in the greater Cleveland area. Salary, Benefits, Productivity Bonus, and Partnership track available. Geropsych experience and Board Certification preferred. Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. EOE.

PENNSYLVANIA

Conemaugh Health System

Pennsylvania-70 miles east of Pittsburgh - Memorial Medical Center, affiliated with Conemaugh Health System is seeking a BC/BE Child and Adolescent psychiatrist as Director of Child and Adolescent and an Adult Psychiatrist interested in seeing child and adolescent patients to join our hospital based psychiatry practice. Position will have Administrative and clinical responsibilities. Highly competitive compensation package, including a signing. The hospital is the largest and most comprehensive health care provider in west central Pennsylvania that provides a full range of services to thousands of patients and their families every year. Beautiful and family friendly community, one of the nation's lowest crime rates, a diversified economic base, outstanding school systems, short commutes and big-city amenities without big city hassles. **Call Mary Lynn Mahla at (814) 534-3221 Email: mmahla@conemaugh.org or fax at 814-534-3895**

STATE COLLEGE: Child or General Psychiatrist to see children & adults -outpatient only.
CLARION-General Psychiatrist for inpatient and partial programs.
SHIPPENSBURG-near Harrisburg. Medical Director - General, Gero & Addiction Services. Inpatient & sub acute programs.
Salary, bonus, & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

Country Setting, Pennsylvania
Located one hour from Pittsburgh, an extremely successful, financially strong accredited hospital with a highly trained staff is looking for a Psychiatrist to join them. Opportunity for subspecialty work in addition to General Adult Psychiatry. Strong assistance from PA's and NP's. Position offers above average compensation, full benefits and relocation package. Enjoy a light call schedule of 1:6. Sophisticated country setting with all amenities related to a metro area. Contact John McCusker, Alpha Physician Search at 800.504.3411 or johnm@alphaps.org . View additional opportunities at www.alphaps.org .

SOUTH CAROLINA

Psychiatric Physician needed in Midlands Area Hospital to provide psychiatric care to adult inpatients. Must be a graduate of an accredited School of Medicine with 2-3 years experience. Board certification or eligibility with active track to certification required. Must be licensed to practice medicine in SC. Email resume to HCRecruiter01@gmail.com.

AIKEN: Great location & family oriented community. **Child Psychiatrist** for inpatient & partial program patient care. Salary & benefits offered. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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ONE HOUR FROM MYRTLE BEACH - Medical Director, Inpatient and Outpatient Geriatric Psychiatry - Due to growth, Horizon Health has an opening on a new 12-bed geriatric psychiatry program in a general hospital in Florence-a lovely area. The Behavioral Health program is part of a 372-bed hospital system that serves a nine-county area. The cost of living is relatively low in Florence and the residents are known for their southern hospitality. Offering directorship stipend and income guarantee, however, salary with benefits may be an option. Board Certification in Adult Psychiatry is required. Contact Terry B. Good, 866-865-7380, Fax: 804-684-5663; E-mail: terry.good@horizonhealth.com. EOE

TENNESSEE

Board-certified/eligible psychiatrist needed for a full time position in a large Psychiatry Service at James H. Quillen VAMC in Johnson City, Tennessee. Primary responsibility will be managing adult patients with diverse mental illnesses in an outpatient setting. Join a staff of 25 prescribers, including 15 psychiatrists, at ETSU-affiliated residency training program with 34 general adult and med-psych residents. Clinical appointment and some teaching expected. Call is backup to residents and shared amongst 15 staff psychiatrists. Largest department of psychiatry in a 200 mile radius of Johnson City, TN. NO STATE INCOME TAX, LOW COST OF LIVING, BEAUTIFUL MOUNTAINOUS REGION. **Contact George R. Brown, MD, Chief of Psychiatry, for more details at 423-926-1171, ext. 7708**

East Tennessee State University - College of Medicine - Department of Psychiatry and Behavioral Sciences - Two Full-Time Positions - General Psychiatrist and Child Psychiatrist - 770160, 814300 - RE-ADVERTISED. Full-time positions available for General Psychiatrist and Child Psychiatrist. General Psychiatrist position may include inpatient and/or outpatient. Responsibilities include training of psychiatric residents and medical students and research activities. Salary is competitive with funding available through the medical school, faculty private practice and extramural contracts. ETSU is located in the Tri-Cities area, rated #1 place in North America in cost-of-living, crime rate, climate and health care. **Applicants should submit a CV and two letters of reference to Merry N. Miller, M.D., Chair, Department of Psychiatry and Behavioral Sciences, ETSU, Box 70567, Johnson City, TN 37614-1707. Telephone inquires should be made at 423-439-2235 or e-mail at lovedayc@etsu.edu. AA/EOE**

Deadlines:
Oct 5 issue - Sep 21
Oct 19 issue - Oct 5

Director of Residency Training
Department of Psychiatry,
Vanderbilt University

Vanderbilt University is recruiting a Residency Training Director for the Department of Psychiatry. We are seeking an outstanding psychiatrist with strong academic credentials, significant executive or program administration experience, and the energy and vision to lead the residency program. The current Director is becoming Director of the Child & Adolescent Psychiatry Division of our Department.
The program trains a total of 32 residents over four years and is fully accredited by the ACGME. The residents train at the Vanderbilt University Hospital, the Vanderbilt Psychiatric Hospital and the Nashville VA Hospital. The department has prominent research programs in mood, psychotic and substance-related disorders and benefits from the resources in molecular neuroscience, neuroimaging, and psychology research at Vanderbilt University. Vanderbilt is located in Nashville, Tennessee, an area with significant educational and cultural opportunities. This position offers a competitive salary.

To apply, candidates should send a letter of interest, CV, and the names of three persons to contact for references to:
Sherron Buchanan, Assistant to Chair, Department of Psychiatry, 1601 23rd Ave. South, Suite 3060, Nashville, TN 37212

Vanderbilt University is an Affirmative Action/Equal Opportunity Employer with a strong institutional commitment to diversity in all areas.

Medical Director
Northwest Tennessee

A Medical Director is needed for a 22-bed adult psychiatric program located within a 142-bed acute care hospital. Psychiatrist will be hired as Medical Director to oversee 22-bed adult psychiatric unit. Offering competitive SALARY, including insurance, relocation, and loan repayment. Conveniently located less than 2 hours from Memphis and Nashville, TN. Near Kentucky Lake where outdoor activities are plentiful, excellent housing, family oriented with great school system. No state income tax. Excellent practice opportunity with solid support from hospital and staff. Contact Diane Odom 972-420-4083, fax 972-420-8233, e-mail diane.odom@horizonhealth.com

TEXAS

Texas
Ranked as one the best places to live in the Lone Star State. A thriving community with turn of the century architecture, beautiful properties, family neighborhoods and natural lakes dot its landscape. A short drive you will find yourself in the bustling Dallas/Ft. Worth Metroplex. Join a well-organized and skilled behavioral health team delivering inpatient care to an adult and geriatric patient population and a successful outpatient program. Unbeatable financial package with complete benefits. Call today to learn more about this great opportunity in this friendly Texas town!

John McCusker
800.504-3411 johnm@alphaps.org
View available opportunities at
www.alphaps.org

Psychiatrist or PCP experienced in Geriatrics
Clinical, Supervisory and Administrative Responsibility with Geriatric Psychiatry Group. FT $200,000.00/yr compensation DOE. Benefits+Bonus+Sign on Bonus
Chart Review, Supervision of NP/PA, Phone Consults. PT 5 - 20hrs/mth $100.00+/hr DOE $1000.00/mth min+Sign on Bonus.
Expertise in psychopharmacology, psychotherapy, community or geriatric psychiatry desired.
Willingness to work with multidisciplinary team. Will train on special needs of Geriatric Population. TX license required. Positions available in Houston and San Antonio.
Visit: www.seniorpsychiatry.com/Fax CV: 800-318-0120/Email: hr@seniorpsychiatry.com

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Come to beautiful San Antonio, Texas!!

Psychiatrists

The Center for Health Care Services, a 2006 APA Gold Award winner, is actively seeking full-time/part-time/contract psychiatrists for our Adult & Child Programs. The Center Psychiatrists are at the leading edge of the delivery of mental health service, providing assessment and treatment of clients, and leadership of a team of skilled and dedicated mental health professionals. Must be board eligible or board certified.

The Center offers:
- *Attractive salary*
- *Excellent benefits package, including retirement benefits and an internal CME program.*

San Antonio offers:
- *Great climate year round*
- *Ranked among the best value cost of living*
- *Arts, Theatre, Sports and Entertainment, Amusement parks and more*
- *Easy access to beaches, Mexico, the Texas Hill Country, more*

If you are interested in learning more about service at The Center, please submit your C.V. in confidence to:

The Center for Health Care Services
Attn: HR Director
3031 IH 10 West
San Antonio, Texas 78201
Fax: 210-731-1310
staffing@chcs.hhscn.org

EOE

AUSTIN: Busy private practice group seeking adult and/or child psychiatrist. Texas license and BE/BC required. Primarily out-patient. In patient optional. Ample referrals. Office well staffed and equipped. Austin is a great place to live and raise a family. Contact Neuropsychiatric Associates of Austin @ (512) 454-5716 or e-mail np_associates@prodigy.net.

Texas Forest Country - The Burke Center, a JCAHO accredited CMHC serving East Texas, has an opening for either a full-time **general or child psychiatrist**. The position is outpatient only, M-F, 8-5, primarily based in Nacogdoches. Other options include part time employment, contract arrangements, and providing services by telemedicine from your home. Enjoy an excellent lifestyle with a 40-hour week, no call, competitive salary, fantastic benefits, low cost of living, and great recreational opportunities in nearby national forests. Houston is less than 2 hours away. Please fax or email CV to:

Mark Janes, M.D.
Fax: (936) 634-8601
Email: markj@burke-center.org.

HOUSTON - The Menninger Department of Psychiatry and Behavioral Sciences of Baylor College of Medicine is seeking an experienced board-certified psychiatrist for **Chief of Psychiatry at Ben Taub General Hospital**, a major teaching, service, and research hospital of the College. Applicants with a current Texas Medical license and/or community hospital experience are encouraged to apply. Please send a confidential CV and any additional information which might be of use to the search committee to John Oldham, MD, Baylor College of Medicine, Department of Psychiatry, One Baylor Plaza, BCM350, Houston, TX 77030 or email joldham@menninger.edu Baylor College of Medicine is an Equal Opportunity, Affirmative Action and Equal Access employer.

McALLEN and SAN ANGELO: General, Geriatric or Child Psychiatrist - private practice. Service Directorship & caseload stipend offered. **GREENVILLE - Dallas area.** Private practice. Income guarantee & practice start up support offered. Great practice opportunities & income potential. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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HOUSTON - Faculty PTSD Investigator at Baylor College of Medicine (BCM) and Houston VA in Texas
The Menninger Department of Psychiatry and Behavioral Sciences at BCM and the Houston VA are recruiting for an established independent investigator at mid-career or senior level for research in Post Traumatic Stress Disorder. Responsibilities include collaborating with 35 funded investigators and 150 staff at the VA Health Services Research and Development Center of Excellence (one of 15 nationwide), VA Substance Abuse QUERI and the MIRECC in Houston and investigators at BCM with NIH grants and Centers studying anxiety, depressive, psychotic, substance use, and geriatric disorders and treatment implementation. Faculty also have joint or adjunct appointments at Rice University, The University of Texas School of Public Health and Texas A&M University. For more information, please visit our websites at http://www.bcm.edu/psychiatry and http://www.hsrd.houston.med.va.gov.
Requirements include doctoral degree in behavioral, medical, or social sciences related to clinical or health services in Post Traumatic Stress Disorder with grant funding and mentoring experience. Applicants must be United States citizens.
Applicants should email cover letter, CV and 4 names of references to: Thomas Kosten MD, Vice Chair of Psychiatry, c/o: doloresr@bcm.edu Baylor College of Medicine is an Equal Opportunity/Affirmative Action/Equal Access Employer

VIRGINIA

VIRGINIA COMMONWEALTH UNIVERSITY: Dept. of Psychiatry recruiting BE/BC **faculty psychiatrist at Assistant or Associate Professor level,** for mixed inpatient-outpatient position. Inpatient responsibilities include daily teaching rounds on nine beds acute inpatient unit, and outpatient work includes supervision, faculty practice, and visiting community geriatric locations. Fellowship in geriatrics preferred. Pursuit of scholarly work encouraged and supported. VCU is a large urban university with robust health science campus and 750 beds university hospital. Department of Psychiatry employs over 85 full time faculty and is nationally ranked in federally funded research. Richmond, the State Capital, has moderate climate and a rich mix of historical and contemporary facilities. Excellent suburban housing, public/private schools. Internet provides comparative cost of living. Send CV to Marie Baker-Roach, Human Resources, Department of Psychiatry, VCU/MCV, Box 980710, Richmond, VA 23298. VCU is an EEO/AA employer. Women, minorities, and persons with disabilities encouraged to apply.

Child Psychiatrist

Virginia Commonwealth University: Medical College of Virginia Hospitals, Division of Child & Adolescent Psychiatry in the Department of Psychiatry, recruiting Virginia license-eligible BE/BC child psychiatrist faculty as Inpatient/Outpatient attending. Position located in professional shortage area; J-1 candidates welcome to apply. Will be responsible for administration and clinical care as well as teaching and supervision of medical students, residents and child fellows. In addition, consultation work with community agencies will be available. Interest in teaching and academic work, as well as ability to work on interdisciplinary team, required. Department has nine fulltime child psychiatrists and child research institute, over 85 fulltime faculty and well-funded research in genetics, addictions, child and women's mental health and psychopharmacology. VCU is a large urban university with robust health science campus and 750-bed university hospital. Richmond, the State Capital, has moderate climate and rich mix of history with modern facilities, excellent suburban housing, public/private schools. See comparative cost of living via Internet at www.coli.org/. Send CV to Bela Sood, MD, c/o Marie Baker-Roach, VCU, Box 980710, Richmond VA 23298. Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Women, minorities, and persons with disabilities are encouraged to apply.

Coastal, Virginia
Adult Psychiatrist needed on Virginia's Chesapeake Bay. Excellent earning potential with guaranteed salary of 240K. Inpatient Psychiatry and option for private practice if desired. Escape the ordinary, enjoy coastal living, beautiful homes, great schools, and access to major cities.

John McCusker
800.504-3411 johnm@alphaps.org
View available opportunities at www.alphaps.org

Chair, Addictions Psychiatry

The Department of Psychiatry, Medical College of Virginia at Virginia Commonwealth University, in collaboration with VCU Institute for Drug and Alcohol Studies, is recruiting a strong academic leader to chair the Division of Addiction Psychiatry. Doctoral level applicant should have career commitment to addictions research and a track record of research/funding. Responsible for developing teaching and clinical programs needed to support teaching/research. Resources available to support an expanded research program. Funded ACGME accredited Fellowship Program. We have strong programs in psychiatric genetics, epidemiology, pharmacology, toxicology, and women's health. Laboratory and community based research are active areas for collaboration. New Dean is a strong supporter of psychiatric research. Department of Psychiatry has over 85 full-time faculty, 38 residents, multiple fellowships and research centers. VCU is a large urban university with robust health science campus and 750-bed university hospital. Richmond, the State Capital, has moderate climate, a rich history, cultural activities, excellent choices for urban, suburban, or country living, outstanding public/private schools. See comparative cost of living via Internet at www.coli.org/. Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Women, persons with disabilities, and minorities are encouraged to apply. Send applications to Joel J. Silverman, M.D., Chairman, c/o Marie Baker-Roach, Department of Psychiatry, MCV/VCU Box 980710, Richmond, VA 23298.

Virginia Licensed Psychiatrist to join a large multi-disciplinary group of providers w/ several locations in the Virginia Beach area. Excellent compensation & benefits. Fax Resume to: Christian Psychotherapy Service, 757-497-1327 or call 757-490-0377.

Adult Psychiatrist - Central Virginia Community Services is recruiting a Psychiatrist Board certified in Adult and/or Gerontology. Will provide outpatient services, Program for Assertive Treatment, crisis stabilization and sub-acute medical detox to support addiction and co-occurring residential treatment. Will participate in call along with other medical staff. Full time with benefits. Contact David Brunstetter, MD @ david.brunstetter@cvcsb.org or 434-847-8000.

WASHINGTON

The University of Washington and Harborview Medical Center (HMC) in Seattle, WA is accepting applications for a full-time geriatric psychiatrist (MD degree) at the rank of Instructor or Assistant Professor. This position is 1.0 FTE and will work half time doing hospital consultation work with a large team consisting of another psychiatrist, psychologist, nurse and social worker. The other half time will be spent working in geriatric outpatient services. The position will also be responsible for teaching residents and medical students. Start date January 1, 2008. **Please send application and CV to Peter Roy-Byrne MD, Chief Psychiatry, Harborview Medical Center 325 9th Ave. Box 359911, Seattle, WA 98104**. The UW is building a culturally diverse faculty and strongly encourages applications from females and minority candidates. The UW is and EOE/AA employer. University of Washington faculty engage in teaching, research, and service.

Private Practice Opportunity-Spokane
BE/BC Psychiatrist to join 4 others in busy, well established group. No start up costs. Flexible practice, shared overhead, Minimal call. Eastern WA is a tertiary referral center with 500k Plus Catchment pop, teaching opportunities, good schools, affordable housing, abundant cultural, recreational resources for rural or urban living. 509-455-9090 or davidg6789@aol.com

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Puyallup, WA - Psychiatry

Fabulous opportunity! The growing community of Puyallup, Washington is seeking a BC/BE psychiatrist who is searching for a practice with plenty of flexibility and growth opportunities. This position includes both a psychiatric consultation practice within a medical hospital environment as well as a private practice component within an outpatient office setting. This is an opportunity to be both part of a psychiatric team and to establish a solo practice which would be unique in this community where there are currently no other private psychiatric practices. We are located very close to Seattle/Tacoma and all the activities associated with large cities or you can choose a more rural lifestyle in the smaller communities outside of the Puyallup area. Qualified applicants must be flexible, self-motivated, and committed to program development and patient care. If you would like more information concerning this opportunity, please Email your CV to *MultiCare Health System Provider Services at providerservices@multicare.org or fax your CV to 866-264-2818.*

Refer to opportunity #534-645

Puyallup, WA - Psychiatry ARNP

The growing community of Puyallup, Washington is seeking a psychiatric ARNP to provide psychiatric evaluations and psychiatric medication management to individuals receiving counseling services at Good Samaritan Behavioral Healthcare. Experience and expertise working with children and adolescents is essential although there is the opportunity to work with clients of all ages. Located 40 minutes south of Seattle and 30 minutes from an international airport, Puyallup and the surrounding communities provide a broad range of educational and cultural activities for all ages. Nestled between the Cascade Mountains and the shores of Puget Sound, the region's year round temperate climate affords outdoor enthusiasts endless recreational opportunities. Qualified applicants must be flexible, self-motivated, and committed to program development and patient care. If you would like more information concerning this opportunity, please call 800-621-0301 or email your CV to *blazenewtrails@multicare.org or fax your CV to 866-264-2818.*

Refer to Opportunity #566-739

MultiCare is a Drug Free Workplace

Western Washington State: Adult/Geriatric/Forensic Psychiatrist (BE/BC with a WA state license) applications considered. Western State Hospital is a fully accredited (JCAHO) and certified (CMS) 997 bed hospital serving adult, geriatric and forensic populations. Annual salary up to $158,304 DOQ. Excellent benefits, including hospitalization/medical insurance, retirement and vacation leave, plus optional deferred income plan. Send CV to Norma Jones, Medical Staff Coordinator; Western State Hospital; 9601 Steilacoom Blvd. SW; Lakewood, WA 98498-7213. E-Mail: JONESNL2@DSHS.WA.GOV.

Puyallup, WA - Psychiatry

The growing community of Puyallup, Washington is seeking a BC/BE psychiatrist to provide psychiatric evaluations and psychiatric medication management services to individuals receiving counseling services at Good Samaritan Behavioral Healthcare. Experience and expertise working with children and adolescents is essential although there is the opportunity to work with clients of all ages. Located 40 minutes south of Seattle and 30 minutes from an international airport, Puyallup and the surrounding communities provide a broad range of educational and cultural activities for all ages. Nestled between the Cascade Mountains and the shores of Puget Sound, the region's year round temperate climate affords outdoor enthusiasts endless recreational opportunities. Qualified applicants must be flexible, self-motivated, and committed to program development and patient care. If you would like more information concerning this opportunity, please call 800-621-0301 or email your CV to *blazenewtrails@multicare.org or fax your CV to 866-264-2818.*

Refer to Opportunity ID #565-739

MultiCare is a Drug-Free Workplace

WEST VIRGINIA

PSYCHIATRIST - William R. Sharpe, Jr. Hospital, a 150-bed, JCAHO-accredited, state psychiatric hospital and winner of APA Award for state/university collaboration, is searching for a BE/BC psychiatrist. This is a full time faculty position with West Virginia University with regionally competitive salaries and excellent benefits and no call duty. Position will remain open until filled. Contact Abe Adel, MD at 304-269-1210 or email a CV and cover letter to bettygumfoster@wvdhhr.org. WVU is an AA/EO employer.

WISCONSIN

Adult Psychiatrists

Child and Adolescent Psychiatrists

The University of Wisconsin Department of Psychiatry is seeking BC/BE Child and Adolescent Psychiatrists and BC/BE Adult Psychiatrists to join our expanding clinical and research programs. Primary responsibilities include outpatient or inpatient clinical care, supervision of residents, and teaching of medical students and residents. Administrative and research experience is highly valued. Candidates will also have the opportunity to participate in collaborative and independent research within a Department nationally recognized for excellence in developmental and emotions research.

Please send letter of interest and your CV to:

Jeff Charlson
Department Administrator
University of Wisconsin School of Medicine and Public Health
Department of Psychiatry
6001 Research Park Boulevard
Madison, WI 53719
or via email to jtcharls@wisc.edu

Adult Psychiatrist - La Crosse, WI
BC/BE general adult psychiatrist needed to join four psychiatrists. In-patient and out-patient practice (1:5 call) with Franciscan Skemp Healthcare - Mayo Health System, multispecialty group/healthcare network including 200+ physicians/associate providers. Initial salary guarantee with subsequent productivity-based compensation and excellent benefit package. La Crosse, city of 52,000 (metro area 120,000), is located in west-central Wisconsin on the scenic Mississippi River, offering unlimited recreational, cultural and educational opportunities in a family environment. Contact Bonnie Guenther or Mike Hesch, Physician Services, at 800-269-1986 or email: guenther.bonnie@mayo.edu or hesch.michael@mayo.edu.

Franciscan Skemp
Mayo Health System

Madison, WI - noted as "U.S. Best City", two years, seeks a BC/BE child psychiatrist. *Capitol Associates*, well-recognized for more than 20 years, is Madison's largest, independent, licensed mental health clinic and is dedicated to comprehensive inpatient/outpatient care. CA boasts 14 mental health professionals, including 2 psychiatrists. A university town surrounded by many lakes, Madison has abundant recreational activities, high educational standards and support for the arts. Please consider joining our caring, energetic team. Capitol Associates, LLC, Attention: Johna Gerasch, PhD (Managing Partner), 440 Science Dr., Suite 200, Madison, WI 53711. (608) 238-5176, ext. 314.

WYOMING

WYOMING: General Psychiatrist. Position duties include covering Inpatient and Outpatient services. Salary, benefits and bonus. Join a great staff & stable physician team. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

International

AUSTRALIA & NEW ZEALAND
PSYCHIATRIC JOBS
Gen. Adult - Child & Adoles. - Forensics
Locum Tenens or Permanent Jobs
Salary = $250-350,000 per annum
www.IMRpsychiatry.com

Fellowships

Department of Health and Human Services
National Institutes of Health
National Institute of Mental Health
(Position Available)

The National Institute of Mental Health (NIMH), a major research component of the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS), offers a full-time Clinical Fellow position for a PGY-4 or PGY-5 physician at one of the premier research sites in the U.S., the 300 acre Bethesda campus of the NIH, near Washington D.C. which houses state-of-the-art facilities dedicated to research. The strong scientific environment and outstanding equipment resources at NIH make this a unique opportunity for an outstanding scientist/physician. The position is open to MD's trained in psychiatry or neurology and will be hired as Clinical Fellows. The candidates' function would be to assist in the management of an 11-bed inpatient facility dedicated to schizophrenia research at the Clinical Research Center in Bethesda, Maryland, and to participate in outpatient clinical duties related to clinical research. The candidate will be part of a multidisciplinary clinical team who participates in the clinical care of patients. The clinical fellow may also choose to participate in a multidisciplinary research team that uses molecular biological, genetic and neuroimaging tools to map genetic and neurochemical mechanisms associated with normal higher cognitive function as well as dysfunction in neurospychiatric illnesses such as schizophrenia. In addition to their clinical work, there is opportunity for outstanding candidates to develop their own research projects within the Branch. Possible areas of concentration include 1) Functional MRI and spectroscopic studies assessing neurofunctional and neurochemical substrates of higher cognitive function, particularly as regards working memory and frontal lobe function, 2) Positron Emission Tomography studies, 3) Pharmacogenetic studies involving phase II drug trials based on genotype. For imaging research studies familiarity with computational and statistical methods for neuroimaging confers an advantage but is not absolutely required. Competitive stipends depend on level of experience. Letter of interest outlining experience and research goals, CV, and three recommendation letters sent to: Daniel R. Weinberger, M.D., NIH, Building 10, Rm. 4S235; 9000 Rockville Pike; Bethesda MD 20892-1365 USA. Phone: (301) 402-7564; FAX: (301) 480-7795. Weinberd@mail.nih.gov. This position is subject to a background investigation.

DHHS, NIH and NIMH are Equal Opportunity Employers

Post-Doctoral Fellow wanted for a UCLA brain imaging research group focusing on drug/alcohol dependence. This position is for someone who wants to 'hit the ground running.' Our group has accumulated a large amount of positron emission tomography and magnetic resonance imaging data in tobacco-dependent smokers that can be analyzed and written-up for meeting and manuscript presentations. There is also ample opportunity to initiate independent research, including either brain imaging projects or translational research involving brain imaging and related fields (e.g., genetics or treatment).

Eligible applicants must be US citizens or permanent residents and have completed an M.D., Ph.D., or comparable degree. If interested, please email CV/resume and information about research interests to Arthur L. Brody, M.D. at: abrody@ucla.edu

Geriatric Psychiatry Fellowship

The Department of Psychiatry of the State University of Buffalo School of Medicine and Biomedical Sciences (SMBS) has openings for two newly ACGME-accredited PGY 5 Geriatric Psychiatry fellows to begin July 2008. The fellows will participate in a clinical milieu emphasizing understanding the psychiatric aspects of medical conditions along with the medical aspects of psychiatric conditions in the elderly. Rotations will include: Geriatrics, Neurology, Hospice, Day Rehabilitation, Home Health Care, SNF, Inpatient, Outpatient, C/L and Telepsychiatry. Fellows will have the unusual opportunity through collaborative consultation-liaison work to develop clinical expertise and professional relationship skills working closely with trainees and faculty in geriatric medicine and neurology. They will participate in a comprehensive didactic program in preparation for the ABPN geriatric psychiatry certification. Assistance and collaboration with a scholarly effort will be available during the year. Please submit your CV, your letter of interest, three letters of reference including one from your residency training program director, state licenses and any Board or certification exams you have passed to:

Sandra Gilliam
Program Coordinator
Office of Graduate Medical Education
462 Grider St
Buffalo, NY 14215
(716) 961-6955
(716) 961-6960 fax
gilliam3@buffalo.edu

Marion Zucker Goldstein, MD
Professor of Psychiatry
Division and Program Director Geriatric Psychiatry Fellowship
ECMC Department of Psychiatry
462 Grider St.
Buffalo, NY 14215
(716) 898-4256
mzg@buffalo.edu

Steven Dubovsky, MD
Chair and Professor of Psychiatry
dubovsky@buffalo.edu

University of Rochester Geriatric Psychiatry Fellowship

DESCRIPTION: The University of Rochester Geriatric Psychiatry Program offers one-year PGY-5 clinical fellowships in Geriatric Psychiatry. Ours is an ACGME accredited program, successful completion of which makes graduates eligible for the ABPN subspecialty examination in geriatric psychiatry. The fellowship offers training in the care of older patients in a variety of inpatient, long-term care, outpatient, consultation, and palliative care settings. Supervised clinical experiences are complemented by a didactic program, elective offerings, and opportunities to develop individual scholarly and research interests. In addition to the breadth of our clinical programs and patient populations, we have a large cadre of experienced and nationally recognized clinicians, teachers, and researchers serving on our faculty. We pride ourselves on providing a stimulating, rewarding educational experience in a supportive and nurturing environment.

CONTACT: For more information please contact Jeffrey M. Lyness, M.D., Director, Geriatric Psychiatry Fellowship, Department of Psychiatry, University of Rochester Medical Center, 300 Crittenden Boulevard, Rochester, NY 14642-8409 (Phone 585-275-6741; Fax 585-273-1082; E-Mail Jeffrey_Lyness@urmc.rochester.edu) Website: www.urmc.rochester.edu/smd/psych/educ_train/fellowship/geriatrics/index.cfm

The University of Rochester is an equal opportunity/affirmative action employer. Applications from women and minority groups are encouraged.

PSYCHOSOMATIC MEDICINE FELLOWSHIP or CHIEF RESIDENCY AT YALE UNIVERSITY

This ACGME-accredited one-year fellowship has positions available at the PGY-V level or above, starting July 1, 2008, as well as PGY-IV chief resident positions (PGY-IV training would not qualify for subspecialty certification). The program offers training in inpatient and outpatient consultation-liaison psychiatry at Yale New Haven Hospital and at the VA Connecticut Healthcare System, with multiple specialty electives. An Equal Opportunity employer. Please contact Paul Desan, MD, PhD, Yale New Haven Hospital, 20 York St CB2039, New Haven, CT 06504, paul.desan@yale.edu, (203) 785-2618.

PSYCHOSOMATIC MEDICINE/ CONSULTATION-LIAISON PSYCHIATRY COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS AND SURGEONS

The Department of Psychiatry at Columbia University College of Physicians and Surgeons offers a one-year fellowship in Psychosomatic Medicine at New York Presbyterian Hospital-Columbia University Medical Center for board eligible/board certified graduates of approved psychiatric residency programs. The fellowship seeks psychiatrists with outstanding clinical and academic records as evidenced by publications, presentations, teaching experience, and exceptional letters of recommendation, who are interested in an academic career in Psychosomatic Medicine (consultation-liaison psychiatry). Spanish speaking a plus. This is a full-time, ACGME-approved program with clinical, research, and teaching experience at a major tertiary care center. Some call is required. Applicants are sought for the 2008-2009 academic year. To apply, please submit a personal statement, three letters of recommendation, and a C.V., no later than October 15, 2007. For further information applicants should contact Dr. Peter A. Shapiro at Columbia University, College of Physicians and Surgeons, 622 West 168th Street, Box 427, New York, NY 10032; (212) 305-9985, or by email at mf251@columbia.edu. Columbia University is an AAEOE.

INFANT PSYCHIATRY FELLOWSHIP. The Section of Child and Adolescent Psychiatry at Tulane University Health Sciences Center is seeking a full-time Fellow in Infant Psychiatry. This one or two year fellowship includes clinical and research experiences with the multidisciplinary Infant Mental Health group at Tulane. Completion of a fellowship in Child and Adolescent Psychiatry preferred. Faculty appointment at the Instructor level is possible. Applications will be accepted until a suitable qualified candidate is found. Applicants should send letter of interest, updated CV and list references to Charles Zeanah, MD, Vice Chair and Director of Child and Adolescent Psychiatry, 1440 Canal Street TB52, New Orleans, LA 70112. Interested eligible applicants may obtain further information regarding this position by contacting Dr. Zeanah at 504-988-5402 or czeanah@tulane.edu. Tulane is strongly committed to policies of non-discrimination and affirmative action in student admission and in employment.

Psychiatry Fellowships

Virginia Commonwealth University, Department of Psychiatry is offering ACGME fellowships in Geriatrics, Psychosomatics and Forensics. Competitive salary and allowances. Fellowships offer broad-based training in inpatient/outpatient settings, focusing on acute and chronic disease, consultation services, private evaluations, seminars, research and teaching experiences. Applicants must demonstrate good communication skills, and have completed approved residency in psychiatry. J-1 applicants eligible. Applications should be sent to Joel Silverman, MD, Chairman, c/o Marie Baker-Roach, Department of Psychiatry, Box 980710, Richmond, VA 23298-0710. Virginia Commonwealth University is Equal Opportunity/Affirmative Action employer and encourages applications from women, minorities, and persons with disabilities.

THE 2008 PAUL JANSSEN FELLOWSHIP IN TRANSLATIONAL NEUROSCIENCE RESEARCH AT COLUMBIA UNIVERSITY

The Paul Janssen Fellowship is awarded, for up to two years, to an outstanding young physician-investigator (must have M.D. degree) to conduct novel translational research in the field of neuroscience as it relates to psychiatric disease and medicine. The Paul Janssen Fellow will be assigned both a basic scientist mentor and a clinical investigator mentor from the faculty at Columbia University to serve as joint mentors. The fellow will take a basic observation made by the basic science mentor and apply it to the study of disease or treatment with the clinical research mentor. Candidates from the international neuroscience community, holding an M.D. or M.D./Ph.D. degrees, and preferably having completed initial fellowship research training, are invited to apply. The award provides a stipend, commensurate with experience, as well as some funding for research costs. The stipend provided may require supplemental funding by the mentors.
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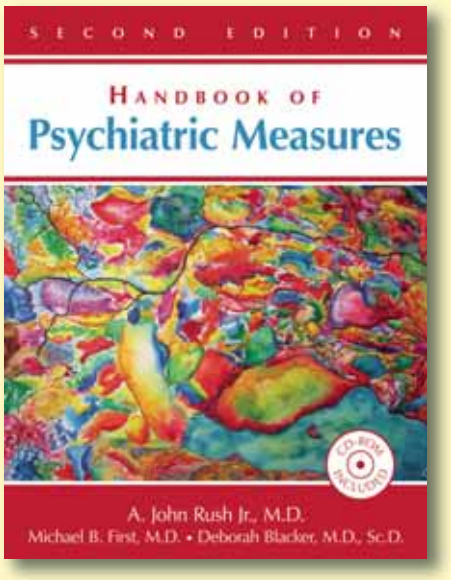

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BRIEF SUMMARY. See package insert for full prescribing information.

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/m^2 basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m^2 basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m^2 basis). The fertility of female rats was reduced. ***Pregnancy—Pregnancy Category C:*** There are no adequate and well-controlled studies in pregnant women. GEODON should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. ***Labor and Delivery:*** The effect of GEODON on labor and delivery in humans is unknown. ***Nursing Mothers:*** It is not known whether, and if so in what amount, GEODON or its metabolites are excreted in human milk. It is recommended that women receiving GEODON should not breast feed. ***Pediatric Use:*** The safety and effectiveness of GEODON in pediatric patients have not been established. ***Geriatric Use:*** Of the approximately 4500 patients treated with GEODON in clinical studies, 2.4% (109) were 65 years of age or over. In general, there was no indication of any different tolerability for GEODON or of reduced clearance of GEODON in the elderly compared to younger adults. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to GEODON, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients. **ADVERSE REACTIONS—** ***Adverse Findings Observed in Short-term, Placebo-Controlled Trials:*** The following findings are based on the short-term placebo-controlled premarketing trials for schizophrenia (a pool of two 6-week, and two 4-week fixed-dose trials) and bipolar mania (a pool of two 3-week flexible-dose trials) in which GEODON was administered in doses ranging from 10 to 200 mg/day. ***Adverse Events Associated with Discontinuation:*** Schizophrenia: Approximately 4.1% (29/702) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 2.2% (6/273) on placebo. The most common event associated with dropout was rash, including 7 dropouts for rash among GEODON patients (1%) compared to no placebo patients (see **PRECAUTIONS**). Bipolar Mania: Approximately 6.5% (18/279) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 3.7% (5/136) on placebo. The most common events associated with dropout in the GEODON-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash and vomiting, with 2 dropouts for each of these events among GEODON patients (1%) compared to one placebo patient each for dystonia and rash (1%) and no placebo patients for the remaining adverse events. ***Adverse Events at an Incidence ≥5% and at Least Twice the Rate of Placebo:*** The most commonly observed adverse events associated with GEODON in schizophrenia trials were somnolence (14%) and respiratory tract infection (8%). The most commonly observed adverse events associated with the use of GEODON in bipolar mania trials were somnolence (31%), extrapyramidal symptoms (31%), dizziness (16%), akathisia (10%), abnormal vision (6%), asthenia (6%), and vomiting (5%). The following list enumerates the treatment-emergent adverse events that occurred during acute therapy, including only those events that occurred in 2% of GEODON patients and at a greater incidence than in placebo. Schizophrenia: Body as a Whole—asthenia, accidental injury, chest pain. Cardiovascular—tachycardia. Digestive—nausea, constipation, dyspepsia, diarrhea, dry mouth, anorexia. Nervous—extrapyramidal symptoms, somnolence, akathisia, dizziness. Respiratory—respiratory tract infection, rhinitis, cough increased. Skin and Appendages—rash, fungal dermatitis. Special Senses—abnormal vision. Bipolar Mania: Body as a Whole—headache, asthenia, accidental injury. Cardiovascular—hypertension. Digestive—nausea, diarrhea, dry mouth, vomiting, increased salivation, tongue edema, dysphagia. Musculoskeletal—myalgia. Nervous—somnolence, extrapyramidal symptoms, dizziness, akathisia, anxiety, hypesthesia, speech disorder. Respiratory—pharyngitis, dyspnea. Skin and Appendages—fungal dermatitis. Special Senses—abnormal vision. ***Dose Dependency:*** An analysis for dose response in the schizophrenia trials revealed an apparent relation of adverse event to dose for the following: asthenia, postural hypotension, anorexia, dry mouth, increased salivation, arthralgia, anxiety, dizziness, dystonia, hypertonia, somnolence, tremor, rhinitis, rash, and abnormal vision. ***Extrapyramidal Symptoms (EPS):*** The incidence of reported EPS for GEODON patients in the short-term, placebo-controlled schizophrenia trials was 14% vs 8% for placebo. Objectively collected data from those trials on the Simpson-Angus Rating Scale and the Barnes Akathisia Scale did not generally show a difference between GEODON and placebo. ***Vital Sign Changes:*** GEODON is associated with orthostatic hypotension (see **PRECAUTIONS**). ***Weight Gain:*** In short-term schizophrenia trials, the proportions of patients meeting a weight gain criterion of ≥7% of body weight were compared, revealing a statistically significantly greater incidence of weight gain for GEODON patients (10%) vs placebo patients (4%). A median weight gain of 0.5 kg was observed in GEODON patients vs 0.0 kg in placebo patients. Weight gain was reported as an adverse event in 0.4% of both GEODON and placebo patients. During long-term therapy with GEODON, a categorization of patients at baseline on the basis of body mass index (BMI) showed the greatest mean weight gain and the highest incidence of clinically significant weight gain (>7% of body weight) in patients with a low BMI (<23) compared to normal (23-27) or overweight (>27) patients. There was a mean weight gain of 1.4 kg for patients with a "low" baseline BMI, 0.0 kg for patients with a "normal" BMI, and a 1.3 kg mean weight loss for patients with a "high" BMI. ***ECG Changes:*** GEODON is associated with an increase in the QT_c interval (see **WARNINGS**). In schizophrenia trials, GEODON was associated with a mean increase in heart rate of 1.4 beats per minute compared to a 0.2 beats per minute decrease among placebo patients. ***Other Adverse Events Observed During the Premarketing Evaluation of GEODON:*** Frequent adverse events are those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. Schizophrenia: Body as a Whole—*Frequent:* abdominal pain, flu syndrome, fever, accidental fall, face edema, chills, photosensitivity reaction, flank pain, hypothermia, motor vehicle accident. Cardiovascular System—*Frequent:* tachycardia, hypertension, postural hypotension; *Infrequent:* bradycardia, angina pectoris, atrial fibrillation; *Rare:* first-degree AV block, bundle branch block, phlebitis, pulmonary embolus, cardiomegaly, cerebral infarct, cerebrovascular accident, deep thrombophlebitis, myocarditis, thrombophlebitis. Digestive System—*Frequent:* anorexia, vomiting; *Infrequent:* rectal hemorrhage, dysphagia, tongue edema; *Rare:* gum hemorrhage, jaundice, fecal impaction, gamma glutamyl transpeptidase increased, hematemesis, cholestatic jaundice, hepatitis, hepatomegaly, leukoplakia of mouth, fatty liver deposit, melena. Endocrine—*Rare:* hypothyroidism, hyperthyroidism, thyroiditis. Hemic and Lymphatic System—*Infrequent:* anemia, ecchymosis, leukocytosis, leukopenia, eosinophilia, lymphadenopathy; *Rare:* thrombocytopenia, hypochromic anemia, lymphocytosis, monocytosis, basophilia, lymphedema, polycythemia, thrombocythemia. Metabolic and Nutritional Disorders—*Infrequent:* thirst, transaminase increased, peripheral edema, hyperglycemia, creatine phosphokinase increased, alkaline phosphatase increased, hypercholesteremia, dehydration, lactic dehydrogenase increased, albuminuria, hypokalemia; *Rare:* BUN increased, creatinine increased, hyperlipemia, hypocholesteremia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hyperchloremia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. Musculoskeletal System—*Frequent:* myalgia; *Infrequent:* tenosynovitis; *Rare:* myopathy. Nervous System—*Frequent:* agitation, extrapyramidal syndrome, tremor, dystonia, hypertonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, hypesthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, buccoglossal syndrome, choreoathetosis, diplopia, incoordination, neuropathy; *Infrequent:* paralysis; *Rare:* myoclonus, nystagmus, torticollis, circumoral paresthesia, opisthotonos, reflexes increased, trismus. Respiratory System—*Frequent:* dyspnea; *Infrequent:* pneumonia, epistaxis; *Rare:* hemoptysis, laryngismus. Skin and Appendages—*Infrequent:* maculopapular rash, urticaria, alopecia, eczema, exfoliative dermatitis, contact dermatitis, vesiculobullous rash. Special Senses—*Frequent:* fungal dermatitis; *Infrequent:* conjunctivitis, dry eyes, tinnitus, blepharitis, cataract, photophobia; *Rare:* eye hemorrhage, visual field defect, keratitis, keratoconjunctivitis. Urogenital System—*Infrequent:* impotence, abnormal ejaculation, amenorrhea, hematuria, menorrhagia, female lactation, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; *Rare:* gynecomastia, vaginal hemorrhage, nocturia, oliguria, female sexual dysfunction, uterine hemorrhage. **Adverse Finding Observed in Trials of Intramuscular GEODON:** In these studies, the most commonly observed adverse events associated with the use of intramuscular GEODON (≥5%) and observed at a rate on intramuscular GEODON (in the higher dose groups) at least twice that of the lowest intramuscular GEODON group were headache (13%), nausea (12%), and somnolence (20%). **Adverse Events at an Incidence >1% in Short-Term Fixed-Dose Intramuscular Trials:** The following list enumerates the treatment-emergent adverse events that occurred in ≥1% of GEODON patients (in the higher dose groups) and at least twice that of the lowest intramuscular GEODON group. Body as a Whole—headache, injection site pain, asthenia, abdominal pain, flu syndrome, back pain. Cardiovascular—postural hypotension, hypertension, bradycardia, vasodilation. Digestive—nausea, rectal hemorrhage, diarrhea, vomiting, dyspepsia, anorexia, constipation, tooth disorder, dry mouth. Nervous—dizziness, anxiety, insomnia, somnolence, akathisia, agitation, extrapyramidal syndrome, hypertonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. Respiratory—rhinitis. Skin and Appendages—furunculosis, sweating. Urogenital—dysmenorrhea, priapism. **DRUG ABUSE AND DEPENDENCE—** ***Controlled Substance Class:*** GEODON is not a controlled substance. **OVERDOSAGE**—In premarketing trials in over 5400 patients, accidental or intentional overdosage of GEODON was documented in 10 patients. All patients survived without sequelae. In the patient taking the largest confirmed amount (3240 mg), the only symptoms reported were minimal sedation, slurring of speech, and transitory hypertension (BP 200/95).

References: 1. Daniel DG, Potkin SG, Reeves KR, Swift RH, Harrigan EP. Intramuscular (IM) ziprasidone 20 mg is effective in reducing acute agitation associated with psychosis: a double-blind, randomized trial. *Psychopharmacology*. 2001;155:128-134. **2.** Lesem MD, Zajecka JM, Swift RH, Reeves KR, Harrigan EP. Intramuscular ziprasidone, 2 mg versus 10 mg, in the short-term management of agitated psychotic patients. *J Clin Psychiatry*. 2001;62:12-18. **3.** Brook S, Walden J, Benattia I, Siu CO, Romano SJ. Ziprasidone and haloperidol in the treatment of acute exacerbation of schizophrenia and schizoaffective disorder: comparison of intramuscular and oral formulations in a 6-week, randomized, blinded-assessment study. *Psychopharmacology*. 2005;178:514-523. **4.** Brook S, Lucey JV, Gunn KP, for the Ziprasidone IM Study Group. Intramuscular ziprasidone compared with intramuscular haloperidol in the treatment of acute psychosis. *J Clin Psychiatry*. 2000;61:933-941. **5.** Data on file. Pfizer Inc, New York, NY.

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Control acute agitation with

GEODON®

for ***Injection*** *(ziprasidone mesylate)*

In schizophrenia. . .

Rapid control* with low EPS[1-4]

- **Low incidence of movement disorders[1-4]**
- **Smooth transition, with continued improvement, from IM to oral therapy[3,4]**
- **May be used concomitantly with benzodiazepines[2,3,5]**

*In 2 pivotal studies vs control, significance was achieved at the 2-hour primary end point (10 mg study) and at the 4-hour primary end point (20 mg study).

GEODON®
Oral Capsules *(ziprasidone HCl)*
and ***Injection*** *(ziprasidone mesylate)*

GEODON for Injection is indicated for the treatment of acute agitation in schizophrenic patients for whom treatment with GEODON is appropriate and who need intramuscular antipsychotic medication for rapid control of the agitation.

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.

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

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

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

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

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.