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PSYCHIATRIC NEWS

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inside

PERIODICALS:
TIME-SENSITIVE MATERIALS

Credit: Jolene Butts Freeman

Psychiatrist Patrice Harris, M.D., participates in "White Coat Wednesday," when an estimated 10,000 physicians around the nation flooded Capitol Hill with phone calls demanding that Congress act to avert a threatened pay cut for doctors treating Medicare patients. Harris is chair of the AMA's Council on Legislation, which is instrumental in formulating the AMA's legislative goals and activities. The call-in event was originally scheduled for Wednesday, November 17, but because the physician response was so great, it was continued the next day. See story at right.

Congress Votes Another Delay In Large Medicare Cuts

The Congressional action followed an AMA-sponsored "White Coat Wednesday" in which physicians swamped Congress with phone calls demanding that legislators undo the pay cut and reform the payment formula.

BY MARK MORAN

It has become a familiar story, and an expensive one.

Congress once again postponed—this time, for one month—a scheduled across-the-board cut in Medicare physician payments. The reduction of a stunning 24.9 percent will go into effect on January 1, 2011, unless Congress heeds the demands of organized medicine for a permanent fix to the Medicare physician payment formula.

(The 24.9 percent payment cut was mandated by the 2011 Medicare Physician Fee Schedule Proposed Rule, issued earlier this year.)

On November 18, Senate leaders agreed to a 31-day reprieve from the 23 percent Medicare physician payment cut that was scheduled to take effect on December 1, and on November 26 the House of Representatives followed suit.

The congressional action followed urgent lobbying by physician groups and a "White Coat Wednesday" coordinated

please see ***Medicare Cut*** *on page 29*

AMA Describes Principles To Guide New Care Model

Hospital and large health systems will have an advantage in the formation of accountable care organizations and are poised to capture market share, so an important consideration is how to level the playing field for physicians in small-group or solo practices.

BY MARK MORAN

Accountable care organizations (ACOs)—the coalitions of physicians and hospitals being touted as models for coordinated care—should be physician led, ensure voluntary physician and patient participation, and enable independent physicians to participate.

That's what delegates to the AMA House of Delegates asserted last month during the AMA's Interim Meeting in San Diego. Delegates approved 13 principles for ACOs (see page 8) addressing governance, voluntary participation of patients and doctors, use of revenues and savings, flexibility in patient referral and antitrust laws, costs associated with starting physician-led ACOs including geographic and patient selection differences, quality reporting, and use of electronic records.

ACOs have become a potential model for coordinated delivery of medical care within a reformed health care system and were designated in the Patient Protection and Affordable Care Act (the health care reform law approved by Congress earlier this year) for a demonstration project within the Medicare program. Generally, ACOs refer to coalitions of physicians and hospitals responsible for coordinating medical care for populations of patients across the continuum of care, yet questions remain about what kind of entities will qualify as ACOs and how they will be structured and operate.

(An October 2009 report by the Urban Institute titled "Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality Quandaries?" outlines the potential of ACOs for more efficient, cost-effective quality care, as well as the problems still to be resolved. That report cited three essential characteristics of an ACO: the ability to provide and manage the continuum of care across different

please see ***ACOs*** *on page 8*

Don't Forget To Vote!

APA voting members with an e-mail address on file with APA will receive an e-mail link to their personalized online ballot for APA's 2011 election on **December 22**; paper ballots will be mailed that same day. The deadline for receipt of ballots is **February 7.** Information about the candidates and the election can be accessed on APA's Web site at <http://www.psych.org/Resources/Governance/Elections.aspx>.

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DB Says Governor's Order Jeopardizes MH Care

A new requirement that many patients in public mental health programs provide documentation of their legal residency status may prevent access to care for not only illegal immigrants but also poor patients who lack such documents.

BY RICH DALY

Psychiatrists in Arizona are opposing a new requirement by the state that all patients in publically funded treatment programs—other than Medicaid—provide documentation of their legal residency.

The Arizona Psychiatric Society (APS) wrote Gov. Jan Brewer (R) in October to oppose a new requirement that all patients treated in the state's mental health programs document their legal U.S. residency status by November to remain in those programs.

"Not only must care be suspended, but there has been no provision for the appropriate transfer of care to any alternate heath care entity, governmental authority, etc.," said the letter from APS President Michael Brennan, M.D.

The result of dropping treatment for such patients could leave them vulnerable to suicide and place people in the public at risk of homicide by those whose untreated illnesses lead them to violence, he wrote.

The new policy, enacted through an executive order by the governor, may end treatment for an estimated 7,000 Arizona residents, most of whom are illegal aliens. However, the documentation requirement also could affect U.S. citizens and legal residents who are too poor or too ill to locate or obtain the necessary paperwork, according to Brennan.

"Some people just don't have the documents to prove their citizenship," Brennan told *Psychiatric News*, and thus the new policy imperils the health of some citizens who are not targets of the new rule.

In addition, the policy change has created a potential ethics violation for physicians under their "duty to protect" their patients from suicide, he said.

"It essentially required physicians to stop their patients' care," he said.

The governor had not responded to the APS letter as of late November, and her representatives did not respond to requests for comment from *Psychiatric News*.

please see ***Order*** *on page 28*

Important Annual Meeting Announcements

Early-Bird Registration Ends January 3!

- **Register Early and Save on Fees!**
  APA members can now register, enroll in courses, and make hotel reservations for APA's 2011 annual meeting in Hawaii at advanced registration fees. Registration and hotel information, including hotel rates and descriptions, can be accessed on APA's Web site at <www.psych.org/annualmeeting>. This year's Convocation lecturer is human-rights activist and Nobel Peace Prize recipient Archbishop Desmond Tutu.

- **Look for Annual Meeting Information Online**
  Visit <www.psych.org/annualmeeting> to view the entire Annual Meeting Advance Registration Packet. This contains information on airline reservations, registration, housing, courses, local information about Hawaii, and other topics. The site will be updated as specific details on the scientific program are finalized.

- **New This Year!**
  Pre- and post-meeting tours will be offered to the outer Hawaiian islands. While in Honolulu, be sure to take advantage of the many tours and fun activities available for the whole family. Don't be left out—sign up now! Information on tour packages is posted on APA's Web site.

More information is available by calling the APA Meetings and Conventions Department at (703) 907-7822 or by e-mailing apa@psych.org.

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How Does APA 'Work'?

BY CAROL A. BERNSTEIN, M.D.

Many of our members have told me that they have little understanding of APA's governance structure through which the Association carries out its work to meet its missions: to promote the highest quality care for individuals with mental illness and substance use disorders and their families, promote psychiatric education and research, advance and represent the profession of psychiatry, and serve the professional needs of its membership.

If you find your eyes glazing over as you read this and your finger itching to turn the page, please resist the urge. Every APA member has a role to play in the Association and making it effective, and APA's successes benefit you and your patients. This is no time to be on the sidelines. Understanding how APA works will demystify the process and, I hope, encourage you to become more involved in your Association. We need your help to make APA even more relevant to members and strengthen its function as the voice of psychiatry.

Here is a brief overview: APA is a member organization with a full-time staff of about 187 in Arlington, Va. It is led by our medical director and CEO, Dr. Jay Scully, who is responsible for day-to-day operations.

The Board of Trustees, composed of officers and trustees elected by the membership, governs the Association. The Board's primary function is to manage the affairs of the Association and formulate and implement its policies. Reporting to the Board are 10 councils, most of which are organized around topic areas important to psychiatry: advocacy and government relations, communications, medical education and lifelong learning, research and quality care, minority mental health and health disparities, addiction psychiatry, adult psychiatry, and children, adolescents, and their families.

Another important part of APA consists of its district branches (DBs) and state associations (SAs). There are 74 DBs, most of which are statewide, and two SAs—New York and California—that encompass multiple DBs. All of these entities are separately incorporated and have no direct operational connection to APA. Members pay dues to the national APA and their DB/SA. The amount of "local dues" varies widely. For most DBs, the national organization collects the total amount and then distributes the local dues to the DBs/SAs.

While members, through components and the Board of Trustees, set policies and directions for APA's work at the national level, most of the implementation is done by staff. That work includes advocating on behalf of the field and our patients in Congress on issues such as parity, reimbursement, and health care access; publishing our journals and books, including *DSM*; providing educational opportunities to our members through annual meetings in May and October; working with media (print, digital, TV, and radio) to address major psychiatric issues of concern to the public; and collaborating with other organizations such as the AMA, American Board of Psychiatry and Neurology, American Association of Directors of Psychiatric Residency Training, American Association of Chairs of Departments of Psychiatry, and others that address subspecialty practice, psychiatric education, and research.

On the DB level, much work focuses around local legislative issues pertaining to insurance, liability, scope of practice, and access to care. Each DB is represented at the national level through elected representatives to the APA Assembly, which meets twice a year. The role of the Assembly is to provide information and advice to the Board of Trustees and to facilitate communication about local and member issues to and from the Board and the national organization. Through their Assembly representatives, APA members have input into APA policies and programs.

One of the biggest challenges to helping our members be knowledgeable about our Association has been in the area of communication. Over the years, both the Assembly and the Board have worked on developing more effective ways of communicating with the members. I anticipate that with the development of a new Web site and electronic communication vehicles in the next year, we will be able to streamline our delivery of information and make it easy for you to access the vast amount of information that APA has available, in the right amount and in a timely way.

The communication gap is a particular issue for our young psychiatrists: our residents, fellows, and early career psychiatrists who are eager for mentorship and career development. Without understanding the work of APA and its significance to our profession, it is unlikely that they will be willing to get involved and stay involved. I believe that local leadership must work with Board and Assembly members and leaders in academia to reach out to our members where they live and work. One idea under discussion is holding one grand rounds a year at each academic facility on the major issues that APA is addressing and how local members can get involved. This would be an opportunity for DB and national leadership not only to educate members about APA's work for them and our profession, but also to engage members in a personal way and invite their input, commitment, and involvement.

I hope you will join me in advocating for this type of initiative to ensure that APA members connect in a meaningful way at the local level. We must continue to enhance our governance structure so that it works synergistically with national and local staff to engage the membership in activities that are significant for our field.

I welcome your thoughts about these ideas and other ways in which we can reach out to you to make sure that you are up to date on our work and how we can be of greater assistance to you and your patients on a day-to-day basis. ■

AMA Recommends Strategies To Reduce Violence in ED

A key AMA council notes that psychiatric patients who are appropriately medicated are no more likely to be violent than the general population.

BY MARK MORAN

A resource document outlining essential services necessary to address emergency department violence was approved at last month's meeting of the AMA House of Delegates.

The document, in the form of a report by the AMA's Council on Science and Public Health (CSAPH), is designed to assist in the implementation of procedures to protect physicians and other staff in emergency departments (EDs) and to assure optimal care for patients, including those with psychiatric or behavioral conditions. The AMA will make it available to hospitals, emergency medicine departments, physicians, mental health clinicians, patient advocates, and law-enforcement organizations.

Credit: Mark Moran

Louis Kraus, M.D., a member of the Section Council on Psychiatry and the AMA Council on Science and Public Health, testifies at last month's meeting of the AMA House of Delegates in San Diego.

Child psychiatrist Louis Kraus, M.D., vice chair of the Section Council on Psychiatry and a member of the CSAPH who helped write the report, told *Psychiatric News* that care and management of patients with psychiatric illness is a critical focus of the document. "The report emphasizes—and a number of people testified in hearings on the document—that psychiatric patients who are appropriately medicated are no more likely to be violent than the general population," Kraus said.

The report notes that hospital EDs are treating an increasing number of patients with mental and substance use disorders because of the decline in availability of federal- , state- , and community-funded services.

The report also draws attention to APA's Practice Guideline for the Psychiatric Evaluation of Adults, which describes specific approaches for the emergency evaluation of psychiatric patients. The AMA report also notes that a monograph available on the APA Web site titled *Safe MD* discusses practical applications and approaches to safe practices including those recommended for managing aggressive patients.

"Several patient characteristics that may increase the risk of aggression are noted, as are several tips for working safely with potentially dangerous patients," according to the CSAPH report. "Use of a predetermined emergency department triage system or scale to ensure timely and appropriate treatment of patients who are very distressed, acutely psychotic, violent, or aggressive can be helpful. Where possible, EDs should have dedicated treatment rooms for psychiatric patients that avoid exacerbation of the patient's illness. Facilities with significant psychiatric presentations should consider hiring dedicated psychiatrically trained staff."

The CSAPH report examines data on the occurrence of violence in the ED, explains current standards that apply to workplace safety and security in hospital settings, and reviews recommendations of various organizations on how to mitigate violence in the ED, with some attention to handling patients with psychiatric conditions.

The CSAPH has for several years addressed some of the issues most important to psychiatry. A report on use of antipsychotic medication in children, which Kraus has been instrumental in writing, will be brought to the House of Delegates at the June 2011 meeting in Chicago, for example.

A CSAPH report on health programs for impaired physicians was also the subject of considerable debate at the November meeting, but was ultimately referred back to the CSAPH for reconsideration. That report gives an overview of the development and operation of physician health programs and addresses the barriers to use of these programs and the effectiveness of their confidentiality safeguards. It also recommends the following as essential components of a state-sponsored physician health program:

- Contingency management that includes both positive and negative consequences
- Random drug testing
- Linkage with the 12-step programs
- Management of relapses by intensified treatment and monitoring
- Use of a continuing-care approach and a focus on lifelong recovery

But in reference committee hearings, some delegates expressed concern that the report focused too exclusively on addiction without sufficiently addressing other issues relevant to physician impairment, including other psychiatric illness and the so-called "disruptive physician."

Kraus, in an interview with *Psychiatric News*, said that disruptive behavior is not an uncommon reason for referring physicians for treatment, but is a problematic designation that can be misused. "It's not in the *DSM*, and hospital personnel can use this construct to discipline a physician who challenges the administration," he said.

Other items that the CSAPH dealt with that were approved by the AMA include a report on health risks associated with the BP Gulf oil spill and resolutions on possible rescheduling of medical cannabis, return of children and adolescents to play or sports practice following a concussion, and improved residency training on the care of gay and transgender patients.

The reports on ED violence and physician health programs as well as other items addressed by the CSAPH are posted at <www.ama-assn.org/ama/pub/meeting/reports-resolutions.shtml>. ■

AMA Holds Firm on Support Of Health Insurance Mandate

Support for the individual mandate to buy insurance was approved as AMA policy in 2006 and is necessary for other health insurance market reforms contained in the new health care reform law.

BY MARK MORAN

When the AMA House of Delegates votes to approve policy, people take notice. But sometimes what this policymaking body decides *not* to decide is also noteworthy.

Two high-profile items on the house agenda—rescinding the AMA's support for the individual mandate to buy health insurance as part of health care reform and a resolution supporting civil marriage for same-sex couples and repeal of the Defense of Marriage Act—were the subject of lengthy and sometimes passionate debate but were ultimately "referred" for later decision.

A resolution brought to the house by delegations from Kansas, Alabama, the District of Columbia, Florida, and Georgia, as well as the American Society of General Surgeons, would have called on the AMA to "support the use of tax incentives and other noncompulsory measures, rather than a federally imposed requirement that individuals purchase health insurance."

The individual mandate—which was included in the Patient Protection and Affordable Care Act (PPACA)—is one of the more politically charged elements of the new health care reform law. And the resolution brought by the surgeons and the five states asserted that "polling throughout the past year has repeatedly shown that a solid majority of the American people oppose a federal mandate that individuals must purchase health insurance."

The resolution also noted that 21 states are challenging the constitutional authority of Congress to mandate that individuals must either purchase health insurance or pay a tax as a fine.

Supporters of the resolution testified during reference committee hearings (where all items are debated prior to the meeting of the house) that the mandate conflicts with existing AMA policy in support of pluralism and free-market economic approaches, and that there are noncompulsory measures—such as tax incentives and health savings accounts—that could effectively serve as alternatives to a federally imposed requirement.

But John McIntyre, M.D., APA senior delegate to the Section Council on Psychiatry and a member of the AMA's Council on Medical Services (which has been central in formulating AMA health care reform policy), emphasized that the individual mandate was approved by the House of Delegates as AMA policy more than four years ago, in June 2006. And he said that the mandate—which was a requirement of the private insurance industry for its support of the law passed this year by Congress—was necessary to win support for other health insurance reforms advocated by the AMA.

"The mandate is a part of the AMA's support for the principle of individual responsibility to purchase insurance," McIntyre told *Psychiatric News* after the meeting. "You can't have these other reforms, such as elimination of exclusions based on preexisting conditions, unless the pool of insured is large enough. And during the negotiations around the law, it was the private insurers that required it, or they wouldn't participate."

Credit: Mark Moran

Psychiatrist Paul O'Leary, M.D., testifies at the AMA House of Delegates in support of a resolution calling on the AMA to support civil marriage for same-sex couples and the repeal of the Defense of Marriage Act.

During reference committee hearings, Erick Eiting, M.D., M.P.H., assistant commissioner for government relations for the Medical Society of the State of New York, said the PPACA was far from perfect for

please see ***Insurance Mandate*** *on page 20*

Stimulant Treatment Doesn't Appear To Raise Drug-Abuse Risk

Having attention-deficit/hyperactivity disorder in childhood may raise the risk of using alcohol or drugs in adolescence, but stimulant treatment does not appear to increase that risk.

BY AARON LEVIN

Attention-deficit/hyperactivity disorder (ADHD) is associated with increased risk of illicit drug use. However, the slowly growing body of scientific literature on the topic shows mixed outcomes about the relationship between stimulant treatment and drug use, said Brooke Molina, Ph.D., an associate professor of psychiatry at the University of Pittsburgh, at the American Academy of Child and Adolescent Psychiatry (AACAP) annual meeting in New York in October.

"Some studies show protective effects of stimulants, some show predisposing effects, and some show no association at all," said Molina. "This literature is still relatively new, and we cannot say if stimulant treatment protects against later drug abuse."

These studies also have problems, including a large range of sample sizes, different age ranges at follow-up, and varying ways that treatment and outcomes were operationalized, she pointed out.

Molina began her career by studying children of alcoholics and noticed that their symptoms overlapped with those of children with ADHD. In addition, core symptoms of ADHD, such as inattention, impulsivity, hyperactivity, and restlessness, are also implicated in addiction.

"There are also similarities in brain areas implicated and in genetic vulnerabilities," she said. "In ADHD, we need to think about both impairments and symptoms."

At the AACAP meeting, Molina reported on eight-year outcomes of the association between ADHD treatment and substance use from the NIMH-sponsored Multimodal Treatment Study of Children With ADHD (MTA).

The MTA was a large, multisite, randomized treatment trial of 436 patients with a narrow age range (7 to 9.9 years at baseline).

The initial MTA trial randomly assigned patients to one of four treatment conditions: medication only, behavioral treatment only, combined medication and behavioral, or assessment and referral.

Molina studied risk for substance use among these children in the years after the formal end of treatment. Treatment didn't appear to have much effect on rates of substance use, which were fairly high in both the ADHD and control groups. At the two-year follow-up, the two groups receiving behavioral therapy showed slight protective effects, but that disappeared at three years, she said.

"By eight years, there was no visible harm, but no protective effect either," said Molina. "Use of behavioral therapies was associated with reduced substance use or experimentation in early adolescence. We'll have more information at 12 years, but adolescent substance abuse appears to be episodic and socially mediated."

Early ADHD symptom patterns were the most predictive, regardless of treatment type.

"ADHD increases risk for substance use disorders—especially tobacco and marijuana—in adolescents, but [use of] stimulants is not associated with any visible harm," commented discussant Paula Riggs, M.D., a professor of psychiatry at the University of Colorado at Denver School of Medicine.

Psychiatrists need to be aware of other factors as well, said Riggs.

"The neurological literature is reporting that dopamine agonists in adults with Parkinson's disease are associated with new onset of pathological gambling and compulsive sexual behavior, but the psychiatric literature is not yet onto this," she said.

There may also be social forces acting to affect teen drug use, said Riggs. The rise found in 2008 and 2009 in teenagers' illicit drug use may have been due to a reduction in perceived risk paralleling increased visibility of medical marijuana.

"Does ADHD itself increase the risk of conduct disorder, which is a leading risk factor for substance disorder?" she asked. Possibly, although diagnosis of persistent oppositional defiant disorder after treatment may also indicate that the youth are hanging out with bad peers.

On the same panel, Sylvie Mrug, Ph.D., of the University of Alabama-Birmingham, discussed data on peer rejection from the MTA study.

Mrug hypothesized that peer rejection may be one of the missing links that

please see ***Stimulant*** *on page 29*

Combat Reactions Oceans Apart For British, U.S. Soldiers

British and American experts in military psychiatry discuss the often divergent ways that troops from the two countries have reacted to similar combat experiences.

BY AARON LEVIN

The wars in Iraq and Afghanistan may be a natural experiment in military mental health, one that has allowed researchers to observe similarities and differences between the two Western armies providing the bulk of the fighting forces.

The United States and the United Kingdom have been allies in those two struggles for twice as long as they were in World War II, said Simon Wessely, M.Sc., M.D., a professor and head of the Department of Psychological Medicine and director of the King's Centre for Military Health Research at the Institute of Psychiatry at King's College London. He spoke at a panel discussion with U.S. researchers in Washington, D.C., in November sponsored by King's College London.

The two countries' armed forces have been fighting on the same terrain against the same enemy and taking proportionately similar casualties.

Those commonalities make it possible to compare how their troops have dealt with the mental health aftermath of combat, said Wessely.

There are also methodological parallels that help researchers study the issue. As the Iraq war began in 2003, Wessely was asked to set up a study on the health of British troops in hopes of avoiding mistakes that occurred in the Gulf War of 1991.

"We agreed to use the same measures as the U.S. to trace, monitor, and follow up on the health of British forces," he said.

These ongoing studies have shown where the experiences of the two countries' soldiers are similar and where they differ. Combat exposure remains a major risk factor for soldiers of both nations.

"The differences lie not on the battlefield, but in the cultural traditions of the two countries," Wessely told *Psychiatric News* after his talk. "For instance, we have very different health care systems and very different attitudes toward alcohol."

British Soldiers' PTSD Rates Lower

British posttraumatic stress disorder (PTSD) rates are surprisingly low, about 2 percent to 3 percent, compared with U.S. rates of 12 percent to 15 percent, said Wessely.

This is likely not due to greater British resilience, but to different stressors facing the U.S. troops, he noted.

Many of the symptoms of PTSD—avoidance, numbing, anger, hypervigilance, exaggerated startle response—may actually be useful in combat. Problems arise when troops exhibit those reactions after they return home.

"If the symptoms of PTSD are adaptive, maybe U.S. troops are better adapted to war," said another panelist, Col. David Benedek, with some irony. Benedek is a professor of psychiatry and deputy chair of the Department of Psychiatry at the Uniformed Services University of the Health Sciences and associate director of the university's Center for the Study of Traumatic Stress.

In addition, the United States uses more reservists, who have proven to be more vulnerable psychologically, and it deploys troops for a year at a time, longer than the usual British tour of duty. British troops also stay at home for twice the length of time that they are deployed. American soldiers remain at home for only one year following a deployment. Military psychiatrists have said that is not enough time to recover from the stresses of war.

Another difference between the two countries is the increase in mental health problems that appear as time passes following deployment, said Wessely.

American troops are screened as they return to their home bases in the United States or Europe and again six to nine months later. They report more symptoms at the second assessment, indicating either a delay in onset or a greater willingness to acknowledge symptoms.

The United Kingdom doesn't screen its troops on the way home. "But we have observed no similar [rise in symptoms over time] in the U.K.," said Wessely, although rates of psychological problems did rise among British troops when their time in Iraq was extended without warning in the middle of their scheduled tours of duty.

"That taught us to manage the expectations of our troops," he said. "You have to stick with your promise."

Alcohol Problems Fewer in U.S. Troops

Wessely noted another difference in military cultures. About 15 percent to 20 percent of British troops are returning with significant alcohol problems, higher than rates for U.S. troops.

"Our rates of alcoholism trouble me," he said.

To illustrate the greater comfort with alcohol that characterizes British military culture, Wessely said that parts of his research planning had taken place while sharing a few rounds of drinks with his colleagues.

That would never be acknowledged by U.S. personnel, said Benedek.

"No American military leader would ever admit that anything good came out of having alcohol at a discussion," he said.

Systems of care within the military services are similar, noted Wessely, but differ once a soldier leaves active service. British veterans are treated by their country's National Health Service, while former U.S. soldiers can either enter the Department of Veterans Affairs system or use private medical resources.

Stigma Affects Both Nations' Troops

Like their American counterparts, British troops are reluctant to seek help for psychological problems because doing so goes against the grain of the warrior culture.

Returning U.S. soldiers report being easily startled, avoiding crowds, shutting down emotionally, and driving in the middle of the road, as they did in Iraq to avoid roadside bombs, said psychiatric epidemiologist Charles Hoge, M.D., a retired U.S. Army colonel and former director of the Division of Psychiatry and Behavioral Sciences at Walter Reed Army Institute of Research in Silver Spring, Md.

Furthermore, once they are home, half of U.S. troops who screen positive for PTSD won't come in for treatment, he said, and many who do begin treatment don't complete a 10- or 12-session course of therapy.

The way the mental health profession presents itself to soldiers may be yet another source of stigma, Hoge suggested. "Perhaps we shouldn't be using terms like 'wound' or 'illness,' but rather 'transitions,' " he said.

And how troops are asked about their psychological symptoms may play an important role in the answers they provide. Questionnaire responses are different on anonymous surveys than on ones in which the soldier gives his or her name, said Benedek.

"[Just administering] the surveys tells them that we're checking for illness and we suspect it's there," he said. "Perhaps we're sending a message that there is an expectation in U.S. society to see symptoms."

Yet, there is hope for improving the lives of veterans returning from the current fighting.

"Military culture is changing," said Hoge. "This is the first war where there was a commitment to study the mental health of the people fighting it as it was going on."

Information about the King's Centre for Military Health Research is posted at <www.kcl.ac.uk/kcmhr>. ■

Children of Deployed Parents Taken For More Mental Health Visits

In military families, the rates of visits to clinicians are quite different if the children's mothers or fathers are deployed overseas than if the parents are stationed stateside.

BY AARON LEVIN

Children of military parents who were deployed overseas had significantly fewer overall visits to health care providers than did children whose parents were stationed at home, but children of deployed parents had more mental health visits, according to a new study published online November 8 in *Pediatrics*.

The children of deployed parents recorded 11 percent fewer outpatient visits for physical health issues during the parent's deployment, but 11 percent more visits for mental or behavioral health, wrote Gregory Gorman, M.D., M.H.S., an assistant professor of pediatrics at the Uniformed Services University of the Health Sciences in Bethesda, Md., and colleagues.

Those percentages may seem modest but have significant implications, given the large absolute numbers involved, said Gorman in an interview with *Psychiatric News*.

"That's an extra 60,000 visits for which providers—mostly in primary care—need to be ready to recognize and manage mental health symptoms at a time when pediatric mental health resources are already in great demand," he said.

"Visits" covered outpatient office visits to any type of provider, whether primary care or mental health specialists.

The retrospective cohort study linked medical records from October 2005 through September 2007 for 642,397 children of military personnel with the deployment records of 442,722 parents.

The children were aged 3 to 8, with an average age of 5. The deployed parents' average age was 34, and about 90 percent were male.

Over two-thirds of the visits in the study were made to civilian providers under the authority of Tricare, the Department of Defense's health insurance management contractor.

The study covered more than 6.5 million patient visits, including 611,115 mental health visits. The most common mental health diagnosis was attention-deficit/hyperactivity disorder, accounting for 30.1 percent of all mental health diagnoses.

Among the mental health visits, the relative rate of mental disorders was 1.19, and of stress disorders was 1.18. The relative rate of anxiety disorders was 1.14, but was not statistically significant.

"The overall outcomes are not only statistically significant, they are also meaningful in the real world; I'm just relieved that they are not greater," said Shelley MacDermid Wadsworth, Ph.D., M.B.A., a professor of child development and family studies and director of the Center for Families and the Military Family Research Institute at Purdue University.

The pattern of mental health visits diverged sharply depending on whether the father or mother was deployed. When the mother deployed and the father was home taking care of the children, the incidence rate ratio for mental health visits was 0.70. When the father deployed and the mother was at home, the rate rose to 1.19.

The difference may arise because mothers, generally the primary caregivers, are more attuned to their children's emotional status and were thus more likely to take them to the doctor when they saw behavior that concerned them, said Gorman.

Men's attitudes toward symptoms might plausibly account for some of the gender dif-

please see ***Children*** *on page 8*

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ACOs

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institutional settings, including ambulatory, inpatient and postacute care; the capacity to plan budgets and resource needs prospectively; and sufficient size to support comprehensive, valid, and reliable performance measurement. According to the Urban Institute report, payers would contract directly with ACOs, and physician payment might be configured in a variety of ways with two being prominently discussed: capitation, in which the ACO would be paid a lump sum for care of a population of patients, or a "shared savings program." Under the latter, physicians would continue to be paid on a fee-for-service basis but the payer would establish expected total expenditures, and if the ACO provides the care its patients need for less than expected and quality standards are met, the ACO is rewarded with a portion of the savings as a bonus.)

Debate about ACOs and the role of physicians took center stage at the AMA meeting that occurred in the immediate aftermath of the November 2 elections in which Republicans took control of the U.S. House of Representatives.

Several other reports and resolutions related to public health and advocacy were approved with the support or active involvement of members of the Section Council on Psychiatry (see page 4). But the political uncertainty created by the midterm elections overshadowed debate about other high-profile topics such as support of civil marriage for same-sex couples and repeal of AMA support for an individual insurance mandate as part of health care reform, causing both of those items to be referred to the AMA Board of Trustees (see page 4).

John McIntyre, M.D., APA senior delegate to the Section Council on Psychiatry and a member of the AMA's Council on Medical Services, said that ACOs are a promising model for expanding access and containing cost within a coordinated system of care, but that many issues remain to be resolved regarding how they would be structured, financed, and operated.

One especially prominent issue for physicians is that under existing laws governing the referral of patients to hospitals or other entities in which a physician has a financial interest, doctors cannot legally form an ACO.

"We need to have some form of antitrust relief," he told *Psychiatric News*. "Otherwise, physicians who try to bond together to form an ACO or clinical integration system will run afoul of existing laws. The Affordable Care Act addresses this subject in terms of so-called 'safe harbors' to protect physicians, and the principles approved by the house express the AMA's support for that kind of protection."

The AMA principles state that "federal and state anti-kickback and self-referral laws and the federal Civil Monetary Penalties (CMP) statute (which prohibits payments by hospitals to physicians to reduce or limit care) should be sufficiently flexible to allow physicians to collaborate with hospitals in forming ACOs without being employed by the hospitals or ACOs. This is particularly important for physicians in small- and medium-sized practices who may want to remain independent but otherwise integrate and collaborate with other physicians . . . for purposes of participating in the ACO."

A second crucial issue, McIntyre said, is how to level the playing field so that physicians in small-group practices can compete with hospitals and other large systems of care in the formation of ACOs.

"Hospital systems and large group practices are going to be able to grab market share as ACOs, and smaller physician-led groups are liable to be squeezed out," McIntyre said. "So the question is how ACOs can be developed in such a way that physicians have a central role and small-group practices can be included."

According to the latest AMA Physician Practice survey, 78 percent of office-based physicians in the United States work in practices with nine or fewer physicians. A majority of those are in either solo practices or practices of two to four physicians.

McIntyre said the Council on Medical Services will examine issues surrounding ACOs at its meeting in January and bring a report back to the House of Delegates next June.

At the meeting in San Diego, delegates also called on the AMA to develop a toolkit that provides physicians with best practices for starting and operating an ACO, including governance structures, organizational relationships, and quality reporting and payment distribution mechanisms. The toolkit should include legal governance models and financial business models to assist physicians in making decisions about potential physician-hospital alignment strategies.

"The take-away message is that if physician-led ACOs are going to be financially viable, there need to be significant changes in federal laws and regulations concerning how physicians work together as part of a collaborative organization," McIntyre said. ■

Children

continued from page 6

ferences, Wadsworth, who was not involved in the study, told *Psychiatric News*.

"Men and women behave differently toward the health care system," she said. "Women may respond to symptoms when a child complains, while men take more of a 'shake-it-off' attitude."

The researchers also found that fewer mental health visits were recorded during deployment for children of single parents than for children of married parents. That may occur because many of those children are cared for during the parent's deployment by adults outside the immediate family who may be less aware of the child's changing emotional states, said Gorman. Those caregivers may also be taking the children in their charge to outside civilian practitioners, and thus the visits were not recorded in the military database.

In any case, the data emphasize the need to continue extra support to children and families of deployed troops and collaboration between providers of primary care services to children and child mental health specialists, Gorman emphasized.

"We have to educate these pediatric providers to be more comfortable in managing these issues and these patients," he said.

The researchers did not have access to parental medical records and so could not know if the parents had been diagnosed with any mental conditions that might have contributed to the symptoms or behaviors that led to the child's mental health visit. Without further research that includes such data, they caution against assigning direct causation between parents' deployment and their children's visits for mental and behavioral health issues.

"The good thing about the study is that the numbers are large, so there's good population data, but it's hard to know why something has happened," said Wadsworth.

Gorman and his colleagues are addressing that issue as they continue research into specific diagnostic subgroups of children.

"Wartime Military Deployment and Increased Pediatric Mental and Behavioral Health Complaints" is posted at <http://pediatrics.aappublications.org/cgi/reprint/peds.2009-2856v1>. ■

Principles for Accountable Care Organizations

At the Interim Meeting of the AMA House of Delegates last month in San Diego, delegates approved the following 13 principles for how accountable care organizations would be configured and operate. Here is a summary of those principles:

- The goal of an accountable care organization (ACO) is to increase access to care, improve the quality of care, and ensure the efficient delivery of care. Within an ACO, a physician's primary ethical and professional obligation is the well-being and safety of the patient.
- ACOs must be physician-led to ensure that a physician's medical decisions are not based on commercial interests but rather on professional medical judgment that puts patients' interests first. Where a hospital is part of an ACO, the governing board of the ACO should be separate and independent from the hospital governing board.
- Physician and patient participation in an ACO should be voluntary. Any physician organization or other entity that creates an ACO must obtain the written affirmative consent of each physician to participate in the ACO. Physicians should not be required to join an ACO as a condition of contracting with any public or private payer or being admitted to a hospital medical staff.
- Any savings and revenues of an ACO should be retained for patient care services and distributed to the ACO participants. (Savings might accrue if, for instance, an ACO provides care for a defined population for less than the capitated amount or the expenditure target established by a payer.)
- Federal and state anti-kickback and self-referral laws should be sufficiently flexible to allow physicians to collaborate with hospitals in forming ACOs without being employed by the hospitals or ACOs.
- Additional resources should be provided up-front to encourage ACO development, and the Centers for Medicare and Medicaid Services should provide grants to physicians to finance up-front costs of creating an ACO.
- The ACO spending benchmark should be adjusted for differences in geographic practice costs and risk adjusted for individual patient risk factors.
- Quality performance standards must be consistent with AMA policy regarding quality, including the use of nationally accepted, physician specialty–validated clinical measures developed by the AMA Physician Consortium for Performance Improvement (in which APA is a participant).
- An ACO must be afforded procedural due process if a contract with any payer-public or private—is terminated because of ACO failure to meet quality performance standards.
- ACOs should be allowed to use different payment models, including fee-for-service, capitation, partial capitation, medical homes, care management fees, and shared savings (see related story). Any capitation payments must be risk-adjusted.
- The Consumer Assessment of Healthcare Providers and Systems Patient Satisfaction Survey should be used as a tool to determine patient satisfaction and whether an ACO meets the patient-centeredness criteria required by the ACO law.
- Interoperable health information technology and electronic health record systems are key to the success of ACOs. Medicare must ensure systems are interoperable to allow physicians and institutions to effectively communicate and coordinate care and report on quality.
- If an ACO bears risk (as may be possible in a capitated payment arrangement), the ACO must abide by the financial solvency standards pertaining to risk-bearing organizations.

The full text of the AMA's principles for ACOs is posted at <www.ama-assn.org/assets/meeting/2010i/i-10-ref-comm-j.pdf>.

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References: 1. Reisberg B, Doody R, Stöffler A, Schmitt F, Ferris S, Möbius HJ, for the Memantine Study Group. Memantine in moderate-to-severe Alzheimer's disease. *N Engl J Med.* 2003;348:1333-1341. **2.** Tariot PN, Farlow MR, Grossberg GT, Graham SM, McDonald S, Gergel I, for the Memantine Study Group. Memantine treatment in patients with moderate to severe Alzheimer disease already receiving donepezil: a randomized controlled trial. *JAMA.* 2004;291:317-324. **3.** Cummings JL, Schneider E, Tariot PN, Graham SM, for the Memantine MEM-MD-02 Study Group. Behavioral effects of memantine in Alzheimer disease patients receiving donepezil treatment. *Neurology.* 2006;67:57-63. **4.** Data on file. Forest Laboratories, Inc. **5.** NAMENDA® (memantine HCl) Prescribing Information. Forest Pharmaceuticals, Inc., St Louis, Mo. **6.** 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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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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Rev. 04/07

Judges on Mission to Change Courts' View of Mentally Ill

A partnership between the American Psychiatric Foundation and a national judges' group will train jurists to recognize mental illness in defendants and understand when treatment is more appropriate than incarceration.

BY RICH DALY

Credit: Rich Daly

Participating in a meeting at APA headquarters on the new partnership between the Judges' Leadership Initiative and the American Psychiatric Foundation (APF) are (from left) Fred Osher, M.D., director of health systems and services policy at the Council of State Governments Justice Center; Steven Leifman, an associate administrative judge for Miami-Dade County and a board member of the APF; and Paul Burke, executive director of APF. One goal of the partnership is to develop a training module for judges on mental illnesses and the criminal justice system.

Credit: Rich Daly

Kathryn Zenoff (center), a judge for the Illinois Appellate Court, discusses ways to better inform judges nationwide that untreated mental illness may lead some defendants into the criminal justice system. Pictured with her at the inaugural meeting of the Judges' Leadership Initiative partnership are Wesley Sowers, M.D., a clinical associate professor of psychiatry at the University of Pittsburgh Medical School, and Stephanie Le Melle, M.D., an associate clinical professor of psychiatry at Columbia University Medical Center.

Kathryn Zenoff, an Illinois appellate court judge, has noticed a growing trend throughout her judicial career: the same small group of defendants would repeatedly appear before her, usually on misdemeanor criminal charges, be convicted, and then sentenced for short periods to the local jail.

These defendants were not career criminals, she realized, but part of a growing number of people with untreated mental illness who were pulled into the criminal-justice system when they suffered a psychiatric crisis.

"I've seen this issue in my career as a judge, up close and personal," Zenoff told *Psychiatric News*.

She and other judges nationwide took action, sometimes individually and recently in partnership, to address the problem through reforms of their local or state criminal-justice and health systems that aimed to reduce incarceration rates while increasing treatment for people with mental illness.

And now the American Psychiatric Foundation (APF) has joined in these judges' mission. In July the APF launched a partnership with the Judges' Leadership Initiative (JLI)—a group that has provided technical support since 2004 to judges, like Zenoff, seeking to change jurisdictions' approaches to people whose untreated mental illness escalated into a psychiatric crisis, resulting in their arrest.

The partnership held its inaugural meeting October 26 at APA headquarters in Arlington, Va., The focus of the meeting was the creation and dissemination of guides for judges to help them recognize arrestees with untreated mental illness and understand the treatments and local resources available for this population.

Judges "have moved forward in their communities and developed a range of programming," said Fred Osher, M.D., director of health systems and services policy at the Council of State Governments Justice Center (CSGJC), who is helping to lead the partnership, in an interview with *Psychiatric News* before the meeting. But "they have not been at the table with the psychiatric leaders in their communities, and [theirs] has been a missing voice in too many of the communications" about the problem of the criminalization of mental illness. "At the end of the day this is all about collaboration."

More Judges Need to Participate

Steven Leifman, an associate administrative judge for Miami-Dade County and a board member of APF, likened the type of training needed by state judges to the approach used when Crisis Intervention Teams (CIT) are created in police departments. CIT police units receive specialized training to guide their interactions with people experiencing a psychiatric crisis, and all of the members of a police force with a CIT unit also receive generalized training on mental illness.

While specialized mental health courts are a key part of the answer, he said, mental illness is so pervasive among criminal defendants that all judges need training to at least recognize it and know what alternatives are available.

"We're kind of driving blindly sometimes, so it's a good thing to collaborate with the psychiatric community," Leifman told *Psychiatric News* at the meeting.

Evelyn Stratton, a justice of the Ohio Supreme Court, told *Psychiatric News* at the meeting that the initiative's success will depend on producing information and outreach that interests all judges, not just those who are specialists or already have an interest in mental health issues.

The APF partnership adds to a growing effort to address untreated mental illness among criminal defendants—mental health courts have increased from a handful in the mid-1990s to more than 500 today. However, the problem of how best to deal with mentally ill defendants remains daunting.

For example, approximately 16.9 percent of inmates in U.S. jails and prisons have a serious mental illness, while only an estimated 5.4 percent of the general U.S. population have such a condition, according to a 2009 CSGJC study.

Such high rates of incarceration of people with mental illness stem largely from the overreliance of states and localities on the justice system to accommodate people with mental illness, while underfunding their public mental health care system, according to the judges and psychiatrists at the meeting. That funding imbalance also is evident in the May finding by the Treatment Advocacy Center that three times as many people with serious mental illness are in jails and prisons than are in hospitals.

Ironically, prison is the one place where people are constitutionally guaranteed to receive needed mental health care. In practice, such care often is elusive in overcrowded and underfunded prisons, according to psychiatrists involved in the partnership. Avoiding the need for incarceration by using clinically effective community treatment options and steering untreated people toward mental health care is another goal of the new partnership.

Judges also can help address the dearth of quality mental health care in their communities by not only acting as influential supporters for expanded mental health facilities and programs but by acting as advocates for the specific types of programs that their psychiatrist partners have identified as having demonstrated efficacy.

"Judges are among the most respected members of their communities, and they are assumed to not have any [financial or political] interests in the outcome," Osher said at the meeting. "That's why there are not any better advocates of [expanded] mental health services" than these jurists.

Grant Sparked Changes

Such judicial advocacy on behalf of people with mental illness in Miami-Dade County began 10 years ago when local judges used a grant from the National GAINS Center of the Substance Abuse and Mental Health Services Administration to "map out" how the criminal-justice system and the mental health system interacted (*Psychiatric News*, November 19).

"They didn't" was the chief finding of that initiative, Leifman said at the meeting.

What the Miami-Dade judges learned led to a judges' partnership that urged local elected officials to enact systemic reforms, such as mental illness awareness training for local police, a jail-diversion program for people with mental illness, and passage of a $22 million bond issue to build a first-of-its-kind combined jail, treatment, and reintegration housing facility. The results of those and related efforts include sustained drops in both misdemeanor and felony recidivism rates in recent years, Leifman said.

"The goal of the court should not be to develop a system of mental health care within the justice system," Leifman said. "We should be aiming to prevent people from entering that system in the first place."

Information on the JLI is posted at <www.psychfoundation.org/OurPrograms/Judges-Leadership-Initiative.aspx> and <http://consensusproject.org/JLI/>. Information on the National GAINS Center's initiatives is posted at <http://gainscenter.samhsa.gov/html/>. ■

Blumenthal 'Rocks'

Susan Blumenthal, M.D., M.P.A., a retired rear admiral in the Public Health Service and former U.S. assistant surgeon general, has been named a Rock Star of Science by Geoffrey Beene Gives Back and *GQ* magazine to raise public awareness about the importance of science to society. She joins a list of 17 other medical researchers and eight celebrity musicians in the campaign.

Blumenthal was the country's first deputy assistant secretary for women's health. She is now director of the Health and Medicine Program at the Center for the Study of the Presidency and Congress, where she directs and co-chairs the Commission on U.S. Federal Leadership in Health and Medicine, which has been influential in promoting research, global health, and health care reform efforts.

More information is posted on the Rock Stars of Science Web site at <www.rockstarsofscience.org/>. ■

Cymbalta is indicated in adults for[1]:

- The treatment of major depressive disorder (MDD). The efficacy of Cymbalta was established in 4 short-term trials and 1 maintenance trial.
- The treatment of generalized anxiety disorder (GAD). The efficacy of Cymbalta was established in 3 short-term trials and 1 maintenance trial.
- The management of diabetic peripheral neuropathic pain (DPNP).
- The management of fibromyalgia.

Reference: 1. Cymbalta full Prescribing Information.

Cymbalta® duloxetine HCl DELAYED RELEASE CAPSULES

Terms and Conditions

Reimbursement offered for up to 60 days of Cymbalta therapy to a maximum of $700. Prescriptions for more than 2 capsules per day are not eligible for reimbursement. Limit one reimbursement per person.

Offer void where prohibited by law. Valid only in the United States for US residents. Offer not valid for patients whose prescription claims for Cymbalta are reimbursed, in whole or in part, by (1) any governmental program, including, without limitation, Medicaid, Medicare, or any other federal or state program, such as Champus, the VA, TRICARE, or a state pharmaceutical assistance program, or (2) any third-party payer in the state of Massachusetts. By accepting this offer, patient agrees to notify his/her insurance carrier of reimbursement if required to do so by law or under the terms of coverage.

Additional exclusions may apply and this offer may be terminated, rescinded, revoked, or amended by Lilly USA, LLC, at any time without notice. Cymbalta® and the Cymbalta Logo are registered trademarks of Eli Lilly and Company.

Every Day, I think about what medication is the right choice for my patients.

Introducing the **Cymbalta Promise program**—a part of Every Day Connections. The Cymbalta Promise program is designed to help get the right patients on the right treatment—whether it's Cymbalta or not. If you and your patients who are new to Cymbalta are not satisfied, your patients may be reimbursed 100% of their out-of-pocket prescription costs for up to the first 60 days on Cymbalta. Ask your Cymbalta representative or visit cymbaltapromise.com to learn more. Restrictions apply. See full Terms and Conditions below. This program is not a guarantee of efficacy. It provides a trial period that may help patients and doctors assess the efficacy, safety, and tolerability of Cymbalta.

Every Day Connections

Important Safety Information About Cymbalta

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

Contraindications

- Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs. These interactions 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 serotonin reuptake inhibitors and are then started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome.

  At least 14 days should elapse between discontinuation of an MAOI and initiation of therapy with Cymbalta. In addition, at least 5 days should be allowed after stopping Cymbalta before starting an MAOI.

See Important Safety Information, including Boxed Warning, above and on next page, and Brief Summary of full Prescribing Information on following pages.

Lilly

Cymbalta® DELAYED RELEASE duloxetine HCl CAPSULES

Important Safety Information About Cymbalta *(Cont.)*

Contraindications *(Cont.)*

- Cymbalta was associated with an increased risk of mydriasis; therefore, it should not be used in patients with uncontrolled narrow-angle glaucoma and used cautiously in patients with controlled narrow-angle glaucoma.

Warnings and Precautions

- **Clinical Worsening and Suicide Risk**

  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 within the first few months of treatment and when changing the dose. Consider changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or includes symptoms of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, or suicidality that are severe, abrupt in onset, or were not part of the patient's presenting symptoms. If discontinuing treatment, the medication should be tapered. **Families and caregivers of patients being treated with antidepressants for any indication should be alerted about the need to monitor patients. Prescriptions for Cymbalta should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.**

- Hepatic failure, sometimes fatal, has been reported in patients treated with Cymbalta. Cymbalta should be discontinued in patients who develop jaundice or other evidence of clinically significant liver dysfunction and should not be resumed unless another cause can be established.

- Because it is possible that Cymbalta and alcohol may interact to cause liver injury or that Cymbalta may aggravate pre-existing liver disease, Cymbalta should ordinarily not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease.

- Orthostatic hypotension and syncope have been reported with therapeutic doses of Cymbalta. This tends to occur within the first week of therapy but can occur at any time during Cymbalta treatment, particularly after dose increases. Consideration should be given to discontinuing Cymbalta in patients who experience symptomatic orthostatic hypotension and/or syncope.

- 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 Cymbalta 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. Concomitant use with serotonin precursors (e.g., tryptophan) is not recommended. Treatment with duloxetine 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.

- SSRIs and SNRIs, including Cymbalta, may increase the risk of bleeding events. Patients should be cautioned about the risk of bleeding associated with concomitant use of Cymbalta and NSAIDs, aspirin, warfarin, or other drugs that affect coagulation.

- On abrupt or tapered discontinuation, spontaneous reports of adverse events, some of which may be serious, have been reported during the marketing of SSRIs and SNRIs. A gradual reduction in dose rather than abrupt cessation is recommended when possible.

(cont.)

Important Safety Information About Cymbalta *(Cont.)*

Warnings and Precautions *(Cont.)*

- Cymbalta should be used cautiously in patients with a history of mania or with a history of a seizure disorder.
- In clinical trials across indications relative to placebo, treatment with Cymbalta was associated with mean increases of up to 2.3 mm Hg systolic and diastolic blood pressure. There was no significant difference in the frequency of sustained (3 consecutive visits) elevated blood pressure. Blood pressure should be measured prior to initiating treatment and periodically measured throughout treatment.
- Co-administration of Cymbalta with potent CYP1A2 inhibitors or thioridazine should be avoided.
- SSRIs and SNRIs, including Cymbalta, have been associated with cases of clinically significant hyponatremia that appeared to be reversible when Cymbalta was discontinued. Elderly patients may be at greater risk of developing hyponatremia with SSRIs and SNRIs.
- The effect that alterations in gastric motility may have on the stability of the enteric coating of Cymbalta is unknown. As duloxetine is rapidly hydrolyzed in acidic media to naphthol, caution is advised in using Cymbalta in patients with conditions that may slow gastric emptying (e.g., some diabetics).
- Cymbalta should ordinarily not be administered to patients with any hepatic insufficiency or patients with end-stage renal disease (requiring dialysis) or severe renal impairment (creatinine clearance <30 mL/min).
- As observed in DPNP trials, Cymbalta treatment worsens glycemic control in some patients with diabetes. In the extension phases (up to 52 weeks) of the DPNP studies, an increase in HbA_{1c} in both the Cymbalta (0.5%) and the routine care groups (0.2%) was noted.
- Cymbalta is in a class of drugs known to affect urethral resistance. If symptoms of urinary hesitation develop during Cymbalta treatment, this effect may be drug-related. In postmarketing experience, urinary retention has been observed.

Use in Specific Populations

- Pregnancy and Nursing Mothers: Use only if the potential benefit justifies the potential risk to the fetus or child.

Adverse Events

- The most commonly reported adverse events (≥5% and at least twice placebo) for Cymbalta vs placebo in controlled clinical trials (N=4843 vs 3048) were: nausea (25% vs 9%), dry mouth (14% vs 6%), somnolence* (11% vs 3%), constipation* (11% vs 4%), decreased appetite* (8% vs 2%), and increased sweating (7% vs 2%).

  In addition to the adverse events listed above, DPNP trials also included: dizziness (13% vs 6%) and asthenia (5% vs 1%).

  * Events for which there was a significant dose-dependent relationship in fixed-dose studies, excluding three MDD studies that did not have a placebo lead-in period or dose titration.

- In placebo-controlled clinical trials, the overall discontinuation rates due to adverse events were: **MDD:** 9% vs 5%; **GAD:** 15% vs 4%; **DPNP:** 14% vs 7%; **FM:** 20% vs 12%.

  The common adverse events reported as a reason for discontinuation and considered to be drug related were: **MDD:** nausea (1.3% vs 0.5%). **GAD:** nausea (3.7% vs 0.2%), vomiting (1.3% vs 0%), dizziness (1.0% vs 0.2%). **DPNP:** nausea (3.5% vs 0.4%), dizziness (1.6% vs 0.4%), somnolence (1.6% vs 0%), fatigue (1.1% vs 0%). **FM:** nausea (1.9% vs 0.7%), somnolence (1.5% vs 0%), fatigue (1.3% vs 0.2%).

See Brief Summary, including Boxed Warning, of full Prescribing Information on following pages.

Lilly

CYMBALTA®

(duloxetine hydrochloride) Delayed-Release Capsules for Oral use
Brief Summary: Consult the package insert for complete prescribing information.

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

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

INDICATIONS AND USAGE: Major Depressive Disorder—Cymbalta is indicated for the acute and maintenance treatment of major depressive disorder (MDD). The efficacy of Cymbalta was established in four short-term trials and one maintenance trial in adults.

Generalized Anxiety Disorder—Cymbalta is indicated for the a treatment of generalized anxiety disorder (GAD). The efficacy of Cymbalta was established in three short-term trials and one maintenance trial in adults.

Diabetic Peripheral Neuropathic Pain—Cymbalta is indicated for the management of neuropathic pain (DPNP) associated with diabetic peripheral neuropathy.

Fibromyalgia—Cymbalta is indicated for the management of fibromyalgia (FM).

CONTRAINDICATIONS: Monoamine Oxidase Inhibitors—Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated due to the risk of serious, sometimes fatal, drug interactions with serotonergic drugs. These interactions 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 serotonin reuptake inhibitors and are then started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome *[see Warnings and Precautions]*.

Uncontrolled Narrow-Angle Glaucoma—In clinical trials, Cymbalta use was associated with an increased risk of mydriasis; therefore, its use should be avoided in patients with uncontrolled narrow-angle glaucoma *[see Warnings and Precautions]*.

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 of differences (drug vs placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1.

Table 1

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

No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide.

It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression.

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for 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 discontinuation can be associated with certain symptoms *[see Warnings and Precautions, Discontinuation of Treatment with Cymbalta]*.

Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for Cymbalta should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose.

Screening Patients for Bipolar Disorder—A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Cymbalta (duloxetine) is not approved for use in treating bipolar depression.

Hepatotoxicity—There have been reports of hepatic failure, sometimes fatal, in patients treated with Cymbalta. These cases have presented as hepatitis with abdominal pain, hepatomegaly, and elevation of transaminase levels to more than twenty times the upper limit of normal with or without jaundice, reflecting a mixed or hepatocellular pattern of liver injury. Cymbalta should be discontinued in patients who develop jaundice or other evidence of clinically significant liver dysfunction and should not be resumed unless another cause can be established.

Cases of cholestatic jaundice with minimal elevation of transaminase levels have also been reported. Other postmarketing reports indicate that elevated transaminases, bilirubin, and alkaline phosphatase have occurred in patients with chronic liver disease or cirrhosis.

Cymbalta increased the risk of elevation of serum transaminase levels in development program clinical trials. Liver transaminase elevations resulted in the discontinuation of 0.3% (82/27,229) of Cymbalta-treated patients. In these patients, the median time to detection of the transaminase elevation was about two months. In placebo-controlled trials in any indication, elevation of ALT >3 times the upper limit of normal occurred in 1.1% (85/7,632) of Cymbalta-treated patients compared to 0.2% (13/5,578) of placebo-treated patients. In placebo-controlled studies using a fixed dose design, there was evidence of a dose response relationship for ALT and AST elevation of >3 times the upper limit of normal and >5 times the upper limit of normal, respectively.

Because it is possible that duloxetine and alcohol may interact to cause liver injury or that duloxetine may aggravate pre-existing liver disease, Cymbalta should ordinarily not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease.

Orthostatic Hypotension and Syncope—Orthostatic hypotension and syncope have been reported with therapeutic doses of duloxetine. Syncope and orthostatic hypotension tend to occur within the first week of therapy but can occur at any time during duloxetine treatment, particularly after dose increases. The risk of blood pressure decreases may be greater in patients taking concomitant medications that induce orthostatic hypotension (such as antihypertensives) or are potent CYP1A2 inhibitors *[see Warnings and Precautions and Drug Interactions]* and in patients taking duloxetine at doses above 60 mg daily. Consideration should be given to discontinuing duloxetine in patients who experience symptomatic orthostatic hypotension and/or syncope during duloxetine therapy.

Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions—The development of a potentially life-threatening serotonin syndrome or NMS-like reactions have been reported with SNRIs and SSRIs alone, including Cymbalta 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.

Cymbalta® (duloxetine hydrochloride) PV 7211 AMP

The concomitant use of Cymbalta with MAOIs intended to treat depression is contraindicated *[see Contraindications]*.

If concomitant treatment of Cymbalta with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases *[see Drug Interactions]*.

The concomitant use of Cymbalta with serotonin precursors (such as tryptophan) is not recommended *[see Drug Interactions]*.

Treatment with duloxetine 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.

Abnormal Bleeding—SSRIs and SNRIs, including duloxetine, may increase the risk of bleeding events. Concomitant use of aspirin, non-steroidal anti-inflammatory drugs, warfarin, and other anti-coagulants may add to this 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 duloxetine and NSAIDs, aspirin, or other drugs that affect coagulation.

Discontinuation of Treatment with Cymbalta—Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo.

During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Activation of Mania/Hypomania—In placebo-controlled trials in patients with major depressive disorder, activation of mania or hypomania was reported in 0.1% (2/2,489) of duloxetine-treated patients and 0.1% (1/1,625) of placebo-treated patients. No activation of mania or hypomania was reported in DPNP, GAD, or fibromyalgia placebo-controlled trials. Activation of mania or hypomania has been reported in a small proportion of patients with mood disorders who were treated with other marketed drugs effective in the treatment of major depressive disorder. As with these other agents, Cymbalta should be used cautiously in patients with a history of mania.

Seizures—Duloxetine has not been systematically evaluated in patients with a seizure disorder and such patients were excluded from clinical studies. In placebo-controlled clinical trials, seizures/convulsions occurred in 0.03% (3/9,445) of patients treated with duloxetine and 0.01% (1/6,770) of patients treated with placebo. Cymbalta should be prescribed with care in patients with a history of a seizure disorder.

Effect on Blood Pressure—In clinical trials across indications, relative to placebo, duloxetine treatment was associated with mean increases of up to 2.1 mm Hg in systolic blood pressure and up to 2.3 mm Hg in diastolic blood pressure. There was no significant difference in the frequency of sustained (3 consecutive visits) elevated blood pressure. In a clinical pharmacology study designed to evaluate the effects of duloxetine on various parameters, including blood pressure at supratherapeutic doses with an accelerated dose titration, there was evidence of increases in supine blood pressure at doses up to 200 mg twice daily. At the highest 200 mg twice daily dose, the increase in mean pulse rate was 5.0 to 6.8 beats and increases in mean blood pressure were 4.7 to 6.8 mm Hg (systolic) and 4.5 to 7 mm Hg (diastolic) up to 12 hours after dosing.

Blood pressure should be measured prior to initiating treatment and periodically measured throughout treatment *[see Adverse Reactions, Vital Sign Changes]*.

Clinically Important Drug Interactions—Both CYP1A2 and CYP2D6 are responsible for duloxetine metabolism.

Potential for Other Drugs to Affect Cymbalta—*CYP1A2 Inhibitors*—Co-administration of Cymbalta with potent CYP1A2 inhibitors should be avoided *[see Drug Interactions]*.

CYP2D6 Inhibitors—Because CYP2D6 is involved in duloxetine metabolism, concomitant use of duloxetine with potent inhibitors of CYP2D6 would be expected to, and does, result in higher concentrations (on average of 60%) of duloxetine *[see Drug Interactions]*.

Potential for Cymbalta to Affect Other Drugs—*Drugs Metabolized by CYP2D6*—Co-administration of Cymbalta with drugs that are extensively metabolized by CYP2D6 and that have a narrow therapeutic index, including certain antidepressants (tricyclic antidepressants [TCAs], such as nortriptyline, amitriptyline, and imipramine), phenothiazines and Type 1C antiarrhythmics (e.g., propafenone, flecainide), should be approached with caution. Plasma TCA concentrations may need to be monitored and the dose of the TCA may need to be reduced if a TCA is co-administered with Cymbalta. Because of the risk of serious ventricular arrhythmias and sudden death potentially associated with elevated plasma levels of thioridazine, Cymbalta and thioridazine should not be co-administered *[see Drug Interactions]*.

Other Clinically Important Drug Interactions—*Alcohol*—Use of Cymbalta concomitantly with heavy alcohol intake may be associated with severe liver injury. For this reason, Cymbalta should ordinarily not

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be prescribed for patients with substantial alcohol use *[see Warnings and Precautions and Drug Interactions]*.

CNS Acting Drugs—Given the primary CNS effects of Cymbalta, it should be used with caution when it is taken in combination with or substituted for other centrally acting drugs, including those with a similar mechanism of action *[see Warnings and Precautions and Drug Interactions]*.

Hyponatremia—Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including Cymbalta. In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Cases with serum sodium lower than 110 mmol/L have been reported and appeared to be reversible when Cymbalta was discontinued. 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 Use in Specific Populations]*. Discontinuation of Cymbalta 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. More severe and/or acute cases have been associated with hallucination, syncope, seizure, coma, respiratory arrest, and death.

Use in Patients with Concomitant Illness—Clinical experience with Cymbalta in patients with concomitant systemic illnesses is limited. There is no information on the effect that alterations in gastric motility may have on the stability of Cymbalta's enteric coating. In extremely acidic conditions, Cymbalta, unprotected by the enteric coating, may undergo hydrolysis to form naphthol. Caution is advised in using Cymbalta in patients with conditions that may slow gastric emptying (e.g., some diabetics).

Cymbalta has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable coronary artery disease. Patients with these diagnoses were generally excluded from clinical studies during the product's premarketing testing.

Hepatic Insufficiency—Cymbalta should ordinarily not be used in patients with hepatic insufficiency *[see Warnings and Precautions and Use in Specific Populations]*.

Severe Renal Impairment—Cymbalta should ordinarily not be used in patients with end-stage renal disease or severe renal impairment (creatinine clearance <30 mL/min). Increased plasma concentration of duloxetine, and especially of its metabolites, occur in patients with end-stage renal disease (requiring dialysis) *[see Use in Specific Populations]*.

Controlled Narrow-Angle Glaucoma—In clinical trials, Cymbalta was associated with an increased risk of mydriasis; therefore, it should be used cautiously in patients with controlled narrow-angle glaucoma *[see Contraindications]*.

Glycemic Control in Patients with Diabetes—As observed in DPNP trials, Cymbalta treatment worsens glycemic control in some patients with diabetes. In three clinical trials of Cymbalta for the management of neuropathic pain associated with diabetic peripheral neuropathy, the mean duration of diabetes was approximately 12 years, the mean baseline fasting blood glucose was 176 mg/dL, and the mean baseline hemoglobin A_{1c} (HbA_{1c}) was 7.8%. In the 12-week acute treatment phase of these studies, Cymbalta was associated with a small increase in mean fasting blood glucose as compared to placebo. In the extension phase of these studies, which lasted up to 52 weeks, mean fasting blood glucose increased by 12 mg/dL in the Cymbalta group and decreased by 11.5 mg/dL in the routine care group. HbA_{1c} increased by 0.5% in the Cymbalta and by 0.2% in the routine care groups.

Urinary Hesitation and Retention—Cymbalta is in a class of drugs known to affect urethral resistance. If symptoms of urinary hesitation develop during treatment with Cymbalta, consideration should be given to the possibility that they might be drug-related. In post marketing experience, cases of urinary retention have been observed. In some instances of urinary retention associated with duloxetine use, hospitalization and/or catheterization has been needed.

Laboratory Tests—No specific laboratory tests are recommended.

ADVERSE REACTIONS: Clinical Trial Data Sources—The data described below reflect exposure to duloxetine in placebo-controlled trials for MDD (N=2327), GAD (N=668), DPNP (N=568) and FM (N=876). The population studied was 17 to 89 years of age; 64.8%, 64.7%, 38.7%, and 94.6% female; and 85.5%, 84.6%, 77.6%, and 88% Caucasian for MDD, GAD, DPNP, and FM, respectively. Most patients received doses of a total of 60 to 120 mg per day.

The stated frequencies of adverse reactions represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse reaction of the type listed. A reaction was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. Reactions reported during the studies were not necessarily caused by the therapy, and the frequencies do not reflect investigator impression (assessment) of causality.

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 practice.

Adverse Reactions Reported as Reasons for Discontinuation of Treatment in Placebo-Controlled Trials—Major Depressive Disorder—Approximately 9% (209/2,327) of the patients who received duloxetine in placebo-controlled trials for MDD discontinued treatment due to an adverse reaction, compared with 4.7% (68/1,460) of the patients receiving placebo. Nausea (duloxetine 1.3%, placebo 0.5%) was the only common adverse reaction reported as a reason for discontinuation and considered to be drug-related (i.e., discontinuation occurring in at least 1% of the duloxetine-treated patients and at a rate of at least twice that of placebo).

Generalized Anxiety Disorder—Approximately 15.3% (102/668) of the patients who received duloxetine in placebo-controlled trials for GAD discontinued treatment due to an adverse reaction, compared with 4.0% (20/495) for placebo. Common adverse reactions reported as a reason for discontinuation and considered to be drug-related (as defined above) included nausea (duloxetine 3.7%, placebo 0.2%), vomiting (duloxetine 1.3%, placebo 0.0%), and dizziness (duloxetine 1.0%, placebo 0.2%).

Diabetic Peripheral Neuropathic Pain—Approximately 14.3% (81/568) of the patients who received duloxetine in placebo-controlled trials for DPNP discontinued treatment due to an adverse reaction, compared with 7.2% (16/223) for placebo. Common adverse reactions reported as a reason for discontinuation and considered to be drug-related (as defined above) were nausea (duloxetine 3.5%, placebo 0.4%), dizziness (duloxetine 1.6%, placebo 0.4%), somnolence (duloxetine 1.6%, placebo 0.0%), and fatigue (duloxetine 1.1%, placebo 0.0%).

Fibromyalgia—Approximately 19.5% (171/876) of the patients who received duloxetine in 3 to 6 month placebo-controlled trials for FM discontinued treatment due to an adverse reaction, compared with 11.8% (63/535) for placebo. Common adverse reactions reported as a reason for discontinuation and considered to be drug-related (as defined above) included nausea (duloxetine 1.9%, placebo 0.7%), somnolence (duloxetine 1.5%, placebo 0.0%), and fatigue (duloxetine 1.3%, placebo 0.2%).

Adverse Reactions Occurring at an Incidence of 5% or More and at least Twice Placebo Among Duloxetine-Treated Patients in Placebo-Controlled Trials—Pooled Trials for all Approved Indications—The most commonly observed adverse reactions in Cymbalta-treated patients (incidence of at least 5% and at least twice the incidence in placebo patients) were nausea, dry mouth, constipation, somnolence, hyperhidrosis, and decreased appetite.

In addition to the adverse reactions listed above, DPNP trials also included dizziness and asthenia.

Adverse Reactions Occurring at an Incidence of 5% or More Among Duloxetine-Treated Patients in Placebo-Controlled Trials—The incidence of treatment-emergent adverse reactions in placebo-controlled trials (N=4843 Cymbalta; N=3048 placebo) for approved indications that occurred in 5% or more of patients treated with duloxetine and with an incidence greater than placebo were: nausea, headache, dry mouth, fatigue (includes asthenia), insomnia* (includes middle insomnia, early morning awakening, and initial insomnia), dizziness, somnolence* (includes hypersomnia and sedation), constipation*, diarrhea, decreased appetite* (includes anorexia), and hyperhidrosis. *Events for which there was a significant dose-dependent relationship in fixed-dose studies, excluding three MDD studies which did not have a placebo lead-in period or dose titration.

Adverse Reactions Occurring at an Incidence of 2% or More Among Duloxetine-Treated Patients in Placebo-Controlled Trials—Pooled MDD and GAD Trials—Table 3 in full PI gives the incidence of treatment-emergent adverse reactions in MDD and GAD placebo-controlled trials (N=2995 Cymbalta; N=1955 placebo) for approved indications that occurred in 2% or more of patients treated with duloxetine and with an incidence greater than placebo were: Cardiac Disorders—palpitations; Eye Disorders—vision blurred; Gastrointestinal Disorders—nausea, dry mouth, diarrhea, constipation*, abdominal pain (includes abdominal pain upper, abdominal pain lower, abdominal tenderness, abdominal discomfort, and gastrointestinal pain), vomiting; General Disorders and Administration Site Conditions—fatigue (includes asthenia); Investigations—weight decreased*; Metabolism and Nutrition Disorders—decreased appetite (includes anorexia); Nervous System Disorders—dizziness, somnolence (includes hypersomnia and sedation), tremor; Psychiatric Disorders—insomnia (includes middle insomnia, early morning awakening, and initial insomnia), agitation (includes feeling jittery, nervousness, restlessness, tension, and psychomotor agitation), anxiety, decreased libido (includes loss of libido), orgasm abnormal (includes anorgasmia), abnormal dreams (includes nightmare); Reproductive System and Breast Disorders—erectile dysfunction, ejaculation delayed, ejaculation disorder (includes ejaculation failure and ejaculation dysfunction); Respiratory, Thoracic, and Mediastinal Disorders—yawning; Skin and Subcutaneous Tissue Disorders—hyperhidrosis; Vascular Disorders—hot flush. *Events for which there was a significant dose-dependent relationship in fixed-dose studies, excluding three MDD studies which did not have a placebo lead-in period or dose titration.

Diabetic Peripheral Neuropathic Pain—Treatment-emergent adverse events that occurred in 2% or more of patients treated with Cymbalta in the premarketing acute phase of DPNP placebo-controlled trials (N=115 Cymbalta 20 mg once daily; N=228 Cymbalta 60 mg once daily; N=225 Cymbalta 60 mg twice daily; N=223 placebo) with an incidence greater than placebo were: Gastrointestinal Disorders—nausea, constipation, diarrhea, dry mouth, vomiting, dyspepsia, loose stools; General Disorders and Administration Site Conditions—fatigue, asthenia, pyrexia; Infections and Infestations—nasopharyngitis; Metabolism and Nutrition Disorders—decreased appetite, anorexia; Musculoskeletal and Connective Tissue Disorders—muscle cramp, myalgia; Nervous System Disorders—somnolence, headache, dizziness, tremor; Psychiatric Disorders—insomnia; Renal and Urinary Disorders—pollakiuria; Reproductive System and Breast Disorders—erectile dysfunction; Respiratory, Thoracic and Mediastinal Disorders—cough, pharyngolaryngeal pain; Skin and Subcutaneous Tissue Disorders—hyperhidrosis.

Fibromyalgia—Treatment-emergent adverse events that occurred in 2% or more of patients treated with Cymbalta in the premarketing acute phase of FM placebo-controlled trials (N=876 Cymbalta; N=535 placebo) and with an incidence greater than placebo were: Cardiac Disorders—palpitations; Eye Disorders—vision blurred; Gastrointestinal Disorders—nausea, dry mouth, constipation, diarrhea, dyspepsia; General Disorders and Administration Site Conditions—fatigue (includes asthenia); Immune System Disorders—seasonal allergy; Infections and Infestations—upper respiratory tract infection, urinary tract infection, influenza, gastroenteritis viral; Investigations—weight increased; Metabolism and Nutrition Disorders—decreased appetite (includes anorexia); Musculoskeletal and Connective Tissue Disorders—musculoskeletal pain, muscle spasm; Nervous System Disorders—headache, dizziness, somnolence (includes hypersomnia and sedation), tremor, paraesthesia, migraine, dysgeusia; Psychiatric Disorders—insomnia (includes middle insomnia, early morning awakening, and initial insomnia), agitation (includes feeling jittery, nervousness, restlessness, tension, and psychomotor agitation), sleep disorder, abnormal dreams (includes nightmare), orgasm abnormal (includes anorgasmia), libido decreased (includes loss of libido); Reproductive System and Breast Disorders—ejaculation disorder (includes ejaculation failure and ejaculation dysfunction), penis disorder; Respiratory, Thoracic, and Mediastinal Disorders—cough, pharyngolaryngeal pain; Skin and Subcutaneous Tissue Disorders—hyperhidrosis, rash, pruritus; Vascular Disorders—hot flush.

Effects on Male and Female Sexual Function—Changes in sexual desire, sexual performance and sexual satisfaction often occur as manifestations of psychiatric disorders or diabetes, but they may also be a consequence of pharmacologic treatment. Because adverse sexual reactions are presumed to be voluntarily underreported, the Arizona Sexual Experience Scale (ASEX), a validated measure designed to identify sexual side effects, was used prospectively in 4 MDD placebo-controlled trials. In these trials, patients treated with Cymbalta experienced significantly more sexual dysfunction, as measured by the total score on the ASEX, than did patients treated with placebo. Gender analysis showed that this difference occurred only in males. Males treated with Cymbalta experienced more difficulty with ability to reach orgasm (ASEX Item 4) than males treated with placebo. Females did not experience more sexual dysfunction on Cymbalta than on placebo as measured by ASEX total score. Physicians should routinely inquire about possible sexual side effects. See Table 6 in full PI for specific ASEX results.

Vital Sign Changes—In clinical trials across indications, relative to placebo, duloxetine treatment was associated with mean increases of up to 2.1 mm Hg in systolic blood pressure and up to 2.3 mm Hg in diastolic blood pressure. There was no significant difference in the frequency of sustained (3 consecutive visits) elevated blood pressure *[see Warnings and Precautions]*. Duloxetine treatment, for up to 26-weeks in placebo-controlled trials typically caused a small increase in heart rate compared to placebo of up to 3-4 beats per minute.

Weight Changes—In placebo-controlled clinical trials, MDD and GAD patients treated with Cymbalta for up to 10-weeks experienced a mean weight loss of approximately 0.5 kg, compared with a mean weight gain of approximately 0.2 kg in placebo-treated patients. In DPN placebo-controlled clinical trials, patients treated with Cymbalta for up to 13-weeks experienced a mean weight loss of approximately 1.1 kg, compared with a mean weight gain of approximately 0.2 kg in placebo-treated patients. In fibromyalgia studies, patients treated with Cymbalta for up to 26 weeks experienced a mean weight loss of approximately 0.4 kg compared with a mean weight gain of approximately 0.3 kg in placebo-treated patients. In one long-term fibromyalgia 60-week uncontrolled study, duloxetine patients had a mean weight increase of 0.7 kg.

Laboratory Changes—Cymbalta treatment in placebo-controlled clinical trials, was associated with small mean increases from baseline to endpoint in ALT, AST, CPK, and alkaline phosphatase; infrequent, modest, transient, abnormal values were observed for these analytes in Cymbalta-treated patients when compared with placebo-treated patients *[see Warnings and Precautions]*.

Electrocardiogram Changes—Electrocardiograms were obtained from duloxetine-treated patients and placebo-treated patients in clinical trials lasting up to 13-weeks. No clinically significant differences were observed for QTc, QT, PR, and QRS intervals between duloxetine-treated and placebo-treated patients. There were no differences in clinically meaningful QTcF elevations between duloxetine and placebo. In a positive-controlled study in healthy volunteers using duloxetine up to 200 mg twice daily, no prolongation of the corrected QT interval was observed.

Other Adverse Reactions Observed During the Premarketing and Postmarketing Clinical Trial Evaluation of Duloxetine—Following is a list of treatment-emergent adverse reactions reported by patients treated with duloxetine in clinical trials. In clinical trials of all indications, 27,229 patients were treated with duloxetine. Of these, 29% (7,886) took duloxetine for at least 6 months, and 13.3% (3,614) for at least one year. The following listing is not intended to include reactions (1) already listed in previous tables or elsewhere in labeling, (2) for which a drug cause was remote, (3) which were so general as to be uninformative, (4) which were not considered to have significant clinical implications, or (5) which occurred at a rate equal to or less than placebo.

Reactions are categorized by body system according to the following definitions: frequent adverse reactions are those occurring in at least 1/100 patients; infrequent adverse reactions are those occurring in 1/100 to 1/1000 patients; rare reactions are those occurring in fewer than 1/1000 patients. Cardiac Disorders—*Frequent:* palpitations; *Infrequent:* myocardial infarction and tachycardia; Ear and Labyrinth Disorders—*Frequent:* vertigo; *Infrequent:* ear pain and tinnitus; Endocrine Disorders—*Infrequent:* hypothyroidism; Eye Disorders—*Frequent:* vision blurred; *Infrequent:* diplopia and visual disturbance; Gastrointestinal Disorders—*Frequent:* flatulence; *Infrequent:* eructation, gastritis, halitosis, and stomatitis; *Rare:* gastric ulcer, hematochezia, and melena; General Disorders and Administration Site Conditions—*Frequent:* chills/rigors; *Infrequent:* feeling abnormal, feeling hot and/or cold, malaise, and thirst; *Rare:* gait disturbance; Infections and Infestations—*Infrequent:* gastroenteritis and laryngitis; Investigations—*Frequent:* weight increased; *Infrequent:* blood cholesterol increased; Metabolism and Nutrition Disorders—*Infrequent:* dehydration and hyperlipidemia; *Rare:* dyslipidemia; Musculoskeletal and Connective Tissue Disorders—*Frequent:* musculoskeletal pain; *Infrequent:* muscle tightness and muscle twitching; Nervous System Disorders—*Frequent:* dysgeusia, lethargy, and parasthesia/hypoesthesia; *Infrequent:* disturbance in attention, dyskinesia, myoclonus, and poor quality sleep; *Rare:* dysarthria; Psychiatric Disorders—*Frequent:* abnormal dreams and sleep disorder; *Infrequent:* apathy, bruxism, disorientation/confusional

state, irritability, mood swings, and suicide attempt; *Rare:* completed suicide; Renal and Urinary Disorders—*Infrequent:* dysuria, micturition urgency, nocturia, polyuria, and urine odor abnormal.; Reproductive System and Breast Disorders—*Frequent:* anorgasmia/orgasm abnormal; *Infrequent:* menopausal symptoms, and sexual dysfunction; Respiratory, Thoracic and Mediastinal Disorders—*Frequent:* yawning; *Infrequent:* throat tightness; Skin and Subcutaneous Tissue Disorders—*Infrequent:* cold sweat, dermatitis contact, erythema, increased tendency to bruise, night sweats, and photosensitivity reaction; *Rare:* ecchymosis; Vascular Disorders—*Frequent:* hot flush; *Infrequent:* flushing, orthostatic hypotension, and peripheral coldness.

Postmarketing Spontaneous Reports—The following adverse reactions have been identified during postapproval use of Cymbalta. Because these reactions are 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.

Adverse reactions reported since market introduction that were temporally related to duloxetine therapy and not mentioned elsewhere in labeling include: anaphylactic reaction, aggression and anger (particularly early in treatment or after treatment discontinuation), angioneurotic edema, erythema multiforme, extrapyramidal disorder, glaucoma, gynecological bleeding, hallucinations, hyperglycemia, hypersensitivity, hypertensive crisis, muscle spasm, rash, restless legs syndrome, seizures upon treatment discontinuation, supraventricular arrhythmia, tinnitus (upon treatment discontinuation), trismus, and urticaria.

Serious skin reactions including Stevens-Johnson Syndrome that have required drug discontinuation and/or hospitalization have been reported with duloxetine.

DRUG INTERACTIONS: Both CYP1A2 and CYP2D6 are responsible for duloxetine metabolism.

Inhibitors of CYP1A2—When duloxetine 60 mg was co-administered with fluvoxamine 100 mg, a potent CYP1A2 inhibitor, to male subjects (n=14) duloxetine AUC was increased approximately 6-fold, the C_{max} was increased about 2.5-fold, and duloxetine t1/2 was increased approximately 3-fold. Other drugs that inhibit CYP1A2 metabolism include cimetidine and quinolone antimicrobials such as ciprofloxacin and enoxacin *[see Warnings and Precautions]*.

Inhibitors of CYP2D6—Concomitant use of duloxetine (40 mg once daily) with paroxetine (20 mg once daily) increased the concentration of duloxetine AUC by about 60%, and greater degrees of inhibition are expected with higher doses of paroxetine. Similar effects would be expected with other potent CYP2D6 inhibitors (e.g., fluoxetine, quinidine) *[see Warnings and Precautions]*.

Dual Inhibition of CYP1A2 and CYP2D6—Concomitant administration of duloxetine 40 mg twice daily with fluvoxamine 100 mg, a potent CYP1A2 inhibitor, to CYP2D6 poor metabolizer subjects (n=14) resulted in a 6-fold increase in duloxetine AUC and C_{max}.

Drugs that Interfere with Hemostasis (e.g., NSAIDs, Aspirin, and Warfarin)—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 this risk of bleeding. Altered anticoagulant effects, including increased bleeding, have been reported when SSRIs or SNRIs are coadministered with warfarin. Patients receiving warfarin therapy should be carefully monitored when duloxetine is initiated or discontinued *[see Warnings and Precautions]*.

Lorazepam—Under steady-state conditions for duloxetine (60 mg Q 12 hours) and lorazepam (2 mg Q 12 hours), the pharmacokinetics of duloxetine were not affected by co-administration.

Temazepam—Under steady-state conditions for duloxetine (20 mg qhs) and temazepam (30 mg qhs), the pharmacokinetics of duloxetine were not affected by co-administration.

Drugs that Affect Gastric Acidity—Cymbalta has an enteric coating that resists dissolution until reaching a segment of the gastrointestinal tract where the pH exceeds 5.5. In extremely acidic conditions, Cymbalta, unprotected by the enteric coating, may undergo hydrolysis to form naphthol. Caution is advised in using Cymbalta in patients with conditions that may slow gastric emptying (e.g., some diabetics). Drugs that raise the gastrointestinal pH may lead to an earlier release of duloxetine. However, co-administration of Cymbalta with aluminum- and magnesium-containing antacids (51 mEq) or Cymbalta with famotidine, had no significant effect on the rate or extent of duloxetine absorption after administration of a 40 mg oral dose. It is unknown whether the concomitant administration of proton pump inhibitors affects duloxetine absorption *[see Warnings and Precautions]*.

Drugs Metabolized by CYP1A2—*In vitro* drug interaction studies demonstrate that duloxetine does not induce CYP1A2 activity. Therefore, an increase in the metabolism of CYP1A2 substrates (e.g., theophylline, caffeine) resulting from induction is not anticipated, although clinical studies of induction have not been performed. Duloxetine is an inhibitor of the CYP1A2 isoform in *in vitro* studies, and in two clinical studies the average (90% confidence interval) increase in theophylline AUC was 7% (1%-15%) and 20% (13%-27%) when co-administered with duloxetine (60 mg twice daily).

Drugs Metabolized by CYP2D6—Duloxetine is a moderate inhibitor of CYP2D6. When duloxetine was administered (at a dose of 60 mg twice daily) in conjunction with a single 50 mg dose of desipramine, a CYP2D6 substrate, the AUC of desipramine increased 3-fold *[see Warnings and Precautions]*.

Drugs Metabolized by CYP2C9—Duloxetine does not inhibit the *in vitro* enzyme activity of CYP2C9. Inhibition of the metabolism of CYP2C9 substrates is therefore not anticipated, although clinical studies have not been performed.

Drugs Metabolized by CYP3A—Results of *in vitro* studies demonstrate that duloxetine does not inhibit or induce CYP3A activity. Therefore, an increase or decrease in the metabolism of CYP3A substrates (e.g., oral contraceptives and other steroidal agents) resulting from induction or inhibition is not anticipated, although clinical studies have not been performed.

Drugs Metabolized by CYP2C19—Results of *in vitro* studies demonstrate that duloxetine does not inhibit CYP2C19 activity at therapeutic concentrations. Inhibition of the metabolism of CYP2C19 substrates is therefore not anticipated, although clinical studies have not been performed.

Monoamine Oxidase Inhibitors—Switching Patients to or from a Monoamine Oxidase Inhibitor—At least 14 days should elapse between discontinuation of an MAOI and initiation of therapy with Cymbalta. In addition, at least 5 days should be allowed after stopping Cymbalta before starting an MAOI *[see Contraindications and Warnings and Precautions]*.

Serotonergic Drugs—Based on the mechanism of action of SNRIs and SSRIs, including Cymbalta, and the potential for serotonin syndrome, caution is advised when Cymbalta is co-administered with other drugs that may affect the serotonergic neurotransmitter systems, such as triptans, linezolid (an antibiotic which is a reversible non-selective MAOI), lithium, tramadol, or St. John's Wort. The concomitant use of Cymbalta with other SSRIs, SNRIs or tryptophan is not recommended *[see Warnings and Precautions]*.

Triptans—There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of Cymbalta with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases *[see Warnings and Precautions]*.

Alcohol—When Cymbalta and ethanol were administered several hours apart so that peak concentrations of each would coincide, Cymbalta did not increase the impairment of mental and motor skills caused by alcohol.

In the Cymbalta clinical trials database, three Cymbalta-treated patients had liver injury as manifested by ALT and total bilirubin elevations, with evidence of obstruction. Substantial intercurrent ethanol use was present in each of these cases, and this may have contributed to the abnormalities seen *[see Warnings and Precautions]*.

CNS Drugs—*[see Warnings and Precautions]*.

Drugs Highly Bound to Plasma Protein—Because duloxetine is highly bound to plasma protein, administration of Cymbalta to a patient taking another drug that is highly protein bound may cause increased free concentrations of the other drug, potentially resulting in adverse reactions.

USE IN SPECIFIC POPULATIONS: Pregnancy—Teratogenic Effects, Pregnancy Category C—In animal reproduction studies, duloxetine has been shown to have adverse effects on embryo/fetal and postnatal development.

When duloxetine was administered orally to pregnant rats and rabbits during the period of organogenesis, there was no evidence of teratogenicity at doses up to 45 mg/kg/day (7 times the maximum recommended human dose [MRHD, 60 mg/day] and 4 times the human dose of 120 mg/day on a mg/m^2 basis, in rat; 15 times the MRHD and 7 times the human dose of 120 mg/day on a mg/m^2 basis in rabbit). However, fetal weights were decreased at this dose, with a no-effect dose of 10 mg/kg/day (2 times the MRHD and ≈1 times the human dose of 120 mg/day on a mg/m^2 basis in rat; 3 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis in rabbits).

When duloxetine was administered orally to pregnant rats throughout gestation and lactation, the survival of pups to 1 day postpartum and pup body weights at birth and during the lactation period were decreased at a dose of 30 mg/kg/day (5 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis); the no-effect dose was 10 mg/kg/day. Furthermore, behaviors consistent with increased reactivity, such as increased startle response to noise and decreased habituation of locomotor activity, were observed in pups following maternal exposure to 30 mg/kg/day. Post-weaning growth and reproductive performance of the progeny were not affected adversely by maternal duloxetine treatment.

There are no adequate and well-controlled studies in pregnant women; therefore, duloxetine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects—Neonates exposed to SSRIs or serotonin and norepinephrine reuptake inhibitors (SNRIs), late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome *[see Warnings and Precautions]*.

When treating pregnant women with Cymbalta during the third trimester, the physician should carefully consider the potential risks and benefits of treatment. The physician may consider tapering Cymbalta in the third trimester.

Labor and Delivery—The effect of duloxetine on labor and delivery in humans is unknown. Duloxetine should be used during labor and delivery only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Duloxetine is excreted into the milk of lactating women. The estimated daily infant dose on a mg/kg basis is approximately 0.14% of the maternal dose. Because the safety of duloxetine in infants is not known, nursing while on Cymbalta is not recommended. However, if the physician determines that the benefit of duloxetine therapy for the mother outweighs any potential risk to the infant, no dosage adjustment is required as lactation did not influence duloxetine pharmacokinetics.

Pediatric Use—Safety and effectiveness in the pediatric population have not been established *[see Boxed Warning and Warnings and Precautions]*. Anyone considering the use of Cymbalta in a child or adolescent must balance the potential risks with the clinical need.

Geriatric Use—Of the 2,418 patients in premarketing clinical studies of Cymbalta for MDD, 5.9% (143) were 65 years of age or over. Of the 1,074 patients in the DPNP premarketing studies, 33% (357) were 65 years of age or over. Of the 1,761 patients in FM premarketing studies, 7.9% (140) were 65 years of age or over. Premarketing clinical studies of GAD did not include sufficient numbers of subjects age 65 or over to determine whether they respond differently from younger subjects. In the MDD and DPNP studies, no overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. SSRIs and SNRIs, including Cymbalta have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event *[see Warnings and Precautions]*.

Gender—The half-life of duloxetine is similar in men and women. Dosage adjustment based on gender is not necessary.

Smoking Status—Duloxetine bioavailability (AUC) appears to be reduced by about one-third in smokers. Dosage modifications are not recommended for smokers.

Race—No specific pharmacokinetic study was conducted to investigate the effects of race.

Hepatic Insufficiency—*[see Warnings and Precautions]*.

Severe Renal Impairment—*[see Warnings and Precautions]*.

DRUG ABUSE AND DEPENDENCE: Abuse—In animal studies, duloxetine did not demonstrate barbiturate-like (depressant) abuse potential. While Cymbalta has not been systematically studied in humans for its potential for abuse, there was no indication of drug-seeking behavior in the clinical trials. However, it is not possible to predict on the basis of premarketing experience the extent to which a CNS active drug will be misused, diverted, and/or abused once marketed. Consequently, physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse of Cymbalta (e.g., development of tolerance, incrementation of dose, drug-seeking behavior).

Dependence—In drug dependence studies, duloxetine did not demonstrate dependence producing potential in rats.

OVERDOSAGE: Signs and Symptoms—In postmarketing experience, fatal outcomes have been reported for acute overdoses, primarily with mixed overdoses, but also with duloxetine only, at doses as low as 1000 mg. Signs and symptoms of overdose (duloxetine alone or with mixed drugs) included somnolence, coma, serotonin syndrome, seizures, syncope, tachycardia, hypotension, hypertension, and vomiting.

Management of Overdose—There is no specific antidote to Cymbalta, but if serotonin syndrome ensues, specific treatment (such as with cyproheptadine and/or temperature control) may be considered. In case of acute overdose, treatment should consist of those general measures employed in the management of overdose with any drug.

NONCLINICAL TOXICOLOGY: Carcinogenesis, Mutagenesis, and Impairment of Fertility—Carcinogenesis—Duloxetine was administered in the diet to mice and rats for 2 years.

In female mice receiving duloxetine at 140 mg/kg/day (11 times the maximum recommended human dose [MRHD, 60 mg/day] and 6 times the human dose of 120 mg/day on a mg/m^2 basis), there was an increased incidence of hepatocellular adenomas and carcinomas. The no-effect dose was 50 mg/kg/day (4 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis). Tumor incidence was not increased in male mice receiving duloxetine at doses up to 100 mg/kg/day (8 times the MRHD and 4 times the human dose of 120 mg/day on a mg/m^2 basis).

In rats, dietary doses of duloxetine up to 27 mg/kg/day in females (4 times the MRHD and 2 times the human dose of 120 mg/day on a mg/m^2 basis) and up to 36 mg/kg/day in males (6 times the MRHD and 3 times the human dose of 120 mg/day on a mg/m^2 basis) did not increase the incidence of tumors.

Mutagenesis—Duloxetine was not mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) and was not clastogenic in an *in vivo* chromosomal aberration test in mouse bone marrow cells. Additionally, duloxetine was not genotoxic in an *in vitro* mammalian forward gene mutation assay in mouse lymphoma cells or in an *in vitro* unscheduled DNA synthesis (UDS) assay in primary rat hepatocytes, and did not induce sister chromatid exchange in Chinese hamster bone marrow *in vivo*.

Impairment of Fertility—Duloxetine administered orally to either male or female rats prior to and throughout mating at doses up to 45 mg/kg/day (7 times the maximum recommended human dose of 60 mg/day and 4 times the human dose of 120 mg/day on a mg/m^2 basis) did not alter mating or fertility.

PATIENT COUNSELING INFORMATION: See FDA-approved Medication Guide and Patient Counseling Information section of full PI.

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How the AMA Is Working To Secure Your Future

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

The AMA and its Resident and Fellow Section (RFS) met in San Diego for five days in early November and demonstrated that the field of psychiatry continues to have a strong presence in the RFS. Among the psychiatry residents attending the meeting were our current APA resident delegate, Paul O'Leary, M.D., and Steve Koh, M.D., the APA alternate resident delegate and chair of the APA Assembly Committee of Area Members-in-Training Representatives.

The recent RFS meeting focused on the AMA's advocacy agenda, and there was considerable discussion about how the recent national election results might change health care reform efforts on Capitol Hill, particularly the outlook for implementation of the new health reform law. At least partly at the urging of its student, resident, and young physician members, the AMA has shifted over the past five years into being a strong advocate of coverage for the uninsured, through a system much like the one President Obama signed into law. Unfortunately, the AMA's resulting support of federal health reform also provoked anger from some of its members, particularly in high-resource specialties that could face tighter utilization review and lower incomes.

Despite the criticisms, at this meeting AMA leadership reaffirmed what psychiatrists have known for years: our country cannot survive when our patients cannot access even basic health services.

The AMA continues working to keep our future practices viable, with renewed congressional lobbying to end Medicare's use of the sustainable growth rate (SGR) to determine physician reimbursement (see page 1). The SGR is a complex economic formula that has led to threatened Medicare pay cuts to all specialties of about 23 percent by the end of this year. Even if you don't treat Medicare patients, your hospital and your program depend on Medicare revenues, and these cuts would mean a massive decrease in the financial support available for medical education and training. Your AMA delegation and the RFS are also working hard to restore Medicare payment for consultations (eliminated earlier this year), an issue of serious concern to psychiatrists.

On residency issues in particular, the AMA Council on Medical Education provided a report on its efforts to expand access to economic-hardship and public-service-based loan repayment programs, on which many of us will depend if we choose to work in academia or in the community mental health system. Sadly, with massive federal budget cuts looming, especially in light of the Republican takeover of the House of Representatives, we are unlikely to see major loan relief in the near future.

Every AMA meeting also includes a wide variety of focused requests from passionate physician-advocates nationwide. We debated and adopted a report of the Council on Ethical and Judicial Affairs addressing physicians' use of social-networking sites, the rescheduling of cannabis to permit more research into its beneficial and harmful effects, and routine HIV screening that does not require special consent. An issue that received considerable attention was a resolution advocating for federal recognition of same-sex civil marriages, which was referred to the AMA Board of Trustees for study (see page 4). APA has already adopted a policy supporting the right of same-sex couples to marry.

All of us who work with gay and lesbian patients have seen how strongly they are affected because our nation considers them second-class citizens. A number of psychiatrists, including Drs. O'Leary and David Fassler, made impassioned statements in support of the resolution on same-sex marriage rights, and it was a shining moment for APA and for psychiatry.

The AMA meeting is also a venue for residents to caucus with leaders of APA and other psychiatric societies. Our biggest question was: where are the jobs? Residents in many parts of the country are having difficulty finding that first job, especially those who do not want to start a solo practice.

In response, APA said it is working to improve its job bank, but we were reminded that we have a much more important resource: our district branch (DB). If your department chair or professors aren't able to help with your job search, your DB's leadership is made up of psychiatrists who know their local community and can give you a helping hand. Most DBs meet every month and welcome residents to their meetings—drop them an e-mail and start networking!

Finally, all of us from the APA member-in-training leadership want to thank those of you who have gone the extra mile and become members of both APA and the AMA. As the only organization in which all of medicine speaks with one voice, the AMA is the strongest advocate for improving the quality of our training, our lives, and our careers. When you join AMA, we as psychiatrists get more representation and a stronger ability to carry your issues forward, and the organization gets the funding it needs to solve those issues. Many of you face financial difficulties, and it is not easy to pay your dues each year. Still, every time you do so, you are making a solid investment in your own future and ensuring that you will be respected, heard, and fairly compensated.

When the AMA asks for your support, please join or renew—we need your help to secure psychiatry's future! ■

Kayla Pope, M.D., J.D., is APA's member-in-training trustee, the Robert L. Stubblefield AACAP resident member to the AMA, and a clinical research fellow at NIMH and Children's National Medical Center.

association news

Innovative MH Programs Win APA Achievement Awards

Trailblazing programs that help people with mental illness receive well-deserved recognition from APA.

BY MARY WARD

APA presented its annual Psychiatric Services Achievement Awards at the 2010 Institute on Psychiatric Services in Boston in October to innovative programs that deliver services to mentally ill or disabled persons, have overcome obstacles, and can serve as models for other programs. The award competition was supported by Pfizer Inc. The awards have been given since 1949.

Following a video shown at the Opening Session about the Achievement Awards program and the 2010 winning programs, the awards were presented by Jill Williams, M.D., chair of the Achievement Awards Committee. All winning programs participated in a workshop at the institute highlighting their unique efforts.

Two Gold Award winners each received a $10,000 check and a plaque. Silver and Bronze Award winners were presented with a $7,500 and $5,000 check, respectively, and a plaque.

Gold Achievement Awards

• **St. Bernard Family Resiliency Project** of the Louisiana State University Health Sciences Center's Department of Psychiatry in New Orleans won in the category of academically or institutionally sponsored programs. The program was recognized for successful integration of mental health services into the school system and youth leadership and community outreach for children and families recovering from the traumatic effects of Hurricane Katrina. Howard Osofsky, M.D., program director, and Joy Osofsky, Ph.D., program co-director, accepted the award.

• **The DIAMOND Program** (Depression Improvement Across Minnesota, Offering a New Direction) of the Institute for Clinical Systems Improvement won the Gold Award for community-based programs. The award was accepted by Pam Pietruszewski, M.A., Michael Trangle, M.D., and Mark Williams, M.D.

The program was recognized for its innovative, evidence-based collaborative treatment model, which integrates psychiatric consultation and care management into the treatment of major depression in primary care clinics.

Silver Achievement Award

• **The Project for Psychiatric Outreach to the Homeless** of the Center for Urban Community Services in New York City was recognized for its efforts and innovative approaches to bringing psychiatric treatment services to homeless adults and individuals living in supportive housing. Van Yu, M.D., director of the center, accepted the award.

Credit: Ellen Dallager

Seated, from left: Jill Williams, M.D., chair, Achievement Awards Committee; Linda Bueno, American Psychiatric Foundation; Pam Pietruszewski, the DIAMOND Program; Ilise Lombardo, M.D., Pfizer Inc.; Beatrice Kovasznay, M.D., Ph.D., Achievement Awards Committee. Second row, from left: Mary Ward, APA; Van Yu, M.D., Project for Psychiatric Outreach to the Homeless; Howard Osofsky, M.D., and Joy Osofsky, Ph.D., St. Bernard Family Resiliency Project; Michael Trangle, M.D., the DIAMOND Program; James Tew, M.D., Behavioral Health Laboratory at Philadelphia and Pittsburgh VA Medical Centers; Mark Williams, M.D., the DIAMOND Program; Johanna Klaus, Ph.D., Behavioral Health Laboratory at Philadelphia and Pittsburgh VA Medical Centers; and Gerard Gallucci, M.D., Achievement Awards Committee.

Bronze Achievement Award

• **The Behavioral Health Laboratory at the Philadelphia and Pittsburgh Veterans Affairs Medical Centers** in Pennsylvania received the Bronze Award in recognition of its leadership in the dissemination of psychiatric expertise and evidence-based behavioral health management in primary care settings. The award was accepted by Johanna Klaus, Ph.D., and James Tew, M.D.

More information about the 2010 winners can be accessed at <http://ps.psychiatryonline.org/content/vol61/issue10/index.dtl> by scrolling down to "APA Achievement Awards." A video about the winning programs is posted at <www.psych.org/achievementawards>. Information about the 2011 competition is available from Mary Ward at (202) 907-8592 or mward@psych.org. ■

Mary Ward is a staff member of APA's Office of Healthcare Systems and Financing.

government news

Screening Mandate Will Be Boon To Early Mental Illness Detection

Private insurers and many Medicaid plans will be required to cover the cost of screening beneficiaries for psychiatric illness, which is expected to decrease the number of individuals whose mental illness goes undetected.

BY RICH DALY

Screening for psychiatric illness in adults and children nationwide is expected to increase as coverage mandates in the new health care law for both private and public insurance programs go into effect over the next few years. And that increase could help cut the rates of untreated mental illness, said mental health advocates.

Supporters of increased access to mental health care gathered for a Capitol Hill briefing in November to hail the expected benefits of the health care reform law. Those benefits came via provisions that include a requirement that all health insurance plans participating in the new state health insurance exchanges—planned for launch by 2014—cover services recommended by the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee of Immunization Practices at the Centers for Disease Control and Prevention, and the Health Resources and Services Administration.

Among the recommendations are an annual depression screening for all youth aged 12 to 18 and depression screenings for adults "when staff-assisted depression care supports are in place to ensure accurate diagnosis, effective treatment, and follow-up," according to the USPSTF.

Importantly, the law mandates that all insurance plans that were issued after September cover 100 percent of the cost of preventive care, including mental health screenings, when they are offered by in-network providers.

These coverage requirements serve only as a floor, and thus more-generous screening coverage requirements established in some states could remain in place.

Credit: Rich Daly

Rep. Doris Matsui (D-Calif.) describes her efforts to include insurance coverage requirements for prevention services under the health care reform legislation enacted in March. She spoke at a briefing on Capitol Hill in November.

"There are too many people who do not receive the care they need," said Rep. Doris Matsui (D-Calif.) at the November briefing, which was sponsored by the TeenScreen National Center for Mental Health Checkups at Columbia University. "This law will help address that."

As a member of one of the committees that wrote the House version of the health care legislation, Matsui advocated for the inclusion of preventive care and "wellness provisions."

Also included in the law was an expansion of the federal Medicaid Early and Periodic Screening, Diagnostic, and Treatment benefit, which includes a mental health assessment as part of its covered well-child visits. Many Medicaid plans are required to offer such assessments to comply with the requirements of the federal insurance parity law enacted in 2008. The parity law requires most private insurers to offer the same level of coverage for screening, diagnosis, and treatment of psychiatric disorders as they do for other types of medical conditions.

Researchers and public-health policymakers have long touted the benefits of mental health screening, including that for substance use disorders, in primary care, which is the only medical point of contact for the vast majority of the population. They maintain that routine screening for mental illness is the most effective way to lower the rate of untreated mental illness, which in 2009 stood at 62 percent of people with symptoms of such illness, according to a Substance Abuse and Mental Health Services Administration

please see ***Screening*** *on page 28*

Health Reform Opponents May Undo MH Access Expansion

Efforts to thwart threats to health care reform provisions that benefit people with mental illness could be complicated by the law's unpopularity and potential problems with its implementation.

BY RICH DALY

A public that is still split over the Democrat-led health care law and the increase in Republican members of Congress after the November elections could endanger provisions of the law that benefit people with psychiatric disorders, say mental health advocates.

These advocates, including APA, are nervously watching congressional Republicans for indications of how they will target the wide-ranging health care law enacted in March. Since the bill passed without support from any Republicans in Congress, members of that party have declared their intent to "repeal and replace" the law with more limited "market-based reforms."

Mental health advocates are especially concerned that provisions considered critical to expanding access to treatment for people with mental illness will be those targeted for repeal.

"Regardless of the party in charge in Congress or media narrative, APA is always concerned about defending the advances in mental health treatment and coverage that have been enacted into law," said Matthew Sturm, an associate director of APA's Department of Government Relations, in an interview with *Psychiatric News*.

Beyond Republicans' announced intentions to target some or all of the law for repeal, supporters of various provisions of the law are concerned that their efforts to protect it could be complicated by problems such as insurers' dropping coverage for certain populations. Several insurers have dropped their individual, child-only, or Medicare Advantage policies, including Harvard Pilgrim Health Care in New England, which ended its Medicare Advantage plan for 22,000 seniors over concerns about "the long-term viability" of the plan in light of the health care law's changes.

Additionally, the Kaiser Family Foundation's September tracking poll of public opinion found likely voters equally divided at about 45 percent each on whether they supported or opposed the law, percentages that have changed little in the past six months. The poll results have been disappointing to President Obama and congressional leaders who were hopeful that the legislation would quickly gain popularity after its passage.

The law's defenders also face challenges from unexpected implementation complications. For instance, about 30 companies providing limited-coverage policies to 1 million employees have received one-year exemptions from the Department of Health and Human Services to the law's coverage mandates after the companies found their policies would not meet the law's minimum coverage requirements. The exemptions angered health care reform advocates who were concerned that the move weakened the law.

These factors could feed Republican efforts to push through repeals of some provisions of the law—possibly even with the support of some Democrats, according to advocates.

Short of a repeal of the entire health care law, it remains unclear what provisions the GOP will target first. One of the most likely approaches could entail cutting off funding for the federal agencies or departments, such as Health and Human Services, that are responsible for implementing the law's provisions, according to advocates. Such a move worries advocates because it could affect the implementation of the law's state-based insurance exchanges—or marketplaces—which require participating insurers to provide mental health care coverage at parity with that for other types of medical care.

Republicans would likely have the support of insurers if they moved to roll back the requirement for parity coverage within those state exchanges, said Andrew Sperling, director of federal legislative advocacy for the National Alliance on Mental Illness, in an interview with *Psychiatric News*. Insurers have long opposed various parity-law requirements over concerns that they will raise the cost of the policies that the companies sell.

The best indication of other likely Republican targets in the health law may be provisions they have already targeted for repeal in the current Congress. For instance, in September the Senate came within four votes of approving an amendment to tax legislation that would have eliminated funding for the federal health care law's $11 billion Prevention and Public Health Fund. The fund was needed, according to a letter APA and other health care advocates sent to members of Congress, to pay for local health departments' illness-prevention programs, such as those that provide immunizations.

The nonprofit Center on Budget and Policy Priorities estimated that the amendment would have cut the number of people gaining insurance under the law by 2 million and would have increased premiums by as much as 4 percent for people with coverage through the new health insurance exchanges—due to the smaller number of healthy people being included in insurance pools.

Another likely target for Republican repeal efforts is the Community Living Assistance Services and Supports (CLASS) Act, a voluntary long-term-care insurance program that will provide cash benefits to help cover the cost of nursing-home care, a home-care attendant, equipment and supplies, and home improvements to aid disabled beneficiaries. Mental health advocates said the program is needed to keep the soaring cost of long-term services

please see ***Health Reform*** *on page 28*

legal news

APA Backs Order for Major Prisoner Release

APA's amicus brief urges the Supreme Court to order California to cut its prison population dramatically to provide the mental health treatment that many inmates need but do not receive.

BY RICH DALY

Two decades of legal fights over California's treatment of prisoners with mental illness reached the Supreme Court this year when the Court agreed to review the central issue of prison overcrowding.

The case has drawn amicus briefs from APA and other mental health organizations and advocacy groups, which view overcrowded prison populations nationwide as one of the biggest barriers to the provision of quality mental health care for prisoners with mental illness.

APA and other groups in the mental health field filed their amicus brief at the beginning of November in support of a lower federal court's ruling that California must release more than 38,000 inmates from a state system that is at twice its capacity so that the state can provide mental and other types of medical care to which prisoners are entitled under Supreme Court interpretations of the U.S. Constitution's protections from "cruel and unusual punishments."

California opposes the lower-court order on the basis that the overcrowding issue is beyond the mandate of the three-judge panel that issued it and that has provided oversight of medical reforms (including the extent of and manner in which mental health care is provided) in the state's prison system.

The Supreme Court review of the case, *Schwarzenegger v. Plata*, follows hearing 20 years of California lawsuits by inmates' advocates seeking improved mental and other types of health care. The Court heard arguments in the case on November 30.

The Court's eventual ruling on the overcrowding issue is critical to prisoner health, according to mental health advocates, and is potentially precedent-setting for prisons across the nation.

"The key [issue] is the extent and impact of overcrowding on the mental health care of prisoners," said Paul Appelbaum, M.D., a past president of APA and a member and former chair of APA's Council on Psychiatry and Law, in an interview with *Psychiatric News*. APA's amicus brief, he said, outlines the extent to which overcrowding is "the prime negative factor for mental health delivery."

Overcrowding has undercut the delivery of mental health care in the California penal system, according to the amicus brief, resulting in inadequate medication management, poor access to clinicians, lack of suicide prevention programs, deficiencies in medical-record keeping, and other problems. Appelbaum and others noted that the inmate population is too large to recruit enough clinicians to provide quality care, given budget constraints.

Additionally, the amicus brief cited research and clinical knowledge of mental illness factors showing that prison overcrowding can exacerbate existing mental illness.

Treatment Requirements Lacking

"Clinical experience supports the conclusion that crowding may create pervasive and intractable problems for the provision of minimally adequate mental health care," the brief states. "To ensure that prisoners are evaluated for mental illness and afforded minimally adequate treatment, there must be sufficient clinical staff, space in which to provide treatment and perform screening and clinical evaluations, and clinical facilities to accommodate inmates requiring higher levels of care."

Such overcrowding, which necessitates the use of gyms and community rooms as dormitories, has additional negative effects on inmates' mental health. The unavailability of gyms and community rooms for their designed purposes and the lack of proper sleeping facilities prevent activities needed to help keep prisoners mentally healthy, including proper sleep, exercise, and vocational activities, Lewis Bossing, a senior staff attorney at the Bazelon Center, told *Psychiatric News*.

APA was joined in its brief by the California Psychiatric Association, American Psychological Association, California Psychological Association, American Academy of Psychiatry and the Law, Forensic Mental Health Association of California, National Alliance on Mental Illness, and Bazelon Center for Mental Health Law.

"We thought it was important to remind everyone that there is a constitutional standard for mental health care," Bossing said.

Despite a federal court takeover of the supervision of California's prisoner health care system in the 1990s and successive increases in clinical staff and treatment facilities, the state has been overwhelmed by a "tidal wave" of new prisoners in the last 15 years, Appelbaum said. An increase in the prison population was accompanied by a flood of inmates with mental illness, including up to 18,000 such inmates in 1995 and 34,000 in 2008, according to state estimates.

Law Said Judges Can Intervene

Such burgeoning prisoner populations nationwide led to the Prison Litigation Reform Act (PL 104-134), which was enacted in 1996 and authorized panels of federal judges to issue prisoner-release orders in state prison systems but only when prison overcrowding is the primary cause of a violation of a constitutional right and when no other action will correct the problem.

A three-judge in California ruled in January that although prison overcrowding was not the only cause of the constitutional violations, it was the primary cause of a lack of constitutionally adequate mental and general health care. The panel of judges concluded that reforms of the prison health care system were impossible until the overcrowding was addressed. They ordered California to cut its prison population within two years from 200 percent of its design capacity to 137.5 percent, which would require the early release of up to 46,000 inmates.

The California prison system population is currently 165,000, though it was designed to house only 80,000.

Any long-term solution to the conflict between the needs of burgeoning prison populations and the needs of inmates with psychiatric disorders, Bossing said, will have to include aggressive jail-diversion programs and other treatment interventions for those who are arrested. Otherwise large numbers of people with untreated psychiatric conditions will continue to add to the overcrowding and aggravate the problems of prisons' already inadequate treatment system.

The APA amicus brief in* Schwarzenegger v. Plata *is posted at <www.abanet.org/publiced/preview/briefs/pdfs/09-10/09-1233_AppelleeAmCu9MentalHealthGrps.pdf>. More information on the case is posted at <www.scotusblog.com/case-files/cases/schwarzenegger-v-plata/>. ■

professional news

Insurance Mandate

continued from page 4

doctors or patients, but did provide meaningful insurance reform—especially guaranteed issue and an end to discrimination based on preexisting conditions.

"Though we need these reforms to protect our patients, they also create an incentive to delay purchasing private insurance until they become sick," Eiting testified. "An individual mandate is the safeguard that prevents this from happening. It ensures that healthy people contribute to the pool so they can get the care they need when they become sick. Without a mandate, healthy people opt out of coverage, leaving a pool of only sick people. This drives up costs of insurance, creating a greater incentive for more healthy people to opt out, eventually creating a death spiral.

"My fear is that without an individual mandate, private insurance will go away. We already see this happening with BlueCross BlueShield in Oregon, where they have stopped writing policies for child-only coverage," Eiting said. "We cannot have a system that drives insurance companies to deny coverage to the sickest people who need it the most."

Even more indicative of divisions within the House of Delegates was protracted debate on a resolution written by the Medical Student Section that would have, if approved, called on the AMA to recognize that denial of civil marriage to same-sex couples contributes to health care disparities among gay and lesbian individuals and to support the repeal of the Defense of Marriage Act (DOMA).

The resolution received the vocal support of members of the Section Council on Psychiatry who noted that APA has a policy supporting civil marriage. But most striking was the virtually unanimous support for the resolution among the youngest members of the House of Delegates, who have brought to the AMA a keen interest in public health and social-justice issues.

"Same-sex couples form long-term, healthy, and satisfying relationships similar to those of heterosexual couples," said psychiatrist Paul O'Leary, M.D., a delegate from the Resident and Fellow Section. He added that there are advantages to civil marriage—emotional, physical, and economic—that accrue to parents and children of same-sex couples.

But a number of physicians said they believed support of civil marriage is a social and political issue, not a medical one, that is divisive within American society generally and within the House of Delegates.

The influence on the debate of the recent Republican sweep to victory in midterm Congressional elections—which occurred just four days prior to the meeting of the AMA delegates—was evident in remarks made by Madelyne Butler, M.D., president of the Florida Medical Association.

She said the AMA would need Republican support for the Medicare Patient Empowerment Act, an AMA-sponsored bill allowing Medicare patients to keep their benefits when they contract privately with a physician of their choice. (Under current regulations, the only way physicians can negotiate a separate fee is by formally "opting out" of Medicare, which removes the physician from Medicare for two years and necessitates each patient's signing a statement acknowledging that he or she cannot be reimbursed by Medicare for services provided by that physician. The AMA-sponsored bill would allow physicians and patients to contract privately with each other for a fee different from the Medicare fee, while still allowing patients to use Medicare benefits for partial reimbursement. With little or no debate at all, delegates at the San Diego meeting approved a resolution calling on the AMA to "commit to a well-funded and top-priority legislative and grassroots campaign" to ensure passage of the bill.)

But Butler said support for civil marriage and repeal of DOMA by the House of Delegates would dominate headlines and jeopardize Congressional support for the private-contracting bill.

"This will be a headline item if we pass this resolution," she told delegates during reference committee hearings on the civil-marriage resolution. "It will alienate our patients, and it will alienate the new Republican majority that has taken over the House [of Representatives]. I would not want it put forth that this is the major issue facing medicine today or trumpeted in the newspapers that this is the only thing we have done at this meeting." ■

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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.

- Significantly higher rates of response and remission vs placebo in MDD and GAD in adults[4,5]

- 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.
- 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.

Please see Boxed Warning on first page and additional Important Safety Information on next page.

Lexapro®
escitalopram oxalate

Visit the LEXAPRO website at www.lexapro.com

LEXAPRO: Proven efficacy in MDD in adolescents aged 12 to 17, and in MDD and GAD in adults[1-5]

Warnings and Precautions (continued)

- 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. LEXAPRO [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2009. **2.** 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. **3.** 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. **4.** 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. **5.** 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.

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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 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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Depression Symptoms Linked To Nighttime Light Exposure

Dim-light exposure at night—comparable to having a television on in a darkened room—appears to be capable of triggering depression in animals.

BY JOAN AREHART-TREICHEL

Exposure to constant bright light at night seems to be a trigger for depression-like symptoms in mice, Randy Nelson, Ph.D., a professor and chair of neuroscience at Ohio State University, reported in the December 28, 2009, *Behavioral Brain Research.*

Now Nelson, Tracy Bedrosian, a doctoral student in neuroscience at Ohio State University, and their colleagues have found that exposure to even dim light at night appears to be capable of triggering depression-like symptoms in hamsters.

Bedrosian presented these new study data on November 17 at the annual meeting of the Society for Neuroscience in San Diego.

The study involved 16 female Siberian hamsters that had their ovaries removed to ensure that ovarian hormones would not interfere with the study's results. Half were housed in a standard light-dark cycle of 16 hours of light (at 150 lux) followed by eight hours of total darkness. The other half were exposed to a different light-dark cycle—16 hours of light (at 150 lux) followed by eight hours of dim light (5 lux), which was the equivalent of having a television on in a darkened room.

After eight weeks in their lighting condition, the animals were tested for depression-like behaviors.

The researchers used two tests for depression-like behaviors—the sucrose-intake test and Porsolt's swim test—that are used in basic research and in the preclinical testing of antidepressants by pharmaceutical companies.

In the sucrose-intake test, rodents are offered sugar water, which they usually like. If they do not show much interest in it, it is interpreted to be a sign of the anhedonia that depressed patients exhibit.

In the swim test, rodents are placed in a swim tank and observed to see whether they continue to search for an escape from the water or give up and just float on top of the water. If they give up, it is interpreted as a sign of the despair or helplessness that depressed patients often feel.

The hamsters exposed to dark nights enjoyed sugar water, whereas the hamsters exposed to dim-light nights enjoyed it less, suggesting that the dim-light hamsters were experiencing anhedonia. The hamsters exposed to dark nights did not give up in their search for an escape from water, whereas the hamsters exposed to dim-light nights did, suggesting that the dim-light hamsters were experiencing despair or helplessness.

In brief, it looked as if the dim light at night might have initiated depression in hamsters that had been exposed to it, the researchers concluded.

The researchers then compared the brains of the hamsters that had been exposed to dim-light nights with the brains of the hamsters that had been exposed to dark nights to gain some understanding of how the dim light might have actuated depression.

The hippocampi from the dim-light group had significantly fewer dendritic spines than those from the dark night group. Since the hippocampus is known to play a key role in depressive disorders, the researchers concluded that dim light might have reduced the number of dendritic spines in the hippocampus and thereby initiated the depression-like symptoms.

But how might dim light have brought about dendritic spine changes? The stress hormone cortisol didn't seem to be implicated since the researchers found no difference in cortisol levels between the two groups of hamsters. Their hypothesis is that the hormone melatonin might have been the culprit. They are planning to conduct further research to see whether that is the case.

Meanwhile, whether the results from these two animal studies hold implications for humans remains to be seen. "In seasonal affective disorder (SAD), people receive less light than normal due to the short day lengths," Bedrosian told *Psychiatric News*. "Since we studied more light, not less, our work is not directly related to SAD. However, our findings do suggest that chronic exposure to light at night could be one contributor to depressive disorders unrelated to predispositions for SAD or other conditions."

Regarding the question of whether people should avoid even night-lights to minimize the risk of getting night-light-initiated depression, Bedrosian had this to say: "We will need to do future work to understand how light at night affects mood in humans. However, if there is indeed a link, then perhaps people should minimize exposure to artificial light at nighttime. So, avoiding sleeping with a night-light, not falling asleep with the bedroom TV on all night long, and perhaps using dark curtains to block out street light might be a good idea. Exposure to light at night is unnatural and has only arisen in the past century, so minimizing exposure certainly can't hurt." ■

Are Clinicians too Quick to Diagnose Bipolar Illness in Children?

Treatment for the extreme emotional outbursts seen in some children may benefit more from family therapy than from psychopharmacology.

BY AARON LEVIN

The statistical rise in diagnoses of pediatric bipolar disorder over the last several years has stirred debate among child psychiatrists, and there's no lack of argument about its implications, said Allan Josephson, M.D.

"Office-based visits with a diagnosis of bipolar disorder for youth have risen 40 times in 10 years, from 25 per 100,000 in 1994-95 to 1,003 per 100,000 in 2002-03," he said at the annual meeting of the American Academy of Child and Adolescent Psychiatry in New York in October.

There are good and bad outcomes of this development, said Josephson, a professor and vice chair for child and adolescent psychiatry services and CEO of the Bingham Child Guidance Center at the University of Louisville.

Bipolar disorder does exist in children and adolescents and may well have been underdiagnosed in the past, so the increased attention to the disorder has brought needed treatment to children.

However, some irritable, explosive children are lumped into the bipolar category, possibly because no other label seems to fit, said discussant Gabrielle Carlson, M.D., a professor of psychiatry and pediatrics and director of child and adolescent psychiatry at Stony Brook University School of Medicine in New York.

Other researchers have proposed a diagnosis of "severe mood dysregulation" for these children, who are characterized by chronic irritability, hyperarousal, and hyper-reactivity, but not the episodic manic symptoms typical of *DSM-IV* bipolar illness.

"The emphasis on bipolar disorder as an explanation [for this behavior] has also communicated the unhealthy idea that children's behavioral problems lie outside the child's or the family's control," said Josephson. "It changed the point of control from the child to 'chemicals.' That leads to misguided therapies, focusing on disease elements to the neglect of psychosocial aspects of development."

A number of changes within the profession of child psychiatry also have contributed to the confusion over diagnosis and nomenclature, he said.

These include having less time available for clinical work and for collecting developmental and family histories. There is a narrowing emphasis on neuroscience today, along with insufficient integration between the biological and psychological sides of psychiatry.

In her discussion, Carlson reported that she sees children with what she called "difficult temperaments." They have rages and meltdowns, adapt poorly to change, and have trouble transitioning. They exhibit poor sleep patterns, poor planning and working-memory abilities, and a need for immediate gratification.

Like children with pervasive developmental disorders, they misread social cues and can't put their frustrations into words.

"I call these children 'diagnostically homeless' because there is still not a systematic way of identifying them," she said. "These explosive outbursts are the most lethal thing we have in child psychiatry and are responsible for much disability."

Part of the problem is that the outbursts appear in a variety of disorders described in *DSM-IV*—oppositional defiant disorder, attention-deficit/hyperactivitity disorder, bipolar disorder, and others. They are therefore analogous to a high fever: they complicate a number of disorders, said Carlson.

"We should consider them as a modifier for existing disorders, like we do with psychosis," she said.

Criteria for bipolar disorder can be confusing in young patients, especially when discrete episodes of illness are often less discernable than they are in adults. Conflicting diagnoses arise from clinical observation of dysregulated affect and behavior or, more specifically, rages and other emotional outbursts, said Josephson.

In fact, some dysregulation may be inevitable, he said. "All children have poorly regulated, irritable behavior at some point in their development, so learning how to regulate behavior and affect are normal, fundamental processes of child development."

But the extreme outbursts that bring parents into the clinic are not solely the responsibility of the child, said Josephson.

"Kids do not do this alone," he said. "Regulation in child development is deeply embedded in the child's relations with others, especially caregivers."

Thus, poor regulation of affect and behavior has roots beyond disease, he said. Many of those roots are planted firmly in the whole family's life experience.

For instance, parents who yell at their children are modeling impulsivity and contributing to the child's psychopathology.

Many of these children also have a sense of entitlement, which is often based in either indulgence or emotional neglect by the parents. Indulgence removes roadblocks to frustration and, with them, any incentive to develop self-regulation, he said. Neglect communicates the feeling that the child is on its own in the world and has to look out for himself or herself because no one else will.

Intervention involves work with the entire family, said Josephson. The child's view of his entitlement is a target, but so are parental and marital dynamics. Parents must be educated to tolerate the child's rage. Indulgent parents must learn not to give in easily, while neglectful ones must be helped to engage the child.

"Clinicians must hold families empathically accountable for how they interact with their children," said Josephson. "Parents must then be empathically available to their children and must hold them accountable for their behavior." ■

Don't Blame Amygdala for Meth Users' Aggression

Researchers set out to learn why individuals who use methamphetamine often act aggressively. The answer, to their surprise, may not lie in the amygdala, but in the ventral inferior frontal gyrus.

BY JOAN AREHART-TREICHEL

Methamphetamine (meth) is a powerfully addictive drug that can cause aggression and violent behavior.

But how does it accomplish this? The answer, or at least part of it, now appears to have been found—meth works in the ventral inferior frontal gyrus region of the prefrontal cortex of the brain.

The study's senior investigator was Edythe London, Ph.D., a professor of psychiatry and behavioral sciences at the University of California at Los Angeles Semel Institute. Results were published online November 1 in the *Archives of General Psychiatry*.

The study included 76 subjects aged 18 to 55—half were meth-dependent volunteers and half were drug-free control volunteers. They were recruited using radio, Internet, and newspaper ads. All participated in the study on a residential basis for two to four weeks.

First the researchers evaluated subjects for aggression and found, as they had expected, that the meth-users group was more aggressive than the control group was. They also tested subjects for their ability to recognize emotional states and to describe them. The meth group turned out to be less adept at this exercise, and their deficits in recognizing and describing their emotional states correlated with their aggression scores. These results, too, were not surprising, the researchers noted.

But then came something that did surprise them. While subjects performed an emotion-arousing and emotion-regulating task, their brains were imaged with fMRI scans, and the scans showed that the amygdala in the meth group was just as good at regulating itself as the amygdala in the control group was. Therefore it looked as if amygdala function could not explain the aggression often displayed by meth users.

While the researchers were scanning the subjects' brains, however, they discovered something else—that the ventral aspect of the inferior frontal gyrus in the prefrontal cortex of the meth group was significantly less activated than the same brain area in the control group. Thus, a faulty ventral inferior frontal gyrus emerged as a possible explanation for aggressive behavior in the meth-using group.

The question then was how might a faulty ventral inferior frontal gyrus lead to aggression in meth users? Perhaps by dampening emotional insight, the researchers reasoned, since this area of the brain is known to be involved in emotional insight, and this group had difficulty recognizing and describing emotional states, and this difficulty in turn correlated with their aggression scores.

If this conclusion is correct, it has clinical implications, London told *Psychiatric News*. "Lack of emotional insight (alexithymia) and the ventral inferior frontal gyrus may be more useful therapeutic targets [for aggressive meth users] than emotional regulation and amygdala function are."

London noted as well that drugs other than meth can make people aggressive. "A large variety of drugs that affect brain function have been linked to aggression," she pointed out. "These include alcohol, hallucinogens, psychomotor stimulants such as amphetamines (including meth), and cocaine. While, the molecular mechanisms of action of these agents differ from one another, a unifying mechanism that can lead to aggression is an imbalance between subcortical systems that promotes rapid responses to environmental stimuli before cortical circuits important for evaluating the circumstances can come into play."

The study was funded by the National Institutes of Health, the UCLA General Clinical Research Center, the Katherine K. and Thomas P. Pike Chair in Addiction Studies, the Marjorie Green Family Trust, and a Guggenheim grant.

An abstract of "Neural Correlates of Affect Processing and Aggression in Methamphetamine Dependence" is posted at <http://archpsyc.ama-assn.org/cgi/content/abstract/archgenpsychiatry.2010.154v1>. ■

journal digest

BY JENNIFER KELLY

Gene Implicated in Depression

A gene underlying major depression may have been found.

Scientists examined gene expression in the hippocampus of postmortem brain tissue taken from 21 individuals who had suffered from major depression and from 18 nondepressed controls matched for age, gender, and postmortem interval. They found more than twice as much expression of one gene in the depressed group than in the control group. The gene, called MKP-1, is known to be involved in neuronal plasticity, function, and survival.

A model in rats was also included in the study to assess whether the MKP-1 gene helps play a role in the function and control of depressive behaviors. The chronic unpredictable stress (CUS) model was used, and according to the authors it is one of the most validated animal models used to study depression.

This model allows scientists to study behaviors commonly seen in depression, such as anhedonia, helplessness, and other symptoms, in rats.

The administration of the commonly prescribed selective serotonin reuptake inhibitor fluoxetine to rats reversed the expression and up-regulation of the MKP-1 gene in the hippocampus by blocking MKP-1 expression. However, an increase in MKP-1 expression in rodents exposed to the CUS model but without antidepressant treatment led to depression-like behaviors in the animals.

The MKP-1 gene may be a notable player in major depression and might serve as a target for new kinds of depression treatments, the researchers concluded. Their findings were published online October 17 in *Nature Medicine.* The senior investigator was Ronald Duman, Ph.D., a professor of psychiatry and pharmacology at Yale University.

The study was funded by multiple U.S. Public Health Service grants and the Connecticut Mental Health Center.

An abstract of "A Negative Regulator of MAP Kinase Causes Depressive Behavior" is posted at <www.nature.com/nm/journal/vaop/n/current/full/nm.2219.html>.

Jaundice Linked With Autism

Danish researchers conducted a follow-up study of all children born in Denmark from 1994 to 2004. Out of the some 700,000 children, about 36,000 had neonatal jaundice, and about 500 received a diagnosis of autism. After a number of possible confounding factors were considered in the equation, those with jaundice had a 67 percent greater risk of having autism than those without jaundice did—a statistically significant difference.

The lead investigator was Rikke Maimburg, Ph.D., of Aarhus University in Denmark. The study was reported online October 11 in *Pediatrics* and was funded by the University of Aarhus Research Foundation and the Augustinus Foundation.

An abstract of "Neonatal Jaundice, Autism, and Other Disorders of Psychological Development" is posted at <http://pediatrics.aappublications.org/cgi/content/abstracts/peds.2010-0052v1>.

Should Anxiety or Depression Be Contraindication for Surgery?

Individuals who are anxious or depressed before surgery may have a slightly increased risk of death within 30 days following surgery, according to a study examining files of all individuals admitted to an intensive care unit of Veterans Affairs hospitals. The study, published in the October *Archives of Surgery*, excluded individuals who were admitted following heart procedures such as percutaneous catheterizations, angioplasty, and stenting, among others.

Thad Abrams, M.D., M.S., an associate professor in the Department of General Internal Medicine of the Carver College of Medicine at the University of Iowa, and colleagues studied more than 35,000 patients admitted to the intensive care units of Veterans Health Administration hospitals that provided care in an acute care setting from 2003 to 2006. An existing psychiatric condition was identified in one-fourth of the patients, including 16 percent with depression, 8 percent with posttraumatic stress disorder, 7 percent with anxiety disorders, 2 percent with bipolar disorder, and 2 percent with psychosis. The risk of dying within 30 days of surgery was associated with depression and anxiety, but not with the other psychiatric conditions.

Moreover, the 30-day death rates among those with psychiatric conditions were higher for those undergoing respiratory or digestive system procedures, but not procedures involving the circulatory, nervous, or musculoskeletal system.

The study was funded by a grant from the Department of Veterans Affairs, Veterans Health Administration; the Health Services Research and Development Service; as well as a postdoctoral fellowship award in health services research to Abrams by the Office of Academic Affiliations at the University of Iowa.

An abstract of "Influence of Psychiatric Comorbidity on Surgical Mortality" is posted at <http://archsurg.ama-assn.org/cgi/content/abstract/145/10/947>.

Fish Oil No Help in Postpartum Depression

Although some epidemiological studies have suggested that fish-oil supplements can help prevent postpartum depression, a randomized, controlled trial conducted in Australia has failed to find that this is the case.

The study, conducted in five Australian maternity hospitals, included more than 2,000 women who were less than 21 weeks pregnant. Half of the women received daily 800 mg DHA-rich fish-oil capsules, while the other half received a daily placebo of vegetable-oil capsules without DHA. The researchers found that the percentage of women reporting high levels of depressive symptoms during the first six months postpartum did not differ significantly between the DHA and control groups.

The study results were reported online October 19 in the *Journal of the American Medical Association* by Maria Makrides, Ph.D., of the Women's and Children's Health Research Institute in Adelaide, Australia, and colleagues. The study was funded by the Australian National Health and Medical Research Council.

"Effect of DHA Supplementation During Pregnancy on Maternal Depression and Neurodevelopment of Young Children" is posted at <http://jama.ama-assn.org/cgi/reprint/304/15/1675>.

Rivastigmine Fails to Show Benefits in ICU Patients

Rivastigmine as an "add-on" therapy to haloperidol for critically ill ICU patients

please see ***Journal Digest*** *on page 29*

Order

continued from page 2

In addition to the residency policy, the state also recently implemented a series of budget cuts affecting non-Medicaid beneficiaries in state mental health programs who are legal residents and who are able to prove their legal residency status. The cuts, enacted in July to close the state's budget deficit, eliminated those beneficiaries' transportation, psychotherapy, case management, and inpatient psychotherapy and medical treatments. Specific cuts included dropping access for these patients to Assertive Community Treatment and Intensive Recovery Teams, which are case-management programs that follow national models.

Additionally, the budget cuts ended the provision of supported housing for seriously mentally ill beneficiaries in the public system. However, in a Web posting, the governor's office noted that none of the beneficiaries with serious mental illness would have to leave their existing supportive housing "until other safe, stable housing is found."

Of particular concern to psychiatrists treating this patient population was the elimination of reimbursement for all but two brand-name antipsychotic medications.

Karen Sanders, associate director for publicly funded services at APA, said that one Arizona psychiatrist has reported that a patient switched from a antipsychotic for which coverage was halted to a covered antipsychotic went into a coma and required hospitalization before partially recovering.

"This is a draconian measure to enact simply because of budget constraints," said Brennan, about the clinical impact of the severely restricted drug formulary.

Among patients affected by the formulary cut, Brennan said, are psychologically impaired veterans whose disability payments make them ineligible for Medicaid-funded treatment but who need ongoing mental health care.

The governor's office noted that this non-Medicaid patient population will continue to have access to crisis telephone services and mobile crisis intervention services.

Additionally, "if funding allows," then the state's regional behavioral health authorities are authorized to offer inpatient psychiatric stabilization for up to 72 hours.

A future concern, Sanders noted, is that the legislature is considering adopting the restricted antipsychotic formulary for the state's Medicaid program if more budget cuts are needed.

More information on the Arizona budget cuts is posted at <www.azdhs.gov/bhs/updates/documents/Fact%20Sheet%20050310.pdf>. ■

government news

Health Reform

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from wiping out the savings of people who are disabled. However, it likely will be targeted because critics believe it will add billions of dollars annually to the federal budget.

Not all Republican health care initiatives may be opposed by APA. For instance, APA is likely to join other physician groups in supporting Republicans' stated plans to pursue tort reform. A typical package of tort-reform proposals would produce $54 billion in net government savings, in part, through a reduction in medical tests used for defensive medicine by physicians worried about lawsuits and reimbursed by federally funded health insurance programs, according to the Congressional Budget Office, which is the nonpartisan accounting arm of Congress.

Although psychiatrists have one of the lowest malpractice lawsuit rates in medicine, malpractice reform remains an important APA priority. APA has stood with the AMA and allied medical specialty societies in supporting tort-reform proposals. These include caps on noneconomic damages and the use of health courts to lower the cost burden for physicians and to cut the cost defensive medicine.

A copy of the APA letter about the prevention fund is posted at <http://healthyamericans.org/assets/files/Johanns%20Sign%20On.pdf>. ■

Screening

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(SAMHSA) report released in November. Additionally, 40 percent of people with symptoms of serious mental illness were found to have gone without treatment, according to the SAMHSA report.

The economic cost of such widespread lack of needed treatment—which shows up in disability, unemployment, substance abuse, homelessness, inappropriate incarceration, suicide, and "wasted lives"—is more than $100 billion annually, according to the National Alliance on Mental Illness.

"If care providers consistently screen and intervene with early-stage substance abuse, the health care system can avert enormous human and economic costs," said A. Thomas McLellan, Ph.D., deputy director of the Office of National Drug Control Policy, in testimony before a House of Representatives subcommittee in June.

The need for increased mental illness prevention and early-detection efforts also has been stressed as critical by suicide-prevention advocates, who note that the vast majority of suicide victims had untreated mental illness.

Kelly Kelleher, M.D., director of the Center for Innovation in Pediatric Practice, praised the ability of screening tools to help detect psychiatric conditions, especially in children.

"Early detection is key," said Kelleher, during the November Capitol Hill briefing. "The earlier we can identify these conditions, the better the chance we have to treat and reverse their effects."

As a member of the American Academy of Pediatrics Task Force on Mental Health, Kelleher helped develop a mental health toolkit for pediatricians that incorporates mental health screening in patient visits.

A key federal official, Richard Frank, Ph.D., deputy assistant secretary for planning and evaluation at the Department of Health and Human Services, also hailed the promise of screening tools to help detect illness early when it is most amenable to treatment and to get psychiatric treatment to people who might not otherwise seek it out. The health law's provisions are expected to spur wider use of these screening tools, which physicians have not widely adopted in the past due in part to a lack of insurance reimbursement for them.

"This area is ripe for movement now," Frank said, about the expanded screening coverage requirements in the health care law. ■

Applications Sought for *Residents' Journal*

The *American Journal of Psychiatry* is inviting applications for the position of associate editor for the *AJP Residents' Journal* for the 2011-2012 academic year. The position begins next July, when the current associate editor, Sarah Fayad, M.D., becomes editor in chief.

According to Joseph Cerimele, M.D., the current editor in chief, applicants must be an APA member-in-training, as well as a PGY-3 resident in 2011 or a PGY-4 resident in 2011 with planned ACGME-approved fellowship training at a U.S. residency program.

This electronic journal is produced by and for psychiatry residents. In addition to articles written and peer reviewed by residents, each issue contains a table of contents of the current *American Journal of Psychiatry*, with special links to the articles and to *AJP* Audio, a downloadable MP3 file featuring highlights from the issue. APA members can access the journal at <http://ajp.psychiatryonline.org/misc/Residents_Journal.dtl>.

The position, which requires 10 to 15 hours of work a week, entails peer review of manuscripts on a weekly basis; decisions about manuscript acceptance; correspondence with authors; manuscript editing prior to publication; participation in biweekly conference calls with *AJP Residents' Journal* editor in chief and quarterly conference calls with the *AJP* editor in chief and editorial staff; collaboration with others to develop innovative ideas for the *AJP Residents' Journal;* and participation in a presentation about the *AJP Residents' Journal* at APA's annual meeting.

Applicants are asked to e-mail a CV and a personal statement of up to 750 words describing their professional interests, qualifications, and reasons for applying for the position and ideas for journal development to joseph.cerimele@mssm.edu. The deadline for applications is February 15, 2011. ■

letters to the editor

Clarification

The treatment afforded to inmates in the psychiatric special housing unit in California was mischaracterized in the article "Psychiatrists Decry Punishment That Isolates Prisoners" in the September 3 issue.

Inmates on the psychiatric service unit may attend 10 hours of topic-specific psychotherapy groups a week. Inmates are seen by a psychologist/case manager at least weekly and often daily as needed. They also are seen by a unit psychiatrist at least weekly as well. They are able to stand alone in yards where they are within seeing and speaking range of other inmates in the unit. They can earn access to personal radios and televisions. During the year I worked in the psychiatric service unit, many inmates requested to remain in the facility because of the quality of treatment they were receiving.

There is still much to be done to treat incarcerated inmates with mental illness, but in California the *Coleman v. Wilson* lawsuit and the receiver have been some of the best allies correctional psychiatry has had. If only mentally ill parolees had access to similar services, reincarceration rates would plummet.

LEE HAMILTON, D.O.
Napa, Calif.

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

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with delirium failed to confer benefit. In fact, use of the medication in addition to haloperidol was associated with worse outcomes. Therefore, the study was stopped prematurely after reaching an enrollment of only 104 out of 440 planned participants.

The study, reported by Maarten M.J. van Eijk, M.D., and colleagues, was published online November 5 in *The Lancet*. The senior investigator was Arjen Slooter, M.D., Ph.D., of the University Medical Center of Utrecht in the Netherlands.

Patients included in the study were randomized to receive haloperidol plus placebo, as a control, or haloperidol plus rivastigmine. Patients randomized to receive rivastigmine were given 1.5 mg of that drug two times daily initially, and this dose was titrated upward to a maximum dose of 12 mg. Patients in the other arm of the study received placebo two times daily.

The researchers found that the use of rivastigmine increased, although not significantly, the rate of death and the duration of delirium to five days in rivastigmine-treated patients compared with three days in control patients. It was also reported that patients receiving additional treatment with rivastigmine had more severe delirium (p=0.004), longer stays in the ICU (p < 0.0001), and spent a greater percentage of days (10 percent vs. 3 percent) during the study in a coma, compared with control patients (p<0.0001).

The study was funded by the Netherlands Organisation for Health Research and Development, Netherlands Brain Foundation, and Novartis.

An abstract of "Effect of Rivastigmine as an Adjunct to Usual Care With Haloperidol on Duration of Delirium and Mortality in Critically Ill Patients: A Multicentre, Double-Blind, Placebo-Controlled Randomised Trial" is posted at <www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)61855-7/abstract>.

Risk of Nonsuicide Mortality With Ziprasidone

Results of the "Ziprasidone Observational Study of Cardiac Outcomes" (ZODIAC) study fail to show an increased risk in nonsuicide deaths in schizophrenia patients taking ziprasidone, when compared with deaths for patient taking olanzapine.

The study, published in *AJP in Advance* on November 1 by Brian Strom, M.D., M.P.H., and colleagues, was required as part of an agreement by the manufacturer of ziprasidone, Pfizer Inc., and the Food and Drug Administration (FDA) in 2000 and the Swedish Medical Products Agency in 2001, following FDA approval of the second-generation antipsychotic.

Data from 18,154 patients representing 18 countries were included in the analysis. Patients were enrolled between February 2002 and March 2007 if their psychiatrist was willing to start or switch the individual's medication to either olanzapine or ziprasidone. Patients were randomized in a 1:1 fashion to receive treatment with either ziprasidone or olanzapine and were followed for one year.

According to the authors, the study was carried out in order to further document the safety and risks associated with the use of ziprasidone concerning the QTc interval. The goal of the open-label, randomized study was to evaluate the incidence of nonsuicide mortality after one year of treatment. Prior to the drug's approval, due to small populations included in clinical trials, the potential effects on cardiac mortality of ziprasidone in terms of "real-world use" were considered uncertain.

"It is very reassuring that, if there is any clinical importance of the mild QT prolongation caused by ziprasidone, it is sufficiently small that it could not be detected even in a study this massive," Strom told *Psychiatric News*. He is the chair of the Department of Biostatistics and Epidemiology at the University of Pennsylvania School of Medicine.

The study was fully funded by Pfizer Inc.

An abstract of "Comparative Mortality Associated With Ziprasidone and Olanzapine in Real-World Use Among 18,154 Patients With Schizophrenia: The Ziprasidone Observational Study of Cardiac Outcomes (ZODIAC)" is posted at <http://ajp.psychiatryonline.org/cgi/content/abstract/appi.ajp.2010.08040484v1>. ■

Medicare Cut

continued from page 1

by the AMA in which physicians around the nation flooded Capitol Hill with phone calls on Wednesday and Thursday, November 17 and 18 (see photo on page 1). The event was originally scheduled for one day, but the response was so great—the AMA estimated that about 10,000 phone calls were made to congressional offices—that it was extended for another day.

The AMA is hoping Congress will hold off on the 2011 pay cut for a full year to provide time for legislators to work out a permanent fix to the payment formula, especially the sustainable growth rate (SGR) component of that formula. The SGR requires that increases in expenditures by the government for physician services be offset by decreases in physician payment.

With remarkable regularity since 2003, the formula has called for ever more substantial pay cuts, only to have them postponed by Congress following lobbying by individuals and doctor and senior-citizen groups. But each postponement adds to the mounting costs to the government; at APA's Institute on Psychiatric Services in October, APA Director of Government Relations Nicholas Meyers said each month the cut is postponed, the cost to the government is $1.3 billion, so that the price tag for another 13-month postponement would be on the order of $16 billion.

Yet pay cuts of the kind now demanded by the payment formula will make it difficult for many physicians to continue treating Medicare patients. Meyers noted at the institute that for psychiatrists, the pending cut in payments would mean a reduction on the order of $20 per service per CPT code.

So APA, AMA, and other physician groups continue to demand a complete overhaul of the formula.

"Congress is to be congratulated for once again deferring an ill-conceived payment cut in Medicare payments to physicians," APA President Carol Bernstein, M.D., said. "However, we urge our lawmakers to finally enact a permanent fix to the SGR so that both doctors and patients can focus their energies on the critical issues of health care reform and implementation of parity."

APA leaders active in the AMA House of Delegates have been vocal as well. "Congress must be willing to act on a replacement to the SGR payment method," said Patrice Harris, M.D., chair of the AMA's Council on Legislation and a member of the Section Council on Psychiatry (the psychiatric delegation to the AMA House of Delegates consisting of APA, the American Academy of Child and Adolescent Psychiatry, and the American Academy of Psychiatry and the Law). "Some people refer to this effort as a 'doctor fix,' but it's really about ensuring access to health care for our patients. It is increasingly impossible for physicians to participate in Medicare without fair and adequate reimbursement," she said.

"Physicians are very worried about being able to care for older Americans and veterans under the Medicare and Tricare plans," added Kenneth Certa, M.D., also a member of the Section Council on Psychiatry. "The SGR formula was put into place in the late '90s to try to limit the costs of these programs. Unfortunately, limiting payment to physicians does not mean the cost of providing care will be limited. The rise in overhead costs alone far exceeds what the SGR supports. Congress has recognized this time and again, delaying implementing the cuts that the SGR mandates.

"Physicians will be unable to continue to care for this important population," Certa told *Psychiatric News*. "They cannot afford to pay their office staff, rent, equipment costs, and their own expenses—often hundreds of thousands of dollars of medical school debt. Seniors and veterans could lose access to care." ■

Stimulant

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explains persistence of symptoms and impairment into adolescence and adulthood.

ADHD not only affects the individual diagnosed with the disorder but also his or her relationships with classmates and other peers, she suggested.

Peer rejection is much more common in children with ADHD. Mrug and colleagues' studies compared children in the MTA study with non-ADHD classmates by asking each member of one group to rate each member of the other.

Students with ADHD were ranked lower by their peers on several scales. About 53 percent of adolescents with ADHD were rejected by their peers, compared with 14 percent of their randomly selected classmates. Just 3 percent of the ADHD subjects were termed "popular," compared with 23 percent of the non-ADHD students.

This rejection persists over time and is resistant to ADHD treatment, she said. "As with other children, rejection leads to antisocial behavior, depression, and anxiety, much like ADHD does."

Children with ADHD often have fewer social and cognitive skills and fewer chances for positive interactions, cooperation, and conflict resolution. They produce more inept social responses but don't see themselves as inept. They are more likely to be victimized by peers.

Even at eight years into the study, it is still possible to see greater impairment in those who were rejected by peers at baseline.

Many children with ADHD are rejected by their peers but it's the rejection, rather than the ADHD itself that explains many of the negative outcomes in middle adolescence, said Mrug.

"Peer rejection is real, and it is prognostic of long-lasting outcomes," she said. "It is very important to discern peer rejection early from interviews with parents and children."

The Child Behavior Check List also has useful questions that can provide that information, she noted.

"With early intervention, children can be referred to social skills training, but that alone won't stop peer rejection," said Mrug. They also need to be directed to activities or places (like field trips or clubs) where they can develop a sense of social belonging.

"We need to help these children compensate for peer rejection by helping them form friendships and prevent longer-term problems like smoking, anxiety, and peer victimization," said Mrug. ■

APA Creates Forum On Integrated Care

APA members interested in learning more about integrated care and how it relates to psychiatry are invited to join a new electronic forum created by APA's Council on Healthcare Systems and Financing. "Integrated care" refers to treatment-delivery models in which physicians work together to coordinate their patients' care. Examples of integrated care models are patient-centered medical homes, accountable care organizations (see page 1), medical neighbors, and health homes.

There are about 50 APA members and staff participating in the electronic forum so far. It is being staffed by Karen Sanders of APA's Office of Healthcare Systems and Financing.

More information is available by contacting Sanders at (703) 907-8590 or ksanders@psych.org.

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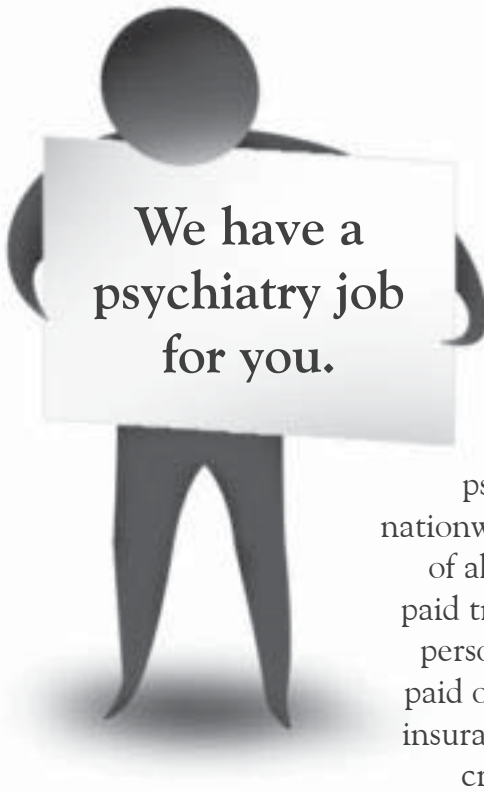

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Gary B. Kaplan, M.D., Director, Mental Health Service
VA Boston Healthcare System
940 Belmont St., Brockton, MA 02301
Email: Eugene.Francois@va.gov and a copy to: vhabhsjobs@med.va.gov

VA Boston is an Affirmative Action/Equal Opportunity Employer with a strong institutional commitment to diversity in all areas. U.S. citizenship required.

Build Your Future

The Los Angeles County Department of Mental Health offers rewarding work, opportunities for advancement, and collaborative work environments. You can build your career in a wide variety of settings, including clinics, jail and juvenile justice sites, field based treatment and other specialized programs, while enjoying your place in the sun. Urgent care positions (FT, PT, evenings and weekends) are also available.

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LAC DMH
LOS ANGELES COUNTY DEPARTMENT OF MENTAL HEALTH

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For more information, call (213) 637-2659

Roderick Shaner, M.D.
Medical Director

Department of Veterans Affairs

VA Boston Healthcare System

Staff Psychiatrists

The VA Boston Healthcare System (VABHS) is recruiting academically oriented inpatient, residential and outpatient psychiatrists for positions in our Mental Health Service. VABHS is a New England regional referral center for Veterans' health care. The Service has strong and longstanding affiliations with Harvard Medical School (HMS) and Boston University School of Medicine (BUSM) and has major campuses located in Jamaica Plain and Brockton.

Duties include direct clinical care and support of the academic mission of the medical center, including supervision of psychiatry residents and medical students and the opportunity to participate in research. Candidates must be Board Certified or Board Eligible and individuals with ongoing experience in addiction psychiatry, geriatrics and/or serious mental illnesses are preferred. These positions offer a highly competitive VA salary and a faculty appointment at BUSM or HMS commensurate with experience.

Please send a letter of interest, CV, and contact information for three references to:

Gary B. Kaplan, M.D., Director, Mental Health Service
VA Boston Healthcare System
940 Belmont Street, Brockton, MA 02301
or email materials to: Eugene.Francois@va.gov
with a copy to vhabhsjobs@med.va.gov

VA Boston is an Affirmative Action/Equal Opportunity Employer with a strong institutional commitment to diversity in all areas. Must be a U.S. citizen.

The **West Palm Beach** Department of Veterans Affairs Medical Center has an excellent career opportunity for an **Assistant Chief, Mental Health & Behavioral Science Service (MH&BS)** who will provide input, advice and counsel for the Chief, MH&BS Service. The incumbent will assist in comprehensive Medical Center strategic planning, programming, and general administration. Responsible for direct supervision of all psychiatrists and physician assistants. Ensures direct compliance with all CPRS documentation procedures and ensures psychiatrist and PA compliance with national and local performance measures, including timely health care screening and completion of clinical reminders for all patients. Responsible for providing a complement of comprehensive health care services to our veterans and experience should include a full range of mental health programs.

An active, unrestricted license in any state is required, as well as U.S. Citizenship.

Benefits include: comprehensive salary package to include performance pay; 26 days of vacation, 13 days of sick leave, 10 Federal holidays; excellent health/life insurance coverage and a retirement package including a tax-deferred savings plan.

Submit: Letter of Introduction, VA Form 2850 (Federal Application) and Curriculum Vitae (CV) to:

VA Medical Center
Attn: 05/Barbara.Pratte
7305 N. Military Trail
West Palm Beach, FL 33410
Employment Information Center: (561) 422-6694

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Geriatric Psychiatrist for Los Angeles, CA

Send your CV to:
Betsy Wallace
Recruitment Coordinator & Administrative Assistant
Asana Telemedicine & Healthcare Management
Asana Integrated Medical Group
Email: bwallace@asanamg.com ■ Telephone: (818) 532-1294 ■ Fax: (818) 991-1200

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Heal the sick, advance the science, share the knowledge.

Adult Inpatient Psychiatrist

Mayo Clinic's Department of Psychiatry and Psychology in Rochester, Minnesota is seeking an outstanding psychiatrist to join our adult hospitalist team. This primarily clinical position involves leading a dedicated multidisciplinary team in the care of acutely ill patients on our inpatient units. Interest and skills in managing treatment resistant depression, co-morbid addictive disorders, complex associated medical problems, and systems improvement is highly desirable. Research and educational opportunities are available and encouraged. The position requires leadership expertise and includes extensive collaboration with residents, allied health professionals, and medical students.

The position carries an academic appointment at the Mayo Clinic College of Medicine (rank commensurate with experience). To learn more about Mayo Clinic and Rochester, MN, please visit **www.mayoclinic.org/physician-jobs/**

The compensation package at the Mayo Clinic is highly competitive and includes exceptional professional benefits. For further information, please send a detailed letter of intent and complete curriculum vitae by e-mail or traditional mail by February 1, 2011, to:

Timothy Lineberry, MD
c/o Sandra J. Stevens
Inpatient Division
Department of Psychiatry and Psychology
Mayo Clinic
200 1st Street SW
Rochester, MN 55905
Email: Stevens.Sandra@mayo.edu

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Community Psychiatrists Wanted

Adult Psychiatry positions benefit eligible, available immediately. Jobs entail performance of Psychopharmacologic Evaluations and ongoing medication management. Psychiatrist will participate in multi-disciplinary treatment teams at full-service, public sector Outpatient clinics located throughout the Greater Boston, MA area. Additional duties include leadership role at multidisciplinary staff meetings, consultation to the Substance Abuse Team and/or other Agency Teams, may include supervision of a prescribing Clinical Nurse Specialist, and supervision of a PGYIII Resident on Community Rotation possible, which would provide eligibility for an MGH/Harvard appointment.

Pay commensurate with credentials and experience and includes sign on bonus. NSMHA offers a comprehensive benefits package including competitive salaries, medical / dental insurance and generous paid time off. Benefits available at 20 hours.

Interested candidates should send cover letter and C.V. to:

North Suffolk Mental Health Association
Attn: Recruiter
301 Broadway
Chelsea, MA 02150
Fax: 617-889-4635
Email: gethired@northsuffolk.org

We are an equal opportunity employer.

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APA Annual Meeting Self-Assessment in Psychiatry

For all Annual Meeting attendees, the APA offers a new 100-question Self-Assessment examination approved by the American Board of Psychiatry and Neurology. This Self-Assessment is designed to help practicing psychiatrists assess their level of knowledge regarding current psychiatric practice and clinical advances. Results from this activity can be used to plan your educational schedule at the AM.

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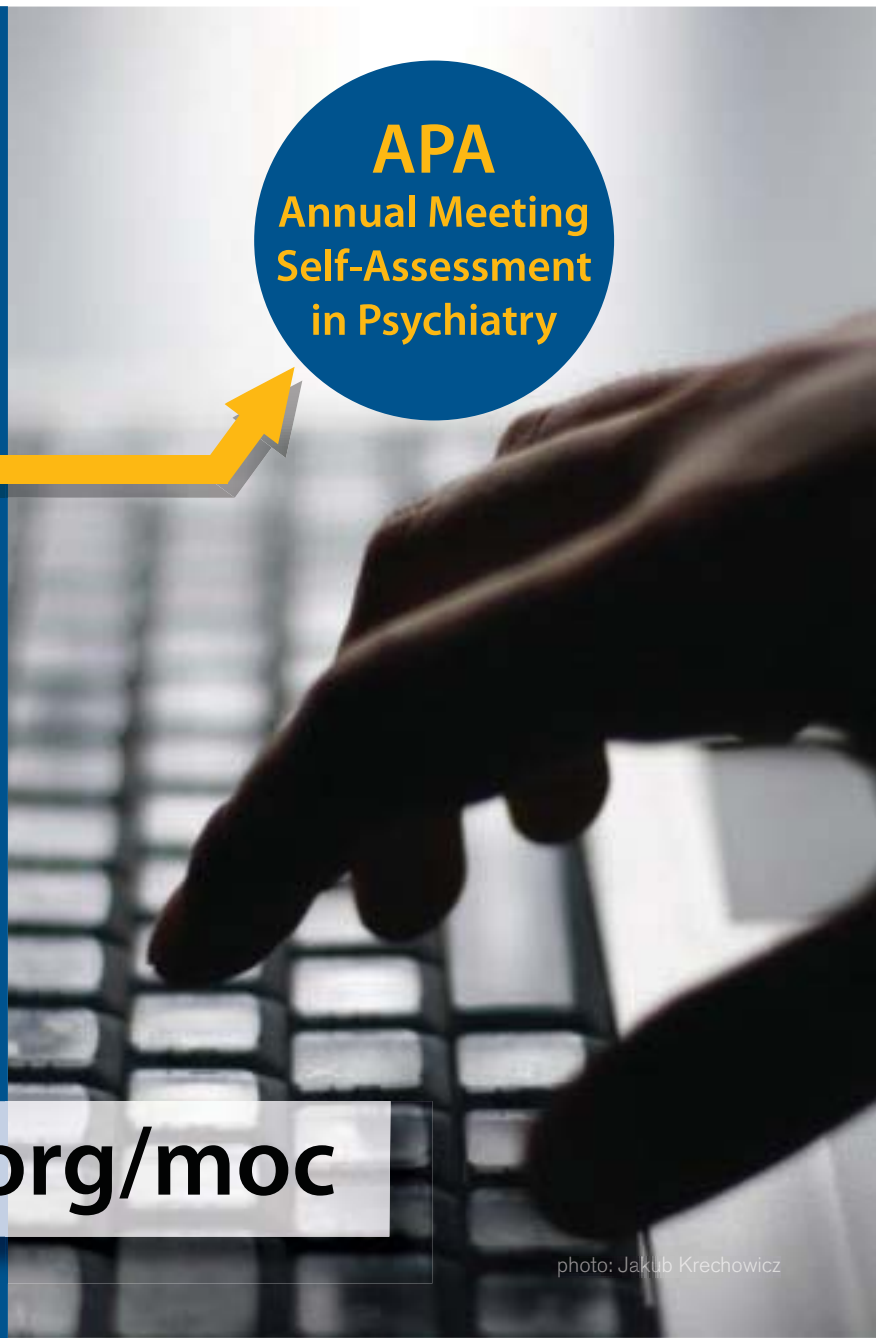

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Issue	Deadline (Friday, 2 p.m. E.T.)
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February 4	January 21

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Nationwide

Universal Health Services, Inc. (UHS) is one of the nation's largest and most respected hospital management companies, operating through our subsidiaries behavioral health treatment facilities nationwide. We are currently recruiting new Psychiatrists for diverse practice positions at our facility locations below as well as in other areas.

For more detailed information about individual locations or other UHS locations contact: Joy Lankswert, In-house Physician Recruiter @ 866-227-5415 ext: 222 or email joy.lankswert@uhsinc.com.

- **ALASKA-** Anchorage- Inpatient & Residential OR Outpatient
- **ALABAMA-** Dothan- Child Psychiatrist
- **COLORADO-** Boulder AND Colorado Springs
- **FLORIDA-** Orlando- Medical Director (Child); Panama City-General and Child Psychiatrist positions
- **GEORGIA-** Atlanta
- **ILLINOIS-** Chicago Suburb (Child)
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- **PENNSYLVANIA-** Philadelphia and State College, Shippensburg
- **SOUTH CAROLINA-** Columbia and Aiken
- **TENNESSEE-** Nashville area - Medical Director (Child)
- **TEXAS-** Austin, Dallas, San Angelo
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ALASKA

ANCHORAGE: 2 positions - Inpatient and RTC (Child/Adol) **OR** Outpatient (Adult/Adol or Child/Adol). Salary, benefits & bonus - limited call. Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

ARIZONA

Medical Director

Come live and work in the Tucson, Arizona, area - a vibrant Southwestern community located in the incomparable **Sonoran Desert!**

Community Partnership of Southern Arizona (CPSA) is recruiting for a Medical Director to oversee the daily activities in our Medical Management departments including Performance Improvement/Quality Management, Care Management/Utilization Management and Pharmacy Services Management.

The successful candidate will possess an unrestricted license to practice medicine (MD/DO) in the State of Arizona and be board certified or qualified in psychiatry by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry; and have at least two years experience working in a managed care setting with two years experience in medical administration and management. Knowledge of quality management and performance improvement and utilization management principles and practices is also required.

CPSA is the administrative organization responsible for coordination of publicly funded behavioral health treatment and prevention services in Southern Arizona (Pima County). We are a community-based, nonprofit organization dedicated to ensuring that individuals and families receive accessible, high-quality behavioral health services that are member and family driven, recovery oriented, respectful of cultural differences, and that foster hope and self-determination.

For more information about us, please access our website at **www.cpsa-rbha.org.** For more information about this career opportunity, please contact Edward M. Gentile, D.O., M.B.A., at 520-901-6816, or upload your curriculum vitae to our career webpage or email to **hrrecruiting@cpsa-rbha.org.** EEO Employer.

CALIFORNIA

Outpatient Adult Psychiatrist needed for a progressive county mental health system, in the Central Valley less than two hours from San Francisco and Yosemite. Recovery-oriented treatment provided in a multidisciplinary setting. Excellent salary scale with steps starting from 179K to 217K; additional 5% differential for board certification. No call requirements at this time. Full benefit package including medical, vision/dental, vacation, sick time. Excellent retirement package with deferred comp. plan avail.

Fax CV to Uday Mukherjee, MD at 209-525-6291 or call 209-525-6119; e-mail at umukherjee@stanbhrs.org.

ACADEMIC LEADERS IN CHILD AND ADOLESCENT PSYCHIATRY

The Department of Psychiatry at UCSD (http://psychiatry.ucsd.edu/) is seeking candidates for full-time leaders in child and adolescent psychiatry. Child Psychiatrist candidates must be board eligible/certified in general and child and adolescent psychiatry. A research track record and experience in an important area of child/adolescent psychopathology is necessary. Due to the increasing evidence of the long-term destructive effects of stress and abuse, experience in the understanding and study of trauma and its sequelae secondary to abuse and/or neglect is particularly encouraged. Individuals must have or be able to become licensed in the State of California. Candidates who apply should have a proven track record in research and leadership in academic or academic-related settings, and a capacity to head a program in child and adolescent psychiatry. A demonstrated research track record of productivity and success in obtaining peer reviewed research grants is required. Preference is to make an appointment at the full professor level, but the candidate's academic rank and series will be determined by individual academic qualifications and achievements. Salary is based upon University of California salary scales.

The University of California, San Diego is an equal opportunity and affirmative action employer with a strong institutional commitment to excellence through diversity. Candidates should send curriculum vitae and other supporting documents by **January 15, 2011** to Search Committee C2, UCSD Department of Psychiatry, 9500 Gilman Drive, La Jolla, CA 92093-0603.

Butte County Behavioral Health Department invites applications for the position of Psychiatrist, regular help and contracted. This position, under general direction, provides clinical assessments and treatment services to alleviate suffering in clients with behavioral health disorders. The regular help monthly equivalent salary range for this position is $11,803-$15,817, and includes a comprehensive benefits package featuring retirement, health insurance, leave time, life insurance, and more. The contracted psychiatrist position is paid at $125.00 an hour and does not include a benefits package.

For Regular Help psychiatrist, please submit a Butte County regular help application to: Butte County Human Resources, 3-A County Center Drive, Oroville, CA 95965, Recruitment# 104125045. The application can be obtained and submitted to the Human Resources Department website at www.buttecounty.net/personnel. Applications may also be mailed to the above address. For additional information, please feel free to call (530) 538-6950 or (530) 538-7651. The Regular Help Psychiatrist is a continuous recruitment.

For Contract Psychiatrist, please e-mail a curriculum vitae or resume to: DBH-HR@buttecounty.net.

Contracts are on an annual basis, and positions are to be filled immediately. Butte County is an EOE/AA Employer.

BE/BC Psychiatrist for CA Hospitals/Prisons. $160-185/hr. Up to $44k/mo. 8-12hr/day. Wknds $42/on call. Alameda Co. up to 270k/yr. H1/J1 Welcome.

Tel: (707)694-6890/
(707)226-2426/(707)694-3805
Fax: (415)814-5764
bayareadoctors@gmail.com

COMMUNITY PSYCHIATRY FACULTY

The Department of Psychiatry at UCSD (http://psychiatry.ucsd.edu/) is seeking faculty candidates with expertise in community and public psychiatry. The faculty selected will provide leadership for two new Fellowship programs in Community Psychiatry for Adult and Child Psychiatry. The programs are being initiated by the UCSD Department of Psychiatry in collaboration with The Community Mental Health Program of San Diego County. Strong preference will be given to candidates with documented track record of peer-reviewed publications and research grants. Board Certification in adult psychiatry is necessary, and Board Certification or eligibility in Child and Adolescent Psychiatry will be preferred. Candidates must have or be eligible for a California Medical licensure. The academic rank and series will be determined by the individual's academic qualifications and achievements. Salary is based upon University of California salary scales.

The University of California, San Diego is an equal opportunity and affirmative action employer. Candidates should send curriculum vitae and other supporting documents by **January 15, 2011** to Search Committee CPP, UCSD Department of Psychiatry, 9500 Gilman Drive, La Jolla, CA 92093-0603.

Large psychiatric medical/legal practice throughout CA is expanding. We are looking for **psychiatrists** to perform workers' compensation evaluations. **Interested?** CA QME Certification required. Please call, 310-517-1883 direct line- ask for Angela.

BC/BE Psychiatrists for CA-CDCR/DMH locations. $187/hr. PT/FT. On call $43/hr. H1/J1 considered. (805) 703-3729 Phone. (805) 832-6469 Fax. intuitivehealthservices@intuitivehealthservices.com.

FACULTY POSITION

The UCSD Eating Disorder Treatment Program seeks applicants for a senior program director of the UCSD adolescent and adult eating disorder program. This person must be a psychiatrist or psychologist with familiarity with empirically supported treatments for eating disorders, program development and management, business and budgetary responsibilities, and related administration. This will be a UCSD faculty position, will report directly to the executive director, Walter Kaye, and will be responsible for overseeing the management of clinical programs offering a continuum of care for adolescents and adults with anorexia and bulimia nervosa. The academic rank and series will be determined by the individual's academic qualifications and achievements. Salary is based upon University of California salary scales.

The University of California, San Diego is an equal opportunity and affirmative action employer. Candidates should send curriculum vitae and other supporting documents by **January 15, 2011** to Search Committee ED, UCSD Department of Psychiatry, 9500 Gilman Drive, La Jolla, CA 92093-0603.

Mental Health

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.

Medical Director
for San Diego County Psychiatric Hospital

The San Diego County Psychiatric Hospital is a free-standing adult facility located in the heart of the County and is a key component in the County Behavioral Health Division's continuum of care. The Medical Director can play a leading role in the development of the overall County safety net health system, and is a key medical leader in the dynamic, innovative Health & Human Services Agency. Teaching opportunities available. Requires proven leadership and supervisory skills. Interest in primary care integration helpful. Salary competitive.

CV and letter of interest can be submitted online at www.sdcounty.ca.gov/hr. For questions about the application process, please contact Gloria Brown, Human Resources Analyst at (619) 531-5117 or **Gloria.Brown@sdcounty.ca.gov**. Questions about the position may be directed to Marshall Lewis, MD, Behavioral Health Clinical Director, HHSA at **Marshall.Lewis@sdcounty.ca.gov.**

COLORADO

IMMEDIATE OPENING for full-time psychiatrist in new High Security Forensic Institute at the Colorado Mental Health Institute @ Pueblo. Employed by the University of Colorado School of Medicine with full benefits, 4 1/2 weeks paid vacation, excellent CME program on campus, a strong, stable medical staff with little turnover, option for flexible schedule, including 4 ten-hour days, and a new salary schedule with optional paid call. We have no J1-Visa opportunities at this time.

For further information, phone or e-mail
A.O. Singleton, III, M.D.
Chief of Medical Staff
(719) 546-4637; al.singleton@state.co.us.

CONNECTICUT

Yale University - CMHC

The Yale University School of Medicine seeks psychiatrists for 2 full-time faculty positions at the **Connecticut Mental Health Center [CMHC] for July 2011** that will carry academic appointments at the Assistant or Associate Professor level in the Department of Psychiatry. One is for the Medical Director of the Substance Abuse Treatment Unit [SATU], a program with strong clinical, research, and training components. Preference will be given to applicants with special training in Addictions who will be eligible for certification in Addiction Psychiatry at the time of appointment. The second position is within the Hispanic Clinic and preference will be given to candidates who are bilingual. Outstanding clinical and teaching skills are required in both positions for roles in patient care as well as supervision of psychiatry residents and other trainees at CMHC, a core site for training and research within Yale's Department of Psychiatry. The positions include protected time for participation in a variety of Departmental research and educational activities. Applicants must be board certified or eligible in psychiatry, licensed to practice in CT and be legally employable.

Please send a CV and 3 references by **January 15, 2011** to Jeanne Steiner, D.O., Medical Director CMHC, 34 Park St., New Haven, CT, 06519. Direct inquiries to jeanne.steiner@yale.edu. Yale University is an affirmative action/equal opportunity employer. Yale values diversity in its faculty, students, and staff, and especially encourages applications from women and underrepresented minority scholars.

FLORIDA

ORLANDO - Medical Director (Child Psychiatrist) - Inpatient and Residential Treatment Programs.
PANAMA CITY - Gulf Coast Living! General and Child Psychiatrist Staff Positions - Inpatient Services. Contact Joy Lankswert, Inhouse recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

PSYCHIATRIST; FULL TIME, FL LICENSE REQUIRED; Aventura, FL; private practice located equidistant between Miami and Ft. Lauderdale; children/adolescent/adult/geriatric pts; email CV to aventuraoffices@bellsouth.net or FAX to Dusty: 305-935-1717.

DAYTONA - MELBOURNE - ORLANDO - OCALA-
Psychiatrists needed for rapidly expanding Nursing Home Service. Great support. No call. Average Salary 210K + benefits. Part-time available. Some travel required. Must have FL Medicare & FL Medicaid individual provider #s. No Restrictions (H1B Candidates Considered). Call our Clinical Coordinator, Linda at 866-936-5250.

GEORGIA

PRIVATE PRACTICE OPPORTUNITY

Be the only psychiatrist accepting new patients in Hall County. GA. 50 miles north of Atlanta. Earning potential well over $200,000. Email CV to mkingphd@gmail.com.

Psychiatrist - Metro-Atlanta (contract)

Cobb-Douglas Community Services Board, a behavioral healthcare organization in metro Atlanta, seeks a part-time, BC/BE Psychiatrist for Community Outpatient Behavioral Health clinic. Please email CV to cholt@cobbcsb.com.

Medical College of Georgia
Augusta, GA
Growing Department Seeks New Faculty in Adult, Child and Adolescent, Neuroscience and Public Psychiatry Programs

The Medical College of Georgia (MCG) Department of Psychiatry and Health Behavior is recruiting MD and PhD faculty in adult, consultation/liaison, forensic, child and adolescent and public psychiatry. Both clinician-educator and research intensive positions are available, including a dedicated research neuroscientist position in psychotic disorders. The department, which is growing and financially stable, has strong training programs in general, child and adolescent, and forensic psychiatry, an internship program in health psychology, and competitively funded clinical and preclinical research. Our new public psychiatry partnership with the Georgia Department of Behavioral Health and Developmental Disabilities to manage and provide clinical care to the regional state hospital (located only five miles from the medical school campus), expands our faculty recruitment, educational and clinical research opportunities. MCG's strong research infrastructure includes core laboratories, statistical consultation and core genetics facilities. Extensive research training program for junior faculty includes a master's program in clinical translational, internal grant programs with generous career development awards.

Augusta, home of Masters Golf Tournament, is a charming Southern city with low cost of living (particularly housing), and is close to Georgia/Carolina mountains and Georgia/Florida coast. The position has excellent salary and benefits. Academic appointment depends on qualifications. MCG is an equal employment, equal access and equal educational opportunity and affirmative action institution. It is the policy of the University to recruit, hire, train, promote and educate persons without regard to age, disability, gender, national origin, race, religion, sexual orientation or veteran status.

See http://www.mcg.edu/som/psychiatry/ for more information. Contact: Donald Manning, MD, Director of Public Psychiatry, dmanning@mcg.edu or (706) 721-6719.

HAWAII

This is your opportunity to live and work in Hawaii!

The Adult Mental Health Division of the State of Hawaii Department of Health is recruiting psychiatrists. We have openings for outpatient psychiatrists to work at Community Mental Health Centers in Hilo, Kona, Maui, and in Honolulu County, and for inpatient psychiatry at the Hawaii State Hospital in Kaneohe, on Oahu.

Employment with the State of Hawaii offers competitive salaries and benefits. Benefits include 21 days of vacation per year, 21 days of sick leave per year, 13 paid state holidays, liability insurance, medical/vision/dental insurance, and a generous pension plan with vesting after 5 years of service.

For more information about the outpatient positions, contact Mr. Wayne Law at 808-832-5770. For the Hawaii State Hospital, contact Dr. Jim Westphal at 808-236-8236.

ILLINOIS

Immediately seeking **Child/Adolescent Psychiatrist** for Summit Clinical Services, a well-established multidisciplinary mental health practice, composed of M.Ds, Licensed Psychologists, Licensed Clinical Social Workers, and Licensed Clinical Professional Counselors, in Chicago's western suburbs. The position offers an excellent opportunity to quickly build a practice among experienced professionals known for providing quality mental health services in a caring and respectful manner. Willingness to also be on staff at nearby hospital is desirable. Must be comfortable working with a conservative Christian patient population. Flexible hours, set by individual clinician, and generous compensation based on the number of hours worked. Benefits include health insurance and Flexible Spending Account; disability insurance, 401K; and opportunity for partnership and profit sharing.

For more information about our practice, see our Website at **www.summitclinical.com**. Contact Dan Wyma, M.D., at Summit Clinical Services, (630) 260-0606.

Chicago Area
Psychiatrist Addiction & Pain Program

Advocate Christ Medical Center, Department of Psychiatry seeks a qualified and experienced Liaison Psychiatrist for our addiction and pain program. Candidates must be experienced in addiction psychiatry and psychosomatic medicine, hold a current Illinois license and be board certified or board eligible.

Advocate Christ Medical Center (ACMC) is a 695-bed, not-for-profit teaching, research and referral medical center located in the southwest suburbs of Chicago. ACMC is part of Advocate Health Care, Chicago's largest provider of care and one of the nation's leading integrated health systems. The selected candidate for this highly visible position will lead the addictions detox and medical psych unit which is joined with an active pain program and cooperate with a multidisciplinary consultation liaison service for hospital based medical and surgical services. There further exists the opportunity to teach and supervise medical students and residents. This exciting part time salaried position includes health and retirement benefits. The incumbent may also enjoy an opportunity to perform out patient work seeing substance abuse patients and general psychiatry as part of a progressive multi specialty psychiatric group practice located in Orland Park, Illinois. To apply directly, please submit a CV and cover letter to: donna.kutka@advocatehealth.com or for more information contact Donna C. Kutka, RN, MS, Director, Physician Recruitment, at 708.684.5009.

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

Consultation Liaison Medical Director

The Department of Psychiatry and Behavioral Sciences at Northwestern University Feinberg School of Medicine is recruiting a psychiatrist for the full-time position of Medical Director of Consultation-Liaison Psychiatry Service at Northwestern Memorial Hospital. Academic rank is open dependent on qualifications. Additional responsibilities include leadership and teaching responsibilities for our Psychosomatic Medicine Fellowship as well as the training of psychiatry residents and medical students. Must be ABPN board-certified in Psychosomatic Medicine and Illinois licensure preferred or eligible. Start date is immediate. Position open until filled. Applicants should respond by mailing or emailing a CV and letter of interest by November 1, 2010 to Cathy Frank, M.D., Vice-Chair, Department of Psychiatry and Behavioral Sciences, 446 E. Ontario, Suite 7-203, Chicago, IL 60611, or by email to p-zolicoffer@northwestern.edu.

Northwestern University is an affirmative action/equal opportunity employer. Women and minorities are encouraged to apply. Hiring is contingent upon eligibility to work in the United States.

Chicago Suburb - Streamwood. Child Psychiatrists. Diverse position options - Inpatient, Residential, and Outpatient. Salary and Benefits for fulltime or hourly for part-time O/P only. Contact Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc.com.

KANSAS

Civilian General/Adult Psychiatrist Opportunity at Fort Riley, KS.

Work as a civilian Psychiatrist at Irwin Army Community Hospital and help serve those who serve our country! Trustaff hires healthcare professionals to work as civilians at military and VA hospitals nationwide. We are seeking Psychiatrists for immediate long term full-time opportunities at Irwin Army Community Hospital, located at Fort Riley near Kansas State University in greater **Manhattan, KS.**

Working as a part of the hospital's Behavioral Health Team, you will have the rewarding opportunity to care for active duty military and their dependents. **As a company we are offering:** Exceptional Compensation Plan $270-$300k per year,Relocation, Continuing Education Assistance, 40 hour work week, 4 or 5 days per week M-F., limited on-call,Malpractice 100% Covered, Any state license is acceptable to work at this facility. **Contact:** Christine Fuka, 877-880-0346 x 1105, Fax: 866-546-3115, Email: cfuka@trustaff.com, www.trustaffgovernmenthealthcare.com.

MAINE

Adult inpatient psychiatrist. Mid Coast Hospital is an independent, non-profit community hospital located in beautiful coastal Maine one of Maine's most desirable regions. We are searching for a second inpatient psychiatrist for our 12-bed unit. Our team uses a multi-disciplinary approach to treat both voluntary and involuntary patients. This is a full-time position for a BC/BE psychiatrist. Share on-call responsibilities with eight other physicians. 40-hour week. Generous benefits, excellent work environment. Please send letter of introduction with CV to: mmackellar@midcoasthealth.com.

ADDICTION PSYCHIATRY - MAINE COAST. Pen Bay Medical Center has an opportunity for a full-time BC/BE adult psychiatrist with qualifications in addiction medicine to join our hospital-employed, community-based integrated behavioral health network. Participate in a multi-disciplinary team approach to serve a diverse client base. Competitive salary and comprehensive benefit package including loan repayment program. Mid-Coast Maine offers some of the most spectacular natural beauty and outdoor recreation found anywhere as well as rich cultural opportunities, great schools and safe communities. Contact John Bragg at jbragg@penbayhealthcare.org or (207) 596-8214.

MAINE

We are currently recruiting for outpatient psychiatrists to work with children and/or adults. BC/BE. We have full-time and part-time opportunities. Positions involve direct patient care at one or more of our community mental health centers located in Kittery, Springvale, Biddeford, and Westbrook. Our physicians work with a multi-disciplinary team providing outpatient services to a variety of programs.

Counseling Services, Inc. is a comprehensive and integrated community mental health center serving adults and children with serious mental health and substance abuse issues. Our programs are comprised of Community Support Teams, including Psychiatric Services, Assertive Community Treatment (ACT), Community Integration (CI), Outpatient Therapy, Crisis Response Services, and Complementary Therapies.

We offer a comprehensive salary and benefits package. If you are interested in exploring opportunities with us, please contact the Human Resources Department at 207-294-7096. A resume and cover letter may be sent to: Counseling Services, Inc., P.O. Box 1010, Saco, Maine 04072 or human.resources@csimaine.com. We invite you to visit us online at **www.counselingservices.org**. We are an equal opportunity employer.

BE/BC Adult and Child Psychiatrists
Acadia Hospital, the nation's first Psychiatric Magnet Hospital, is a 74 bed community-based, full service psychiatric hospital located in Bangor, Maine. We are currently recruiting for BE/BC adult and child psychiatrists to cover our inpatient and outpatient units. We offer acute psychiatric care for adults and children, as well as substance abuse programs, and have recently opened a 10 bed psychiatric observation unit. Acadia Hospital is a teaching site for Tufts and University of New England medical schools. Positions are tailored to specialty interest. Acadia Hospital offers a competitive salary, full benefits, moving expenses and a loan repayment program. The area offers an international airport, symphony, and the University of Maine flagship campus. Four season outdoor activities include boating, hiking, biking, skiing and golfing. The area includes excellent school systems, affordable housing and a safe living environment. Bangor is located less than one hour from Acadia National Park and two hours New England's largest ski resorts. Acadia accepts and supports candidates working toward/on a J-1 Visa Process. Contact: Nancy Barrows at nbarrows@emh.org or apply on line at www.acadiahospital.org - careers.

MARYLAND

The VA Maryland Health Care System (VAMHCS,), Mental Health Clinical Center (MHCC) is actively recruiting for a **full time psychiatrist to work at the Perry Point Medical Center** as clinical manager of inpatient mental health. This position is 50% administrative and 50% clinical; providing clinical care on the two inpatient units. Perry Point is a small town on the Chesapeake Bay about 35 miles north of Baltimore City. The MHCC is the largest clinical center within the VAMHCS and is organized into four Sub-Product lines: Inpatient Mental Health; Residential Treatment; Community (outpatient) Mental Health; and Special Programs (Addictions and Trauma). Mental health activities are conducted at all divisions and sites. Mental Health Professionals assigned across the various Sub-Product Lines consist of nurse practitioners, addiction therapists, vocational rehabilitation specialist, physician assistants, etc. The hospital has inpatient, outpatient, and residential programs for substance abuse, PTSD, and the chronically mentally ill. It also has a program in schizophrenia affiliated with the University of Maryland. The VAMHCS offers competitive salary rates, health, and life insurance, retirement planning including Thrift Savings Plan, generous paid leave and educational opportunities plus the satisfaction of serving those who served. **Please mail your CV and Letter of Interest to Human Resources Management Service, Attn: Kenneth Reil, Jr., HR Specialist, P.O. Box 1045, Perry Point, MD 21902 or send by e-mail to Kenneth.ReilJr@va.gov.** The VAMHCS is an Equal Opportunity Employer.

Springfield Hospital Center is seeking Board-certified or Board-eligible **general psychiatrists** for our 350-bed MHA adult inpatient facility. Salary is negotiable, within MHA guidelines. Our rural, tobacco-free campus is 22 miles west of Baltimore, convenient to the Chesapeake Bay, Washington, and a variety of cultural, historic, sports, and recreational venues. Benefits include 27 paid days off in the first year, subsidized health insurance, free parking, a generous retirement program, and a truly pleasant workplace. A Medical Services physician is always on campus to attend to patients' somatic needs. Staff psychiatrists are not expected to work after hours, but some choose to supplement their salary by providing evening and weekend/holiday coverage under contract. In addition, we offer after-hours coverage contracts to psychiatrists who are not full-time staff members. Please send CV to **Jonathan Book, M.D., Clinical Director, SHC, 6655 Sykesville Road, Sykesville, MD 21784. For questions, call (410)970-7006 or e-mail JBook@dhmh.state.md.us.** EOE.

MASSACHUSETTS

Child and/or Adult Psychiatrist to join, busy, large, established private psychiatric group practice. Work consists of outpatient psychiatric treatment, both psychotherapy and psychopharmacology, and some hospital consultations. A lot of flexibility in terms of job and schedule. Please send C.V. to Paul Menitoff, M.D. Greater Lowell Psychiatric Associates, LLC 9 Acton Road Suite 25 Chelmsford, MA 01824.

Starr Psychiatric Center seeks a 20-40 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.

Exceptional Professional Opportunity for psychiatrist to provide high quality care as part of a well respected multidisciplinary private group practice loacted 2 hours north of NYC in Columbia County/Hudson Valley, NY and **neighboring Berkshire County, MA**. Inpt/outpt. Flexible hours.

Excellent salary packages $200,000 + (with opportunity for additional income). **Call Dennis Marcus, M.D.** at (413)528-1845, fax CV to (413)528-3667 or email to scppcmd@yahoo.com.

CAMBRIDGE: Consultation Liaison Psychiatry Position

PSYCHIATRIST: Cambridge Health Alliance is seeking a half- to full-time psychiatrist to join our Consultation-Liaison Psychiatry Service serving a multi-ethnic and diverse patient population. The position will include some inpatient work but will be focused on outpatient work and program development within Women's Health, Medical Specialty, and Primary Care Clinics. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment coupled with a strong academic tradition and existing collaboration with medicine, make this an ideal opportunity for candidates interested in integrated medical and psychiatric care with underserved populations. We have strong training programs in Primary Care, Adult and Child Psychiatry, and Psychosomatic Medicine and innovative educational programs for medical students. These programs provide many opportunities for teaching and research. Academic appointment is anticipated, as determined by the criteria of Harvard Medical School.

Qualifications: BC, strong clinical skills, commitment to public sector populations, team oriented, problem solver, interested in working closely with primary care and medical specialists. Fellowship training in Psychosomatic Medicine, as well as bilingual and/or bicultural abilities, is desirable. Interest and experience with substance use disorders preferred. We offer competitive compensation and excellent benefits package.

Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. CV & letter to Susan Lewis, Department of Psychiatry, 1493 Cambridge Street, Cambridge, MA; Fax: 617-665-1204. **Email preferred:** SLewis@challiance.org.

CAMBRIDGE HEALTH ALLIANCE: Director, Child/Adolescent Inpatient Psychiatry Service

Cambridge Health Alliance, Division of Child and Adolescent Psychiatry, Harvard Medical School. Full-time Director of Child/Adolescent Inpatient Psychiatry Services at our Cambridge campus. Work in a dynamic setting with multidisciplinary teams on two inpatient units using a nationally recognized program for restraint reduction. Candidates will be expected to contribute to the academic programs of the department including teaching child psychiatry fellows, general psychiatry residents, medical students, and other trainees. Academic appointment, as determined by the criteria of Harvard Medical School, is anticipated.

Qualifications: BC, demonstrated commitment to public sector populations, strong clinical skills, strong leadership and management skills, team oriented, problem solver. Interest and experience in clinical operations, with proven leadership skills in communication, team building and conflict resolution. Bilingual and/or bicultural abilities are desirable. Interest and experience with dual diagnosis and/or substance use disorders preferred. Competitive compensation, excellent benefit package.

Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. CV & letter to Joel Goldstein, MD, Dept. of Psychiatry, 1493 Cambridge Street, Cambridge, MA 02139. Fax 617-665-1204. Email: JoGoldstein@challiance.org (email preferred).

Psychiatrist - Fitchburg, MA Adult Patient Psychiatrist

Community Health Connections is a non-profit healthcare facility seeking a general psychiatrist who is Board Certified or a Board eligible graduate of a USGME qualified Adult Psychiatry Residency Program. The Psychiatrist we seek will consult with primary care and behavioral health providers regarding individual cases, medication management, and care modalities for our diverse population. This is a full time position with generous benefits and excellent work environment. Qualified applicants please submit your resume and cover letter to hr@chcfhc.org or mail to Community Health Connections, Attn: HR Dept., 275 Nichols Road, Fitchburg, MA 01420 or fax to 978-665-5959. Reference Job Listing # 78. EOE.

Medical Director/Teaching Position - Geropsychiatric Unit - Horizon Health, in partnership with Cambridge Health Alliance (CHA), a nationally recognized, innovative health care system located in Cambridge, Somerville and Boston's Metro North area that is comprised of three campuses and over 15 well established primary and specialty care practices, seeks a Geropsychiatrist for Medical Director on a 22-bed inpatient Geropsychiatric Unit at CHA's Whidden Hospital Campus. This position will oversee the provision of care on the unit, lead quality initiatives, supervise & teach residents & other MH trainees, and provide direct patient care. Academic appointment, as determined by the criteria of Harvard Medical School, is anticipated. Please **call Terry B. Good, Horizon Health, at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. CHA is an EEO employer, and women and minority candidates are strongly encouraged to apply.

The Department of Psychiatry at Mount Auburn Hospital, affiliated with Harvard Medical School, is recruiting for a full-time and a half-time position in our Outpatient Psychiatry Service. Responsibilities include evaluation and treatment of adult patients with a variety of psychiatric disorders, including dual diagnosis patients, and coordination of care with other psychiatric clinicians and with primary care and specialty physicians. Position includes participating in the teaching activities of the Department. Academic appointment to the clinical faculty at Harvard Medical School is anticipated.

Please send letter of interest and cv to: Joseph D'Afflitti, M.D., Chair, Department of Psychiatry, Mount Auburn Hospital, 330 Mount Auburn Street, Cambridge, MA 02138; tel: 617 499-5008; email: jdafflit@mah.harvard.edu.

MICHIGAN

Directorship Position - An Easy Income of $220k to $240k (Or More) - No long workdays necessary to make a great income. Clinical and part-time admin. responsibilities on adult psychiatric services in the Saginaw, MI area. C/A work is also available. Salary w/benefits or contract arrangement available. Close to Lake Huron. Only an hour and a half to Detroit and Ann Arbor. Staff Psychiatry position also available. Please call **Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

MISSOURI

Very Lucrative Opportunity Right Near Springfield- Outpatient work and consults. Also share call for 10-bed geropsychiatric unit. Offering very attractive employment compensation package. Springfield is a great city (161,000 population)-not too large and not too small. Branson is an hour away. Please call Terry B. Good at 1-804-684-5661, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

NEW YORK CITY & AREA

General Adult and Addiction Psychiatrists

The Department of Psychiatry at The Mount Sinai Medical Center (MSMC) in Manhattan has openings for General Adult and Addiction Psychiatrists. The FT/PT positions include outpatient work at the World Trade Center Mental Health Program with opportunities for teaching and clinical research. An academic appointment will be offered at Mount Sinai School of Medicine (MSSM) commensurate with experience. Applicants who have completed their residency training prior to July 2005 must be certified in General Adult Psychiatry by The American Board of Psychiatry and Neurology. Qualified candidates must possess an MD or DO degree, be comfortable with using an electronic medical record, and preferably have experience in treating mood and anxiety disorders. Spanish and/or Polish speaking physicians are strongly encouraged to apply. The MSMC 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. The MSMC/MSSM is an equal opportunity/affirmative action employer. We recognize the power and importance of a diverse employee population and strongly encourage applicants with various experiences and backgrounds.

Interested applicants should contact Fatih Ozbay, MD, Associate Medical Director of the WTC Mental Health Program by sending their CVs via email to natacha.lamour@mssm.edu.

PSYCHIATRIST

Stony Brook University's Department of Psychiatry and Behavioral Science has a F/T or P/T position immediately available for a board certified/eligible psychiatrist in University-affiliated inpatient service located at Eastern Long Island Hospital, 23-bed adult unit in scenic Greenport, NY. Position includes faculty appointment and academic opportunities. N.Y. State license necessary. To apply, submit cover letter and CV to Mark J. Sedler, M.D., MPH, Department of Psychiatry and Behavioral Science, Health Sciences Center, T-10, Room 020, Stony Brook University, Stony Brook, NY 11794-8101; or fax (631) 444-1560. For a full position description or application procedures, visit www.stonybrook.edu/jobs (Ref. #F-6508-10-09).

Stony Brook University/SUNY is an equal opportunity/affirmative action employer.

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

Long Island College Hospital

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: Deborah Dwoskin, 718-780-1159.

Rockland Psychiatric Center, a state psychiatric hospital affiliated with NYU and located 30 minutes north of NYC in the scenic lower Hudson Valley, has openings for inpatient psychiatrists. We offer regular hours, optional on-call for extra pay, excellent benefits including state retirement system. Weekly grand rounds, large medical staff, collegial atmosphere. With 430 inpatient beds and 11 clinics in 5 surrounding counties, there are many opportunities for movement and advancement once on staff.

Send CV to Mary Barber, MD, Clinical Director
rpmeb01@omh.state.ny.us.

NEW YORK STATE

PSYCHIATRIST OPENINGS at **CENTRAL NEW YORK PSYCHIATRIC CENTER**, a State-operated, forensic, JCAHO Accredited Facility, is seeking full time Psychiatrists for our Inpatient Facility in Marcy, NY, and for our Correction-based programs including: **Arthurkill, Auburn, Clinton, Coillins, Elmira, Five Points, Great Meadow, Groveland, Hudson River VTC, Marcy RMHU, and Sullivan**.
- Board Certified: $174,798*.
- Licensed: $168,421.
- Limited Permit: $107,318-119,449*
- A 4% general salary increase is pending.

NY State provides a generous and comprehensive benefits package including an outstanding Pension Plan; opportunities may exist for additional compensation and for NHSC Loan Forgiveness.

Contact: Dr. Jonathan Kaplan, Clinical Director (Code 311)
Call at: 845-483-3443, Fax: 845-483-3455.
E-mail: CN00025@OMH.STATE.NY.US.

St. Lawrence County Mental Health Clinic in Canton, NY seeks full time (35 hrs/week) BC/BE psychiatrist to join interdisciplinary treatment team in providing outpatient mental health services to both children and adults. Competitive salary and excellent fringe package and malpractice coverage.

Canton is situated between the Adirondack foothills and the St. Lawrence River Valley with four universities nearby. St. Lawrence County is an EO/AAE, federally designated as MHPSA.

Submit letter of interest and CV to Dan Dodge, LCSW-R, St. Lawrence County Mental Health Clinic, 80 State Highway 310, Suite 1, Canton, NY 13617. Email: ddodge@co.st-lawrence.ny.us. If you have questions, please call 315-386-2167.

Exceptional Professional Opportunity for psychiatrist to provide high quality care as part of a well respected multidisciplinary private group practice loacted 2 hours north of NYC in Columbia County/Hudson Valley, NY and **neighboring Berkshire County, MA**. Inpt/outpt. Flexible hours.

Excellent salary packages $200,000 + (with opportunity for additional income). **Call Dennis Marcus, M.D.** at (518)697-8010, fax CV to (413)528-3667 or email to scppcmd@yahoo.com.

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.

PSYCHIATRISTS

The Dutchess County Department of Mental Hygiene has openings for full-time and part-time BE/BC Psychiatrists in its outpatient mental health programs. Salary is competitive, based on experience, certification and schedule. 14 - 37 ½ hours/week; no evenings, weekends or on-call. Liberal fringe benefits, including membership in NYS Retirement System. Extra duty opportunities. **Call or send resume in confidence to:**

Kenneth M. Glatt, Ph.D., ABPP
Commissioner
Dutchess County Department of Mental Hygiene
230 North Road, Poughkeepsie, NY 12601
Telephone #: (845) 486-2750
Fax #: (845) 485-2759
Dutchess County is an AA/EO Employer

NORTH CAROLINA

Carolina Partners in Mental HealthCare, PLLC is seeking **BE/BC psychiatrists** for our practices in Wake Forest and Raleigh, NC. PAs and NPs also welcome to apply. Private outpatient practices, full partnership from day one - no investment required. FT, PT flexible. Carolina Partners has ten offices in Raleigh, Durham, Cary, Chapel Hill, Burlington and Wake Forest, North Carolina. Good opportunity to control your life and clinical practice, while making a good income!

Contact Executive Director or send CV to: Carolina Partners in Mental HealthCare, 1502 W. Hwy 54, Suite 103, Durham, NC 27707. Phone 919-967-9567; Fax 919-882-9531; Email carolinapartners@bellsouth.net. Find us online at www.carolinapartners.com.

Adult Staff Psychiatrist
Emergency Room Psychiatrist
Charlotte, NC

Carolinas HealthCare System has unique opportunities for Adult Staff Psychiatrists at its Behavioral Health Center. The center is part of a 874- bed regional teaching facility nestled in the heart of Charlotte. Join an outstanding team of psychiatrists in a very collegial working environment.
Adult Staff Position - Inpatient and outpatient.
Emergency Room Psychiatry Position - Work in the facility's in-house emergency department. Rotating shifts.
Excellent benefits package which includes:
- **Two weeks CME**
- **Paid vacation**
- **Short and long-term disability**
- **401K, 457B and pension plan**

Opportunity for extra income by seeing private patients or by taking shifts in the ER
Interested applicants should email their CV to Elaine Haskell at: elaine.haskell@carolinashealthcare.org **or call 800-847-5084 for more information.**

EOE/AA

OHIO

Child and Adolescent Psychiatrist

The Department of Psychiatry at The MetroHealth System, a major teaching hospital of Case Western Reserve University, is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) child and adolescent psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a top1% ranked hospital. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

Consultation-Liaison Psychiatrist

The Case Western Reserve University Department of Psychiatry at MetroHealth is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) consultation-liaison psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a hospital ranked in the top 1% for outcomes and efficiency. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

Addiction Psychiatrist

The Department of Psychiatry at The MetroHealth System, a major teaching hospital of Case Western Reserve University, is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) addiction psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a top1% ranked hospital. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

JOIN THE VA! - NORTHEAST, OHIO

Louis Stokes Cleveland VA Medical Center a teaching affiliate of Case Western Reserve University (CWRU) seeks quality board certified applicants for full or part-time **Psychiatrist** positions at the **Lorain, Mansfield, Sandusky** and **Youngstown** Community Outpatient Clinics. The primary responsibilities are providing ambulatory patient care in a multi-disciplinary setting. The VA offers a competitive salary with comprehensive health care and federal benefits package.

Send CV to: Judy Trepkowski, Human Resources Specialist, 05(B), Louis Stokes Cleveland VAMC, 10000 Brecksville Road, Brecksville, OH 44141, Fax: 440-740-2385. We are a diversified and Equal Opportunity Employer.

Geriatric Psychiatrist

The Department of Psychiatry at The MetroHealth System, a major teaching hospital of Case Western Reserve University, is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) geriatric psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a top1% ranked hospital. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

OREGON

BC/BE Psychiatrists
Oregon State Hospital (OSH)
Salem, Oregon

Oregon Department of Human Services (DHS), OSH is looking for Oregon BC/BE Psychiatrists. OSH offers FT, PT and flexible opportunities in our general adult, geriatric, and forensic programs. A generous and comprehensive benefit and PERS retirement package is included, as well as a new hospital in 2011 which will incorporate state-of-the-art architecture, treatment space and technology. Salary is very competitive and includes psychiatric differential, certification pay and opportunities for additional on-call work. Dr. Mark Diamond, CMO, invites you to call and/or send your CV to us today! Phone: (503) 945-2887; email: lila.m.lokey@state.or.us; fax: (503) 945-9910; mail: Human Resources, 2600 Center Street NE, Salem, OR 97301-2682. Please visit our website at www.oregon.gov/DHS/mentalhealth/osh. The State of Oregon is an Equal Opportunity Employer.

PENNSYLVANIA

PENNSTATE HERSHEY
Milton S. Hershey Medical Center

DIRECTOR OF NEUROSTIMULATION

The Penn State Department of Psychiatry is recruiting a psychiatrist to be its Director of Neurostimulation. Responsibilities include supervising and growing clinical services in ECT, DBS, rTMS, and VNS. Teaching and research are expected. There are opportunities for collaboration with other neuroscience departments.

With our clinical partner, Pennsylvania Psychiatric Institute, the Department staffs four clinics and an inpatient facility with 74 beds. Our current psychiatry faculty numbers 52, and we have 24 residents and fellows.

The successful candidate should have strong clinical and teaching skills and potential for scientific and scholarly achievement. An established program of research and a history of extramural grant funding are desirable. The successful candidate will also have a demonstrated ability to promote productive collaboration with colleagues in psychiatry and other disciplines.

Candidates with interest and skills in this area should send a curriculum vitae and cover letter to:

Alan J. Gelenberg, M.D.
Professor and Interim Chair
Penn State Hershey Medical Center
Department of Psychiatry, H073
500 University Drive, P.O. Box 850
Hershey, PA 17033
Phone: 717.531.8516
Fax: 717.531.6491
agelenberg@hmc.psu.edu

Penn State Hershey Medical Center is committed to affirmative action, equal opportunity and the diversity of its workforce.

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 an **Adult Psychiatrist** 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.

PHILADELPHIA: 3 positions. Chief Medical Officer and Child Psychiatrist - Inpatient Services - little call. Admission Services Physician (Mon-Fri w/ no call).
STATE COLLEGE: Child OR General Psychiatrist - Inpatient OR All Outpatient (O/P J1 eligible). Salary & benefits. Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

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. Psychiatric Hospitalist positions are available for weekday and weekend rounding and Crisis. 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.

RHODE ISLAND

Rhode Island Hospital and The Miriam Hospital
Affiliated Hospitals of the Warren Alpert Medical School of Brown University

Psychiatry Positions Available

- **Emergency Psychiatrist** The region's largest emergency psychiatry facility is seeking a child/adolescent emergency psychiatrist who is also interested in seeing adult patients; other available positions include flexible evening and weekend rotations.
- **Geriatric Psychiatrist** A program with extensive multidisciplinary clinical, research, and teaching is seeking someone with Geriatric psychiatry board certification/eligibility. Interests should include outpatient and nursing home consultation.
- **Outpatient Psychiatrist** We are seeking candidates with an interest in the medical/psychiatry interface.
- **Consultation-Liaison Psychiatrist** We are seeking candidates to provide clinical services, teaching and supervision in medical primary care and other specialty areas.
- **Inpatient Psychiatrist** Our program has 46 inpatient beds located in a general medical hospital. We are seeking an additional inpatient attending for a new unit.

Positions eligible to be considered for Faculty appointment at Brown University. Opportunities for research for applicants with appropriate background and interests. Applicants must be Board Certified or eligible (within three years of training completion). Salary and benefits competitive and commensurate with level of training and experience.

Please send CV's along with a letter of interest to Richard J. Goldberg, M.D., Psychiatrist-in-Chief, APC-9, Rhode Island Hospital, 593 Eddy Street, Providence, RI 02903 and/or email: rj-goldberg@lifespan.org.

TEXAS

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.

Harris County Jail
Second shift 2:00 PM to 10:00 PM
Perform psychiatric evaluations
& medication management
Some on call at 24/7 facility

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 income 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 or go on-line at www.mhmraharris.org to complete application.

VIRGINIA

PSYCHIATRIST - INPATIENT TREATMENT
Southwestern Virginia Mental Health Institute

We invite you to consider our psychiatrist opening for inpatient treatment. Our hospital has 156 inpatient beds and is located in Marion, Virginia, in the heart of the ***Blue Ridge Mountains***.

The position offers a new challenge and reward every day and includes:
- Competitive salary (Call and negotiate with us!).
- Sign-on bonus up to $10,000.
- Relocation allowance up to $8,000.
- Generous state benefits including low cost health, dental and vision insurance; employer paid long and short term disability, long-term care, life insurance, and malpractice insurance; employee contribution to defined benefit retirement; 457-b Deferred Compensation Plan available; and medical and family tax-deferred reimbursement accounts. Assuming a salary of $185,000 the total compensation including benefits would amount to $258,466. The amount would be approximately $265,000 if health benefits included family coverage.
- No on-call required; compensated on-call available.
- Medical school affiliation.
- Monday through Friday 8-5 work day affords a work/life balance.

Come and see all that Southwestern Virginia has to offer:
- A paradise for outdoor enthusiasts who enjoy kayaking, canoeing, hunting, fishing, hiking, biking, horseback riding, or camping.
- Five state parks in the Blue Ridge Highlands Region.
- Historic Barter Theater located in Abingdon, Virginia.
- Historic Lincoln Theater located in Marion, Virginia.
- Numerous arts, crafts, antique, and music festivals.
- Several local wineries featuring outdoor summer concerts and wine-tasting/tours.
- Local farmers' markets.
- Close to several metropolitan areas and airports.

I look forward to your call at (276) 783-1204 to discuss the job opportunity we have available, and share with you some of the wonderful things the region of Southwestern Virginia has to offer.

Ruby L. Wells, Human Resource Analyst
Southwestern Virginia Mental Health Institute
340 Bagley Circle
Marion, VA 24354
Phone: 276-783-1204
Fax: 276-783-0844
E-mail: Ruby.wells@dbhds.virginia.gov
Website: www.swvmhi.dbhds.virginia.gov
Job Application Site: https://jobs.agencies.virginia.gov
EOE

VIRGINIA COMMONWEALTH UNIVERSITY, School of Medicine, is recruiting a BE/BC psychiatry educator to serve as Ambulatory Care Division Chair in large, financially stable department. Duties include development of new programs, resident and student education, direction of general and specialty clinics, clinical care and a significant role in overall departmental leadership. Experience in academic ambulatory care, psychiatric education and administration desired. Ambulatory Care Clinics are located at the VCU Medical Campus, and have an estimated 16,000 patient visits/year. Department of Psychiatry has over 75 full-time faculty, 39 residents, multiple fellowships and research centers including an addiction genetics research center. Richmond, the State Capital, has moderate climate and rich mix of history, a diverse multicultural community, excellent housing and public/private schools.

Send applications to Joel J. Silverman, M.D., Chairman, c/o Takeya McLaurin, Department of Psychiatry, MCV/VCU Box 980710, Richmond, VA 23298. Please contact Dr. Joel Silverman at jsilverman@mcvh-vcu.edu.

Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Men, women, persons with disabilities, and minorities are encouraged to apply.

F5591 VTCC Director

EXCITING LEADERSHIP OPPORTUNITY FOR CREATIVE MENTAL HEALTH PROFESSIONAL in a nationally recognized psychiatric hospital for children and adolescents located in an urban academic medical center. The Department of Psychiatry is currently seeking an individual to serve as Director of the Virginia Treatment Center for Children (VTCC). The Director is responsible to the VCU Health System and to the Chair, Department of Psychiatry for the effective management of multiple integrated functions of VTCC. These functions include the clinical care of inpatients and outpatients, multi-disciplinary teaching of students from various disciplines, and development and implementation of meaningful research. Statewide outreach to improve children's mental health is essential, as is maintaining integrative teaching and clinical research relationships within the University. **Specific VTCC duties include:**
- Supervision and coordination of the Executive Committee which include directors of Clinical Services Operations, Medical Services, Support Services, Utilization Management and Quality Improvement, Education and the Business Office.
- Planning and budgeting for the Treatment Center including establishing, monitoring, and maintaining annual service and financial goals and objectives.
- Ensuring that services meet standards of accrediting entities and that continuous quality improvement processes are in place.
- Working collaboratively with community agencies/organizations to ensure children referred to the Treatment Center receive appropriate care and to promote the development and delivery of comprehensive, quality services for children/adolescents in Virginia with mental health needs.
- As a faculty member in Psychiatry, the Director is expected to perform usual faculty duties, including teaching, research, and clinical care, where relevant.

QUALIFICATIONS: Doctoral degree in a mental health discipline, experience in the provision of clinical services to children/adolescents/families, strong administrative experience, including personnel and budget management, experience in teaching and research.

Send CV to Joel Silverman, MD, Chair, 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.

Child Psychiatrist
Position F3248

Virginia Commonwealth University: Medical College of Virginia Hospitals, Division of Child & Adolescent Psychiatry in the Department of Psychiatry, is recruiting a Virginia license-eligible BE/BC child psychiatrist faculty. Will work as Inpatient/Outpatient attending and will be responsible for administration and clinical care as well as teaching and supervision of medical students, residents and child fellows. In addition, consultation work with community agencies will be available. Must have an interest in teaching and academic work, as well as the ability to work on interdisciplinary team. Demonstrated experience working in and fostering a diverse faculty, staff, and student environment or commitment to do so as a faculty member at VCU.Department has seven full-time child psychiatrists, a child research institute, over 80 full-time faculty and well-funded research in genetics, child and women's mental health, addictions and psychopharmacology. VCU is a large urban university with robust health science campus and 750-bed university hospital.

Richmond, State Capital, has moderate climate and rich mix of history with modern facilities, excellent suburban housing, public/private schools. Internet provides comparative cost of living.

Send CV to Joel Silverman, **VCU**, PO Box 980710, Richmond VA 23298 (Fax 804-628-1247). Virginia Commonwealth University is an equal opportunity/affirmative action employer. Women, minorities and persons with disabilities are encouraged to apply.

Child Mental Health Researcher

VIRGINIA COMMONWEALTH UNIVERSITY Department of Psychiatry and the Division of Child and Adolescent Psychiatry is recruiting an experienced **Child Mental Health Researcher**. The successful candidate will conduct research, mentor faculty and trainees, prepare grant applications, and manage staff and research projects. Faculty member will be required to have an established research agenda and a clear potential for external funding, as appropriate, and potential for scholarship or creative expression to complement and expand existing expertise in the Department of Psychiatry. Additionally, candidate must have an appropriate level of peer reviewed publications; excellent organizational, management and oral/written communication skills; ability to work with multiple disciplines; familiarity with clinical aspects of child mental health. Collaboration with our International Virginia Institute for Psychiatric and Behavioral Genetics is encouraged. Demonstrated experience working in and fostering a diverse faculty, staff, and student environment or commitment to do so as a faculty member at VCU.

VCU Department of Psychiatry employs over 80 full-time faculty and has well-funded research in genetics, addictions, child and women's mental health, and psychopharmacology. VCU is a large urban university with robust health science campus and 750-bed university hospital. Richmond, the State Capital, has moderate climate and rich mix of history with modern facilities, excellent suburban housing, and public/private schools. Internet provides comparative cost of living.

Send CV to Joel Silverman, Chairman, Department of Psychiatry, **VCU**, Box 980710, Richmond, VA 23298 (Fax 804-628-1247). Virginia Commonwealth University is an equal opportunity/affirmative action employer. Women, minorities and persons with disabilities are encouraged to apply.

VIRGINIA COMMONWEALTH UNIVERSITY: Department of Psychiatry, School of Medicine, 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 Addictions Fellowship. Strong programs in psychiatric genetics, epidemiology, pharmacology, toxicology, and women's health. State funded health practitioner impairment program, Behavioral Public Health, laboratory and community based research are active areas for collaboration. Wonderful work environment. 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.

Send applications to Joel J. Silverman, M.D., Chairman, c/o Takeya McLaurin, 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.

Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Men, women, persons with disabilities, and minorities are encouraged to apply.

Staff Psychiatrist # 2010

Valley Community Services Board located in the beautiful Shenandoah Valley is seeking a Full-time BE/BC psychiatrist. This position is 100 % Outpatient, Monday - Friday. VCSB offers health/dental/life insurance, paid sick and annual leave and participation in the Virginia Retirement System. Candidate will receive 5 days allowable for CME training plus $2,500.00 per year for educational requirements. Salary range is $155K- $175K depending on experience.

To apply for this position, submit a CV or resume along with a VCSB Employment Application, which is available on our website, **www.vcsb.org**. Applications should be submitted to Human Resources 85 Sanger's Lane, Staunton, VA. 24401, or e-mailed to sgray@vcsb.org or Fax to 540-213-7501. For additional information feel free to call 540-213-7340 or 540-213-7559.

WASHINGTON

The University of Washington and Harborview Medical Center (HMC) in Seattle, WA is accepting applications for a hospital-based psychiatrist at the rank of Acting Instructor or Acting Assistant Professor. This position is 1.0 FTE and will work doing a combination of inpatient psychiatry and hospital psychiatry consultation work with a large team consisting of another psychiatrist, psychologist, nurse and social worker. Two half-days a week will be spent in an ambulatory outpatient setting seeing patients. There is an MD requirement for this position. The position will also be responsible for teaching residents and medical students. Application deadline is Sept 15, 2010. Start date Jan 2, 2011 (sooner is possible).

Please send application and CV to: Peter Roy-Byrne MD, Chief Psychiatry, Harborview Medical Center 325 9th Ave. Box 359911, Seattle, WA 98104 or email roybyrne@uw.edu. The UW is building a culturally diverse faculty and strongly encourages applications from females and minority candidates. The UW is and EOE/AA employer.

Summit Research Network (Seattle) LLC is seeking a licensed, board certified Psychiatrist to work with adult and pediatric/adolescent populations in clinical research trials. Must be comfortable working in a team environment as a Sub Investigator and Principal Investigator in primarily psychiatric pharmaceutical research at our site in **Seattle, WA.**

This position is part time with the potential to increase to full time. Summit offers competitive salary based on experience/credentials with an excellent benefit package.

Please send inquiries and CV to: James R. Hockley, MBA, Summit Research Network Management, Inc., 2701 NW Vaughn St., Ste.350; Portland, OR or via email: jhockley@summitnetwork.com.

Fellowships

FELLOWSHIP PUBLIC PSYCHIATRY at YALE

Yale University School of Medicine is accepting applications for a one-year Fellowship in Public Psychiatry for **July 2011**, based at the Connecticut Mental Health Center [CMHC], for individuals interested in public mental health and administration. 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 the New Haven area. Child & Adolescent trained psychiatrists may apply for a combined advanced fellowship position with CMHC and the Yale Child Study Center. All 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.

PGY5 Fellowship Position at Silver Hill Hospital/Yale University Department of Psychiatry

In collaboration with the Yale University Department of Psychiatry, Silver Hill Hospital, a private psychiatric hospital with 129 beds in New Canaan, CT, is offering a one year PGY5 fellowship position. The Hospital provides long-term residential treatment programs as well as inpatient treatment. The position offers experience working in the following core areas: General Psychiatry; Substance Use Rehabilitation; Treatment of Severe Personality Disorders; and Treatment of Adolescents. Additional educational and research elective opportunities are available through the Yale Department of Psychiatry.

Interested applicants should contact Ann Cohen DePalma at 203.785.2095.

PGY 5 Fellowship in University Student Mental Health at The University of Chicago

This post-residency training program focuses on teaching the knowledge and skills necessary to provide mental health care to a university student community. The program will train future student mental health psychiatrists, and includes mentorship by the faculty based at the Student Counseling and Resource Service at The University of Chicago, an active student mental health service staffed by six psychiatrists and over 20 non-physician psychotherapists serving a population of approximately 14,000 extraordinary students. Clinical skills for this fellowship include training in psychosocial treatments for students including short-term psychotherapy, crisis intervention, and group psychotherapies that are particularly important in this population, such as cognitive behavioral procrastination groups and eating disorder groups. It will also include intensive training in the unique aspects of psychopharmacology in this setting, such as addressing target symptoms without impairing cognition. Other aspects of training would be treatment of Attention Deficit Hyperactivity Disorder, substance abuse, mood and anxiety disorders, and first break psychotic disorders. The fellowship will also include administrative aspects of student mental health. This includes an understanding of the university's processing of applications for mental health disability accommodation, consultation for students going on and off medical leave for psychiatric reasons, providing liaison to the Department of Psychiatry for services provided to students, and doing training sessions for groups around campus who are likely to deal with troubled students. The fellow will receive supervision and training on becoming a good consultant for behavioral health issues on campus. These consultations include inquiries by faculty, University staff, and peers about how to deal with troubled students. The fellow will have experience and education on how to be an effective mental health expert as a member of the team of student life and student services professionals.

Please send a personal statement, curriculum vitae, and three letters of recommendation by **February 4, 2011** to: Thomas A. M. Kramer M.D., Director, Student Counseling and Resource Service, The University Of Chicago, 5737 South University, Chicago, IL 60637.

For information about the Student Counseling and Resource Service at The University of Chicago: **http://counseling.uchicago.edu.**

The Department of Psychiatry, Indiana University School of Medicine has a position open for a two year **Clinical Research and Neuroimaging Mood Disorders Fellowship**. Applications are invited from candidates with a PhD or a MD degree. The fellowship experience will involve extensive participation in NIH, private foundation and industry sponsored research projects for investigation of pathophysiology of mood disorders and effects of treatment. Experience in clinical trials and/or neuroimaging research is desirable. To apply please send curriculum vitae and letter of interest by fax or e-mail to:

Amit Anand, MD
Director, Mood and Emotional Disorders Across the Life Span (MEDALS) Center
Department of Psychiatry and Radiology
UH 3124
550 North University Boulevard
Indianapolis, IN 46202
Fax: 317-274-1497, email: aanand@iupui

Fellowship In College of Mental Health The Ohio State University Columbus, OH

The Ohio State University Counseling and Consultation Service offers a Psychiatry Fellowship in College Mental Health for the 2011-12 academic year with training specific to a culturally and clinically diverse student population of over 56,000. This full-time, salaried position has benefits and no call or weekend duties. Candidates must be eligible for board certification and Ohio medical licensure. Mail CV, letter of interest and 3 letters of recommendation including letter from residency training director to: Denise Deschenes, M.D., Counseling and Consultation Service, 4th Floor, Younkin Success Center, 1640 Neil Ave., Columbus, OH, 43201-2333, (614) 292-5766, deschenes.2@osu.edu; www.ccs.osu.edu. **Application deadline: February 1, 2011.** To build a diverse workforce, Ohio State encourages applications from individuals with disabilities, veterans and women. EEO/AA employer.

PSYCHOSOMATIC MEDICINE FELLOWSHIPS 2011-2012 NY Medical College/Westchester Med. Ctr. FLEXIBLE STARTING TIME

Established C/L Group in tertiary care hospital, ACGME accredited. 45 minutes from NYC. Opportunity to work in Burn, High-Risk OB, HIV, Transplant as well as General Med/Surg. Research opportunities. Psychiatry residency & NYS limited permit or license required. Competitive salary and benefits. **Contact:** Yvette Smolin, MD, Training Director, BHC Room N301, Valhalla, NY 10595 (914) 493-8424 smoliny@wcmc.com.

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