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Newspaper of the
American
Psychiatric
Association

PSYCHIATRIC NEWS

inside

PERIODICALS:
TIME-SENSITIVE MATERIALS

Credit: Rich Daly

Sen. Olympia Snowe (R-Maine) was presented with APA's highest honor for legislators, the Jacob K. Javits Award, by APA Medical Director James H. Scully Jr., M.D., last month. She was recognized for "her significant contributions to the cause of Americans with mental illness," which includes increasing access to treatment.

APA Honors Senator for Years Of MH Care Advocacy

Sen. Olympia Snowe's strong support—against the stance of her Republican colleagues—for ending Medicare's discriminatory mental health care copay draws APA's praise, as does her work to boost Medicaid assistance to the states.

BY RICH DALY

Advocates for expanded federal support of mental health care have achieved a number of major legislative victories in recent years, which have often come through very small vote margins in Congress. One of the members of Congress who has provided the critical votes to squeeze such major legislation through has been Sen. Olympia Snowe (R-Maine), whom APA recently honored.

APA Medical Director James H. Scully Jr., M.D., presented Snowe with the Jacob K. Javits Award at her Capitol Hill office on September 16. The award recognizes a public official who has made a significant contribution to the care of people with mental illness.

"I am deeply honored to receive this award from the American Psychiatric Association, whose leadership and advocacy on behalf of mental illness have improved the lives of millions of Americans nationwide," said Snowe in a written statement. "As we strive to improve access to quality, affordable health care in our nation, it is incumbent upon Congress to ensure parity when it comes to these services upon which so many rely."

Snowe's legislative efforts include bucking the majority of her party to provide votes in support of several measures to expand funding for mental health treatment; those measures then passed by narrow margins. Recent examples of these votes include her 2008 support for passage of the Medicare Improvements for Patients and Providers Act (PL 110-275), which included a gradual reduction of Medicare's 50 percent coinsurance charge for outpatient mental health services to the 20 percent charged for other outpatient services. Snowe was among a hand-

please see ***Senator*** *on page 28*

Geller, Jeste Vie to Become APA's Next President-Elect

Two psychiatrists whose resumes show extensive clinical, research, and APA experience are nominated to compete for the post of president-elect in the next APA election.

BY KEN HAUSMAN

APA Vice President Jeffrey Geller, M.D., and At-Large Trustee Dilip Jeste, M.D., have been tapped by the Nominating Committee to face off for the president-elect post in the 2011 APA election.

Geller, a professor of psychiatry and director of public-sector psychiatry at the University of Massachusetts Medical School, first served on the Board of Trustees as an Area trustee and now is APA vice president; in 2006 he received the Ron Shellow Award in the APA Assembly, where he served as Area 1 representative.

Jeste is a distinguished professor of psychiatry and neurosciences at the University of California, San Diego. He is a member of the Institue of Medicine and of the *DSM-5* Task Force, a founding director of the American Psychiatric Institute for Research and Education, and former president of the American Association for Geriatric Psychiatry.

The position of secretary is also up for election this year, having last year

please see ***Election*** *on page 30*

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Illegal to Base Military Discharge On Sexual Orientation, Judge Rules

Plaintiffs presented evidence that discharges under the policy had dropped substantially since fighting began in Afghanistan and argued that the evidence contradicts the common belief that homosexuals in the military compromise military readiness.

BY MARK MORAN

A California district court ruling that the military's "Don't Ask, Don't Tell" (DADT) policy regarding gays in the military is unconstitutional has roiled debate about the policy and added momentum to a movement to repeal it.

The September 9 ruling by Judge Virginia Phillips of the U.S. District Court for the Central District of California was issued two weeks before a Department of Defense appropriations bill was scheduled to come before the Senate containing a provision to repeal the policy. But on September 21, Senate Democrats failed by four votes to muster the necessary 60 votes to overcome a filibuster by Republicans blocking the bill and the repeal provision, as well as a number of other Democratic priorities tacked on to the bill.

(The *New York Times* reported that same day that some Republican senators said they would consider voting for repeal later in the year when the military completes a study of the effects of repeal ordered by Secretary of Defense Robert Gates.)

In her decision, Phillips wrote, "The Don't Ask, Don't Tell Act infringes the fundamental rights of United States service members in many ways. It denies homosexuals serving in the Armed Forces the right to enjoy 'intimate conduct' in their personal relationships. The Act denies them the right to speak about their loved ones while serving their country in uniform; it punishes them with discharge for writing a personal letter, in a foreign language, to a person of the same sex with whom they shared an intimate relationship before entering military service; it discharges them for including information in a personal communication from which an unauthorized reader might discern their homosexuality."

The suit was brought against the government and Gates by the Log Cabin Republicans, a group of gay Republicans.

The DADT policy was instituted in 1993 under the Clinton administration restricting the U.S. military from efforts

please see ***Sexual Orientation*** *on page 30*

Important Annual Meeting Announcements: Housing and Registration Open Earlier

- **For APA Members Only: Make Housing Reservations, Select Courses, and Register Early!**
  As another member benefit, APA members will have an exclusive opportunity to register, enroll in courses, and make hotel reservations for APA's 2011 annual meeting in Hawaii beginning November 2. Nonmembers will not be able to do so until November 15. Registration and hotel information, including hotel rates and descriptions, will go live on APA's Web site at <www.psych.org> on November 2. APA members may access this information by logging into Members Corner.

- **Look for Annual Meeting Information Online**
  Beginning November 2, visit <www.psych.org> to view the entire Annual Meeting Advance Registration Packet. This will include 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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  Phone: (866) 882-6227
  Web Site: www.Mentalhealthparitywatch.org

‘Give an Hour’ of Your Time to Help Those Who Serve Our Country

BY CAROL A. BERNSTEIN, M.D.

It is impossible to turn on the television, listen to the radio, or browse the Internet without being reminded of the heavy toll the current conflicts in Iraq and Afghanistan are taking on our military service members and their families. As you know, their mental health needs must be addressed, particularly if we are to prevent the kind of societal suffering that followed the Vietnam War.

Reports from within the Department of Defense indicate that service members’ mental health continues to be of primary concern to the military leadership. Secretary Robert Gates and Adm. Mike Mullen, chair of the Joint Chiefs of Staff, routinely speak out about the need to provide appropriate mental health care for those in the military and their families. The current administration has deemed this issue a matter of national security, and both Michelle Obama and Jill Biden have made supporting military families a primary focus.

While tremendous energy and resources have been allocated by the government, far too many returning troops and family members continue to suffer. The suicide rate among Army soldiers now surpasses that in the civilian population. Recent reports indicate that as many as 35 percent of the men and women returning from duty in Afghanistan or Iraq are experiencing significant mental health difficulties including depression, anxiety, and posttraumatic stress. In addition, we estimate that similar numbers are reporting signs of traumatic brain injury. Many individuals encounter significant problems with reintegration when they come home; some experience family conflicts, while others turn to substance abuse. Finally, we are seeing a concerning number of veterans of Iraq and Afghanistan in the criminal justice system and in homeless shelters.

Unfortunately, returning veterans contending with combat-related stresses are not routinely seeking the mental health treatment they need. Many worry that getting mental health care will jeopardize their career or standing. Given the military culture’s emphasis on confidence, strength, and bravery, others are reluctant to expose their vulnerabilities to counselors who are often military personnel themselves.

Psychiatry can and must play a primary role in ameliorating the emerging mental health crisis within the military community. APA has been instrumental in the growth of a national nonprofit organization named Give an Hour *(Psychiatric News*, March 7, 2008, and May 16, 2008). We have partnered with Give an Hour (GAH) in its effort to provide free mental health care to those who serve and their families. The partnership of APA, the American Psychiatric Foundation, and GAH is an excellent example of how we can apply the knowledge and expertise of psychiatry to educate, inform, and engage with community organizations. To date GAH has recruited more than 5,000 psychiatrists and other licensed mental health professionals to provide free evaluation, treatment, and other services to members of the military, veterans of Afghanistan and Iraq, their families, and their communities.

By providing services that are separate from the military establishment, GAH offers an option to men and women who might otherwise fail to seek or receive appropriate services. There is no paperwork to submit to insurance companies and no cost to the patient. Also, there is no limit to the number of sessions one can receive.

In addition to donating direct psychiatric and other mental health services, GAH providers help with outreach and education. By speaking at conferences, participating on panels, and reaching out to the media in their communities, GAH providers help reduce the stigma frequently associated with mental health treatment. GAH also offers immediate access to mental health services to people who do not have access or who might fail to seek help through the military or VA. Parents, siblings, partners, and other loved ones typically not covered by military insurance also can benefit from the professional help that GAH provides.

Our membership has much to offer this outstanding program and similar organizations such as the Soldier’s Project in California. Our most senior colleagues have vast knowledge and expertise—whether in the area of combat stress or in treating and assisting family members. Many of us have extensive local networks that could work with GAH to coordinate the communitywide provision of critical services to military families. I would especially like to encourage our early-career psychiatrists to get involved with this effort, engage their communities, and make a difference to our military population. I invite you to join Give an Hour and to let your colleagues know about this opportunity. I look forward to hearing your thoughts and comments regarding APA’s efforts to support the men and women and their families who serve our country. You can learn more about Give an Hour at <www.giveanhour.org>. Information about volunteering your services can be accessed by clicking on “For Providers” on the left side of the homepage. ■

Data From Trauma Victims Point to PTSD Biomarkers

Emory University researchers combine epidemiological and genetic data to understand the effects of trauma on a highly traumatized African-American population.

BY AARON LEVIN

An Emory University research team is tying to gather epidemiological data on thousands of inner-city residents in Atlanta with DNA samples to seek out correlation between social and biological risk factors for posttraumatic stress disorder.

The Grady Trauma Project has recruited more than 3,000 participants so far from the general medical clinic at Grady Health System. That number will grow to a projected 8,000 by 2013. About 94 percent of participants are African American, and 65 percent are female; their average age is 39.

"High rates of trauma are the rule rather than the exception in this population," principal investigator Kerry Ressler, M.D., Ph.D., told attendees at the 2010 E.Y. Williams Symposium on PTSD and African Americans, held at the Howard University College of Medicine in Washington, D.C., in September. Ressler is a Howard Hughes Medical Investigator, an associate professor of psychiatry and behavioral sciences at Emory, and co-director of the Fulton County Mental Health System's trauma clinic.

> **"High rates of trauma are the rule rather than the exception in this population."**

The symposium honors the late E.Y. Williams, M.D., a Howard graduate and chair of its Department of Psychiatry from 1952 to 1970.

Trauma rates among the Atlanta-area participants are as high as those among returning combat veterans, said Ressler. Many have lifetime histories of being victims of physical attack, child abuse, or rape. Those traumas also happen in a broader social context, he said. Individuals with PTSD are more likely to be poor, to live in unsafe neighborhoods, or to have a family member who was in jail or who was murdered. About 82 percent of those people have experienced two or more forms of trauma.

"These trauma exposures occur early in life and often include physical or emotional abuse or neglect and other forms of family violence," said Ressler.

People without childhood trauma were at low risk for PTSD after experiencing adult trauma, but child trauma or abuse was associated with increased risk of psychiatric problems following adult trauma.

For instance, on average, persons who experienced two or three types of trauma after childhood recorded a PTSD Symptoms Scale score of 9.8 if they had no history of child abuse, but 14.9 if they had experienced one type of child abuse, and 19.0 with two types of child abuse. Similar patterns were observed for depression.

"If children are raised in a stressful environment, adaptations during development may alter the stress/threat response system," priming them for the hyperarousal characterizing PTSD, said Ressler.

Given that background, the Emory researchers looked for biological correlates of the PTSD symptoms in a subset of their study population.

They chose an HPA axis gene, FKBP5, a chaperone protein involved in glucocorticoid receptor feedback sensitivity, which is associated with PTSD.

Polymorphisms in the FKBP5 gene were associated with distinct patterns of PTSD symptoms in adults when genotype was plotted against childhood abuse. People with the GG variant had only a minor rise in PTSD symptom scores when exposed to even two types of childhood abuse. However, those with the AA allele recorded significantly higher scores, while the AG allele results were in between.

"FKBP5 is one genetic mechanism by which childhood trauma may increase risk in adults for PTSD symptoms, possibly through increased sensitization of fear pathways," said Ressler.

The project team also sampled 362 of these highly traumatized subjects for a pooled genomewide association study to identify genes associated with PTSD risk or resilience. Of those subjects, 188 had PTSD, while 174 did not. The two groups were matched for gender, age, trauma history, and substance use history.

Comparing the results of that initial study with mRNA from the amygdala narrowed the list down to 17 candidate genes. The top candidate was ADCYAP1R1, a gene regulating expression of pituitary adenylate cyclase-activating peptide (PACAP) in the bed nucleus of the stria terminalis in the amygdala.

Other researchers have shown that PACAP in that region and the related PAC1 receptor are upregulated following chronic stress.

Higher levels of PACAP increase anxiety and startle response in rodents. The peptide had been studied in mice in tests of fear and extinction but not in humans, said Ressler.

Significant differences appeared in the role of PACAP levels in this group of humans, he said. Women with higher PACAP levels recorded greater startle responses and higher intrusive, avoidant, and hyperarousal symptom scores, compared with women with lower PACAP levels. No significant differences were observed in the same measures between men with higher or lower PACAP levels.

Those results were predicted by one single-nucleotide polymorphism in ADCYAP1R1. The polymorphism is found in a piece of DNA that is sensitive to estrogen, suggesting that the abnormal stress response is mediated by estrogen regulation of ADCYAP1R1 and explain why the effect is specific to women.

Ultimately, research into these and other biomarkers may contribute to better diagnosis and treatment monitoring and may lead to quick blood tests that could be combined with an interview in the emergency room to help clinicians assess risk for PTSD, said Ressler.

The study is sponsored by the National Institute of Mental Health, National Science Foundation, Howard Hughes Medical Institute, Burroughs-Wellcome Fund, Anxiety Disorders Association of America, and NARSAD.

The Web site for the Grady Trauma Project is <www.psychiatry.emory.edu/GTP.htm>. ■

Credit: A. Levin

Kerry Ressler, M.D., Ph.D., the keynote speaker at Howard University's E.Y. Williams Symposium on PTSD and African Americans, speaks with Williams's daughter, retired psychiatrist and neurologist Shirley Williams, M.D., at the meeting.

APA/AACAP Revise Treatment Guide For Parents

APA and the American Academy of Child and Adolescent Psychiatry (AACAP) have released a revised and expanded version of the guide "The Use of Medication in Treating Childhood and Adolescent Depression: Information for Patients and Families."

The guide, originally published in 2005, is intended to help parents and families make informed decisions about care for a child or adolescent with depression. The new version, presented in a question-and-answer format, has been updated and revised based on recent research on the effectiveness of various treatments for depression in children and adolescents and has been expanded to include discussion of a range of medication and psychotherapy treatments, suicide risk, and actions parents can take to help their children during treatment.

The guide was developed jointly by APA and AACAP in consultation with a national coalition of parents, clinicians, and professional associations and has been endorsed by the National Alliance on Mental Illness, the Suicide Prevention Action Network, Mental Health America, and the Depression and Bipolar Support Alliance.

It was written by a panel of experts appointed by the presidents of APA and AACAP and co-chaired by child psychiatrists Christopher Kratochvil, M.D., and David Fassler, M.D.

"The guide was developed with extensive input from parents. It was designed to help answer the questions they have about these medications," said Fassler in a statement. "Parents need as much information as possible to advocate for their children and to make informed decisions about treatment options." Fassler is a clinical professor of psychiatry at the University of Vermont and treasurer of APA.

Kratochvil, a professor of psychiatry and pediatrics at the University of Nebraska Medical Center, added, "This was a collaboration of groups, including patient advocacy and professional organizations, who wanted to provide reliable and up-to-date information to parents about the treatment of depression. Additionally, we wanted to make it readily accessible to patients and families, available for downloading off of the Internet at no charge."

The new guide is posted at <www.parentsmedguide.org>, a joint Web site of APA and AACAP. ■

Understanding the problems of children and families requires experts in child psychiatry, pediatrics, genetics, neurobiology, epidemiology, psychology, nursing, social work and social policy.

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Marijuana, Prescription Meds Drive Spike in Drug Use

Previous concerns by federal health officials over "doctor shopping" by drug abusers give way to a call by these officials for more patient education on the need to dispose unneeded prescribed medications.

BY RICH DALY

The overall national rate of drug use increased from 2008 to 2009, and the two drug categories that accounted for most of that increase were prescription drugs and marijuana.

The overall rate of illicit drug use in the United States rose from 8 percent of the population over age 11 in 2008 to 8.7 percent one year later, according to the nation's most comprehensive annual substance use survey. Results of the National Survey on Drug Use and Health, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), released on September 16, identified nonmedical uses of marijuana and prescription drugs as the key drivers of the increase.

For instance, 2.5 percent of the population used "psychotherapeutic" drugs for nonmedical purposes in 2008, but this figure grew to 2.8 percent in 2009. The vast majority of these drugs—defined in the report as all pain relievers, tranquilizers, stimulants, and sedatives—were originally prescribed to someone.

Federal antidrug officials identified the growing use of marijuana as a different but parallel problem. The survey found 6.1 percent of the population acknowledged using marijuana in 2008; 6.6 percent did so in 2009.

The growth in the use of these two drug categories stems at least in part from the public's view of them as intrinsically "medical" products and therefore relatively harmless, said Gil Kerlikowske, director of the Office of National Drug Control Policy, at a press conference in September addressing the new data.

To illustrate this point, particularly about changing attitudes toward marijuana use, drug-control advocates noted that 14 states have legalized medical marijuana, and eight are considering such measures in their legislatures or on their November election ballots.

"There's clearly a movement to medicalize pot," agreed Stevan Gressitt, M.D., founding director of the Maine Institute for Safe Medicine at the University of New England, in an interview with *Psychiatric News*. "The voters have said that."

Medical Use of Marijuana

Also, 81 percent of Americans support legalizing marijuana for medical use, according to an ABC News/*Washington Post* national poll released earlier this year. It's a view not generally supported by medical groups and policymakers.

"Associating marijuana with medicine sends the wrong message," said Kerlikowske.

Similar misconceptions apply to prescribed medicine.

"Young people think that if it's in the medicine cabinet, then it can't be bad for you," said Kerlikowske.

The number of youth who said they used marijuana in the month prior to the survey increased from 15.2 million in 2008 to 16.7 million in 2009, he noted.

The increasing number of people misusing marijuana is not yet reflected in abuse or addiction rates. For instance, 4.3 million people were classified as dependent on or abusers of marijuana or hashish in both 2002 and 2009. However, addiction to prescription medications has increased, from 1.5 million in 2002 to 1.9 million in 2009.

Physicians' Roles Changing

The latest data indicate that a previously identified source of prescription drugs for many people who abuse them—multiple prescriptions from different physicians obtained by addicted people who "doctor shop"—may be less of a concern than a new source of such drugs. The survey found that more than half of those who said they abused prescription painkillers, which included but was not limited to people addicted to them, obtained such drugs from a relative or friend, and 80 percent of that group said that the medication was originally prescribed to their relative or friend by a single physician.

H. Westley Clark, M.D., M.P.H., director of the Center for Substance Abuse Treatment at SAMHSA, told *Psychiatric News* that the data suggest that physicians should focus less on screening for patients who are doctor shopping than on educating their patients to dispose of their unneeded prescription medications properly. Clark called this a "very important" step that physicians need to take.

Gressitt agreed that the misuse of prescription medications is a growing problem driven mainly by an older population who requires more powerful medications and the greater prevalence of 90-day prescriptions.

"That may lead to an oversupply" of prescription medications in circulation, Gressitt said.

Congress has begun to advance legislation to encourage prescription-drug disposal programs, including a bill (S 3397) passed by the Senate in August that would authorize state and local disposal programs to accept controlled substances. Similar legislation (HR 5809) passed the House in September. Supporters of the legislation said it was needed because many people have had few disposal options since federal law disallows turning in controlled substances to state or private disposal programs (*Psychiatric News*, September 3).

Despite a lack of specific legal authority to do so, many prescription-drug takeback programs already accept such controlled substances, Clark said.

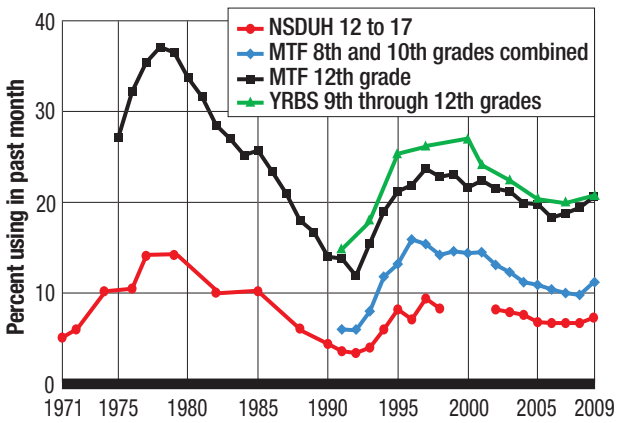
Information about the SAMHSA substance use survey is posted at <http://oas.samhsa.gov/nsduhLatest.htm>. ■

Credit: Rich Daly

Gil Kerlikowske, the U.S. "drug czar," calls on physicians to educate their patients about the need for proper disposal of unused prescription medications to prevent adolescents and others from stealing and abusing them. Such thefts are a major factor behind the growing problem of prescription drug abuse in the nation.

'Medicalization' of Drugs Blamed for Rise in Illicit Use

Results from a new national survey reflect other recent findings that marijuana and prescription drug use by youth has increased. Antidrug officials blame the rise on the "medicalization" of those substances. That is, adolescents increasingly see them as medical products that are not as dangerous as other types of drugs.



MTF = Monitoring the Future; NSDUH = National Survey on Drug Use and Health; YRBS = Youth Risk Behavior Survey

Source: National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration, September 2010

NIMH Head Urges More Emphasis On Mental Illness as Brain Disorder

To catch up with other medical disciplines that have sharply reduced morbidity and mortality, psychiatry must evolve into "clinical neuroscience" and reconceptualize its understanding of the roots of mental disorders.

BY AARON LEVIN

Credit: David Hathcox

Thomas Insel, M.D.: "We're in the middle of a revolution. We have the chance to change the world—not tomorrow, but by staying on course."

Research progress on psychiatric disorders must follow the cues of cardiology and oncology, taking major steps forward to find the causes of psychopathology and develop cures for mental illness, stated the director of the National Institute of Mental Health (NIMH).

"We're in the middle of a revolution," said Thomas Insel, M.D. "We have the chance to change the world—not tomorrow, but by staying on course."

NIMH has laid out that course over the last few years by shifting its grants in directions that it hopes will produce "disruptive innovations," said Insel in the inaugural lecture of the George Washington Institute for Neuroscience at George Washington University in Washington, D.C., in September.

The new institute is a multidisciplinary center that promotes research and training in the mechanisms of normal and pathological brain function.

please see ***Brain Disorder*** *on page 31*

11 Large Institutions Chosen For *DSM-5* Field Trials

This article is part of a series of commentaries by the chair of the *DSM-5* Task Force on the manual's development. It will continue until the release of *DSM-5* in May 2013.

BY DAVID J. KUPFER, M.D.

My article in the series on *DSM-5* activity that began in the October 1 *Psychiatric News* introduced readers to the *DSM-5* field trials—a vital component to developing diagnostic criteria that involves taking the proposed revisions from each of the 13 *DSM-5* work groups into the field to observe their impact on diagnosis and patient care. As noted, having practitioners such as solo clinicians and those in independent group practices test proposed revisions is important for examining *DSM-5* in the context of its everyday use. However, it is equally important that draft criteria are examined in sizable, diverse populations as well.

Large academic medical institutions usually house general psychiatric as well as specialty clinics, such as pediatric psychiatry clinics or substance use treatment clinics. This makes them a popular choice among patients. Those institutions' affiliation with medical school training programs means an abundance of available clinicians, as well as the necessary infrastructure for conducting clinical research. As a result, these large settings provide an ideal backdrop for recruiting high volumes of psychiatric patients who represent a wide array of characteristics, including various ages, cultures and ethnicities, socioeconomic backgrounds, and potential diagnoses. *DSM-5*'s developers recognize the importance of recruiting broad samples of patients, and this is reflected in the *DSM-5* field trials using two distinct designs—the routine clinical practice design described in my previous article and a second design for large, academic-medical settings.

In May, APA began soliciting applications from institutions interested in serving as potential recruitment sites for the large-setting design. After receiving approximately 60 submissions, 11 institutions were chosen. The selection was based on a number of factors, including patient volume, clinician staffing, and the prevalence and types of mental disorders typically seen in the setting. Among the 11 institutions are four sites that will recruit pediatric and adolescent samples only. They are the New York State Psychiatric Institute at Columbia University Medical Center in New York City; Baystate Medical Center in Springfield, Mass.; Children's Hospital in Aurora, Colo.; and Lucile Packard Children's Hospital at Stanford University in Stanford, Calif.

The remaining seven sites will recruit adult and geriatric participants: the Department of Veterans Affairs in Dallas; University of California, Los Angeles; University of Texas Health Science Center in San Antonio; University of Pennsylvania in Philadelphia; the Mayo Clinic in Rochester, Minn.; the Centre for Addiction and Mental Health in Toronto; and the Menninger Clinic, Baylor College of Medicine, and the DeBakey VA Medical Center in Houston.

Not only do the field-trial sites provide a wide geographical representation for

please see **DSM-5** *on page 31*

David J. Kupfer, M.D., is chair of the *DSM-5* Task Force and a professor of psychiatry at the University of Pittsburgh Medical Center and Western Psychiatric Institute and Clinic.

Active in AMA? Let Us Know!

The AMA House of Delegates is composed primarily of physicians representing specialty organizations and physicians representing state medical societies. The AMA Section Council on Psychiatry continues to work well with the other medical specialty organizations involved in the AMA. It also wants to strengthen its relationship with the state medical societies, which comprise slightly more than half of the House of Delegates. To that end, APA would like to connect with psychiatrists who hold (or have held) leadership positions in their state or county medical society.

If you are a leader in your local or state medical society, or if you know of a psychiatrist colleague who has such involvement, please contact Becky Yowell at BYowell@psych.org or the section council chair, Carolyn Robinowitz, M.D., at carolynrobinowitz@usa.net.

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

Don't Fall Victim to Medicare's Provider Drop Rule

There is a problem with Medicare's Provider Enrollment, Chain, and Ownership System, commonly known as PECOS, which is meant to provide a secure database of Medicare providers. As noted in the May 24 edition of Psychiatric Practice and Managed Care, starting next January Medicare will not pay for orders or referrals by physicians who are not registered in PECOS. (The Centers for Medicare and Medicaid Services [CMS] had moved the compliance date to July 6, 2010, as had been specified by the Affordable Care Act, but then CMS announced the rule would not be enforced until January 2011, as originally planned.) The problem is that even though you may have enrolled in Medicare or opted out since 2003 and were included in PECOS, if you don't file at least one claim every 12 months, you are supposed to be deleted automatically from PECOS, that is, disenrolled from Medicare.

Since CMS enrollment officials recognized that this rule created a serious problem for doctors who opt out of Medicare—the opt-out period is two years at a time—and thus may not file claims then, these doctors are supposed to have a special code attached to their file that keeps them from being kicked out of the system for that period. Each time they opt out, they will be added to PECOS for the two-year opt-out period.

Unfortunately, there is no such protection for doctors who don't see Medicare patients very often but wish to remain Medicare providers. This is the case, for example, for child psychiatrists who on rare occasions may wish to see a Medicare patient or for physicians who don't generally see Medicare patients but wish to continue to see a patient who has aged into Medicare.

Currently doctors who haven't filed any claims for the past year receive no warning when they're about to be disenrolled from Medicare. Instead, they receive an after-the-fact notice from Medicare telling them that they are no longer part of the system, and that if they wish to see Medicare patients, they must file Form 855 and re-enroll. Once they file the 855, they may retroactively file claims going back 30 days from the date an accepted 855 was filed.

What does this mean for you? If you don't re-enroll promptly, you may not get paid for Medicare claims. This is also true for any claims for services you provided before you were deactivated, since the law says that you may file claims that go back only 12 months.

Here's the take-home message: File your claims in a timely manner, and if you get a notice from Medicare, pay attention to it.

Ellen Jaffe of APA's Office of Healthcare Systems and Financing has discussed this issue on several occasions with CMS officials. She was told that CMS is aware that the abrupt dropping of physicians from Medicare is a problem and that CMS is working to develop a way of warning providers so that those who wish to remain in Medicare can take steps to ensure they are not disenrolled. ■

CMS Answers Medicare Queries

The Centers for Medicare and Medicaid Services has a new section on its Web site with answers to frequently asked Medicare questions. This is a valuable resource for times when APA's Managed Care Help Line is not available. Check it out: <http://questions.cms.hhs.gov/app/answers/list>.

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

Still Time to Get 2% Increase For 2010 Medicare Claims

To encourage electronic prescribing (eRx), the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) authorized an incentive program for Medicare providers who use a qualified eRx system when filing claims for 55 specified CPT codes. This program is separate from the ongoing Physician Quality Reporting Initiative, and you don't have to register to participate in it.

Unlike other CMS incentive programs, this one is especially appropriate for psychiatrists. Of the 55 CPT codes that are eligible for the incentive, nine are psychiatry codes, three are health and behavior assessment/intervention codes, and 36 are evaluation and management (E/M) codes. The only other specialty codes included are for ophthalmology.

To qualify for this incentive program, you must use codes in the denominator of the measure (see box at right) for at least 10 percent of your total Part B Medicare claims—this should be no problem for psychiatrists. And you need to report only the eRx measure for a minimum of 25 encounters before December 31 to receive the full 2 percent incentive, which is based on the value of your total Medicare Part B claims for the calendar year.

How It Works

The electronic prescribing system used can be either a stand-alone system that is used only for prescribing or can be part of an electronic health record system.

A qualified eRx system must be capable of doing all of the following:

- Generating a complete active medication list incorporating electronic data received from applicable pharmacies and pharmacy benefit managers, if available.
- Selecting medications, printing prescriptions, electronically transmitting prescriptions, and conducting all alerts (as defined in the next item).
- Providing information related to lower cost and therapeutically appropriate alternatives, if any. (The availability of an eRx system to receive tiered formulary information would meet this requirement.)
- Providing information on formulary or tiered medications, patient eligibility, and authorization requirements received from the patient's drug plan, if available.

If you are using an e-prescribing system that meets these criteria and can electronically prescribe a medication for patients when using any of the eligible CPT codes, just include the code G8553 when you file your claims.

More information on the eRx incentive program is posted at <www.cms.gov/ERXIncentive/>. ■

Codes Eligible for eRx Incentive

90801, 90802, 90804*, 90805, 90806*, 90807, 90808*, 90809, 90862, 92002, 92004, 92012, 92014, 96150*, 96151*, 96152, 99201, 99202, 99203, 99204, 99205,99211, 99212, 99213, 99214, 99215, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99315, 99316, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99345, 99347, 99348, 99349, 99350, G0101, G0108, G0109

* APA has asked the Centers for Medicare and Medicaid Services (CMS) why these codes are included in this incentive, since 90804, 90806, and 90808 denote psychotherapy without E/M (which means there should be no prescribing done when these codes are used) and since codes 96150, 96151, and 96152 are not to be used by physicians. CMS's response will appear in a future issue.

Consultation Coding Update

As most of you are aware, Medicare no longer reimburses for services coded as consultations. It is not that Medicare no longer covers consultations, but that those that have occurred since January 1 must be identified with codes other than the evaluation and management (E/M) codes listed in the AMA's Current Procedural Terminology (CPT) as being for inpatient and outpatient consultations.

APA is working with the AMA and other specialty societies to have CMS either restore the consultation codes or at least provide an equitable way to use other CPT codes that will appropriately reflect the work done in a consultation.

APA's Office of Healthcare Systems and Financing has been monitoring how private insurers are responding to this new Medicare policy. Although some companies are still paying for claims using the consultation codes, several seem to have stopped recently, and it's reasonable to believe that more will follow Medicare's lead over time.

Questions? Call APA's Managed Care Help Line at (800) 343-4671. ■

How to Claim Retroactive 5% Medicare Increase

The health care reform act that became law on March 23 retroactively reinstated the 5 percent increase in Medicare payments for a number of psychotherapy codes (90804-90819 and 90921-90824) that had been in effect in 2008 and 2009. This year, as anyone who bills Medicare is well aware, the fee schedule has been a moving target, with Congress passing corrections for only months at a time to the fee-schedule decreases demanded by the sustainable growth rate formula.

By June 1, all Medicare carriers and contractors should have been paying fees that reflected the 5 percent increase. In July, APA sent a letter to the Medicare medical directors asking them how they were going to handle payment of the 5 percent increase for claims filed before June 1. All of the responses, including one that came on September 13, stated that the Centers for Medicare and Medicaid Services had not released any instructions about issuing payment for the 5 percent owed retroactively for claims filed prior to June.

What this means to psychiatrists who want to recover that money is that they must request claim reopenings for each claim for which they are due the 5 percent. Of course, it's possible that even when a claim is reopened, it may be months before a payment is made.

If you want to reopen a claim, you should check your Medicare contractor's Web site or call its customer service number for information on how to proceed.

If you need additional assistance, contact APA's Managed Care Help Line at (800) 343-4671. ■

Treat today with NAMENDA

Proven efficacy and tolerability

- Improves function, delays onset of behavioral symptoms, and provides benefits in cognition[1-3]
- Proven safety and tolerability with low risk of gastrointestinal side effects may lead to therapy persistence[4,5]
- Reduces caregiving time, cost, and caregiver distress[3,6,7]
- Effective first-line and in combination with an acetylcholinesterase inhibitor[1,2]

Broad patient access–covered on 98% of Medicare Part D formularies[4]

Namenda® memantine HCl

Extending memory and function

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

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

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.

Forest Pharmaceuticals, Inc.

For more details, please visit **www.namenda.com**.

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

62-1014307R R2 03/09

Namenda
memantine HCl ®

Tablets/Oral Solution
Rx Only

Brief Summary of Prescribing Information.

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

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

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

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

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

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

Special Populations
Hepatic Impairment
Namenda undergoes partial hepatic metabolism, with about 48% of administered dose excreted in urine as unchanged drug or as the sum of parent drug and the N-glucuronide conjugate (74%). 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

Passion for Sports Used To Defeat Mental Illness

A psychiatrist who is a two-time badminton champion and a domestic abuse survivor finds that her love of the game can be used to bring about a win-win situation for everyone.

BY EVE BENDER

Photos courtesy of Batool Kazim, M.D.

Batool Kazim, M.D., and Ajit Umrani play their hardest in the mixed doubles quarterfinals in the New York Open Division Badminton Event in June. Kazim began playing badminton as a child growing up in Lahore, Pakistan.

Boston-area psychiatrist Batool Kazim, M.D., has never underestimated the morale-boosting power of a good, clean win by a hometown sports team for its diehard fans. In fact, she has harnessed the power of healthy competition to benefit her own patients with serious mental illness and now would like to do the same for residents of her country of origin, Pakistan.

In her own life, Kazim has fought hard to be a part of sporting competitions in a country where women were not afforded the same opportunities as men, and only through skill and determination has she triumphed.

As a preteen growing up in the 1970s in Lahore, Pakistan, Kazim was searching for her niche—a way to either fit in or distinguish herself from her peers. She ended up doing both in ways she never imagined possible.

Her father played badminton—a popular sport in parts of Europe and the Middle East—and Kazim sometimes played with him and his friends at a club with an indoor court close to their home. The adults found that she excelled at the game. In no time, the 12-year-old was winning school competitions and lugging trophies home from her games. She began playing with her brothers and winning against them, but at age 13 was relegated to play with girls because of the customs of the time.

Not Playing by the Rules

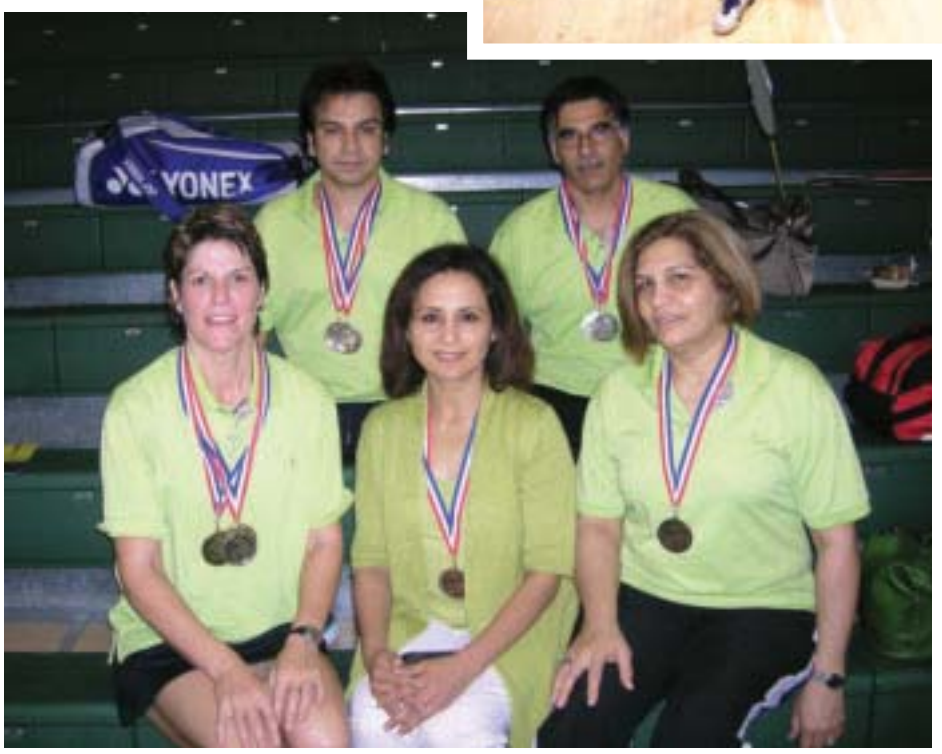
Kazim found that the girls weren't as competitive, and their style of play wasn't as fast paced or aggressive as that of the boys.

To continue to excel at the sport she now loved, she had to subvert the system. "So I cut off my long hair and dressed in my brothers' clothes and started playing with the boys," Kazim told *Psychiatric News* in an interview. For two years, she attended a girl's school during the day, came home, and pretended to be a boy on the badminton court, she said. Her parents offered their support because they also wanted her to excel at the sport.

After winning a tournament held at Punjab University in 1977 against the reigning champion, Kazim won three rounds of badminton and was entered into the quarterfinals at the Pakistan National Tournament, this time playing in the women's singles division. At this tournament, national champion Tariq Wadood was also playing badminton. Kazim was hoping only to get Wadood's autograph that year, but she got something much better—an offer from Wadood's coach to play in the tournament as Wadood's partner, a proposal met with happy surprise by Kazim's family and the starstruck Kazim, now 14 years old. "We played that year and won the finals," Kazim recalled.

From that point on, Kazim played as an amateur until the age of 18, when she entered medical school and had to devote all of her time to her studies. Kazim would not play again for 17 years.

Kazim's original plan was not to go to medical school, but veterinary school, and always told the dogs, cats, tortoises, and birds she owned as a young girl growing up in Lahore that her high marks in science would go a long way toward fulfilling her dreams and ensuring their health and longevity. That plan fell by the wayside as she found that while pursuing her bachelor of medicine and bachelor of surgery degrees at the Allama Iqbal Medical College of Punjab University, she excelled in the care of human patients during her five years of clinical rotations. While Kazim's supervisors encouraged her to specialize in internal medicine or surgery, Kazim was drawn to psychiatry because she found that mental health issues were rarely addressed in routine patient care. She completed a six-month internship in psychiatry and followed it with internships in internal medicine and surgery, all six-months long.



Batool Kazim, M.D. (bottom row, center), returned to the sport of badminton after a long hiatus to play in the U.S. Open Senior International in Los Angeles last July. Members of her team, the "Magnificent Seven," included (clockwise, from top left) Muqueet Rana, Tariq Wadood, Ismat Shikh, Kazim, and Lisa Campbell.

Mission Became Treating the Poor

After completing her internships, Kazim ran a clinic specializing in providing free medical care to women and children in an impoverished section of Lahore. When she found that clinic funding was dwindling, she ran the clinic out of her parents' home and relied on donations to purchase medications for her patients.

In her final year of medical school, Kazim became part of a semi-arranged marriage (that is, the marriage was arranged by their families, but the couple had a say in the matter), and her family grew to include two sons, Syed and Azam, born a year apart. In 1990, she moved to the United States with her husband and children, aged 2 and 3 at the time. They eventually settled close to New York City, where her husband started a neurology residency program and Kazim began a psychiatry internship at Beth Israel Medical Center in July 1995.

Appearances Are Deceiving

Kazim appeared to be thriving during her internship and later as a psychiatry resident at the University of Massachusetts Medical Center, where she eventually earned a position as chief resident. But what none of her fellow residents or supervisors realized was that she was barely surviving at home as a victim of domestic violence. With the help of the legal system, Kazim was able to extricate herself and her two sons from her tumultuous and sometimes violent home life.

In Kazim's case, and in the case of other Muslim women, one of the most "soul-crushing" aspects of domestic abuse is when it is justified through a false interpretation of certain verses in the Quran, she said. "These verses are taken out of context completely" by the abusers, she noted. "Muslims strive to try to emulate the prophet Mohammed, who was the most benevolent, kind, and soft-spoken man."

Speaking out about domestic violence was part of Kazim's recovery—she began lecturing on the topic beginning two years ago to a variety of audiences in this country and abroad "to make this world a bit safer for my 7-year-old daughter, Sarah, and for all the silent women in the world," she said.

She met her current husband, William Cox, Ed.D., eight years ago while working at Westborough State Hospital in Westborough, Mass., where she was an attending psychiatrist. While there, she sought to resolve some of the verbal and physical conflicts between patients on her unit by finding a pingpong table and setting it up in the day hall.

please see ***Passion*** *on page 31*

You Can Assist In Flood Relief

In July, monsoon rains flooded portions of Pakistan, and according to estimates from the United Nations, more than 2,000 people have died, and more than 21 million people have been injured or are homeless.

Batool Kazim, M.D., a psychiatrist originally from Pakistan, told *Psychiatric News* that she has been working with the Pakistan Flood Relief Group to raise awareness of the need to aid flood victims. The relief group has a Web site with information about the damage and the need for clothing, food, and financial resources in Pakistan. Visitors to the site, <www.pakflood.org>, are also welcome to donate money that will go to flood victims.

"The magnitude of the disaster is still unfolding and is unimaginable," Kazim said.

She is also involved with the Pakistan Association of Greater Boston and the Association of Pakistani Physicians of New England, through which physicians have been volunteering their time in Pakistan coordinating relief efforts and treating victims of the flood.

The Web site of the Pakistan Association of Greater Boston is <www.pagb.org>; the Web site for the Association of Pakistani Physicians of New England is <www.appne.net>.

Innovative Funding Strategy Pays Off in California

Using rates of emergency psychiatric treatment as a gauge of effectiveness of a California tax initiative to expand mental health care shows that the effort is bringing benefits to people with mental illness.

BY RICH DALY

A drop in the number of patients treated after suffering a psychiatric crisis since passage of California's 2004 voter initiative to fund expansion of the state's public mental health system suggests that the system's treatment and prevention programs have been effective, according to new research.

California's Mental Health Services Act (MHSA), which established an annual tax on people who make over a million dollars a year and dedicated that revenue to public mental health programs, had distributed about $3.2 billion by Fiscal 2008-2009. That surge in funding appears to have helped expand noninstitutional community-based programs that provide management of serious mental illness and reduced the need for inpatient psychiatric care of people whose conditions have deteriorated due to lack of treatment, according to a study in the October *Psychiatric Services*.

The study, led by Tim Bruckner, Ph.D., an assistant professor in the Public Health Department of the School of Social Ecology at the University of California, Irvine, was based on previous research that used the incidence of involuntary treatment as a gauge of the overall functioning of public mental health systems.

Based on this "canary in the coal mine" approach to assessing the effectiveness of the MHSA, Bruckner and colleagues examined the incidence of 72-hour and 14-day involuntary psychiatric civil commitments and found that the 14-day holds were 10 percent fewer by 2007, three years after the law took effect. The number of 72-hour holds did not fall below expected numbers after disbursement of MHSA funds, however.

The authors concluded that the lower-than-expected number of involuntary 14-day hospitalizations may indicate an important shift toward community-based treatment programs.

"Results indicate that the structure and funding of the MHSA may have provided enhanced resources and diverted clients to less-restrictive treatment settings," Bruckner and his colleagues said.

Psychiatrists Seeing Positive Effect

It's an impact of the law that psychiatrists in the state also say they see.

Robert Cabaj, M.D., medical director of Community Behavioral Health Services in San Francisco's Department of Public Health and chair of APA's Council on Advocacy and Government Relations, told *Psychiatric News* that he agreed that the reduction in two-week emergency hospitalizations may be due to increased availability of community-based services funded by the 2004 law—especially intensive case management.

"I truly believe the added intensive case management in the counties (San Francisco, for example, was able to add more than 400 new intensive case management slots in the effort to 'do what ever is needed') has led to the reduced hospitalizations," Cabaj said. "We have cut our acute inpatient psych beds in San Francisco by more than half, but have had no increase in recidivism or emergency services—an effect I explain solely by the increased access to care and intensive case management."

Roderick Shaner, M.D., medical director of the Los Angeles County Department of Mental Health, told *Psychiatric News* that although follow-up data are required to assess whether the decrease in longer involuntary hospitalization found in the study will be reflected in better mental health outcomes, the study's findings reflect his anecdotal experiences.

"The great majority of California mental health system stakeholders believe that MHSA has had significant positive effects on many aspects of mental health treatment in California," Shaner said. "Most remarkable among these positive effects is a more focused and effective approach toward community reintegration and improved quality of life for individuals with mental illness."

Program Improvements Needed

Shaner noted that questions remain over how to improve the overall effectiveness of the range of programs and planning processes associated with the MHSA, including greater effectiveness for individuals with emergency mental health needs. The need to improve those programs is suggested by the study's finding that there was no decrease in 72-hour emergency hospitalizations.

Among those local programs are new prevention initiatives by counties, including the Early Psychosis Project, which Los Angeles County launched to identify people who are at risk for psychosis due to "destabilized lives." The aim of the project is to prevent or minimize problems, Cabaj noted.

Another looming challenge that could undermine expansions in such local mental illness prevention and treatment efforts is a state budget shortfall of nearly $20 billion. In light of that budget gap, a growing number of legislators have raised the possibility of diverting some MHSA funds to other health programs not related to mental health.

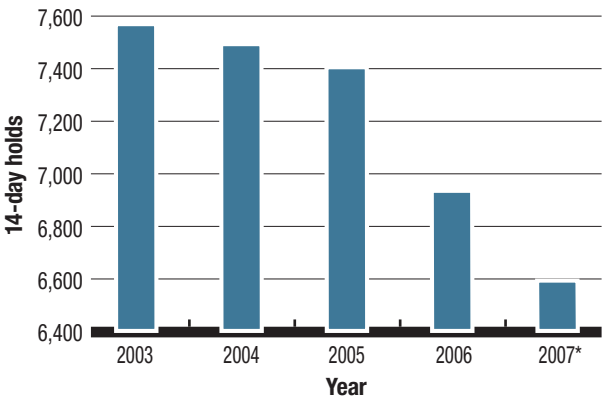
"One argument in support of sustaining MHSA funds would involve demonstrated effectiveness of the counties' improved management and treatment of persons with severe mental illness," noted Bruckner and colleagues.

Supporters of the MHSA funding program have emphasized that it should remain focused on local prevention and treatment programs since they offer far less expensive treatment than do inpatient facilities for patients who lacked such early interventions and have decompensated due to their untreated illnesses.

"Involuntary Civil Commitments After the Implementation of California's Mental Health Services Act" is posted at <http://psychservices.psychiatryonline.org/>. ■

Involuntary Admissions Decline In Wake of 'Millionaire Tax'

Researchers found that since funding from the 2004 millionaire tax has begun to be distributed to county mental health programs, involuntary emergency inpatient admissions to psychiatric hospitals have dropped 10 percent below their expected levels. The study authors, whose annual data were averaged and rounded below, credit increasing access to expanded local prevention and treatment programs as spending from the tax revenue has increased.



*2007 data include only the first half of the year.

Source: Tim Bruckner, Ph.D., et al., *Psychiatric Services*, October 2010

Are You Ready to Help Patients Assess Medicare Options?

Psychiatrists treating Medicare patients should be prepared for their questions about plan selection for 2011.

BY MARK MORAN

Open enrollment for Medicare begins November 15, and patients may be requesting clinicians' advice in making choices.

Each year Medicare Advantage plans (the program in which beneficiaries receive coverage through Medicare-approved managed care companies) change what they charge and what they cover. Individuals can select a new health plan for their 2011 coverage and can add, drop, or change their prescription drug coverage. Enrollees in original Medicare can also choose to switch to Medicare Advantage.

Open enrollment ends December 31.

Enrollees in Medicare health plans or the Part D prescription drug program who are satisfied with their coverage do not need to do anything.

Approximately 5 percent of beneficiaries enrolled in Medicare Advantage and prescription drug plans must choose a new health plan or else choose original Medicare because their current plan is not renewing its contract with Medicare in 2011.

Most of these "nonrenewals" occur because private fee-for-service plans made business decisions to leave Medicare in certain areas of the country. Beneficiaries should be notified of nonrenewal before the end of this month.

Enrollees in nonrenewing health plans who do not enroll in another health plan will receive medical coverage under original Medicare. However, individuals in Part D prescription drug plans that do not renew must reenroll in another Part D plan to continue to receive drug coverage, according to the Centers for Medicare and Medicaid Services (CMS).

(An exception is made for beneficiaries eligible for the Part D low-income subsidy; they will automatically be enrolled in a zero-premium drug plan if they do not select a plan.)

CMS is encouraging beneficiaries enrolled in Medicare Advantage and Medicare prescription drug plans to review their current health and drug plan coverage for any changes their plans may be making for 2011 before the annual enrollment period begins.

In a statement released at the end of September, CMS said the majority of Medicare beneficiaries enrolled in Medicare health and prescription drug plans this year should find little or no change in benefits in 2011 but will see more drug plans offering coverage in the prescription drug coverage gap.

CMS also said that premiums for individuals enrolled in Medicare Advantage plans will be 1 percent lower on average in 2011 than this year, while enrollment in Medicare Advantage is expected to increase by 5 percent.

"Despite the claims of some, Medicare Advantage remains strong and a robust option for millions of seniors who choose to enroll or stay in a participating plan today and in the future," said CMS Administrator Donald Berwick, M.D., in a statement.

CMS noted that the new health care reform law provides some new benefits to Medicare beneficiaries in 2011, including free wellness visits, some new free health screenings, and a 50 percent discount on brand-name drugs for seniors who fall into the coverage gap.

More information on Medicare plans and open enrollment is posted at <www.cms.gov/center/openenrollment.asp>. The Medicare Plan Finder is posted at <www.medicare.gov/find-a-plan/questions/home.aspx>. ■

Major Funding Commitment Helps Kendra's Law Succeed

New York's effort to fund outpatient civil commitment programs appears to have expanded treatment for people ordered to receive mental health care without reducing services in other parts of the public mental health system.

BY RICH DALY

New York state's aggressive funding of its outpatient civil-commitment program since it was launched in 1999 sets the state apart from the level-funding approach most other states have used when launching similar initiatives.

New research indicates that the generous funding has led to expanded treatment for people with mental illness in the criminal justice system, without reducing treatment availability in other parts of the state's public mental health system, as critics feared would occur.

Results of an examination of New York state's assisted outpatient treatment (AOT) program, published in the October *Psychiatric Services*, found that the program did not disadvantage voluntary mental health treatment recipients by focusing resources on patients ordered to treatment by the courts.

The study authors, led by Jeffrey Swanson, Ph.D., of the Psychiatry and Behavioral Sciences Department at Duke University School of Medicine, examined state administrative data from 1999 through 2007 to gauge the impact of the law, known as Kendra's Law. It allows court-ordered AOT for people with severe mental illness who have been noncompliant with treatment and as a result have been arrested or hospitalized.

After comparing trends in the use of enhanced outpatient services by both involuntary and voluntary treatment recipients with severe mental illness, the researchers found that most of the new $125 million in funding that the state initially allocated went to people under court-ordered treatment. However, treatment provided to both involuntary and voluntary patients "expanded steadily."

"In the short run, services to individuals who were not under AOT may have been delayed, or some individuals may have been displaced from services by the influx of new court-ordered persons in the system of care," said Swanson and colleagues. "However, the findings of this study suggest that in the long run AOT is a program that came bearing new services and has left in its wake a system of care with greater capacity to serve all persons with serious mental illness, voluntary patients no less than involuntary ones."

It's a finding that New York psychiatrists who have worked with the AOT program endorse.

"For the people it serves, [AOT] does a very good job," said Steven Hoge, M.D., former director of the Division of Forensic Psychiatry at Bellevue Hospital at New York University School of Medicine.

Additionally, Hoge told *Psychiatric News* that "protected funding has been very useful" in maintaining robust AOT programs. In fact, he added, at least three times as many people with severe mental illness in New York also could benefit from the program if funding were expanded further.

Gary Collins, M.D., director of the NYU/Bellevue Hospital Center AOT Program, told *Psychiatric News* that he has seen similarly beneficial clinical outcomes.

However, Collins cautioned that research has yet to demonstrate a causal relationship between AOT and the clinical outcomes, and more comprehensive research on the New York AOT program is needed.

Hoge agreed that some data offered by the state on the long-term efficacy of the program are limited, because the state compared one-year pre-AOT patient outcomes with their outcomes for only the first six months after leaving AOT. Other research has indicated that clinical outcomes—other than propensities for violence—begin to deteriorate to their pre-AOT levels more than a year after leaving an AOT program.

The positive violence-prevention-related results from the AOT program led the New York legislature to approve a five-year extension of the program this past summer after mental health advocates campaigned for the program's renewal (*Psychiatric News*, June 4).

"A majority of states that have court-mandated outpatient treatment programs legislated them but did not adequately fund them, and subsequently [they] are very highly underutilized," Collins said. So New York's decision to provide substantial funding for its program "has been one of the reasons that there has been significantly higher enrollment in New York state's AOT program."

Similar AOT programs in other states have struggled because of a lack of additional funding, including a law to expand outpatient civil commitment in New Jersey that Gov. Chris Christie (R) put on

please see ***Funding*** *on page 29*

Cymbalta® DELAYED RELEASE
duloxetine HCl CAPSULES

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.

Every Day, I wonder if my depression is improving.

Or if it ever will.

We created Every Day Connections for patients who feel like this. Ask your Cymbalta representative or visit cymbalta.com to learn about the **Touchpoints Patient Support program** from Lilly.

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 CAPSULES
duloxetine HCl

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.

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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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Obesity and Eating Disorders: Are They Close Relatives?

Research on obesity and eating disorders is converging. Among other findings, studies indicate that brain circuits involved in reward or pleasure may also be involved in obesity and eating disorders.

BY JOAN AREHART-TREICHEL

Although obesity and eating-disorders research tend to be separate fields, the two are now converging in an intriguing manner. They're showing that some of the same peptide hormones are involved in both conditions.

The hormones, discovered about 15 years ago, are leptin, ghrelin, and the endocannabinoids. They have a substantial impact on people's appetite, energy metabolism, and food intake. All act on the hypothalamus. Leptin decreases food intake; ghrelin and the endocannabinoids increase it.

Obese people have been found to have an abnormally high level of leptin in their bloodstream. They are resistant to the effects of leptin in much the same way that people with type 2 diabetes are resistant to the effects of insulin. Individuals with anorexia nervosa or with bulimia nervosa have been found to have abnormally low concentrations in their bloodstream.

Ghrelin levels have been found to be abnormally high in the bloodstream of individuals with anorexia; they have been found to be abnormally low in the bloodstream of individuals with bulimia or binge-eating disorder.

Biology Can Trump Willpower

Such discoveries have some important implications, Walter Kaye, M..D., a professor of psychiatry at the University of California, San Diego, and an anorexia researcher, explained during a recent interview. "They demonstrate that there is powerful biology underlying obesity and eating disorders, that it's not just a matter of willpower."

Michael Schwartz, M.D., a professor of medicine at the University of Washington and an obesity researcher, agreed: "Most people had argued that obesity is a disorder primarily of willpower. These data suggest that there is an underlying biological problem directly involved in obesity."

But at the same time, it's not just these hormones that dictate food consumption in obesity and eating disorders, scientists are finding. The brain does too.

For instance, Kaye found that when subjects with anorexia and healthy control subjects were offered a tasty treat, the insula—a brain region that processes gestation and links it to reward—responded less in the anorexia subjects than in the controls.

Cary Savage, Ph.D., an obesity researcher at the University of Kansas, showed pictures of snacks to obese and healthy-weight subjects. The anterior cingulate cortex was activated considerably more in the former than in the latter. This brain region has also been implicated in activities other than eating that some people may find rewarding—alcohol dependence, cocaine dependence, and pathological gambling. "These findings of increased activity in reward centers of the brain are consistent with other data indicating that obese individuals make food choices and consume more based on the hedonic aspects of eating," Savage told *Psychiatric News*.

Several neuroimaging studies have also demonstrated abnormal activation of the anterior cingulate cortex in subjects with bulimia.

Yet Many Questions Remain

Yet many questions about the roles of leptin, ghrelin, and the endocannabinoids in obesity and eating disorders press for answers. For example, leptin is reduced in people with anorexia as long as they are malnourished, but the levels rise as they recover from their illness. Does this finding mean that leptin levels do not contribute to anorexia, but result from malnutrition? Several variants in the ghrelin gene have been linked with binge-eating disorder. Does this finding mean that the gene variants promote binge eating? Researchers said that it is unlikely that binge eating would lead to the gene variants.

Regardless of whether these hormones contribute to obesity and eating disorders or are affected by them, do they act alone or in concert? The situation is more complicated than scientists originally thought, Rene Klinkby Stoving, M.D., Ph.D., told *Psychiatric News*. He is an associate professor of endocrinology at Odense University in Denmark and has studied these hormones and their functions.

Kaye concurred with that observation, explaining that "there are a number of different neuropeptides, not just leptin, ghrelin, and the endocannabinoids, that signal something about energy metabolism in the body to the brain. Furthermore, they seem to interact with each other and even show some redundancy. That is, there are many energy signals, and maybe you can affect one of them, but then others seem to take up the slack."

And once leptin, ghrelin, or the endocannabinoids signal the hypothalamus, what happens then? Is that the point where higher-order areas of the brain ignore the hormones' signals and nudge a person into overeating or undereating? Very possibly. Or perhaps the nudging comes later. In any event, it is the brain, not the hormones, that influence the overeating or under-eating decisions.

For as Schwartz explained, "The system that leptin, ghrelin, and the endocannabinoids are acting on is designed to promote stability in body mass. But sometimes an emotional or psychiatric problem can be so severe as to override the ability of that homeostatic system to compensate. One example in my view is anorexia nervosa. It overwhelms the normal response to weight loss. If healthy people lost as much weight as is typical in a patient with anorexia nervosa, you would have changes in leptin and ghrelin that would potentially activate the drive to eat and induce other metabolic responses that favor the recovery of lost weight."

"Circuits that play a key role in reward or pleasure in the brain may be where the pathology in anorexia and bulimia, and in obesity, ultimately lies," Kaye speculated. ■

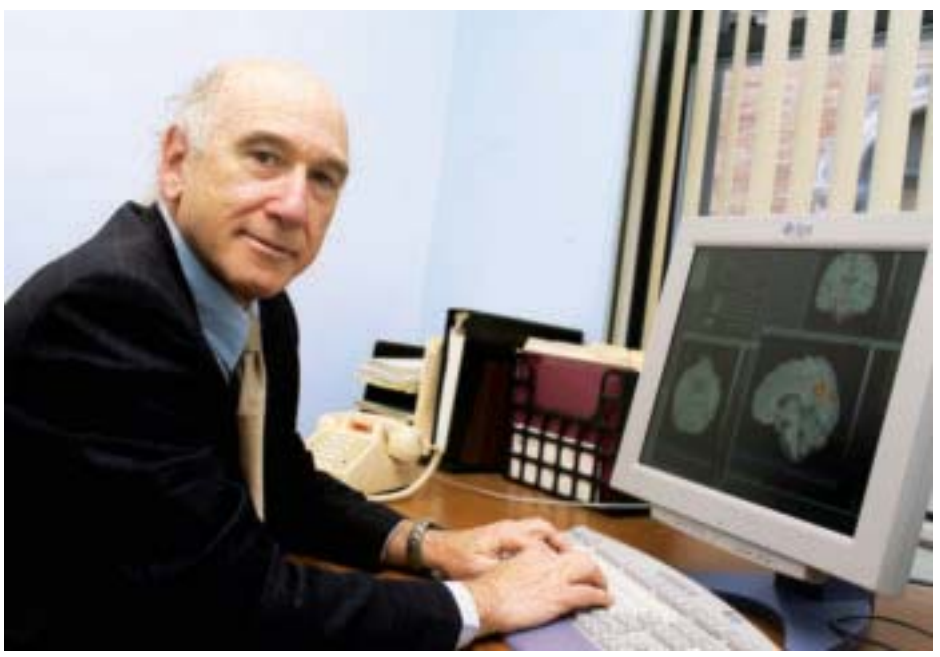


Photo courtesy of the University of Pittsburgh Medical Center

Walter Kaye, M.D.: "There are a number of different neuropeptides, not just leptin, ghrelin, and the endocannabinoids, that signal something about energy metabolism in the body to the brain."

Peptides May Be Treatment Targets

The finding that the peptide hormones leptin, ghrelin, and the endocannabinoids are implicated in obesity and eating disorders (see accompanying article) is prompting some scientists to study whether these hormones, or compounds that act on them, might constitute effective new treatments for these conditions.

For example, researchers at Albany (N.Y.) Medical College discovered that injecting small fragments of leptin into subjects could control appetite, blood glucose levels, and weight gain. The drug can now be administered orally, using technology developed by Aegis Therapeutics. "The combination of Albany's highly effective peptide with Aegis' noninvasive…peptide delivery technology promises to lead to the first orally active peptide anti-obesity and diabetes drug," Edward Maggio, Ph.D., CEO of Aegis Therapeutics, reported at the annual meeting of the Endocrine Society in San Diego in June.

Rene Klinkby Stoving, M.D., Ph.D., an associate professor of endocrinology at Odense University in Denmark, and colleagues are conducting a pilot study to see whether an endocannabinoid receptor agonist, dronabinal, can increase weight and subdue motor restlessness in subjects with anorexia nervosa. The study is being funded by the U.S. National Institutes of Health.

However, no panaceas can be expected from such research.

One reason is that after leptin was discovered, there was great hope that administering it as a drug would be a treatment for obesity. It did lead to weight loss in obese people for a while, but eventually ceased to do so as they developed resistance to it.

Another reason concerns the endocannabinoid receptor antagonist rimonabant. It was approved by the European Union's regulatory agency in 2006 as an obesity treatment. Although it leads to modest weight loss, it can also cause some troublesome side effects, notably anxiety and depression.

Credit: © 1995 Amgen Inc.

An obese mouse lacking the leptin gene and leptin can be seen next to a normal littermate.

APA Voting Moving To Online Only

Is Your Correct E-Mail Address on File? Note December 1 deadline.

APA's national elections are transitioning to an all-electronic process with a fast, easy, and secure means to vote online. Online voter participation has steadily increased, reaching a rate of 50 percent in APA's last election, and shows promise of continued growth. Beginning with the 2011 election, all eligible voting members with a valid e-mail address on file will receive only an electronic ballot.

To ensure you get your electronic ballot, please update your contact information in Members Corner on APA's Web site at <https://myaccount.psych.org/MembershipProfileUpdate/tabid/163/Default.aspx> by December 1. E-mails from APA will include a link to personalized electronic ballots, voting instructions, and candidate information.

Voting members without a valid e-mail address on file will still be sent a paper ballot for the 2011 election. APA members with questions or comments may e-mail them to election@psych.org.

Neonatal Vitamin D Levels Linked to Schizophrenia Risk

The relationship between vitamin D and schizophrenia is likely to represent underlying genetic predispositions requiring gene-by-environment studies to elucidate.

BY MARK MORAN

Both low and high concentrations of neonatal vitamin D were associated with increased risk of schizophrenia in an individually matched case-control study of a large Danish birth cohort.

Neonates with concentrations of 25 hydroxyvitamin D3 in the three lowest quintiles—as measured in dried neonatal blood samples—had a significantly increased risk of schizophrenia compared with those in the fourth quintile. Surprisingly, neonates in the fifth or highest quintile also had a significantly increased risk, according to a report in the September *Archives of General Psychiatry*.

Lead author John McGrath, M.D., of the Department of Psychiatry at the University of Queensland, Australia, and colleagues said that the association between high concentrations of vitamin D and schizophrenia is surprising, but not without precedent: similar nonlinear U-shaped relationships (in which high and low concentrations are more significantly associated with an outcome than concentrations in the middle range) have been found between vitamin D and neonatal growth outcomes, and in some adult studies between vitamin D and cancer and cardiovascular disease.

"The chance to prevent a serious disorder like schizophrenia via simple, safe, and cheap nutritional supplements is a scenario that has not previously seemed plausible."

The authors urged caution in the interpretation of the result, saying the U-shaped relationship could reflect underlying genetic predispositions requiring gene-by-environment studies to elucidate.

However, severely low concentrations of vitamin D have been associated with a range of disorders, including neurologic and neuropsychiatric disorders, and the current study strongly underscores the possibility of its involvement in some cases of schizophrenia, they suggested.

"Of particular interest to the hypothesis linking vitamin D deficiency and schizophrenia, the enzyme required for the production of [vitamin D] has now been identified in the human brain, and there is evidence from rodent models demonstrating that transient prenatal vitamin D deficiency results in persistent changes in adult brain structure, neurochemistry, and behavior," the authors wrote.

In the study, 424 individuals with schizophrenia and 424 controls matched for sex and date of birth were compared for concentrations of neonatal vitamin D using measurements taken from dried neonatal blood samples. These dried blood spots have been systematically collected from individuals born in Denmark since May 1, 1981, and stored in the Danish Newborn Screening Biobank.

(In a study published in May this year in *Paediatric Perinatal Epidemiology* titled "The Utility of Neonatal Dried Blood Spots for the Assessment of Neonatal Vitamin D Status," McGrath and colleagues showed that dried neonatal blood spot levels of vitamin D are significantly related to mothers' levels and to infant cord blood.)

Vitamin D concentrations were grouped within five quintiles: less than 19.7 nonmoles per liter (nmol/L), 19.7 to 30.9 nmol/L, 31.0 to 40.4 nmol/L, 40.5 to 50.9 nmol/L, and 51 nmol/L or greater.

Compared with neonates in the fourth quintile (between 40.5 and 50.9 nmol/L), those in each of the lower three quintiles had a twofold elevated risk of schizophrenia. Those in the highest quintile also had a significantly increased risk, a little less than twofold.

McGrath told *Psychiatric News* that vitamin D levels in the study are treated as a continuous variable and that while lower neonatal levels were found associated with higher risk for disease, it is only one of many factors influencing progression to schizophrenia. "Of course, schizophrenia is a heterogenous disease, and no one in the field believes that any one factor can explain all schizophrenia," he said.

But in the *Archives* report, McGrath and colleagues noted that schizophrenia is associated with a substantial burden of disability and that in the absence of major advances in the efficacy of treatments, interventions that offer the prospect of reducing the incidence of the disorder should be pursued vigorously. "It is acknowledged that there is an urgent need to undertake more research that focuses on the environmental risk factors and gene [by] environmental associations with schizophrenia," they said.

"Mindful of these issues, we note that hypovitaminosis D is prevalent in many societies and is a particular concern in pregnant and lactating women. From a public-health perspective, the chance to prevent a serious disorder like schizophrenia via simple, safe, and cheap nutritional supplements is a scenario that has not previously seemed plausible.

"While there is much more work to be done, if future studies confirm the association between developmental vitamin D deficiency and risk of schizophrenia, it raises the tantalizing prospect of the primary prevention of this disabling group of brain disorders in a manner comparable with folate supplementation and the prevention of spina bifida."

An abstract of "Neonatal Vitamin D Status and Risk of Schizophrenia: A Population-Based Case-Control Study" is posted at <http://archpsyc.ama-assn.org/cgi/content/abstract/67/9/889>. ■

Data Show Reason for Concern If Mothers Carry Herpes Virus

A possible link between herpes simplex virus 2 and schizophrenia becomes clearer as the result of a study using a large national birth cohort and a central psychiatric register to shed light on the hypothesis.

BY AARON LEVIN

A large case-control study based on Danish birth and psychiatric records has added more evidence to back the theory that an association exists between mothers' infection with herpes simplex virus 2 (HSV-2) and the risk of schizophrenia in their children.

The results were unaffected by adjustment for place of birth, parental age, or immigrant status, wrote Preben Mortensen, M.D., and colleagues in the September *Schizophrenia Research*. Mortensen is a professor and director of the National Centre for Register-Based Research at the University of Aarhus in Denmark.

The study confirms a similar association published in 2008 by Stephen Buka, M.D., and others, but there have been several other reports on this potential relationship that have produced equivocal results. The prior studies were limited by small sample sizes, limited statistical power, and lack of data on some confounders, Mortensen noted.

The new research is based on 602 cases of schizophrenia among 1.5 million children born in Denmark from 1981 to 1994 and an equal number of controls matched for gender and exact date of birth. None of the controls had a history of schizophrenia at the time the evaluation was conducted.

Blood was drawn from newborns within a week of birth, but the antibodies reflected the mothers' exposure to infection, said the authors. "Maternal [immunoglobin G] is transferred across the placenta, and the child has not produced any specific amount of IgG at the age when the blood sample was taken."

About 24 percent of the blood samples from schizophrenia cases had HSV-2 antibodies above the cutoff levels for seropositivity, compared with 17 percent of the samples from the matched controls, an incidence-rate ratio of 1.56.

Maternal HSV-2 May Be Risk Factor For Childhood Schizophrenia

Maternal herpes simplex virus (HSV-2) infection is associated with higher incidence-rate ratios of schizophrenia in offspring. Data were controlled for age, sex, and date of birth. (Cut-off = 0.101 optical density units, using the maximum likelihood interference method.)

Exposure	Cases (N=602)	Controls (N=602)	Incidence-rate ratio (95% confidence interval)
HSV-2 seropositivity	147 (24.4%)	103 (17.1%)	1.56 (1.17–2.07), p=0.002
HSV-2 seronegativity	455 (75.6%)	499 (82.9%)	1.00 Reference

Source: Preben Mortensen, M.D., et al., *Schizophrenia Research*, September 2010

Parental age, parents' immigrant status, maternal mental illness history, and whether the child was born in an urban area had no effect on the association between HSV-2 antibodies and schizophrenia.

The researchers did, however, note a trend toward greater schizophrenia risk among children born before 36 weeks of gestation, but absolute numbers were so small (seven cases and two controls) that gestational age had no statistically significant effect on the association.

The study was supported by a grant from the Stanley Medical Research Institute.

A second study, published in the September *Archives of General Psychiatry* by Danish, British, and American researchers (including Mortensen) and based on Danish and Swedish birth cohorts, suggested that as birth weight declined, risk for any psychiatric diagnosis increased. A similar pattern held true regarding schizophrenia for birth weights below 3,000 grams.

In Mortensen and colleagues' study of HSV-2 exposure, adjusting for parental history of mental illness reduced that ratio somewhat, but the effect was largely due to the father's mental illness history, said the authors. Of the 147 seropositive cases in that study, 34 fathers were diagnosed with mental illness, but 23 had diagnoses outside of the schizophrenia spectrum.

"If the association was due only to genetic stratification, it should be equally confounded by maternal mental illness," they wrote.

However, there may be a path other than genetics through which the mothers contributed to schizophrenia risk, the researchers suggested. Risk for HSV-2 seropositivity is increased by early initiation of sexual activity, having more sexual partners, low socioeconomic status, and a history of other sexually transmitted diseases.

An abstract of "A Danish National Birth Cohort Study of Maternal HSV-2 Antibodies as a Risk Factor for Schizophrenia in Their Offspring" is posted at <www.schres-journal.com/article/S0920-9964(10)01365-4/abstract>. An abstract of "Birth Weight, Schizophrenia, and Adult Mental Disorder: Is Risk Confined to the Smallest Babies" is posted at <http://archpsyc.ama-assn.org/cgi/content/abstract/67/9/923>. ■

Teens' Ethnicity Could Hone Substance-Use Interventions

Clinicians and policymakers could help reduce substance abuse among adolescents by focusing on the differing factors that are more likely to contribute to such behavior among youth from various ethnic backgrounds.

BY RICH DALY

Newly identified links between adolescent substance use and factors in their ethnic backgrounds may provide valuable tools that if incorporated into prevention programs could help youngsters avoid substance abuse problems.

Previous research has identified significant racial and ethnic differences in adolescents' use of cigarettes, alcohol, and marijuana. A new study examined whether specific outside factors were more likely to influence substance use problems for youth from certain ethnic backgrounds.

As it turns out, not only are adolescents from some ethnic groups more likely to use certain substances, but that use may be mitigated by environmental influences from family members, schools, and the teens' individual outlooks, according to a study funded by the Rand Corporation and published in the September *Journal of Studies on Alcohol and Drugs*.

Regina Shih, Ph.D., an associate behavioral and social scientist at Rand, and her colleagues surveyed an ethnically diverse group of about 5,500 seventh and eighth graders in 16 Southern California middle schools about their alcohol, tobacco, and marijuana use and evaluated the extent to which individual, family, and school factors affected the various racial and ethnic differences in use of the substances. Researchers obtained parental consent for the students who were included in the survey. Spanish-speaking staff were available at each survey administration, and survey booklets were available in Spanish and Korean.

Overall, the survey respondents had rates of lifetime and past-month substance use that were comparable to those found by previous national surveys. For example, 29.2 percent of eighth graders surveyed reported alcohol use at some point in their lives, compared with the 28.8 percent lifetime alcohol use found among eighth graders nationally by the 2007 National Survey on Drug Use and Health administered by the Substance Abuse and Mental Health Services Administration.

The study found that after adjusting for gender, grade, and family structure, however, Hispanics reported higher and Asians reported lower lifetime and past-month use of the three substances about which the researchers asked, compared with non-Hispanic Caucasians. Rates of substance use did not differ between non-Hispanic African Americans and Caucasians.

Specific factors were associated with lower likelihood of substance use among different ethnic groups of adolescents, including Hispanic youth's lower reported ability to resist peer pressure and less fear that substance use is accompanied by unwanted consequences. In contrast, substance use by Hispanic youth was much less affected by family or school factors than was the case among other ethnic groups surveyed.

A different array of factors affected substance use by Asian children. They were much less likely to use alcohol if they had certain perspectives that the researchers asked about. For example, if they confirmed that they had strong respect for their parents and if they did not witness heavy alcohol use by parents or any alcohol use by older siblings, then the respondents were less likely to use alcohol.

Asian survey respondents' perceptions that their peers and others at their school drank alcohol correlated with a higher likelihood that they would drink.

The ethnic-group-specific findings could help improve the efficacy of substance abuse prevention programs, the authors suggested. For instance, "interventions that aim to provide a more realistic estimation of perceived peer use may be particularly salient to reduce substance use in younger Asian adolescents," Shih and her colleagues said in their report.

Sandra Walker, M.D., chair of APA's Council on Minority Mental Health and Health Disparities, agreed that the findings could help to better inform clinicians about ways to approach young patients from differing ethnic backgrounds.

"From the perspective of clinical usefulness, I think that it is worthy to try to identify motivational factors that may deter substance abuse in youth prior to their establishing patterns of substance use," Walker told *Psychiatric News*. "This study does seem to suggest that different educational approaches might be emphasized, depending on the group one targets."

Ray Hsiao, M.D., codirector of the Adolescent Substance Abuse Program at Seattle Children's Hospital, noted that the new study is consistent with previous ethnic-specific findings in adults and is a good addition to the limited literature on adolescents.

"It may be helpful for the general clinician who works with various ethnic populations to understand the difference in prevalence and need for screening," Hsiao told *Psychiatric News*.

The new research is "important," said Elinore McCance-Katz, M.D., Ph.D., because it includes a large sample size and focuses on the initial substances that young people begin using. She is a professor of psychiatry at the University of California, San Francisco, and state medical director of the California Department of Alcohol and Drug Programs.

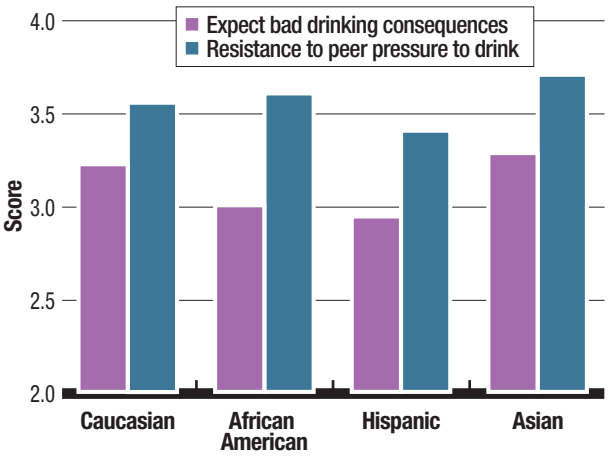
"What I took from this article was that there are specific, modifiable factors—for example, resistance, self-efficacy, and positive and negative expectancies—that appear to be related to substance use," McCance-Katz told *Psychiatric News*.

The findings can help clinicians and the developers of prevention interventions to

please see ***Ethnicity*** *on page 28*

Ethnic Factors Impact Alcohol Use in Youth

Differing factors appear to carry more weight in preventing substance use among adolescents from certain ethnic groups. For instance, Asian children are less likely to use alcohol because they are more apt to expect bad outcomes from it, while higher use in Hispanic youth may be linked to the larger influence that peer pressure has on them.



Source: Regina Shih, Ph.D., et al., *Journal of Studies on Alcohol and Drugs*, September 2010

FDA Reviews Use of Controversial Clinical Trials Design

BY TAMMIE LEE DEMLER

A report released by the Government Accountability Office (GAO) in August regarding the Food and Drug Administration's (FDA) oversight of new drug applications concluded that the "FDA has limited the indications" for which a certain type of clinical trial known as "an inferiority trial" can be used.

The GAO report was issued in response to a request from Congress, which makes policy and funding decisions based on information provided in these reports.

Noninferiority trials are intended to determine that the effect of a new drug is not worse than that of an approved (reference) treatment. Most clinical trials, in contrast, are set up to demonstrate that one intervention (that is, drug treatment) is superior to another.

The noninferiority design is based on the difference, if any, between the effectiveness of a new drug and an approved active control. Such trials may be useful particularly when a placebo group cannot be included (for example, for ethical reasons) or when there appears to be some other advantage in contrast to the standard approved treatment (for example, fewer side effects, lower cost), but the results of noninferiority trials are not seen as credible as those measuring superiority.

Noninferiority trials are subject to inconsistent design and interpretation and provide only estimates of the effectiveness of the new drugs. Minor differences, falling within a predetermined acceptable margin, allow the new drug to be considered at least as effective as the control. Generations of noninferiority trials may result in an unintended outcome of "biocreep," whereby successively approved new drugs become no more effective than placebo based on comparisons of sequentially less-effective controls.

The clinically acceptable noninferiority margin used for the majority of approved new drug applications (NDAs) reviewed for the report ranged from 5 percent to 20 percent, with 10 percent being the most commonly used.

The GAO examined only new molecular entities, excluding over-the-counter medications and agents used for diagnosis and those aiding absorption of other drugs. Of the 175 NDAs submitted between 2002 and 2009, 43 (25 percent) included evidence collected by noninferiority trials. The GAO noted that "many of these applications were for antimicrobial drugs, such as those treating bacteria, viral, and fungal infections."

Of the 43 noninferiority-supported NDAs submitted, only 18 were approved, and 11 of the remaining NDAs were approved using other information to support approval. There was only one psychiatric medication for which an NDA was submitted on the basis of primary evidence from noninferiority trials. The FDA advised the potential sponsor that it "did not consider it appropriate to use noninferiority trials to support the approval of the drug for the indication being sought—the treatment of schizophrenia."

The FDA released a draft guidance in March that included recommendations on how to select an active control in noninferiority trials, how to evaluate the results, and how to set the noninferiority margin (the absolute maximum threshold of clinical allowable difference in effectiveness from control versus that of the NDA).

The GAO examined the FDA review of the characteristics of the trials and reaffirmed that the FDA had minimized the potential for biocreep and that the new drugs were more effective than a placebo.

The GAO reported that the experts who reviewed the FDA guidance statement expressed that there should be more emphasis on the use of noninferiority trials as a means of last resort when seeking approval for new drugs. Advocates of the noninferiority study design promote the benefit of bringing new drugs to market without the ethical issues of placebo comparisons.

Highlights of the report, "FDA's Consideration of Evidence From Certain Clinical Trials," are posted at <www.gao.gov/highlights/d10798high.pdf>. ■

Treat your patients with the demonstrated efficacy of LEXAPRO[1-5]

In adolescents aged 12 to 17 with Major Depressive Disorder (MDD)[1]

In adults with MDD and Generalized Anxiety Disorder (GAD)[1]

Lexapro® escitalopram oxalate

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Lexapro or any other antidepressant in a child, adolescent or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients less than 12 years of age.

Please see additional Important Safety Information on following pages.

There is no generic available for LEXAPRO

- Significantly improved MDD symptoms in adolescents[2]

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

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

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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St. Louis, MO 63045 USA
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Rev. 05/09

COMPILED BY MARK MORAN

Regulatory Briefs

• Alkermes Inc. announced in September that the U.S. Food and Drug Administration (FDA) Psychopharmacologic Drugs Advisory Committee voted 12-1 that ***Vivitrol (naltrexone for extended-release injectable suspension)*** should be approved for the treatment of opioid dependence. Though not binding, the advisory committee's recommendation will be considered in the FDA review of the supplemental new drug application submitted by Alkermes.

"The advisory committee meeting outcome underscores the strength of the clinical data for Vivitrol and the need for new treatment options," said Richard Pops, chief executive officer of Alkermes, in a statement. "We believe that, if approved, Vivitrol would offer a new path to recovery as the first nonaddictive, once-monthly medication for patients with opioid dependence."

• In September, the FDA issued a safety labeling change for ***Risperdal (risperidone) tablets***, ***Risperdal oral solution***, and ***Risperdal M-Tab oral disintegrating tablets.*** The labeling change is an added warning that priapism has been reported during postmarket surveillance of the medications. Adverse reactions, based on postmarketing experience, now include priapism, hypothermia, sleep apnea syndrome, urinary retention, diabetes mellitus, and hypoglycemia.

The FDA also issued a labeling change for ***Risperdal Consta (risperidone) long-acting injection*** to indicate that adverse reactions observed during premarket evaluation of the drug include abdominal pain, upper respiratory tract infection, presence of glucose in urine, initial insomnia, delayed ejaculation, and pruritus. Adverse reactions observed in postmarketing experience include urinary retention, diabetes mellitus, and hypoglycemia.

Details of the labeling changes are posted at <www.fda.gov/Safety/MedWatch/SafetyInformation/ucm225299.htm>.

• In September the FDA accepted for review a new drug application for the ***Aricept Patch (donepezil transdermal system)*** for treatment of Alzheimer's disease. The application was submitted to the FDA by Eisai Inc. on June 30.

Industry Briefs

• The FDA announced in September that Forest Pharmaceuticals Inc. entered into a plea agreement in which the company accepted responsibility for criminal actions including distribution of an unapproved new drug, distribution of a misbranded drug, and obstruction of an FDA inspection. Forest has agreed to pay more than $300 million, including $164 million in criminal penalties. The plea agreement is the culmination of a multiyear investigation conducted by the FDA's Office of Criminal Investigations in cooperation with its law-enforcement partners and the U.S. Attorney's Office for the District of Massachusetts, according to the FDA.

Charges against Forest are primarily for its marketing and distribution of ***Levothroid (levothyroxine sodium tablets)*** for treatment of hypothyroidism in the 1990s. At the time, the drug was considered a "new drug" within the meaning of the Federal Food Drug and Cosmetic Act, and manufacturers were required to obtain approved applications from the FDA by August 2000. Forest Pharmaceuticals did not obtain drug approval and ignored a subsequent warning letter to stop manufacture and distribution of the drug, according to the FDA.

But the company also is charged with distribution of a misbranded drug because of the company's off-label promotion of ***Celexa (citalopram)*** for pediatric use when it was approved only for use in adults. Celexa is a selective serotonin reuptake inhibitor for the treatment of adult depression.

Research Briefs

• Vanda Pharmaceuticals Inc. announced in September that it has initiated a phase 3 clinical trial to evaluate ***tasimelteon*** in patients with non-24-hour sleep-wake disorder, a condition experienced primarily by totally blind individuals that results in abnormal night sleep patterns and chronic daytime sleepiness. Tasimelteon binds to high-affinity melatonin receptors located in the brain that are believed to regulate circadian rhythms, or sleep/wake cycles.

The study is designed to investigate the efficacy and safety of 20 mg of tasimelteon versus placebo in totally blind individuals with the disorder, with a target enrollment of 160 individuals. It includes a six-month treatment period and an optional open-label extension. The primary endpoint of the study is improvement in total sleep time during the night.

• Forest Laboratories Inc. and Gedeon Richter announced in September the preliminary results from an eight-week phase 2 clinical trial of the antipsychotic agent ***cariprazine*** for the treatment of bipolar depression.

A total of 233 patients were randomized to enter one of two active (low dose or high dose) treatment arms or receive a placebo. The primary endpoint was the Montgomery-Asberg Depression Rating Scale (MADRS) score. Although the overall difference observed between the drug-treated and placebo-treated groups was not statistically significant, over the course of the trial there was evidence of a clinically relevant treatment effect in the high-dose arm of the study compared with placebo. Approximately 9 percent of patients discontinued the study early due to adverse events in the high-dose study arm compared with 3 percent in the placebo arm. The companies are considering conducting an additional phase 2 dose-response trial examining a wider range of doses.

• The top 10 of the world's 50 largest pharmaceutical companies have lower estimated clinical-trial approval success rates than do smaller firms in that group, according to a study by the Tufts Center for the Study of Drug Development (CSDD). But the largest firms also tended to terminate trials earlier in clinical testing, the study found. Failing early lets drug developers redirect resources into other projects and avoid more costly later-stage failures.

"While the very largest firms had lower approval success rates, they did make the decision to terminate earlier in the development process, which can help improve productivity of their new product pipelines," said Tufts CSDD Director of Economic Analysis Joseph DiMasi, who conducted the study. "The ultimate objective is to have higher success rates for drugs that are taken into clinical testing and earlier terminations of those that likely won't survive late clinical testing or regulatory review or be successful in the marketplace."

The study was based on 1,734 compounds that entered clinical testing from 1993 to 2004 for the top 50 companies that had 2006 revenues of more than $1 billion.

The study was reported in the September/October **Tufts CSDD Impact Report** ***and is available by subscription at <http://csdd.tufts.edu/reports/description/impact_reports>.*** ■

clinical & research news

Ethnicity

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understand what mediates substance use and help identify more effective interventions "with a focus on specific factors that might contribute to individual risk of substance use," she noted.

However, the usefulness of the research, Walker noted, may be limited by the disparate size of the ethnic groups it included, which varied from more than 3,000 Hispanic youth to only about 200 African-American youth.

The authors of the study acknowledged that the racial makeup of their respondents was limited by the specific demographics of Southern California and "is not necessarily generalizable to the larger population of middle-school adolescents in the United States."

Despite those limitations, Shih and her colleagues maintained that their study is "an important first step" in estimating ethnic differences in substance use among adolescents and identifying what individual, family, and school factors contribute to ethnic differences in alcohol and drug use among that age group. Such information may add to the few existing alcohol and drug prevention and intervention programs that appeal to the strengths of the young students' specific ethnic cultures.

"These findings may inform public-health intervention efforts that aim to reduce consumption during the period of greatest risk for substance-use initiation and escalation," Shih and colleagues noted, referring to the middle-school age group.

"Racial/Ethnic Differences in Adolescent Substance Use: Mediation by Individual, Family, and School Factors" is posted at <www.jsad.com/jsad/article/RacialEthnic_Differences_in_Adolescent_Substance_Use_Mediation_by_Individ/4485.html>. ■

association news

Senator

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ful of Republicans voting to break a GOP filibuster against the legislation.

"All patients need leaders like Sen. Snowe," said immediate past APA President Alan Schatzberg, M.D. "She has recognized that physical and mental health cannot be treated separately and has taken bold steps to ensure they are dealt with in the same way legislatively."

The APA Council on Advocacy and Government Relations recommends the recipient of the Javits award every two years; that selection must be approved by the Board of Trustees.

Snowe also was one of only two Republicans to support passage this past summer of a six-month, $24 billion extension in federal Medicaid assistance to states (PL 111-226). The Medicaid legislation was strongly supported by APA and other mental health organizations, because without the new federal funds, states were expected to impose massive cuts on their Medicaid programs. Medicaid programs are the largest payers of mental health treatment in the nation, so funding cuts could have had a devastating impact on those who depend on the program for their mental health care.

Snowe "has set a sterling example of how determination and bipartisanship can address some of the nation's biggest problems and improve the quality of life for Mainers," said Julie Pease, M.D., president of the Maine Association of Psychiatric Physicians.

Snowe noted that the award was especially meaningful to her because its namesake, the late Sen. Jacob Javits (R-N.Y.), serves as a continuing inspiration to her efforts to find bipartisan support for federal commitments to expand funding for and access to health care.

Other recent efforts by Snowe to support treatment for psychiatric illness include her support for a measure (S 3028) by Sen. John Kerry (D-Mass.) that would eliminate the Medicare 190-day lifetime limit for beneficiaries receiving care in a psychiatric hospital. No such lifetime limit exists for other Medicare specialty inpatient hospital services.

In a wide-ranging discussion with Scully after receiving the award, Snowe addressed another issue on which APA has been calling for a policy change: congressional enactment of an overhaul of the Medicare physician payment formula. That formula has led the government to impose a 23 percent pay cut on participating physicians to go into effect in December, following several postponements earlier this year.

Previous recipients of the Javits award include former Sen. Gordon Smith (R-Ore.) and the late Sen. Paul Wellstone (D-Minn.). ■

We are APA

Queens County DB Boasts 100% Trainee Membership

Jamaica Hospital Medical Center; program director: Richard Deucher, M.D.

NSLIJHS-Albert Einstein College of Medicine at Long Island Jewish Medical Center; program director: Bruce Levy, M.D.

All of the psychiatry residency programs in the area covered by the Queens County Psychiatric Society have become members of APA's 100% Club. That means that all of the psychiatry residents in these programs are members of APA.

Each program in the 100% Club receives a framed group picture of its residents and faculty and a major psychiatry textbook, and each resident receives an online subscription to APA's *Focus: The Journal of Lifelong Learning.* Both the textbook and journal are published by American Psychiatric Publishing Inc.

"Residents from Jamaica Hospital Medical Center, Long Island Jewish Medical Center, Mount Sinai Services-Elmhurst Hospital Center, and Creedmoor Psychiatric Center are essential members of our organization," said Adam Chester, D.O., president of the Queens County Psychiatric Society. "We have successfully recruited all our residents into APA by emphasizing the importance of membership and by following through with local programs of interest to members at all levels of their careers. Our activities are designed to promote learning, provide networking opportunities, and foster good psychiatric practices."

Mount Sinai Services-Elmhurst Hospital Center; program director: David Schnur, M.D.

Creedmoor Psychiatric Center; program director: Mark Sorensen, M.D.

Among those activities is a "Meet and Greet" each fall, at which trainees get to know each other and the society's leadership. The educational component of this event is designed specifically for trainees, based on topics of their choosing. There is also an annual "Best Paper" contest, held each spring, which showcases the cutting-edge research conducted by the society's resident members.

"Our residents actively participate in all our educational activities," Chester continued. "We offer programs from therapy and pharmacology to technology, ethics, and other aspects of a modern psychiatric practice. By providing a wide range of programs, our trainees see the benefits of membership from the start of their careers, and retention of members remains high. We are proud of our members in training and strive to provide them with a positive and meaningful educational experience."

Psychiatry residents and directors of residency programs seeking more information about APA's 100% Club should visit <www.psych.org/100percentclub>. ■

legal news

Funding

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hold this summer because no new funding was allocated to implement it (*Psychiatric News*, September 17).

However, the New York program has begun to show signs of strain after more than 10 years.

For instance, some of New York's AOT services have had trouble recruiting psychiatrists in recent years, Hoge said, because funding hasn't allowed salaries to keep up with inflation. Additionally, many private and some public hospitals do not participate in the AOT program because it can take up to 60 days to obtain the necessary court order for continuing treatment, and the facilities don't want to bear the uncompensated costs of holding and treating the patient for that time or the legal costs to obtain an AOT order.

Another ongoing challenge for AOT programs is that they are not the universal solution some politicians may believe them to be, because their effectiveness is predicated on at least some amount of "patient buy in."

"In part, it requires someone to accept the fact that they are going to be ordered to treatment that they would prefer not to take, but if someone is going to tell them they have to take it, then they'll comply," Hoge said. "It certainly seems to apply to a fair number of patients whose treatment courses have been problematic."

The practical limits of the AOT program were evident when officials tried to institute an AOT program for inmates leaving Rikers Island prison. That inmate population frequently dropped out of the program, and many were unable to be located again.

"Robbing Peter to Pay Paul: Did New York State's Outpatient Commitment Program Crowd Out Voluntary Service Recipients?" is posted at <http://psychservices.psychiatryonline.org>. ■

Sexual Orientation

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to discover or reveal closeted gay, lesbian, and bisexual service members or applicants, but barring those who are openly gay, lesbian, or bisexual from military service.

The Obama administration has opposed the policy while saying it is the responsibility of Congress to repeal it, and in February, Gates—along with Adm. Mike Mullen, chair of the Joint Chiefs of Staff—told the Senate Armed Services Committee that Congress should repeal DADT. It was at that time that Gates and Mullen proposed the study group to examine issues associated with repealing the policy (*Psychiatric News*, March 5).

APA, AMA Seek Repeal

APA has explicitly called for repeal of the policy, and at last year's Interim Meeting of the AMA's House of Delegates, the AMA voted with little debate to advocate for repeal (*Psychiatric News*, December 18, 2009).

"The hiding and lying that gay service members are required to do under the policy is damaging to people's mental health," said psychiatrist Mary Barber, M.D., an APA member and past president of the Association of Gay and Lesbian Psychiatrists, in an interview with *Psychiatric News* following the court's decision.

Barber said the matter of a person's sexual orientation is bound to come up in all sorts of routine ways, such as the choice of whether to list a partner as an emergency contact, which can place service members in potentially compromising positions. And she said it invariably is a subject that arises in clinical situations, so that the policy has disrupted the doctor-patient relationship.

(Barber noted that in March, following the meeting with the Senate Armed Services Committee, Gates ordered revisions to the DADT policy exempting some categories of confidential information—including information provided to psychotherapists—from being used to discharge service personnel.)

Conservative groups responded with equal fervor to the court's decision. Tony Perkins, president of the Family Research Council, said in a statement, "It is hard to believe that a district court–level judge in California knows more about what impacts military readiness than the service chiefs who are all on the record saying the law on homosexuality in the military should not be changed. Once again, homosexual activists have found a judicial activist who will aid in the advancement of their agenda. This is a decision for Congress that should be based upon the input of the men and women who serve and those who lead them."

In fact, Mullen was explicit in his testimony before the Senate Armed Services Committee in April that he opposed DADT. "[S]peaking for myself and myself only, it is my personal belief that allowing gays and lesbians to serve openly would be the right thing to do," he said. "No matter how I look at this issue, I cannot escape being troubled by the fact that we have in place a policy which forces young men and women to lie about who they are in order to defend their fellow citizens."

Discharges Drop Since Fighting Begins

How the court's decision will affect the DADT policy is uncertain and depends on a number of fluid variables, including whether the government will choose to appeal the decision. At press time, a press officer for the Justice Department told *Psychiatric News* that a decision to appeal was still under consideration.

John Davidson, legal director for Lambda Legal—a gay legal-rights organization that welcomed the court's decision—said there is some legal question about the extent to which a district court ruling can be applied outside the court's specific jurisdiction.

In response to that question, Dan Woods, the attorney representing the Log Cabin Republicans in the case, said simply, "We think it can." He added, "Our view is that the decision should prevent the government from enforcing or applying the policy in the future wherever it is in force."

He said the Log Cabin Republicans chose to file suit in Los Angeles because there are affected service members and military bases in the area. "We are happy to strike this blow for equality so that all Americans who have been fighting to protect our rights will have their own constitutional rights observed."

In their suit, the Log Cabin Republicans put forward several case histories of service members who performed at a very high level in combat and who were widely praised by superiors and subordinates alike, but who either left the service voluntarily or were forced to do so because their sexual orientation became known.

Interestingly, the group also presented evidence that the number of service members discharged under DADT had fallen substantially in the period since fighting began in Afghanistan and Iraq, compared with previous years since establishment of the policy. From 1994 to 2001, 7,856 service members were discharged under the policy, while from 2002, when fighting began, to 2009, 5,167 were discharged, according to the plaintiffs. From 2001 to 2002 alone, the figure dropped from 1,227 to 885.

In her ruling, Phillips said the evidence contradicted the prevailing belief that homosexuals in the military compromise military readiness.

> **"The Don't Ask, Don't Tell Act infringes the fundamental rights of United States service members in many ways."**

"Defendants' discharge of homosexual service members pursuant to the Act not only has declined precipitously since the United States began combat in Afghanistan in 2001, but Defendants also delay individual enforcement of the Act while a service member is deployed in a combat zone," she wrote. "If the presence of a homosexual soldier in the Armed Forces were a threat to military readiness or unit cohesion, it surely follows that in times of war it would be more urgent, not less, to discharge him or her, and to do so with dispatch. The abrupt and marked decline—50 percent from 2001 to 2002 and steadily thereafter—in Defendants' enforcement of the Act following the onset of combat in Afghanistan and Iraq, and Defendants' practice of delaying investigation and discharge until after combat deployment, demonstrate that the Act is not necessary to further the Government's interest in military readiness."

Phillips's ruling in the case,* Log Cabin Republicans v. United States of America and Robert M. Gates, Secretary of Defense, *is posted at <www.cacd.uscourts.gov>. ■

Talbott Appointed

John Talbott, M.D., has been named editor in chief of the *Journal of Nervous and Mental Disease*, the second oldest psychiatric journal in the United States. He succeeds Eugene Brody, M.D., who became the journal's ninth editor in 1968.

Talbott, a former APA president and long-time editor of the APA journal *Psychiatric Services*, is a clinical professor of psychiatry at the University of Maryland School of Medicine in Baltimore. ■

Jeffrey Geller, M.D., and Dilip Jeste, M.D., will compete for the office of president-elect.

Election

continued from page 1

been separated from the formerly combined position of secretary-treasurer. The incumbent, Roger Peele, M.D., of Rockville, Md., and former Area 4 Trustee Sidney Weissman, M.D., of Chicago will face off in that contest.

Two of APA's seven Areas will vote for trustees in the next election. In elections for Area trustee, the Area Council rather than the APA Nominating Committee chooses the candidates.

In Area 2, which includes all of the district branches in New York state, James Nininger, M.D., is running for a second three-year term against Jack Drescher, M.D. Both are from New York City.

In Area 5, which encompasses all of the Southern states as well as the military and Puerto Rico district branches, James Greene, M.D., of Memphis, Tenn., will compete against Gary Weinstein, M.D., of Louisville, Ky.

Also to be elected is the member-in-training trustee-elect (MITTE). The candidates vying for this post are Kurt Cousins, M.D., a second-year resident at the University of Maryland/Sheppard-Pratt; David Driver, M.D., a third-year resident at Georgetown University; and Alik Widge, M.D., a second-year resident at the University of Washington. The MITTE serves in that position without a vote for one year, after which he or she becomes the voting member-in-training trustee for a one-year term.

Beginning with the upcoming election, all members for whom APA has a valid e-mail address on file will receive an electronic ballot. Other members will receive a paper ballot along with instructions on how to vote online if they so choose.

Ballots will be mailed on December 22 along with candidate information and voting instructions.

The deadline for receipt of all ballots is 5 p.m. Eastern time on February 7, 2011.

More information on the election process is posted at <www.psych.org/resources/governance/elections.aspx>. ■

2011 World Congress To Be Held in Buenos Aires

The World Congress of Psychiatry, organized by the World Psychiatric Association every three years, is the main international scientific event in the field of psychiatry. The next World Congress, whose theme is "Our Heritage and Our Future," aims to provide a comprehensive overview of those achievements that have stood the test of time and of the most promising current trends in psychiatric research and practice, with the contribution of the most prominent experts of the various topics.

The next World Congress—the 15th—will be held from September 18 to 22, 2011, at the Sheraton Buenos Aires Hotel and Convention Center.

An outstanding scientific program is being put together, according to Mario Maj, M.D., the president of the World Congress. The list of the keynote lectures and core symposia is already posted on the Web site of the Congress, <www.wpa-argentina2011.com.ar>.

To help attendees get the most out of their trip to Buenos Aires, a schedule of tours is also being offered. Descriptions can be found at <www.wpa-argentina2011.com.ar/local_tours.htm>.

Submissions are still being accepted. The deadline for symposia and workshop submissions is October 31. The deadline for submissions of WPA section and zonal symposia, oral communications, and posters is November 30. Submission guidelines can be found on the World Congress Web site.

Attendees can earn up to 32 Category 1 credits.

Registration and other information about the World Congress is posted at <www.wpa-argentina2011.com.ar/>. ■

Suspension

David Ray Mitchell, M.D., has been suspended for one year from APA and the Oklahoma Psychiatric Physicians Association. Mitchell was found to have violated Section 1 of the *Principles of Medical Ethics With Annotations Especially Applicable to Psychiatry* by the ethics committees of the district branch and APA. He was found to have committed a boundary violation with a patient. ■

Brain Disorder

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Neuropsychiatric illnesses are the leading cause of years lost to disability or death from noncommunicable causes, noted Insel.

Progress Lags in Psychiatric Illness

Advances in research and changes in practice have cut deaths from heart disease by 63 percent since 1965, but similar progress has not happened for mental illness, he pointed out.

"We have to move the agenda," he said. "Diagnosis still comes by observation, illness is detected late, prediction is poor, etiology is often unknown, prevention is not well developed, treatment is by trial and error, and there are no cures and no vaccines."

Prevalence and mortality have not decreased, and the culture surrounding them is sunk in low expectations. "This is the only area of medicine where people don't talk about cure and prevention," he said.

The burden of mental disorders is magnified by its relatively high prevalence (approximately 6 percent) and the fact that these illnesses are chronic disorders and usually begin early in life.

He suggested three main areas on which neuroscience research needs to concentrate to tackle the large public-health problem that mental illness presents: a renewed emphasis on psychiatric disorders as brain disorders, an increasing recognition of the role of child and adolescent development, and achievement of advances in understanding the genetic basis of mental illness risk factors.

Field May Shift to Clinical Neuroscience

Brain lesions may be the realm of neurology, but psychiatric illness is defined by the physiology of neural circuits in the brain, said Insel. A different approach and different training may be needed to understand and treat those illnesses. In 10 years, he suggested, psychiatry might be better termed "clinical neuroscience."

He cited the example of Area 25 in the subgenual cingulate, a region that becomes overactive in depression, but where activity declines when depression is treated with an SSRI. Imaging studies show brain changes—but only in treatment responders. Deep brain stimulation (DBS) near Area 25 also turns down activity, he noted, and the research on DBS shows how knowledge gleaned from brain mapping, circuitry, and imaging can converge to improve understanding of disease and its treatment.

Second, mental disorders are also developmental disorders, he pointed out. Many begin before age 15, while normal brain development continues until age 25.

The cortex in patients with attention-deficit/hyperactivity disorder (ADHD) seems to take longer to mature. Individuals with the disorder "end up at the same point but two or three years late," he said. "So is ADHD a disease of attention and behavior in children, or is it one of cortical maturation? The challenge is to see what is going wrong in the organ of interest."

Third, while genetics are another key component of mental illness, Insel acknowledged that understanding how hundreds of variations map onto brain pathways is a complex challenge. Many variants express only in the human brain and only during development. Many other genes that contribute to mental illness have not yet been identified.

"We need to move from description to mechanism and to approach all of these problems from many levels: molecular, cellular, systemic, individual, and social," he said.

Learning which early variations in brain structure, circuitry, and function foretell later disorder might lead to interventions that can prevent the development of frank illness.

Eventually, the foundation of brain circuitry, development, and genetics will support a better understanding of pathophysiology, prevention, and personalized medicine, all leading to Insel's goal of a comprehensive public-health approach to psychiatric disorders.

The George Washington Institute for Neuroscience has scheduled a dozen more lectures by other neuroscience researchers between now and next May.

Information about the George Washington Institute for Neuroscience is posted at <www.gwumc.edu/neuroscience>. ■

Passion

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"Bill helped me find and set up the table and challenged me to a match, and I promptly won," she said. Each day, Kazim kicked off her heels and started playing with the patients and mental health workers. She also organized tournaments among the patients, who became excited about playing the game.

Return to the World of Sports

After a 17-year hiatus from professional sports, Kazim began playing badminton again, and last year she traveled to Sydney, Australia, to compete in the World Masters Games with a group of seasoned professionals with whom she'd played in the past. "The Magnificent Seven," as the team called themselves, won the bronze medal.

Kazim currently divides her time between teaching medical students as an instructor in psychiatry at Harvard Medical School, lecturing in the United States and abroad, and treating patients at a clinic affiliated with Massachusetts General Hospital.

She is a member of Harvard Medical School's Cross-Cultural Care Committee, and she treats a diverse group of ethnic minorities who are economically disadvantaged.

"I'm very bothered by the prevalent racial and ethnic disparities in health care, something I see every day in my clinical work," she said. Although she is bolstered by the impact she has on the lives of her patients and their families, she said she is frustrated because "the reality is that the system does not reward those working with such a complex patient population because of fiscal constraints."

Kazim explained that everyone who works with a patient "has a role on the team, but the patient is the captain of the team." This approach resonates with her patients, she said, and helps them feel empowered and more in control of their lives.

Kazim has incorporated her love of the game not only in her daily work, but also in a larger plan to give back to her homeland. Last year, she met with a group of nearly 100 psychiatrists of Pakistani origin to discuss how to combat the extremism plaguing the country and promote mental health among its residents.

"In past years," she explained, "Pakistan has boasted world champions in hockey, badminton, cricket, and squash. Currently, our sports teams are not doing well, and that demoralizes our entire nation."

Building Role Models

Young people need role models to emulate, Kazim said, but since the government in Pakistan is mired in corruption, role models are few, she pointed out. She devised a plan to work with other physicians to supervise and fund better facilities and athletic and mental skills training for the country's sports teams to help them to excel once again.

"If these teams are performing well, it will raise the morale of the entire country," she noted. She envisions a time when boys and girls living in Pakistan can look up to sports figures, as she did as a young girl, Kazim said.

As for her own involvement in champion-level sports, Kazim plans to compete again in the World Masters games again when they are held in Torino, Italy, in 2013.

"Playing badminton internationally has been a dream fulfilled for me," she said. "I have found myself once again." ■

DSM-5

continued from page 7

data collection, but also they will allow us to examine potential changes in criteria and diagnoses in the context of important demographic variables. Additionally, diverse settings increase our ability to examine thoroughly diagnoses of high public-health significance. For instance, the use of Veterans Administration hospitals will help us better understand potential changes to patients diagnosed with posttraumatic stress disorder and mild traumatic brain injury—two increasingly prevalent conditions that significantly impact quality of life.

How will these field-trial studies differ from those being conducted in routine clinical settings? The aims of the two field-trial designs are largely the same: to determine whether the proposed changes are acceptable to clinicians and patients, whether they are stable over time and among different clinicians, and whether they improve diagnosis as well as aspects of treatment planning (for example, whether changes in the treatment plan are made in response to data collected on the severity of a patient's symptoms). In both designs, patients will be interviewed using diagnostic checklists to help clinicians assess all *DSM-5* proposed criteria. Patients and clinicians will also complete measures to assess potential symptoms that patients frequently endorse, as well as the severity of symptoms they are currently experiencing. However, greater staffing and resources in these larger field-trial sites will allow us to assess patients on three visits, rather than the two visits utilized in the routine clinical-setting design. This means more data can be collected over longer periods, allowing us to observe how a patient's symptoms may change (or not change, as the case may be) over time. Furthermore, these sites permit us to include additional clinicians, which helps us determine whether different practitioners will arrive at the same diagnosis when assessing the same patient.

Finally, the larger settings also include the option of conducting videotaped assessments among a small subset of participants. These taped interviews can be reviewed by expert clinicians whose input may help us better determine whether the diagnoses the patients are given are accurate.

Although the use of two field-trial designs increases the complexity of this project, the tradeoff is a more precise understanding of how the future of psychiatric diagnosis might impact patients and clinicians. Given that *DSM-5* is proposing some significant changes from how psychiatric disorders are diagnosed in *DSM-IV*, rigorous field-trial testing becomes all the more necessary for ensuring the safety and benefit of patients and the public. As such, in my next article, I will discuss the details of what is perhaps the most significant departure from *DSM-IV*—the introduction of dimensional assessments to enhance diagnosis and increase measurement-based care. ■

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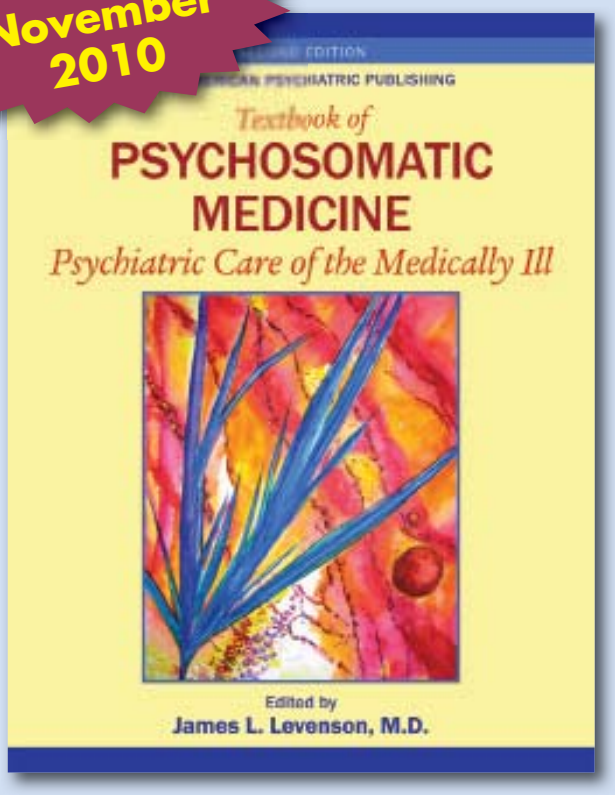

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PSYCHIATRIST
Affective Disorders Specialist

The Department of Psychiatry is seeking a **Psychiatrist—Affective Disorders Specialist** to join the faculty of Dartmouth Medical School at Dartmouth-Hitchcock Medical Center in Lebanon, NH.

This newly created position, Director of the Affective Disorders Service, will develop and lead an affective disorders program that involves research, clinical care and teaching. The successful applicant will provide clinical consultations and supervise affective disorder specialty care. He/she will lead affective disorders training for medical students, residents and fellows. In addition, he/she will be expected to build an externally supported affective disorders research program.

The ideal candidate will be a skilled clinician and enthusiastic teacher, with strong interest and experience in research related to affective disorders. Candidates should be board certified or eligible in Psychiatry. Academic rank and salary will be consistent with experience. A letter of interest, CV and three letters of reference should be addressed to William C. Torrey MD, Vice Chair for Clinical Services for the Department of Psychiatry and chair of this search, and sent to Kami Carter at Kami.L.Carter@Dartmouth.edu.

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PSYCHIATRIST
FULL TIME

The Dept. of Psychiatry at Morristown Memorial Hospital, part of **Atlantic Health** and a teaching hospital affiliated with the Mount Sinai School of Medicine, is seeking a full-time BE/BC psychiatrist to join our growing team of psychiatrists and allied health professionals.

Clinical responsibilities would include providing inpatient care on our voluntary psychiatric unit and providing psychiatric consultations for medical-surgical patients as part of our psychosomatic medicine service as well as supervision of medical students. ECT experience would be a plus. The position includes a competitive compensation package including 5 1⁄2 weeks of vacation annually, complete health insurance and a generous pension plan. Morristown Memorial Hospital is conveniently located off of Route 287 at Exit 34 and is close to Routes 80 and 10.

Please contact: **Thomas Zaubler, MD, Chairman, Department of Psychiatry; Thomas.zaubler@atlantichealth.org or call (973) 971-5942**. Please be sure to attach your CV.

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PSYCHIATRIST

The Department of Psychiatry and the Lineberger Comprehensive Cancer Center of the University of North Carolina (UNC) School of Medicine at Chapel Hill are seeking an early career psychiatrist to join the UNC Psycho-oncology Service.

DESCRIPTION

This is a full time fixed-term position at the (Clinical track) Clinical Assistant or Clinical Associate Professor level. This clinical service is a component of the UNC Comprehensive Cancer Support Program.

Responsibilities will include: providing inpatient and outpatient clinical consultation and psychiatric management for cancer patients; medical leadership for a multidisciplinary psycho-oncology team; teaching medical students, residents, and other health care trainees and clinicians; and participation in the clinical research activities of the Comprehensive Cancer Support Program.

The successful candidate should have strong clinical skills, a record of scholarly achievement; evidence of effective leadership and demonstrated ability to promote a collegial environment that fosters ongoing collaboration. Candidates should have clinical experience working with cancer patients as evidenced by completion of a fellowship in psycho-oncology or psychosomatic medicine, or similar training at the interface of psychiatry and medicine. Special consideration will be given to candidates with an established record of extramural funding.

Applicants must have an M.D. and be eligible for North Carolina licensure. Rank and salary will be commensurate with experience.

CONTACT

Applicants should forward curriculum vitae and three letters of reference to Donald L. Rosenstein, M.D., Director, Comprehensive Cancer Support Program, 3134 Physicians Office Building, 170 Manning Drive, CB# 7305, The University of North Carolina at Chapel Hill, Chapel Hill, NC 27599-7305

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INPATIENT PSYCHIATRIST

DARTMOUTH MEDICAL SCHOOL. The Department of Psychiatry, in a unique collaboration with the State of New Hampshire, is seeking a **PSYCHIATRIST** to join our faculty at the New Hampshire Hospital.

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

Academic duties include teaching and supervision of medical students and residents. Research opportunities available and encouraged.

Candidates should be board certified or eligible in Psychiatry. Academic rank and salary will be consistent with experience. A letter of interest, curriculum vitae and three letters of reference should be addressed to William C. Torrey MD, Vice Chair for Clinical Services for the Department of Psychiatry, and sent to Kami Carter at Kami.L.Carter@Dartmouth.edu.

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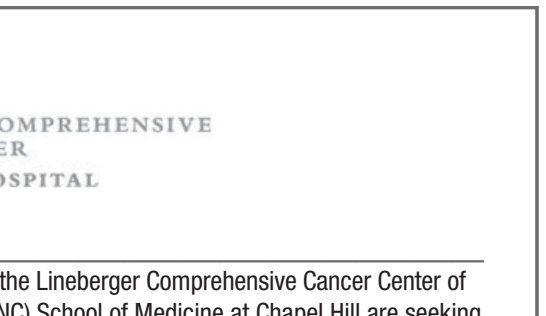

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Diego Coira, M.D., Chairman
Department of Psychiatry & Behavioral Medicine
Hackensack University Medical Center
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Hackensack, New Jersey 07601
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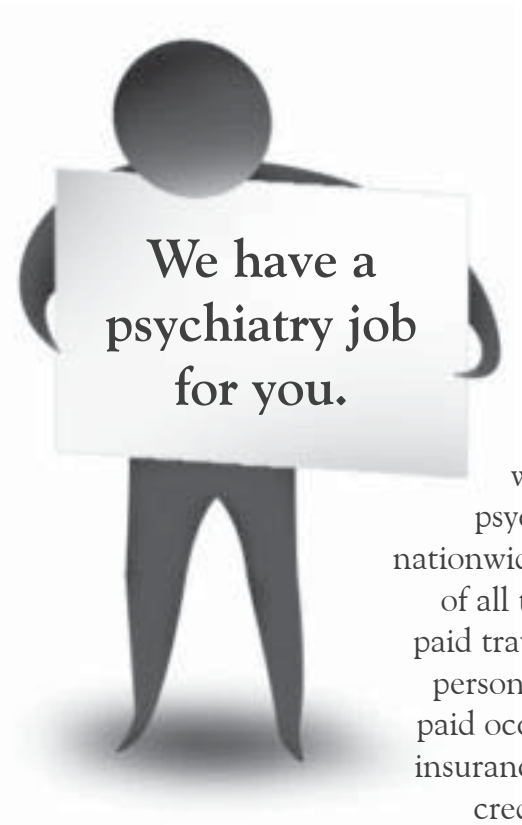

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For full consideration, applications must be received by November 30, 2010. Position is open until filled, but no later than January 31, 2011. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-03R-11 to Juli Koeberlein at juli.koeberlein@ucdmc.ucdavis.edu.
For more information regarding this position, you may contact the Search Committee Chair, Dr. Marjorie Solomon at Marjorie.solomon@ucdmc.ucdavis.edu.
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CHIEF, MENTAL HEALTH SERVICE

The Southeast Louisiana Veterans Health Care System (VA) and the Department of Psychiatry and Behavioral Sciences at the Tulane University School of Medicine, New Orleans, seek a candidate to fill the position of Chief, Mental Health Service. All candidates will have clinical, administrative, teaching and research responsibilities and must have academic credentials to be qualified for a faculty appointment at Tulane University School of Medicine.

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

Interested applicants can mail a curriculum vitae by November 30, 2010 to **Patricia Skinner** (11D), Southeast Louisiana Veterans Health Care System, P.O. Box 61011, New Orleans, LA 70161-1011 or can e-mail a CV to **Patricia.skinner@va.gov**. Applications for this position will be accepted until a suitable qualified candidate is identified.

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A letter of interest, curriculum vitae and three letters of recommendation addressed to William Torrey, MD, Vice Chair for Clinical Services should be sent to Kami Carter at Kami.L.Carter@Dartmouth.edu.

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Department of Psychiatry and Behavioral Sciences
401 E. Chestnut Street, Suite 610, Louisville, KY 40202
P: 502-813-6664 ; F: 502-813-6665; kelly.moore@louisville.edu

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UNIVERSITY OF LOUISVILLE

Interventional Neuropsychiatrist

The Department of Psychiatry, (in collaboration with the Departments of Neurology and Radiology, and the Section of Neurosurgery) at Dartmouth Medical School (DMS) and Dartmouth-Hitchcock Medical Center (DHMC) is seeking a senior level faculty member to build and lead a new program in Interventional Neurotherapeutics.

The successful candidate will be an established clinical scientist who will strengthen existing basic, translational, and clinical research programs at DMS and DHMC that address the treatment of neuropsychiatric disorders such as refractory mood disorders, substance use disorders, cognitive impairment associated with brain disease and obsessive-compulsive disorder. He/she will have a track record of federal funding in his/her area of interest and experience in the application of neuromodulatory procedures such as deep brain stimulation, rTMS, ECT, VNS or related techniques to neuropsychiatric disorders. The successful candidate will strengthen collaborative links (and provide vision and leadership to) between existing programs at DMS and DHMC in the clinical and experimental use of deep brain stimulation and vagus nerve stimulation, animal models of alcoholism, human and animal neuroimaging, neuro-psychopharmacology, epilepsy and neuropathic pain, as well as animal and human studies of neural circuitry related to reward behavior and attentional mechanisms.

Curriculum vitae, a letter of interest, and representative publications should be addressed to Thomas McAllister, MD, Search Co-Chair, and sent to Kami Carter at Kami.L.Carter@Dartmouth.edu.

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PSYCHIATRIST

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EOE/AA

Psychiatrist

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VA Medical Center
James Erickson
Administrative Assistant to the Chief of Staff
4815 N. Assembly
Spokane, WA 99205

Phone: 509-434-7211
Fax: 509-434-7100
E-mail: James.Erickson@va.gov

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Practice Management for Early Career Psychiatrists: A Reference Guide

Created by the American Psychiatric Association's Office of Healthcare Systems and Financing, this handbook provides APA members with an overview of many of the things they need to be aware of as a psychiatrist. Although specifically designed to meet the needs of **Residents** and **Early Career Psychiatrists** (ECPs), the information it contains may also be of value to those who have been in practice for years. Contents include:

I. STARTING OUT

1. Conducting an Effective Job or Practice Search
2. Negotiating an Employment Contract
3. Licensing and Board Certification
4. Practice Options

II. ESTABLISHING YOUR PRACTICE

5. Incorporation Options
6. Buying or Leasing Office Space and Equipment
7. Medical Professional Liability Insurance
8. Hiring and Managing Administrative Staff
9. Selecting Computer Applications and Software
10. Marketing Your Practice Effectively
11. Putting Your Practice on a Budget

III. MAINTAINING YOUR PRACTICE

12. Managing Relationships with Other Clinicians
13. Managing Appointment Scheduling
14. Insurance Terminology
15. Verifying Benefit Coverage Accurately and Efficiently
16. Coordinating Benefits for Patients with More than One Source of Insurance Coverage
17. Implementing Electronic Billing Capabilities
18. Increasing the Success Rate of Collections Efforts
19. Avoiding Common Procedure Coding Problems

IV. PATIENT CARE ISSUES

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22. Informed Consent
23. Civil Commitment
24. Medical Records
25. Conducting a Patient Satisfaction Survey

V. MANAGED CARE ISSUES

26. Defining Managed Care
27. Getting on Managed Care Panels
28. Reviewing and Negotiating Contracts
29. Appealing Reimbursement Denials
30. Getting Paid
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Issue	Deadline (Friday, 2 p.m. E.T.)
November 5	October 22
November 19	November 5

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MedOptions has immediate opportunities for adult and geriatric psychiatrists in **Connecticut, Maryland, Massachusetts, Pennsylvania and Rhode Island.**

We are a leading provider of behavioral health services to long-term care facilities. Our group of clinicians provides services at 450 skilled nursing and assisted living facilities.

MedOptions offers a flexible schedule at locations close to where you live or work. Our psychiatrists are supported by a clinical team that includes nurse practitioners, physician assistants, clinical psychologists and licensed clinical social workers. The work shares many similarities with consultation liaison psychiatry, especially in that medical colleagues are most appreciative of our efforts.

We offer a competitive compensation package, full benefits starting at 24 hours/week and relocation assistance.

For consideration, please contact:

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UHS

Universal Health Services, Inc. (UHS) is one of the nation's largest and most respected hospital management companies, operating through our subsidiaries behavioral health facilities nationwide. **We are currently recruiting new Psychiatrists for diverse practice positions in the following locations:**

- **FLORIDA-** Orlando (Medical Director)
- **GEORGIA-** Atlanta & Moultrie
- **SOUTH CAROLINA-** Aiken & Greenville
- **KENTUCKY-** Louisville area
- **TENNESSEE-** Nashville Area-C/A Medical Director

- **PENNSYLVANIA-** Philadelphia, State College, Clarion, Shippensburg
- **CONNECTICUTT-** N. Stonington (Addiction)
- **MASSACHUSETTS- BOSTON**- Brookline, Westwood, Pembroke, Attleboro, Lowell

- **MICHIGAN-** Grand Rapids
- **MISSOURI-** Kansas City

- **NEVADA-** Las Vegas
- **COLORADO-** Denver & Boulder
- **WYOMING-** Casper & Cheyenne
- **TEXAS-** Austin, Dallas, San Angelo, McAllen

Competitive compensation packages and benefits offered including bonus and student loan assistance opportunities depending on location. For more detailed information about individual locations as well as other UHS locations **contact Joy Lankswert, In-house physician recruiter @ 866-227-5414 ext: 222 or email joy.lankswert@uhsinc.com. UHS website: www.uhsinc.com.**

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.**

BE/BC Psychiatrists for **CA locations.** $160-185/hr. Up to $44k/month 8-12hr/day Wknds $42/hr on call.

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

Work in sunny San Diego and enjoy ideal weather year around. The County of San Diego Psychiatric Hospital is now hiring Psychiatrists.

The San Diego County Psychiatric Hospital (SDCPH) is conveniently located in the heart of San Diego County. Just minutes away from beautiful beaches and parks, the historic Gaslamp District downtown, San Diego Zoo, SeaWorld, Petco Park and beautiful housing communities.

SDCPH is a publicly funded, free-standing psychiatric hospital. It is a locked facility and a component of the San Diego County Behavioral Health Services' continuum of care. Our Psychiatrists work with a dynamic team of medical and nursing professionals to provide emergency services and crisis intervention-oriented acute inpatient treatment for adult residents of San Diego County. Come join our team and make a difference!

For more information on the duties go to www.sdcounty.ca.gov/hr. Interested candidates may email their resume to **Gloria.Brown@** sdcounty.ca.gov.

Butte County Behavioral Health Department invites applicationsfor the position of Medical Director. This position, under administrative direction, plans, organizes, and manages the medical services component of the Butte County Department of Behavioral Health. The salary range for this position is $211,584 -$259,000 annually, and includes a comprehensive benefits package featuring retirement, health insurance, leave time, life insurance, and more.

Please submit a Butte County regular help application to: Butte County Human Resources, 3-A County Center Drive, Oroville, CA 95965, **Recruitment# 104116044**. 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.

This is a continuous recruitment; open until filled. Butte County is an Equal Opportunity Employer.

J1 and H1 Opportunities in California

Adult and child psychiatrists in out-patient and hospital practices near the Bay Area of California. Locations meet criteria for designated shortage area. Please view our web site at CommunityPsychiatry.com or call (800) 244-5807 for more information. Fax: (916) 285-0338 or Email stephanimartinez@communitypsychiatry.com your CV with CA in the subject line.

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**

California Department of Mental Health

CARE AND TREATMENT WITH RESPECT AND DIGNITY — PATTON STATE HOSPITAL — PATTON CA

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.

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.

COLORADO

Psychiatry opportunities in Colorado: DENVER, COLORADO SPRINGS, BOULDER

Join our successful team of clinicians. Full/Part time - flexible schedules. Inpatient/Outpatient, blend of both. Compass Health Systems was founded in July 1990. Physician owned and operated. Contact sfaulkner@compass.md or (786) 347-0355.

Horizon Health seeks **Medical Director** and **Attending Psychiatrist** in **Greeley, CO** for a 22-bed Adult and Adolescent inpatient program and an outpatient psychotherapy and medication management clinic that sees all ages. Inpt srvcs operated on modified hospitalist model with core of three doctors covering inpt and outpt srvcs following either 6 adults or 4 adolescents based upon a 50% assign't to inpt and a 50% assign't in outpt. Call only every third week Monday through Thursday. Physicians hand off call responsibilities to our dedicated weekend doctors at 5:01 pm on Friday and enjoy weekends off with their families free of call responsibilities!

One hour from **Denver, Boulder, and Estes Park!** Great quality of life with outstanding salary and benefits. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

CONNECTICUT

Director, Adult Resident Outpatient Clinic

The Institute of Living/Hartford Hospital is seeking an experienced psychiatrist with a demonstrated commitment to resident education, to serve as a full-time teaching attending and educational administrator in the resident outpatient clinic. The psychiatrist will participate in the supervision and didactic teaching of residents and medical students and work collaboratively with the clinic administrator and its multi-disciplinary staff, joining a mature and collegial faculty peer group. Expertise in both clinical psychopharmacology and psychotherapy is preferred. Applicants with an interest and expertise will be considered for the role of Assistant Program Director. In addition to educational duties, some hours are devoted to outpatient treatment. The Institute of Living also supports opportunities for work within subspecialties as well as participation in our growing research centers. Applicants will be eligible for academic appointment through our affiliation with the University Of Connecticut School Of Medicine. Applicants must be Board-Certified or Board-Eligible and eligible for licensure in the state of Connecticut.

Please visit our website at **www.instituteofliving.org**. Applications for employment are to be submitted to Theodore F. Mucha, M.D.; Medical Director, Institute of Living, 200 Retreat Avenue, Hartford, CT 06106. Phone: 860-545-7260 **Fax:** 860-545-7068. **Email:** tmucha@harthosp.org. EOE M/F/D/V.

PSYCHIATRIST - Outpatient center is seeking a bilingual Psychiatrist Spanish/English to work with a dynamic community health center that provides behavioral health and primary care services. **Responsibilities include:** working with a multidisciplinary team to provide quality, state-of-the-art psychiatric services, providing psychiatric assessment and treatment recommendations for incoming patients, ongoing assessment and medication monitoring of patient caseload, and consultation with primary care staff to provide integrated, holistic care.

QUALIFICATIONS: CT license to practice psychiatry; Board certified or eligible for certification; experience with community mental health. Bilingual preferred. Position located in Stamford, CT.

PSYC APRN - Outpatient center is seeking a bilingual Psychiatrist Spanish/English to work with a dynamic community health center that provides behavioral health and primary care services. **Responsibilities include:** working with a multidisciplinary team to provide quality, state-of-the-art psychiatric services, providing psychiatric assessment and treatment recommendations for incoming patients, ongoing assessment and medication monitoring of patient caseload, and consultation with primary care staff to provide integrated, holistic care.

QUALIFICATIONS: CT license or license eligible; experience with community mental health. Bilingual preferred. Position located in Stamford, CT. For both positions, please fax CV or Resume to 203-621-3714.

FULL TIME & PART TIME CHILD PSYCHIATRISTS CENTRAL CONNECTICUT

The child psychiatry division of Saint Francis Hospital and Medical Center, in Hartford Connecticut, is seeking a full and part time outpatient child psychiatrist (BE/BC). Inpatient opportunities are available, if compatible with the applicants' interests. The child psychiatry service works collaboratively with a large group of pediatric primary care practices in central Connecticut, and has particular interest in the treatment of children with autism and other early developmental disorders. These outpatient positions involve psychiatric evaluation and management of children and adolescents with a variety of disorders, and are supported by skilled social workers and therapists in our outpatient division. Our psychiatric service includes 4 inpatient units, including two child and adolescent units, a large multi-site outpatient psychiatric service, and a consult-liaison service. The hospital is a teaching site for University of Connecticut Medical School and The University of Hartford.

We offer very competitive salaries with an excellent benefit package. For more information about this opportunity, please contact Christine Bourbeau in the Recruitment Office at 800.892.3846 or fax/email your CV to 860.714.8894.

Email address:
CBourbea@stfranciscare.org
Visit our Website at:
www.saintfranciscare.com
EEO/AA-M/F/D/V
Pre-employment drug testing.

View the classifieds online at pn.psychiatryonline.org

FLORIDA

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.

Florida Licensed BE/BC Psychiatrist and advanced registered nurse practitioner needed for a Joint Commission Accredited community mental health center and psychiatric hospital. Excellent benefits and location. Contact: Suresh P. Rajpara, M.D., Chief Medical Officer, Oakwood Center of the Palm Beaches, 1041 45th Street, West Pam Beach, FL 33407. Phone: (561) 383-5917; Fax: (561) 514-1504. srajpara@oakwoodcenter.org.

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.

GEORGIA

FT Psychiatrist position with Behavioral Health Services of South Georgia. Provides evaluation and treatment for MH/AD disorders. Comprehensive psychiatric evaluations and diagnoses and ongoing treatment. Team approach und Psychosocial Rehabilitation model. Service area includes Cook, Lowndes and Tift counties in South GA. Current medical license to practice psychiatry in GA required. Computer skills plus EMR system use required. Send CV to BHSGA, 3120 N Oak St Ext, Suite C, Valdosta, GA 31602, ATTN: HR Mgr or email to mcorbett@bhsga.com.

Tired of managed care and spending less time with patients and more on paperwork?

Dwight D. Eisenhower Army Medical Center, Behavioral Health Care Line (Joint Commission accredited) at Fort Gordon, Georgia is seeking Board Certified Psychiatrists with an active and valid medical license for Department of Defense positions. Medical license in Georgia is not necessary for this federal position. Outpatient positions for the evaluation and treatment of active duty service members with posttraumatic stress disorder, substance addiction, depression, chronic pain, and other psychiatric disorders are available. The following positions are also available: Clinical Director, Clinical Health Psychologist, Licensed Clinical Social Workers, Certified Recreational Therapist, and Certified Occupational Therapist for an Inpatient Substance Abuse Unit and Outpatient Behavioral Health Services. Positions come with full benefits including competitive salary, health benefits, vacation, 401K, malpractice coverage, and funds for CME. Fort Gordon is located in Augusta, Georgia which has been designated the most affordable city for housing in the US. It is home to the Masters, and is the second largest city in Georgia, providing the amenities of a much larger city in a smaller setting.

To apply, contact Trish Beam at (706)787-6377.or e-mail at trish.beam@us.army.mil.

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

Chicagoland VA Hospital seeks f/t outpt psychiatrist to join dynamic, growing dept; eligible for academic appt expected. EEOC employer, US citizenship and electronic proficiency req.

Send c.v. to valerie.davis5@va.gov.

NW suburbs of Chicago. BHCA , the Leader in Mental Health and substance abuse, is looking for **2 BC/BE Psychiatrists** to serve in several roles. Outpt, inpt, C/L, research, detox, TMS. www.Mentalhealthchicago.com. **Email CV to: Blaise2001@aol.com. 847 895-4540**

IL licensed BC Adult or Child Psychiatrist for Private Practice, Hinsdale. Part time outpatient, potential for full time. Agree to be on staff at local hospital, take call three times per month. Carry own malpractice insurance, willing to be medicare provider. **Email CV to LYBURDA@COMCAST.NET.**

Methodist

Methodist Medical Center in Peoria, Illinois seeks two general adult Psychiatrists for its busy behavioral health service. Methodist, a 353-bed teaching facility affiliated with the University of Illinois College of Medicine, is the predominant behavioral health caregiver in the community and offers a full continuum of care in a modern state-of-the-art facility. The current physicians provide a mixture of inpatient/outpatient care and share a reasonable call coverage situation. An outstanding compensation and benefit package is offered.

Peoria is a great mid-size city centrally located 2 1/2 hours from Chicago and St. Louis. The community offers affordable housing, excellent schools, and a safe quality lifestyle notorious in the Midwest. **Please respond to:** Sheri Johns, Physician Recruiter, Methodist Medical Center of Illinois, 800-621-8543, email: sjohns@mmci.org. **Please visit our website: www.mymethodist.net.**

KANSAS

Bert Nash Community Mental Health Center, Inc

The Bert Nash Community Mental Health Center, in **Lawrence KS**, has an immediate opening for a full time adult psychiatrist for outpatient work. Lawrence is home of the University of Kansas and Haskell Indian Nations University. Commuting distance from Kansas City and Topeka. Visit our website www.bertnash.org and click on Employment for more information, or contact Karan Baucom, Human Resource Manager at kbaucom@bertnash.org Ph. 785-830-1734.

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 an 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. Must have or be willing to obtain certification for ECT and a waiver for suboxone management. 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.

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

EHP® BEHAVIORAL SERVICES, LLC

We are seeking an ambitious, board-certified psychiatrist to assume a leadership role as the Medical Director of a 26-bed community hospital psychiatric unit. Preference is given to candidates who demonstrate superior interpersonal skills with hospital management, administrative and clinical support staff.

EHP is a multi-discipline, multi-location behavioral health practice with two private offices and an exclusive contractual agreement to provide consultation, crisis intervention, inpatient, partial hospital and outpatient services at Union Memorial Hospital in Baltimore, Maryland. Individuals will be given the opportunity to gain experience in all phases of our operation; however, the primary initial focus will be on inpatient service.

EHP offers the security of 17 years in operation. Our compensation percentage ranges from 65% to 80% of collections. Members may participate in a 401K plan with up to a 3% company match, and benefits such as health, dental, vision, short-term disability, long-term disability and life insurance are available. Members who elect to join the management track will enjoy ownership and profit sharing opportunities.

Interested parties should forward a cover letter and CV to: EHP at 3333 N. Calvert Street, Suite 670, Baltimore, MD 21218 via mail, 410-933-9085 via fax or sar@psychbillinc.com via e-mail. Should you have any questions, please feel free to contact Steven A. Rose, RN at 410-933-9000, extension 210.

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

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.

High Point Treatment Center is seeking a **40 hr week psychiatrist** to allocate 20 hrs managing 8-beds Inpatient Psychiatric Unit and 20 hrs allocated to outpatient services located in Plymouth, MA. Salary ranging from $170,000 - $190,000. No weekends. Paid holidays and leave time. Health benefits available. If willing to work an additional 1 hr per day salary range would be $200,000 - $215,000.

We are also seeking an **Outpatient psychiatrist**. Up to full time in Outpatient Clinics located in Southeastern MA. Salary ranging from $180,000 - $200,000.

If interested in either opening, please contact Jim Horvath at 508-408-6155 or email to jim.horvath@hptc.org.

CAMBRIDGE:
Outpatient Consultation Liaison Psychiatry Position

PSYCHIATRIST: Cambridge Health Alliance is seeking a half- to full-time psychiatrist to join our outpatient Consultation-Liaison Psychiatry Service serving a multi-ethnic and diverse patient population. The position will be focused on clinical 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: Outpatient Psychiatry

OUTPATIENT PSYCHIATRIST: Cambridge Health Alliance is seeking a half- to full-time psychiatrist, to join our adult outpatient service with integrated addictions and dual diagnosis programs serving a multi-ethnic and diverse patient population. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment to improving the health of our communities, coupled with a strong academic tradition, make this an ideal opportunity for candidates interested in caring for underserved populations in a rich clinical environment. We have strong adult and child residency training programs which provide many opportunities for teaching, as well as innovative programs for HMS students. 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. Bilingual and/or bicultural abilities are desirable. Interest and experience with dual diagnosis and/or 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.**

Boston North Shore—Northeast Hospital Corp, a local nonprofit medical and psychiatric system has openings for inpatient attending psychiatrists at BayRidge Hospital and Beverly Hospital. BayRidge Hospital is a 62 bed free-standing psychiatric facility in Lynn, a teaching site for Boston University School of Medicine. At Beverly Hospital, a 240 bed community hospital, a position as an attending on the 18 bed psychiatric unit can be combined with duties on the consultation-liaison service. At both sites, there is no required night call (participation in a lucrative call system is optional), a competitive salary, and a full benefit package including generous time off as well as reimbursement for malpractice insurance and CME expenses. In addition, there are current openings for night and weekend "moonlighting" psychiatrists.

Contact Barry Ginsberg, M.D.
Chief and Administrative Director
NHC Dept. of Psychiatry
60 Granite Street, Lynn MA 01904
Phone (781) 477-6964, Fax (781) 477-6967
Email- bginsber@nhs-healthlink.org

St. Elizabeth's Medical Center
A CARITAS FAMILY HOSPITAL

Psychiatry
St. Elizabeth's Medical Center-BOSTON

St. Elizabeth's Medical Center (SEMC) is seeking a BC/BE Psychiatrist for a position in Boston. In addition to the 32 adult beds, there is a new 16-bed inpatient geriatric psychiatry unit, an outpatient clinic, partial hospital program and a fully accredited Psychiatric Residency Program. Our specially trained team of health care professionals includes: Board-certified psychiatrists, internal medicine hospitalists, clinical social workers, geriatric and psychiatric nursing staff, nutritionists, occupational therapists, and physical therapists. Responsibilities will include clinical care, and teaching residents, medical students and physician assistants.

SEMC is a community-based 317-bed tertiary care hospital and part of Caritas Christi Health Care, the second largest health network in Eastern Massachusetts. Academic appointment available to qualified applicants. Competitive salary and excellent fringe benefits are offered.

Interested applicants should send a current CV, and contact information for three references to: Christine Kady, Physician Recruiter, at Christine.Kady@caritaschristi.org or call 617-562-7717.

WORCESTER, DIRECTOR OF CLINICAL AND PROFESSIONAL SERVICES

The University of Massachusetts Medical School, Division of Public Sector Psychiatry is seeking an experienced, board certified psychiatrist to serve as CLINICAL LEADER at the closely affiliated Worcester State Hospital (WSH). Worcester State Hospital is a JACHO accredited Department of Mental Health hospital, providing inpatient services to patients who require intermediate and long term care for severe and persistent mental illness and/or acute forensic evaluations. WSH is a short walk from the medical school and the Brudnick Neuropsychiatric Research Institute is contiguous with the hospital. The Director of Clinical and Professional Services serves as a member of the hospital leadership, provides supervision to other psychiatrists, and performs clinical consultations and other patient services as needed. Candidates should have a career interest in Public Sector Psychiatry. Research interest and experience would be an added qualification. Faculty appointment and teaching at the medical school and at WSH (rotation site for 3rd year medical students and PGY 2 residents) is part of the job.

Send letter of interest and C.V. to:
Jeffrey Geller, MD
MPH, Director, Public Sector Psychiatry, UMMS
55 Lake Avenue North
Worcester, MA 01655
or to jeffrey.geller@umassmed.edu. AA/EOE.

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

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.

MICHIGAN

Great OPPORTUNITY!

Psychiatrist part-time or full-time for a well-established private group in Jackson, MI, 30-40 minutes from Ann Arbor or Lansing. Fax resume to 517-782-0310 or call 517-782-2442.

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. Please call **Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

J1 and H1 Opportunities in Michigan

Adult and child psychiatrists in out-patient and hospital practices, near Ann Arbor, Michigan. Locations meet criteria for designated shortage area. Please view our web site at Community-Psychiatry.com or call (800) 244-5807 for more information. Fax: (916) 285-0338 or Email stephanimartinez@communitypsychiatry.com your CV with MI in the subject line.

MISSISSIPPI

Region IV Mental Health Services, a community mental health center, designated as an HSA, located in north Mississippi, is seeking to employ two psychiatrists to work in its outpatient facilities. Monday/Friday 8:00 a.m. - 5:00 p.m./ no weekends, holidays, or on call. Great compensation package.

Call Charlie Spearman, Sr.
662-665-1000. www.timberhills.com

MISSOURI

Small Town/Big Opportunity: Income Potential $280k to $350k+ - Extremely lucrative opportunity close to Springfield. Medical Director position—Help mold & shape this program; Can be inpatient and nursing homes or inpatient and outpatient work. Unit is a 10-bed geropsychiatric program; outpatient adult &/or geriatric. Strong hospital support for behavioral health with plans for expansion. Please call Terry B. Good at 1-804-684-5661, Fax #: 804-684-5663; **Email: terry.good@horizonhealth.com.**

MONTANA

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

NEW JERSEY

Westampton - East of Philadelphia. 2 positions. General/Addiction AND Geriatric Psychiatrists. Fulltime positions - limited call! Contact Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc.com.

BERGEN REGIONAL MEDICAL CENTER

Attending Psychiatrists
Full Time, Part Time & Per Diem
On Call Coverage - Weekends/Holidays

Join the hospital as large as your multiplicity of skills!

Bergen Regional Medical Center is the largest hospital in New Jersey, spread over 65 rolling acres in Paramus. We are seeking several Attending Psychiatrists with exceptional diagnostic, pharmacological, counseling and team building skills to admit and treat patients, participate in departmental education and research, assume administrative duties as assigned and provide leadership in interdisciplinary treatment settings.

Requirements include an MD or DO along with completion of your residency in Behavioral Health, valid NJ licensure to practice and to prescribe controlled substances (DEA and CDS). Board certification (or current active participation in the examination process) is essential as is formal, supervised training and/or clinical experience.

We offer competitive compensation and full benefits. To learn more about us andapply online, visit: **www.bergenregional.com or email your CV, indicating Job Code: AP/PN to: ahuggins@bergenregional.com** or send CV indicating Job Code to: HR Dept., Bergen Regional Medical Center, 230 East Ridgewood Ave., Paramus, NJ 07652. Fax: (201) 967-4109. EOE.

NEW MEXICO

Presbyterian Healthcare Services (PHS) in New Mexico has openings in general adult and child/adolescent psychiatry. PHS is New Mexico's largest private, non-profit integrated healthcare system. The Behavioral Medicine Program is a full-service psychiatry department covering inpatient and outpatient care, intensive outpatient treatment, emergency and consultative psychiatry and mental health services embedded in primary care. These are full-time employed positions with the 500+ provider Presbyterian Medical Group. PHS provides competitive salary and benefits including malpractice insurance and relocation allowance. Additional information about PHS can be found at www.phs.org.

Contact: Susan Camenisch,
Physician Recruiter, PHS
E-mail: scamenisc@phs.org
Phone: 1-866-742-7053

NEW YORK CITY & AREA

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.

PSYCHIATRIC EMERGENCY ROOM COVERAGE

Brookdale University Hospital and Medical Center-seeks BC/BE Psychiatrists for full time, part-time, and per diem positions. Salaries and hourly rates recently increased with differential.

Please fax CV to Seeth Vivek, M.D., at 718-206-7169 or e-mail to SVivek@JHMC.org.

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

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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.

NEW YORK STATE

Psychiatrist

Broome Co. Mental Health Dept. seeking Board Certified Psychiatrist to work in outpatient clinic setting. Please submit a cover letter, along with Resume and Salary request to: BC Mental Health Dept. Attn: A. Mack, 229-231 State Street, 4th Floor Binghamton, NY 13901.

The Albany Medical Center (AMC) Faculty Practice Group is currently recruiting for two psychiatric faculty positions to join the Department of Psychiatry: one child psychiatrist and one general psychiatrist. Responsibilities include patient care, didactic and clinical instruction for residents and medical students. Participation in clinical research is encouraged.

We are also recruiting for an additional exciting new position with NYS Office of Mental Health (OMH) in Albany, NY: 0.5 as Dir of Bureau of Psych Serv and Research Institute Support, reporting directly to OMH Medical Dir and overseeing OMH-academic med ctr residency affiliations, assisting Med Dir in his role overseeing NYS Research Institutes, devel statewide CME; 0.5 AMC Outpatient Training Clinic.

Albany is located within easy driving distance of Boston and New York City. It offers excellent schools and diverse recreational and cultural opportunities. **Please visit us at: www.amc.edu/GreatPlace.**

Send CV to: Jana Mastandrea, Physician Recruitment Coordinator, Albany Medical Center, MC 47, 47 New Scotland Ave, Albany, NY 12208; email mastanj@mail.amc.edu, (518) 262-1333, Fax (518) 262-6996.

ELMIRA PSYCHIATRIC CENTER
Board Certified and Board Eligible Adult and Adolescent Psychiatrists

- Inpatient & Outpatient Programs (Adult & Children's) throughout Central New York.
- Immediate Adult Outpatient Opportunity on the Scenic Finger Lakes.
- All positions **Mon-Fri Days**
- **No managed care Insurance Demands.**
- **Optional** on-call pay.
- Student loan forgiveness program.
- Excellent NYS benefits package.
- Location offers: excellent housing values; little traffic; regional airport; Major College and University access (Cornell); 4hr drive to NYC, Toronto & Philadelphia.
- Lucrative Private Practice Opportunities.

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

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

St. Lawrence 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.

NORTH CAROLINA

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

Wilmington, North Carolina
Psychiatry Opportunity

New Hanover Regional Medical Center (NHRMC) seeks to hire Inpatient-based Psychiatrists to provide services within the medical center and a 62-bed Behavioral Health Hospital. NHRMC provides inpatient and outpatient psychiatric services for adults. Staff is specially trained to evaluate and treat patients for depressions, adjustment disorders, bipolar disorder, schizophrenia, psychotic and personality disorders. Inpatient units include: Dual-Diagnosis Unit, Behavioral Medicine Unit and Progressive Treatment Unit. Team consists of four physicians and two mid-level providers. Call is 1 in 5.

Being a Southern coastal town, Wilmington offers a variety of activities from an historic riverfront downtown, Thalian Hall performing arts center, museums, beaches and water activities, fishing, nightlife and great restaurants. Wilmington offers many family oriented communities and activities. Additionally, area schools are identified as some of the top in the state while the local university provides further educational opportunities. For more information about the Wilmington area, you may go to http://www.wilmingtonchamber.org/.

Position is a hospital employment model with excellent salary and benefits. Interested candidates should forward their CV to Elaine Haskell, at elaine.haskell@carolinashealthcare.org or call 800-847-5084.

FirstHealth OF THE CAROLINAS

PSYCHIATRIST
General Adult Psychiatry
Substance Abuse

FirstHealth of the Carolinas is a leading healthcare system that puts patients first. We are seeking a **Psychiatrist** at **Moore Regional Hospital in Pinehurst, NC.**

To qualify you must be a graduate from an accredited school of medicine and residency program in Psychiatry. Sub-specialty in addiction preferred. Active NC Medical License required.

For more information and to apply online, please visit **www.firsthealth.jobs**. An equal opportunity employer.

Appalachian State University, Boone, NC.

Counseling Center seeks staff psychiatrist to offer outpatient services to students. Full-time nine months, part-time summers. Excellent salary and benefits. NC license and board certification required. **To apply see http://counseling.appstate.edu/** or contact Search chair, Dr. Carol O'Saben, 828-262-3180 or osabencl@appstate.edu.

ROANOKE VALLEY/LAKE GASTON: Adult psychiatrist for private practice, primarily outpatient. Admit to 20-bed behavioral health unit at Halifax Regional.

Location: I-95 corridor, northeastern NC. Lake Gaston - 10 miles from Roanoke Rapids. 3 hours to Atlantic Ocean, 1 1/2 hours to Richmond, VA, Raleigh, NC and Norfolk/Virginia Beach. Outstanding water activities. Area population: 85,000.

Send letter and CV to Pam Ballew
at pballew@halifaxrmc.org.
www.visithalifax.com;
www.halifaxregional.org

OHIO

Northeast Ohio Geriatric Psychiatry Opportunity

Western Reserve Senior Care, an innovative home visit practice that makes visits to seniors in assisted living facilities, is recruiting for a FT or PT BC/BE Geriatric Psychiatrist. Make a true difference as you make visits to homebound seniors while managing the full scope of senior mental health issues including dementias and mood disorders. This opportunity offers a perfect balance of superb lifestyle and excellent compensation. Practice is affiliated with world class health systems in Cleveland, OH. Full time or part time considered. **Email CV to wmills@westernreserveseniorcare.com.**

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

One Hour to PHILADELPHIA - Two Hours from WASHINGTON, DC --Pretty Area - Amish Country -and so close to several amazing metro areas. Seeking a Psychiatrist for inpatient work in a med/surg hospital in eastern PA near Harrisburg. Can be primarily adult or gero or a mix of both. Offering salary/benefits, relo pkg, and bonus plan. Please call Terry B. Good at 1-804-684-5661, Fax #: 804-684-5663; **Email: terry.good@horizonhealth.com.**

PHILADELPHIA and suburbs- Adult Psychiatrist-Inpatient services. Child Psychiatrist-RTC OR Partial O/P.
CLARION-just east of Pittsburgh. Child Psychiatrist for inpatient & partial programs.
SHIPPENSBURG: General Psychiatrist with interest in Dual Diagnoses.
STATE COLLEGE: Child OR General Psychiatrist-Inpatient or all Outpatient. Fulltime positions some J1 eligible. Salary & benefits. Contact Joy Lankswert @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

Medical Director—Community Behavioral Health, part of Philadelphia's nationally recognized Department of Behavioral Health & Mental Retardation Services, currently has an exceptional opportunity for a Medical Director.

This senior leadership position will help us continue the system transformation initiative in Philadelphia, while providing direction to our team of psychiatrists and psychologists as we work to ensure the highest quality of behavioral healthcare to residents of the city. This highly visible position requires a MD or DO degree, a minimum of 10 years of direct care experience in general psychiatry or child psychiatry, including at least 5 years in a supervisory or management position, PA licensure, and board certification. Previous experience working with the Medical Assistance population and familiarity with MA regulations is also required.

For immediate consideration, please submit your C.V. with salary requirements in confidence to:
Director of Human Resources, CBH,
801 Market Street, Suite 700,
Philadelphia, PA, 19107.

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.

TENNESSEE

EAST TENNESSEE STATE UNIVERSITY JAMES H. QUILLEN COLLEGE OF MEDICINE DEPARTMENT OF PSYCHIATRY & BEHAVIORAL SCIENCES

GENERAL PSYCHIATRIST AND CHILD PSYCHIATRIST

Full-time positions available for General Psychiatrist and Child Psychiatrist. General Psychiatrist position may include inpatient and/or outpatient. Responsibilities include training of psychiatric residents and medical students and research activities. Salary is competitive with funding available through the Medical School, faculty private practice and extramural contracts. ETSU is located in the Tri-Cities area, rated #1 place in North America in cost-of-living, crime rate, climate and health care.

Applicants should submit a CV and two letters of reference to: Merry N. Miller, M.D., Chair, Department of Psychiatry and Behavioral Sciences, ETSU, Box 70567, Johnson City TN 37614. Telephone inquiries should be made at (423)439-2235 or e-mail at lovedayc@etsu.edu. AA/EOE.

Director Child Psychiatry Division

The Department of Psychiatry at **Vanderbilt University Medical Center** is currently recruiting a board certified child psychiatrist to provide leadership to a growing division of child psychiatry. This position responsibility will include the development of an expanding clinical program and quality improvement initiatives. Teaching of residents, child fellows, and medical students will be essential facets of the position, as well as scholarly pursuits in a specific area of expertise.

The department staffs a child and adolescent in patient unit, and a busy clinic of outpatient services. Our faculty has research interests in eating disorders, PTSD, anxiety and mood disorders, and autism. We currently have 19 full time faculty members in the Division of Child and Adolescent Psychiatry as well as 7 Child Fellows.

The successful candidate should have strong clinical skills and an established record of scholarly achievement. An established program of research and history of extramural grant funding are highly desirable. The successful candidate will also have evidence of leadership and demonstrated ability to promote an environment that fosters 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:

Keith G. Meador, MD,ThM, MPH
Professor and Vice-Chair for Faculty Affairs of Psychiatry
Professor, Center for Biomedical Ethics and Society
Vanderbilt University
1601 23rd Ave. South
Nashville, TN 37212.
Phone: (615) 936-6826
Fax: 615-343-8400
keith.meador@vanderbilt.edu.

Vanderbilt University Medical Center is committed to affirmative action, equal opportunity, and diversity in the workforce.

Professor - Cognitive Disorders/ Geriatric Psychiatry

The Department of Psychiatry at Vanderbilt University Medical Center is currently recruiting for a senior position in geriatric psychiatry to participate in a medical center wide initiative in Cognitive Disorders. This opportunity may include a designated endowed chair for the appropriate candidate. The position will include opportunities to collaborate with colleagues across the University in research and the development of relevant clinical and academic programs consistent with the interests of the successful candidate.

The successful candidate should have strong clinical skills and an established record of scholarly achievement. An established program of research and history of extramural grant funding are highly desirable. The successful candidate will also have evidence of leadership and demonstrated ability to promote an environment that fosters productive collaboration with colleagues in psychiatry and other disciplines.

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

Keith G. Meador, MD, MPH
Professor and Vice-Chair for Faculty Affairs in Psychiatry
Vanderbilt University
1601 23rd Ave. South
Nashville, TN 37212
Phone: (615) 936-6826
keith.meador@vanderbilt.edu.

Vanderbilt University Medical Center is committed to affirmative action, equal opportunity, and diversity in the workforce.

TEXAS

Adult Psychiatrists - San Antonio, TX

Vericare (www.vericare.com) is the leader in providing mental health services to residents of long term care. We have immediate, salaried positions for Adult or Geriatric Psychiatrists in San Antonio. We offer flexible scheduling, 100% paid malpractice, administrative support, no on call/weekend requirement and a complete benefits package. Board Certified preferred. **Call Sanel Lekic at 800-257-8715 x1166 or email your resume/inquiry to slekic@vericare.com.**

AUSTIN area: Child Psychiatrist - Residential Treatment Program. Employed position with salary & benefits.
McALLEN: Salaried employment OR Private Practice. Inpatient & Outpatient. General Psychiatrist.
WEST TEXAS San Angelo: Child Psychiatrist. Salaried Employment or Private Practice.
DALLAS: Independent contractor for part-time - full-time inpatient caseload.
Contact: Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc.com.

JOIN OUR MISSION OF SERVICE TO OUR COMMUNITY!

Metrocare Services is north Texas' leading nonprofit organization dedicated to helping people with mental illness and developmental disabilities live healthier lives. When you join Metrocare Services, you play an important role in the lives of the people we serve.

Metrocare has an exciting opportunity for a Staff Psychiatrist in Dallas, TX. The Psychiatrist will provide psychiatric assessments, medication management and continuity of care for adults in an outpatient clinic. This position has the potential of a career path leading into an Associate Medical Director's position.

Must be a graduate from an accredited Medical School with a specialty in psychiatry. Experience in the delivery of mental health treatment of adults and some leadership experience. Licensed in the State of Texas; board eligible or certified. Must have computer experience.

Metrocare provides an EXCELLENT compensation and benefits package, including a sign-on bonus. We offer medical, healthcare spending account with company contributions, dental, vision, and 403(b) plan with a company match. Other great benefits include 10 paid holidays, generous personal leave, tuition reimbursement, CME and licensure reimbursements, and much more.

For immediate consideration, please submit CV to Email: Yolanda.Ross@metrocareservices.org, Phone: 214-743-6142, Fax (214) 630-3625, **Website: www.metrocareservices.org.**

VIRGINIA

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.

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.

VALLEY community services board

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.

WEST VIRGINIA

BC/BE Psychiatrist

West Virginia University School of Medicine Department of Behavioral Medicine and Psychiatry is recruiting an entry level BC/BE psychiatrist to assume a full time faculty position for general inpatient and outpatient services, including teaching and other scholarly activities at **Fairmont General Hospital in Fairmont, WV**. Applicants must be board certified/eligible in Psychiatry by October 1, 2010. This non tenure, clinical emphasis track position will offer diverse experiences in clinical and administrative psychiatry.

Applications will be accepted until November 15, 2010. Salaries are competitive and benefits are excellent.

Please forward letter of interest, curriculum vitae, and three letters of recommendation to Carl R. Sullivan, M.D., Vice Chair, Department of Behavioral Medicine and Psychiatry, c/o Laura Blake, blakel@wvuh.com, Fax 304-293-0230. WVU is an AA/EO employer.

Shenandoah Valley- Recruiting 3rd psychiatrist for Behavioral Health department in multidisciplinary community health center **90 minutes from Washington/Baltimore**. Experience/training in addictionology and/or child/adolescent psychiatry a plus. Salaried position w/ incentive compensation, standard benefits. Approved site for Federal Loan Repayment. Contact Tina Burns 304 596 2610, ext 1066; tburns@svms.net FAX 304 263 0984. Visit our website www.svms.net.

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BC/BE Psychiatrist

West Virginia University School of Medicine Department of Behavioral Medicine and Psychiatry is recruiting an entry level BC/BE psychiatrist to assume a full time faculty position for general inpatient and outpatient services, including teaching and other scholarly activities at **City Hospital in Martinsburg, WV**. Applicants must be board certified/eligible in Psychiatry by June 30, 2010. This non tenure, clinical emphasis track position will offer diverse experiences in clinical and administrative psychiatry.

Applications will be accepted until November 15, 2010. Salaries are competitive and benefits are excellent.

Please forward letter of interest, curriculum vitae, and three letters of recommendation to Carl R. Sullivan, M.D., Vice Chair, Department of Behavioral Medicine and Psychiatry, c/o Laura Blake, blakel@wvuh.com, Fax 304-293-0230. WVU is an AA/EO employer.

WISCONSIN

Luther Midelfort
Mayo Health System

Eau Claire, Wisconsin: Luther Midelfort - Mayo Health System, is seeking a **BC/BE Adult Psychiatrist** with interest in inpatient and outpatient work. The ideal physician will be collaborative and engaging in their approach to patients and non-physician team members. Call of 1:7. Outpatient unit is attached to a newly renovated 20 bed inpatient unit.

Luther Midelfort - Mayo Health System is a vertically integrated, physician directed hospital and multi-specialty clinic of 250 physicians owned by Mayo Clinic. Our physicians practice evidence-based, protocol-driven medicine.

Eau Claire is a university community with a metro area of 95,000, located 90 minutes east of Minneapolis. Business Week ranked Eau Claire as the best place to raise your kids in the State of Wisconsin for 2009. Eau Claire was also ranked one of the safest small cities in US (12/09). Outstanding schools, a family oriented community, a state with a favorable malpractice climate, and a strong compensation and benefits package may be expected.

For more information, contact Cyndi Edwards 800-573-2580, fax 715-838-6192, or e-mail edwards.cyndi@mayo.edu . You may also visit our website at **www.luthermidelfort.org EOE** EOE.

STATE OF WISCONSIN DEPARTMENT OF CORRECTIONS

Psychiatry Director
WI Department of Corrections

We are looking for a board-certified psychiatrist for a full-time administrative position centered in Madison, WI. This position is responsible for oversight of psychiatric care within the Department, including supervision of other psychiatrists, development of formulary policy, and coordination of quality improvement activities. The position works closely with, and reports to, the Mental Health Director (also a psychiatrist).

Starting salary: Between $215,000 and $227,500 per year depending on qualifications and experience, plus an excellent state benefits package.

Qualifications: Board certification in general psychiatry is required. Administrative and forensic experience is helpful.

Application Information
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Or, for further information, contact:
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Mental Health Director
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Fellowships

FELLOWSHIPS and CHIEF RESIDENCIES in PSYCHOSOMATIC MEDICINE AT YALE UNIVERSITY

This ACGME-accredited one-year fellowship has Psychosomatic Medicine Fellowship positions available at the PGY-V level or above, starting July 1, 2011, as well as PGY-IV chief resident positions (PGY-IV training would not qualify for subspecialty certification). The program offers training in consultation-liaison psychiatry at Yale New Haven Hospital and at the VA Connecticut Healthcare System. Contact Paul Desan, MD, PhD, Yale New Haven Hospital, 20 York St CB2039, New Haven, CT 06504. paul.desan@yale.edu, (203) 785-2618.

MGH Schizophrenia Fellowship

The Massachusetts General Hospital Schizophrenia Program under the leadership of Dr. Donald Goff is seeking applicants for a new and innovative, one-year fellowship at the PGY-V level. Now in its 2nd year, the Schizophrenia Fellowship aims to provide a complete experience in key aspects of schizophrenia care, including pharmacology and medical health monitoring. In addition to providing direct clinical care to patients in our first episode program, our community clinic, and our clozapine clinic, fellows participate in the MGH Schizophrenia Program's educational curriculum. The MGH Schizophrenia Program is known for its research programs, and fellows have the opportunity to participate in ongoing projects.

Qualified applicants will have completed and accredited psychiatry residency in the US and have passed all necessary exams to obtain a medical license in Massachusetts. Applications are now being accepted for the 2011/2012 academic year.

Interested applicants should contact Oliver Freudenreich, M.D., Director, MGH Schizophrenia Fellowship. Phone (617) 912-7835, e-mail ofreudenreich@partners.org.

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.

STANFORD UNIVERSITY

RESEARCH TRAINING FELLOWSHIPS IN CLINICAL PSYCHOLOGY. Stanford University Department of Psychiatry and Behavioral Sciences anticipates openings for postdoctoral fellows to begin 7/2011 and 9/2011 of the 2011-12 academic year. NIMH-funded training fellowships are designed for those who plan to pursue careers in clinical research with a specialization in adult disorders including mood, anxiety, eating disorders, insomnia, or related areas. These are one- to three-year positions contingent upon funding. Fellows will participate in research projects with faculty mentors and are also expected to develop their own investigations. Candidates should have a clearly identified area of interest and demonstrated capability in scholarly research. Stipends for NIMH training fellowships are $47,500 plus benefits. These positions are open to PhDs and MDs. Candidates are encouraged to contact faculty in their area of interest before applying (http://psychiatry.stanford.edu).

Requirements: All PhD applicants must have: 1) attended an APA-accredited graduate program; 2) completed an APA-accredited internship; 3) completed all requirements for their PhD prior to beginning their appointment. MD applicants must have completed an approved residency program. Applicants must be US citizens.

To apply: Send the following as email attachments to Beth Sherman (bsherman@stanford.edu): 1) a cover letter specifying research aims; 2) your CV; 2) three letters of recommendation sent by email directly from your recommenders to Beth Sherman (bsherman@stanford.edu). (Questions: bsherman@stanford.edu.) Minority candidates are strongly encouraged to apply. **Application deadline is 1/5/2010.**

RESEARCH FELLOWSHIP IN SUBSTANCE ABUSE M.D. or Ph.D.

Columbia University/New York State Psychiatric Institute fellows receive extensive training in clinical and/or laboratory research. For interested psychiatrists, the fellowship has a two-year, ACGME-accredited training program in addiction psychiatry sponsored by Columbia University and New York Presbyterian Hospital. The addiction psychiatry program provides comprehensive clinical and research training experiences in a variety of substance abuse treatment settings. Individuals with strong research interests are encouraged to apply.

For applications:
Frances R. Levin, M.D.
Director Research Fellowship in Substance Abuse
1051 Riverside Drive, Unit 66
New York, NY 10032
(212) 543-6105, Fax: (212) 543-6018
FRL2@columbia.edu

In accordance with Federal funding regulations, this announcement is directed to U.S. citizens, non-citizen nationals and foreign nationals with permanent resident status. Columbia University is an AA/EEO employer.

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

Addiction Psychiatry Fellowship- One-year, PGY-5 position, to begin July 1, 2011, at the University of Illinois at Chicago, Department of Psychiatry. Fellow will acquire expertise in treating addictions through comprehensive training in a variety of inpatient, outpatient, and consultative settings, including residential and outpatient detoxification, rehabilitation, and relapse prevention. Ethnically diverse, adolescent through geriatric patient populations, including dual-diagnosis patients. Opportunities for supervised teaching and clinical or basic science research in addictions. No on-site night call. Rodney Eiger, M.D., Fellowship Director.

Behavioral Neurology/Neuropsychiatry Fellowship- PGY-5 and 6 - This UCNS-accredited program is a one- or two-year interdisciplinary fellowship to begin July 1, 2011. Offers clinical/research training in neurodegenerative diseases, neuropsychiatric and neurobehavioral syndromes, as well as cognitive neuroscience. Supervision is provided by faculty of the UIC's Neuropsychiatry/Neurobehavioral Programs, Center for Cognitive Medicine, and Neurology faculty. Michael J. Schrift, DO, MA, Fellowship Director.

PRIME Residency- One-year, PGY-4 position, to begin July 1, 2011 at the Jesse Brown VA Med Ctr/University of Illinois at Chicago, Department of Psychiatry. The trainee will receive psychiatric consultation-liaison training as a member of a primary care team (PRIME) and will educate primary care team about identification and management of common psychiatric disorders. Resident will participate in ongoing didactic programs and provide care in community-based outpatient clinics. Opportunities for clinical research, electives in ECT, home care, telepsychiatry, addiction and geriatric psychiatry available. Supervision is provided by faculty from the Depts of Psychiatry and Medicine at JBVA Medical Center and the University of Illinois at Chicago.

Women's Mental Health Fellowship- This is a one-year, PGY 4 or 5 position, to begin July 1, 2011, at the University of Illinois at Chicago, Department of Psychiatry. We are seeking an exceptional candidate who wants to develop expertise in reproductive and gender-linked psychiatric disorders. Our program has received the ACP Award for Creativity in Psychiatric Education, and the APA Gold Award in recognition of our pioneering work in women's mental health.

USMLE Step 3 required for all the above positions. Detailed descriptions and applications are on the Residency web site: http://www.psych.uic.edu/education/residents/fellowships. Mail applications to: Robert W. Marvin, MD, Dept. of Psychiatry (MC 913), 912 S. Wood St., Chicago, IL 60612. Questions to e-mail: recruit@psych.uic.edu; or by phone: (312) 996-3583, on or before December 31, 2010. The UIC and JBVA are AA/EOE.

OREGON HEALTH & SCIENCE UNIVERSITY/PORTLAND VA MEDICAL CENTER, OHSU/PVAMC in Portland, Oregon is recruiting Addiction Psychiatry, Geriatric Psychiatry, and Psychosomatic Medicine Fellows for the academic year beginning July 1, 2011. Fellowships are ACGME-accredited at the PGY5 level. These are OHSU fellowships based primarily at the PVAMC, with teaching provided by OHSU faculty. Portland is a beautiful and livable city with easy access to many outdoor recreational activities. Detailed information for fellowships may be found on-line at **http://www.ohsu.edu/psychiatrytraining.**

- **Addiction Psychiatry Fellowship.** OHSU offers two Addiction Psychiatry fellowship positions. The fellowship is based at the Portland VA hospital and includes rotations in the Opioid treatment and Buprenorphine programs, the general substance abuse treatment programs [including co-occurring disorders], smoking cessation, pain/addiction clinics, consult/liaison, and child/adolescent. OHSU is the site of the MARC [Methamphetamine Research Center], a Node of NIDA's Clinical Trials Network and the One Sky Center for Native American Addiction and Mental Health. A second year devoted to research in the addictions is possible for selected candidates. Contact Michael Resnick MD, V3-SATP, P.O. Box 1035, Portland, OR 97207; Michael.Resnick@va.gov.

- **Psychosomatic Medicine Fellowship.** Flexible program with clinical and research opportunities. Training sites include ambulatory care, specialty services, and consultation to inpatient med/surg. Research and clinical strengths in health services, mental disorders in primary care, pain, end-of-life/palliative care, ethics, Parkinson's disease, and substance abuse. Contact Todd Eisenberg MD, Portland VA Med. Ctr., P.O. Box 1034 (P3MHDC), Portland, OR 97207; Todd.Eisenberg2@va.gov.

INOVA HEALTH SYSTEM

Entering its 34th year, this ACGME-accredited fellowship on Psychosomatic Medicine is currently accepting applications for three PGY-5 positions to start July 1, 2011. Under the guidance of **Dr. Thomas Wise** and **Dr. Catherine Crone**, the fellowship offers consultation-liaison training in a wide variety of medical specialties in both inpatient and outpatient settings. This includes: oncology, ob/gyn, HIV, trauma, organ transplantation, pulmonary medicine, and cardiology. Didactic seminars address clinical, biological, and psychodynamic approaches to understanding the medically ill. Opportunities in teaching, research, and outpatient psychotherapy are readily available. Training is tailored to fellow's area of interest and career goals. The fellowship is based at Inova Fairfax Hospital, an 833-bed tertiary care teaching facility located in the suburbs of Washington, D.C.

Interested individuals should contact:

Catherine Crone, M.D.
PM Fellowship Program Director
George Washington University
Medical Center
c/o Inova Fairfax Hospital
3300 Gallows Road Falls Church, VA 22042
Phone: 703-776-3380
E-mail: cathy.crone@inova.org.

Residencies

PGY 2 and PGY 4/5 Residency Positions at Yale University

Each year the **Yale University Department of Psychiatry** admits four residents at the PGY2 level. The Department also has PGY 4 and 5 positions available. Sites include the Connecticut Mental Health Center, Silver Hill Hospital, VA Connecticut Healthcare System, Yale New Haven Hospital and Yale University Health Services. Positions include inpatient, outpatient, ER and C-L. Each position offers clinical and academic opportunities.

Applicants interested in **PGY 2 or 4/5 positions** should contact Ann Cohen DePalma at 203.785.2095.

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Volunteer for DSM-5 Field Trials

American Psychiatric Institute for Research and Education
Practice Research Network is recruiting

Practicing Psychiatrists

As the 2013 date for publication of the fifth edition of *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) draws near, the research and clinical experts working on DSM-5 will be finalizing the diagnostic criteria and testing potential revisions and assessment tools in field trials across a number of clinical settings.

The DSM-5 Field Trials involving practicing psychiatrists will focus primarily on 1) the feasibility and clinical utility of the proposed modifications to the diagnostic criteria for a broad range of disorders in the full range of clinical settings, and 2) the feasibility and clinical utility of cross-cutting and diagnostic-specific dimensional measures that are incorporated into the diagnostic scheme for DSM-5.

Practicing psychiatrists interested in volunteering for potential participation in DSM-5 field trials should send an email to aparesearch@psych.org with the following information:

- Full name
- Institution or organizational affiliation
- Mailing address
- Job title
- Preferred e-mail
- Area of expertise (e.g., child psychiatry, geriatric psychiatry, etc.)

This information will help determine your eligibility to participate in the DSM-5 field trials.

For information about revisions to the DSM please visit www.DSM5.org

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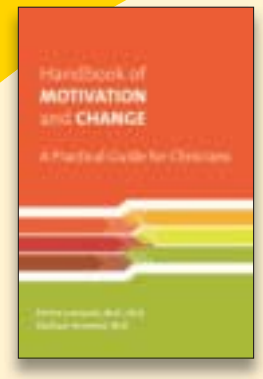

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A Clinical Handbook

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This well-documented and articulate manual gathers in one place the psychodynamic psychotherapy thinking and research on each of the Axis II personality disorders. The book includes the work of 22 contributing writers in addition to the three primary authors, John F. Clarkin, Ph.D., Peter Fonagy, Ph.D., and Glen O. Gabbard, M.D. The focus of the book is the psychodynamic conceptualization, assessment, and treatment of the personality disorders as currently described in the Diagnostic and Statistical Manual of Mental Disorders. The authors conclude that new research and reviews indicate that psychodynamic treatments are effective for personality disorders, and their impact is as great as that of cognitive-behavioral treatments.

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A Comprehensive Review of Its Cost-Effectiveness

Edited by Susan G. Lazar, M.D.
Group for the Advancement of Psychiatry

This book reviews the stigma associated with psychiatric illness and its true cost to society. *Psychotherapy Is Worth It* examines attitudes undermining the provision of psychiatric care including psychotherapy and the resulting lack of treatment leading to increased morbidity and mortality.

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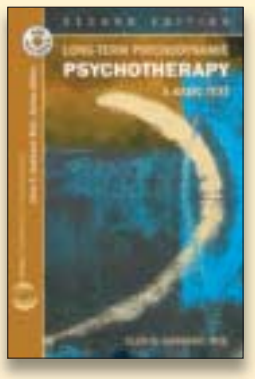

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