Volume 44
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September 18, 2009

Newspaper of the
American
Psychiatric
Association

PSYCHIATRIC NEWS

inside

PERIODICALS:
TIME-SENSITIVE MATERIALS

Credit: David Hathcox

With the passing of Sen. Edward Kennedy last month, mental health advocates have lost a passionate ally. The photo above was taken in February 2003 at a press briefing announcing the introduction of the Sen. Paul Wellstone Mental Health Equitable Treatment Act, a later version of which became law in October 2008. Looking on are (from left) Rep. James Ramstad (R-Minn.), Rep. Patrick Kennedy (D-R.I.), and Sen. Pete Domenici (R-N.M.). See page 3.

Companies Search For 'Magic Bullet' That Can Defeat Alzheimer's

Researchers and drug companies hope new biologics and other drugs will soon become available to stop or even reverse the disease process in the brain.

BY JUN YAN

Pharmaceutical companies are racing to develop new classes of drugs to stop or reverse the course of Alzheimer's disease, but the forecast for many drug candidates remains somewhat murky.

Alzheimer's affects an estimated 5 million people in the United States, and the prevalence doubles for every five years beyond the age of 65, according to the Centers for Disease Control and Prevention. As life expectancy continues to rise and the elderly population grows faster than other age segments, Alzheimer's looms as one of the largest public health problems. By 2050, the worldwide prevalence of Alzheimer's is expected to quadruple.

Currently, three cholinesterase inhibitors (donepezil, rivastigmine, and galantamine) and one NMDA (N-methyl-D-aspartic acid) glutamate receptor antagonist (memantine) are approved by the FDA for the treatment of Alzheimer's. These drugs slow disease progression with modest efficacy, but none is able to stop or reverse the mental decline.

In recent years, several promising new drug candidates have been eagerly pursued by drug companies in research and

please see ***Alzheimer's*** *on page 34*

Aftereffects of Katrina Still Hobbling MH Services

Closing the one remaining public psychiatric hospital in New Orleans may—or may not—eliminate some barriers to child mental health care in the city.

BY AARON LEVIN

Too few psychiatrists and mental health professionals and too little sustainable funding continue to present barriers to care for children four years after Hurricane Katrina washed over New Orleans, even as Louisiana health officials close down the city's only remaining public inpatient psychiatric hospital in a budget-cutting move.

Collectively, the events reflect the still-unsettled state of New Orleans' mental health services.

"New Orleans is in an unprecedented mental health crisis," said Mordecai Potash, M.D., an associate professor of clinical psychiatry in the Department of Psychiatry and Neurology at Tulane University. "Seventy percent of the population has returned to the city, but we have only 50 percent of the inpatient beds that we had before the storm."

Studies from the Kaiser Family Foundation and Harvard University have shown increases both in severe mental illness that was not present before Katrina and in psychiatric problems exacerbated by the storm and its aftermath, said Potash in an interview.

The status of federally funded children's mental health services in the city and in surrounding Jefferson, Orleans, Plaquemines, and St. Bernard parishes was detailed in a report from the U.S. Gov-

please see ***Katrina*** *on page 34*

Photo courtesy of CityPass

APA's 2009 Institute on Psychiatric Services will be held in New York City October 8 to 11. The Big Apple is ready to welcome you! You can register online or register on site at the meeting, which is being held at the Sheraton New York Hotel and Towers. See page 2 for more information.

Contents

Features

Volume 44
Number 18
September 18, 2009

Departments

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Walker Honored for Efforts to Combat Substance Use in American Indians

An American-Indian psychiatrist is recognized for decades of work to understand and alleviate substance abuse in American Indians.

BY AARON LEVIN

A psychiatrist working within a community must understand its history, just as one who works with a single patient understands what brought that person into the office, said Roger Dale Walker, M.D., a professor of psychiatry and of public health and preventive medicine at Oregon Health and Science University in Portland.

Walker is a health services researcher and a clinician who specializes in substance abuse issues. He also directs the One Sky Center, a national resource for programs that have helped American-Indian and Alaska-Native communities prevent and treat substance abuse and other mental health problems.

"You need to understand the background and history and why the community is the way it is," he told *Psychiatric News*. "We have to be thorough and careful to establish trust and confidence in offering help, just as we are when treating an individual."

Decades of work at that intersection of communities and individuals led to Walker's recognition in July as American Indian Physician of the Year by the Association of

please see ***Walker*** *on page 33*

Credit: Aaron Levin

Roger Dale Walker, M.D., is honored as the American Indian Physician of the Year by the Association of American Indian Physicians at its annual meeting in Arlington, Va.

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We've Lost a Champion

BY NICHOLAS M. MEYERS
ALAN F. SCHATZBERG, M.D.

All of us lost a great friend and champion with the death of Sen. Edward Kennedy last month. As a new observer of the national political scene from the Washington, D.C., perspective, I asked Nick Meyers of our Department of Governmental Relations to coauthor this column.

Personally, I was struck by the outpouring of sadness and affection at the passing of the senator. In an era of strident politics, the bipartisan tributes to him were particularly notable—it isn't very often that you find a staunch conservative like Sen. Orrin Hatch of Utah talking about the good works of a friend on the Democratic side of the aisle in the Senate.

Although Sen. Kennedy's personal life was at times chaotic, he overcame losses and adversities, turned outward professionally, embraced his career, and devoted himself to public service.

And what a remarkable career it was. He focused on improving the lives of millions of Americans who were poor, disabled, often politically voiceless, and in desperate need of a champion. They found their voice in Sen. Kennedy. And so did we.

These are among Sen. Kennedy's achievements that have been important to us, to cite just a few:

- Ensuring that pregnant women cannot be fired for taking pregnancy leave.
- The Family and Medical Leave Act, which gives employees unpaid leave for childbirth and other family medical emergencies.
- Protections for women victimized by domestic abuse.
- The Americans With Disabilities Act, landmark legislation that protects disabled employees and requires employers to make reasonable accommodations for their disabled workers.
- The Ryan White Comprehensive AIDS Resources Emergency Act, a law providing better access to care for poor and uninsured HIV/AIDS patients and their families.
- Special Medicaid protections for families of children with special needs (including those with severe mental illness).

These are extraordinary achievements by any standard. They are also testament to the remarkable political skills that Sen. Kennedy brought to bear on the issues he cared about. Nowhere has this been more evident than in his tenacious, relentless struggle to end discrimination against patients seeking treatment for mental illness and substance use disorders, culminating first in the dramatic override of President Bush's veto of the Medicare reform bill and then in the enactment of last year's "parity law" (The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act).

Regarding the Medicare bill, APA (and all of medicine) was very active in the effort to get it through, since it included major improvements in coverage of treatment of psychiatric illness, such as the phasing out of the 50 percent coinsurance requirement that has been a feature of Medicare since the program started in the 1960s. Despite our success in getting both the House and Senate to pass this and other APA-lobbied mental health improvements, the Senate was unable to muster the 60 votes needed to cut off debate on the bill and override the president's earlier veto.

We knew from our excellent Capitol Hill sources that enough Republicans were eager to vote to override the Bush veto, but only if the Democrats could find the 60 votes, and they were one vote short, with Sen. Kennedy back home recovering from brain cancer surgery. How frustrating to come so close to enacting major improvements in Medicare that APA has sought for decades and to be one single vote shy of success—one vote shy, that is, until Sen. Kennedy stunned onlookers as he strode into the Senate chamber, asked the clerk how he was recorded, and cast his "aye" vote in a clear voice, cutting off debate and allowing the Senate to proceed—as we knew it would—to override the president's veto. It was an astonishing moment of political theater. Great theater, true, but it

please see ***From the President*** *on page 31*

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MH Groups Intensify Efforts To Pass Health Care Reform

The fight for health care reform has included vast spending—including some from physicians' groups—to sway an increasingly skeptical public and legislators to enact major reform legislation.

BY RICH DALY

The effort to overcome political obstacles in Congress to enacting far-reaching health care reform this fall has drawn the support of a broad spectrum of advocates, including mental health organizations.

Several of these organizations have urged their members and others to participate in the increasingly contentious national debate over health care reform. These efforts have included providing public information on the mental-health-related aspects of reform bills under consideration and coordinating campaigns to win passage of health care reform legislation.

Credit: Rich Daly

Rep. Jim Moran (D-Va.) tells attendees at a contentious town-hall meeting in Northern Virginia last month that the health care overhaul should include coverage for mental health care. "These are services that anyone [with insurance] should expect," he said.

APA has undertaken efforts to inform its members of various legislative proposals under consideration, including weekly updates on legislative developments from its Department of Government Relations (DGR). A special health reform update sent via e-mail urged psychiatrists to attend their local town-hall meetings with members of Congress and "share support for crucial provisions ensuring access to coverage and reforming Medicare payment for physicians." Moreover, *Psychiatric News* has run in-depth coverage in each issue since health care reform first appeared on the new administration's agenda.

Nicholas Meyers, director of DGR, added that APA is targeting its legislative advocacy to areas where the most direct impact on patients and members can be realized. For example, APA joined with the Bazelon Center for Mental Health Law in highlighting loopholes in proposed legislation in the Senate Committee on Health, Education, Labor, and Pensions that could have substantially undermined last year's mental health parity law. The problem was addressed by subsequent legislative changes. Other areas of attention include workforce and reimbursement.

Many town-hall meetings held this past summer by members of Congress drew national media coverage when angry constituents loudly protested expansions in the power and cost of government that health reform could bring (see article below). The negative reactions at the meetings went hand in hand with dropping public support for the effort. An August Kaiser Family Foundation poll found that the portion of the public who thought that the nation as a whole would benefit from reform dropped to 45 percent from 51 percent in the preceding month.

But health care reform supporters felt encouraged at some town-hall meetings. At two such events led by President Obama in July and August, members of the public specifically asked Obama about the inclusion of mental health care in health care reform, and he expressed support for it.

"I've long been a supporter of mental health services as part of a package, and I think that's important," Obama said at a town-hall meeting in Shaker Heights, Ohio, in July. Obama also called for more preventive care.

Mental health advocates said that their efforts to expand access to mental health care has a proven record of effectiveness.

"We were successful in enacting mental health parity, and grass-roots advocacy was an important part of that," said Steve Vetzner, a spokesperson for Mental Health America.

The parity law enacted in 2008, known as the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, requires health plans that cover 50 or more workers and offer mental health benefits to have the same service coverage and payment requirements as those for other health benefits.

Chris Koyanagi, a policy director at the Bazelon Center for Mental Health Law,

please see ***MH Groups*** *on page 33*

Path to Health Care Reform Becoming a Steeper Climb

Public discontent over enacting some type of health care reform grows, but supporters are trying to fight the rising tide.

BY RICH DALY

Public support for health care reform in the United States has weakened following an August congressional recess marked by contentious town-hall meetings around the country during which critics voiced concerns about the cost and the large government role that such legislation is expected to bring.

Growing opposition is borne out in numerous public-opinion polls, including an August tracking poll by the Kaiser Family Foundation. Among the findings of the nationally representative monthly phone survey of more than 1,200 adults was that support for major health reform declined from 62 percent in February to 53 percent in August, while opposition rose from 34 percent to 42 percent.

The public's cold feet could stem from growing concern about health care reform's costs and impact on them and their families. For instance, the Kaiser poll found in February that only 12 percent thought they would be worse off after reform, but in August, 31 percent thought that would be the case.

Thus, shortly before Congress resumed deliberations over health care reform, a substantial portion of the population appeared unwilling to pay the cost they believe it will entail. While 55 percent of respondents to the Kaiser survey said they would be unwilling to pay more in either insurance premiums or taxes to cover health care reform, 42 percent were willing to accept additional costs as the trade-off for a more comprehensive health care system.

Credit: Rich Daly

Attendees at a town-hall meeting in Northern Virginia last month argue passionately both for and against health care reform legislation pending in Congress.

Credit: Rich Daly

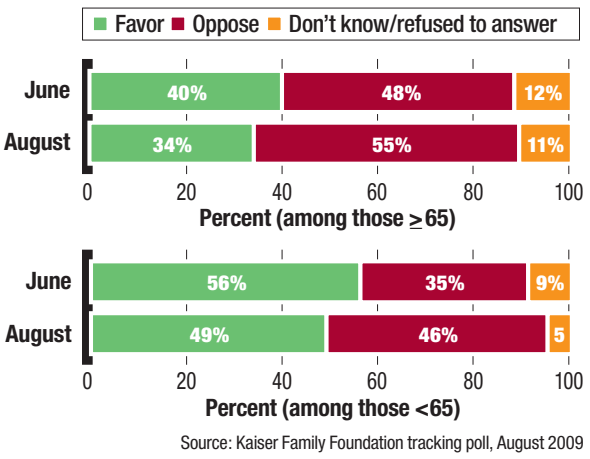
The public resistance to paying for more widely available health insurance coverage predates the current legislative fight to enact health care reform. An August *Health Affairs* article by researchers who examined public opinion in January found that while most people supported expanding access to health coverage, only a minority was willing to pay for coverage expansions. The Internet-based survey of 3,344 U.S. adults found that the only specific revenue-raising proposal that drew a bare majority of support was an increase in federal income taxes to expand Medicaid to cover half of the uninsured population, estimated to be about 47 million.

Meanwhile, the decline in public support for major health care reform has led reform advocates to plan campaigns to convince the public about the value they see in

please see ***Health Reform*** *on page 33*

Fewer Favor M.D. Pay Cuts To Pay for Reform

Recent polls have found shrinking public support for any proposed tax-revenue scheme to fund health care reform. And as shown below, also declining is the percentage of the public in favor of cutting Medicare physician fees to pay for health care reform.



Source: Kaiser Family Foundation tracking poll, August 2009

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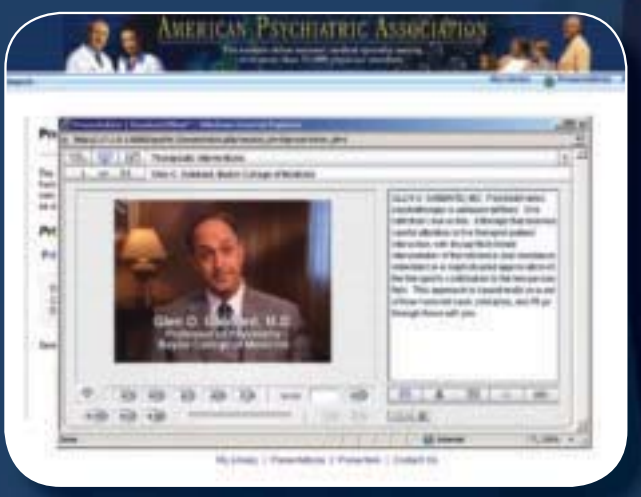

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States React to Passage Of Federal Parity Law

Among the 24 state legislatures that considered some form of mental health parity legislation, six approved aligning their parity laws with the federal parity law. Two other states may act on parity bills before year's end.

BY RICH DALY

State legislative actions on mental health insurance parity in 2009 focused on strengthening statutes that provide fewer insurance mandates than those approved last year under the landmark federal parity law.

The efforts in some states to conform their statutes to the requirements set by the federal law—the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008—included adding insurance coverage requirements for substance use disorders and making out-of-pocket costs the same as those required for other types of health care. At least 24 legislatures have considered some type of parity expansion measure so far this year, and six have enacted such legislation.

The new state laws—generally aimed at insurance plans not covered under the federal law—aim to simplify state regulators' enforcement efforts, because all plans will have to follow the same rules, according to parity advocates.

The state actions were not required by the federal parity law, because it does not apply to state-regulated insurance plans. Instead, the federal law applies to other insurers, such as those that cover the 82 million people who fall under the Employee Retirement Income Security Act (ERISA). Other plans covered by the federal parity law bring the total number of insured who could be affected by federal parity requirements to about 113 million people.

In Alaska, the legislature updated the state's parity law in April to reflect provisions in the federal parity law, and the governor signed it in August. Had the state not taken action, Alaska Rep. Lindsey Holmes (D) wrote to his colleagues in support of the bill, the state's division of insurance would not have been able to enforce the law when the federal law became effective.

The Alaska bill (HB 222) establishes the same requirements for state-regulated insurers that the federal parity law establishes for plans it regulates. Among the changes is a requirement that state-regulated plans cover the treatment of substance use disorders. The federal law requires parity coverage of treatment for substance abuse only when such coverage is already provided. In addition, the measure matches state law to the Genetic Information Nondiscrimination Act (PL 110-233)—enacted in 2008—barring insurers from discriminating on the basis of subscribers' or applicants' genetic information and requiring continuity of coverage for students taking medically necessary leaves of absence from college.

The other states to pass such measures were New York, Arkansas, Colorado, South Carolina, and West Virginia.

New York voted to make permanent the 2006 parity measure known as Timothy's Law. That law requires insurers issuing group health policies to cover a minimum of 30 inpatient days and 20 outpatient visits for the treatment of mental illness. Other features require health insurance policies of employers with more than 50 employees or members to include care for "biologically based mental illnesses" at the same coverage level as for other medical conditions. These illnesses are defined as "schizophrenia/psychotic disorders, major depression, bipolar disorder, delusional disorders, panic disorder, obsessive-compulsive disorder, bulimia, and anorexia" in adults and children.

"Added to the federal law, [the state insurance parity requirements] are an extremely potent combination," Seth Stein, J.D., executive director and general counsel of the New York State Psychiatric Association, told *Psychiatric News*.

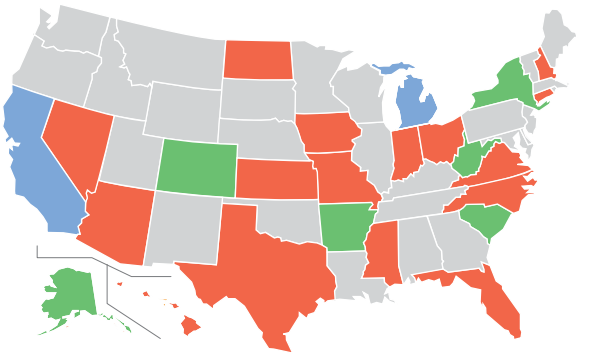
Parity legislation in West Virginia (HB 3288) was vetoed by Gov. Joe Manchin III (D) in May over concerns that it would undermine existing state parity law. However, he signed a revised bill in June after the legislature made technical changes. The legislation brings the state's parity law in line with the federal one by prohibiting group health plans that offer mental health and substance abuse coverage from imposing greater treatment limitations and financial requirements on those benefits than on those for other types of medical care.

In Colorado, legislation conforming to the federal parity law was signed on June 1. That legislation (HB 1338), which was sponsored by state Rep. Edward Casso (D), requires coverage of "biologically based mental illness and mental disorders" but does not define them. It also includes provisions to match the federal genetic information discrimination law.

The South Carolina parity measure (SB 390) became law on June 3, without the governor's signature. It expands a 2005 state parity law by adding substance abuse coverage. The expansion was driven by the inclusion of substance abuse coverage in the federal law, said Richard Frierson, M.D., a former president of the South Carolina Psychiatric Association. Legislators were willing to support the measure because the state's research on the inclusion of substance abuse coverage for its employees since 2002 showed minimal additional costs.

States Seek to Match Federal Parity Effort

In the wake of the 2008 federal mental health insurance parity law, at least 24 legislatures have considered some type of parity expansion measure so far this year, and six of them succeeded in passing increased parity requirements.



In addition, expanded parity coverage could have many important long-term benefits for the state. "This will help increase productivity [of people with a substance use disorder], so in the long run it could save the state a lot of money," Frierson told *Psychiatric News*.

The legislation enacted in Arkansas (HB 2195) in April copied federal parity requirements for ERISA plans and applied them to insurers regulated by state law. These new coverage requirements also specifically include insurers that cover state and school employees.

please see ***Parity*** *on page 34*

Bill Would Improve MH Care For Geriatric Patients

Supporters are pushing to have the measure, which focuses on primary care, added to health care reform legislation Congress is considering.

BY RICH DALY

A bill before Congress aims to improve the mental health of older Americans through better coordination and training of primary care physicians to diagnose mental illness and reduce record suicide rates among this population.

The bill, the Positive Aging Act of 2009 (HR 3191), was introduced by Rep. Patrick Kennedy (D-R.I.) in July to spur the use of improved psychiatric screening and diagnostic tools by primary care physicians and improve the training of those clinicians in identifying mental disorders in their geriatric patients. The measure also would encourage increased collaboration with mental health professionals on site in primary care settings that serve low-income seniors.

"The disconnect between primary care and mental health care means that older adults seen by their primary care physicians are too often misdiagnosed or improperly treated, and they continue to suffer from depression and other mental illnesses that complicate their medical conditions and lead to excess physical disability," said Charles Reynolds III, M.D., president of the American Association for Geriatric Psychiatry (AAGP), in a written statement.

The legislation, which is supported by APA and allied mental health groups, targets that disconnect by authorizing funding for Medicare pilot programs that offer mental health screenings, referrals for follow-up care and consultations, and the provision of the leading "evidence-based protocols" for treating common mental health disorders. Grants would fund community-based mental health treatment outreach teams to provide services in primary health care facilities where many older Americans receive medical treatment.

Kennedy said that mental health screenings and preventive care are critical to seniors' overall health. The need for the legislation is highlighted by studies suggesting that 20 percent of elderly Americans experience a mental disorder at any given time, but more than 50 percent of those cases go untreated.

"An even bigger problem is that there are effective treatments for the disorders, but our system does a poor job of integrating these much-needed services," said Rep. Ileana Ros-Lehtinen (R-Fla.), a cosponsor of the bill.

Other data that demonstrate the need for increased mental health care for this population include findings that men aged 85 and older have the highest rate of suicide in the nation, and untreated depression is the leading risk factor in such deaths, Reynolds said.

"It's tragic that one-third of older adults who commit suicide have seen their primary care physician in the week before completing suicide, and 70 percent have seen their doctors within the prior month," Reynolds said.

These are among other provisions of the legislation:

- Establish a deputy director for older adult mental health services in the Center for Mental Health Services (CMHS).
- Include representatives of the elderly and geriatric mental health professionals on an advisory council at CMHS.
- Include efforts to target substance abuse in older adults among the priority funding projects for the federal government.
- Require states that receive mental health block grants to detail their mental health outreach and services for older citizens.

The AAGP has called on its members and other mental health advocates to contact their legislators and urge them to include the provisions of the bill in health care reform legislation.

The legislation was originally introduced in 2002 after Kennedy consulted with the AAGP and other mental health advocates on changes needed to improve the care that seniors receive for psychiatric illness.

The text of the Positive Aging Act of 2009 can be accessed at <http://thomas.loc.gov> by searching on the bill number, HR 3191. ■

Federal Officials Tout Benefits Of Electronic Records

Some health experts agree that information technology will have benefits but caution that it carries serious security risks and is unlikely to reduce costs.

BY RICH DALY

Federal health officials recently said that expanded nationwide use of health information technology (HIT) by physicians and medical facilities is critical to improving patient care and controlling spiraling health care costs. They expect a massive federal funding program to spur widespread adoption of such electronic record systems by physicians, whose resistance has limited the use of such systems.

Widespread adoption of HIT, including electronic medical records (EMRs), will spur improvements in acute care, chronic care, and preventive care, according to David Blumenthal, M.D., national coordinator for health information technology at the Department of Health and Human Services.

During an online briefing in August, Blumenthal discussed his experience with HIT systems in private practice during the last 10 years. He credited HIT with preventing the loss of notes and records that can occur with paper documents, as well as with reducing inefficiencies. For example, he said, physicians who treat older patients—who are more likely to receive care from multiple clinicians—would benefit from a unified electronic record that would note whether the patient already had undergone a needed test. Similarly, HIT systems could facilitate better care coordination among physicians and alert them if they are about to prescribe medications that conflict with those prescribed by other clinicians.

"It is important for clinicians to be able to share information," Blumenthal emphasized.

In addition, said Mary Wakefield, R.N., administrator of the government's Health Resources and Services Administration, improved care coordination facilitated by expanded use of HIT should help control health care costs, which have grown to 17 percent of the U.S. economy. Better information exchange between clinicians will help detect serious illness at an earlier stage and allow treatment before conditions advance and more costly treatments are needed.

The push by federal officials to urge broad physician adoption of HIT systems seeks to overcome long-standing clinician resistance to them on the basis of cost concerns and their ability to protect the privacy of patient information.

Only about 12 percent of physicians have adopted HIT systems, according to a 2008 Congressional Budget Office report. Another study, published on July 3, 2008, in the *New England Journal of Medicine*, found that only 4 percent of physicians had adopted fully functional EMRs, and those who had tended to be in larger practices (*Psychiatric News*, August 1, 2008).

Physicians Can Be Reimbursed

The federal government has made widespread HIT adoption a major policy priority. The centerpiece of the initiative is a federal program to reimburse physicians up to $44,000 over five years—beginning in 2011—for their costs in installing electronic record systems. The program, created in the American Recovery and Reinvestment Act of 2009 (ARRA, PL 111-5), includes $17 billion in grants to encourage the use of EMRs, HIT (which includes the software and hardware needed to operate EMRs), and e-prescribing (*Psychiatric News*, March 20). The law also includes penalties for physicians who have not installed EMR systems by 2015.

"With that funding and physicians' commitment to put patient care first, this is going to happen," Blumenthal said. "And it's the right thing to do."

Privacy Protections Mandated

The federal law also includes a mandate for regulators to develop strong patient-privacy protections. These aim to address the concerns of physician and patient-advocacy organizations that putting patient records into a system accessible to many authorized users would exponentially increase the risk of privacy violations. For instance, in 2008 health organizations reported 97 data breaches, up from 64 the previous year. A much larger jump in reported breaches is expected this year, in part due to a new California law that requires reports of unauthorized disclosures of electronic medical records, according to media reports.

"We are leaving no stone unturned in trying to keep this information private and secure," Blumenthal stated.

In 2008 congressional testimony, Robert Plovnick, M.D., M.S., director of the

please see ***Records*** *on page 33*

Data Help Military, VA Focus Mental Health Initiatives

Epidemiologists and health services researchers are publishing new studies to clarify the mental health needs of veterans.

BY AARON LEVIN

The Department of Veterans Affairs (VA) and the Department of Defense have stepped up efforts in recent years to develop and refine procedures for identifying, preventing, and treating mental health problems among veterans and active-duty personnel. That sense of urgency also lies behind the steady flow of epidemiological studies tracking mental health status and risk factors among these populations.

A report in the September *American Journal of Public Health* assessed data on 289,328 veterans of the wars in Iraq and Afghanistan who had entered VA health care for the first time between April 2002 and March 31, 2008. Of those veterans, 106,726 (or 37 percent) received new mental health diagnoses. That compared with 28 in the first cohort of 439 veterans (6 percent) in April 2002, and thus represented a sixfold increase in six years. Adding psychosocial and behavioral problems (like marital and family problems) to the mix increased prevalence to almost 43 percent, according to Karen Seal, M.D., M.P.H., of the San Francisco VA Medical Center and the University of California, San Francisco, and colleagues.

About 22 percent (62,929) of the veterans were newly diagnosed with PTSD, four to seven times the prevalence rate at the start of the Iraq invasion. The prevalence rates of depression and alcohol and drug abuse disorders rose as well.

The prevalence of new mental health diagnoses increased steadily as time passed. Of the veterans entering VA care at the beginning of 2004, 14.6 percent had received mental health diagnoses after one year, 20.3 percent after two years, and 27.5 percent after four years.

After adjustment for sociodemographic and military service characteristics stratified by component type, younger (aged 24 and under) active-duty troops had a greater risk for new mental health diagnoses (aside from depression) compared with veterans over age 40. They also had twice the risk for PTSD and alcohol-use disorders, and five times the risk for drug-use disorders. Some of that difference may be due to differential combat exposure, wrote the authors.

However, among National Guard and Reserve troops, the risk for depression and PTSD was higher among the older cohort.

Seal noted that these rates are higher than some previously reported among troops on active duty, perhaps reflecting "that veterans seeking VA care may have less stigma- and career-related concerns than do active military personnel about disclosing mental health problems, and VA clinicians may be more apt to record mental health diagnoses in the clinical record than are military health providers."

An increased willingness to seek mental health care may be reflected in a study that found persons with current or past active-duty military experience recorded similar psychological distress scores on the 2007 Behavioral Risk Factor Surveillance System survey as those without such experience, but were more likely to have had recent mental health treatment, according to Marc Safran, M.D., M.P.A., senior psychiatrist at the Centers for Disease Control and Prevention, and colleagues, in the June *International Journal of Public Health*.

Whether this reflects a lessening of stigma regarding treatment should be explored in future research, wrote Safran and colleagues.

The number of suicides among active troops and veterans has reached the point where the Army recently commissioned a $50 million study through the National Institute of Mental Health to seek solutions to the problem *(Psychiatric News*, August 21).

In a July 2007 article in the *Journal of Epidemiology and Community Health*, Mark Kaplan, Ph.D., a professor of community health at Oregon's Portland State University, and colleagues found that veterans were twice as likely to die of suicide compared with nonveterans in the general population. Kaplan used data on 320,890 men drawn from the U.S. National Health Interview Surveys.

Suicide is a rare and complex phenomenon, so no single cause will be found for its increased prevalence among veterans, said Kaplan in an interview. He suggested that a number of factors may contribute to their risk: desensitization to death and killing, a culture of stoicism and an allied difficulty in articulating feelings, a lack of preparation for life after the service, and a familiarity with firearms.

Kaplan pointed out that 8 out of 10 suicides among younger veterans in their study involved guns, and suicide by firearms is usually impulsive and lethal. Thus, the chance of rescue or survival is very slim.

More recently, other VA researchers reported on the relationship between PTSD and suicidal ideation in veterans presenting for mental health care at the VA Puget Sound Health Care System from 2004 to 2007.

They studied 435 veterans of the Iraq or Afghan war assessed and referred for mental health treatment, wrote psychologist Matthew Jakupcak, Ph.D., and colleagues in the August *Journal of Traumatic Stress*. Jakupcak is a researcher at the Mental Illness Research, Education, and Clinical Center at the VA Puget Sound Health Care System and an acting assistant professor in the Department of Psychiatry and Behavioral Sciences at the University of Washington School of Medicine in Seattle.

To evaluate these veterans, they used the military version of the PTSD Checklist, the Patient Health Questionnaire depression subscale, and the Addiction Severity Index. Patients were recorded as having suicidal ideation if they endorsed at least one of five items drawn from the Mississippi Scale for PTSD and the Scale for Suicidal Ideation.

Data were available for 407 veterans, 187 with suicidal ideation and 220 without. After controlling for age, depression, and substance abuse, veterans with PTSD were four times more likely to acknowledge suicidal ideation than those without.

The researchers also analyzed data from the veterans who screened positive for PTSD (n=202) to examine the effects of psychiatric comorbidities. Veterans with PTSD and one comorbidity (depression or substance abuse) were no more likely to exhibit suicidal ideation than those with only PTSD. However, those with at least two comorbidities were 5.7 times more likely to exhibit suicidal ideation.

"Current findings underscore the importance of assessing for suicidal ideation in [Iraq and Afghan] veterans, especially among PTSD veterans with complex psychiatric profiles," the researchers wrote.

"This confirms prior research showing that veterans with mental health problems are at higher risk for suicidality," said Jakupcak in an interview. These problems cannot be viewed in isolation, he said. "Many veterans are presenting with complex physical injuries, pain, traumatic brain injuries, and psychiatric symptoms."

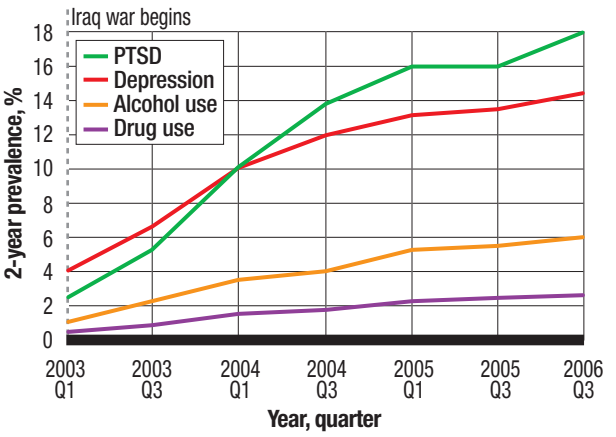
Finally, a small, qualitative study of 16 returning veterans of the current conflicts concluded that the strategies needed to cope with combat made reintegration into life back home more difficult. That conflict led veterans to feel burdensome to people around them and into failed relationships with civilians, said Lisa Brenner, Ph.D., of the VA's Mental Illness Research, Education, and Clinical Center in Denver and an assistant clinical professor of psychology at the University of Colorado School of Medicine.

"Working with veterans to decrease their suicide risk is likely to require multiple interventions and creative adaptations of existing approaches," wrote Brenner in the July 2008 *Journal of Mental Health Counseling*.

An abstract of "Trends and Risk Factors for Mental Health Diagnoses Among Iraq and Afghanistan Veterans Using Department of Veterans Affairs Health Care, 2002–2008" is posted at <www.ajph.org/cgi/content/abstract/99/9/1651>. An abstract of "Posttraumatic Stress Disorder as a Risk Factor for Suicidal Ideation in Iraq and Afghanistan War Veterans" is posted at <www3.interscience.wiley.com/journal/122519727/abstract?CRETRY=1&SRETRY=0>. ■

Vets In VA System Show More MH Diagnoses

Before the start of the war in Iraq, the combined two-year prevalence of PTSD, depression, alcohol-use disorders, and drug-use disorders among veterans of action in Afghanistan was about 6 percent. After the Iraq war began, however, the overall rate of these mental disorders rose to 37 percent by 2006 among veterans of both wars. The data are reported by quarter of veterans' entry into the Department of Veterans Affairs health care system.



Source: Karen Seal et al., *American Journal of Public Health*, September 2009

Plant Family Tree To See History Of Mental Illness

An online tool can help people trace mental illness in their family.

BY JOAN AREHART-TREICHEL

Ancestor research is a popular hobby among Americans these days. But few think about building a family tree as far as mental illnesses are concerned. Yet having such a family tree could help them better understand which mental illnesses, if any, tend to run in their families.

Thus, Families for Depression Awareness, a nonprofit organization helping families cope with depressive disorders, has developed a free online tool to help people build a family tree for depression and bipolar disorder. It is called the Mental Health Family Tree. An individual can use the tool to build the tree online and then print out a hard copy or to print out a blank form of the tree and then inscribe information on it by hand.

By sharing their mental health family trees with their clinicians, clinicians can perhaps more quickly and more accurately diagnose any mood disorders that they have. In fact, clinicians could ask patients to fill out a blank copy of the Mental Health Family Tree before arriving for an appointment or while waiting in their offices before an appointment.

"It's an interesting tool," Stephen Strakowski, M.D., chair of psychiatry at the University of Cincinnati and a bipolar disorder authority, told *Psychiatric News*. "I ran a made-up subject through quickly, and it works fairly easily. There are some limitations—for example, it doesn't link second-degree relatives necessarily well—but it is nonetheless functional. Clinicians may find it useful."

The Mental Health Family Tree is posted at <www.MentalHealthFamilyTree.org>. The Web site for Families for Depression Awareness is <www.FamilyAware.org>. ■

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

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.** Wimo A, Winblad B, Stöffler A, Wirth Y, Möbius HJ. Resource utilisation and cost analysis of memantine in patients with moderate to severe Alzheimer's disease. *Pharmacoeconomics.* 2003;21:327-340. **7.** Winblad B, Poritis N. Memantine in severe dementia: results of the ³M-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.

62-1014307R R2 03/09

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Brief Summary of Prescribing Information.

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

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

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

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

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

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

Special Populations
Hepatic Impairment
Namenda undergoes partial hepatic metabolism, with about 48% of administered dose excreted in urine as unchanged drug or as the sum of parent drug and the N-glucuronide conjugate (74%). No dosage adjustment is needed in patients with mild or moderate hepatic impairment. Namenda should be administered with caution to patients with severe hepatic impairment.

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 (see CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION in Full Prescribing Information).

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, paranoic reaction, thinking abnormal, crying abnormal, appetite increased, paronia, delirium, depersonalization, necrosis, 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, retina 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: aspiration pneumonia, asthenia, atrioventricular block, bone fracture, carpal tunnel syndrome, cerebral infarction, chest pain, cholelithiasis, claudication, colitis, deep venous thrombosis, depressed level of consciousness (including loss of consciousness and rare reports of coma), dyskinesia, dysphagia, encephalopathy, gastritis, gastroesophageal reflux, grand mal convulsions, intracranial hemorrhage, hepatitis (including increased ALT and AST and hepatic failure), hyperglycemia, hyperlipidemia, hypoglycemia, ileus, increased INR, impotence, lethargy, malaise, myoclonus, neuroleptic malignant syndrome, acute pancreatitis, Parkinsonism, acute renal failure (including increased creatinine and renal insufficiency), prolonged QT interval, restlessness, sepsis, Stevens-Johnson syndrome, suicidal ideation, sudden death, supraventricular tachycardia, tachycardia, tardive dyskinesia, thrombocytopenia, and hallucinations (both visual and auditory).

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
Signs and symptoms associated with memantine overdosage in clinical trials and from worldwide marketing experience include agitation, confusion, ECG changes, loss of consciousness, psychosis, restlessness, slowed movement, somnolence, stupor, unsteady gait, visual hallucinations, vertigo, vomiting, and weakness. The largest known ingestion of memantine worldwide was 2.0 grams in a patient who took memantine in conjunction with unspecified antidiabetic medications. The patient experienced coma, diplopia, and agitation, but subsequently recovered.

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.

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Psychiatrists Key Ingredient In Medicine's Melting Pot

Just as America is largely a land of immigrants, so too is American psychiatry. And just as many immigrants find their American dream, so do many immigrant psychiatrists.

BY JOAN AREHART-TREICHEL

In 1993, Bengi Melton, M.D., a Turkish psychiatrist, had an adventure that changed her life dramatically. She was backpacking in Europe and while in Greece met by happenstance a fourth-generation Texan touring the world. A romance sprang up. They decided to marry. In 1997, Melton moved to Houston and eventually joined the ranks of the many American psychiatrists who hail from other countries.

Not all psychiatrists practicing in the United States who come from other countries make the leap from Turkey to Texas or come because of romance, of course. But no matter where they come from or why, they too have intriguing stories to tell. So *Psychiatric News* decided to focus on the stories of Melton and four other psychiatrists who immigrated to the United States within the past 10 to 15 years. The other four are Vadim Baram, M.D., a St. Louis psychiatrist who emigrated from Ukraine to the United States in 1995; Vladimir Bokarius, M.D., Ph.D., a Los Angeles psychiatrist who emigrated from Russia in 2001; Gonzalo Laje, M.D., a Maryland psychiatrist who emigrated from Argentina in 1999; and Saima Shafiq, M.D., a New Jersey psychiatrist who emigrated from Pakistan in 1994.

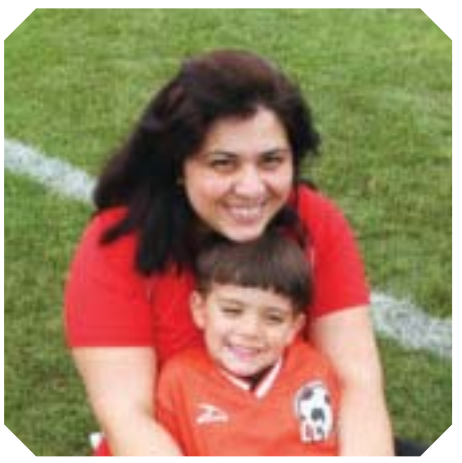
Although each of these psychiatrists' stories is unique, some common threads run through them, notably a steely determination to succeed in spite of numerous obstacles.

Master Plan Laid Out

Before Baram left Ukraine, he had a master plan not only to do a psychiatry residency in the United States, but also to establish himself professionally here after residency. "I put a lot of effort into it," he said. "It took about four years for me to get through all the certification exams and to find a residency program."

Shafiq came to this country with her husband, also a physician from Pakistan. "We came over after medical school to finish our specialization in different fields. I chose psychiatry for a number of reasons. I was always interested in it. The residency has reasonable working hours, and I had two small children at the time. And of course the job market is very good."

Laje was training in psychiatry in Argentina when he seriously began considering coming to the United States. "My interest was in clinical research. At that time I was working on anxiety disorders, and I got in touch with an American psychiatrist, Michael Lebowitz, and he was kind enough to invite me to spend some time with him at his Columbia University anxiety clinic. Initially my idea was not to come to the U.S. to stay; it was to go back and set up some clinical research in Argentina. But I really liked it here and decided that I wanted to stay."



Bengi Melton, M.D.

Challenges and Then Some

However, simply liking the United States was not enough for a foreign-born, newly minted physician, such as Shafiq, to adapt easily to this country or to transform established physicians from other countries, such as Bokarius, into "American" psychiatrists. They had to overcome daunting hurdles beyond those faced by American medical graduates who desire to become psychiatrists.

There was cultural shock, for example. "When you come from a country like Pakistan, which is basically third world, and psychiatry and medical care are not as good as in the United States, you face certain handicaps," Shafiq said.

Vadim Baram, M.D.

Gonzalo Laje, M.D.

There was language. When Baram came to the United States, he said, "I was able to read English, but in regard to English comprehension and talking, it was a challenge."

Laje found that the language unique to psychiatric intervention had to be honed. "Although I had a pretty good English background, the subtleties of the language in psychotherapy sometimes got in the way," he recalled. "The vocabulary, the way people said things, what they meant with the use of certain words—that took an extra layer of thinking."

Vladimir Bokarius, M.D., Ph.D.

Saima Shafiq, M.D.

As for the U.S. Medical Licensing Examinations that graduates of foreign medical schools, as well as graduates of U.S. medical schools, have to take to be accepted into a psychiatry residency program, Laje did not have any problem with them, but he knows many medical graduates from other countries who have.

"The exams in general do not ask strange, obscure questions," he said. "They are very reasonable. The issue for a foreigner is to read them fast and to be able to answer the questions within the allotted time frame."

An obstacle for Melton, who was already an established psychiatrist in Turkey, was the need to repeat a psychiatry residency in the United States if she wished to practice here. This meant once again reading basic science, going through the routine of being an intern, and taking call, as well as working with classmates who were fresh out of medical school and a little younger than she was. "But I did it," she said. "I did what I had to do."

To work as a specialist in the United States, Bokarius also had to do a residency here. But he thought, "Why should I do a neurology residency again? I want to broaden my horizons. What would make me a better pain specialist?" Psychiatry, he decided, would be a good addition. "And I'm so glad that I did it, not just because I broadened my horizons, but because I got a beautiful new specialty."

Career Challenges Tackled

Yet even after they became licensed or board-certified U.S. psychiatrists, Baram, Bokarius, Laje, Melton, and Shafiq encountered new obstacles.

Some were similar to those facing U.S.-born early-career psychiatrists.

Baram was eager to establish a private practice, but found that a psychiatry residency had done little to prepare him for the business aspects of such a venture.

please see ***Melting Pot*** *on page 32*

International Medical Graduates Make Widespread Contributions

According to a 2005 report from the University of Washington's Center for Health Workforce Studies, 9 out of 10 foreign-trained physicians practicing medicine in the United States—that is, international medical graduates (IMGs)—were foreign born. (The rest were U.S. born.) Thus data about IMGs mostly concern foreign-born physicians and provide valuable insights into their role in American medicine.

- According to data from the AMA, there were 902,053 physicians in the United States in 2006. Of these physicians, 228,665 (25 percent) were IMGs.
- According to 2006 and 2007 AMA data, 20 percent of IMGs received their medical degrees in India, 9 percent in the Philippines, 6 percent in Mexico, 5 percent in Pakistan, and 3 percent in the Dominican Republic. Altogether they received medical degrees from 127 countries.
- According to 2008 AMA data, 37 percent of IMGs practiced internal medicine, 31 percent psychiatry, 28 percent anesthesiology, and 28 percent pediatrics; the largest number is located in New Jersey, followed by New York, Florida, and Illinois.
- According to APA's Division of Education, the percentage of U.S. psychiatry residents who are IMGs has dropped from 40 percent in 1999 to 31 percent in 2008.
- According to APA's Department of Membership, the percentage of APA members who are IMGs has stayed steady in the past decade—25 percent in 1999 and 26 percent now.
- Foreign-born IMGs "come from vastly different cultural, linguistic, and medical-education backgrounds than do their American counterparts," an article in the January-February 2007 *Academic Psychiatry* noted. "They play a key role in the delivery of health care, especially to underserved populations."

Effective Addiction Strategy Is Often Overlooked

BY MEGAN TESTA, M.D.

A valuable strategy that can help many addicts is often overlooked by psychiatrists, in part because of the way our profession conceptualizes addiction treatment. Yet this intervention, needle-exchange programs, can go a long way to reducing some of the serious risks that our intravenous drug using patients confront.

As psychiatrists, we think of addiction as "use despite consequences." *DSM* defines substance-dependence using criteria that identify individuals who continue to use substances in spite of negative physical, emotional, and social consequences. We know that it typically takes a long time for someone with an addiction to realize that he or she must change and that, even with this realization, the addict will usually suffer multiple consequences before achieving recovery.

Unfortunately, the medical model by which we practice does not include effective methods for treating addicts who are not yet ready to give up their habits. During medical school and residency, we were taught about the stages of change, and recommendations for intervention at the precontemplative stage are few: advise patients to quit using and reassure them that when they are ready to quit, you will help them. During subsequent visits, we continue to inquire about patients' drug-use habits to reassess their readiness to change. Often it is only when a patient is ready to quit using that our psychiatric interventions come into play. However, when we focus our efforts on only patients who are ready and willing to pursue sobriety, we fail many patients.

A population that suffers greatly in this model is intravenous (IV) drug users, who—by nature of the route through which they use their drug of choice—are at high risk for serious, but often preventable, health problems. The injection process carries the inherent risk of infection, and many IV drug users contract cellulitis, endocarditis, hepatitis C, and HIV.

Fortunately for IV drug users, there is a strategy that operates on the principle of meeting addicts where they are, regardless of their motivations about recovery, with the aim of reducing the incidence of injection-related harm. And we psychiatrists can help ensure that this strategy becomes more readily applied.

The best known harm-reduction strategy is needle exchange—the simple intervention of collecting dirty injection equipment from IV drug users and providing sterile equipment in exchange. Needle exchange has been around since the 1980s. Its efficacy in preventing HIV transmission in this population, without increasing the incidence or prevalence of drug-use behavior, has been clearly established in multiple research studies. Needle exchange is endorsed by APA, as well as the AMA, World Health Organization, Centers for Disease Control and Prevention, and National Institutes of Health.

Yet despite this body of expert opinion, needle-exchange programs are not readily available in the United States. Part of the problem is purely legislative; for 20 years the federal government has had a ban on the use of federal dollars to establish and operate needle-exchange programs.

But part of the problem lies with providers. Because of our training, we tend to see just one positive outcome for addicts—sobriety. We receive little to no training in harm reduction, and we are not trained in proper drug-injection techniques ourselves, much less how to teach these techniques to IV drug users. Furthermore, we have an aversion to harm-reduction strategies, which many physicians believe makes them complacent in the face of drug abuse.

I recently had the opportunity to volunteer at the needle-exchange program at Cleveland's Free Clinic. I came to appreciate that a psychiatrist operating under the standard medical model can play only a limited role in the treatment of addicts who are injecting drugs. I was humbled by watching the outreach workers meet with IV drug users in the streets, without judgment or anticipation of their eventual progression to a desired stage of change. I learned firsthand that for many people with drug addictions, it is the development of a relationship with someone in the health care field who cares foremost about keeping them as safe as possible—no matter what type of behavior they are engaging in—that ultimately leads to recovery.

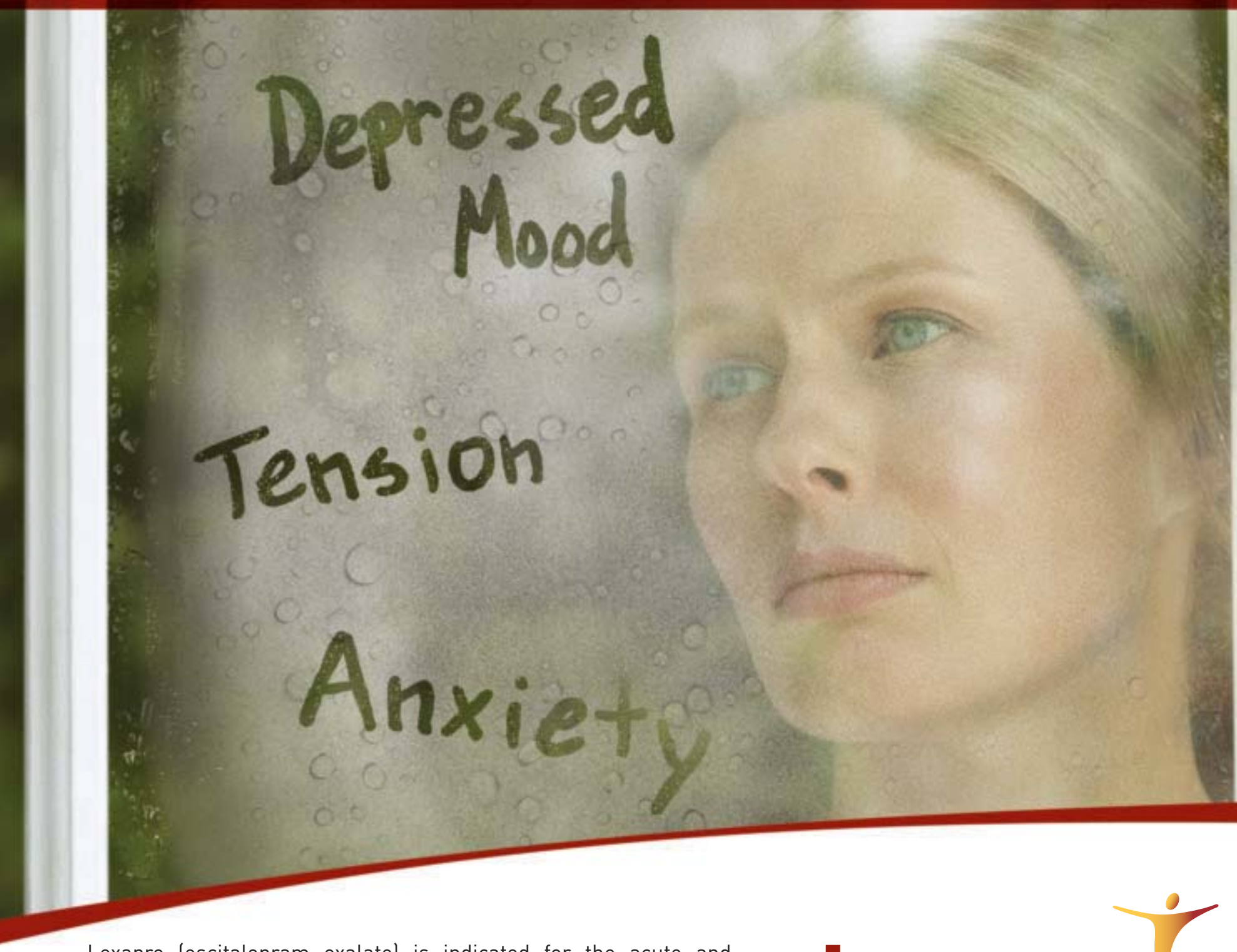
On July 24 the House of Representatives passed HR 3293, which includes a repeal of the funding ban on needle-exchange programs. I hope that psychiatrists will advocate for passage of this bill in the Senate by contacting their senators about its merits. We can also work to transform our profession's approach to patients with addiction by adopting harm-reduction strategies in our treatment of IV drug users.

We know that mounting consequences do not dissuade addicts from using drugs. It is time to abandon the attitude that reducing harm, when possible, would serve as a detriment to recovery. ■

Megan Testa, M.D., is a PGY-3 resident at University Hospitals of Cleveland and a recipient of the APA/BMS Public Psychiatry Fellowship.

Treat core symptoms[1,2]

of Major Depressive Disorder (MDD) & Generalized Anxiety Disorder (GAD)



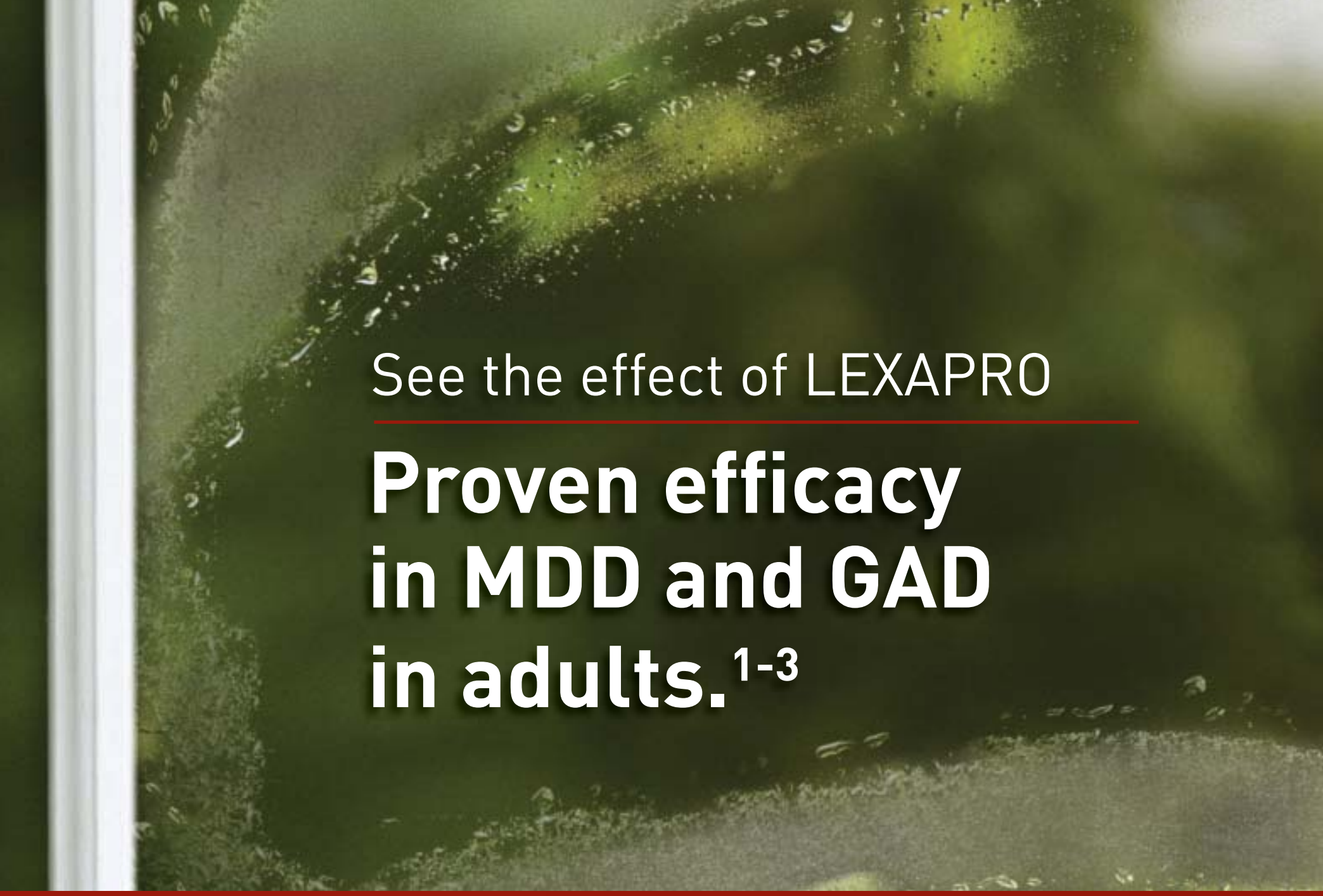
Lexapro (escitalopram oxalate) is indicated for the acute and maintenance treatment of major depressive disorder (MDD) in adults and adolescents aged 12-17 years. Lexapro is also indicated for the acute treatment of generalized anxiety disorder (GAD) in adults.

Lexapro® escitalopram oxalate

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of 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 less than 12 years of age.

Please see additional Important Safety Information on following pages.



- Significantly higher rates of response and remission vs placebo in adults[2,4]
- Significantly improved quality-of-life (QOL) scores vs placebo in adults[1,2]

Lexapro (escitalopram oxalate) is indicated for the acute and maintenance treatment of major depressive disorder (MDD) in adults and adolescents aged 12-17 years. Lexapro is also indicated for the acute treatment of generalized anxiety disorder (GAD) in adults.

IMPORTANT SAFETY INFORMATION (continued)

Contraindications

- Lexapro is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs). There have been reports of serious, sometimes fatal, reactions with some cases resembling neuroleptic malignant syndrome (NMS) and serotonin syndrome. Features may include 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. Serotonin syndrome was reported for two patients who were concomitantly receiving linezolid, an antibiotic which has MAOI activity. Lexapro should not be used in combination with an MAOI or within 14 days of discontinuing an MAOI. MAOIs should not be initiated within 14 days of discontinuing Lexapro.
- Lexapro is contraindicated in patients taking pimozide or with hypersensitivity to escitalopram or citalopram.

Warnings and Precautions

- All patients treated with antidepressants should be monitored appropriately and observed closely for clinical worsening, suicidality and unusual changes in behavior, especially within the first few months of treatment or when changing the dose. Consideration should be given to changing the therapeutic regimen, including discontinuing medication, in patients whose depression is persistently worse, who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Families and caregivers of patients treated with antidepressants should be alerted about the need to monitor patients daily for the emergence of agitation, irritability, unusual changes in behavior, or the emergence of suicidality, and report such symptoms immediately. 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.

- Prescribed to over 18 million US patients[5]
- Widely available on health plan formularies without restrictions[6]

- A major depressive episode may be the initial presentation of bipolar disorder. In patients at risk for bipolar disorder, treating such an episode with an antidepressant alone may increase the likelihood of precipitating a mixed/manic episode. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine if they are at risk for bipolar disorder. Lexapro should be used cautiously in patients with a history of mania or seizure disorder. Lexapro is not approved for use in treating bipolar depression.
- The concomitant use of Lexapro with other SSRIs, SNRIs, triptans, tryptophan, antipsychotics or other dopamine antagonists is not recommended due to potential development of life-threatening serotonin syndrome or neuroleptic malignant syndrome (NMS)-like reactions. Reactions have been reported with SNRIs and SSRIs alone, including Lexapro, but particularly with drugs that impair metabolism of serotonin (including MAOIs). Management of these events should include immediate discontinuation of Lexapro and the concomitant agent and continued monitoring.
- Patients should be monitored for adverse reactions when discontinuing treatment with Lexapro. During marketing of Lexapro and other SSRIs and SNRIs, there have been spontaneous reports of adverse events occurring upon discontinuation, including dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias), anxiety, confusion, headache, lethargy, emotional lability, insomnia and hypomania. A gradual dose reduction rather than abrupt cessation is recommended whenever possible.

Please see additional Important Safety Information on next page.

Lexapro®
escitalopram oxalate

Visit the LEXAPRO website at www.lexapro.com

LEXAPRO: Proven efficacy in MDD and GAD in adults[1-3]

Warnings and Precautions (continued)

- SSRIs and SNRIs have been associated with clinically significant hyponatremia. Elderly patients and patients taking diuretics or who are otherwise volume-depleted appear to be at a greater risk. Discontinuation of Lexapro should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted.
- SSRIs (including Lexapro) and SNRIs may increase the risk of bleeding. Patients should be cautioned that concomitant use of aspirin, NSAIDs, warfarin or other anticoagulants may add to the risk.
- Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro does not affect their ability to engage in such activities.
- Lexapro should be used with caution in patients with severe renal impairment or with diseases or conditions that alter metabolism or hemodynamic responses. 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.
- For pregnant or nursing mothers, Lexapro should be used only if the potential benefit justifies the potential risk to the fetus or child.

Adverse Reactions

- In clinical trials of MDD, the most common adverse reactions in adults treated with Lexapro (approximately 5% or greater and at least twice the incidence of placebo) were nausea (15% vs 7%), insomnia (9% vs 4%), ejaculation disorder (9% vs <1%), fatigue (5% vs 2%), somnolence (6% vs 2%), and increased sweating (5% vs 2%). In pediatric patients, the overall profile of adverse reactions was similar to that seen in adults; however, the following additional adverse reactions were reported at an incidence of at least 2% for Lexapro and greater than placebo: back pain, urinary tract infection, vomiting, and nasal congestion.
- In clinical trials of GAD, the most common adverse reactions in adults treated with Lexapro (approximately 5% or greater and at least twice the incidence of placebo) were nausea (18% vs 8%), ejaculation disorder (14% vs 2%), insomnia (12% vs 6%), fatigue (8% vs 2%), decreased libido (7% vs 2%) and anorgasmia (6% vs <1%).

Please see accompanying brief summary of prescribing information for LEXAPRO, including Boxed Warning.

References: 1. Burke WJ, Gergel I, Bose A. Fixed-dose trial of the single isomer SSRI escitalopram in depressed outpatients. *J Clin Psychiatry.* 2002;63:331-336. **2.** Davidson JRT, Bose A, Korotzer A, Zheng H. Escitalopram in the treatment of generalized anxiety disorder: double-blind, placebo controlled, flexible-dose study. *Depress Anxiety.* 2004;19:234-240. **3.** LEXAPRO [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2009. **4.** Wade A, Lemming OM, Hedegaard KB. Escitalopram 10 mg/day is effective and well tolerated in a placebo-controlled study in depression in primary care. *Int Clin Psychopharmacol.* 2002;17:95-102. **5.** SDI, April 2008. Depression and Anxiety Treatment Market Overview. Based on longitudinal analysis of US electronic retail pharmacy claims submitted for third-party reimbursement. **6.** Data on file, Forest Laboratories, Inc.

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Lexapro® escitalopram oxalate

LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION **Rx Only**

Brief Summary: For complete details, please see full Prescribing Information for Lexapro.

WARNINGS: 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 less than 12 years of age. *[See Warnings and Precautions: Clinical Worsening and Suicide Risk, Patient Counseling Information: Information for Patients, and Used in Specific Populations: Pediatric Use].*

INDICATIONS AND USAGE: Major Depressive Disorder-Lexapro (escitalopram) is indicated for the acute and maintenance treatment of major depressive disorder in adults and in adolescents 12 to 17 years of age [*see Clinical tudies*]. A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, a suicide attempt or suicidal ideation. **Generalized Anxiety Disorder**-Lexapro is indicated for the acute treatment of Generalized Anxiety Disorder (GAD) in adults [*see Clinical Studies*]. Generalized Anxiety Disorder (DSM-IV) is characterized by excessive anxiety and worry (apprehensive expectation) that is persistent for at least 6 months and which the person finds difficult to control. It must be associated with at least 3 of the following symptoms: restlessness or feeling keyed up or on edge, being easily fatigued, difficulty concentrating or mind going blank, irritability, muscle tension, and sleep disturbance.

CONTRAINDICATIONS: Monoamine oxidase inhibitors (MAOIs)-Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated [*see Warnings and Precautions*]. **Pimozide**-Concomitant use in patients taking pimozide is contraindicated [*see Drug Interactions*]. **Hypersensitivity to escitalopram or citalopram**-Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Lexapro.

WARNINGS AND PRECAUTIONS: 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	Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated
	Increases Compared to Placebo
<18	14 additional cases
18-24	5 additional cases
	Decreases Compared to Placebo
25-64	1 fewer case
≥65	6 fewer cases

No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide. It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression. All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for 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 Dosage and Administration*]. 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 [*see also Patient Counseling Information*]. 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. **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions**-The development of a potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported with SNRIs and SSRIs alone, including Lexapro treatment, but particularly with concomitant use of serotonergic drugs (including triptans) with drugs which impair metabolism of serotonin (including MAOIs), or with antipsychotics or other dopamine antagonists. 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). Serotonin syndrome, in its most severe form can resemble neuroleptic malignant syndrome, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs, and mental status changes. Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms. The concomitant use of Lexapro with MAOIs intended to treat depression is contraindicated. 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. The concomitant use of Lexapro with serotonin precursors (such as tryptophan) is not recommended. Treatment with Lexapro and any concomitant serotonergic or antidopaminergic agents, including antipsychotics, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated. **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*]. **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. **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. **Hyponatremia**-Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including Lexapro. In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH), and was reversible when Lexapro was discontinued. Cases with serum sodium lower than 110 mmol/L have been reported. Elderly patients may be at greater risk of developing hyponatremia with SSRIs and SNRIs. Also, patients taking diuretics or who are otherwise volume depleted may be at greater risk [*see Geriatric Use*]. Discontinuation of Lexapro should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted. Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which may lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. **Abnormal Bleeding**-SSRIs and SNRIs, including Lexapro, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants may add to the risk. Case reports and epidemiological studies (case-control and cohort design) have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding. Bleeding events related to SSRIs and SNRIs use have ranged from ecchymoses, hematomas, epistaxis, and petechiae to life-threatening hemorrhages. Patients should be cautioned about the risk of bleeding associated with the concomitant use of Lexapro and NSAIDs, aspirin, or other drugs that affect coagulation. **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*]. **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.

ADVERSE REACTIONS: Clinical Trials Experience-Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. **Clinical Trial Data Sources; Pediatrics (6 -17 years)**-Adverse events were collected in 576 pediatric patients (286 Lexapro, 290 placebo) with major depressive disorder in double-blind placebo-controlled studies. Safety and effectiveness of Lexapro in pediatric patients less than 12 years of age has not been established. **Adults**-Adverse events 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 reactions 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; Pediatrics (6 -17 years)**-Adverse events were associated with discontinuation of 3.5% of 286 patients receiving Lexapro and 1% of 290 patients receiving placebo. The most common adverse event (incidence at least 1% for Lexapro and greater than placebo) associated with discontinuation was insomnia (1% Lexapro, 0% placebo). **Adults**-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; Adults**-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 Reactions in Placebo-Controlled Clinical Trials; Major Depressive Disorder; Pediatrics (6 -17 years)**-The overall profile of adverse reactions in pediatric patients was generally similar to that seen in adult studies, as shown in Table 2. However, the following adverse reactions (excluding those which appear in Table 2 and those for which the coded terms were uninformative or misleading) were reported at an incidence of at least 2% for Lexapro and greater than placebo: back pain, urinary tract infection, vomiting, and nasal congestion. **Adults**-The most commonly observed adverse reactions 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. 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.

TABLE 2
Treatment-Emergent Adverse Reactions Observed with a Frequency of ≥ 2% and Greater Than Placebo for Major Depressive Disorder

Adverse Reaction	Lexapro (N=715)	Placebo (N=592)
Autonomic Nervous System Disorders		
Dry Mouth	6%	5%
Sweating Increased	5%	2%
Central & Peripheral Nervous System Disorders		
Dizziness	5%	3%
Gastrointestinal Disorders		
Nausea	15%	7%
Diarrhea	8%	5%
Constipation	3%	1%
Indigestion	3%	1%
Abdominal Pain	2%	1%
General		
Influenza-like Symptoms	5%	4%
Fatigue	5%	2%
Psychiatric Disorders		
Insomnia	9%	4%
Somnolence	6%	2%
Appetite Decreased	3%	1%
Libido Decreased	3%	1%
Respiratory System Disorders		
Rhinitis	5%	4%
Sinusitis	3%	2%
Urogenital		
Ejaculation Disorder[1,2]	9%	<1%
Impotence[2]	3%	<1%
Anorgasmia[3]	2%	<1%

[1]Primarily ejaculatory delay.
[2]Denominator used was for males only (N=225 Lexapro; N=188 placebo).
[3]Denominator used was for females only (N=490 Lexapro; N=404 placebo).

Generalized Anxiety Disorder; Adults-The most commonly observed adverse reactions in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia. Table 3 enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients.

TABLE 3
Treatment-Emergent Adverse Reactions Observed with a Frequency of ≥ 2% and Greater Than Placebo for Generalized Anxiety Disorder

Adverse Reactions	Lexapro (N=429)	Placebo (N=427)
Autonomic Nervous System Disorders		
Dry Mouth	9%	5%
Sweating Increased	4%	1%
Central & Peripheral Nervous System Disorders		
Headache	24%	17%
Paresthesia	2%	1%
Gastrointestinal Disorders		
Nausea	18%	8%
Diarrhea	8%	6%
Constipation	5%	4%
Indigestion	3%	2%
Vomiting	3%	1%
Abdominal Pain	2%	1%
Flatulence	2%	1%
Toothache	2%	0%
General		
Fatigue	8%	2%
Influenza-like Symptoms	5%	4%
Musculoskeletal System Disorder		
Neck/Shoulder Pain	3%	1%
Psychiatric Disorders		
Somnolence	13%	7%
Insomnia	12%	6%
Libido Decreased	7%	2%
Dreaming Abnormal	3%	2%
Appetite Decreased	3%	1%
Lethargy	3%	1%
Respiratory System Disorders		
Yawning	2%	1%
Urogenital		
Ejaculation Disorder[1,2]	14%	2%
Anorgasmia[3]	6%	<1%
Menstrual Disorder	2%	1%

[1]Primarily ejaculatory delay.
[2]Denominator used was for males only (N=182 Lexapro; N=195 placebo).
[3]Denominator used was for females only (N=247 Lexapro; N=232 placebo).

Dose Dependency of Adverse Reactions-The potential dose dependency of common adverse reactions (defined as an incidence rate of ≥5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). Table 4 shows common adverse reactions that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group.

TABLE 4
Incidence of Common Adverse Reactions in Patients with Major Depressive Disorder

Adverse Reaction	Placebo (N=311)	10 mg/day Lexapro (N=310)	20 mg/day Lexapro (N=125)
Insomnia	4%	7%	14%
Diarrhea	5%	6%	14%
Dry Mouth	3%	4%	9%
Somnolence	1%	4%	9%
Dizziness	2%	4%	7%
Sweating Increased	<1%	3%	8%
Constipation	1%	3%	6%
Fatigue	2%	2%	6%
Indigestion	1%	2%	6%

Male and Female Sexual Dysfunction with SSRIs-Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence.

TABLE 5
Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials

Adverse Event	Lexapro	Placebo
	In Males Only	
	(N=407)	(N=383)
Ejaculation Disorder (primarily ejaculatory delay)	12%	1%
Libido Decreased	6%	2%
Impotence	2%	<1%
	In Females Only	
	(N=737)	(N=636)
Libido Decreased	3%	1%
Anorgasmia	3%	<1%

There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Priapism has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes**-Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes**-Patients treated with Lexapro in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes**-Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes**-Electrocardiograms from Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to an increase of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Reactions Observed During the Premarketing Evaluation of Lexapro**-Following is a list of treatment-emergent adverse events, as defined in the introduction to the ADVERSE REACTIONS section, reported by the 1428 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. The listing does not include those events already listed in Tables 2 & 3, those events for which a drug cause was remote and at a rate less than 1% or lower than placebo, those events which were so general as to be uninformative, and those events reported only once which did not have a substantial probability of being acutely life threatening. Events are categorized by body system. Events of major clinical importance are described in the Warnings and Precautions section. Cardiovascular - hypertension, palpitation. Central and Peripheral Nervous System Disorders - light-headed feeling, migraine. Gastrointestinal Disorders - abdominal cramp, heartburn, gastroenteritis. General - allergy, chest pain, fever, hot flushes, pain in limb. Metabolic and Nutritional Disorders - increased weight. Musculoskeletal System Disorders - arthralgia, myalgia jaw stiffness. Psychiatric Disorders - appetite increased, concentration impaired, irritability. Reproductive Disorders/Female - menstrual cramps, menstrual disorder. Respiratory System Disorders - bronchitis, coughing, nasal congestion, sinus congestion, sinus headache. Skin and Appendages Disorders - rash. Special Senses - vision blurred, tinnitus. Urinary System Disorders - urinary frequency, urinary tract infection. **Post-Marketing Experience; Adverse Reactions Reported Subsequent to the Marketing of Escitalopram**-The following additional adverse reactions have been identified from spontaneous reports of escitalopram received worldwide. These adverse reactions have been chosen for inclusion because of a combination of seriousness, frequency of reporting, or potential causal connection to escitalopram and have not been listed elsewhere in labeling. However, because these adverse reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events include: Blood and Lymphatic System Disorders: anemia, agranulocytis, aplastic anemia, hemolytic anemia, idiopathic thrombocytopenia purpura, leukopenia, thrombocytopenia. Cardiac Disorders: atrial fibrillation, bradycardia, cardiac failure, myocardial infarction, tachycardia, torsade de pointes, ventricular arrhythmia, ventricular tachycardia. Ear and Labyrinth Disorders: vertigo Endocrine Disorders: diabetes mellitus, hyperprolactinemia, SIADH. Eye Disorders: diplopia, glaucoma, mydriasis, visual disturbance. Gastrointestinal Disorders: dysphagia, gastrointestinal hemorrhage, gastroesophageal reflux, pancreatitis, rectal hemorrhage. General Disorders and Administration Site Conditions: abnormal gait, asthenia, edema, fall, feeling abnormal, malaise. Hepatobiliary Disorders: fulminant hepatitis, hepatic failure, hepatic necrosis, hepatitis. Immune System Disorders: allergic reaction, anaphylaxis. Investigations: bilirubin increased, decreased weight, electrocardiogram QT prolongation, hepatic enzymes increased, hypercholesterolemia, INR increased, prothrombin decreased. Metabolism and Nutrition Disorders: hyperglycemia, hypoglycemia, hypokalemia, hyponatremia. Musculoskeletal and Connective Tissue Disorders: muscle cramp, muscle stiffness, muscle weakness, rhabdomyolysis. Nervous System Disorders: akathisia, amnesia, ataxia, choreoathetosis, cerebrovascular accident, dysarthria, dyskinesia, dystonia, extrapyramidal disorders, grand mal seizures (or convulsions), hypoaesthesia, myoclonus, nystagmus, Parkinsonism, restless legs, seizures, syncope, tardive dyskinesia, tremor. Pregnancy, Puerperium and Perinatal Conditions: spontaneous abortion. Psychiatric Disorders: acute psychosis, aggression, agitation, anger, anxiety, apathy, completed suicide, confusion, depersonalization, depression aggravated, delirium, delusion, disorientation, feeling unreal, hallucinations (visual and auditory), mood swings, nervousness, nightmare, panic reaction, paranoia, restlessness, self-harm or thoughts of self-harm, suicide attempt, suicidal ideation, suicidal tendency. Renal and Urinary Disorders: acute renal failure, dysuria, urinary retention. Reproductive System and Breast Disorders: menorrhagia, priapism. Respiratory, Thoracic and Mediastinal Disorders: dyspnea, epistaxis, pulmonary embolism, pulmonary hypertension of the newborn. Skin and Subcutaneous Tissue Disorders: alopecia, angioedema, dermatitis, ecchymosis, erythema multiforme, photosensitivity reaction, Stevens Johnson Syndrome, toxic epidermal necrolysis, urticaria. Vascular Disorders: deep vein thrombosis, flushing, hypertensive crisis, hypotension, orthostatic hypotension, phlebitis, thrombosis.

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 and Precautions*]. The concomitant use of Lexapro with other SSRIs, SNRIs or tryptophan is not recommended. **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 and Precautions*]. **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 and Precautions*]. **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 may potentiate the risk of bleeding. Altered anticoagulant effects, including increased bleeding, have been reported when SSRIs and SNRIs are coadministered with warfarin. Patients receiving warfarin therapy should be carefully monitored when Lexapro is initiated or discontinued. **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.

USE IN SPECIFIC POPULATIONS: 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 also 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 and Precautions*]. 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**-Escitalopram is excreted in human breast milk. Limited data from women taking 10-20 mg escitalopram showed that exclusively breast-fed infants receive approximately 3.9% of the maternal weight-adjusted dose of escitalopram and 1.7% of the maternal weight-adjusted dose of desmethylcitalopram. There were two reports of infants experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a racemic citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of racemic citalopram by its mother and, in the second case, no follow-up information was available. Caution should be exercised and breastfeeding infants should be observed for adverse reactions when Lexapro is administered to a nursing woman. **Pediatric Use**-Safety and effectiveness of Lexapro has not been established in pediatric patients (less than 12 years of age) with Major Depressive Disorder. Safety and effectiveness of Lexapro has been established in adolescents (12 to 17 years of age) for the treatment of major depressive disorder [*see Clinical Studies*]. Although maintenance efficacy in adolescent patients with Major Depressive Disorder has not been systematically evaluated, maintenance efficacy can be extrapolated from adult data along with comparisons of escitalopram pharmacokinetic parameters in adults and adolescent patients. Safety and effectiveness of Lexapro has not been established in pediatric patients less than 18 years of age with Generalized Anxiety Disorder. **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. SSRIs and SNRIs, including Lexapro, have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event [see *Hyponatremia*]. 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.

DRUG ABUSE AND DEPENDENCE: Abuse and Dependence; Physical and Psychological Dependence-Animal studies suggest that the abuse liability of racemic citalopram is low. Lexapro has not been systematically studied in humans for its potential for abuse, tolerance, or physical dependence. The premarketing clinical experience with Lexapro did not reveal any drug-seeking behavior. However, these observations were not systematic and 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. Consequently, physicians should carefully evaluate Lexapro patients for history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse (e.g., development of tolerance, incrementations of dose, drug-seeking behavior).

OVERDOSAGE: Human Experience-In clinical trials of escitalopram, there were reports of escitalopram overdose, including overdoses of up to 600 mg, with no associated fatalities. During the postmarketing evaluation of escitalopram, Lexapro overdoses involving overdoses of over 1000 mg have been reported. As with other SSRIs, a fatal outcome in a patient who has taken an overdose of escitalopram has been rarely reported. Symptoms most often accompanying escitalopram overdose, alone or in combination with other drugs and/or alcohol, included convulsions, coma, dizziness, hypotension, insomnia, nausea, vomiting, sinus tachycardia, somnolence, and ECG changes (including QT prolongation and very rare cases of torsade de pointes). Acute renal failure has been very rarely reported accompanying overdose. **Management of Overdose**-Establish and maintain an airway to ensure adequate ventilation and oxygenation. Gastric evacuation by lavage and use of activated charcoal should be considered. Careful observation and cardiac and vital sign monitoring are recommended, along with general symptomatic and supportive care. Due to the large volume of distribution of escitalopram, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. There are no specific antidotes for Lexapro. In managing overdosage, consider the possibility of multiple-drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of any overdose.

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

Tips on How to Contract With Private Insurers

The terms of your contracts with insurers or managed care organizations (MCOs) can affect many aspects of your practice, including how much you are paid, which services you are permitted to provide, and how you are expected to provide them. So before you sign any contract, it's vital that you take the time to read it thoroughly. You cannot rely on the word of colleagues who say they signed a contract with the same company, the terms were good, and their lawyer approved it.

Each contract is different, even from the same company. A contract with one physician may be written at a time and under circumstances that are different from another physician's. Also, don't assume that a renewal contract is the same as the one received "last year." Often it is not.

As insurers and psychiatrists have become more sophisticated about the managed care environment, contracts have become more sophisticated and complex as well. Companies may include important contract features in appendixes, addendums, or "attachments" such as provider manuals, which, if you're not careful, you may be unaware of until it's too late. You must be certain to obtain all documents referenced in a contract and to review them all before entering into a contract. If there is any provision in the contract that you do not understand, do not sign it until you get an explanation and are certain that you can comply with that provision.

In the 1990s, insurers and MCOs sometimes used risk-based contracts, which transferred the risk of expensive patient care to the physician through capitation or case rates, but over the years this practice has largely been abandoned.

Now most contracts stipulate the fees that will be paid to in-network physicians for specific procedure *(CPT)* codes and which physicians will be paid for which *CPT* codes. For instance, some insurers pay psychiatrists only for the psychiatry *CPT* codes (the 908xx series) even though it is just as appropriate for psychiatrists to use the evaluation and management (E/M) codes (the 992xx series) when they do patient evaluations and medical management. This kind of information is rarely found in the body of the contract, but should be available in either the appendixes or attachments. Be sure you find out how much you'll be paid and what *CPT* codes you're permitted to use before you sign the contract.

Contracts should also define the physician's status with the insurer in various settings. While some contracts may apply to only specific settings, others stipulate that an in-network psychiatrist is in-network at *every* place he or she provides services. This requirement has been problematic for some psychiatrists who practice in clinics that accept many forms of insurance but who have private practices where no insurance is accepted. If the clinic's contract with an insurer says it covers all its psychiatrists in all practice settings, then psychiatrists who see a patient in that plan in their private practice are considered in-network providers there as well and will be paid only the in-network fees negotiated under the clinic contract.

Even if the clinic's contract with the insurer does not stipulate that all places of service are covered, psychiatrists who want to be considered out of network in other settings must notify the insurer of this fact.

Because many insurance companies are having trouble maintaining an adequate number of psychiatrists in their networks to meet enrollees' needs, they may make it difficult for psychiatrists to sever their relationship. APA's Managed Care Help Line has received calls from members who were unable to get out of their contracts for many months because an insurer maintained it hadn't received faxes or e-mails that the doctors had sent to convey their change in status. We recommend that any notifications about a change in status with an insurer be done in writing and be sent by registered mail, return receipt requested. This way you will have a record of the company's having received your request.

Other Points to Remember

- Review the contract for any billing and balance-billing provisions that restrict your ability to bill patients.

- Review credentialing requirements. Personal information, such as medical history, may be unwarranted if it does not currently affect your ability to practice medicine.

- Study the confidentiality terms in the contract; federal and state laws supersede contractual requirements.

- Study utilization-review requirements to learn procedures for prior authorization, concurrent review, retrospective review, use of formulary restrictions, access to physician reviewers, and appeal mechanisms. These topics are frequently covered in the provider manual, which you should review before the execution of a contract.

- Be aware that contracts give insurers the right to conduct quality-assurance audits. This is standard and will not create any problems for you if you do appropriate documentation.

- Pay attention to how the insurer authorizes services in an emergency. Most companies have a utilization-management process in place that can authorize emergency services at any time, but the flexibility of the authorization process varies. Ask detailed questions about the process before signing a contract.

- Know when each of your current contracts expires and consider renegotiating if you feel you are not being adequately compensated. You have nothing to lose.

- Ask questions. Contract negotiation may be possible, especially since there is such a shortage of psychiatrists on insurance panels. Even if you cannot negotiate, be sure to ask questions on items about which you are unclear to ensure you are not entering into a contract that you can't live with.

- Make sure that all representations are in writing. You should obtain any changes or clarifications to the terms of the contract in the body of the contract itself. Any additional clarifications made by representatives of the insurance company that do not agree with the contract should be incorporated in an amendment that conforms to the contractual requirements.

Summing It Up

We can't emphasize it too much: Don't sign any contract until you're sure you thoroughly understand what you're agreeing to. Also, always check with your malpractice carrier to make sure nothing in the contract conflicts with your policy. And always check with your lawyer.

The AMA has created a detailed model managed care contract, with annotations that explain the reasons for including its various components. In an ideal world, this is the kind of contract you'd be presented with when you join an insurance network. The model contract is posted at <www.ama-assn.org/ama1/pub/upload/mm/368/mmcc_4th_ed.pdf>.

A more in-depth discussion of contracting, which includes definitions of the terms you may encounter in a contract, is posted at <www.psych.org/Departments/HSF/ManagingYourPractice/ManagedCareIssues/ReviewingandNegotiatingContracts.aspx>. If you have other questions about contracting, call APA's Managed Care Help Line at (800) 343-4671. ■

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.

Q&A From APA's Help Line Database: Billing Medicare Patients for Missed Sessions

Q I have a Medicare patient who consistently misses appointments without calling to cancel. I know I can't bill Medicare for the sessions, but am I permitted to charge this patient a missed-session fee?

A As long as the missed-session fee applies to all your patients and you can establish that the Medicare patient was aware of it, you may bill the patient directly for this fee. Medicare permits you to charge your standard missed-appointment fee since it is a physician fee that Medicare does not cover. If you have an office policy of billing for missed appointments, it would be smart to have your patients sign an acknowledgment of this policy and keep it with their medical record so there will be no question that billing for missed appointments is appropriate.

Changing Your Medicare Enrollment Status

APA's Managed Care Help Line receives frequent calls from psychiatrists who are unsure about what steps to take with Medicare when they change their practice situations. According to the Help Line's contacts at the Centers for Medicare and Medicaid Services, there's not much to it.

The most frequent situation that arises is that of a psychiatrist who works at a clinic or other facility where he or she sees Medicare patients and wants to start a private practice where Medicare patients will be seen as well. In this case, the psychiatrist needs to contact the enrollment office of the Medicare carrier or administrative contractor that serves the locale where the psychiatrist practices and update his or her information with the new practice address. If the new practice is incorporated, the psychiatrist must also supply its name and register for a Type 2 NPI for the new entity at the NPPES Web site at <https://nppes.cms.hhs.gov/NPPES/Welcome.do>. The provider's Type 1 NPI stays the same, but payments will be made to the corporation using the new NPI.

Some psychiatrists who see Medicare patients in a clinic or hospital setting do not want to deal with Medicare when they start a private practice. Since they will be continuing to see Medicare patients at the facility where they work, they cannot opt out of Medicare. Thus, if they see any Medicare patients in their private practice (even if it's unintentional), they must file claims with Medicare for them and correct their enrollment status with Medicare to get paid.

More information on opting out of Medicare is posted at <http://psych.org/MainMenu/PsychiatricPractice/ManagingYourPractice/QuickPracticeInfo/MedicareOptOut.aspx>. ■

NOW APPROVED FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER EITHER AS MONOTHERAPY OR AS ADJUNCTIVE THERAPY TO LITHIUM OR VALPROATE

As monotherapy or as adjunctive therapy when oral medications* may not be enough to help maintain stability†

WHY WAIT TO PRESCRIBE RISPERDAL® CONSTA®?

- RISPERDAL® CONSTA® significantly delayed time to relapse when used alone‡ or as adjunctive therapy§ to lithium or valproate‖[1]
- Proven efficacy with guaranteed medication coverage when administered every 2 weeks[1]
- Flexibility in administration sites, with deltoid and gluteal options to match your patient's preference¶[1]

***Lithium or valproate.**

†Patients judged to be stable for at least 4 weeks (in adjunctive therapy trial) or at least 8 weeks (in monotherapy trial) were randomized in the double-blind phase.

‡Up to 104 weeks in a multicenter, randomized, double-blind, placebo-controlled study in 303 patients with Bipolar I Disorder.

§52-week, multicenter, randomized, double-blind, placebo-controlled study in 124 patients with Bipolar I Disorder.

‖Adjunctive treatment consisted of mood stabilizers (primarily lithium and valproate), antidepressants, and/or anxiolytics. All other antipsychotics were discontinued after the first 3 weeks of the initial injection.

¶Deltoid administration is only appropriate for patients with adequate muscle mass.

Reference: 1. RISPERDAL® CONSTA® Prescribing Information. Ortho-McNeil-Janssen Pharmaceuticals, Inc, Titusville, NJ.

Risperdal CONSTA® risperidone Long-Acting Injection

RISPERDAL® CONSTA® (risperidone) long-acting injection is indicated for the maintenance treatment of Bipolar I Disorder, either as monotherapy or as adjunctive therapy to lithium or valproate.

IMPORTANT SAFETY INFORMATION FOR RISPERDAL® CONSTA®

WARNING: Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death 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. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of patients with dementia-related psychosis.

Cerebrovascular Adverse Events (CAEs): CAEs, including fatalities, have been reported in elderly patients with dementia-related psychosis taking oral risperidone in clinical trials. The incidence of CAEs with risperidone was significantly higher than with placebo. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported with the use of antipsychotic medications, including RISPERDAL® CONSTA®. 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, hyperosmolar coma or death has been reported in patients treated with atypical antipsychotics (APS), including RISPERDAL® CONSTA®. 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.

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, RISPERDAL® CONSTA® elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.

Orthostatic Hypotension: RISPERDAL® CONSTA® 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. RISPERDAL® CONSTA® should be used with caution in patients with known cardiovascular disease, and conditions that would predispose patients to hypotension.

Leukopenia, Neutropenia and Agranulocytosis have been reported with antipsychotics, including risperidone. Patients with a pre-existing low white blood cell count (WBC) or a history of leukopenia/neutropenia should have frequent complete blood cell counts during the first few months of therapy. At the first sign of a decline in WBC and in the absence of other causative factors, discontinuation of RISPERDAL® CONSTA® should be considered.

Potential for Cognitive and Motor Impairment: RISPERDAL® CONSTA® has the potential to impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that RISPERDAL® CONSTA® does not affect them adversely.

Seizures: RISPERDAL® CONSTA® should be used cautiously in patients with a history of seizures or with conditions that potentially lower seizure threshold.

Dysphagia: Esophageal dysmotility and aspiration can occur. Use cautiously in patients at risk for aspiration pneumonia.

Priapism has been reported. Severe priapism may require surgical intervention.

Thrombotic Thrombocytopenic Purpura (TTP) has been reported.

Administration: RISPERDAL® CONSTA® should be injected into the deltoid or gluteal muscle, and care must be taken to avoid inadvertent injection into a blood vessel.

Suicide: The possibility of suicide attempt is inherent in mental illness. Close supervision of high-risk patients should accompany drug therapy.

Increased sensitivity in patients with Parkinson's disease or those with dementia with Lewy bodies has been reported. Manifestations and features are consistent with NMS.

Use RISPERDAL® CONSTA® with caution in patients with conditions and medical conditions that could affect metabolism or hemodynamic responses (e.g. recent myocardial infarction or unstable cardiac disease).

Maintenance Treatment: Patients should be periodically reassessed to determine the need for continued treatment.

Commonly Observed Adverse Reactions for RISPERDAL® CONSTA®: The most common adverse reactions in clinical trials in patients with bipolar disorder were weight increased (5% in monotherapy trial) and tremor and Parkinsonism (≥10% in adjunctive therapy trial).

Please see accompanying brief summary of full Prescribing Information for RISPERDAL® CONSTA®.

Visit our Web site at www.risperdalconsta.com.

Janssen® Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

June 2009 01CS09086A

RISPERDAL® CONSTA®

(risperidone) LONG-ACTING INJECTION

Brief Summary

BEFORE PRESCRIBING RISPERDAL® CONSTA®, PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death 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. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of patients with dementia-related psychosis. *[See Warnings and Precautions]*

RISPERDAL® CONSTA® (risperidone) is indicated for the treatment of schizophrenia *[see Clinical Studies (14.1) in full PI]*.

RISPERDAL® CONSTA® is indicated as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder *[see Clinical Studies (14.2, 14.3) in full PI]*.

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

WARNINGS AND PRECAUTIONS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of dementia-related psychosis (see Boxed Warning).

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia-Related Psychosis: Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73-97) in trials of oral risperidone in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with oral risperidone compared to patients treated with placebo. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis *[See also Boxed Warning and Warnings and Precautions]* **Neuroleptic Malignant Syndrome (NMS):** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. 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. The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases in which the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology. 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. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS. 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:** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome 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 the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown. The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown. Given these considerations, RISPERDAL® CONSTA® should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. 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. In patients who do 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 of tardive dyskinesia appear in a patient treated with RISPERDAL® CONSTA®, drug discontinuation should be considered. However, some patients may require treatment with RISPERDAL® CONSTA® despite the presence of the syndrome. **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including RISPERDAL®. 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. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. 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. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug. **Hyperprolactinemia:** As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male subjects. 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. An increase in pituitary gland, mammary gland, and pancreatic islet cell neoplasia (mammary adenocarcinomas, pituitary and pancreatic adenomas) was observed in the risperidone carcinogenicity studies conducted in mice and rats *[see Nonclinical Toxicology]*. 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. **Orthostatic Hypotension:** RISPERDAL® CONSTA® may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose-titration period with oral risperidone, probably reflecting its alpha-adrenergic antagonistic properties. Syncope was reported in 0.8% (12/1499 patients) of patients treated with RISPERDAL® CONSTA® in multiple-dose studies. Patients should be instructed in nonpharmacologic interventions that help to reduce the occurrence of orthostatic hypotension (e.g., sitting on the edge of the bed for several minutes before attempting to stand in the morning and slowly rising from a seated position). RISPERDAL® CONSTA® should be used with particular caution in (1) patients with known cardiovascular disease (history of myocardial infarction or ischemia, heart failure, or conduction abnormalities), cerebrovascular disease, and conditions which would predispose patients to hypotension, e.g., dehydration and hypovolemia, and (2) in the elderly and patients with renal or hepatic impairment. Monitoring of orthostatic vital signs should be considered in all such patients, and a dose reduction should be considered if hypotension occurs. Clinically significant hypotension has been observed with concomitant use of oral RISPERDAL® and antihypertensive medication. **Leukopenia, Neutropenia, and Agranulocytosis:** *Class Effect:* In clinical trial and postmarketing experience, events of leukopenia/neutropenia have been reported temporally related to antipsychotic agents, including risperidone. Agranulocytosis (including fatal cases) has also been reported. Possible risk factors for leukopenia/neutropenia include preexisting low white blood cell count (WBC) and a history of drug induced leukopenia/neutropenia. Patients with a preexisting low WBC or a history of drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of RISPERDAL® CONSTA® should be considered at the first sign of a decline in WBC in the absence of other causative factors. Patients with neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000/mm^3) should discontinue RISPERDAL® CONSTA® and have their WBC followed until recovery. **Potential for Cognitive and Motor Impairment:** Somnolence was reported by 5% of patients treated with RISPERDAL® CONSTA® in multiple-dose trials. Since risperidone 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 treatment with RISPERDAL® CONSTA® does not affect them adversely. **Seizures:** During premarketing testing, seizures occurred in 0.3% (5/1499 patients) of patients treated with RISPERDAL® CONSTA®. Therefore, RISPERDAL® CONSTA® should be used cautiously in patients with a history of seizures. **Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's dementia. RISPERDAL® CONSTA® and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. *[See also Boxed Warning and Warnings and Precautions]* **Priapism:** Priapism has been reported during postmarketing surveillance *[see Adverse Reactions (6.9) in full PI]*. Severe priapism may require surgical intervention. **Thrombotic Thrombocytopenic Purpura (TTP):** A single case of TTP was reported in a 28 year-old female patient receiving oral RISPERDAL® in a large, open premarketing experience (approximately 1300 patients). She experienced jaundice, fever, and bruising, but eventually recovered after receiving plasmapheresis. The relationship to RISPERDAL® therapy is unknown. **Body Temperature Regulation:** Disruption of body temperature regulation has been attributed to antipsychotic agents. Both hyperthermia and hypothermia have been reported in association with oral RISPERDAL® or RISPERDAL® CONSTA® use. Caution is advised when prescribing RISPERDAL® CONSTA® for patients who will be exposed to temperature extremes. **Administration:** RISPERDAL® CONSTA® should be injected into the deltoid or gluteal muscle, and care must be taken to avoid inadvertent injection into a blood vessel. *[See Dosage and Administration (2) and Adverse Reactions (6.8) in full PI]* **Antiemetic Effect:** Risperidone has an antiemetic effect in animals; this effect may also occur in humans, and may mask signs and symptoms of overdosage with certain drugs or of conditions such as intestinal obstruction, Reye's syndrome, and brain tumor. **Suicide:** There is an increased risk of suicide attempt in patients with schizophrenia or bipolar disorder, and close supervision of high-risk patients should accompany drug therapy. RISPERDAL® CONSTA® is to be administered by a health care professional *[see Dosage and Administration (2) in full PI];* therefore, suicide due to an overdose is unlikely. **Use in Patients with Concomitant Illness:** Clinical experience with RISPERDAL® CONSTA® in patients with certain concomitant systemic illnesses is limited. Patients with Parkinson's Disease or Dementia with Lewy Bodies who receive antipsychotics, including RISPERDAL® CONSTA®, are reported to have an increased sensitivity to antipsychotic medications. Manifestations of this increased sensitivity have been reported to include confusion, obtundation, postural instability with frequent falls, extrapyramidal symptoms, and clinical features consistent with the neuroleptic malignant syndrome. Caution is advisable when using RISPERDAL® CONSTA® in patients with diseases or conditions that could affect metabolism or hemodynamic responses. RISPERDAL® CONSTA® 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 clinical studies during the product's premarket testing. Increased plasma concentrations of risperidone and 9-hydroxyrisperidone occur in patients with severe renal impairment (creatinine clearance <30 mL/min/1.73 m^2) treated with oral RISPERDAL®; an increase in the free fraction of risperidone is also seen in patients with severe hepatic impairment. Patients with renal or hepatic impairment should be carefully titrated on oral RISPERDAL® before treatment with RISPERDAL® CONSTA® is initiated at a dose of 25 mg. A lower initial dose of 12.5 mg may be appropriate when clinical factors warrant dose adjustment, such as in patients with renal or hepatic impairment *[see Dosage and Administration]*. **Osteodystrophy and Tumors in Animals:** RISPERDAL® CONSTA® produced osteodystrophy in male and female rats in a 1-year toxicity study and a 2-year carcinogenicity study at a dose of 40 mg/kg administered IM every 2 weeks. RISPERDAL® CONSTA® produced renal tubular tumors (adenoma, adenocarcinoma) and adrenomedullary pheochromocytomas in male rats in the 2-year carcinogenicity study at 40 mg/kg administered IM every 2 weeks. In addition, RISPERDAL® CONSTA® produced an increase in a marker of cellular proliferation in renal tissue in males in the 1-year toxicity study and in renal tumor-bearing males in the 2-year carcinogenicity study at 40 mg/kg administered IM every 2 weeks. (Cellular proliferation was not measured at the low dose or in females in either study.) The effect dose for osteodystrophy and the tumor findings is 8 times the IM maximum recommended human dose (MRHD) (50 mg) on a mg/m^2 basis and is associated with a plasma exposure (AUC) 2 times the expected plasma exposure (AUC) at the IM MRHD. The no-effect dose for these findings was 5 mg/kg (equal to the IM MRHD on a mg/m^2 basis). Plasma exposure (AUC) at the no-effect dose was one third the expected plasma exposure (AUC) at the IM MRHD. **Neither the renal or adrenal tumors, nor osteodystrophy, were seen in studies of orally administered risperidone.** Osteodystrophy was not observed in dogs at doses up to 14 times (based on AUC) the IM MRHD in a 1-year toxicity study. The renal tubular and adrenomedullary tumors in male rats and other tumor findings are described in more detail in Section 13.1 (Carcinogenicity, Mutagenesis, Impairment of Fertility). The relevance of these findings to human risk is unknown. **Monitoring: Laboratory Tests:** No specific laboratory tests are recommended.

ADVERSE REACTIONS: The following are discussed in more detail in other sections of the labeling: • Increased mortality in elderly patients with dementia-related psychosis • Cerebrovascular adverse events, including stroke, in elderly patients with dementia-related psychosis • euroleptic malignant syndrome • Tardive dyskinesia • Hyperglycemia and diabetes mellitus • Hyperprolactinemia • Orthostatic hypotension • Leukopenia/Neutropenia and Agranulocytosis • Potential for cognitive and motor impairment • Seizures • Dysphagia • Priapism • Thrombotic Thrombocytopenic Purpura (TTP) • Disruption of body temperature regulation • Avoidance of inadvertent injection into a blood vessel • Antiemetic effect • Suicide • Increased sensitivity in patients with Parkinson's disease or those with dementia with Lewy bodies • Diseases or conditions that could affect metabolism or hemodynamic responses • Osteodystrophy and tumors in animals The most common adverse reactions in clinical trials in patients with schizophrenia (≥ 5%) were headache, parkinsonism, dizziness, akathisia, fatigue, constipation, dyspepsia, sedation, weight increased, pain in extremity, and dry mouth. The most common adverse reactions in the double-blind, placebo-controlled periods of the bipolar disorder trials were weight increased (5% in the monotherapy trial) and tremor and parkinsonism (≥ 10% in the adjunctive treatment trial). The most common adverse reactions that were associated with discontinuation from the 12-week double-blind, placebo-controlled trial in patients with schizophrenia (causing discontinuation in ≥1% of patients) were agitation, depression, anxiety, and akathisia. Adverse reactions that were associated with discontinuation from the double-blind, placebo-controlled periods of the bipolar disorder trials were hyperglycemia (one patient in the monotherapy trial) and hypokinesia and tardive dyskinesia (one patient each in the adjunctive treatment trial). The data described in this section are derived from a clinical trial database consisting of 2392 patients exposed to one or more doses of RISPERDAL® CONSTA® for the treatment of schizophrenia. Of these 2392 patients, 332 were patients who received RISPERDAL® CONSTA® while participating in a 12-week double-blind, placebo-controlled trial. Two hundred two (202) of the 332 were schizophrenia patients who received 25 mg or 50 mg RISPERDAL® CONSTA®. The conditions and duration of treatment with RISPERDAL® CONSTA® in the other clinical trials varied greatly and included (in overlapping categories) double-blind, fixed- and flexible-dose, placebo- or active-controlled studies and open-label phases of studies, inpatients and outpatients, and short-term (up to 12 weeks) and longer-term (up to 4 years) exposures. Safety was assessed by collecting adverse events and performing physical examinations, vital signs, body weights, laboratory analyses, and ECGs. In addition to the studies in patients with schizophrenia, safety data are presented from a trial assessing the efficacy and safety of RISPERDAL® CONSTA® when administered as monotherapy for maintenance treatment in patients with bipolar I disorder. The subjects in this multi-center, double-blind, placebo-controlled study were adult patients who met DSM-IV criteria for Bipolar Disorder Type I and who were stable on risperidone (oral or long-acting injection), were stable on other antipsychotics or mood stabilizers, or were experiencing an acute episode. After a 3-week period of treatment with open-label oral risperidone (n=440), subjects who demonstrated an initial response to oral risperidone in this period and those who were stable on risperidone (oral or long-acting injection) at study entry entered into a 26-week stabilization period of open-label RISPERDAL® CONSTA® (n=501). Subjects who demonstrated a maintained response during this period were then randomized into a 24-month double-blind, placebo-controlled period in which they received RISPERDAL® CONSTA® (n=154) or placebo (n=149) as monotherapy. Subjects who relapsed or who completed the double-blind period could

choose to enter an 8-week open-label RISPERDAL®CONSTA® extension period (n=160). Safety data are also presented from a trial assessing the efficacy and safety of RISPERDAL® CONSTA® when administered as adjunctive maintenance treatment in patients with bipolar disorder. The subjects in this multi-center, double-blind, placebo-controlled study were adult patients who met DSM-IV criteria for Bipolar Disorder Type I or Type II and who experienced at least 4 episodes of mood disorder requiring psychiatric/clinical intervention in the previous 12 months, including at least 2 episodes in the 6 months prior to the start of the study. At the start of this study, all patients (n = 275) entered into a 16-week open-label treatment phase in which they received RISPERDAL® CONSTA® in addition to continuing their treatment as usual, which consisted of various mood stabilizers (primarily lithium and valproate), antidepressants, and/or anxiolytics. Patients who reached remission at the end of this 16-week open-label treatment phase (n = 139) were then randomized into a 52-week double-blind, placebo-controlled phase in which they received RISPERDAL® CONSTA® (n = 72) or placebo (n = 67) as adjunctive treatment in addition to continuing their treatment as usual. Patients who did not reach remission at the end of the 16-week open-label treatment phase could choose to continue to receive RISPERDAL®CONSTA® as adjunctive therapy in an open-label manner, in addition to continuing their treatment as usual, for up to an additional 36 weeks as clinically indicated for a total period of up to 52 weeks; these patients (n = 70) were also included in the evaluation of safety. Adverse events during exposure to study treatment 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. Throughout this section, adverse reactions are reported. Adverse reactions are adverse events that were considered to be reasonably associated with the use of RISPERDAL® CONSTA® (adverse drug reactions) based on the comprehensive assessment of the available adverse event information. A causal association for RISPERDAL® CONSTA® often cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The majority of all adverse reactions were mild to moderate in severity. **Commonly-Observed Adverse Reactions in Double-Blind, Placebo-Controlled Clinical Trials - Schizophrenia:** Table 1 lists the adverse reactions reported in 2% or more of RISPERDAL® CONSTA®-treated patients with schizophrenia in one 12-week double-blind, placebo-controlled trial. **Table 1.** Adverse Reactions in ≥ 2% of RISPERDAL® CONSTA®-Treated Patients with Schizophrenia in a 12-Week Double-Blind, Placebo-Controlled Trial, **System/Organ Class, Percentage of Patients Reporting Event RISPERDAL® CONSTA® 25 mg (N=99)** first, **50 mg (N=103)** second, **Placebo (N=98)** third, Adverse Reaction, **Eye disorders**: Vision blurred 2, 3, 0; **Gastrointestinal disorders:** Constipation 5, 7, 1; Dry mouth 0, 7, 1; Dyspepsia 6, 6, 0; Nausea 3, 4, 5; Toothache 1, 3, 0; Salivary hypersecretion 4, 1, 0; **General disorders and administration site conditions:** Fatigue* 3, 9, 0; Edema peripheral 2, 3, 1; Pain 4, 1, 0; Pyrexia 2, 1, 0; **Infections and infestations:** Upper respiratory tract infection 2, 0, 1; **Investigations**: Weight increased 5, 4, 2; Weight decreased 4, 1, 1; **Musculoskeletal and connective tissue disorders:** Pain in extremity 6, 2, 1; **Nervous system disorders:** Headache 15, 21, 12; Parkinsonism* 8, 15, 9; Dizziness 7, 11, 6; Akathisia* 4, 11, 6; Sedation* 5, 6, 3; Tremor 0, 3, 0; Syncope 2, 1, 0; Hypoesthesia 2, 0, 0; **Respiratory, thoracic and mediastinal disorders:** Cough 4, 2, 3; Sinus congestion 2, 0, 0; **Skin and subcutaneous tissue disorders:** Acne 2, 2, 0; Dry skin 2, 0, 0. * Fatigue includes fatigue and asthenia. Parkinsonism includes extrapyramidal disorder, musculoskeletal stiffness, muscle rigidity, and bradykinesia. Akathisia includes akathisia and restlessness. Sedation includes sedation and somnolence. **Commonly-Observed Adverse Reactions in Double-Blind, Placebo-Controlled Clinical Trials – Bipolar Disorder:** Table 2 lists the treatment-emergent adverse reactions reported in 2% or more of RISPERDAL® CONSTA®-treated patients in the 24-month double-blind, placebo-controlled treatment period of the trial assessing the efficacy and safety of RISPERDAL® CONSTA® when administered as monotherapy for maintenance treatment in patients with Bipolar I Disorder. **Table 2.** Adverse Reactions in ≥2% of Patients with Bipolar I Disorder Treated with RISPERDAL® CONSTA® as Monotherapy in a 24-Month Double-Blind, Placebo-Controlled Trial, **System/Organ Class, Percentage of Patients Reporting Event, RISPERDAL® CONSTA® (N=154)** first, **Placebo (N=149)** second, Adverse Reaction, **Investigations:** Weight increased 5, 1; **Nervous system disorders:** Dizziness 3, 1; **Vascular disorders:** Hypertension 3, 1. Table 3 lists the treatment-emergent adverse reactions reported in 4% or more of patients in the 52-week double-blind, placebo-controlled treatment phase of a trial assessing the efficacy and safety of RISPERDAL® CONSTA® when administered as adjunctive maintenance treatment in patients with bipolar disorder. **Table 3.** Adverse Reactions in ≥ 4% of Patients with Bipolar Disorder Treated with RISPERDAL® CONSTA® as Adjunctive Therapy in a 52-Week Double-Blind, Placebo-Controlled Trial, **System/Organ Class, Percentage of Patients Reporting Event, RISPERDAL® CONSTA® + Treatment as Usual[a] (N=72)** first, **Placebo + Treatment as Usual[a] (N=67)** second, Adverse Reaction, **General disorders and administration site conditions:** Gait abnormal 4, 0; **Infections and infestations:** Upper respiratory tract infection 6, 3; **Investigations:** Weight increased 7, 1; **Metabolism and nutrition disorders:** Decreased appetite 6, 1; Increased appetite 4, 0; **Musculoskeletal and connective tissue disorders:** Arthralgia 4, 3; **Nervous system disorders:** Tremor 24, 16; Parkinsonism[b] 15, 6; Dyskinesia[b] 6, 3; Sedation[c] 7, 1; Disturbance in attention 4, 0; **Reproductive system and breast disorders:** Amenorrhea 4, 1; **Respiratory, thoracic and mediastinal disorders:** Cough 4, 1. [a] Patients received double-blind RISPERDAL® CONSTA® or placebo in addition to continuing their treatment as usual, which included mood stabilizers, antidepressants, and/or anxiolytics. [b] Parkinsonism includes muscle rigidity, hypokinesia, cogwheel rigidity, and bradykinesia. Dyskinesia includes muscle twitching and dyskinesia. [c] Sedation includes sedation and somnolence. **Other Adverse Reactions Observed During the Premarketing Evaluation of RISPERDAL® CONSTA®:** The following additional adverse reactions occurred in < 2% of the RISPERDAL® CONSTA®-treated patients in the above schizophrenia double-blind, placebo-controlled trial dataset, in < 2% of the RISPERDAL® CONSTA®-treated patients in the above double-blind, placebo-controlled period of the monotherapy bipolar disorder trial dataset, or in < 4% of the RISPERDAL® CONSTA®-treated patients in the above double-blind, placebo-controlled period of the adjunctive treatment bipolar disorder trial dataset. The following also includes additional adverse reactions reported at any frequency in RISPERDAL® CONSTA®-treated patients who participated in other studies, including double-blind, active-controlled and open-label studies in schizophrenia, and in the open-label phases of the bipolar disorder studies. **Blood and lymphatic system disorders:** anemia, neutropenia **Cardiac disorders:** tachycardia, atrioventricular block first degree, palpitations, sinus bradycardia, bundle branch block left, bradycardia, sinus tachycardia, bundle branch block right **Ear and labyrinth disorders:** ear pain, vertigo **Endocrine disorders:** hyperprolactinemia **Eye disorders:** conjunctivitis, visual acuity reduced **Gastrointestinal disorders:** diarrhea, vomiting, abdominal pain, stomach discomfort, gastritis **General disorders and administration site conditions:** injection site pain, chest discomfort, chest pain, influenza like illness, sluggishness, malaise, induration, injection site induration, injection site swelling, injection site reaction, face edema **Immune system disorders:** hypersensitivity **Infections and infestations:** nasopharyngitis, influenza, bronchitis, urinary tract infection, rhinitis, ear infection, pneumonia, lower respiratory tract infection, pharyngitis, sinusitis, viral infection, infection, localized infection, cystitis, gastroenteritis, subcutaneous abscess **Injury and poisoning:** fall, procedural pain **Investigations:** blood prolactin increased, alanine aminotransferase increased, electrocardiogram abnormal, gamma-glutamyl transferase increased, blood glucose increased, hepatic enzyme increased, aspartate aminotransferase increased, electrocardiogram QT prolonged **Metabolism and nutritional disorders:** anorexia, hyperglycemia **Musculoskeletal, connective tissue and bone disorders:** posture abnormal, myalgia, back pain, buttock pain, muscular weakness, neck pain, musculoskeletal chest pain **Nervous system disorders:** coordination abnormal, dystonia, tardive dyskinesia, drooling, paresthesia, dizziness postural, convulsion, akinesia, hypokinesia, dysarthria **Psychiatric disorders:** insomnia, agitation, anxiety, sleep disorder, depression, libido decreased, nervousness **Renal and urinary disorders:** urinary incontinence **Reproductive system and breast disorders:** oligomenorrhea, erectile dysfunction, galactorrhea, sexual dysfunction, ejaculation disorder, gynecomastia, breast discomfort, menstruation irregular, menstruation delayed, menstrual disorder **Respiratory, thoracic and mediastinal disorders:** nasal congestion, pharyngolaryngeal pain, dyspnea, rhinorrhea **Skin and subcutaneous tissue disorders:** rash, eczema, pruritus **Vascular disorders:** hypotension, orthostatic hypotension **Discontinuations Due to Adverse Reactions:** Schizophrenia Approximately 11% (22/202) of RISPERDAL® CONSTA®-treated patients in the 12-week double-blind, placebo-controlled schizophrenia trial discontinued treatment due to an adverse event, compared with 13% (13/98) who received placebo. The adverse reactions associated with discontinuation in two or more RISPERDAL® CONSTA®-treated patients were: agitation (3%), depression (2%), anxiety (1%), and akathisia (1%). Bipolar Disorder In the 24-month double-blind, placebo-controlled treatment period of the trial assessing the efficacy and safety of RISPERDAL® CONSTA® when administered as monotherapy for maintenance treatment in patients with bipolar I disorder, 1 (0.6%) of 154 RISPERDAL® CONSTA®-treated patients discontinued due to an adverse reaction (hyperglycemia). In the 52-week double-blind phase of the placebo-controlled trial in which RISPERDAL® CONSTA® was administered as adjunctive therapy to patients with bipolar disorder in addition to continuing with their treatment as usual, approximately 4% (3/72) of RISPERDAL® CONSTA®-treated patients discontinued treatment due to an adverse event, compared with 1.5% (1/67) of placebo-treated patients. Adverse reactions associated with discontinuation in RISPERDAL® CONSTA®-treated patients were: hypokinesia (one patient) and tardive dyskinesia (one patient). **Dose Dependency of Adverse Reactions in Clinical Trials:** Extrapyramidal Symptoms: Two methods were used to measure extrapyramidal symptoms (EPS) in the 12-week double-blind, placebo-controlled trial comparing three doses of RISPERDAL® CONSTA® (25 mg, 50 mg, and 75 mg) with placebo in patients with schizophrenia, including: (1) the incidence of spontaneous reports of EPS symptoms; and (2) the change from baseline to endpoint on the total score (sum of the subscale scores for parkinsonism, dystonia, and dyskinesia) of the Extrapyramidal Symptom Rating Scale (ESRS). As shown in Table 1, the overall incidence of EPS-related adverse reactions (akathisia, dystonia, parkinsonism, and tremor) in patients treated with 25 mg RISPERDAL® CONSTA® was comparable to that of patients treated with placebo; the incidence of EPS-related adverse reactions was higher in patients treated with 50 mg RISPERDAL® CONSTA®. The median change from baseline to endpoint in total ESRS score showed no worsening in patients treated with RISPERDAL® CONSTA® compared with patients treated with placebo: 0 (placebo group); -1 (25-mg group, significantly less than the placebo group); and 0 (50-mg group). Dystonia *Class Effect:* Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups. **Changes in Body Weight:** In the 12-week double-blind, placebo-controlled trial in patients with schizophrenia, 9% of patients treated with RISPERDAL® CONSTA®, compared with 6% of patients treated with placebo, experienced a weight gain of >7% of body weight at endpoint. In the 24-month double-blind, placebo-controlled treatment period of a trial assessing the efficacy and safety of RISPERDAL® CONSTA® when administered as monotherapy for maintenance treatment in patients with bipolar I disorder, 11.6% of patients treated with RISPERDAL® CONSTA® compared with 2.8% of patients treated with placebo experienced a weight gain of >7% of body weight at endpoint. In the 52-week double-blind, placebo-controlled trial in patients with bipolar disorder, 26.8% of patients treated with RISPERDAL® CONSTA® as adjunctive treatment in addition to continuing their treatment as usual, compared with 27.3% of patients treated with placebo in addition to continuing their treatment as usual, experienced a weight gain of >7% of body weight at endpoint. **Changes in ECG:** The electrocardiograms of 202 schizophrenic patients treated with 25 mg or 50 mg RISPERDAL® CONSTA® and 98 schizophrenic patients treated with placebo in the 12-week double-blind, placebo-controlled trial were evaluated. Compared with placebo, there were no statistically significant differences in QTc intervals (using Fridericia's and linear correction factors) during treatment with RISPERDAL® CONSTA®. The electrocardiograms of 227 patients with Bipolar I Disorder were evaluated in the 24-month double-blind, placebo-controlled period. There were no clinically relevant differences in QTc intervals (using Fridericia's and linear correction factors) during treatment with RISPERDAL® CONSTA® compared to placebo. The electrocardiograms of 85 patients with bipolar disorder were evaluated in the 52-week double-blind, placebo-controlled trial. There were no statistically significant differences in QTc intervals (using Fridericia's and linear correction factors) during treatment with RISPERDAL® CONSTA® 25 mg, 37.5 mg, or 50 mg when administered as adjunctive treatment in addition to continuing treatment as usual compared to placebo. **Pain Assessment and Local Injection Site Reactions:** The mean intensity of injection pain reported by patients with schizophrenia using a visual analog scale (0 = no pain to 100 = unbearably painful) decreased in all treatment groups from the first to the last injection (placebo: 16.7 to 12.6; 25 mg: 12.0 to 9.0; 50 mg: 18.2 to 11.8). After the sixth injection (Week 10), investigator ratings indicated that 1% of patients treated with 25 mg or 50 mg RISPERDAL® CONSTA® experienced redness, swelling, or induration at the injection site. In a separate study to observe local-site tolerability in which RISPERDAL® CONSTA® was administered into the deltoid muscle every 2 weeks over a period of 8 weeks, no patient discontinued treatment due to local injection site pain or reaction. Clinician ratings indicated that only mild redness, swelling, or induration at the injection site was observed in subjects treated with 37.5 mg or 50 mg RISPERDAL® CONSTA® at 2 hours after deltoid injection. All ratings returned to baseline at the predose assessment of the next injection 2 weeks later. No moderate or severe reactions were observed in any subject. **Postmarketing Experience:** The following adverse reactions have been identified during postapproval use of risperidone; because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency: agranulocytosis, alopecia, anaphylactic reaction, angioedema, atrial fibrillation, diabetic ketoacidosis in patients with impaired glucose metabolism, inappropriate antidiuretic hormone secretion, hypothermia, intestinal obstruction, jaundice, mania, pancreatitis, priapism, QT prolongation, sleep apnea syndrome, thrombocytopenia, and water intoxication. In addition, the following adverse reactions have been observed during postapproval use of RISPERDAL® CONSTA®: cerebrovascular disorders, including cerebrovascular accidents, and diabetes mellitus aggravated. Retinal artery occlusion after injection of RISPERDAL® CONSTA® has been reported during postmarketing surveillance. This has been reported in the presence of abnormal arteriovenous anastomosis. Serious injection site reactions including abscess, cellulitis, cyst, hematoma, necrosis, nodule, and ulcer have been reported with RISPERDAL® CONSTA® during postmarketing surveillance. Isolated cases required surgical intervention.

DRUG INTERACTIONS: The interactions of RISPERDAL® CONSTA® with coadministration of other drugs have not been systematically evaluated. The drug interaction data provided in this section is based on studies with oral RISPERDAL®. **Centrally-Acting Drugs and Alcohol:** Given the primary CNS effects of risperidone, caution should be used when RISPERDAL® CONSTA® is administered in combination with other centrally-acting drugs or alcohol. **Drugs with Hypotensive Effects:** Because of its potential for inducing hypotension, RISPERDAL® CONSTA® may enhance the hypotensive effects of other therapeutic agents with this potential. **Levodopa and Dopamine Agonists:** RISPERDAL® CONSTA® may antagonize the effects of levodopa and dopamine agonists. **Amitriptyline:** Amitriptyline did not affect the pharmacokinetics of risperidone or of risperidone and 9-hydroxyrisperidone combined following concomitant administration with oral RISPERDAL®. **Cimetidine and Ranitidine:** Cimetidine and ranitidine increased the bioavailability of oral risperidone by 64% and 26%, respectively. However, cimetidine did not affect the AUC of risperidone and 9-hydroxyrisperidone combined, whereas ranitidine increased the AUC of risperidone and 9-hydroxyrisperidone combined by 20%. **Clozapine:** Chronic administration of clozapine with risperidone may decrease the clearance of risperidone. **Lithium:** Repeated doses of oral RISPERDAL® (3 mg twice daily) did not affect the exposure (AUC) or peak plasma concentrations (C_{max}) of lithium (n=13). **Valproate:** Repeated doses of oral RISPERDAL® (4 mg once daily) did not affect the pre-dose or average plasma concentrations and exposure (AUC) of valproate (1000 mg/day in three divided doses) compared to placebo (n=21). However, there was a 20% increase in valproate peak plasma concentration (C_{max}) after concomitant administration of oral RISPERDAL®. **Digoxin:** Oral RISPERDAL® (0.25 mg twice daily) did not show a clinically relevant effect on the pharmacokinetics of digoxin. **Topiramate:** Oral RISPERDAL® administered at doses from 1-6 mg/day concomitantly with topiramate 400 mg/day resulted in a 23% decrease in risperidone Cmax and a 33% decrease in risperidone $AUC_{0\text{-}12\ hour}$ at steady state. Minimal reductions in the exposure to risperidone and 9-hydroxyrisperidone combined, and no change for 9-hydroxyrisperidone were observed. This interaction is unlikely to be of clinical significance. There was no clinically relevant effect of oral RISPERDAL® on the pharmacokinetics of topiramate. **Drugs That Inhibit CYP 2D6 and Other CYP Isozymes:** Risperidone is metabolized to 9-hydroxyrisperidone by CYP 2D6, an enzyme that is polymorphic in the population and that can be inhibited by a variety of psychotropic and other drugs *[see Clinical Pharmacology (12.3) in full PI].* Drug interactions that reduce the metabolism of risperidone to 9-hydroxyrisperidone would increase the plasma concentrations of risperidone and lower the concentrations of 9-hydroxyrisperidone. Analysis of clinical studies involving a modest number of poor metabolizers (n≅70 patients) does not suggest that poor and extensive metabolizers have different rates of adverse effects. No comparison of effectiveness in the two groups has been made. *In vitro* studies showed that drugs metabolized by other CYP isozymes, including 1A1, 1A2, 2C9, 2C19, and 3A4, are only weak inhibitors of risperidone metabolism. Fluoxetine and Paroxetine: Fluoxetine (20 mg once daily) and paroxetine (20 mg once daily), CYP 2D6 inhibitors, have been shown to increase the plasma concentration of risperidone 2.5-2.8 fold and 3-9 fold respectively. Fluoxetine did not affect the plasma concentration of 9-hydroxyrisperidone. Paroxetine lowered the concentration of 9-hydroxyrisperidone by about 10%. When either concomitant fluoxetine or paroxetine is initiated or discontinued, the physician should re-evaluate the dose of RISPERDAL® CONSTA®. When initiation of fluoxetine or paroxetine is considered, patients may be placed on a lower dose of RISPERDAL® CONSTA® between 2 to 4 weeks before the planned start of fluoxetine or paroxetine therapy to adjust for the expected increase in plasma concentrations of risperidone. When fluoxetine or paroxetine is initiated in patients receiving the recommended dose of 25 mg RISPERDAL® CONSTA®, it is recommended to continue treatment with the 25-mg dose unless clinical judgment necessitates lowering the RISPERDAL® CONSTA® dose to 12.5 mg or necessitates interruption of RISPERDAL® CONSTA® treatment. When RISPERDAL® CONSTA® is initiated in patients already receiving fluoxetine or paroxetine, a starting dose of 12.5 mg can be considered. The efficacy of the 12.5 mg dose has not been investigated in clinical trials. *[See also DOSAGE AND ADMINISTRATION (2.5) in full PI].* The effects of discontinuation of concomitant fluoxetine or paroxetine therapy on the pharmacokinetics of risperidone and 9-hydroxyrisperidone have not been studied. Erythromycin: There were no significant interactions between oral RISPERDAL® and erythromycin. **Carbamazepine and Other CYP 3A4 Enzyme Inducers:** Carbamazepine co-administration with oral RISPERDAL® decreased the steady-state plasma concentrations of risperidone and 9-hydroxyrisperidone by about 50%. Plasma concentrations of carbamazepine did not appear to be affected. Co-administration of other known CYP 3A4 enzyme inducers (e.g., phenytoin, rifampin, and phenobarbital) with risperidone may cause similar decreases in the

combined plasma concentrations of risperidone and 9-hydroxyrisperidone, which could lead to decreased efficacy of RISPERDAL® CONSTA® treatment. At the initiation of therapy with carbamazepine or other known hepatic enzyme inducers, patients should be closely monitored during the first 4–8 weeks, since the dose of RISPERDAL® CONSTA® may need to be adjusted. A dose increase, or additional oral RISPERDAL®, may need to be considered. On discontinuation of carbamazepine or other CYP 3A4 hepatic enzyme inducers, the dosage of RISPERDAL® CONSTA® should be re-evaluated and, if necessary, decreased. Patients may be placed on a lower dose of RISPERDAL® CONSTA® between 2 to 4 weeks before the planned discontinuation of carbamazepine or other CYP 3A4 enzyme inducers to adjust for the expected increase in plasma concentrations of risperidone plus 9-hydroxyrisperidone. For patients treated with the recommended dose of 25 mg RISPERDAL® CONSTA® and discontinuing from carbamazepine or other CYP 3A4 enzyme inducers, it is recommended to continue treatment with the 25-mg dose unless clinical judgment necessitates lowering the RISPERDAL® CONSTA® dose to 12.5 mg or necessitates interruption of RISPERDAL® CONSTA® treatment. The efficacy of the 12.5 mg dose has not been investigated in clinical trials. *[See also DOSAGE AND ADMINSTRATION (2.5) in full PI]* **Drugs Metabolized by CYP 2D6:** *In vitro* studies indicate that risperidone is a relatively weak inhibitor of CYP 2D6. Therefore, RISPERDAL® CONSTA® is not expected to substantially inhibit the clearance of drugs that are metabolized by this enzymatic pathway. In drug interaction studies, oral RISPERDAL® did not significantly affect the pharmacokinetics of donepezil and galantamine, which are metabolized by CYP 2D6.

USE IN SPECIFIC POPULATIONS: Pregnancy: Pregnancy Category C.: The teratogenic potential of oral risperidone was studied in three embryofetal development studies in Sprague-Dawley and Wistar rats (0.63-10 mg/kg or 0.4 to 6 times the oral maximum recommended human dose [MRHD] on a mg/m² basis) and in one embryofetal development study in New Zealand rabbits (0.31-5 mg/kg or 0.4 to 6 times the oral MRHD on a mg/m² basis). The incidence of malformations was not increased compared to control in offspring of rats or rabbits given 0.4 to 6 times the oral MRHD on a mg/m² basis. In three reproductive studies in rats (two peri/post-natal development studies and a multigenerational study), there was an increase in pup deaths during the first 4 days of lactation at doses of 0.16-5 mg/kg or 0.1 to 3 times the oral MRHD on a mg/m² basis. It is not known whether these deaths were due to a direct effect on the fetuses or pups or to effects on the dams.

There was no no-effect dose for increased rat pup mortality. In one peri/post-natal development study, there was an increase in stillborn rat pups at a dose of 2.5 mg/kg or 1.5 times the oral MRHD on a mg/m² basis. In a cross-fostering study in Wistar rats, toxic effects on the fetus or pups, as evidenced by a decrease in the number of live pups and an increase in the number of dead pups at birth (Day 0), and a decrease in birth weight in pups of drug-treated dams were observed. In addition, there was an increase in deaths by Day 1 among pups of drug-treated dams, regardless of whether or not the pups were cross-fostered. Risperidone also appeared to impair maternal behavior in that pup body weight gain and survival (from Days 1 to 4 of lactation) were reduced in pups born to control but reared by drug-treated dams. These effects were all noted at the one dose of risperidone tested, i.e., 5 mg/kg or 3 times the oral MRHD on a mg/m² basis. No studies were conducted with RISPERDAL® CONSTA®. Placental transfer of risperidone occurs in rat pups. There are no adequate and well-controlled studies in pregnant women. However, there was one report of a case of agenesis of the corpus callosum in an infant exposed to risperidone *in utero*. The causal relationship to oral RISPERDAL® therapy is unknown. Reversible extrapyramidal symptoms in the neonate were observed following postmarketing use of risperidone during the last trimester of pregnancy. RISPERDAL® CONSTA® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Labor and Delivery:** The effect of RISPERDAL® CONSTA® on labor and delivery in humans is unknown. **Nursing Mothers:** Risperidone and 9-hydroxyrisperidone are also excreted in human breast milk. Therefore, women should not breast-feed during treatment with RISPERDAL® CONSTA® and for at least 12 weeks after the last injection. **Pediatric Use:** RISPERDAL® CONSTA® has not been studied in children younger than 18 years old. **Geriatric Use:** In an open-label study, 57 clinically stable, elderly patients ≥ 65 years old) with schizophrenia or schizoaffective disorder received RISPERDAL® CONSTA® every 2 weeks for up to 12 months. In general, no differences in the tolerability of RISPERDAL® CONSTA® were observed between otherwise healthy elderly and nonelderly patients. Therefore, dosing recommendations for otherwise healthy elderly patients are the same as for nonelderly patients. Because elderly patients exhibit a greater tendency to orthostatic hypotension than nonelderly patients, elderly patients should be instructed in nonpharmacologic interventions that help to reduce the occurrence of orthostatic hypotension (e.g., sitting on the edge of the bed for several minutes before attempting to stand in the morning and slowly rising from a seated position). In addition, monitoring of orthostatic vital signs should be considered in elderly patients for whom orthostatic hypotension is of concern *[see Warnings and Precautions (5.7) in full PI]*. Concomitant use with Furosemide in Elderly Patients with Dementia-Related Psychosis In two of four placebo-controlled trials in elderly patients with dementia-related psychosis, a higher incidence of mortality was observed in patients treated with furosemide plus oral risperidone when compared to patients treated with oral risperidone alone or with oral placebo plus furosemide. No pathological mechanism has been identified to explain this finding, and no consistent pattern for cause of death was observed. An increase of mortality in elderly patients with dementia-related psychosis was seen with the use of oral risperidone regardless of concomitant use with furosemide. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis. *[See Boxed Warning and Warnings and Precautions]*

PATIENT COUNSELING INFORMATION: Physicians are advised to discuss the following issues with patients for whom they prescribe RISPERDAL® CONSTA®. **Orthostatic Hypotension:** Patients should be advised of the risk of orthostatic hypotension and instructed in nonpharmacologic interventions that help to reduce the occurrence of orthostatic hypotension (e.g., sitting on the edge of the bed for several minutes before attempting to stand in the morning and slowly rising from a seated position) *[see Warnings and Precautions]*. **Interference with Cognitive and Motor Performance:** Because RISPERDAL® CONSTA® 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 treatment with RISPERDAL® CONSTA® does not affect them adversely *[see Warnings and Precautions]*. **Pregnancy:** Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy and for at least 12 weeks after the last injection of RISPERDAL® CONSTA® *[see Use in Specific Populations]*. **Nursing:** Patients should be advised not to breast-feed an infant during treatment and for at least 12 weeks after the last injection of RISPERDAL® CONSTA® *[see Use in Specific Populations]*. **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 *[see Drug Interactions]*. **Alcohol:** Patients should be advised to avoid alcohol during treatment with RISPERDAL® CONSTA® *[see Drug Interactions]*.

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Is Psychiatry's Future At the Tipping Point?

BY KAYLA POPE, M.D., J.D.

Author Malcolm Gladwell, in his popular book *The Tipping Point*, describes a process by which dramatic changes can take place in the world in a seemingly sudden and unexpected fashion.

He argues that change often does not occur in proportional response to the pressure being applied, but rather change occurs when the accumulation of pressures on a system is great enough to overcome inertia. He refers to the point at which a system is poised to undergo dramatic change as the "tipping point," since it is at this point that the smallest of influences can turn out to be explosive.

Perhaps it is a stretch, but I have begun to wonder about the practice of psychiatry and whether we are approaching our tipping point.

It seems that pressure for change is coming from all quarters—advances in neuroscience and the application of new technologies are challenging the way we conceptualize mental illness, health care reform is challenging the way we provide services to our patients, and pressure to change our relationship with the pharmaceutical industry is challenging the ways in which we develop new therapies and educate practitioners. That all adds up to a lot of stress on the system.

If change is to occur, the key questions become whether we are in a position to direct this change, and do we have a vision for where we would like to go? These are questions that APA leaders have been struggling with and are attempting to address.

As part of this process, our immediate past president, Dr. Nada Stotland, appointed a work group to develop a list of priorities for APA to help the field make these transitions. The work group, led by Dr. Dilip Jeste, an at-large member of the Board of Trustees, began the process of defining APA's agenda for the future by organizing a focus group that met during the APA annual meeting in San Francisco in May.

Ideas presented at the focus-group meeting and from members of the work group were used to develop a survey for the APA membership. The survey addresses a broad range of topics including relationships with other medical professions, models for clinical practice, and the integration of science and clinical evidence into training and mental health care. The "Survey on the Future of Psychiatry" is available for members to complete, and they can do so until September 30. An e-mail with a link to the survey was sent to all members in early August and was resent on September 2. Members who have not received it can contact Miriam Epstein at mepstein@psych.org. Members' survey responses will be used to prioritize the work of APA.

Another effort under way to prepare the field for future challenges is a series of town-hall meetings for members-in-training and early career psychiatrists. Headed by Dr. Carol Bernstein, APA president-elect, these meetings will provide a forum for participants to discuss the future of the field and APA's role in meeting the needs of its members and the patients they treat.

The town-hall meetings will be held in cities across the country over the next year. The series will begin in New York during next month's APA Institute on Psychiatric Services and will be held on Thursday, October 8, from 7 p.m. to 9 p.m. at the Sheraton New York Hotel and Towers.

Future meetings have tentatively been planned for Washington, D.C., Chicago, and San Francisco, with the final meeting to be held in New Orleans during the 2010 APA annual meeting. Residents and early career psychiatrists interested in participating in the New York meeting can find more information on the APA Web site at <www.psych.org/IPS> under "New Sessions Just Added to the Program" or by contacting Jill Gruber at jgruber@psych.org.

We all lead busy lives, and it is often very tempting to stand on the sidelines and watch a scene unfold. However, if we are truly at a tipping point, it may be worth remembering that even the smallest of influences can have a significant impact. That is why it is vital that APA hears from you via the survey and at the town-hall meetings. Your ideas could help determine the future of your field and this organization. ■

Kayla Pope, M.D., J.D., is the APA Board of Trustees' member-in-training trustee-elect.

Errata

• The article in the August 7 issue about APA's annual MindGames competition reported the name of the winning team's institution incorrectly. The winning team was from the Albert Einstein Healthcare Network of Philadelphia. The team members were David Leach, M.D., Mildred Fajardo, M.D., and Basant Pradhan, M.D.

• The article "Psychiatrist Focuses Attention on Often Overlooked Group" in the August 21 issue stated that the psychiatry fellowship in college mental health at Ohio State University is offered by the Department of Psychiatry. In fact, it is offered through the university's Counseling and Consultation Service, a division of the Office of Student Life. ■

Ralph Hoffman, MD, and research assistant Joan Nye, view functional MR images of a patient's cortical activation during auditory hallucinations.

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Schizophrenia Patients Show High Rates of Comorbid Illness

Metabolic conditions were common but so were such medical conditions as epilepsy and viral hepatitis.

BY MARK MORAN

Hospital discharge records of people with a primary diagnosis of schizophrenia showed higher proportions of all comorbid psychiatric conditions and of several general medical conditions than did those of people who did not have schizophrenia.

The general medical conditions included acquired hypothyroidism, obesity, epilepsy, viral hepatitis, type 2 diabetes, essential hypertension, various chronic obstructive pulmonary diseases, and contact dermatitis and other forms of eczema, according to data from the National Hospital Discharge Survey reported in the August *Psychiatric Services* by researchers in the Department of Epidemiology at Walter Reed Army Institute of Research.

The survey data confirm what has been reported before: that patients with schizophrenia have higher rates of morbidity associated with some general medical conditions.

However, the study authors pointed out that virtually all existing studies of comorbid disorders in schizophrenia test hypotheses and have focused on a single comorbid condition in relatively small and nonrepresentative samples. The current study appears to be the first systematic analysis of comorbidity in general with schizophrenia in the U.S. hospitalized population.

"Our study is hypothesis-generating rather than hypothesis-testing, with the main purpose of presenting a systematic review of comorbid conditions," said coauthor Natalya Weber, M.D., M.P.H. "Psychiatrists can see in this very large and representative sample what conditions are more frequently comorbid with a primary diagnosis of schizophrenia compared to any other primary diagnosis among the U.S. hospital discharges."

Weber is health science administrator in the Division of Preventive Medicine at Walter Reed Army Institute of Research.

In the study, 1979 to 2003 data from the National Hospital Discharge Survey, a nationally representative sample, were analyzed.

Out of 5,733,781 discharges during that period, researchers compared records of comorbid conditions among those with a primary diagnosis of schizophrenia (n=26,279) and those with other primary diagnoses (n=1,936,876). Proportional morbidity ratios were calculated.

The researchers found that psychiatric and behavior-related diagnoses accounted for 45 percent of comorbid diagnostic categories among schizophrenia discharges, compared with 15 percent among other discharges.

Further, the proportion of discharges with comorbid psychiatric disorders was much higher among patients discharged with a primary diagnosis of schizophrenia. These conditions included (in descending order of morbidity ratios): mild mental retardation, personality disorders, affective psychoses, nondependent abuse of drugs, adjustment reaction, alcohol dependence, drug dependence, depressive disorder not elsewhere classified, and neurotic disorders.

In addition, discharge records of patients with schizophrenia as the primary diagnosis were significantly more likely to list the following nonpsychiatric comorbid conditions (in descending order of morbidity ratios): acquired hypothyroidism, obesity and other hyperalimentation disorders, asthma, chronic airway obstruction not elsewhere classified, essential hypertension, and type 2 diabetes.

The frequency of cardiovascular and metabolic conditions comes as no surprise and has been reported widely. Psychiatrist John Newcomer, M.D., who has specialized in the research and treatment of metabolic conditions in schizophrenia and who reviewed the report for *Psychiatric News*, said the data likely underestimate the true prevalence of these comorbid conditions—a point the study researchers acknowledged.

"The very nature of the problem with this diagnosis [of schizophrenia] is that the patients tend to receive a lower standard of medical care, so there is going to be massive underestimation," Newcomer told *Psychiatric News*. "If someone has a comorbid diagnosis, that means that someone had to see you and diagnose you and engage you in treatment. We are worried that this is a significant underestimation of the true prevalence [of medical comorbidity]."

Weber acknowledged in an interview that she and her colleagues had expected to see much higher rates of metabolic and cardiovascular disease. "We can only speculate that the conditions are underdiagnosed in patients with schizophrenia."

> **"We can only speculate that the conditions are underdiagnosed in patients with schizophrenia."**

One finding that was somewhat surprising was the frequency of comorbid epilepsy. "It is of interest that epilepsy was twice as prevalent among discharges with schizophrenia," the authors wrote. "This association has no clear pathogenic mechanism and has been reported in only a few previous studies."

Also noteworthy was the frequency of contact dermatitis and other forms of eczema. Weber told *Psychiatric News* that these are typically caused by contact with detergents, oils, solvents, drugs, plants, solar radiation, and other environmental agents.

"We can speculate that these skin diseases could be disproportionally present in patients with schizophrenia due to their higher exposure to these harmful environmental agents as a result of substandard living and working conditions, lower-paid manual jobs, and homelessness," she said. "Although these conditions were found a few times higher among discharges with a primary diagnosis of schizophrenia, they are quite rare—less than 1 percent of all comorbid conditions."

She concluded, "The main message for clinicians is that individuals with schizophrenia have more than their share of associated, and often serious, medical conditions and thus require especially careful medical attention. This may help to timely diagnose and treat comorbid conditions and perhaps take some preventive measurements in those who are predisposed to them."

"Psychiatric and General Medical Conditions Comorbid With Schizophrenia in the National Hospital Discharge Survey" is posted at <http://psychservices.psychiatryonline.org/cgi/content/abstract/60/8/1059>. ■

Mental Health Intervention Crucial For Many Cancer Survivors

Younger long-term cancer survivors with comorbid medical illnesses are especially at risk of suffering serious psychological distress.

BY JOAN AREHART-TREICHEL

The good news is that the number of cancer survivors has steadily increased over the last 30 years. Today there are about 12 million cancer survivors in the United States, representing 4 percent of the population.

The good news is also that many long-term cancer survivors successfully adapt to life after cancer and may even experience psychological growth from having triumphed over their ordeal.

The bad news, however, is that some 6 percent of long-term cancer survivors suffer serious psychological distress, a new study of participants in a major U.S. health survey has revealed. The reasons for the distress include a fear of cancer recurrence, physical deficits due to cancer treatment, and a lack of social support.

The study was headed by Karen Hoffman, M.D., of the Dana-Farber Cancer Institute in Boston. Results were published in the July 27 *Archives of Internal Medicine*.

The National Health Interview Survey is administered annually by the U.S. Census Bureau for the National Center for Health Statistics, which is part of the Centers for Disease Control and Prevention. The survey is the principal source of information about the health of the civilian, noninstitutionalized American population. Hoffman and her coworkers selected subjects for their study from National Health Interview Surveys conducted from 2002 to 2006.

Their subjects included some 4,600 individuals who had survived various kinds of cancer for five years or more (on average for 12 years) and whose average age was 66 at the time they were surveyed. The subjects also included some 122,000 individuals who had never had cancer and who served as controls.

All of the participating subjects had had their psychological distress levels during the previous month measured with a reliable, validated tool called the K6 scale. It asks six questions such as "I feel so sad nothing could cheer me up," "I feel that everything is an effort," or "I feel hopeless." Subjects answered these questions using a 0 to 4 scale, representing a range from "none of the time" to "all of the time." Scores for individual questions were tallied to create a total score ranging from 0 to 24, with higher scores indicating more distress. Individuals with a score of 13 or more were considered to be markedly distressed psychologically.

Hoffman and her colleagues looked to see how many of the cancer survivors in their study had experienced marked psychological distress at the time of responding to the survey and how this number compared with the number of control subjects who had experienced marked psychological distress at the time of responding. The answer was 6 percent for the cancer survivors versus 3 percent for the controls—a highly significant difference.

But who were the individuals who made up this 6 percent? Hoffman and her team then examined sociodemographic and clinical information about them to find out. The data revealed that they tended to be unmarried, to have less than a high school education, to be uninsured, to have trouble dealing with activities of daily living, to be younger, and to have comorbid illnesses, such as heart disease, diabetes, emphysema, or kidney disease. Indeed, the combination of younger age and comorbid illnesses placed cancer survivors at particularly high risk of severe psychological distress; 25 percent of those aged 45 or younger with comorbid illnesses experienced severe psychological distress.

These findings have practical implications, Hoffman and her team believe. For example, clinics for cancer survivors might do well to incorporate some mental health professionals into their staffs to help survivors who are seriously psychologically distressed, they proposed.

An abstract of "Psychological Distress in Long-term Survivors of Adult-Onset Cancer" is posted at <http://archinte.ama-assn.org/cgi/content/short/169/14/1274?home>. ■

Younger Age, Comorbidity Raise MH Risk

Below shows the percentage of long-term cancer survivors by age group who experienced serious psychological distress. The study included 4,600 individuals who had survived cancer for five years or more.

Age at Interview	No. of Comorbid Illnesses		
	0	1	≥ 2
≥ 65	2.0%	2.8%	8.4%
45-64	4.6%	9.1%	20.8%
<45	7.4%	24.6%	33.3%

Source: Karen Hoffman, M.D., et al., *Archives of Internal Medicine*, July 27, 2009

For Major Depressive Disorder (MDD)...

LEXAPRO IS NOW APPROVED for adolescents aged 12 to 17[1]

Lexapro® escitalopram oxalate

DSM-IV-TR criteria for Major Depressive Episode: Five or more symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure in nearly all activities. In children and adolescents, depressed mood can be irritable mood.[2]

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of 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 less than 12 years of age.

Please see additional Important Safety Information on following pages.

IMPORTANT SAFETY INFORMATION (continued)

Contraindications

- Lexapro is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs). There have been reports of serious, sometimes fatal, reactions with some cases resembling neuroleptic malignant syndrome (NMS) and serotonin syndrome. Features may include 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. Serotonin syndrome was reported for two patients who were concomitantly receiving linezolid, an antibiotic which has MAOI activity. Lexapro should not be used in combination with an MAOI or within 14 days of discontinuing an MAOI. MAOIs should not be initiated within 14 days of discontinuing Lexapro.

- Lexapro is contraindicated in patients taking pimozide or with hypersensitivity to escitalopram or citalopram.

Warnings and Precautions

- All patients treated with antidepressants should be monitored appropriately and observed closely for clinical worsening, suicidality and unusual changes in behavior, especially within the first few months of treatment or when changing the dose. Consideration should be given to changing the therapeutic regimen, including discontinuing medication, in patients whose depression is persistently worse, who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Families and caregivers of patients treated with antidepressants should be alerted about the need to monitor patients daily for the emergence of agitation, irritability, unusual changes in behavior, or the emergence of suicidality, and report such symptoms immediately. 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.

NOW
FDA APPROVED
for Major Depressive Disorder (MDD)
in adolescents aged 12 to 17[1]

LEXAPRO provides symptom relief for adolescents with MDD

- **For acute and maintenance treatment[1]**
  - —Patients should be periodically reassessed to determine the need for maintenance treatment[1]
- **Significant improvement in CDRS-R scores starting at week 4[3]**
  - —Full antidepressant effect may take 4 to 6 weeks
- **Flexible dosing with a recommended dose of 10 mg/day[1]**
  - —Titration to 20 mg/day, if necessary, after a minimum of 3 weeks[1]

LEXAPRO is indicated as an integral part of a total treatment program for MDD. Drug treatment may not be indicated for all adolescents with this syndrome.

- A major depressive episode may be the initial presentation of bipolar disorder. In patients at risk for bipolar disorder, treating such an episode with an antidepressant alone may increase the likelihood of precipitating a mixed/manic episode. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine if they are at risk for bipolar disorder. Lexapro should be used cautiously in patients with a history of mania or seizure disorder. Lexapro is not approved for use in treating bipolar depression.
- The concomitant use of Lexapro with other SSRIs, SNRIs, triptans, tryptophan, antipsychotics or other dopamine antagonists is not recommended due to potential development of life-threatening serotonin syndrome or neuroleptic malignant syndrome (NMS)-like reactions. Reactions have been reported with SNRIs and SSRIs alone, including Lexapro, but particularly with drugs that impair metabolism of serotonin (including MAOIs). Management of these events should include immediate discontinuation of Lexapro and the concomitant agent and continued monitoring.
- Patients should be monitored for adverse reactions when discontinuing treatment with Lexapro. During marketing of Lexapro and other SSRIs and SNRIs, there have been spontaneous reports of adverse events occurring upon discontinuation, including dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias), anxiety, confusion, headache, lethargy, emotional lability, insomnia and hypomania. A gradual dose reduction rather than abrupt cessation is recommended whenever possible.

Please see additional Important Safety Information on next page.

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LEXAPRO: Proven efficacy in MDD in adolescents aged 12 to 17[1,3]

Warnings and Precautions (continued)

- SSRIs and SNRIs have been associated with clinically significant hyponatremia. Elderly patients and patients taking diuretics or who are otherwise volume-depleted appear to be at a greater risk. Discontinuation of Lexapro should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted.
- SSRIs (including Lexapro) and SNRIs may increase the risk of bleeding. Patients should be cautioned that concomitant use of aspirin, NSAIDs, warfarin or other anticoagulants may add to the risk.
- Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro does not affect their ability to engage in such activities.
- Lexapro should be used with caution in patients with severe renal impairment or with diseases or conditions that alter metabolism or hemodynamic responses. 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.
- For pregnant or nursing mothers, Lexapro should be used only if the potential benefit justifies the potential risk to the fetus or child.

Adverse Reactions

- In clinical trials of MDD, the most common adverse reactions in adults treated with Lexapro (approximately 5% or greater and at least twice the incidence of placebo) were nausea (15% vs 7%), insomnia (9% vs 4%), ejaculation disorder (9% vs <1%), fatigue (5% vs 2%), somnolence (6% vs 2%), and increased sweating (5% vs 2%). In pediatric patients, the overall profile of adverse reactions was similar to that seen in adults; however, the following additional adverse reactions were reported at an incidence of at least 2% for Lexapro and greater than placebo: back pain, urinary tract infection, vomiting, and nasal congestion.

Please see accompanying brief summary of prescribing information for LEXAPRO, including Boxed Warning.

References: 1. LEXAPRO [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2009. **2.** American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 4th ed (Text Revision). Washington, DC: APA; 2000. **3.** Emslie GJ, Ventura D, Korotzer A, Tourkodimitris S. Escitalopram in the treatment of adolescent depression: a randomized placebo-controlled multisite trial. *J Am Acad Child Adolesc Psychiatry.* 2009;48:721-729.

Visit the LEXAPRO website at www.lexapro.com

Lexapro escitalopram oxalate®

LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION **Rx Only**

Brief Summary: For complete details, please see full Prescribing Information for Lexapro.

WARNINGS: 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 less than 12 years of age. *[See Warnings and Precautions: Clinical Worsening and Suicide Risk, Patient Counseling Information: Information for Patients, and Used in Specific Populations: Pediatric Use].*

INDICATIONS AND USAGE: Major Depressive Disorder-Lexapro (escitalopram) is indicated for the acute and maintenance treatment of major depressive disorder in adults and in adolescents 12 to 17 years of age [*see Clinical Studies*]. A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, a suicide attempt or suicidal ideation. **Generalized Anxiety Disorder**-Lexapro is indicated for the acute treatment of Generalized Anxiety Disorder (GAD) in adults [*see Clinical Studies*]. Generalized Anxiety Disorder (DSM-IV) is characterized by excessive anxiety and worry (apprehensive expectation) that is persistent for at least 6 months and which the person finds difficult to control. It must be associated with at least 3 of the following symptoms: restlessness or feeling keyed up or on edge, being easily fatigued, difficulty concentrating or mind going blank, irritability, muscle tension, and sleep disturbance.

CONTRAINDICATIONS: Monoamine oxidase inhibitors (MAOIs)-Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated [*see Warnings and Precautions*]. **Pimozide**-Concomitant use in patients taking pimozide is contraindicated [*see Drug Interactions*]. **Hypersensitivity to escitalopram or citalopram**-Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Lexapro.

WARNINGS AND PRECAUTIONS: 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	Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated
	Increases Compared to Placebo
<18	14 additional cases
18-24	5 additional cases
	Decreases Compared to Placebo
25-64	1 fewer case
≥65	6 fewer cases

No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide. It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression. All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for 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 Dosage and Administration*]. 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 [*see also Patient Counseling Information*]. 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. **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions**-The development of a potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported with SNRIs and SSRIs alone, including Lexapro treatment, but particularly with concomitant use of serotonergic drugs (including triptans) with drugs which impair metabolism of serotonin (including MAOIs), or with antipsychotics or other dopamine antagonists. 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). Serotonin syndrome, in its most severe form can resemble neuroleptic malignant syndrome, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs, and mental status changes. Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms. The concomitant use of Lexapro with MAOIs intended to treat depression is contraindicated. 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. The concomitant use of Lexapro with serotonin precursors (such as tryptophan) is not recommended. Treatment with Lexapro and any concomitant serotonergic or antidopaminergic agents, including antipsychotics, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated. **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*]. **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. **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. **Hyponatremia**-Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including Lexapro. In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH), and was reversible when Lexapro was discontinued. Cases with serum sodium lower than 110 mmol/L have been reported. Elderly patients may be at greater risk of developing hyponatremia with SSRIs and SNRIs. Also, patients taking diuretics or who are otherwise volume depleted may be at greater risk [*see Geriatric Use*]. Discontinuation of Lexapro should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted. Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which may lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. **Abnormal Bleeding**-SSRIs and SNRIs, including Lexapro, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants may add to the risk. Case reports and epidemiological studies (case-control and cohort design) have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding. Bleeding events related to SSRIs and SNRIs use have ranged from ecchymoses, hematomas, epistaxis, and petechiae to life-threatening hemorrhages. Patients should be cautioned about the risk of bleeding associated with the concomitant use of Lexapro and NSAIDs, aspirin, or other drugs that affect coagulation. **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*]. **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.

ADVERSE REACTIONS: Clinical Trials Experience-Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. **Clinical Trial Data Sources; Pediatrics (6 -17 years)**-Adverse events were collected in 576 pediatric patients (286 Lexapro, 290 placebo) with major depressive disorder in double-blind placebo-controlled studies. Safety and effectiveness of Lexapro in pediatric patients less than 12 years of age has not been established. **Adults**-Adverse events 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 reactions 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; Pediatrics (6 -17 years)**-Adverse events were associated with discontinuation of 3.5% of 286 patients receiving Lexapro and 1% of 290 patients receiving placebo. The most common adverse event (incidence at least 1% for Lexapro and greater than placebo) associated with discontinuation was insomnia (1% Lexapro, 0% placebo). **Adults**-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; Adults**-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 Reactions in Placebo-Controlled Clinical Trials; Major Depressive Disorder; Pediatrics (6 -17 years)**-The overall profile of adverse reactions in pediatric patients was generally similar to that seen in adult studies, as shown in Table 2. However, the following adverse reactions (excluding those which appear in Table 2 and those for which the coded terms were uninformative or misleading) were reported at an incidence of at least 2% for Lexapro and greater than placebo: back pain, urinary tract infection, vomiting, and nasal congestion. **Adults**-The most commonly observed adverse reactions 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. 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.

TABLE 2
Treatment-Emergent Adverse Reactions Observed with a Frequency of ≥ 2% and Greater Than Placebo for Major Depressive Disorder

Adverse Reaction	Lexapro (N=715)	Placebo (N=592)
Autonomic Nervous System Disorders		
Dry Mouth	6%	5%
Sweating Increased	5%	2%
Central & Peripheral Nervous System Disorders		
Dizziness	5%	3%
Gastrointestinal Disorders		
Nausea	15%	7%
Diarrhea	8%	5%
Constipation	3%	1%
Indigestion	3%	1%
Abdominal Pain	2%	1%
General		
Influenza-like Symptoms	5%	4%
Fatigue	5%	2%
Psychiatric Disorders		
Insomnia	9%	4%
Somnolence	6%	2%
Appetite Decreased	3%	1%
Libido Decreased	3%	1%
Respiratory System Disorders		
Rhinitis	5%	4%
Sinusitis	3%	2%
Urogenital		
Ejaculation Disorder[1,2]	9%	<1%
Impotence[2]	3%	<1%
Anorgasmia[3]	2%	<1%

[1]Primarily ejaculatory delay.
[2]Denominator used was for males only (N=225 Lexapro; N=188 placebo).
[3]Denominator used was for females only (N=490 Lexapro; N=404 placebo).

Generalized Anxiety Disorder; Adults-The most commonly observed adverse reactions in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia. Table 3 enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients.

TABLE 3
Treatment-Emergent Adverse Reactions Observed with a Frequency of ≥ 2% and Greater Than Placebo for Generalized Anxiety Disorder

Adverse Reactions	Lexapro (N=429)	Placebo (N=427)
Autonomic Nervous System Disorders		
Dry Mouth	9%	5%
Sweating Increased	4%	1%
Central & Peripheral Nervous System Disorders		
Headache	24%	17%
Paresthesia	2%	1%
Gastrointestinal Disorders		
Nausea	18%	8%
Diarrhea	8%	6%
Constipation	5%	4%
Indigestion	3%	2%
Vomiting	3%	1%
Abdominal Pain	2%	1%
Flatulence	2%	1%
Toothache	2%	0%
General		
Fatigue	8%	2%
Influenza-like Symptoms	5%	4%
Musculoskeletal System Disorder		
Neck/Shoulder Pain	3%	1%
Psychiatric Disorders		
Somnolence	13%	7%
Insomnia	12%	6%
Libido Decreased	7%	2%
Dreaming Abnormal	3%	2%
Appetite Decreased	3%	1%
Lethargy	3%	1%
Respiratory System Disorders		
Yawning	2%	1%
Urogenital		
Ejaculation Disorder[1,2]	14%	2%
Anorgasmia[3]	6%	<1%
Menstrual Disorder	2%	1%

[1]Primarily ejaculatory delay.
[2]Denominator used was for males only (N=182 Lexapro; N=195 placebo).
[3]Denominator used was for females only (N=247 Lexapro; N=232 placebo).

Dose Dependency of Adverse Reactions-The potential dose dependency of common adverse reactions (defined as an incidence rate of ≥5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). Table 4 shows common adverse reactions that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group.

TABLE 4
Incidence of Common Adverse Reactions in Patients with Major Depressive Disorder

Adverse Reaction	Placebo (N=311)	10 mg/day Lexapro (N=310)	20 mg/day Lexapro (N=125)
Insomnia	4%	7%	14%
Diarrhea	5%	6%	14%
Dry Mouth	3%	4%	9%
Somnolence	1%	4%	9%
Dizziness	2%	4%	7%
Sweating Increased	<1%	3%	8%
Constipation	1%	3%	6%
Fatigue	2%	2%	6%
Indigestion	1%	2%	6%

Male and Female Sexual Dysfunction with SSRIs-Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence.

TABLE 5
Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials

Adverse Event	Lexapro	Placebo
	In Males Only	
	(N=407)	(N=383)
Ejaculation Disorder (primarily ejaculatory delay)	12%	1%
Libido Decreased	6%	2%
Impotence	2%	<1%
	In Females Only	
	(N=737)	(N=636)
Libido Decreased	3%	1%
Anorgasmia	3%	<1%

There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Priapism has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes**-Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes**-Patients treated with Lexapro in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes**-Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes**-Electrocardiograms from Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to an increase of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Reactions Observed During the Premarketing Evaluation of Lexapro**-Following is a list of treatment-emergent adverse events, as defined in the introduction to the ADVERSE REACTIONS section, reported by the 1428 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. The listing does not include those events already listed in Tables 2 & 3, those events for which a drug cause was remote and at a rate less than 1% or lower than placebo, those events which were so general as to be uninformative, and those events reported only once which did not have a substantial probability of being acutely life threatening. Events are categorized by body system. Events of major clinical importance are described in the Warnings and Precautions section. Cardiovascular - hypertension, palpitation. Central and Peripheral Nervous System Disorders - light-headed feeling, migraine. Gastrointestinal Disorders - abdominal cramp, heartburn, gastroenteritis. General - allergy, chest pain, fever, hot flushes, pain in limb. Metabolic and Nutritional Disorders - increased weight. Musculoskeletal System Disorders - arthralgia, myalgia jaw stiffness. Psychiatric Disorders - appetite increased, concentration impaired, irritability. Reproductive Disorders/Female - menstrual cramps, menstrual disorder. Respiratory System Disorders - bronchitis, coughing, nasal congestion, sinus congestion, sinus headache. Skin and Appendages Disorders - rash. Special Senses - vision blurred, tinnitus. Urinary System Disorders - urinary frequency, urinary tract infection. **Post-Marketing Experience; Adverse Reactions Reported Subsequent to the Marketing of Escitalopram**-The following additional adverse reactions have been identified from spontaneous reports of escitalopram received worldwide. These adverse reactions have been chosen for inclusion because of a combination of seriousness, frequency of reporting, or potential causal connection to escitalopram and have not been listed elsewhere in labeling. However, because these adverse reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events include: Blood and Lymphatic System Disorders: anemia, agranulocytis, aplastic anemia, hemolytic anemia, idiopathic thrombocytopenia purpura, leukopenia, thrombocytopenia. Cardiac Disorders: atrial fibrillation, bradycardia, cardiac failure, myocardial infarction, tachycardia, torsade de pointes, ventricular arrhythmia, ventricular tachycardia. Ear and Labyrinth Disorders: vertigo Endocrine Disorders: diabetes mellitus, hyperprolactinemia, SIADH. Eye Disorders: diplopia, glaucoma, mydriasis, visual disturbance. Gastrointestinal Disorders: dysphagia, gastrointestinal hemorrhage, gastroesophageal reflux, pancreatitis, rectal hemorrhage. General Disorders and Administration Site Conditions: abnormal gait, asthenia, edema, fall, feeling abnormal, malaise. Hepatobiliary Disorders: fulminant hepatitis, hepatic failure, hepatic necrosis, hepatitis. Immune System Disorders: allergic reaction, anaphylaxis. Investigations: bilirubin increased, decreased weight, electrocardiogram QT prolongation, hepatic enzymes increased, hypercholesterolemia, INR increased, prothrombin decreased. Metabolism and Nutrition Disorders: hyperglycemia, hypoglycemia, hypokalemia, hyponatremia. Musculoskeletal and Connective Tissue Disorders: muscle cramp, muscle stiffness, muscle weakness, rhabdomyolysis. Nervous System Disorders: akathisia, amnesia, ataxia, choreoathetosis, cerebrovascular accident, dysarthria, dyskinesia, dystonia, extrapyramidal disorders, grand mal seizures (or convulsions), hypoaesthesia, myoclonus, nystagmus, Parkinsonism, restless legs, seizures, syncope, tardive dyskinesia, tremor. Pregnancy, Puerperium and Perinatal Conditions: spontaneous abortion. Psychiatric Disorders: acute psychosis, aggression, agitation, anger, anxiety, apathy, completed suicide, confusion, depersonalization, depression aggravated, delirium, delusion, disorientation, feeling unreal, hallucinations (visual and auditory), mood swings, nervousness, nightmare, panic reaction, paranoia, restlessness, self-harm or thoughts of self-harm, suicide attempt, suicidal ideation, suicidal tendency. Renal and Urinary Disorders: acute renal failure, dysuria, urinary retention. Reproductive System and Breast Disorders: menorrhagia, priapism. Respiratory, Thoracic and Mediastinal Disorders: dyspnea, epistaxis, pulmonary embolism, pulmonary hypertension of the newborn. Skin and Subcutaneous Tissue Disorders: alopecia, angioedema, dermatitis, ecchymosis, erythema multiforme, photosensitivity reaction, Stevens Johnson Syndrome, toxic epidermal necrolysis, urticaria. Vascular Disorders: deep vein thrombosis, flushing, hypertensive crisis, hypotension, orthostatic hypotension, phlebitis, thrombosis.

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 and Precautions*]. The concomitant use of Lexapro with other SSRIs, SNRIs or tryptophan is not recommended. **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 and Precautions*]. **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 and Precautions*]. **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 may potentiate the risk of bleeding. Altered anticoagulant effects, including increased bleeding, have been reported when SSRIs and SNRIs are coadministered with warfarin. Patients receiving warfarin therapy should be carefully monitored when Lexapro is initiated or discontinued. **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.

USE IN SPECIFIC POPULATIONS: 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 also 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 and Precautions*]. 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**-Escitalopram is excreted in human breast milk. Limited data from women taking 10-20 mg escitalopram showed that exclusively breast-fed infants receive approximately 3.9% of the maternal weight-adjusted dose of escitalopram and 1.7% of the maternal weight-adjusted dose of desmethylcitalopram. There were two reports of infants experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a racemic citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of racemic citalopram by its mother and, in the second case, no follow-up information was available. Caution should be exercised and breastfeeding infants should be observed for adverse reactions when Lexapro is administered to a nursing woman. **Pediatric Use**-Safety and effectiveness of Lexapro has not been established in pediatric patients (less than 12 years of age) with Major Depressive Disorder. Safety and effectiveness of Lexapro has been established in adolescents (12 to 17 years of age) for the treatment of major depressive disorder [*see Clinical Studies*]. Although maintenance efficacy in adolescent patients with Major Depressive Disorder has not been systematically evaluated, maintenance efficacy can be extrapolated from adult data along with comparisons of escitalopram pharmacokinetic parameters in adults and adolescent patients. Safety and effectiveness of Lexapro has not been established in pediatric patients less than 18 years of age with Generalized Anxiety Disorder. **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. SSRIs and SNRIs, including Lexapro, have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event [see *Hyponatremia*]. 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.

DRUG ABUSE AND DEPENDENCE: Abuse and Dependence; Physical and Psychological Dependence-Animal studies suggest that the abuse liability of racemic citalopram is low. Lexapro has not been systematically studied in humans for its potential for abuse, tolerance, or physical dependence. The premarketing clinical experience with Lexapro did not reveal any drug-seeking behavior. However, these observations were not systematic and 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. Consequently, physicians should carefully evaluate Lexapro patients for history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse (e.g., development of tolerance, incrementations of dose, drug-seeking behavior).

OVERDOSAGE: Human Experience-In clinical trials of escitalopram, there were reports of escitalopram overdose, including overdoses of up to 600 mg, with no associated fatalities. During the postmarketing evaluation of escitalopram, Lexapro overdoses involving overdoses of over 1000 mg have been reported. As with other SSRIs, a fatal outcome in a patient who has taken an overdose of escitalopram has been rarely reported. Symptoms most often accompanying escitalopram overdose, alone or in combination with other drugs and/or alcohol, included convulsions, coma, dizziness, hypotension, insomnia, nausea, vomiting, sinus tachycardia, somnolence, and ECG changes (including QT prolongation and very rare cases of torsade de pointes). Acute renal failure has been very rarely reported accompanying overdose. **Management of Overdose**-Establish and maintain an airway to ensure adequate ventilation and oxygenation. Gastric evacuation by lavage and use of activated charcoal should be considered. Careful observation and cardiac and vital sign monitoring are recommended, along with general symptomatic and supportive care. Due to the large volume of distribution of escitalopram, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. There are no specific antidotes for Lexapro. In managing overdosage, consider the possibility of multiple-drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of any overdose.

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Strong Link to Suicide Found For Anxiety, Conduct Disorders

Various psychiatric disorders can contribute to higher risks of suicidal thoughts and attempts, but scientists do not yet understand enough about the mechanisms to prevent suicide reliably.

BY JUN YAN

A wide range of mental illnesses can contribute to the increased likelihood of suicidal thoughts and attempts, but only those characterized by anxiety and poor impulse control significantly predict who is more likely to act on suicidal thoughts, according to a multinational study on mental health.

The study was published online in the open-access journal *PLoS Medicine* on August 10 and was derived from data from the massive World Health Organization (WHO) World Mental Health Survey Initiative. The initiative is ongoing and has so far been carried out in 28 countries throughout the world. The study included data from nearly 110,000 adults in 21 countries. Researchers analyzed the data to identify patterns of how suicidal thoughts, plans, and attempts can be predicted by psychiatric disorders preceding such thoughts and behaviors.

In this global initiative, trained research staff in each participating country conducted face-to-face interviews with adults living in the community and collected various data on the respondents' lifetime mental health histories. The WHO Composite International Diagnostic Interview, a structured questionnaire validated for assessing *DSM-IV* psychiatric disorders across various countries and cultures, was the instrument used.

Prior Disorders Pose Varying Risks

In developed countries, 52 percent of adults who had at least suicidal ideation reported a prior psychiatric disorder, compared with 43 percent in developing countries. Among those who made suicide attempts, the prevalences of prior psychiatric disorder were 66 percent and 55 percent, respectively.

One of the surprising findings was that, although it has been widely cited that over 90 percent of people who committed suicide have psychiatric disorders, the rates of psychiatric disorders reported by people in this study with suicidal ideation and attempts were lower than that, said the study's lead author Matthew Nock, Ph.D., professor of the social sciences in the Department of Psychology at Harvard University.

In an interview with *Psychiatric News*, Nock noted that the apparent inconsistency between previous and current data may be explained by several factors. First, it is difficult to make a postmortem psychiatric diagnosis for people who have died of suicide, and thus previous studies may have overestimated the presence of psychiatric disorders. Second, people who "succeed" in suicide may have a higher rate of psychiatric disorders than those who have made nonfatal attempts or have suicidal thoughts. It is also possible that, beyond psychiatric disorders, "there are other factors that contribute to suicide attempts," said Nock.

Country-Type Variations Seen

Analyzed separately, each psychiatric disorder, as identified by the survey, was associated with an increased risk of a subsequent suicide ideation or attempt compared with having no psychiatric disorders, the study authors found. Most of the associations remained statistically significant in both developed and developing countries after controlling for potentially confounding factors.

The magnitude of associations varied by the type of disorder and country type, the study revealed. Mood disorders, including bipolar disorder, depression, and posttraumatic stress disorder (PTSD), were the strongest predictors of suicide attempts in developed countries. However, PTSD, substance use disorders, and conduct disorder were the strongest predictors in developing countries.

Perhaps because past research tended to concentrate in developed countries, the importance of a history of conduct disorder is greatly underappreciated and underresearched, Nock observed. "Clinicians and policy makers should pay more attention to people with a history of conduct disorder in prevention efforts," he said.

Another important predictor for suicidal attempts was the number of comorbid psychiatric disorders, the study found. For example, in developing countries, having one disorder was associated with a risk ratio of 3.9 for suicide attempt compared with having no disorder, while having three disorders was associated with a risk ratio of 14.2.

Suicide Dynamics Still Unknown

Despite more research efforts and public health attention on suicide prevention, the incidence of suicide has declined much in the past two decades, the researchers noted. "Because the population base rate for suicide attempts is low, it is very difficult to study and requires a very large sample," said Nock. The size of this worldwide survey, therefore, was particularly valuable for conducting sophisticated analyses to help understand the causes of suicide.

"One of the most unexpected findings was that, although depression was among the strongest predictors of suicidal thoughts, it was not at all a strong predictor of who is likely to progress from thoughts to attempts," commented Nock. The study also found no association between major depression and impulsive suicidal attempts.

Instead, the study found that PTSD, bipolar disorder, conduct disorder, and substance use disorders were the strongest predictors of individuals with ideation who were at higher risk of making suicide plans and attempts. "Only disorders characterized by anxiety and poor impulse control predict which people with suicide ideation act on such thought," they concluded in the report.

With new insights, Nock admitted, the study poses a number of questions, including "Are there different mechanisms for suicidal thoughts and suicide attempts?" He and his colleagues plan to conduct additional analyses on the data to better understand the risk and protective factors associated with suicidal behaviors, including lifespan risks and symptom clusters.

"We plan to drill down to what types of symptoms are more predictive of suicidal behaviors, because many psychiatric disorders are quite heterogeneous," said Nock.

"Cross-National Analysis of the Associations Among Mental Disorders and Suicidal Behavior: Findings From the WHO World Mental Health Surveys" is posted at <www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed.1000123>. ■

With Obesity Rising in Elderly, Mental Illness Link Gets Attention

Older people are more at risk of obesity if anxious or depressed. But the reason or reasons are not clear.

BY JOAN AREHART-TREICHEL

Older people are more at risk for obesity than younger people are, but especially if they are anxious or depressed. So suggests a study published in the August *British Journal of Psychiatry* that was headed by Mika Kivimaki, Ph.D., an epidemiologist at University College London.

Between 1985 and 1988, some 10,000 civil servants working in London were enrolled in the study. They were 35 to 55 years old at this time.

Both at the time of enrollment and at three other points during the subsequent two decades, they were screened for anxiety and depression with the General Health Questionnaire (GHQ). The GHQ is an instrument that shows high reliability and that has been validated against standardized clinical interviews. It contains 30 questions about various symptoms of anxiety or depression. If a responder answers yes to any of the questions, he or she receives a score of 1. A score of 5 or more indicates that the responder is anxious or depressed.

Also, at the four time points when subjects were screened with the GHQ, their height and weight were measured. Finally, the researchers looked to see whether subjects' vulnerability to obesity changed with age and whether GHQ-defined anxiety or depression influenced such vulnerability.

Subjects were more at risk of obesity as they aged, the researchers found. And within this general trend, there was a growing divergence in obesity prevalence between subjects who had GHQ-defined anxiety or depression and those who did not. Those who were anxious or depressed were increasingly likely to be obese. For example, at age 40, only 6 percent of subjects who were anxious or depressed were obese. That's comparable to the rate in subjects who were not anxious or depressed. But by age 70, of the subjects who were anxious or depressed, 35 percent were obese, while 27 percent were not—a significant difference. These results remained solid even when some possibly confounding factors, such as gender, ethnicity, socioeconomic status, and use of psychotropic drugs were considered.

Thus, as people age, they seem to be increasingly at risk of obesity—even more so if they are anxious or depressed. However, what is not clear is whether anxiety or depression helps set the stage for obesity, whether obesity helps set the stage for anxiety or depression, or whether a common variable, such as pain or disability, can explain the link.

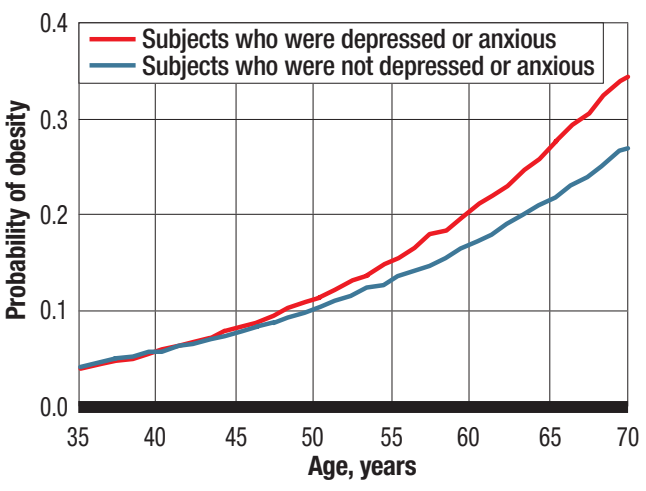
In any event, the findings from this study could have some widespread implications since seniors are the fastest-growing age group in the world, the researchers noted

The study was funded by the British Medical Research Council, the U.S. National Institutes of Health, and other sources.

An abstract of "Association Between Common Mental Disorder and Obesity Over the Adult Life Course" is posted at <http://bjp.rcpsych.org/cgi/content/abstract/195/2/149>. ■

Seniors' Obesity Risk Linked To Anxiety, Depression

In a study of about 10,000 people, researchers found a general upward trend in obesity with age. Within this trend, there was a growing divergence in obesity prevalence between subjects who were anxious or depressed and subjects who were not.



Source: Mika Kivimaki, Ph.D., et al., *British Journal of Psychiatry*, August 2009

Diet's Relationship to Brain Health Provides Much Food for Thought

The brains of older adults whose diets are dominated by vegetables, grains, and monounsaturated oil may be in better shape than their peers whose diets differed from the Mediterranean type.

BY JUN YAN

New research evidence supports a beneficial effect of a Mediterranean type of diet on preventing cognitive decline and Alzheimer's disease in older adults, according to two studies published in the August 12 *Journal of the American Medical Association*.

Dubbed "the Mediterranean diet," this way of eating by people from different cultures near and around the Mediterranean Sea is characterized by a high consumption of fruits, vegetables, legumes, nuts, and fish; a low intake of meats and poultry; the use of olive oil as the main source of fat; and a low-to-moderate intake of wine. The diet has long been linked to a variety of long-term health benefits, such as reduced risks of cardiovascular diseases and cancer, in epidemiological studies.

The two latest studies replicated previous observations from a study published in the June 2006 *Annals of Neurology* by Nikolaos Scarmeas, M.D., an assistant professor of neurology at Columbia University College of Physicians and Surgeons, and colleagues. Taken together, the studies suggested that sticking to these dietary habits for years was associated with a lower incidence of cognitive impairment and Alzheimer's disease in older adults.

One of the current studies, which was conducted in New York between 1992 and 2006, was a follow-up study by Scarmeas's group. During an average of 5.4 years, 282 of 1,880 community-dwelling adults in the study cohort were diagnosed as having newly developed Alzheimer's disease. The mean age of the entire cohort was 77 years at baseline. All participants were asked about their lifestyle habits and tested for neurological functions every 1.5 years or so. Their adherence to the Mediterranean way of eating and level of physical activity were categorized into high, middle, and low levels.

After controlling for age, level of education, and other confounding factors, the authors found that people with high adherence to a Mediterranean type of diet had significantly less risk of developing Alzheimer's than people with low adherence to such diets. Analyzed separately, a high level of physical activity was associated with significantly reduced incidence of Alzheimer's disease compared with a low level of physical activity. The risk difference of disease incidence between middle and low levels of either indicator did not reach statistical significance.

The other study was carried out by Catherine Féart, Ph.D., from Université Victor Segalen Bordeaux 2, France, and colleagues, who followed a cohort of 1,410 older adults in Bordeaux since 2001-2002. The participants had a mean age of 76 at the start of the study, and the median follow-up period was about four years. A higher level of adherence to traditional Mediterranean types of food sources, scored on a scale of 0 to 9, was associated with significantly slower cognitive decline from baseline on the Mini-Mental State Examination, but was not significantly associated with changes in performance on three other cognitive tests for verbal skills and short-term visual and verbal memories.

Different from the New York study, the French study did not find a significant association between adherence to Mediterranean-style diet and the incidence of dementia, but the authors acknowledged that the sample size had not been powered to detect such an association.

Credit: istockphoto/Olga Nayashkova

A diet low in meat and poultry and high in fresh fruits, vegetables, legumes, and nuts, with monounsaturated oil as the main source of fat, is good for the heart and mind.

Before concluding that the way of eating can prevent Alzheimer's disease, David Knopman, M.D., a professor of neurology at the Mayo Clinic, cautioned in an accompanying editorial that this evidence is "moderately compelling" and not specific enough to explain the mechanisms of the diet's protective effects. He pointed out that the cerebrovascular changes associated with Alzheimer's and other types of dementia have their roots in midlife, which may be modified by the Mediterranean diet as it modifies other cardio- and cerebrovascular disorders. To prevent late-life cognitive impairment, people in their midlife should adopt "as many healthy behaviors as possible, including diet," he recommended.

An abstract of "Adherence to a Mediterranean Diet, Cognitive Decline, and Risk of Dementia" is posted at <jama.ama-assn.org/cgi/content/abstract/302/6/638>. An abstract of "Physical Activity, Diet, and Risk of Alzheimer Disease" is posted at <jama.ama-assn.org/cgi/content/abstract/302/6/627>. ■

Data Cast Doubt on Relationship Between Autism, GI Illness

Is there a link between autism and gastrointestinal pathology? A large study sheds some light on the subject, but many questions remain.

BY JOAN AREHART-TREICHEL

Autism and gastrointestinal (GI) disease are linked, some people suggest.

So Samar Ibrahim, M.D., a pediatric gastroenterology fellow at the Mayo Clinic in Rochester, Minn., and colleagues undertook a large population-based study to try to clarify this issue.

They examined nonspecific GI symptoms as well as specific diagnoses of GI diseases in 124 children with autism and in 248 control children from birth to age 21. Nearly all of the youngsters had received their medical care at the Mayo Clinic throughout the years studied; hence detailed, computerized records of their GI symptoms and diagnoses were available for analysis. Ibrahim and his team then compared the GI symptoms and diagnoses of the autism group with those of the control one.

"The biggest finding," Ibrahim told *Psychiatric News*, "was that there was no significant difference in the overall incidence of gastrointestinal symptoms between subjects with autism and normal control subjects. . . ." However, the incidence of symptoms in both groups was high. By age 20, 77 percent of the autism subjects and 72 percent of the control ones had had at least one GI symptom recorded in their medical files.

Nonetheless, the study did find that the incidence of two GI symptoms—feeding difficulties and constipation—was significantly greater in the autism subjects.

As for specific diagnoses of GI diseases, very few in either the autism group or the control group received them. One autism subject had Crohn's disease, another intestinal disaccharidase deficiency, and a third pancreatitis. One control subject had a milk allergy, two had lactose intolerance, and one had pancreatitis. No one in either the autism group or the control group had been diagnosed with celiac disease.

So what should clinicians or parents of autistic children make of these findings, which appeared in the August *Pediatrics*? "Many children with autism are treated with restrictive diets; vitamin, mineral, and other dietary supplements; as well as various medications aimed at putative gastrointestinal disorders," Ibrahim and his group wrote. "The findings from our study suggest that such treatments should not be provided indiscriminately to children with autism unless there is explicit evidence indicating the presence of a gastrointestinal disorder in a specific case."

Regarding feeding difficulties and constipation, the researchers believe that they are due to autistic children's behaviors, not to autism's causing some underlying organic gastrointestinal disease.

"The ritualistic tendencies, need for routine, and insistence on sameness that are characteristic of children with autism may lead these children to choose and demand stereotyped diets that may result in an inadequate intake of fiber, fluids, and other food constituents," the researchers suggested.

In an accompanying editorial, Mark Gilger, M.D., and Carol Anne Redel, M.D., pediatric gastroenterologists at Baylor College of Medicine in Houston, complimented the study on being "well performed." But more research is still needed, they wrote. For instance, it may be possible that in some cases autism-spectrum disorders are linked to specific GI problems, they indicated.

One possibility, they suggested, is Rett syndrome. "Girls with Rett syndrome manifest clear gastrointestinal abnormalities such as gastroesophageal reflux and possibly esophageal dysmotility."

Still another possibility, they pointed out, is that certain genetic abnormalities might underlie both an autism-spectrum disorder and GI problems. Indeed, a growth factor receptor called Met receptor tyrosine kinase is known to function in both brain development and GI repair. A variant in the gene that makes the receptor has been linked with autism. Thus, it is conceivable that this gene variant might contribute to both autism and GI problems, they speculated.

The study was funded by the David and Elaine Dana family and the National Institutes of Health.

An abstract of "Incidence of Gastrointestinal Symptoms in Children With Autism: A Population-Based Study" is posted at <http://pediatrics.aappublications.org/cgi/content/abstract/124/2/680>. ■

journal digest

BY JUN YAN

Alcohol Use

• About 14.5 percent of men aged 65 or older said in a recent survey that they had at least one episode of binge drinking within the past year, which was defined as having five or more drinks on one occasion. In contrast, only 3 percent of women in this age group reported binge drinking. The data were collected in the 2005 and 2006 National Survey on Drug Use and Health, sponsored by the Substance Abuse and Mental Health Services Administration. At-risk drinking, defined as having an average of two or more drinks a day, had a prevalence of 13 percent in men and 8 percent in women of this age group. The rates of binge and at-risk drinking were even higher in men and women aged 50 to 64.

Binge drinking was more common in men who had higher income or who were separated, divorced, or widowed. In women, binge drinking was associated with being employed and using prescription drugs for nonmedical reasons. The use of tobacco and illicit drugs was associated with binge drinking among all respondents.

The study was supported by the National Institute on Drug Abuse.

Blazer DG, Wu L. The Epidemiology of At-Risk and Binge Drinking Among Middle-Aged and Elderly Community Adults: National Survey on Drug Use and Health. AJP in Advance. Published online August 17, 2009

Dementia

• Concentrations of β-amyloid$_{1-42}$ (Aβ42) peptide, total tau protein (T-tau), and tau phosphorylated at position threonine 181 (P-tau) in the cerebrospinal fluid (CSF) may serve as biomarkers to predict the future development of Alzheimer's disease in patients with mild cognitive impairment. Biomarkers that can accurately and sensitively predict the course of a disease, such as low-density-lipoprotein cholesterol levels in blood for cardiovascular disease, are particularly useful for the early diagnosis and prevention of chronic, slowly progressive illnesses. In a multicenter study in Europe and the United States, 750 patients aged 43 to 89 with mild cognitive impairment (MCI) were prospectively followed for a median of three years (range two to 11 years), during which 271 developed Alzheimer's and 59 developed other dementias.

Patients who developed Alzheimer's had significantly lower CSF levels of Aβ42 and higher levels of T-tau and P-tau than those who did not. The authors conducted statistical analyses to compare MCI patients who developed Alzheimer's with MCI patients who did not with controls without Alzheimer's. Combining the Aβ42-tau ratio and T-tau level, the authors found a measurement that could have predicted emergent Alzheimer's with a sensitivity of 83 percent and a specificity of 72 percent. One potential problem was that different study centers had large variations in the biomarker levels, especially for Aβ42. Standardizing the sample handling and testing methods may improve the accuracy and predictive value of the biomarkers, the authors said.

Mattsson K, Zetterberg H, Hansson O, et al. CSF Biomarkers and Incipient Alzheimer Disease in Patients With Mild Cognitive Impairment. JAMA. 2009;302(4):385-393

• Mentally stimulating leisure activities were associated with delayed onset of rapid memory decline in older adults who ultimately developed dementia. The study was a reanalysis of data from the Bronx Aging Study, in which 488 healthy volunteers, aged 75 to 85, were enrolled between 1980 and 1983 and followed until death or loss to follow-up. All volunteers were asked at baseline to estimate about how many days a week they had participated in the following cognitively stimulating leisure activities: reading, writing, crossword puzzles, board or card games, group discussions, and playing music.

Among the 101 persons who eventually developed dementia, each additional day a week of stimulating activities was associated with a 0.18 year delay in the onset of accelerated memory decline. This association was unchanged by the level of education. However, once the decline began, patients who had participated in more baseline activities declined more rapidly than those with fewer activities. These findings were consistent with the cognitive reserve hypothesis, which suggests that certain brain characteristics, reflected in higher education as well as cognitive activities, may protect some persons from the initial neurological deterioration during dementia.

The study was supported in part by a grant from the National Institute on Aging.

Hall CB, Lipton RB, Sliwinski M, Katz MJ, Derby CA, Verghese J. Cognitive Activities Delay Onset of Memory Decline in Persons Who Develop Dementia. Neurology. 2009;73(5);356-361

Depression

• In a randomized, double-blind study of patients with major depressive disorder (MDD), the antidepressant agomelatine was shown to be significantly more effective than placebo. Agomelatine is an agonist of the melatonin MT_1 and MT_2 receptors and an antagonist of the serotonin 5-HT_{2c} receptor. The antidepressant was developed by Servier Laboratories of France and has been approved in Europe for treating adults with MDD. Novartis has bought the rights to the drug and is conducting additional phase 3 clinical trials in the United States.

In this Sevier-sponsored study conducted from 2005 to 2007, 339 patients who had responded to acute treatment with agomelatine (eight or 10 weeks) were randomly assigned to receive either the active drug (n=165) or placebo (n=174) in a double-blind manner for 24 weeks. In the intent-to-treat population, the cumulative six-month relapse rate was 21.7 percent in the agomelatine group and 46.6 percent in the placebo group (p=0.0001). The Kaplan-Meier curves for time to relapse indicated a significantly lower rate of relapse over time in the agomelatine group. Approximately 20 percent of patients withdrew during the acute treatment for lack of sufficient efficacy. During the double-blind, six-month treatment period that followed, 22 percent of the patients in the agomelatine group and 41 percent in the placebo group withdrew for lack of efficacy.

The adverse events were mostly mild to moderate in both groups. The Europe-approved label of agomelatine lists headache, dizziness, somnolence, insomnia, nausea, diarrhea, constipation, anxiety, and other adverse events reported in clinical trials. The drug has been associated with increased hepatic enzyme levels and is contraindicated in patients with liver impairment.

Goodwin GM, Emsley R, Rembry S, Rouillon F. Agomelatine Prevents Relapse in Patients With Major Depressive Disorder Without Evidence of a Discontinuation Syndrome: A 24-Week Randomized, Double-Blind, Placebo-Controlled Trial. J Clin Psychiatry. Published online ahead of print August 11, 2009

• At 9 months of age, newborns of women with postpartum depression had poorer developmental outcomes compared with those born to mothers with anxiety disorders and those born to women with neither anxiety nor depression. The authors first assessed depressive symptoms in nearly 1,000 women on the day after delivery, and then selected 360 who scored the highest and lowest for a second assessment at six months postpartum. The second assessment, using a mailed questionnaire, asked the mothers about their depressive and anxiety symptoms. From all the responses, a final sample of 100 mother-infant dyads was selected for a third assessment of both the mothers and infants at nine months postpartum. This sample included 41 mothers who had scored the highest on depressive and anxiety symptoms and 59 healthy matched controls.

On the basis of home visits, a clinical psychologist diagnosed 22 mothers with major depressive disorder and 19 with anxiety disorders. Each infant was assessed for interaction with its mother, fear regulation, and afternoon cortisol level. The children of MDD mothers had the worst scores for social engagement and fear regulation among the three groups at nine months. Children born to anxious mothers scored worse than children of healthy control mothers in terms of stress reactivity and social engagement, but not in fear regulation. The authors concluded that different maternal diagnoses and behavior patterns can lead to various infant development outcomes through different mechanisms.

Feldman R, Granat A, Pariente C, Kanety H, Kuint J, Gilboa-Schechtman E. Maternal Depression and Anxiety Across the Postpartum Year and Infant Social Engagement, Fear Regulation, and Stress Reactivity. J Am Acad Child Adolesc Psychiatry. 2009;48(9):919-927 ■

letters to the editor

Teaching in an HMO

I spend a few hours every week supervising psychiatry residents in psychotherapy. In one recent month, we talked about how to greet a patient, how to interpret body posture and body language, and how to manage a basic session. We reviewed defense mechanisms and identified possible themes that might appear with each of these patients. We talked about personality makeup and developmental theorists.

These sessions go as well as they can with residents new to psychotherapy. Then a few weeks into the start of a new year, a resident brings up in supervision that her patient has only 20 insurance-paid visits per calendar year. Her patient cannot afford more sessions and can barely make the copays, much less the deductible. The patient spends time expressing fears that she will not be able to come very often, despite acknowledging that she needs and benefits from the sessions. The resident is perplexed. How do you establish rapport, identify goals, and allow patients to arrive at their own conclusions at their own time when you see the patient every two to three weeks?

Hence we change format to CBT, DBT, and IPT: problem-focused therapies. Though these modalities are demonstrated to be effective in helping patients, I am left to wonder if there is a place in modern psychiatry, with new medications and insurance-driven treatment, for the teaching of more traditional insight-oriented therapy.

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.

Though fewer patients can afford this, and perhaps even fewer are actually willing to invest the time and energy in self-discovery, this mode of therapy has, in my opinion, great value for training new and young therapists. I fondly recall my own training at Georgetown and being able to sit with a supervisor and talk about therapy sessions: what the patient did, how I felt, what I did, why I did what I did. These questions are not trivial and are sometimes difficult to answer. Countless hours in supervision have surely expanded my skills, whether it be in medication management, consultation, or therapy.

So we trudge along, trying to accommodate patient needs and insurance restrictions, spreading sessions apart to "make them last" for the length of the year. I find that even with this, I challenge my residents to consider transference/coun-

please see ***Letters*** *on page 33*

Risk Management Tips For Physician Bloggers

As physicians and other health care professionals expand their presence on the Internet, consideration of the following points may be helpful. This is not meant to be an exclusive or exhaustive list of factors to consider.

Confidentiality

Patient information must be kept confidential. There is more to de-identifying information than deleting a name. A study published in the October 2008 *Journal of General Internal Medicine* reviewed 271 medical blogs and found that 45 provided sufficient information for patients to identify their doctors or themselves.

Consequences for breaches of confidentiality could include, but are not limited to, one or more of the following: discipline by your licensing board, a civil lawsuit, and governmental enforcement action (such as by the Office for Civil Rights, the federal agency responsible for enforcing HIPAA's Privacy Rule).

Do not comment about cases, lawsuits, or administrative actions in which you are involved. Doing so can compromise your defense and make an otherwise winnable case indefensible.

Be aware of APA's *Opinions of the Ethics Committee on the Principles of Medical Ethics*, Section Q.4.a, which discusses publication of a casebook and disguising of identity. Although the opinion notes that obtaining the patient's informed consent for publication of the case is one option, the nature of the psychiatrist-patient relationship may place undue pressure on the patient to agree to the psychiatrist's request.

Treatment Relationships

Avoid inadvertently creating a treatment relationship with your Internet readers. Keep in mind that it is the perception of the reader that matters, not the intention of the physician. Make it clear that no treatment relationship with the reader exists, do not post anything that could be perceived to be treatment advice, and clarify that nothing on the site is intended to be medical advice.

Publishing general educational information about a disease or treatment usually is not viewed legally as being "medical advice." However, making suggestions to a person about what his or her diagnosis is or treatment should be is almost always considered "medical advice" and may establish a treatment relationship.

Public Forums

Be aware that you are responsible for all content that you publish and, if you have your own blog, everything that appears on it. Carefully consider the permissions you will give to others with regard to posting content or comments. Ideally, no one but you should be able to publish posts or write comments that appear on your blog.

If others are allowed to write on your blog, be sure that you can and will review all writings before they appear and that they are not misleading or in violation of your ethical or legal obligations. Remember that since you are responsible for all content, all content is held to your standards. For example, even nonphysician contributors should not be allowed to publish patient information on your blog.

Remember that even if no one else can write on your blog, it is still a public forum, and you are responsible for the content. If your intent is to present a fictional story, that should be clear to the readers. AMA Ethics Opinion 5.027 states, "Physicians responsible for the health-related content of an online site should ensure that the information is accurate, timely, reliable, and scientifically sound, and includes appropriate scientific references."

AMA Ethics Opinion 5.027 also discusses conflicts of interest. Generally, any potential conflicts should be disclosed. Refer to the opinion for more information.

Physician Anonymity

Do not assume that you are anonymous, even if you have taken steps to disguise your identity. Because blogs are accessible to such a large population, the ways in which your identity may be discovered increase exponentially, and the amount of detail required for someone to identify you decreases exponentially.

Bottom line: assume that everything you write will be seen by your patients and by the opposing side in any claim, lawsuit, or administrative action.

Other Resources

- Federation of State Medical Boards' "Model Guidelines for the Appropriate Use of the Internet in Medical Practice," posted at <www.fsmb.org/pdf/2002_grpol_Use_of_Internet.pdf>
- "Healthcare Blogger Code of Ethics," posted at <http://medbloggercode.com/the-code>
- Health on the Net Foundation's HONCode, posted at <www.hon.ch/HONcode/Pro/Conduct.html>

Participants in the Psychiatrists' Program, the APA-endorsed Psychiatrists' Professional Liability Insurance Program, managed by PRMS Inc., may access additional valuable resources such as detailed articles and tips on topics of interest and phone consultations through the Risk Management Consultation Helpline at (800) 527-9181 from 8:30 a.m. to 5:30 p.m. Eastern time.

This column is provided by PRMS, manager of the Psychiatrists' Program, for the benefit of members. More information about the Program is available by visiting its Web site at <www.psychprogram.com>; calling (800) 245-3333, ext. 389; or sending an e-mail to TheProgram@prms.com. ■

continued from page 3

was far more than that as evidenced by the long-standing ovation Sen. Kennedy received from his peers in both political parties as they crowded around him to shake his hand and pat him on the back in an outpouring of affection that has been extremely rare in the Senate chamber.

So too was Sen. Kennedy the key player in the effort to pass a comprehensive new "parity" law in the wake of the limited success of the 1996 Mental Health Parity Act. Despite overwhelming and bipartisan support for a broad new parity law, and despite the combined lobbying effort of APA, the AMA, and the entire mental health community, we remained stalled until Sen. Kennedy took the reins in the wake of Sen. Paul Wellstone's untimely death and brought his consummate political skills fully into play.

Kennedy realized that no amount of cajoling would steer the bill through the Senate as long as the business and insurance groups were opposed to it. He and Sen. Pete Domenici (R-N.M.) set up a working group of business, insurance, mental health professionals (APA included), and patients and charged us with working out a compromise that we all would support. He drafted an initial bill that he knew represented the boundaries that could win Senate passage, and then he set the groups talking and negotiating, with key Kennedy and Domenici staff coordinating the effort.

Then Sen. Kennedy set one inflexible requirement: everything was on the table but no change would be accepted unless all of the groups "at the table" agreed to it. The process was arduous. First the parity advocates and the business and insurance groups had to learn to trust each other, not an easy step. At times the negotiations seemed to be heading backward. Certainly there were significant disagreements—sometimes even within the mental health groups—but the senator kept pushing, cajoling, and reprimanding as necessary to keep the groups at the table and talking. The final result was the bipartisan passage of a major advance in ending discrimination against our patients. It was also a firsthand lesson in how skillful a politician Sen. Kennedy was.

Even as he knew he was dying, Sen. Kennedy was still pushing to better the lives of Americans with a comprehensive overhaul of our woefully outdated and inadequate health care system.

APA members, and particularly our patients, owe the senator a very great debt. He will be missed, but his presence remains in the good works he leaves behind—a record of compassion and achievement that few who have served in the Senate have matched or ever will. ■

APA Gains New 100% Club Member

The psychiatry residency program at Albany Medical Center's College of Medicine is now a member of APA's 100% Club. This means that the residents and faculty at the upstate New York facility are all dues-paying members of APA.

"We are delighted," said Victoria Balkoski, M.D., chair of the Department of Psychiatry and director of the residency program. "This reflects outstanding collaboration with the New York State Capital District Branch of APA and our work together educating the residents about APA's very important roles and accomplishments for our patients and our profession."

As 100% Club members, the program receives a group picture of its residents and faculty mounted on a wooden plaque and a major psychiatry textbook, and each resident receives an online subscription to *Focus: The Journal of Lifelong Learning*. Both the textbook and journal are published by American Psychiatric Publishing Inc.

Psychiatry residents and directors of residency programs seeking more information about APA's 100% Club should contact Nancy Delanoche of APA's Division of Education at (703) 907-8635 or e-mail Delanoche at ndelanoche@psych.org. ■

These are the members of Albany Medical Center's College of Medicine psychiatry residency program. First row from left: Tavi Thongdy, M.D., Khalid Elnagar, M.D., Victoria Balkoski, M.D. (department chair and residency program director), Janay Fake, M.D., Kamali Swaminathan, M.D., Maaza G-Amlak, M.D., Hasina Ahmed, M.D., Sanskruti Upasani, M.D., Gabrielli Gorospe, M.D., Hanan Mursi, M.D., and Aparna Iyer, M.D. Second row, from left: Mitchell Cabisudo, M.D., Oksana Kershteyn, M.D. (chief resident), Peggy Serwanski (training coordinator), Irene Mazur, M.D., Alena Antohina, M.D., Arif Shahabuddin, M.D., Jeffrey Winseman, M.D. (associate residency program director), and Mustafa Kaleem, M.D. Third row from left: Myo Kyaw, M.D., Laura Diamond, M.D. (chief resident), Farhan Fazal, M.D., and Zindadil Gandhi, M.D. Fourth row: Oleksandr Osipchuk, M.D. Not pictured are Nicole Tremblay, M.D., and Walter Wahl, M.D.

Melting Pot

continued from page 9

"It seems like all psychiatrists should know research, right?" Laje asked. "But the reality is that it is a sort of specialty. You have to learn the language; you have to learn statistics, methodology. It's a steep learning curve. [Also] my particular research area is genetics. I had to learn genetics. So this was an extra layer of things to learn postresidency and to integrate with my clinical experience."

"I always wanted to combine some research, teaching, and practice," Bokarius reported. "But it's difficult. I don't think it's difficult just in the United States; I think it would be difficult in any country."

"I love psychiatry. "It is emotionally draining, but it gives you satisfaction in seeing your patients get better, get back into the workforce, be more productive."

Still other challenges they faced, and are still facing, derive from being foreign born.

"Currently there is a war going on in Pakistan, and most of my patients are very interested in knowing where I'm from and what is happening in Pakistan," said Shafiq. "So it's difficult maintaining a boundary. I do answer their questions. But I try to be brief and come back to the reason why they are in my office."

Professional Interests Diverse

Even with all the career challenges they are facing, Baram, Bokarius, Laje, Melton, and Shafiq are engaging in an array of professional activities and thriving in their chosen subspecialties. Shafiq works as an adult and child psychiatrist at a community hospital in Denville, N.J. Melton is an assistant professor of psychiatry at Baylor College of Medicine and a staff psychiatrist at the Veterans Administration Hospital in Houston. Baram has a private geriatric psychiatry practice in St. Louis, is doing a little teaching at St. Louis University, and occasionally sees patients in a community clinic. Laje is an adult and child psychiatrist and an associate clinical investigator at the National Institute of Mental Health (NIMH). Bokarius is an attending psychiatrist at Cedars-Sinai Medical Center, a private Los Angeles hospital; medical director of a small corporation involved in consultation services in psychiatry and pain; and a licensed acupuncturist. He learned acupuncture in Russia and uses it to treat pain patients.

Many Rewards Reported

Baram, Bokarius, Laje, Melton, and Shafiq are reaping rich satisfaction from their work.

"I work at least 80 hours a week," Baram reported. "I am running a big practice with the help of a friend. . . . There is plenty of work in the field of geriatric psychiatry. . . . I hope to get some other psychiatrists to join my practice."

Also, since Baram is the only Russian-speaking psychiatrist in St. Louis, he treats numerous Russian-speaking patients and finds such work especially gratifying, he said.

"I love psychiatry!" Shafiq exclaimed. "It is emotionally draining, but it gives you satisfaction in seeing your patients get better, get back into the workforce, be more productive."

"My mentor at NIMH is phenomenal. We have some results, and we have a couple of patents. It has been extremely rewarding for me to do these cool, state-of-the-art things," commented Laje.

"In addition to the more tangible rewards that I receive from my work, one is to practice more Westernized psychiatry," Melton remarked. "[Also,] being from a different culture helps me understand patients from other cultures. In Texas, we have a huge Hispanic population and large African-American and Asian ones. . . . And I feel that I'm finally back to where I started, back home in academic psychiatry—to teach and continue to learn. This is what I really enjoy."

So, just as countless immigrants to the United States find their American dream, so do many immigrant psychiatrists, as the stories of Baram, Bokarius, Laje, Melton, and Shafiq reveal. ■

Collegial Advice Offered

Some foreign-born psychiatrists who are now pursuing successful careers in the United States (see accompanying article) offer some advice to foreign-born medical school graduates contemplating entrance into an American psychiatry residency program or to foreign-born medical school graduates who are already enrolled in such a program.

"The [psychiatry] training here is fantastic," Gonzalo Laje, M.D., a Maryland psychiatrist from Argentina, remarked. "It is structured and has embedded quality-control pieces that make it very good. . . . So for people who want to do it, I would say, definitely go for it. For people who have already started their psychiatry training, I say, follow your dream. If you want to do private practice, you'll have that option. If you want to do research, you'll have that choice. Advocacy, government, military—there are many paths that you can take."

"Hard work pays off; endurance pays off," testified Bengi Melton, M.D., a Houston psychiatrist from Turkey. "If you are here to practice medicine, eventually you will succeed."

"Do not abandon your career objectives even if some failures come up," Vadim Baram, M.D., a St. Louis psychiatrist from Ukraine, advised. "Also, establish connections, because networking is very important."

"Look into minority issues and maybe [provide] some expertise in psychiatry from your country of origin," said Saima Shafiq, M.D., a New Jersey psychiatrist from Pakistan.

A number of people from other countries, especially from countries with ancient histories or cultures, look down on the United States, Vladimir Bokarius, M.D., Ph.D., a Los Angeles psychiatrist from Russia, ventured. "They think, ugh, Americans are barbarians, and their history is, come on, only 300 years!" In fact, he admitted to harboring such an attitude when he moved to the United States. But if you are planning on living and working in the United States, you should dispense with such arrogance, he counseled. "You have to connect with the culture here."

Walker

continued from page 2

American Indian Physicians at its annual meeting in Arlington, Va. Walker, a Cherokee, received the same award 20 years ago.

"It's humbling to be selected again," he said. "I'm honored to be recognized by my peers for our ongoing work."

"Walker has really helped bring attention to the mental health and substance abuse needs of American Indians and Native Alaskans, so that people today are fully cognizant of that need," said Daniel Dickerson, D.O., M.P.H., an assistant research psychiatrist in the UCLA Integrated Substance Abuse Programs at the Semel Institute for Neuroscience and Human Behavior of the David Geffen School of Medicine in Los Angeles. Dickerson is a former chair of APA's Committee of American Indian, Alaska Native, and Native Hawaiian Psychiatrists and has known Walker for eight years.

Within APA, Walker has chaired the Council on Advocacy and Government Relations and the Committee of American Indian, Alaska Native, and Native Hawaiian Psychiatrists, as well as the Strategic Planning Committee in the mid-1990s. He served as speaker of the APA Assembly for the 1996-1997 term.

The One Sky Center began six years ago with funding from the Substance Abuse and Mental Health Services Administration to serve as an advocate as well as a therapist for communities, said Walker.

"Funding for all underserved communities is fragmented," he said. "Our job is to help them manage the process of integrating and allocating those funds."

When one of those 562 groups asks Walker for help, he doesn't just hand out an off-the-shelf formula.

"A lot of preparation goes into a visit to a community," he said, speaking from 30 years' experience.

He tells his students to think of the community as the patient. Just as a physician must integrate the functions and failings of different parts of the body, a healer approaching a community must know the economic, educational, legal, and health care dimensions that influence the course of its illness.

Because tribes are independent, sovereign entities under U.S. law, he begins his discussions with the "ambassadors" from the tribe, knowledgeable members who provide him with an introduction to others within the group.

"Doing the background work brings you status and trust," he said. "They know you respect them."

One Sky staff members visit up to 50 tribal communities a year, following their careful preparation with an intensive two-day stay that sets the stage for further development of specific plans and still more follow-up.

"When we meet with a community, we don't leave," he said. "They become a part of One Sky and we maintain contact over time."

The center's Web site includes a searchable database on 134 programs that have been tried by tribal groups around the country.

Walker helps other Indians and Alaska Natives in another way, too. Over the years, he and his wife, Patricia Silk Walker, Ph.D., M.S.N., a nurse epidemiologist, have helped mentor more than 50 young American-Indian scientists on their way to earning a Ph.D., M.D., or master's degree.

Walker took Dickerson under his wing when Dickerson was still a medical student. He guided Dickerson first toward psychiatry and, once he was in residency at Loma Linda University Medical Center, urged him to consider addiction psychiatry as his specialty. As a result, Dickerson completed an addiction fellowship in psychiatry and research at Yale. Today, Walker and Dickerson are believed to be the only two certified American-Indian addiction specialists in psychiatry, according to Dickerson.

Dickerson returned the favor by mentoring undergraduates and residents. Next year, he will become a mentor for a young researcher.

Expanding that effort has been limited by the lack of a critical mass of American-Indian scientists and health care educators at any one university. In response, the National Institute on Drug Abuse granted Walker funds to set up a national mentor system for American-Indian, Alaska-Native, and Native-Hawaiian addiction researchers, which now includes eight mentors and an equal number of protégés.

"We're picking people with a high likelihood of success and helping them through the sticky patches of graduate school and early career development," said Walker. Workshops in grant writing and scientific paper writing have been held or are planned, for example.

Walker's own research path has combined two parallel tracks: substance abuse among American Indians and general health services and treatment research. He began by looking at vulnerabilities of American Indians to alcohol disorders and to prevention and treatment strategies that worked. He has led one long-term study of 11- to 12-year-old children and their mothers to document how drug or alcohol abuse arises.

"Dale has helped to engage communities in research and bring a community-based, culturally relevant approach to research," said Dickerson.

Being named physician of the year is just another chapter in a career dedicated to helping American Indians. "The award will just motivate me to keep going," he said.

Information about One Sky Center is posted at <www.oneskycenter.org/>. ■

letters to the editor

continued from page 30

tertransference issues. Consider a "med-check" appointment. Does a mildly dysthymic patient who feels lonely need an antidepressant? The biological rationale most residents can identify: increase serotonin. But consider the psychological rationale. Perhaps the medication serves a role as a transitional object to the doctor. Perhaps it gives the patient hope that "someone cares." There are psychological undertones and implications of what we do as doctors in non-"therapy" appointments that are not insignificant and have therapeutic (and sometimes countertherapeutic) effects.

I write this letter to remind trainees as well as mentors that, in fact, there is a role for teaching psychotherapy skills in modern psychiatry, even during an era when HMOs rule the land and 15-minute med checks are the rule rather than the exception.

MATHEW NGUYEN, M.D.
Gainesville, Fla.

MH Groups

continued from page 4

said people with an interest in improving access to mental health care should engage in the health reform debate. Earlier in the summer, the Bazelon Center had focused on sending updates to supporters on features of various health reform bills, but in recent weeks the center began to urge them to take action to support reform.

"It's much more important that people who want reform be heard from at this stage, given the noise from the people who don't" want reform, she said.

The strongly held objections of health reform critics expressed at town-hall meetings about the high costs and expanded government role in health care parallel the reform-related advertising campaigns that are unprecedented in their size and scope. Nationwide, more than $57 million has been spent this year through August on advertising related to health care reform, according to media reports. At $48 million, proponents have far outspent opponents.

The spending is set to increase dramatically as Congress again takes up consideration of a health care reform package this month. Some of the funds will come from the AMA as a member of the new pro-reform coalition called Americans for Stable Quality Care. Other members include the Federation of American Hospitals, the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Service Employees International Union. The coalition announced plans in August to spend $12 million on a television advertising campaign aimed at winning support for current health reform plans.

PhRMA's spending on TV ads is expected to increase to a total of $150 million this fall, according to media reports. By way of comparison, the 2008 presidential campaign of Sen. John McCain spent $126 million on television ads.

The Bazelon Center's information on health care reform and its advocacy efforts is posted at <www.bazelon.org/issues/healthreform/index.htm>. APA's information is posted at <www.psych.org/MainMenu/AdvocacyGovernmentRelations/GovernmentRelations.aspx>. Mental Health America's information is posted at <www.nmha.org/>. ■

Records

continued from page 7

APA Department of Quality Improvement and Psychiatric Services, cited lingering privacy concerns of psychiatrists and other physicians in limiting their switch to HIT systems. Protecting the confidentiality of the patient-physician relationship is particularly critical in psychiatric care because of concerns about employment discrimination and social stigma toward people with mental illness, he noted.

Critics of the HIT effort also have questioned the ability of electronic patient records to reduce health care costs.

"I don't think it will save a bundle of money," said Uwe Reinhardt, the James Madison Professor of Political Economy and Economics at Princeton and a leading expert in health care financing, at a June briefing. "It will initially cost more [to clinicians] to put this in place, but I think it will enhance the quality of the treatment because it's much better informed."

Any cost savings from HIT use likely will come through the collection of electronic patient data by health care researchers looking for promising treatments and potentially dangerous medications, Reinhardt said.

Federal health officials echoed the research-based potential of the electronic patient record and assured the public that regulations will mandate that all personally identifiable patient data are removed before such records are shared with researchers.

A* New England Journal of Medicine *article by Blumenthal on the challenges of HIT is posted at <http://content.nejm.org/cgi/content/full/NEJMp0901592>. ■

Health Reform

continued from page 4

overhauling the health system (see article at top of page 4). Those efforts could be critical to spurring Congress toward enacting health care reform legislation this fall, a target set by President Obama.

Organizing for America, the reconstituted campaign organization of Obama, launched a nationwide bus tour earlier this month to spur passage of health reform legislation with stops in 11 cities—the last stop was in Washington, D.C., as Congress returned from its summer recess. Health Care for America Now, an umbrella organization of groups pushing for comprehensive health care reform, coordinated with the national Democratic Party to hold about 2,000 pro-reform events from late August to mid-September.

Also, mental health advocacy groups are urging their members to continue to contact their congressional representatives and speak out in support of a comprehensive overhaul that includes mental health provisions.

"If we want to be taken seriously, we need to be part of the process where members of Congress hear from their constituents," said Andrew Sperling, J.D., director of legislative affairs for the National Alliance on Mental Illness (NAMI), in an interview with *Psychiatric News*.

Sperling said September is a "critical stage of the process" to enact reform legislation. Members of Congress returned from recess after hearing what voters in their districts thought about the various reform proposals.

The Kaiser poll results are posted at <www.kff.org/kaiserpolls/posr082209pkg.cfm>. The* Health Affairs *poll is posted at <http://content.healthaffairs.org/cgi/content/full/hlthaff.28.5.w909/DC2>. ■

Alzheimer's

continued from page 1

development, and several have recently moved into phase 3 clinical trials (see table). Many molecules in the development pipeline, particularly biologics, target the formation or aggregation of beta amyloid, a peptide that is widely considered by scientists to play a key role in Alzheimer's pathology, particularly in the formation of protein plaques throughout the brain.

One of the drug candidates in phase 3 clinical trials is bapineuzumab, a monoclonal antibody that binds to beta amyloid and clears it from the brain. Johnson and Johnson recently bought the bapineuzumab development program from Elan, an Irish company, for $1.5 billion. However, doubts about bapineuzumab's efficacy emerged after it failed to achieve the primary endpoint in a phase 2 trial. Previous clinical-trial data also raised a safety concern about vasogenic edema, or accumulation of fluid in brain tissues, in some patients. Nevertheless, the trial suggested that the drug may be efficacious in a subset of patients who do not carry the apolipoprotein E4 (ApoE4) allele. The allele increases the risk for developing Alzheimer's, but not all Alzheimer's patients are carriers.

Eli Lilly also has an investigational monoclonal antibody known as solanezumab, in phase 3 clinical development. The antibody neutralizes beta amyloid.

Dimebon (also known as latrepirdine) is another promising candidate currently being tested in phase 3 clinical trials. The drug is a small molecule that was used for years in Russia as an antihistamine under the name of dimebolin. In a phase 2 clinical trial whose results were published in the July 19, 2008, *The Lancet*, patients with mild to moderate Alzheimer's who received dimebon for 26 weeks showed statistically significant benefits in cognitive functions compared with those who received placebo. The drug is being developed by Medivation and Pfizer.

Surprisingly, dimebon was shown to increase the level of beta amyloid in the brain, according to animal research studies released at the International Conference on Alzheimer's Disease (ICAD) in July in Vienna. The finding calls into question the pharmacological rationale and effectiveness of blocking beta amyloid in treating Alzheimer's.

At the ICAD, Abbott announced that it had terminated the development of one investigational drug for Alzheimer's. Two other molecules that interfere with the beta-amyloid formation process—tarenflurbil, developed by Myriad Pharmaceuticals, and tramiprosate, developed by Neurochem—have recently failed clinical trials. Nevertheless, beta amyloid remains the main target for development research.

Meanwhile, molecular targets other than beta amyloid are being explored by small and large pharmaceutical companies in search of magic bullets against Alzheimer's. Eli Lilly's semagacestat inhibits gamma-secretase and is in two phase 3 trials. NIC5-15, a plant-derived substance tested by Humanetics in phase 2 clinical development, is another gamma-secretase inhibitor with insulin-sensitizing effects. Gamma-secretase is involved in the production of beta amyloid, and its inhibition may decrease the production of beta amyloid.

Roche is testing R3487, a molecule it acquired from Memory Pharmaceuticals, as a treatment for both Alzheimer's and schizophrenia. The drug is a nicotinic alpha-7 partial agonist.

Baxter Healthcare and the National Institutes of Health are cosponsoring a phase 3 trial in Alzheimer's patients on the efficacy of an intravenous immunoglobulin product (gammaglobulin IV) it manufactures. In a retrospective, case-control study published in the July 21 *Neurology*, a history of intravenous immunoglobulin use was associated with a lower risk of developing Alzheimer's in four years. It has been speculated that passive immunization with a mixture of human immunoglobulins, or antibodies, derived from human plasma may remove beta amyloid from the body. Other vaccines targeting beta amyloid are also being investigated by pharmaceutical companies.

An abstract of "Effect of Dimebon on Cognition, Activities of Daily Living, Behaviour, and Global Function in Patients With Mild-to-Moderate Alzheimer's Disease: A Randomised, Double-Blind, Placebo-Controlled Study" is posted at <www.thelancet.com/journals/lancet/article/PIIS0140-6736(08)61074-0/abstract>. An abstract of "IV Immunoglobulin Is Associated With a Reduced Risk of Alzheimer Disease and Related Disorders" is posted at <www.neurology.org/cgi/content/abstract/73/3/180>. ■

Selected Drug Candidates in Development For Treating Alzheimer's Disease

Drug Name	Company	Mechanism	Phase
Dimebon (latrepirdine)	Pfizer/Medivation	Anti-beta amyloid	3
Bapineuzumab	Elan/Johnson & Johnson	Anti-beta amyloid monoclonal antibody	3
Semagacestat (LY450139)	Eli Lilly	Gamma-secretase inhibitor	3
Solanezumab (LY2062430)	Eli Lilly	Anti-beta amyloid monoclonal antibody	3
Gammaglobulin IV	Baxter	Passive immunization	3
CERE-110	Ceregene Inc.	Gene therapy to deliver the nerve growth factor gene	2
ACC-001	Elan/Johnson & Johnson	Anti-beta amyloid vaccine	2
PF-4360365	Pfizer	Anti-beta amyloid monoclonal antibody	2
NIC5-15	Humanetics	Insulin sensitization, gamma-secretase inhibitor	2
R3487	Roche	Nicotinic alpha-7 partial agonist	2

Katrina

continued from page 1

ernment Accountability Office (GAO) released in July.

Before Katrina, uninsured children and children from low-income families depended largely on Charity and University hospitals for health care, including mental health services. Charity Hospital has been closed since the hurricane. University has reopened but lacks the combined former capacity of the two hospitals. As a result, much health care has shifted to community-based mental health centers or school-based health centers that provide some mental health services. Two regional human services districts covering the area also offer some services to children. All of these services are at or near their capacity, said Potash.

Numerous federal agencies and programs provide support for mental health services in the region. Medicaid and the State Children's Health Insurance Program together cover 110,000 children in the area, and the Substance Abuse and Mental Health Services Administration funds a number of other programs.

The GAO survey of 18 government, social service, educational, and health care organizations in the area found that they had problems recruiting and retaining child psychiatrists, psychologists, and nurses. These difficulties have grown worse since the storm because many providers who left the area did not return. While from 2004 to 2006 the number of psychiatrists in the nation increased by 3 percent, the number in New Orleans decreased by 21 percent.

The local organizations also pointed out to the GAO the need for reliable funding streams and better reimbursement for services, especially for those rendered outside traditional clinic settings. Some federal programs have provided financial incentives for professionals to work in the New Orleans area, but many were temporary and are due to end this year or in 2010.

Poor public transportation, the loss of personal automobiles in the flood, competing family priorities (like housing problems and unemployment), and stigma about accepting mental health services also create barriers for families seeking help.

Those issues are addressed to some degree by the re-establishment of school-based health centers, said the report. Seven centers existed before Katrina but closed because of storm damage. However, there are now nine, and four more are planned. Locating health centers on school campuses eases transportation problems, and students from other schools can be driven to the centers if needed. Parents don't need to take off work to get their children to appointments, and including mental health services in these centers reduces stigma by masking the type of care a child receives.

Local health officials told the GAO investigators that they could not place a clinic in every school but would develop a system with hubs that would serve 10 feeder schools.

Limited referral services, including beds at local inpatient psychiatric hospitals, was another barrier cited by the GAO. That factor is now complicated by the closure in August of the New Orleans Adolescent Hospital (NOAH). Gov. Bobby Jindal's (R) February budget proposed closing the hospital, moving some patients across Lake Pontchartrain to the Southeast Louisiana Hospital in Mandeville, and expanding community-based services in the city.

The hospital served only young people before Katrina, but housed some adults after the storm.

Maintaining the status quo at NOAH in the face of budget shortfalls would call for significant cuts in existing services, according to a statement by Alan Levine, M.H.S., M.B.A., secretary of the state's Department of Health and Hospitals, justifying the decision. The state's plan shifts funds to expand local clinics, outreach teams, and other community-based systems of care and would also provide transportation to Mandeville for hospitalized patients' families, he said.

NOAH's vulnerability probably arose because it was to be reopened in stages after Katrina, said Potash. Not enough beds were put back into service to bring the per-bed cost down to expected levels, so the per-bed cost remained high.

Families of NOAH patients have filed suit to block the move, but the case won't be heard for several months.

"Both sides are genuinely concerned with the mental health of New Orleans' citizens, but they have different views on meeting those needs even with the financial constraints of the recession," said Potash, who favors keeping NOAH open. "But I haven't heard any clinical arguments for closing NOAH, only financial ones."

Some psychiatric beds remain in the city, primarily at the LSU Interim Hospital at DePaul, formerly operated by Tulane University.

Whether anyone can make a success of expanded community-based treatment is open to question, given the past failures of such ideals in the United States, said Potash. "To do it right, you would need a period of overlap with both in- and outpatient services, see if the outpatient services succeed, then phase out the inpatient services," he said.

That test won't be carried out in New Orleans, since NOAH has closed, but the outcomes will be watched closely.

"Barriers to Mental Health Services for Children Persist in Greater New Orleans, Although Federal Grants Are Helping to Address Them" is posted at <www.gao.gov/new.items/d09563.pdf>. ■

government news

Parity

continued from page 6

Legislatures in California and Michigan had not finished work for the year at press time and continued to consider enactment of parity expansions.

The Alaska bill is posted at <www.legis.state.ak.us/basis/get_fulltext.asp?session=26&bill=HB222>; South Carolina: <www.scstatehouse.gov/sess118_2009-2010/prever/390_20090514.htm>; Colorado: <www.leg.state.co.us/clics/clics2009a/csl.nsf/fsbillcont3/4B1364ED512F0F01872575890071DD65?open&file=1338_enr.pdf>; West Virginia: <www.legis.state.wv.us/Bill_Status/bills_text.cfm?billdoc=HB3288%20ENR%20SUB%202.htm&yr=2009&sesstype=RS&i=3288>; Arkansas: <www.arkleg.state.ar.us/assembly/2009/R/Bills/HB2195.pdf>. ■

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Use the many resources of the APA Job Bank at psych.org/jobbank to meet qualified candidates and make a smart recruitment decision. Advertise in the *Psychiatric Services* and/or *Psychiatric News* classifieds and the APA Job Bank and receive a 10% discount on each. Reach more psychiatrists at the Institute on Psychiatric Services with our bonus distribution of the *Psychiatric Services* October issue (deadline 9/3) and the *Psychiatric News* October 2 issue (deadline 9/4). For more information, contact Alice Kim at (703) 907-7330 or classads@psych.org

Candidates and Employers

During the meeting, stop by the APA Job Bank booth in the APA Member Center to search the database and ask a representative to demonstrate Job Bank features. The Institute on Psychiatric Services is the APA's leading educational conference on clinical issues and community mental health—for more information, visit psych.org/ips

APA Member Center and Job Bank

Location:	Sheraton New York Hotel and Towers Metropolitan Room, 2nd floor	
Hours:	Thursday, October 8	1:30 p.m. - 5:45 p.m.
	Friday, October 9	9:30 a.m. - 12:00 p.m.
		1:30 p.m. - 5:45 p.m.
	Saturday, October 10	9:30 a.m. - 12:00 p.m.

CLASSIFIED ADVERTISING INFORMATION

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All advertising copy, changes and cancellations received after the deadline will be placed in the next available issue. We do not provide proofs of ads before publication.

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 16	October 2
November 6	October 23

The publisher reserves the right to accept or reject advertisements for Psychiatric News. All advertisers in this section must employ without regard for race, sex, age, nationality, or religion in accordance with the law. APA policy also prohibits discrimination based on sexual orientation or country of origin. Readers are urged to report any violations immediately to the executive editor.

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ALABAMA

Taylor Hardin Secure Medical, a 115-bed state forensic psychiatric hospital, seeking licensed/or eligible in Alabama psychiatrists for adult patients committed by the circuit courts. BC in psychiatry required. Experience in forensic psychiatry preferred.
Psychiatrist III - 72 months+ experience in psychiatry with administrative experience ($134,968 - 205,792). See APA Job Bank related ad.
Psychiatrist II - graduation from an accredited school of medicine and Board Certified by ABPN. ($125,316 - 191,044)
Send resume to Joe K. Long, Director of Human Resources, Taylor Hardin Secure Medical, 1301 Jack Warner Parkway N.E., Tuscaloosa, AL 35404; or email clayton.shealy@hardin.mh.alabama.gov with questions. EOE

View the classifieds online at pn.psychiatryonline.org

ARIZONA

MEDICAL DIRECTOR

Aurora Behavioral Health System, a 90 bed JCAH accredited, psychiatric hospital located in Glendale Arizona is seeking a Board Certified Medical Director to join our management team. This position offers diverse clinical and administrative opportunities with oversight of a medical staff comprised of in house and private physicians. Our facility offers high quality mental health and chemical dependency programs for adults and adolescents. We are located in the Phoenix area and are only minutes away from professional sports venues, winter snow skiing, and renowned dining and shopping opportunities. Arizona licensure to practice medicine is required. Certification by the American Board of Psychiatry and Neurology required. Clinical hospital experience in psychiatry is required. Past administrative experience is preferred.

We offer a competitive salary and benefit package, including health insurance, malpractice insurance and a generous leave package including time off for CMEs. For consideration, please send your applications of interest to Laura Miller, Director of Human Resources at: Aurora Behavioral Health System, 6015 W. Peoria Ave, Glendale, AZ 85302.

ARKANSAS

LITTLE ROCK & FAYETTEVILLE-General & Child Psychiatrists. Admin/Clinical & Staff positions. Inpatient & partial programs. Fulltime or part-time positions offering very competitive salary, benefits & bonus. Contact Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc.com

CALIFORNIA

Large Psychiatric medical/legal practice throughout CA is expanding. We are looking for Psychiatrists to perform Workers' Compensation evaluations. Interested? Please call (800) 577-1717 ask Marlene

Psychiatrist Opening at the County of Santa Barbara. Our Lompoc Clinic ACT Program is actively recruiting for an ADULT BOARD CERTIFIED OUTPATIENT PSYCHIATRIST. Call ratio is one weekend out of every 2 months. Salary will pay up to $210,761 plus $5,927.74 cash benefit allowance. We also offer the opportunity for relocation assistance and other incentives. For a more detailed job description and to apply for the position please visit www.sbcountyjobs.com. You may also contact Tarah Cronquist at tcronquist@sbcountyjobs.com, or by calling at 805-884-8098. Job will be open until filled. The County of Santa Barbara strongly promotes diversity and equality in the workforce.

UC DAVIS SCHOOL OF MEDICINE DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

Health Sciences Assistant/Associate Clinical Professor - APSS Clinic. The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting for a Health Sciences Assistant/Associate Clinical Professor in the clinician/teaching series to serve as teaching attending at the Adult Psychiatry Support Services Clinic located next to the UC Davis Medical Center in Sacramento. The Clinic is staffed with four UC Davis faculty, two general psychiatry residents, and two medical students. Experience in teaching and supervision of medical students, residents, and other mental health professional is highly desirable. The successful candidate should be board eligible or certified in general psychiatry, be in possession of or eligible for a California Medical license, and have an interest in psychiatric education and training. The successful candidate will lecture in seminars and case conferences, and provide group and individual supervision of clinical cases. The incumbent will provide clinical teaching for general psychiatry residents, psychology fellows, medical students and other mental health professionals including timely and appropriate evaluation of trainee performance.

For full consideration, applications must be received by November 30, 2009. Position is open until filled, but no later than February 28, 2010. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-06R-09 to juli.koeberlein@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/

San Diego County needs psychiatrist for hospital, possible ER and telepsychiatry. Salary extremely competitive for San Diego - up to 170K plus 10% Boards and extra 5% second Boards. CV to Marshall Lewis, MD, Clinical Dir, County Behavioral Health Div, Marshall.Lewis@sdcounty.ca.gov. Apply now at www.sdcounty.ca.gov/hr.

Karl E. Douyon, M.D., Inc.
Psychiatrists are needed as independent contractors for Locum Tenens positions in California. Pay is $175 per hour depending on location. On call pay is extra. Hours are flexible for weekdays and some weekends. Call 805-644-4093. Fax resumes to 805-830-6300.
karledouyonmd.com

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4-10's and week-ends often available.
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Contact us at: (805) 703-3729 intuitivehealthservices@intuitivehealthservices.com
www.intuitivehealthservices.com

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 a teaching attending on the Psychosomatic Medicine Service located at the UC Davis Medical Center in Sacramento. The Unit is staffed with three UC Davis faculty, general psychiatry residents, and UC Davis medical students. Experience in teaching and supervision of medical students, residents, and other mental health professionals is highly desirable. The successful candidate should be board eligible or certified in general psychiatry, be in possession of, or eligible for, a California Medical license, and have an interest in psychiatric education and training. Completion of a fellowship in Psychosomatic Medicine is highly desirable but not required. The successful candidate will lecture in seminars and case conferences, and provide group and individual supervision of clinical cases. The candidate will also 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 November 30, 2009. Position is open until filled, but no later than February 28, 2010. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-07R-09 to Juli Koeberlein at juli.koeberlein@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/

CALIFORNIA
BC/BE STAFF PSYCHIATRIST

Patton State Hospital is recruiting board certified/eligible psychiatrists. Patton is a Joint Commission accredited, 1500 bed, adult forensic psychiatric hospital, with an extremely interesting and challenging patient population. The hospital is nestled below Arrowhead and the San Bernardino Mountains, 65 miles east of Los Angeles; an hour's drive to beaches, Palm Springs, or mountain lakes and skiing. Salary with Board Certification starts at **$18,622 and goes to $21,311 monthly.** Salary for Board Eligible starts at **$18,146 and goes to $20,711 monthly.** In addition, Patton offers excellent benefits (health, dental, and vision; license renewal; malpractice insurance; tax-deferred compensation; paid annual leave and 12 holidays (plus one personal holiday), as well as seven days per fiscal year of Continuing Medical Education leave). Voluntary on call duty is compensated on an hourly basis over and above base salary. We provide civil service security and retirement plans (including safety retirement). For confidential consideration, send CV to George Christison, M.D., (A) Medical Director, 3102 East Highland Avenue, Patton, California 92369, (909) 425-7326 or Fax (909) 425-6635.

UC DAVIS SCHOOL OF MEDICINE
DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

CHILD PSYCHIATRIST TEACHING ATTENDING. The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting a Health Sciences Assistant/Associate Clinical Professor for the Child Psychiatry Division. The position is in the clinician/teaching academic series. The individual will provide outpatient psychiatry services and teaching at the Child and Adolescent Psychiatry Clinic operated by the County of Sacramento. The clinic serves as a teaching site for general psychiatry residents, child psychiatry residents, postdoctoral psychology fellows and medical students. The successful candidate should be licensed or license eligible in the State of California and board eligible or certified in general psychiatry and child and adolescent psychiatry, 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 candidate will also provide clinical teaching for child and 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 December 31, 2009. Position is open until filled but not later than March 31, 2010. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-01R-10 to Juli Koeberlein at juli.koeberlein@ucdmc.ucdavis.edu. In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

http://www.ucdmc.ucdavis.edu/psychiatry/

UC DAVIS SCHOOL OF MEDICINE
DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

Chief, Addiction Psychiatry Division. The Department of Psychiatry and Behavioral Sciences at the UC Davis School of Medicine is recruiting a ladder rank/in residence Associate Professor or Professor of Psychiatry to develop a new Division of Addiction Psychiatry. The successful candidate will be proposed for an appointment to an endowed professorship in addiction psychiatry which is currently in the process of being established. The candidate will also be proposed for appointment to the Northern California VA Health System to coordinate substance abuse clinical services, research and education at their Sacramento site. The successful candidate should have a record of federally supported research in addiction psychiatry and experience in establishing and growing new research-oriented clinical enterprises. A start-up package will be provided so the candidate may recruit several additional faculty members with experience in addiction psychiatry research. The search committee is chaired by Professor Cameron Carter, Chief of the department's schizophrenia research program and Director of the medical center's Imaging Research Center. The successful candidate should be board certified in general psychiatry, and be in possession of, or eligible for, a California Medical license.

For full consideration, applications must be received by December 31, 2009. Position is open until filled, but no later than December 31, 2009. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-05R-09 to Juli Koeberlein at juli.koeberlein@ucdmc.ucdavis.edu and contact Professor Carter at cameron.carter@ucdmc.ucdavis.edu for more information. 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/

COLORADO

BOULDER: General or Child Psychiatrist. Staff and Admin/Clinical positions. Inpatient & Partial programs. Fulltime positions offering salary, benefits and incentive plan. Newly acquired UHS hospital. Contact: Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Horizon Health, the nation's leader in Psychiatric Contract Management seeks a **Psychiatrist** for a **10-bed Gero-psych** unit less than one hour from **Denver International Airport.** Attractive salary and benefits accompany this exciting new opportunity. Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. EOE.

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Full time psychiatrist, inpatient or outpatient service. Dept of Psychiatry at outstanding ommunity hospital in central CT. Experienced, collegial, professional, multidisciplinary team. Reasonable call, competitive salary & benefits. Respond in confidence to Robert Grillo MD, Chairman Dept Psychiatry Middlesex Hospital robert_grillo_md@midhosp.org

FULL-TIME/PART-TIME/PER DIEM ADULT PSYCHIATRIST
Central Connecticut

Full-time/Part-time/Per Diem opportunity for BC/BE adult psychiatrist at Saint Francis Hospital and Medical Center. You'll work in the adult psychiatric unit with a skilled, multi-disciplinary team of Master's-level therapists, nurses and mental health workers treating a broad spectrum of psychiatric patients. Additional responsibilities may include treating adult patients in a partial hospital or intensive outpatient setting. We offer flexible hours with an opportunity for permanent PT/FT position.

Our central Connecticut location offers a wide range of upscale suburban living choices and all the amenities of the New England region, including first-rate schools, and the pleasures of country and coastal environments. Close proximity to professional sporting events, concerts, ballet, theatres, skiing and boating, and less than two hours to Boston and New York.

For more information about this opportunity, please contact Christine Bourbeau in the Recruitment Office at 800.892.3846 or fax/email your CV to 860.714.8835

Email address: cdoughti@stfranciscare.org
Please visit our website at:
www.saintfranciscare.com

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DELAWARE

WILMINGTON / NEWARK & DOVER: Child Psychiatrist. Inpatient/partial programs. Very competitive salary, benefits & incentive plans. Will sponsor visa candidates. Contact Joy Lankswert @ 866-227-5415; OR email joy.lankswert@uhsinc.com

DISTRICT OF COLUMBIA

Washington, DC
George Washington University Medical Center

Founded in 1977, this ACGME-accredited fellowship in Psychosomatic Medicine is currently accepting applications for three PGY-V positions starting July 1, 2010. Under the guidance of **Thomas N. Wise, M.D.** and **Catherine C. Crone, M.D.,** the fellowship offers training in both inpatient and outpatient settings at a large tertiary care teaching facility that provides care to a diverse socioeconomic and cross-cultural patient population. This includes extensive experience in oncology, Ob-Gyn, HIV, pulmonary, cardiology, and organ transplantation. Emphasis is placed on a balance of clinical experience and didactic teaching addressing the biopsychosocial approach to understanding the medically ill patient. The experience is enhanced further by constant mentoring throughout the academic year along with efforts to tailor the training experience according to the individual fellow's interests and career goals. Opportunities in teaching, research, and outpatient psychotherapy are readily available and strongly encouraged. The program is based at Inova Fairfax Hospital, an 833-bed hospital located near Washington, D.C.

Interested individuals should contact
Catherine C. Crone MD, Fellowship Director
George Washington University Medical Center
c/o Inova Fairfax Hospital
3300 Gallows Rd, Falls Church, VA 22042
(703) 776-3380 Fax: (703) 776-3029
cathy.crone@inova.org

ASSISTANT/ASSOCIATE PROFESSOR - Psychiatry

Howard University invites applications for two tenure-track, assistant/associate professor positions, to begin immediately. Candidates are sought for full time academically oriented psychiatrists to work in our Outpatient Mental Health Clinic program and community based sites. Preference will be given for an addiction psychiatrist for one position. With a faculty appointment, opportunities for resident and medical student supervision, teaching, and involvement in funded clinical research programs will be available. Candidate must be able to be Licensed in the District of Columbia, Board Eligible or Certified in the practice of adult/child psychiatry, and be a citizen of the United States or a permanent resident alien. Salary will commensurate with qualifications and experience. Interested applicants should submit a letter of interest, CV, four recommendation letters to: William B. Lawson, MD, PhD, Chair, Department of Psychiatry and Behavioral Sciences, Howard University Hospital, 2041 Georgia Avenue, N. W., Washington, D. C. 20060; or by email to wblawson@howard.edu : Review of applications will begin immediately until position is filled. Howard University is an HBCU located in downtown Washington that is an AA/EOE/ADA employer DC. Women and members of underrepresented groups are encouraged to apply; an. Howard University does not discriminate on the basis of race, color, national and ethnic origin, sex, marital status, religion or disability.

FLORIDA

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PSYCHIATRISTS to provide inpatient, outpatient and/or community-based services in JCAHO-accredited comprehensive mental health center in **Jacksonville, Florida.** Must be Board Certified or Board Eligible and possess Florida medical license. Full-time position with competitive salary and benefits package. Other part-time opportunities also available. For additional information, contact: Robert Sommers, Ph.D., President/CEO, Renaissance Behavioral Health Systems, Inc., P.O. Box 19249, Jacksonville, FL 32245. Phone: 904-743-1883, ext. 7103. Fax: 904-743-5109. Email: rbhspres@bellsouth.net

GEORGIA

MEDICAL DIRECTOR - BEAUTIFUL AREA - CLOSE TO TALLAHASSEE, FL - Seeking Psychiatrist to head up the very impressive adult and geropsychiatric services (inpatient, PHP & outpatient) in a general hospital in south GA. Opportunity for telepsychiatry. Offering very attractive salary w/benefits and bonus plan. Great quality of life: great climate; great opportunity-have it all. Please **call Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

ATLANTA: General, Geriatric & Child Psychiatrists - Inpatient & partial programs. Full-time or Part-time positions (Mon-Fri) offering salary, benefits & bonus plans. Admin/clinical opportunity for qualified/interested candidates. Weekend moonlighting also available for day shifts only at several UHS hospitals - no overnight call.
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Hospitalist Psychiatrist position and an Office-Based position with a dynamic and expanding 53-bed, adult behavioral health center. Programs include adult psychiatry, chemical dependency and geriatrics, and all patients are admitted on a voluntary basis.

Nestled in the foothills of northwestern Georgia, Rome is surrounded by seven hills and the Coosa, Etowah and Oostanaula Rivers. Rome is a unique small city that has been recognized as the "Number One Small City in the Southeast" and is an hour from Atlanta as well as Chattanooga. Rome boasts a flourishing health care community with more than 350 practicing physicians. Our area enjoys a mild climate and offers quality educational and cultural opportunities.

Floyd offers a competitive salary with great benefits and bonus opportunities. This position is available for J-1 Visa candidates and the qualified candidate will be joining a successful, experienced psychiatric physician already practicing in this role. Outstanding compensation includes full benefits and relocation for the right executive. For confidential consideration, please apply online at www.floyd.org. For more information email Cami Legacy (clegacy@floyd.org) or call 706.509.3964.

KENTUCKY

Radcliff - easy commute from LOUISVILLE: Child or General Psychiatrist for inpatient & outpatient services. Highly competitive salary, benefits, & bonus. Will sponsor visa candidates. Contact Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc.com

LOUISIANA

CHILD PSYCHIATRISTS - DEPARTMENT OF PSYCHIATRY AND NEUROLOGY, TULANE UNIVERSITY SCHOOL OF MEDICINE in New Orleans, LA, is recruiting for BE/BC child psychiatrists at the instructor or assistant professor level, salary commensurate with experience. Clinical responsibilities available in the areas of inpatient psychiatry, community based child and adolescent psychiatry, and early childhood mental health. Teaching responsibilities include the supervision of residents, clinical psychology fellows and interns, and medical students rotating through the clinical facilities serviced by this position as well as the presentation of grand rounds and participation in the didactic series in child psychiatry. Clinical research is strongly encouraged. The persons selected must be professionally competent and be board eligible/certified in general psychiatry. She/he must be eligible for medical licensure in the State of Louisiana and have a current state and federal narcotics number. In addition, candidates must be eligible for clinical privileges at Tulane University Hospital and Clinic under the appropriate staff category and must agree to abide by those privileges as outlined by the current bylaws of the institution. Applications will be accepted until a suitable qualified candidate is found. Send CV and list of professional/academic references to Charley Zeanah, Jr, MD, Professor and Vice Chair, Child and Adolescent Psychiatry, Tulane University School of Medicine, Department of Psychiatry and Neurology, 1440 Canal Street TB52, New Orleans, LA 70112 (czeanah@tulane.edu). Tulane is strongly committed to policies of non-discrimination and affirmative action in student admission and in employment.

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, 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. In addition, candidates must be eligible for clinical privileges at Tulane University Hospital and Clinic under the appropriate staff category and must agree to abide by those privileges as outlined by the current bylaws of the institution. Applications will be accepted until suitable qualified candidates are found. Send CV and list of references to Daniel K. Winstead, MD, Heath Professor and Chair, Department of Psychiatry and Neurology, Tulane University School of Medicine, 1440 Canal Street TB48, New Orleans, LA 70112. For further information, you may contact Dr. Winstead, at 504-988-5246 or winstead@tulane.edu. Tulane is strongly committed to policies of non-discrimination and affirmative action in student admission and in employment.

The Department of Psychiatry and Neurology at Tulane University School of Medicine is recruiting a geriatric psychiatrist for a full-time faculty position. The candidate will spend part of their time at the Southeast Louisiana Veterans Health Care System (SLVHCS) and will also be involved in the new initiatives in both clinical geriatric care and special geriatric education programs at Tulane. Responsibilities include patient care as well as contributing to the various teaching and training programs of Tulane University's Department of Psychiatry and Neurology at the SLVHCS. He/she will be provided the opportunity to pursue their research interests. The person selected for this position must be professionally competent and be board eligible/certified in general psychiatry and in geriatric psychiatry. She/he must be eligible for medical licensure in the State of Louisiana and have a current state and federal narcotics number. In addition, candidates must be eligible for clinical privileges at Tulane University Hospital and Clinic under the appropriate staff category and must agree to abide by those privileges as outlined by the current bylaws of the institution. Salary will be competitive and commensurate with the level of the candidate's academic appointment. Applications will be accepted until a suitable qualified candidate is found. Applicants should send letter of interest, updated CV and list of references to Daniel K. Winstead, MD, Heath Professor and Chair, Department of Psychiatry and Neurology, Tulane University School of Medicine, 1440 Canal Street TB48, New Orleans, LA 70112. Interested and eligible candidates may obtain further information by contacting Daniel K. Winstead, MD at 504-988-5246 or winstead@tulane.edu. Tulane is strongly committed to policies of non-discrimination and affirmative action in student admissions and in employment.

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
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- Part of nationally renowned health system of 7 hospitals, 700+ member physician group, and 35 health centers
- Very competitive salary and benefits
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- Favorable malpractice environment in Louisiana
- Ochsner Health System is an equal opportunity employer.

Please email CVs to: profrecruiting@ochsner.org or call (800) 488-2240. Ref# APSTA09. EOE.

The Southeast Louisiana Veterans Health Care System (SLVHCS), formerly the New Orleans Veterans Affairs Medical Center and the Department of Psychiatry and Neurology at Tulane University School of Medicine seek a candidate to fill the position of Chief, Mental Health Service at SLVHCS. All candidates will have clinical, administrative, teaching and research responsibilities and must be board eligible/certified and have academic credentials to be qualified for a faculty appointment at Tulane University School of Medicine

Applicants should have both clinical and administrative experience, and may be psychiatrists, psychologists, nurses, or social workers. A doctoral degree is required. Applicants must possess a knowledge and understanding of health care policies, missions, and operating programs, and be knowledgeable about mental health care delivery and about mental health information management. He/she will be involved in the design of the Mental Health areas of the new VA hospital planned for Southeast Louisiana. United States citizenship or permanent residency is required. Salary and academic rank will be commensurate with qualifications and experience of the applicant.

We will continue to accept applications until a suitable qualified candidate is found. Interested applicants should mail a curriculum vitae with a list of 7 references to Daniel K. Winstead MD, Tulane Dept. of Psychiatry and Neurology, 1440 Canal Street TB48, New Orleans, LA 70112 or e-mail CV and references to winstead@tulane.edu. Tulane is strongly committed to policies of non-discrimination and affirmative action in student admissions and in employment.

MAINE

Make a difference as the Psychiatric Medical Director of our innovative Portland, Maine community mental health agency. You'll direct a small team of psychiatrists, nurse practitioners, and therapists serving the mental health needs of adults, children, and families. Your primary responsibilities involve supervision, team leadership, supporting clinical integrity, and provision of direct service, with limited after-hours on-call responsibility. This is an excellent opportunity to work with a team to provide innovative client-centered service.

Our location in Greater Portland provides a robust network of professional colleagues, and the cultural amenities of a vibrant small city on the ocean. Portland, listed in two dozen surveys as one of the top 10 most desirable places to live in the US, is connected by Amtrak to Boston (two hours away), and is just an hour from a variety of mountains, lakes and rivers.

Send resume and cover letter to Kristen O'Gara, HR Office, Youth Alternatives Ingraham, 50 Lydia Lane, So. Portland, Me. 04106.

MASSACHUSETTS

Boston area (Lynn) BayRidge Hospital, a nonprofit psychiatric facility on Boston's North Shore, a teaching site for Boston University Medical School, will have a position for an inpatient/partial hospital psychiatrist in January, 2010. This is an opportunity to work in a collegial atmosphere with strong support. No required night call, but participation in a lucrative call system is optional. Full benefit package includes generous time off as well as reimbursement for malpractice insurance and CME.. Contact Barry Ginsberg, M.D., Medical Director, 60 Granite Street, Lynn MA 01904. Phone (781) 477-6964, Fax (781) 477-6967, email bginsber@nhs-healthlink.org

High Point Treatment Center is seeking a 40 hr week psychiatrist to allocate 20 hrs managing 8-beds Inpatient Psychiatric Unit and 20 hrs allocated to outpatient services located in Plymouth, MA. Salary ranging from $170,000 - $190,000. No weekends, paid holidays and leave time. Health benefits available. If willing to work an additional 1 hr per day salary range would be $200,000 - $215,000. If interested, please contact Jim Horvath at 508-503-2455 or email to jim.horvath@hptc.org.

MARLBOROUGH, MASSACHUSETTS - UMass Department of Psychiatry is seeking candidates for a full time psychiatrist at its affiliated general hospital in Marlborough, Massachusetts. The position primarily involves providing treatment and clinical care supervision on the unit's superb partial hospital program and some amount of inpatient coverage. Our Department of Psychiatry has a large clinical faculty with clinical, teaching and academic opportunities at a wide variety of inpatient and outpatient programs. We have faculty development programs, commitment to our care, training and research missions, and a great living and learning environment in Central Massachusetts. If you want to know more about job opportunities or the department in general, please email psychiatryrecruitment@umassmemorial.org or fax to 508-856-5990. AA/EOE

Starr Psychiatric Center seeks a 20-30 hr psychiatrist for dynamic established psychiatric practice On Boston's South Shore. Medical model, multi-disciplinary staff. Stimulating environment, good pay. Clinic has a reputation for successful care, where others have failed. Email davidzstarr@juno.com or call 508.580.2211.

BOSTON areas - Brookline, Jamaica Plain, Pembroke, Lowell and Westwood: Child & General Psychiatrists. Inpatient/partial programs. Staff & Medical Director Positions depending on location. Very competitive salaries, benefits & incentive plans. **NO CALL.** Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com

MICHIGAN

GRAND RAPIDS - Staff Psychiatrist. Inpatient and Outpatient practice position. Collegial clinical care & work environment. Very competitive salary & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

MISSOURI

KANSAS CITY - Staff and potential Admin/Clinical positions. General and specialty inpatient and Partial programs. Fulltime position s offering salary, benefits and incentive plan. Contact Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc.com

Outstanding Financial Opportunity - Close to Springfield - 2 Positions Available -Inpatient and/or outpatient work in southwest MO. Strong hospital support for behavioral health. Unit is a 10-bed geropsychiatric program. Medical Director position available. Can offer salary w/benefits, or income guarantee, or contract with local physician's practice. Psychiatrists with National Health Service Corp. obligation welcome. Please **call Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

MONTANA

Rocky Mountain Paradise! Consider an exciting new practice opportunity for two NEW distinct **Adult** and **Geriatric** Inpatient Psychiatric Units, comprised of **26** total beds in **Helena, MT.** Nestled beneath the foothills of the Montana Rockies, **Helena,** the Capital of Montana, is alive with history and culture. This charming and beautiful Victorian city of 70,000 people provides a diverse attraction with many street festivals, theater, museums, symphonies, fairs and rodeos. There is truly something for everyone here! Excellent practice opportunity with great income ($200K+) and unparalleled quality of life! For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

NEW HAMPSHIRE

Staff Psychiatrist in New England - Package of 180K-210K - Rich Benefits and 15K in Tax Savings. Inpatient focused responsibilities based at Concord Hospital in Concord, NH. Require ECT training/experience. Interest in TMS is desired. Option to participate in clinical teaching. EMR. One hour to Boston, the White Mountains, or the Atlantic Coast. No state income tax or sales tax. **Germaine Lorbert at 800-678-7858, x63704 or glorbert@cejkasearch.com; www.cejkasearch.com.** ID#133805PY.

NEW JERSEY

Psychiatrist - Adult/Child - Immediate Opening Full/Part Time. Work independently in Brand New Facility, all support services included.
Beautiful location and office. Fax CV to Denise Hunt @732701-8418 or email: dhunt@bridgementalhealth.com

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CHILD & ADOLESCENT PSYCHIATRIST/GENERAL ADULT PSYCHIATRIST

Child psychiatrist and General Adult Psychiatrist to join unique, private, fee for service, child, adolescent & adult therapy Center in New Jersey. Center provides wide array of services, provides high quality care, is successful and continues to grow. Locations in Cedar Knolls, Westfield, Ridgewood and Princeton. Openings currently available in each location. Compensation is generous. Hours are flexible. Collegial atmosphere is quite pleasant. E-mail CV to abbazn@aol.com.

Westampton Township - Just East of Philadelphia. Addiction Psychiatrist or General Psychiatrist with interest in dual diagnoses. Dual Diagnoses Unit. Very competitive compensation and benefits. No on site weekend call required. Contact Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc.com

NEW MEXICO

New Mexico Behavioral Health Institute // Las Vegas, New Mexico // Psychiatry Opportunities.

Board Certified/Board Eligible Psychiatrists sought for the State Psychiatric Hospital of New Mexico. Inpatient, Outpatient, Forensic, Geriatric and Child/Adolescent opportunities available.

Extensive Benefit Package, Generous Retirement Plan, Competitive Salary, Flexible Work Schedule. H1 and J1 positions available. In lieu of benefits individuals may opt to contract their services at a very favorable hourly rate.

Location qualifies for up to $5,000/year State Income Tax Rebate and for up to $25,000/year Student Loan forgiveness.

Las Vegas, New Mexico is a beautifully located community at the foothills of the Sangre de Cristo Mountains and is a mere one hour drive from historic Santa Fe and 2 hour drive from metropolitan Albuquerque.

Contact:
Anthony R. Martinez, M.D., Clinical Director
505-454-2416
anthony.martinez1@state.nm.us.
New Mexico Behavioral Health Institute
3695 Hot Springs Boulevard
Las Vegas, New Mexico 87701.
Application instructions at SPO Website:
www.state.nm.us/spo
EOE

NEW YORK CITY & AREA

Psychiatrist - Outpatient

The highly regarded **Pederson-Krag Center** offers positions in the following programs:
ACT - provide on and off-site services collaborating with our multi-disciplinary Smithtown team (P/T)
Partial Hospitalization Program - provide intensive short-term treatment with our Huntington multi-disciplinary team (P/T)
Mental Health Clinic - provide assessments, consultations and treatment services in our clinic programs (P/T)
Positions can be combined for a full-time position.
Flexible schedule. Excellent benefits. Competitive salary.
Mail CV to **Roger Kallhovd, M.D., Pederson-Krag Center, 55 Horizon Drive, Huntington, N.Y. 11743 or fax 631-920-8165 EOE/AA**

PSYCHIATRISTS

Lutheran Medical Center and Lutheran Family Health Center in Southwest Brooklyn, offering a continuum of community-oriented behavioral health services within the Department of Psychiatry, have openings available for the following:

AMBULATORY CLINIC - F/T - ADDICTION & ADULT PSYCHIATRISTS - Tailored for psychiatrists with expertise in psychopharmacology, but also multidisciplinary team participation, where therapists prepare treatment plans. We welcome interests in teaching, geriatrics, HIV populations, and/or Clozaril, among others. Our Ambulatory team offers treatment in facilities that have a federal HPSA (Health Profession Shortage Area) designation for loan repayment purposes, a financial plus. Bilingual English/Spanish, Chinese or Arabic is considered a premium.

INPATIENT/ED MOONLIGHTING PSYCHIATRISTS - Rare blocks of weekly Moonlighting shifts available (Weeknights, Weekends and Holidays) for NYS-licensed Psychiatrists to cover ED/CL/Detox Services and/or Adult Psych Unit. Includes payment of Part-Time malpractice insurance premiums if contracting for blocks of shifts. Ideal setting for Fellows, part-time & pvt practice Psychiatrists to stabilize income in a physician-friendly setting!

Please fax 718-630-8594, email: tirvin@lmcmc.com or send resume/CV to: Tracey Irvin, Dept. of Psychiatry, Lutheran HealthCare, Suite 2-45, 150 55th Street, Brooklyn, NY 11220. EOE/AA M/F/D/V

LUTHERAN HEALTHCARE
www.LutheranHealthCare.com

Child and Adolescent Psychiatrist
P/T - 10-15 hours per week (evenings and/or weekends) in a Child and Family Mental Health Center in Brooklyn. Excellent compensation. No call. Fax resume to (718) 553-6769, or email to clinicaldirector@nypcc.org

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Outpatient Psychiatrists

The Department of Psychiatry at The Mount Sinai Medical Center in Manhattan has an opening for a General Adult Psychiatrist. The FT/PT position includes outpatient work at the World Trade Center Mental Health Program with opportunities for teaching and clinical research. The position will include an academic appointment commensurate with experience. Qualified candidates will possess an MD or DO degree, be board eligible or certified in General Adult Psychiatry and preferably have additional experience in treating mood and anxiety disorders. Spanish and/or Polish speaking physicians are strongly encouraged to apply. The Mount Sinai Medical Center is a premier 1,171 bed tertiary-care facility internationally acclaimed for excellence in clinical care, education and scientific research in nearly every aspect of medicine.

Interested applicants should contact Fatih Ozbay, MD, Associate Medical Director of the WTC Mental Health Program at (212) 241 8462 or email fatih.ozbay@mssm.edu

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PSYCHIATRISTS

FEGS, a leading provider of behavioral health services in the NY metropolitan area, seeks Board Certified/Eligible Psychiatrists for psychiatric evaluations & medication management. FT and PT opportunities available in a variety of outpatient clinics/programs. Flexible options.

BRONX
North Bronx: Article 31 Clinic, Article 16 Clinic, Continuing Day Treatment Program
South Bronx: Child and Adult Psychiatrist for Article 31 Clinic

QUEENS
Rego Park: Article 31 Clinic

Competitive salary, no on-call responsibilities, with malpractice insurance covered by agency. Bilingual Spanish a strong plus. Opportunity for comprehensive, generous benefits. EOE

Apply online at the FEGS Career Website: www.fegs.org/careers
Search by title of Psychiatrist to view all current openings.

On Call Psychiatrists: Psychiatrists, Fellows and Senior Residents to cover days, nights, weekends and Holidays in the Psychiatric Emergency Department at the Long Island College Hospital. Please fax resume to: THE LONG ISLAND COLLEGE HOSPITAL, DEPARTMENT OF PSYCHIATRY, 339 Hicks Street, FAX: (718) 780-1827 Attn: Judith Velez or call 718-780-1065.

Upper Manhattan OR Westchester Child/Adol Assoc Clin Dir. 1 FT or 2 PT pos
Inpt academic clin care with leadership, admin & teaching duties. Daytime hrs- no call, wknds or ev's. 25 day LOS, little mg'd care. AdolMD@gmail.com or 917-710-2456

NEW YORK STATE

ELMIRA PSYCHIATRIC CENTER
Adult and Adolescent Psychiatrists

Board Certified - $172,269 - $176,903
Licensed Physician - $141,751
Limited Permit - $107, 318 - $115,905

- All positions **M-F 8-4:30** with **no managed care insurance demands**
- **Optional** participation in a low stress on-call program with **potential** to earn up to an **extra $74,000/year**
- Student loan repayment available
- Excellent NYS benefits package
- Inpatient, Outpatient and Day Treatment services
- Our location offers: quality housing prices; little traffic; regional airport; Cornell University; 4hr drive to NYC, Toronto & Philadelphia; 5 ½ hr drive to Boston & DC; less than 1hr to Finger Lakes

For further info contact: Patricia Santulli, Director of Human Resources at: Elmira Psychiatric Center, 100 Washington Street, Elmira, NY 14901 or e-mail: elpopms@omh.state.ny.us or call: (607) 737-4726 or fax: (607) 737-4722
An AA//EOE Employer

Central New York Psychiatric Center, a state-operated, JCAHO Accredited facility, is seeking Psychiatrists for full-time positions at its main Inpatient Facility in Marcy, NY, and at its Forensic Outpatient Units throughout New York State, including: Albion, Auburn, Elmira, 5 Points (Romulus) and the Regional Mental Health Unit (Marcy). A position is also anticipated in the Hudson River Area.
- Comprehensive NY State Benefits package available
- Outstanding NY State Pension Plan
- Opportunity for Loan Forgiveness Program
- Opportunities exist for additional compensation

Assistant Psychiatrist: $104,192-$115,970 (general salary increases of 3% in 2009 and 4% in 2010 are scheduled)
Qualifications: Possession of a NY State Limited Permit AND completion of a training program in psychiatry approved by the American Board of Psychiatry and Neurology for entrance into their certifying examination AND eligibility for full and unconditional participation in Medicaid and Medicare programs.
Psychiatrist 1: $161,751 (general salary increase of 4% in 2010 is scheduled)
Qualifications: Possession of a License to practice medicine in NY State OR possession of a Limited Permit and licensure in another state or by written examination in Canada; AND completion of a training program in psychiatry approved by the American Board of Psychiatry and Neurology for entrance into their certifying examination; AND eligibility for full and unconditional participation in Medicaid and Medicare programs.
Psychiatrist 2: $169,707 (general salary increase of 3% in 2009 and 4% in 2010 are scheduled)
Qualifications: Possession of a license to practice medicine in NY State OR possession of a Limited Permit and licensure in another state or by written examination in Canada; AND certified in psychiatry by the American Board of Psychiatry and Neurology; AND eligibility for full and unconditional participation in Medicaid and Medicare programs.

Dr. Jonathan Kaplan, Clinical Director
Central New York Psychiatric Center
Box 300 Marcy, NY 13403
Phone: (315) 765-3624 Fax: (315) 765-3629
E-Mail CN00025@OMH.STATE.NY.US

Ulster County Mental Health, an outpatient clinic with a wide range of services, has a potential opening for Staff Psychiatrist. Position requires a recovery-oriented board certified or board-eligible community psychiatrist to treat adult patients. AOT interest is a bonus. UCMH is located in the beautiful Hudson Valley, two hours north of NYC. Competitive salary, on-site psychopharmacology supervision and collegial atmosphere. No on-call or weekends. Hours and benefits to be determined. FAX CV to JuLita Adamczak, MD, Medical Director, FAX #845-340-4094.

Western New York-Chautauqua Region: Jamestown Psychiatric PC is seeking a Psychiatrist to join our rapidly growing Adult and Child Psychiatric team. Competitive salary and flexible growth opportunities are offered. We will offer a starting bonus to eligible candidates. Loan repayment, J1 or H1 assistance available. Please contact Mrs. Linda Jones, office manager @ lj@psychwebmd.com or Phone 716-483-2603. Fax CV and qualifications to 716-483-2828.

St. Lawrence Psychiatric Center, a fully accredited NYS Office of Mental Health facility, seeks psychiatrists licensed or license-eligible in NY, to work in an outpatient clinic setting. Applicants interested in adult, children/youth, and sex offender inpatient opportunities are also encouraged to apply. In addition to salary ($161,750 to $174,198) and guaranteed additional compensation for voluntary participation in an on-call program, benefits package includes medical/dental/vision insurance, paid vacation, holiday and sick time, an excellent retirement plan, and educational and professional leaves. SLPC is an EO/AAE, federally designated as MHPSA.

Located on the scenic St. Lawrence Seaway in northern New York, St. Lawrence Psychiatric Center is located within reasonable driving distance of many cultural, educational and economic opportunities, including metropolitan Ottawa and Montreal, Canada, and Syracuse, NY. Close proximity to the Adirondack Mountains and Canada offers easy access to a wide variety of unspoiled natural areas and provides abundant recreational opportunities throughout the year.

Submit letter of interest to: Rosella Turnbull, St. Lawrence Psychiatric Center, One Chimney Point Drive, Ogdensburg, NY 13669 or at slmrrmt@omh.state.ny.us. If you have questions, please call (315) 541-2189.

OKLAHOMA

PSYCHIATRIST POSITION

Jim Taliaferro Community Mental Health Center, Oklahoma Department of Mental Health and Substance Abuse Services, is seeking a BE or BC Psychiatrist. Located in southwestern Oklahoma, Lawton is the fourth largest metropolitan area in Oklahoma with a population of 114,916 and 90 miles from Oklahoma City Metro. Area attractions include Lawton Community Theater, Lawton Philharmonic Orchestra, Cameron University, Fort Sill Army Installation, Wichita Mountain Wildlife Refuge, and numerous lakes. Excellent salary and benefits to include health, dental, and retirement plans. Base salary is $185,000 (BE) and $195,500 (BC) with additional potential income of $46, 000 per annum for on-call services. Eligible H-1B visa psychiatrist applicants welcome. Mail or fax CV to HR, ATTN: Sam Banks, Jim Taliaferro Community Mental Health Center, 602 SW 38th St. Lawton, OK 73505, (f): (580) 248-3610, (p): (580) 248-5780. EOE.

PENNSYLVANIA

Horizon Health, in partnership with **St. Vincent Health Center (Voted 5th Best Place to work in Pennsylvania!),** a 436-bed tertiary care hospital in **Erie, PA,** has an exciting opportunity for a **Medical Director** for a **32-bed** Adult and Geriatric Inpatient Psychiatric Program.
Opportunities for input and growth, tertiary care, teaching opportunities in FP residency program and LECOM medical school. Excellent compensation package with full benefits.
Located on the shores of **Lake Erie** with 7 miles of beaches, Erie is the **fourth largest city** in Pennsylvania with a metropolitan population of 280,000. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com
EOE.

Outpatient Clinical Director

The Philadelphia VA Medical Center (PVAMC) seeks candidates for the full-time Director of the Behavioral Health Outpatient Program who will be responsible for the administration of the Mental Health Clinics which provide treatment to approximately 7000 veterans in the Philadelphia area. The PVAMC Behavioral Healthcare Service provides a full range of high quality, restorative and preventative behavioral health services to the veteran population including evidence based psychotherapies. The Philadelphia VAMC is affiliated with the University of Pennsylvania and a faculty appointment may be available in the university's department of Psychiatry. Full federal benefits; including tuition reimbursement under the Education Debt Reduction Program. Salary is commensurate with experience.

Applicants must have U.S. citizenship; M.D. or equivalent degree; an unrestricted license and proficiency in spoken and written English. Demonstrated excellent qualifications in Clinical Care, Education, and Research; ABPN certification or eligibility in Psychiatry are required.

The PVAMC is an equal opportunity, affirmative action employer.

Please submit curriculum vitae, a cover letter, and references to: Philadelphia VA Medical Center, 3900 Woodland Avenue, Philadelphia, PA 19104, Attn: Announcement #297-09

Psychiatrists:

Currently we have exciting full- and part-time positions in a rapidly expanding department. Opportunities include responsibilities in and outside our five-hospital health system. There are immediate openings for child/adolescent, adult and addictions psychiatrists.

There are also practice options in a traditional psychotherapy model. Evening and weekend positions also available. Excellent salaries, no on-call nor rounding responsibilities ever and exceptional benefits package offered. Send CV to Kevin Caputo, M.D., Vice President and Chairman, Department of Psychiatry, Crozer-Keystone Health System, One Medical Center Blvd., Upland, PA 19013 or contact the department manager, Kathy Waring at 610-619-7413

One Hour From Downtown Philadelphia; One and a Half Hours to Baltimore - Seeking a Psychiatrist to work on new 10-bed inpatient geropsychiatric unit in an impressive med/surg hospital in a beautiful Lancaster—close to Harrisburg. Adult unit here as well. Offering attractive salary/benefits, relo pkg, and bonus plan. Great quality of life in a fabulous location. Please call **Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

PHILADELPHIA - Child Psychiatrist - Residential, Inpatient and/or Partial Programs. **CLARION (Western PA) and SHIPPENSBURG (near Harrisburg) - J1 & H1 Eligible.** General or Child Psychiatrists for inpatient & partial program services. Very competitive salary, benefits and incentive plans. Contact Joy Lankswert @ 866-227-5415; OR email joy.lankswert@uhsinc.com

RHODE ISLAND

Lead Psychiatrist/Medical Director Adult Services

The Kent Center a nationally recognized progressive CMHC is seeking a team oriented Board Certified/Board Eligible Adult Psychiatrist whose professional goal aspires to provide medical leadership and direction to a team of colleagues and associate staff while continuing to provide direct client care.

Our Psychiatric Consultation Service Team provides direct psychiatric services to a diverse population focusing on recovery of adult clients with mental health disorders, trauma, and substance abuse.

Team responsibilities include comprehensive evaluations, treatment planning, medication prescribing and monitoring of clients, and consultation services to members of clinical treatment teams.

Competitive salary, comprehensive benefit package including 4 weeks vacation, Blue Cross/Blue Shield medical, dental, life and long term disability insurance and 401K retirement plan. Send resume to Director of Human Resources, The Kent Center, 2756 Post Road, Suite 104, Warwick, RI 02886. Fax 401-691-3398.or e-mail Hr@thekentcenter.org EOE.

Psychiatry

Psychiatrist Adult, Inpatient and Outpatient (Mood Disorders)

The Department of Psychiatry, Rhode Island Hospital, a Lifespan partner and Brown University affiliated program, is seeking a psychiatrist to join an established adult partial hospital program. The program involves treating patients with a wide range of acute conditions, and includes psychiatric management and group therapy components. The partial hospital is one division within a comprehensive department of psychiatry with a full range of clinical and academic programs. The candidate must be Board Certified or eligible, and may be eligible for a clinical appointment at The Warren Alpert Medical School of Brown University. Salary and benefits commensurate with level of training. To learn more about us and our offerings, visit www.lifespan.org. Please send CV along with a letter of interest to Richard J. Goldberg, M.D., Psychiatrist- in-Chief, APC-9, Rhode Island Hospital, 593 Eddy St, Providence, RI 02903 and/or e-mail to rjgoldberg@lifespan.org.

Lifespan is an EOE.

SOUTH CAROLINA

CHIEF of MENTAL HEALTH SERVICE

The WJB Dorn Veterans Affairs Medical Center (VAMC) is seeking an individual with clinical leadership and managerial skills to direct our Mental Health Service. Dorn VA Medical Center, part of the VA Southeast Network (VISN 7), is a 216-bed facility, encompassing medical, surgical, psychiatric, and geriatric care. The medical center provides care to approximately 67,000 veterans in the midlands and upstate South Carolina. Community Based Outpatient Clinics (CBOCs) are located in Anderson, Greenville, Spartanburg, Florence, Orangeburg, Sumter, and Rock Hill, SC, and provide primary care, mental health, and telemedicine services. Dorn VAMC is affiliated with the University of South Carolina (USC) School of Medicine and provides teaching services for students and residents. USC is the state's flagship research university, with Schools of Public Health, Nursing, Pharmacy, and an active Graduate School.

The Chief of Mental Health will assist in planning and development of our long-term strategic initiative to create a "Mental Health Center of Excellence." Applicants should be from one of the four core mental health professional disciplines: Nursing, Psychiatry, Psychology, and Social Work and should have experience and expertise in research, administering programs, clinics, staff, and trainees. This individual will be responsible for oversight, direction, and development of outpatient, inpatient, and tele-mental health services at the Medical Center and its CBOCs and joint program development with the USC School of Medicine. The successful candidate will qualify for a faculty appointment at University of South Carolina commensurate with training and experience.

Columbia's variety in cultural and recreational activities, its location (2 hours from the ocean and 2 hours from the mountains), and weather (mild winters), make it a pleasant place to live. Columbia has an excellent airport, a thriving arts and cultural community, fine restaurants, an abundance of golf courses and mountain-biking trails, and whitewater and trout fishing within the city limits. Large lakes which offer world-class fishing, sailing, water-skiing, and waterfront camping are a short drive away.

Interested individuals should send their CV and 3 professional references to:

Human Resources (05M)
WJB Dorn VA Medical Center
6439 Garners Ferry Road
Columbia, SC 29209-1639
Fax: 803-695-6702
Phone: 803-776-4000, extension 6264
Also refer to: http://www.usajobs.opm.gov #09-188-COS for more information
For specific information concerning the osition, contact:
Dr. Stephen Hawes
Chair, Search Committee
Director of Mental Health Service
803-776-4000, extension 7143

TENNESSEE

Board-certified/eligible psychiatrists needed for full time and part time positions in a large Psychiatry Service at Mountain Home VAMC in Johnson City, Tennessee. Primary responsibility will be managing outpatients with a variety of psychiatric disorders. Join staff of 30 prescribers, including 18 psychiatrists at ETSU-affiliated residency training program with medical students, adult and med-psych residencies. Clinical appointment potential and some teaching expected. Research a plus. On-call (full time positions only) is backup to residents and shared amongst staff psychiatrists. NO STATE INCOME TAX, LOW COST OF LIVING, BEAUTIFUL MOUNTAINOUS REGION, LOTS OF PARKS, GOLF COURSES, LAKES, NATIONAL FOREST.
Inquiries:
Deborah Burchfield, (423) 979-3465, or Deborah.Burchfield@va.gov and George.brown@va.gov. Applications and/or CVs to: James H. Quillen VA Medical Center P.O. Box 4000 (05), Mountain Home, TN 37684 or Fax: (423) 979-3443 or Email: mtnhomehrmservice@med.va.gov

TEXAS

Associate Professor

The Department of Psychiatry at the University of Texas Medical Branch in Galveston is seeking an Associate Professor for our Adult division.

Responsibilities include direct patient care, resident supervision and teaching. Research opportunities are available. The position can be required to work in any of our three locations one of which is located in Webster; the other two are on Galveston Island. The position reports directly to the Chair of the Department. Minimum qualifications are medical doctor with a Texas medical license and must have graduated from an accredited Psychiatry Residency Program. Board certified in Psychiatry and Neurology with experience in clinical psychiatry is preferred.

Candidates with interest and skills in this area should send a curriculum vitae and cover letter to: Robert M.A. Hirschfeld, M.D., The University of Texas Medical Branch, Department of Psychiatry, 301 University, Galveston, TX 77555-0188.

The University of Texas Medical Branch at Galveston is an equal opportunity, affirmative action institution which proudly values diversity. Candidates of all backgrounds are encouraged to apply.

Vericare is currently seeking TeleMed Board Certified Psychiatrists in Texas with Geriatric experience.

Does spending less time in your car and more time seeing patients appeal to you? Or spending more time at home and less time at the office? Do you want to directly impact a population in desperate need of quality care? If yes, then join us at Vericare. Work with our team of dynamic professionals who are breaking through conventional methods of care! Our Telemed service line enables you to provide care to a population who previously had little hope of receiving the care they deserve.

If you are interested in learning how you can join our dynamic Vericare team, **please contact me at 800-257-8715 x1166, slekic@vericare.com or visit us at www.vericare.com.** To be eligible, you must have a medical degree and have completed your residency in psychiatry from an accredited institution, state licensure in good standing, and board certification in adult and/or geriatric psychiatry.

PSYCHIATRISTS: Mental Health Mental Retardation Authority of Harris County (MHMRA) in Houston, Texas is one of the largest mental health centers in the United States. Demands have created the need for additional BC/BE Psychiatrists throughout the Agency.

Northwest Outpatient Clinic
Work 8 to 5 Monday through Friday
Perform psychiatric evaluations & treatment in clinic setting
No on call

Psychiatric Emergency Center
24/7 Mental Health Crisis Unit
Full & Part-time positions available

Texas licensure is required for all positions

MHMRA offers competitive salary plus a generous benefit package. Houston offers excellent quality of life, lower than average cost of living, no state sales tax and exciting cultural, entertainment, sporting and tourists venues.

Contact Charlotte Simmons at (713) 970-7397, or submit your C.V. to charlotte.simmons@mhmraharris.org or fax: 713-970-3386

Texas Gulf Coast Medical Group

Psychiatrist to join a respected and well established large family and multi-specialty practice in Webster, Texas, a Houston suburb. The patients are waiting for you! Brand new officebuilding with EMR and state of the art equipment. Lakes, the ocean, fishing, golfing, excellent schools, and warm temperatures year round. See our website at www.txgulfcoastmed.com or fax your CV to (281) 724-0210

Central West Texas. BC/BE Psychiatrist in an in/outpatient setting.
- 22 bed unit - adult/geriatrics only
- Call 10 nights a month - alternate weekends
- Employee of Shannon Clinic
- 3 yr contract, with 1st year guarantee, $200,000+
- Production and Quality incentives
- Sign on bonus
- Relocation allowance
- 35 days vacation
- Annual CME allowances
- Health/dental/disability/life
- Retirement

San Angelo is a city of 100,000
- Service area of 250,000
- NO TRAFFIC
- Pleasant climate
- Affordable housing
- Exemplary schools
- State University
- Regional airport

Shannon Clinic
Carrie Hallman - 325/481-6390
carriehallman@shannonhealth.org
www.shannonhealth.com

The Department of Psychiatry and Behavioral Sciences of the University of Texas Medical School at Houston has an extraordinary opportunity for psychiatrists seeking to develop and implement new inpatient and outpatient clinical and research initiatives. Under new leadership, the Department is looking to expand clinical and research areas and is seeking general psychiatrists, child and adolescent psychiatrists and geriatric psychiatrists to join a growing academic department dedicated to excellence in clinical care, research and education. The Medical School is part of the University of Texas Health Science Center Houston, located in the Texas Medical Center - the largest medical center in the world. The Department of Psychiatry will shortly be moving into a brand-new building that will house the new Institute of Psychiatry. Individuals applying for these positions must be Board Certified in general psychiatry, child & adolescent psychiatry and geriatric psychiatry or have completed an accredited training in these specialty and subspecialty areas in the United States. Additionally, they must be licensed or be eligible for licensing in the State of Texas. Depending upon the applicant's qualification and credentials, faculty appointments at the level of Assistant Professor, Associate Professor or Professor will be offered. Salary levels are very competitive and also carry excellent fringe benefit packages. To find out more information about these unique academically-driven positions or to apply for them, please write to Jair C. Soares, M.D., Professor and Chair, and include a copy of your curriculum vitae and a letter of interest to 1300 Moursund Street, Houston, Texas 77030, e-mail: Jair.C.Soares@uth.tmc.edu phone 713-500-2507; fax 713-500-2553. The University of Texas Health Science Center at Houston is an EO/AA employer. M/F/D/V

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VIRGINIA

ADDICTIONS PSYCHIATRY, FACULTY CHAIR

The Department of Psychiatry, Medical College of Virginia at Virginia Commonwealth University, in collaboration with the Hunter Holmes McGuire Veterans Administration Medical Center, and VCU Institute for Drug and Alcohol Studies, is recruiting an academic physician Chair for the Division of Addiction Psychiatry. Chair is responsible for developing research, teaching and clinical programs. Funded ACGME accredited Addictions Fellowship. Strong programs in psychiatric genetics, epidemiology, pharmacology, toxicology, and women's health. Emerging School of Public Health. State funded health practitioner impairment program, laboratory and community based research are active areas for collaboration. Department of Psychiatry has over 75 full-time faculty, 39 residents, multiple fellowships and research centers including an addiction genetics research center. The Veterans Administration Medical Center has robust residential and outpatient addictions programming, and an outstanding program in Psychiatry and Primary Care. VCU is Virginia's largest 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. Please contact Dr. Joel Silverman at 804/828-9156 or email jsilverman@mcvh-vcu.edu

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VIRGINIA COMMONWEALTH UNIVERSITY, Department of Psychiatry, School of Medicine, is recruiting a BE/BC Psychiatrist to serve as **Chair, Division of Ambulatory Psychiatry, position available as of July 1, 2008.** Duties include development of new programs, ambulatory care research, ambulatory resident and student education, and direction of general and specialty clinics and staff supervision. Significant experience in academic ambulatory care, teaching, administration and clinical research required. Faculty with funded research preferred. Ambulatory Care Clinics are located at the VCU Medical Campus, and have an estimated 16,000 patient visits/year. Department of Psychiatry employs over 80 fulltime faculty and is nationally ranked in federally funded research. Richmond, the State Capital, has moderate climate and rich mix of history, a diverse multicultural community, excellent housing and public/private schools. Internet provides comparative cost of living. Send CV to Search Committee, c/o Marie Roach, VCU, Box 980710, Richmond VA 23298. Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Women, persons with disabilities, and minorities are encouraged to apply.

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VIRGINIA COMMONWEALTH UNIVERSITY: The Department of Psychiatry, School of Medicine, is recruiting a BE/BC Psychiatrist to serve as Outpatient Director of the Virginia Treatment Center for Children (VTCC), Ambulatory Care Psychiatry, at the VCU Medical Center. Duties include development of new programs, outpatient clinical care, ambulatory resident and student education, and direction of medical clinics and staff supervision. The VTCC is a leader in clinical education and is growing in research capabilities. Academic experience, including clinical education, research and scholarly endeavors, preferred. VCU Department of Psychiatry employs over 80-fulltime faculty and is nationally ranked in federally funded research. Richmond, the State Capitol, has moderate climate and rich mix of history, a diverse multicultural community, excellent housing, and public/private schools. Internet provides comparative cost of living. Send CV to Marie Roach, Human Resources, Department of Psychiatry, VCU, Box 980710, Richmond, VA 23298 (Fax 804-828-1472). VCU is an Equal Opportunity/Affirmative Action employer. Women, minorities, and persons with disabilities are encouraged to apply.

FACILITY MEDICAL DIRECTOR

Eastern State Hospital (ESH), a Joint Commission Accredited Hospital, seeks a BC/BE psychiatrist licensed by the Virginia Board of Medicine. Our new Geriatric Center (150 beds) opened April 2008; the Adult Mental Health Center (150) beds), under construction, opens June 2010.

Candidate will provide direction, oversight and supervision of all Clinical Departments; Psychology, Social Work, Psychosocial Rehabilitation; and supervision and coordination of activities of the Medical Staff. Demonstrated knowledge and experience in administrative and clinical activities in the field of mental health required. Must be experienced and knowledgeable of joint Commission Standards and CMS Regulations. Candidate will also facilitate a broader clinical interface with other facility and community service entities. Educational affiliations include the College of William & Mary, and Eastern Virginia Medical School.

Salary range $175,000-220,000 accompanied by comprehensive state benefits package (paid malpractice, disability, and life and health insurance). ESH has been in continuous operation for 235 years!

Send CV's to:
Human Resources Department
Eastern State Hospital
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Williamsburg, VA 23188-2652
Tour: www.esh.dmhmrsas.virginia.gov
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EOE

WEST VIRGINIA

West Virginia School of Osteopathic Medicine, Lewisburg, WV is seeking a fulltime, tenure, faculty in Psychiatry. Duties include teaching medical students, interns, residents; developing psychiatric curriculum for students years 1-2; developing curriculum, rotational components and evaluation instruments for students years 3-4; maintaining a clinical practice. Research supported but not required. D.O. or M.D. degree, completed residency, board certification or eligibility in Psychiatry and clinical experience in general psychiatry. Must be able to be licensed in WV, which requires a rotating osteopathic internship for osteopathic physicians.

Excellent benefit package including the availability of fully paid malpractice insurance, educational loan repayment. Salary and faculty rank based on experience and training. Information at WWW.WVSOM.EDU . Apply by contacting Leslie Bicksler, Director HR at lbicksler@wvsom.edu , 304/647-6279. AA/EOE.

PSYCHIATRIST-West Virginia University School of Medicine, The Department of Behavioral Medicine and Psychiatry, has ongoing opportunities and faculty positions for full-time, part-time or per diem BE/BC psychiatrists in various locations throughout the state of West Virginia, including its primary clinical, educational and research location in Morgantown, WV, as well as William R. Sharpe Jr. Hospital, a 150-bed, JCAHO-accredited, state psychiatric hospital in Weston, WV. Responsibilities include patient care and teaching, with opportunities for research. Positions will remain open until filled. Contact Susan Clayton at sclayton@hsc.wvu.edu. WVU is an AA/EO employer.

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BOSTON - Available for July 2010. ACGME-Accredited. Three PGY V Fellowship positions at Brigham & Women's/Faulkner Hospitals; **One PGY V Fellowship position** at Brigham and Women's/ West Roxbury VA Hospitals; **One PGY V Fellowship position** at Dana-Farber Cancer Institute/Brigham & Women's Hospital in Psychosocial Oncology available for the July '10 - June '11 academic year. These positions, which offer advanced training in consultation-liaison psychiatry and psychosomatic medicine, also include consultation-liaison experiences with OB/GYN, neurology, burn/trauma, transplantation, emergency psychiatry, psycho-oncology. Excellent supervision, research and liaison support. Fellowship positions include Harvard Medical School appointment. For further information, please contact: David Gitlin, M.D., Director, Psychosomatic Medicine Fellowship Program, Brigham & Women's Hospital, 75 Francis Street, Boston, MA 02115. Phone: 617-732-6701; Fax: 617-738-1275; Email: dgitlin@partners.org

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PSYCHOSOMATIC MEDICINE FELLOWSHIPS AND CHIEF RESIDENCY POSITIONS AT YALE UNIVERSITY

This ACGME-accredited one-year fellowship has five Psychosomatic Medicine Fellowship positions available at the PGY-V level or above, starting July 1, 2010. Applications for Chief Resident positions are also welcome (PGY IV year training does not provide eligibility for subspecialty board 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.

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One year exciting, well-established, fellowship program, one of the first accredited by the ACGME, in a 750-bed university hospital, accepting applications for July 1, 2010. Advanced training offered to psychiatrists who have completed residency. Please write or call: James L. Levenson, M.D., Chairman, C-L Division, VCU Health System, Department of Psychiatry, Box 980268, Richmond, VA. 23298-0268, jlevenson@mcvh-vcu.edu (804) 828-0762 or Sherif Meguid, M.D. aabdel-meguid@mcvh-vcu.edu

Fellowship Positions, University of Illinois at Chicago (UIC) College of Medicine

Addiction Psychiatry Fellowship - Seeking candidate for a 1-year PGY-5 fellowship to start July 1, 2010. The fellowship provides clinical experiences in inpatient, residential, outpatient, and consultative settings. Clinical rotations will take place in a VA hospital, the UIC medical center, a community-based comprehensive outpatient/residential program, an outpatient adolescent program, and an impaired professionals program. The fellow will get experience with the use of various evidence-based practices in these settings as they are applied in detoxification and rehabilitation. The fellow will work with an ethnically and gender-diverse population that includes adolescent thru geriatric patient populations with the range of substance addictions and conditions co-morbid with addictions. The fellow will have will have supervision from a multidisciplinary faculty and get broad experience teaching other health professionals. The fellow will also have a supervised research experience in addiction. No on-site night call. Rodney Eiger, MD, Fellowship Director.

PRIME Residency - This is a PGY-4 position to begin July 1, 2010, at the Jesse Brown VA Medical Center and UIC Department of Psychiatry. The resident will receive psychiatric consultation-liaison training as a member of a primary care team (PRIME) and will educate the primary care team about identification and management of common psychiatric disorders. The resident will participate in ongoing didactic programs and provide care in community-based outpatient clinics. Opportunities for clinical research, electives in ECT, and home care; experiences addiction and geriatric psychiatry are also offered. Supervision is provided by faculty from the Departments of Psychiatry and Medicine at the JBVA Medical Center as well as the University of Illinois at Chicago.

Women's Mental Health Fellowship - This is a PGY-4 or 5 one-year fellowship to start July 1, 2010, at the University of Illinois at Chicago. We are seeking an exceptional candidate who will develop expertise in reproductive and gender-linked psychiatric disorders. Our program has received the ACP Award for Creativity in Psychiatric Education, and the APA Gold Award in recognition of our pioneering work in Women's Mental Health.

USMLE Step 3 is required for the above positions at UIC. For consideration contact Dr. Robert W. Marvin, MD, Director, Residency Education and Training Program, by mail UIC Dept. of Psychiatry (MC 913), 912 S. Wood Street, Chicago, IL 60612; by e-mail: recruit@psych.uic.edu or by phone (312)996-3583 not later than December 1, 2009. Detailed descriptions are posted on the Residency website: http://www.psych.uic.edu/education/residents/fellowships. The UIC and JBVA are AA/EOE.

Geropsychiatry Fellowship, Portland Oregon, Recruiting for July 1, 2010 ACGME-accr PGY5 level, at Ore Hlth Sci Univ and Portland VA Med Center. Flexible program with either research or clinical emphasis. Training sites include inpatient, outpatient, nursing home and community. Research and clinical strengths in end-of-life/palliative care, ethics, mood disorders, dementias, Parkinson's disease, and substance abuse. Opportunity, support and mentoring will be provided to fellow for research training. Contact Linda Ganzini, MD, MPH, Director of Geriatric Psychiatry Training, Mental Health Div, R & D 66 , PO box 1034, Portland, OR 97207 or at Linda.ganzini@va.gov EOE.

Psychosomatic Medicine Fellowship, Portland, Oregon. Recruiting for 07/01/10 ACGME-accredited PGY5 level, at Oregon Health & Science Univ and Portland VA Med Center. Flexible program with clinical and research opportunities. Training sites include ambulatory care, specialty services, and consultation to inpatient med/surg. Research and clinical strengths in health services, mental disorders in primary care, pain, end-of-life/palliative care, ethics, mood disorders, Parkinson's disease, and substance abuse. Contact Dr. Steven Dobscha, Portland VA Med. Ctr., PO Box 1034 (P3MHADM), Portland, OR 97207; at steven.dobscha@va.gov. EOE.

FELLOWSHIP
PUBLIC PSYCHIATRY at YALE

The Connecticut Mental Health Center - Yale University School of Medicine is accepting applications for a one-year Fellowship in Public Psychiatry for July 2010. CMHC is a major site for training, research and clinical service within the Yale and State systems. As a state-funded, academic, urban mental health center it provides a unique setting for psychiatrists to obtain advanced training as they pursue careers as leaders in the field. Fellows spend 50% time in seminars, supervision, and administrative/policy meetings of CMHC and the CT Dept. of Mental Health and Addiction Services; and up to 50% effort providing direct clinical service and/or consultation within public mental health settings in New Haven. Candidates must be eligible for board certification and CT licensure. Minority applicants are encouraged to apply. For further information contact Jeanne Steiner, D.O. Medical Director, CMHC - Yale Univ., 34 Park St New Haven, CT 06519 or Jeanne.Steiner@yale.edu.

POSITION: Geriatric Psychiatry Fellowship
SPONSOR: University of Rochester Medical Center, Department of Psychiatry
DESCRIPTION: The University of Rochester program in Geriatrics and Neuropsychiatry 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. In addition, a two-year Interdisciplinary Geriatrics Fellowship is available that integrates the core disciplines of psychiatry, medicine, and dentistry and prepares trainees as clinical educators. Both fellowships offer training in the care of older patients in a variety of inpatient, long-term care, clinical, consultation, and palliative care services. Supervised clinical experiences are complemented by a didactic program, elective offerings, and opportunities to develop individual scholarly interests. In addition to the breadth of our clinical programs and patient populations, we have a large cadre of experienced and nationally recognized clinicians and researchers serving on our faculty. We pride ourselves on providing a stimulating, rewarding educational experience in a supportive and nurturing environment. Applications are now being accepted for the 2010/2011 academic year.
CONTACT: For more information, please contact Lisa Boyle, M.D., Director, Geriatric Psychiatry Fellowship, Department of Psychiatry, University of Rochester Medical Center, 300 Crittenden Boulevard, Rochester, NY 14642-8409 Phone: 585.275.2824; Fax: 585.273.1082; E-Mail: Lisa_Boyle@urmc.rochester.edu Website: www.urmc.rochester.edu/smd/psych/educ_train/fellowship/geriatrics/index.cfmThe University of Rochester is an equal opportunity/affirmative action employer.

UNIVERSITY OF MINNESOTA

POSTDOCTORAL FELLOW sought for a two-year, NIH-funded project investigating the efficacy and safety of varenicline as a smoking cessation aid for subjects with schizophrenia (See: Schizophr. Res. 103(1-3):328-329, 2008). The candidate must have an M.D. or Ph.D. degree. Residency in psychiatry or clinically relevant experience is highly desirable. The fellowship provides clinical experience in an inpatient setting using evidence-based practices and orients the candidate toward an academic career in psychiatry. Please ubmit curriculum vitae and three references to: S. Hossein Fatemi, M.D., Ph.D., Department of Psychiatry, University of Minnesota School of Medicine, 420 Delaware St SE, MMC 392, Minneapolis, MN 55455. Email: fatem002@umn.edu.

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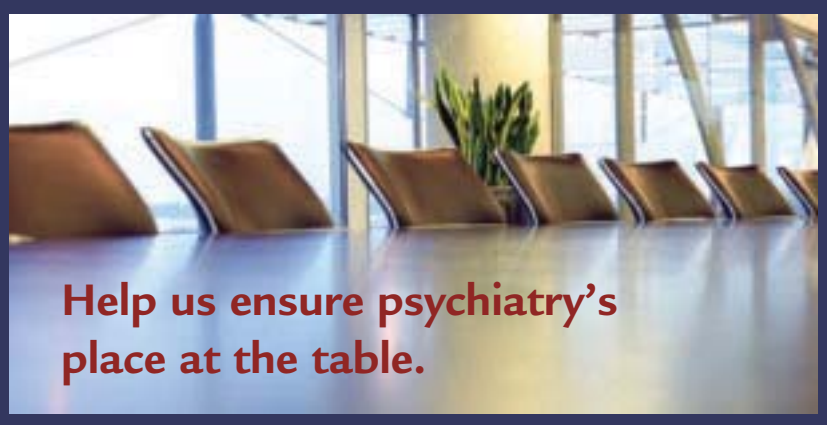

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