Volume 43
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December 5, 2008

Newspaper of the
American
Psychiatric
Association

PSYCHIATRIC NEWS

Inside

PERIODICALS:
TIME-SENSITIVE MATERIALS

Credit: Sylvia Johnson Photography 2008

Blair Romer, M.D., shows off the APA Assembly's Profile of Courage Award, which he received in November for his efforts to fight state hospital officials whose plans for changes at the prison medical facility in Vacaville, Calif., would have threatened patient care. The award was presented by Area 6 Representative Marc Graff, M.D. (center), and Deputy Representative Barbara Yates, M.D. See page 9.

More Professionals See Value Of Volunteering To Help Vets

Two more organizations in the mental health field join APA to support Give an Hour's program of voluntary mental health services for members of the armed forces.

BY AARON LEVIN

Ongoing wars in Iraq and Afghanistan continue to take their toll on members of America's armed forces after they return home, not just while they are in the line of fire.

"All wounds are not physical, but all wounds need attention," said former APA President Carolyn Robinowitz, M.D., the day before Veterans Day. "It's not just the troops but also their family members" who are suffering.

Robinowitz spoke at a press conference organized by Give an Hour, a nonprofit group in which psychiatrists and mental health professionals donate an hour a week of their time to helping these war veterans and their loved ones cope with the stresses of service, combat, and separation (*Psychiatric News*, March 7).

APA and the American Association of Pastoral Counselors have been working with Give an Hour for much of the last year, said founder Barbara Romberg, Ph.D., who welcomed the additional participation of the American Psychological Association and the National Association

please see ***Volunteering*** *on page 36*

Parity Law to Be Focus Of AMA Education Effort

Psychiatrists at the recent AMA meeting testified on resolutions regarding TRICARE payment to physicians, recruitment of mental health clinicians in the TRICARE system, and on support for childhood immunization.

BY MARK MORAN

The AMA will be providing educational materials to physicians and patients about the newly enacted federal parity law on insurance coverage of mental illness and substance abuse.

There was virtually unanimous support from a variety of physicians for the measure approved at last month's Interim Meeting of the House of the Delegates in Orlando, Fla.

Original wording in the resolution, submitted by the Minnesota delegation, called for a "nationwide campaign." Though there was considerable support for such an undertaking, the fiscal note attached to the original wording was $3 million to $7 million, a figure that was widely considered untenable.

Most delegates expressed skepticism that an educational effort would need to cost so much, and the wording finally approved called on the AMA to "develop information to be posted on our Web site that would educate physicians and the public about the benefits now afforded to them by recently passed Mental Health Parity legislation."

The resolution received vocal support from members of the AMA Board of Trustees, residents and medical student representatives, and physicians of all stripes.

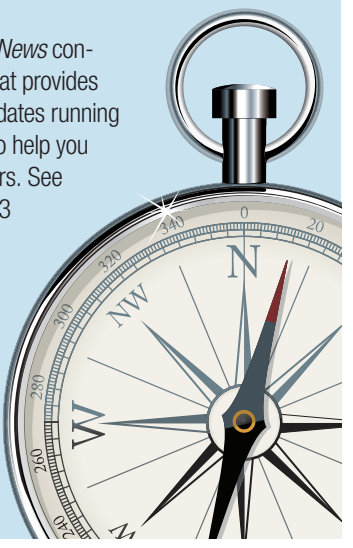
Neurologist and delegate Benjamin Whitten, M.D., of Minnesota said the parity act was a "victory" for the AMA, physicians, and patients. "The AMA has had long-standing policy in support of this," Whitten said.

"We are in a time of fiscal restraint," said AMA board member Peter Carmel, M.D. "But the board is working with a consultant to totally revise our Web site, and it will be a good vehicle for education. We will put up on the AMA Web site the educational materials that are needed to inform both physicians and the lay public about mental health parity."

please see ***Parity*** *on page 36*

Why Should You Vote?

This issue of *Psychiatric News* contains a special section that provides information on the candidates running in APA's 2009 election to help you choose APA's next leaders. See page 17. Also, see page 3 for a special message from APA President Nada Stotland, M.D., M.P.H., on why you should learn about the candidates and cast your ballot. Voting begins on **DECEMBER 22.**



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Is Hispanics' Depression Outcome Affected by Language Choice?

Whether clinical trial participants chose to be addressed in Spanish rather than English was associated with depression severity and outcomes.

BY AARON LEVIN

English-speaking Hispanic participants in a major clinical trial responded better to antidepressant treatment than did their Spanish-speaking peers, but language preference is probably a marker for other medical and social factors, said a report in the November *Psychiatric Services*.

The study, a secondary analysis of the STAR*D study of depression treatments, points to the need for culturally informed approaches to psychiatric diagnosis and care, said Andres Pumariega, M.D., chair of the Department of Psychiatry at the Reading Hospital and Medical Center in Reading, Pa., who was not involved in the report.

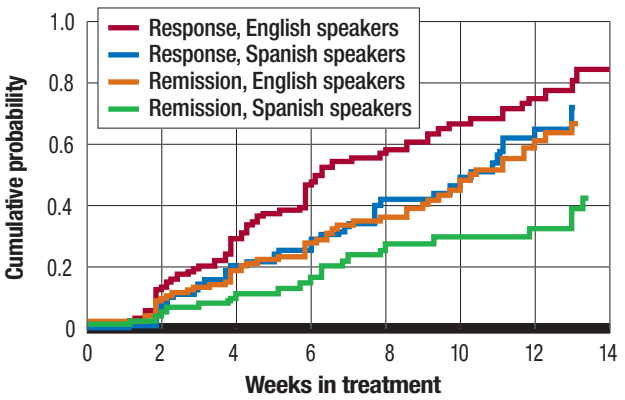
"Psychiatrists and primary care physicians need training in a culturally specific understanding of illness, its cultural expression, and the signs and symptoms of illness for the population we are serving," said Pumariega, chair of APA's Committee of Hispanic Psychiatrists.

In the STAR*D study, researchers led by Ira Lesser, M.D., chair of psychiatry at Harbor-UCLA Medical Center in Los Angeles, sought to find out if Hispanic patients with major depressive disorder who preferred communicating in Spanish (n=74) differed in illness severity or response patterns compared with Hispanic patients who preferred speaking in English (n=121). The participants all were enrolled in the trial from two Southern California treatment sites and accounted for 60 percent of the Hispanics in the STAR*D trial.

Research coordinators who were both bilingual and bicultural assessed participants choosing Spanish, and bilingual and bicultural physicians managed their treatment with the antidepressant citalopram.

Language Linked to Response, Remission

The time to achieve a response or remission was significantly longer for Spanish-speaking STAR*D patients taking citalopram than for their English-speaking peers. (n = 195)



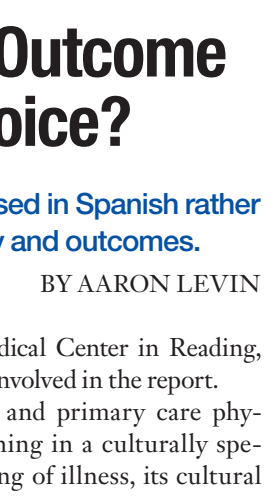
Source: Ira Lesser, *Psychiatric Services*, November 2008

please see ***Language*** *on page 16*

Important Annual Meeting Announcements

- **For APA Members Only: Register Now!**

APA members may now take advantage of an exclusive opportunity to register and make their hotel reservations for APA's 2009 annual meeting in San Francisco. Nonmembers will not be able to do so until December 14. Meeting and hotel information, including rates and hotel descriptions and course information, can be accessed on APA's Web site at <www.psych.org> by clicking on the 2009 annual meeting logo and then logging into Members Corner. San Francisco is a popular city for APA members, so you are advised to act quickly.



- **Look for Annual Meeting Information Online**

APA has gone *green!* The Association is trying to do its part in helping save the environment, while also saving money on printing and mailing costs. Thus, APA is no longer mailing the Annual Meeting Advance Registration Packet, but is instead posting information about the annual meeting on its Web site regarding registration, housing, the preliminary program, courses, and other topics. Access information appears above.

More information is available by contacting Vernetta Copeland at (703) 907-7382 or vcopeland@psych.org.

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- ***Psychiatric News* Web Site:** pn.psychiatryonline.org/
- **APA and the APA Answer Center:** (888) 35-PSYCH in the U.S. and Canada; in other countries: (703) 907-3700. The Answer Center is open Monday through Friday, 8:30 a.m. to 6 p.m. Eastern time. All APA departments and staff may be reached through the Answer Center. Fax: (703) 907-1085 E-Mail: apa@psych.org
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Time to Vote Again

BY NADA STOTLAND, M.D., M.P.H.


Credit: David Hathcox

It does make a difference. Fewer than half of our members vote in our APA elections. I suppose the most optimistic hypothesis is that our members think that any candidates chosen by the Nominating Committee must be excellent potential APA leaders. Less optimistic hypotheses might be these: it doesn't make any difference who is elected because the candidates are interested in personal aggrandizement rather than in the issues affecting our work, or APA has little impact on the world in which we study, teach, and practice psychiatry anyway. Perhaps you find that the biographical information and statements that the candidates provide to *Psychiatric News* don't enable you to differentiate among them. From my vantage point, having spent many years closely observing the function of our Board and Assembly, it makes an enormous difference whom you elect. Some of our leaders have worked hard for APA. Some have spent APA's resources wisely. Some have brought creative ideas and important relationships. Some, but not all.

The Board, which includes APA's officers, makes the decisions about how to spend your hard-earned dues; whether to take official positions on the issues of the day and what positions to take; what state, federal, and Supreme Court cases to weigh in on and what evidence to adduce; what messages about psychiatry to offer the public and how; how to educate elected and appointed government leaders about the importance of psychiatric research, training, and clinical care; and whom to hire as the medical director/chief executive officer of APA, how much salary to pay, and how much to allocate for the running of the APA office.

The president of APA appointed the leadership of the *DSM-V* process; the members of the Board decided whether there should be limits on industry (and some other kinds of) income. They approved an extensive disclosure process. The secretary-treasurer of APA, with a small committee appointed by the president, painstakingly reviewed the disclosure documents for each suggested *DSM-V* participant; the Board voted on each one who passed muster with that committee. Our voting members chose the individuals who made those decisions. As of this writing, Sen. Grassley has not offered a response to the extensive report we provided, at his request, at the beginning of September, but we may face further inquiries or Senate committee hearings. If hearings take place after my term ends in May 2009, the leaders you elect will speak for you.

Our last APA election precipitated complaints from members who felt they should have been better informed about candidates' relationships with the pharmaceutical industry, an issue that turned out to be relevant to the image of our Association and our field. While *Psychiatric News* does ask candidates to disclose their professional activities and sources of income, we may want to pose questions that elicit more specific information in the future. For example, we might want to ask candidates about their views on health care system reform, coercive treatment, the role of psychotherapy or religion in psychiatric practice, as well as expertise in running meetings, managing budgets, working with the media and government officials, and communicating with you. Whatever questions are asked of the candidates, they may not cover issues that matter to you. Now is the time to take the opportunity to "Google" the candidates and, equally important, to contact them directly with your questions about their backgrounds, views, and intentions. When I ran for president-elect, one member e-mailed me to ask whether APA should take positions on "social issues." Probably he did not agree with the answer I sent—but he knew where I stood.

I will chair the Nominating Committee for the 2010 APA election. We will begin our deliberations next July. There will be an announcement in *Psychiatric News* soliciting nominations. You may hear from potential candidates for next year when the current election is decided. Look at the list of officers and other Board members on APA's Web site. What attributes and experiences would you like to see represented? Do you see room for improvement in the balance of, for example, academicians versus private practitioners and senior psychiatrists versus promising new leaders, geographic and subspecialty distribution, and the representation of minority and underserved groups? After you check out this year's candidates and cast your very important vote, let me know what background and experience you would like to see represented among the candidates on next year's ballot.

It's up to *you* to pick the leaders who will take APA where you want us to go. ■

New Discount Policy Announced

Members registering for APA's annual meeting must pay their 2009 dues by the start of the meeting or join the Scheduled Payment Plan to obtain the discounted member registration rate. For more information about the payment plan, please visit the Membership section of APA's Web site at <www.psych.org/Resources/Membership.aspx> or call APA at (888) 35-PSYCH.

Author Battles Silence Surrounding Depression in Black Communities

Author Terrie Williams is passionate about the value of psychotherapy and the need to make it accessible to African-American communities, but says such therapy is not an option for many black people.

BY MARK MORAN

When Terrie Williams, an African-American writer, speaker, and public-relations consultant, wrote about her experience with depression in a 2006 article in *Essence*, a magazine aimed at black women, she and her editors reaped a response they had not counted on.

"I was stunned," she told *Psychiatric News*, by the number of readers who wrote to the magazine to share their stories of often untreated emotional suffering. "It was overwhelming. I wasn't prepared for the depth of pain and gut-wrenching stories from people who just finally have an opportunity to pour out their childhood wounds.

"There was something sobering about receiving so many letters and seeing them in print [and] about the fact that I was the only person they had ever told," said Williams.

The flood prompted her to write a book, *Black Pain: It Just Looks Like We're Not Hurting*, published this year by Scribner. Part confession, part advocacy, part history lesson, and part resource guide to finding treatment and support, the book is a frontal assault on what Williams calls the silence that surrounds depression and other mental illnesses in the black community.

"I wanted the book to be accessible and in your face about why we as individuals and a community are dying," she said in an interview.

Credit: Ellen Dallager

Terrie Williams: "There are a lot of people who believe depression is the devil, who believe that you pray it away and that anything other than prayer is a betrayal of God."

In October Williams brought her message to a special "Conversations" event sponsored by the American Psychiatric Foundation at the APA Institute on Psychiatric Services, where she spoke before an audience with psychiatrist Altha Stewart, M.D.

She 'Lifts the Veil on Black Trauma'

Her book has garnered praise from many quarters, including from APA Director of Minority and National Affairs Annelle Primm, M.D., and Chicago-based community psychiatrist Carl Bell, M.D. In a lengthy quote prefacing the book, Primm wrote that Williams "lifts the veil on Black trauma, loss, and victimization, validating our daily strife and lifelong struggles."

Primm added, "Terrie explains the source and impact of Black psychological wounds and demoralization. She gently removes the armor, looks behind it, and helps us realize that this is shared pain and we are not alone. The book reminds us that the strength and resources of the village must be brought to bear to open the door to break the silence, neutralize the pain, harness hope, and set free our collective spirit."

Williams is also president and founder of the Stay Strong Foundation, which works to "support, educate, and inspire America's youth through a series of programs and events that are designed to raise awareness of teen issues, promote the personal well-being of young people, and enhance their educational and professional development."

Williams is especially passionate about the value of psychotherapy and the need to make it accessible and acceptable to African-American communities.

"I think it's necessary to breathe, to really live," she said. "But as a community [African Americans] are not familiar with therapy and don't feel entitled to the therapeutic community as a whole. It's just not thought of as an option."

But there are exceptions. In the chapter "I Wish It Would Rain," in which she focuses on the legacy of anguish borne by black men, Williams describes the experience of one psychiatrist, Denese Shervington, M.D., M.P.H., a professor of clinical psychiatry at Columbia University Medical Center, who successfully used psychotherapy as an adjunct to a traditional drug-treatment program for cocaine-addicted black men.

"Not only did the black men come to therapy, they came on time, looked forward to their sessions, and were eager to be heard," Williams wrote in her book.

Racially Sensitive Therapists Needed

Williams also wrote that African Americans would "be more receptive to therapy if we could see racially sensitive therapists at rates that were affordable to us."

In an interview with *Psychiatric News*, she said that being racially sensitive doesn't necessarily require that a therapist be of the same race or ethnicity as the patient. Williams calls it a matter of professionalism.

"When I take on a project, I have to identify the different audiences I am trying to address and tailor the message accordingly," she said. "So when you are going to take on a particular patient, if you are really good at what you do, you make it your business to do a little research."

Williams described vignettes of the nuanced social and psychological adjustments black men and women are required to make on a daily basis, accommodations to social conditioning that go largely unnoticed by others: tall, strong, black men who walk or hold themselves differently so as to not to appear intimidating, for example, or the heightened fear some very dark-skinned black men have learned to expect from others.

"Or what happens to your spirit when a white woman clutches her bag in an elevator or on the street [in the presence of a black man] just because it's second nature," Williams said. "It's not just rolling off your back; it's having an effect on you."

Too often, she said, these ingrained responses play out in pathologies with larger, socially tragic consequences. "In the streets every single day, we are taking each other out. We are in pain, and we haven't even named it."

Spirituality Can Play Negative Role

Her book also takes on the subject of spirituality—the need for it in any healing and the importance of Christian spirituality throughout African-American history—but also the resistance some black clergy and churchgoers may have to viewing emotional suffering through the lens of mental health and illness.

"We have a long way to go," Williams told *Psychiatric News*. "There are a lot of people who believe depression is the devil, who believe that you pray it away and that anything other than prayer is a betrayal of God."

She recalled speaking to a church congregation. "The minister stood up and started by saying he had never spoken about this publicly," Williams recalled. "He said that when he was 2 years old, he was told his mother was dead." In fact, it turned out she was in a psychiatric hospital.

But there is evidence that the tide is turning. In this fall's edition of the magazine *Real Health: The Guide to Black Wellness*, the featured article is titled "Take Off the Mask: Understand Depression and Take Control of Your Life."

The article recounted the story of a black teenager who jumped from the window of his parents' apartment. He survived with a shattered leg, broken pelvis and jaw, and fractured wrist. Several months later he was sitting in a wheelchair sharing his story at a congressional briefing on the stigma of mental illness.

"Parents and young adults should know the symptoms and should know where or how to get help," the youngster is quoted as saying. "And if telling my story saves a life, then I know why God saved me and why I have the integrity to tell my story."

Information about the Stay Strong Foundation, including how to volunteer, is posted at <www.thestaystrongfoundation.org>. ■

Organization Raises Profile of Nurses In MH Care

Mental health advocate and former first lady Rosalynn Carter highlights the role of nursing in reassuring patients who may be anxious about receiving mental health care.

BY RICH DALY

Rosalynn Carter continues to lead multiple efforts to improve the circumstances and care of people with mental illness, which she detailed in a recent address to nurse researchers. And when she talks about the special role of nurses throughout medicine, her voice fills with warmth.

"Sometimes the most important part of the healing process is knowing that someone cares, and nurses truly care," said Carter in a speech in Washington, D.C., in October.

Carter, a former first lady and the chair of the Carter Center's Mental Health Task Force, presented the keynote address at a fundraiser held by the Friends of the National Institute of Nursing Research (FNINR).

She described the unique role nurses frequently undertake in tracking the care of those who are too young or sick to advocate for themselves.

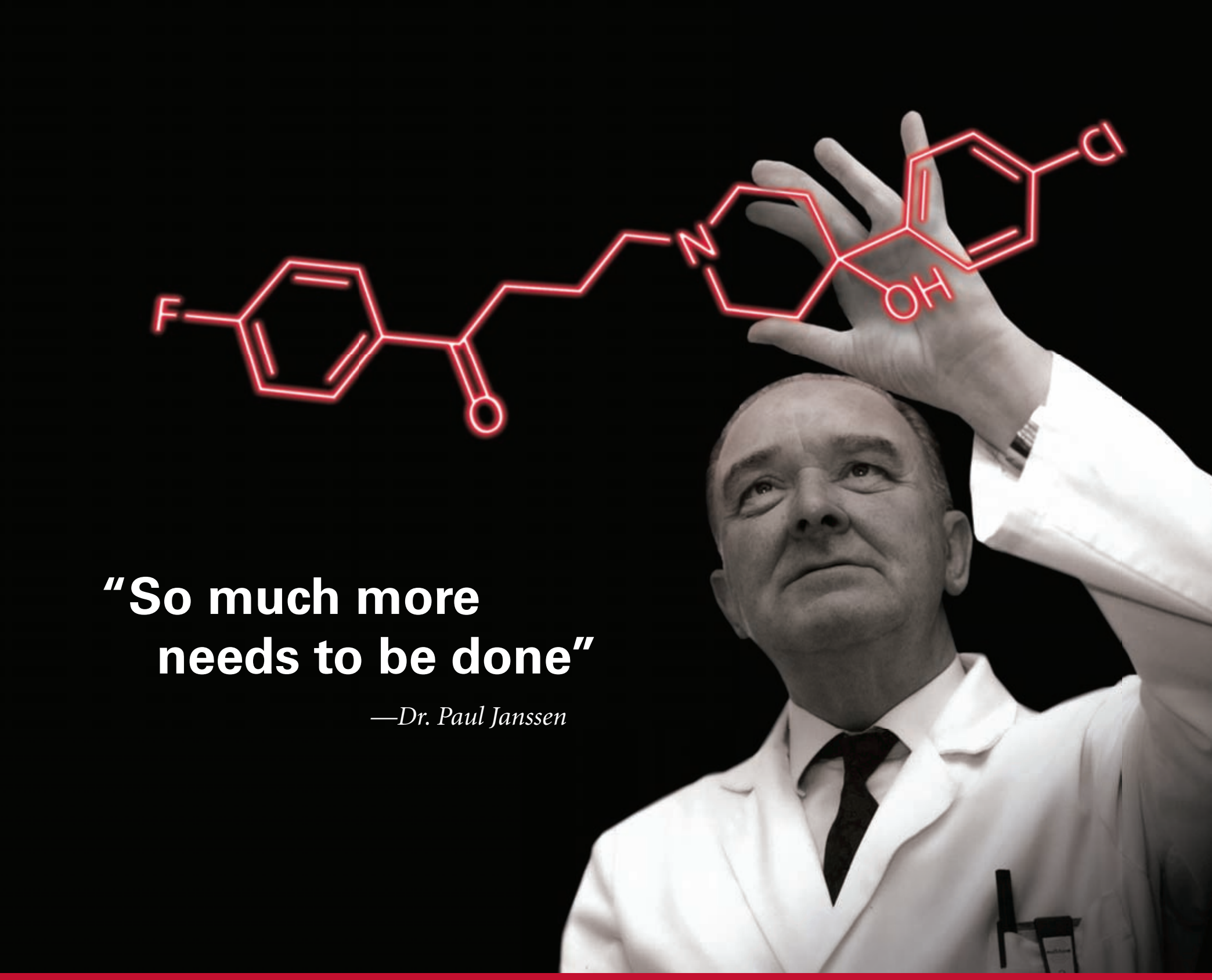
Strengthening the role of nurses in providing mental health care is among the leading priorities of psychiatrist Mary Jane England, M.D., a former APA president who is president of the FNINR.

Among the priorities of the nonprofit FNINR is ensuring that the research conducted on nursing's role in mental health care and other areas of medicine makes its way into clinical settings. The organization also provides federal advocacy for nursing research and explains the role of the National Institute of Nursing Research (NINR) to the media.

The institute has been a leader in end-of-life care, the self-management of chronic illnesses, and depression related to nonmental health conditions.

"The nurses tend to be very translational in moving the science and evidence-

please see ***Nurses*** *on page 41*



“So much more needs to be done”

—Dr. Paul Janssen

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Depression Care no Longer Needs to Be Earthbound

When a long space mission puts strains on astronauts, and no mental health professional is around to help, a computer program can guide the astronauts through problem-solving self-treatment.

BY JUN YAN

An interactive self-help program may serve as an artificial counselor to help astronauts solve psychological and interpersonal problems during prolonged space flights or extended stays in a space station.

This self-guided, multimedia computer program is intended to treat depression using an established behavioral-treatment approach known as problem-solving therapy, which is widely used in psychotherapy in primary care settings, James Cartreine, Ph.D., the principal investigator on this project, told *Psychiatric News*.

The user is guided through the program's series of steps by the prerecorded voice and image of a psychologist (in this case, Mark Hegel, Ph.D., an associate professor of psychiatry and community and family medicine at Dartmouth Medical School).

First, the user is instructed to make a list of concrete, measurable, objective problems being experienced that exacerbate his or her low mood and can directly be addressed by new behaviors such as regular exercise or increased interpersonal interactions. Second, the user is asked to choose one problem from the list that has a reasonable likelihood of being solved and to then devise a clear and specific goal that marks the ultimate solution of the problem. The user is encouraged to brainstorm different ideas to come up with many possible ways to reach the solution of the problem and, with the help of the computer, chooses the action that is most likely to solve the problem.

"This is a step-by-step, structured process, which lends itself to a computerized approach," said Cartreine, a psychologist in the Division of Clinical Informatics at Boston's Beth Israel Deaconess Medical Center. "The computer program is like an interactive workbook to help the user solve problems." He noted that the computer program does not solve the problems for the user, but rather facilitates an individual's own problem-solving behaviors, thus mimicking the strategy of a live therapist in one-on-one sessions.

The program uses the validated nine-item depression scale in the Patient Health Questionnaire, known as the PHQ-9, to assess the severity of the user's depression symptoms at baseline and track clinical progress over time.

The self-guided treatment program is one module of a suite of programs known as the Virtual Space Station. It was developed for NASA and funded by the National Space Biomedical Research Institute, a consortium of organizations and institutions devoted to researching health risks in long-duration space flights. Two additional modules for managing interpersonal conflicts and self-treatment for anxiety and stress are in development.

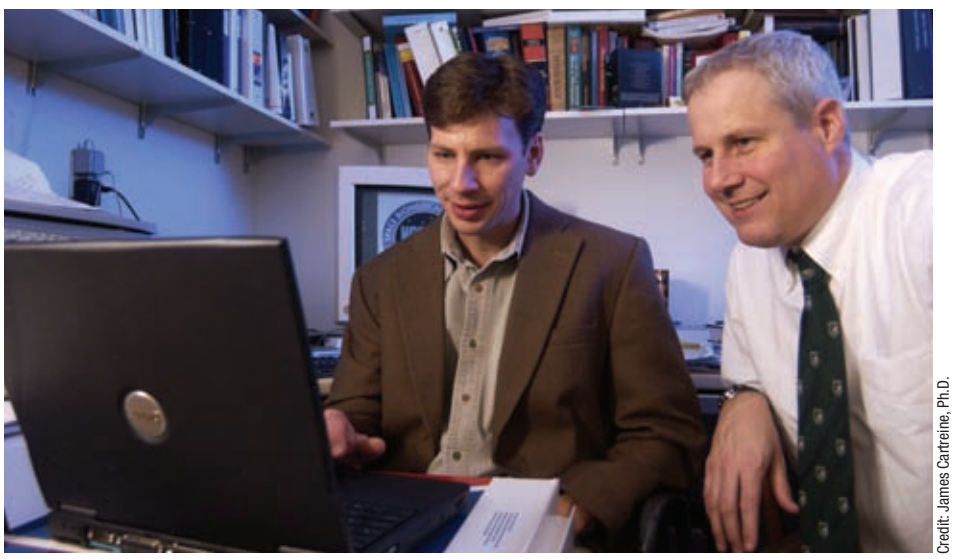
Astronauts are screened for physical and mental health and are generally less vulnerable to illnesses than the average person. But long space flights pose unique challenges to even an otherwise tough person, Jay Buckey, M.D., a professor of medicine at Dartmouth Medical School and a co-investigator on the project, told *Psychiatric News*. He was an astronaut at NASA in the 1990s and flew on a 16-day mission aboard the Columbia space shuttle in 1998.

Many astronauts, however, participate in missions that are much longer than Buckey's. For example, a stint on board an international space station usually lasts four to six months, which could be psychologically challenging.

"On a long flight, if the mission isn't going well, and the crew is in conflict, and no one is getting enough sleep, you can imagine that may be a situation where depression could develop," Buckey said. The isolation and stress may have a significant impact on astronauts' mental health.

The depression self-treatment program has been tried by several researchers stationed in Antarctica, where the isolated condition mimics that of long space flight. A randomized clinical trial of the program, led

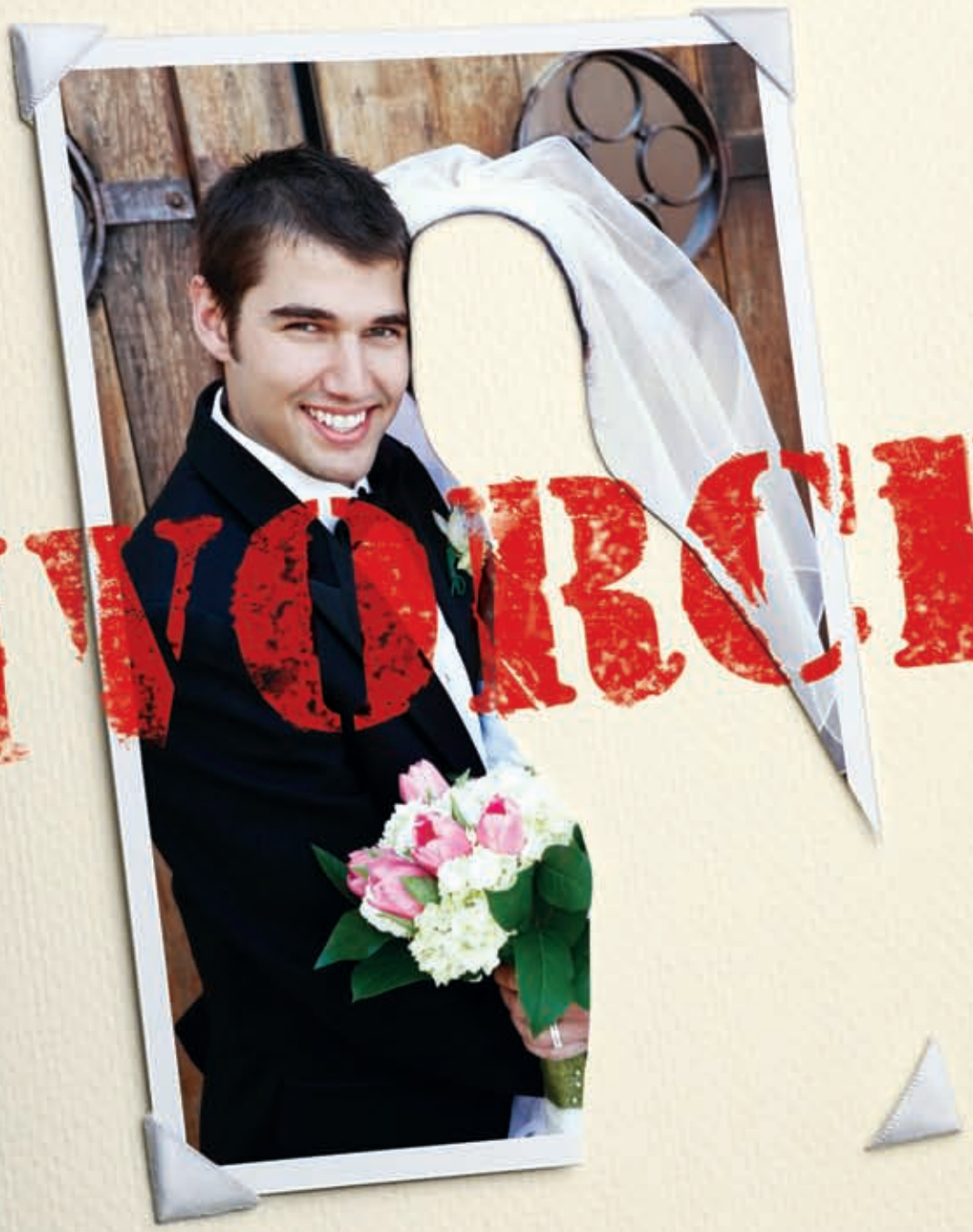
please see ***Depression Care*** *on page 41*



Credit: James Cartreine, Ph.D.

National Space Biomedical Research Institute scientists James Cartreine, Ph.D. (left), and Jay Buckey, M.D., conduct a test run of a self-treatment program for depression on the Virtual Space Station.

Adults with **ADHD** were almost **2 times** more likely to be divorced*[1]



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*Results from a survey of 500 adults with ADHD (self-identified as having been diagnosed with ADHD by a clinician in the community during adulthood) compared with 501 gender- and age-matched controls from a national sample. Adults with ADHD were significantly more likely to be divorced vs controls (28% vs 15%; $P \leq .001$).

Reference: 1. Biederman J, Faraone SV, Spencer TJ, et al. Functional impairments in adults with self-reports of diagnosed ADHD: a controlled study of 1001 adults in the community. *J Clin Psychiatry*. 2006;67:524-540.

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Medicare Fees to Increase An Average of 1.1%

While the government is including financial incentives for using electronic health technology in Medicare, the AMA is demanding major changes to the formula used to set physician fees.

BY MARK MORAN

Physicians are slated next month to begin receiving a 1.1 percent across-the-board payment increase in Medicare.

The payment update is the result of a dramatic, last-minute vote by Congress earlier this year to reverse a scheduled 10.6 percent decrease that was to have gone into effect in July *(Psychiatric News*, August 1). Instead, Congress approved a 0.5 percent increase for the remainder of 2008 and the 1.1 percent increase for 2009.

The change was included in the historic Medicare Improvements for Patients and Providers Act (HR 6331), which reversed the government's 40-year-old discriminatory payment for outpatient psychiatric services.

In addition, the fee schedule for 2009 includes financial incentives for physicians who use electronic health records and who report quality measures. Two Centers for Medicare and Medicaid Services (CMS) quality-improvement programs—the Physician Quality Reporting Initiative (PQRI) and the Electronic Prescribing Incentive Program—will provide financial incentives of up to 4 percent of total Medicare allowed charges for participation. The e-prescribing program offers incentives to clinicians who use a qualified e-prescribing system. Participation in both programs involves the reporting of designated administrative codes on billing claims.

The PQRI program will continue in 2009 with 153 measures, including three on major depressive disorder, and a new measure on screening for unhealthy alcohol use. Physicians who report using at least three measures applicable to their practice between January 1 and December 31, 2009, will receive a bonus of up to 2 percent of their total Medicare allowed charges for that period.

The Electronic Prescribing Incentive Program is new for 2009. Clinicians who meet the requirements for being a successful e-prescriber will be eligible for an additional 2 percent bonus in 2009 and 2010, a 1 percent bonus in 2011 and 2012, and a 0.5 percent bonus in 2013. Clinicians who do not meet the requirements for being a successful e-prescriber will have their payments reduced by 1 percent in 2012, 1.5 percent in 2013, and 2 percent in 2014 and in each subsequent year.

Being a successful e-prescriber means reporting the availability and use of a qualified e-prescribing system in at least 50 percent of covered encounters between January 1, 2009 and December 31, 2009. Information about both programs and about what constitutes a qualified e-prescribing system is posted on APA's Web site at <www.psych.org/pqri>.

Permanent Reform Needed

As in past years, the payment reduction reversal succeeded only in postponing the bad news: under current projections, physicians are slated to face a massive 21 percent payment cut in 2010. And APA, the AMA, and other physician groups remain committed to achieving a permanent reform of the Medicare payment formula, especially the so-called sustainable growth rate (SGR) component. The SGR mandates that increases in volume be balanced by reductions in payment, but does not account for increases in physician costs.

At last month's Interim Meeting of the AMA House of Delegates, delegates approved a report by the AMA's Council on Medical Services calling for a systematic discussion by organized medicine of options for reforming the Medicare payment system. The council has asked for input and feedback from states and specialty societies regarding options that were outlined in the report. CMS will be taking that feedback and finalizing the report for consideration by the house at the AMA's annual meeting in June 2009.

APA's Office of Health Systems and Financing, in collaboration with relevant councils, will be reviewing the report and forwarding comments to the AMA. For complete reporting on the CMS report, see the next issue of *Psychiatric News*.

"The American Medical Association supports rebasing the sustainable growth rate to move forward with a permanent fix," said AMA board member James Rohack, M.D., in a statement issued after last month's House of Delegates meeting in Orlando, Fla. "We agree that it is the best course to address the current Medicare payment crisis and ensure access to health care for America's seniors.

"The AMA continues to work with medical state and specialty societies in an effort to develop a broadly supported approach to reform. We are closely examining Medicare demonstration projects, including the patient-centered medical home and other payment reforms to improve care coordination. We hope to see additional projects so we can build a solid foundation for long-term reform.

"Our ultimate goal is to eliminate the SGR, and we are committed to working with Chairman [Pete] Stark and the. . . chairs and ranking members on the Senate Finance Committee and the House Energy and Commerce Committee to find the best solution."

AMA Acts on Enrollment Delays

At the AMA meeting last month, Medicare payment and other administrative problems associated with the program were prominent on the agenda. Delegates expressed special outrage about lengthy delays experienced in getting enrolled as a Medicare participatng physician, resulting in long periods of uncompensated care.

The House of Delegates easily approved a resolution calling on the AMA to seek legislation mandating that CMS impose a requirement on its carriers and Medicare administrative contractors that complete enrollment and re-enrollment applications must be processed within 30 days of receipt, with appropriate feedback to the applicant.

please see ***Medicare*** *on page 34*

Audit Finds Lax Enforcement Of HIPAA Security Provisions

CMS is urged to adopt an ongoing, proactive monitoring system to ensure compliance with HIPAA standards and replace the current complaint-based system.

BY MARK MORAN

The federal Centers for Medicare and Medicaid Services (CMS) needs to do a better job of monitoring compliance with HIPAA security standards by health plans participating in Medicare, the Medicare Part D prescription drug program, and other public programs, according to a report by the Inspector General's Office.

Specifically, CMS needs to adopt an ongoing, proactive monitoring system to ensure compliance with security standards rather than rely on the "complaint-based" system currently in use by which the agency responds to breaches of security standards when a complaint is received.

The Security Rule of HIPAA (the Health Insurance Portability and Accountability Act of 1996) established national standards that protect the confidentiality and integrity of electronic health information (ePHI) while it is being stored or transmitted between entities. In 2003 the U.S. Department of Health and Human Services delegated to CMS the authority and responsibility to interpret, implement, and enforce the HIPAA Security Rule provisions; conduct compliance reviews and investigate and resolve complaints of HIPAA Security Rule noncompliance; and civil monetary penalties for a covered entity's failure to comply with the HIPAA Security Rule provisions *(Psychiatric News*, June 17, 2005; January 3, 2003).

But an October report from the Inspector General's Office titled "Nationwide Review of the Centers for Medicare and Medicaid Services Health Insurance Portability and Accountability Act of 1996 Oversight" stated that CMS has not lived up to its mandate.

"CMS had taken limited actions to ensure that covered entities adequately implement the HIPAA Security Rule," according to the report. "These actions had not provided effective oversight or encouraged enforcement of the HIPAA Security Rule by covered entities. Although authorized to do so by federal regulations, CMS had not conducted any HIPAA Security Rule compliance reviews of covered entities. To fulfill its oversight responsibilities, CMS relied on complaints to identify any noncompliant covered entities that it might investigate. As a result, CMS had no effective mechanism to ensure that covered entities were complying with the HIPAA Security Rule or that ePHI was being adequately protected.

"Our ongoing audits of various hospitals nationwide indicate that CMS needs to become proactive in overseeing and enforcing implementation of the HIPAA Security Rule by focusing on compliance reviews," the inspector general's report stated. "Preliminary results of these audits show numerous, significant vulnerabilities in the systems and controls intended to protect ePHI at covered entities. These vulnerabilities place the confidentiality and integrity of ePHI at high risk."

Although CMS's complaint-driven enforcement process has furthered the goal of voluntary compliance, the significant vulnerabilities identified at hospitals throughout the country would not generally have been identified in HIPAA Security Rule complaints. In fact, CMS has received very few complaints regarding potential HIPAA Security Rule violations. Including compliance reviews of covered entities in its oversight process will enhance CMS's ability to determine whether the HIPAA Security Rule is being properly implemented, according to the inspector general.

As part of its audit of CMS, the Inspector General's Office audited the HIPAA Security Rule implementation at one hospital and found significant "vulnerabilities" in systems and controls intended to protect ePHI. In addition, the inspector general began audits at seven other hospitals around the country. The preliminary results have also identified significant "vulnerabilities" with the hospitals' implementation of the administrative, technical, and physical safeguard provisions of the HIPAA Security Rule.

"These vulnerabilities place the confidentiality and integrity of ePHI at risk and would not generally be included in complaints," according to the report.

"Nationwide Review of the Centers for Medicare and Medicaid Services Health Insurance Portability and Accountability Act of 1996 Oversight" is posted at <http://oig.hhs.gov/oas/reports/region4/40705064.pdf>. ■

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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 'M-BEST Study (Benefit and efficacy in severely demented patients during treatment with memantine). *Int J Geriatr Psychiatry.* 1999;14:135-146.

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

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

Forest Pharmaceuticals, Inc.

62-1014307R R1 09/08

Namenda
memantine HCl

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Rx Only

Brief Summary of Prescribing Information.

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

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

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

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

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

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

Special Populations
Hepatic Impairment
Namenda undergoes partial hepatic metabolism, with about 48% of administered dose excreted in urine as unchanged drug or as the sum of parent drug and the N-glucuronide conjugate (74%). 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/m^2 basis). There was also no evidence of carcinogenicity in rats orally dosed at up to 40 mg/kg/day for 71 weeks followed by 20 mg/kg/day (20 and 10 times the MRHD on a mg/m^2 basis, respectively) through 128 weeks.

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

No impairment of fertility or reproductive performance was seen in rats administered up to 18 mg/kg/day (9 times the MRHD on a mg/m^2 basis) orally from 14 days prior to mating through gestation and lactation in females, or for 60 days prior to mating in males.

Pregnancy
Pregnancy Category B: Memantine given orally to pregnant rats and pregnant rabbits during the period of organogenesis was not teratogenic up to the highest doses tested (18 mg/kg/day in rats and 30 mg/kg/day in rabbits, which are 9 and 30 times, respectively, the maximum recommended human dose [MRHD] on a mg/m^2 basis).

Slight maternal toxicity, decreased pup weights and an increased incidence of non-ossified cervical vertebrae were seen at an oral dose of 18 mg/kg/day in a study in which rats were given oral memantine beginning pre-mating and continuing through the postpartum period. Slight maternal toxicity and decreased pup weights were also seen at this dose in a study in which rats were treated from day 15 of gestation through the post-partum period. The no-effect dose for these effects was 6 mg/kg, which is 3 times the MRHD on a mg/m^2 basis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Events Reported Subsequent to the Marketing of Namenda, both US and Ex-US
Although no causal relationship to memantine treatment has been found, the following adverse events have been reported to be temporally associated with memantine treatment and are not described elsewhere in labeling: 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/m^2 basis. The potential for induction of central neuronal vacuolation and necrosis by NMDA receptor antagonists in humans is unknown.

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

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

OVERDOSAGE
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

Assembly Looks to Health Reform, Honors Psychiatrist's Courage

A psychiatrist who went into battle against the public system that employed him when it began taking steps he believed were lowering the quality of care wins an APA award for his efforts.

BY KEN HAUSMAN

Psychiatrist Blair Romer, M.D., didn't let the power of his bosses and other state officials scare him away from fighting the good fight on behalf of patients, who happened to be inmates in a California prison's forensic medical facility. Romer is a staff psychiatrist at the state prison at Vacaville who refused to stand by and let officials downgrade the quality of care these psychiatrically ill inmates received.

Romer's efforts won him the Profile of Courage Award from the APA Assembly at its meeting last month in Washington, D.C.

Putting his career in jeopardy, Romer organized and led a protest against prison officials' plan to downgrade the prison hospital's medical license by eliminating the organized medical staff, shifting most mental health care from physicians to nonphysician health care professionals, reducing the nurse-patient ratio, and changing bylaws so that a psychologist could head the medical staff and credentials committee.

Romer enlisted support from the California Psychiatric Association and California Medical Association in his protest, which led to a halt in the imminent downgrade of his facility. His actions led to retaliatory steps by the hospital's executive director and eventually a reprimand, he told the Assembly. He countered with a "whistle-blower" complaint to the California Personnel Board, whose decision failed to back Romer's position.

Romer noted that several months ago the hospital administration indicated that it plans to dismantle the forensic psychiatry service, which he heads, and it has moved him to a tiny office where the furniture will not accommodate his 6-foot, 4-inch body. All this has worn him down, Romer said, and he will leave state service this January.

He emphasized that he was accepting the Assembly's award "for the everyday heroes in mental health," only a few of whom get the recognition they deserve.

The Assembly also addressed several key issues and proposals at its November meeting, many of them affected by fiscal constraints facing APA in light of declining income and rising expenses. Among the issues decided, representatives voted to

• **endorse an APA position statement titled "Principles for Health Care Reform for Psychiatry" that describes positions for which APA will advocate in discussions on reforming the nation's health care system.** The principles focus on ways to increase access to mental health care, including that for substance abuse; describe key elements of quality care; and explain the need for strict confidentiality standards in electronic records systems. The statement also stresses the need to take action to stamp out mental illness stigma and for greater resources to be aimed at increasing the psychiatric workforce, especially in the area of child psychiatry.

Credit: Sylvia Johnson Photography 2008

Assembly Speaker Ronald Burd, M.D., presides over a discussion at the group's November meeting in Washington, D.C.

• **have APA urge President-elect Barack Obama to convene a health care reform planning advisory group that would include health care professionals** "including APA and the AMA, and not only funders of health care."

• **"make available" an award that can go to a psychiatry resident from every U.S. and Canadian training program.** The award will acknowledge residents who have demonstrated the values of "compassion, leadership, community service, or advocacy" for the benefit of their patients, professsion, or community. Each year APA will encourage training directors to submit the name of a resident worthy of the award, which will be in the form of a certificate. Residents do not have to be APA members to be eligible.

• **try to retain medical students** who join APA by having APA e-mail district branches the names of medical-student members in their area so the district branch can assign mentors and engage them in activities that could result in their pursuing psychiatry and remaining APA members.

• have the Steering Committee on Practice Guidelines explore the idea of **"establishing evidence- and consensus-based practice guidelines on the treatment of psychiatric symptoms in the intellectually disabled."** Advocates of this proposal stated that "unsubstantiated approaches sometimes used in the treatment of intellectually disabled patients with psychiatric symptoms can increase the risk of adverse consequences to this population."

• have the APA Election Committee and appropriate staff **apply the same conflict-of-interest disclosure standards** to candidates for APA national office as used when evaluating candidates to be APA journal editors, component participants, and presenters at APA annual and CME meetings.

• **revise the member referendum procedure** in light of the fact that in recent years the percentage of members who vote in APA elections often flirts with the 40 percent minimum participation needed to pass a referendum. The Assembly backed a proposal to put referenda to votes by strength of the Assembly, with such referenda needing two-thirds of votes to pass, when the minimum percentage of ballots to constitute a "valid vote" is not achieved. The Board of Trustees will review this issue.

A summary of actions taken by the Assembly is posted on APA's Web site at <www.psych.org> in the Members Corner section under "Assembly." ■

District Branch Executives Learn How to Maximize Effectiveness

APA's recently revised "Model District Branch" document provides standards that help district branches and state associations best respond to the needs of members and to legislative and other issues.

BY RICH DALY

District branch and state association executives immersed themselves in the organizational tools offered through APA's "Model District Branch" program at the annual executive staff leadership conference held in Washington, D.C., in November.

The conference was attended by many state association and district branch executives, who focused on ways to implement aspects of the "Model District Branch" document, which was created by the APA District Branch Advisory Corresponding Committee in 2007 and revised in October. The model provides the basic guidelines that district branches and state associations can use to provide services to their members more efficiently and comprehensively. It describes the essentials of managing a district branch and optional functions to enhance service delivery and respond to "external pressures."

Credit: Sylvia Johnson Photography 2008

Linda Bueno, director of industry relations for the American Psychiatric Foundation, facilitates a discussion on grant writing with attendees at the executive staff leadership conference. With her are (clockwise, from lower left) Michael Thompson, Andrew Mann, Robin Huffman, Linda Vukelich, Paige De Mille, Rebecca DeFilippo, Pam Armstrong, Deb Wilson, Meryl Camin Sosa, and Annett Schott.

The model provides guidance on activities organized by district branches, qualifications that branch executives should have, and sample bylaws under which the branches can operate. The recommendations for increased efficiency described by the model and at the meeting on such topics as recruitment and retainment of new members are particularly important in a time of lean budgets and shrinking medical-industry support, according to APA leaders.

"This meeting is very valuable for APA," said APA Medical Director James H. Scully Jr., M.D., in comments to the attendees about the benefits provided to the overall Association.

Many attendees agreed that the training and materials provided during the conference were particularly well timed.

"This will be really helpful in making our organization more functional and compliant" with tax and other regulations, said Paige De Mille, executive director of the Utah Psychiatric Association.

De Mille came to the November meeting specifically for insights on

please see ***Executives*** *on page 35*

Nominations Announced

The APA Assembly Nominating Committee announced candidates for speaker-elect and recorder at last month's Assembly meeting in Washington, D.C.

Running unopposed for speaker-elect is the current recorder, Bruce Hershfield, M.D., of Maryland. The Nominating Committee announced that it could find no Assembly member to run against him despite overtures made to "dozens" of members.

Competing to replace Hershfield as Assembly recorder are Priscilla Ray, M.D., and Ann Marie Sullivan, M.D. Ray is a representative of the Texas Society of Psychiatric Physicians, and Sullivan is a representative of the New York County District Branch.

The election will be held at the Assembly's next meeting in May 2009.

FOR PATIENTS WITH SCHIZOPHRENIA

WHEN HE MISSES DOSES, HIS SYMPTOMS MAY NOT BE FAR BEHIND

Why wait? Recommend RISPERDAL® CONSTA®
as his next option.

- Recognize when doses are taken
- Intervene when they are missed

Risperdal® CONSTA®
risperidone Long-Acting Injection

NOW approved for deltoid administration

RISPERDAL® CONSTA® (risperidone) long-acting injection is indicated for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION FOR RISPERDAL® CONSTA®

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of patients with dementia-related psychosis.

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

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

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

Hyperglycemia and Diabetes: Hyperglycemia, some cases extreme and associated with ketoacidosis, hyperosmolar coma or death has been reported in patients treated with atypical antipsychotics (APS), including RISPERDAL® CONSTA®. Patients starting treatment with APS who have or are at risk for diabetes should

undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing.

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

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

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

Seizures: RISPERDAL® CONSTA® should be used cautiously in patients with a history of seizures.

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

Administration: Care should be taken to avoid inadvertent injection into a blood vessel.

Extrapyramidal Symptoms (EPS): The overall incidence of EPS-related adverse events in patients treated with 25 mg and 50 mg of RISPERDAL® CONSTA® and placebo, respectively, were akathisia* (4%, 11%, 6%), Parkinsonism† (8%, 15%, 9%) and tremor (0%, 3%, 0%).

*Akathisia and restlessness

†Extrapyramidal disorder, musculoskeletal stiffness, muscle rigidity, and bradykinesia

Weight Gain: In a 12-week trial, the percentage of patients experiencing weight gain (>7% of baseline body weight) was 6% placebo versus 9% RISPERDAL® CONSTA®.

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

Commonly Observed Adverse Reactions for RISPERDAL® CONSTA®: The most common adverse reactions in clinical trials (≥5%) were headache, Parkinsonism, dizziness, akathisia, fatigue, constipation, dyspepsia, sedation, weight increase, pain in extremities, and dry mouth.

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

Janssen
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November 2008 01CS1026E

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CELEBRATING 50 YEARS IN MENTAL HEALTH

RISPERDAL® CONSTA®

(risperidone) LONG-ACTING INJECTION

Brief Summary

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

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

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of patients with dementia-related psychosis. *[See Warnings and Precautions]*

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

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

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

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

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia-Related Psychosis: Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73-97) in trials of oral risperidone in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with oral risperidone compared to patients treated with placebo. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis *[See also Boxed Warning and Warnings and Precautions]* **Neuroleptic Malignant Syndrome (NMS):** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. **Tardive Dyskinesia:** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. RISPERDAL® CONSTA® should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms of tardive dyskinesia appear in a patient treated with RISPERDAL® CONSTA®, drug discontinuation should be considered. **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including RISPERDAL®. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. **Hyperprolactinemia:** As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time. **Orthostatic Hypotension:** RISPERDAL® CONSTA® may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose-titration period with oral risperidone, probably reflecting its alpha-adrenergic antagonistic properties. Syncope was reported in 0.8% (12/1499 patients) of patients treated with RISPERDAL® CONSTA® in multiple-dose studies. Patients should be instructed in nonpharmacologic interventions that help to reduce the occurrence of orthostatic hypotension (e.g., sitting on the edge of the bed for several minutes before attempting to stand in the morning and slowly rising from a seated position). RISPERDAL® CONSTA® should be used with particular caution in (1) patients with known cardiovascular disease (history of myocardial infarction or ischemia, heart failure, or conduction abnormalities), cerebrovascular disease, and conditions which would predispose patients to hypotension, e.g., dehydration and hypovolemia, and (2) in the elderly and patients with renal or hepatic impairment. Monitoring of orthostatic vital signs should be considered in all such patients, and a dose reduction should be considered if hypotension occurs. Clinically significant hypotension has been observed with concomitant use of oral RISPERDAL® and antihypertensive medication. **Potential for Cognitive and Motor Impairment:** Somnolence was reported by 5% of patients treated with RISPERDAL® CONSTA® in multiple-dose trials. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that treatment with RISPERDAL® CONSTA® does not affect them adversely. **Seizures:** During premarketing testing, seizures occurred in 0.3% (5/1499 patients) of patients treated with RISPERDAL® CONSTA®. Therefore, RISPERDAL® CONSTA® should be used cautiously in patients with a history of seizures. **Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's dementia. RISPERDAL® CONSTA® and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. *[See also Boxed Warning and Warnings and Precautions]* **Priapism:** Priapism has been reported during postmarketing surveillance *[see Adverse Reactions].* Severe priapism may require surgical intervention. **Thrombotic Thrombocytopenic Purpura (TTP):** A single case of TTP was reported in a 28 year-old female patient receiving oral RISPERDAL® in a large, open premarketing experience (approximately 1300 patients). She experienced jaundice, fever, and bruising, but eventually recovered after receiving plasmapheresis. The relationship to RISPERDAL® therapy is unknown. **Body Temperature Regulation:** Disruption of body temperature regulation has been attributed to antipsychotic agents. Both hyperthermia and hypothermia have been reported in association with oral RISPERDAL® or RISPERDAL® CONSTA® use. Caution is advised when prescribing RISPERDAL® CONSTA® for patients who will be exposed to temperature extremes. **Administration:** RISPERDAL® CONSTA® should be injected into the deltoid or gluteal muscle, and care must be taken to avoid inadvertent injection into a blood vessel. *[See Dosage and Administration in full PI and Adverse Reactions]* **Antiemetic Effect:** Risperidone has an antiemetic effect in animals; this effect may also occur in humans, and may mask signs and symptoms of overdosage with certain drugs or of conditions such as intestinal obstruction, Reye's syndrome, and brain tumor. **Suicide:** The possibility of a suicide attempt is inherent in schizophrenia, and close supervision of high-risk patients should accompany drug therapy. RISPERDAL® CONSTA® is to be administered by a health care professional *[see Dosage and Administration in full PI];* therefore, suicide due to an overdose is unlikely. **Use in Patients with Concomitant Illness:** Clinical experience with RISPERDAL® CONSTA® in patients with certain concomitant systemic illnesses is limited. Patients with Parkinson's Disease or Dementia with Lewy Bodies who receive antipsychotics, including RISPERDAL® CONSTA®, are reported to have an increased sensitivity to antipsychotic medications. Manifestations of this increased sensitivity have been reported to include confusion, obtundation, postural instability with frequent falls, extrapyramidal symptoms, and clinical features consistent with the neuroleptic malignant syndrome. Caution is advisable when using RISPERDAL® CONSTA® in patients with diseases or conditions that could affect metabolism or hemodynamic responses. Increased plasma concentrations of risperidone and 9-hydroxyrisperidone occur in patients with severe renal impairment (creatinine clearance <30 mL/min/1.73 m^2) treated with oral RISPERDAL®; an increase in the free fraction of risperidone is also seen in patients with severe hepatic impairment. Patients with renal or hepatic impairment should be carefully titrated on oral RISPERDAL® before treatment with RISPERDAL® CONSTA® is initiated at a dose of 25 mg. A lower initial dose of 12.5 mg may be appropriate when clinical factors warrant dose adjustment, such as in patients with renal or hepatic impairment *[see Dosage and Administration in full PI].* **Osteodystrophy and Tumors in Animals:** RISPERDAL® CONSTA® produced osteodystrophy in male and female rats in a 1-year toxicity study and a 2-year carcinogenicity study at a dose of 40 mg/kg administered IM every 2 weeks. RISPERDAL® CONSTA® produced renal tubular tumors (adenoma, adenocarcinoma) and adrenomedullary pheochromocytomas in male rats in the 2-year carcinogenicity study at 40 mg/kg administered IM every 2 weeks. In addition, RISPERDAL® CONSTA® produced an increase in a marker of cellular proliferation in renal tissue in males in the 1-year toxicity study and in renal tumor-bearing males in the 2-year carcinogenicity study at 40 mg/kg administered IM every 2 weeks. **Neither the renal or adrenal tumors, nor osteodystrophy, were seen in studies of orally administered risperidone.** Osteodystrophy was not observed in dogs at doses up to 14 times (based on AUC) the IM MRHD in a 1-year toxicity study. The renal tubular and adrenomedullary tumors in male rats and other tumor findings are described in more detail in *Nonclinical Toxicology in full PI*. The relevance of these findings to human risk is unknown. **Monitoring: Laboratory Tests:** No specific laboratory tests are recommended.

ADVERSE REACTIONS: The following are discussed in more detail in *Boxed Warning and Warnings and Precautions* sections of the labeling: • Increased mortality in elderly patients with dementia-related psychosis • Cerebrovascular adverse events, including stroke, in elderly patients with dementia-related psychosis • Neuroleptic malignant syndrome • Tardive dyskinesia • Hyperglycemia and diabetes mellitus • Hyperprolactinemia • Orthostatic hypotension • Potential for cognitive and motor impairment • Seizures • Dysphagia • Priapism • Thrombotic Thrombocytopenic Purpura (TTP) • Disruption of body temperature regulation • Avoidance of inadvertent injection into a blood vessel • Antiemetic effect • Suicide • Increased sensitivity in patients with Parkinson's disease or those with dementia with Lewy bodies • Diseases or conditions that could affect metabolism or hemodynamic responses • Osteodystrophy and tumors in animals The most common adverse reactions in clinical trials (≥ 5%) were: headache, parkinsonism, dizziness, akathisia, fatigue, constipation, dyspepsia, sedation, weight increased, pain in extremity, and dry mouth. The most common adverse reactions that were associated with discontinuation from the 12-week double-blind, placebo-controlled (causing discontinuation in ≥ 1% of patients) were agitation, depression, anxiety, and akathisia *[see Adverse Reactions].* The data described in this section are derived from a clinical trial database consisting of 2392 patients exposed to one or more doses of RISPERDAL® CONSTA® for the treatment of schizophrenia. Of these 2392 patients, 332 were patients who received RISPERDAL® CONSTA® while participating in a 12-week double-blind, placebo-controlled trial. Two hundred two (202) of the 332 were schizophrenia patients who received 25 mg or 50 mg RISPERDAL® CONSTA®. The conditions and duration of treatment with RISPERDAL® CONSTA® varied greatly and included (in overlapping categories) double-blind, fixed- and flexible-dose, placebo- or active-controlled studies and open-label phases of studies, inpatients and outpatients, and short-term (up to 12 weeks) and longer-term (up to 4 years) exposures. Safety was assessed by collecting adverse events and performing physical examinations, vital signs, body weights, laboratory analyses, and ECGs. Adverse events during exposure to study treatment were obtained by general inquiry and recorded by clinical investigators using their own terminology. Consequently, to provide a meaningful estimate of the proportion of individuals experiencing adverse events, events were grouped in standardized categories using MedDRA terminology. Throughout this section, adverse reactions are reported. Adverse reactions are adverse events that were considered to be reasonably associated with the use of RISPERDAL® CONSTA® (adverse drug reactions) based on the comprehensive assessment of the available adverse event information. A causal association for RISPERDAL® CONSTA® often cannot be reliably established in individual cases. Further, because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The majority of all adverse reactions were mild to moderate in severity. **Commonly-Observed Adverse Reactions in Double-Blind, Placebo-Controlled Clinical Trials:** Table 1 lists the adverse reactions reported in 2% or more of RISPERDAL® CONSTA®-treated patients with schizophrenia in one 12-week double-blind, placebo-controlled trial. **Table 1. Adverse Reactions in ≥ 2% of RISPERDAL® CONSTA®-Treated Patients with Schizophrenia in a 12-Week Double-Blind, Placebo-Controlled Trial: System Organ Class, Percentage of Patients Reporting Event RISPERDAL® CONSTA® 25mg (N=99)** first, **50 mg (N=103)** second, **Placebo (N=98)** third, **Adverse Reaction, Eye disorders:** Vision blurred 2, 3, 0; **Gastrointestinal disorders:** Constipation 5, 7, 1; Dry mouth 0, 7, 1; Dyspepsia 6, 6, 0; Nausea 3, 4, 5; Toothache 1, 3, 0: Salivary hypersecretion 4, 1, 0; **General disorders and administration site conditions:** Fatigue* 3, 9, 0; Edema peripheral 2, 3, 1; Pain 4, 1, 0; Pyrexia 2, 1, 0; **Infections and infestations:** Upper respiratory tract infection 2, 0, 1; **Investigations:** Weight increased 5, 4, 2; Weight decreased 4, 1, 1; **Musculoskeletal and connective tissue disorders:** Pain in extremity 6, 2, 1; **Nervous system disorders:** Headache 15, 21, 12; Parkinsonism* 8, 15, 9; Dizziness 7, 11, 6; Akathisia* 4, 11, 6; Sedation* 5, 6, 3; Tremor 0, 3, 0; Syncope 2, 1, 0; Hypoesthesia 2, 0, 0; **Respiratory, thoracic and mediastinal disorders:** Cough 4, 2, 3; Sinus congestion 2, 0, 0; **Skin and subcutaneous tissue disorders:** Acne 2, 2, 0; Dry skin 2, 0, 0. * Fatigue includes fatigue and asthenia. Parkinsonism includes extrapyramidal disorder, musculoskeletal stiffness, muscle rigidity, and bradykinesia. Akathisia includes akathisia and restlessness. Sedation includes sedation and somnolence. **Other Adverse Reactions Observed During the Premarketing Evaluation of RISPERDAL® CONSTA®:** The following adverse reactions occurred in < 2% of the patients in the above 12-week double-blind, placebo-controlled trial. In addition, the following also includes adverse reactions reported in RISPERDAL® CONSTA®-treated patients who participated in other studies, including double-blind, active-controlled and open-label studies in schizophrenia. **Blood and lymphatic system disorders:** anemia, neutropenia **Cardiac disorders:** tachycardia, atrioventricular block first degree, palpitations, sinus bradycardia, bundle branch block left, bradycardia, sinus tachycardia, bundle branch block right **Ear and labyrinth disorders:** ear pain, vertigo **Endocrine disorders:** hyperprolactinemia **Eye disorders:** conjunctivitis **Gastrointestinal disorders:** diarrhea, vomiting, abdominal pain, stomach discomfort, gastritis **General disorders and administration site conditions:** injection site pain, chest discomfort, chest pain, influenza like illness, sluggishness, malaise, induration, injection site induration, injection site reaction **Immune system disorders:** hypersensitivity **Infections and infestations:** nasopharyngitis, influenza, bronchitis, urinary tract infection, rhinitis, ear infection, pneumonia, lower respiratory tract infection, pharyngitis, sinusitis, viral infection, infection, localized infection, cystitis, gastroenteritis, subcutaneous abscess **Injury and poisoning:** fall, procedural pain **Investigations:** blood prolactin increased, alanine aminotransferase increased, electrocardiogram abnormal, gamma-glutamyl transferase increased, blood glucose increased, hepatic enzyme increased, aspartate aminotransferase increased **Metabolism and nutritional disorders:** increased appetite, decreased appetite **Musculoskeletal, connective tissue and bone disorders:** myalgia, back pain, arthralgia, buttock pain, muscular weakness, neck pain, musculoskeletal chest pain **Nervous system disorders:** dyskinesia, dystonia, tardive dyskinesia, drooling, paresthesia, dizziness postural, convulsion **Psychiatric disorders:** insomnia, agitation, anxiety, sleep disorder, depression, libido decreased, nervousness **Renal and urinary disorders:** urinary incontinence **Reproductive system and breast disorders:** amenorrhea, erectile dysfunction, galactorrhea, sexual dysfunction, gynecomastia **Respiratory, thoracic and mediastinal disorders:** nasal congestion, pharyngolaryngeal pain, dyspnea, rhinorrhea **Skin and subcutaneous tissue disorders:** rash, eczema, pruritus **Vascular disorders:** hypertension, hypotension, orthostatic hypotension **Discontinuations Due to Adverse Reactions:** Approximately 11% (22/202) of RISPERDAL® CONSTA®-treated patients in the 12-week double-blind, placebo-controlled trial discontinued treatment due to an adverse event, compared with 13% (13/98) who received placebo. The adverse reactions associated with discontinuation in two or more RISPERDAL® CONSTA®-treated patients were: agitation (3%), depression (2%), anxiety (1%), and akathisia (1%). **Dose Dependency**

of Adverse Reactions in Clinical Trials: Extrapyramidal Symptoms: Two methods were used to measure extrapyramidal symptoms (EPS) in the 12-week double-blind, placebo-controlled trial comparing three doses of RISPERDAL® CONSTA® (25 mg, 50 mg, and 75 mg) with placebo, including: (1) the incidence of spontaneous reports of EPS symptoms; and (2) the change from baseline to endpoint on the total score (sum of the subscale scores for Parkinsonism, dystonia, and dyskinesia) of the Extrapyramidal Symptom Rating Scale (ESRS). As shown in Table 1, the overall incidence of EPS-related adverse reactions (akathisia, dystonia, Parkinsonism, and tremor) in patients treated with 25 mg RISPERDAL® CONSTA® was comparable to that of patients treated with placebo; the incidence of EPS-related adverse reactions was higher in patients treated with 50 mg RISPERDAL® CONSTA®. The median change from baseline to endpoint in total ESRS score showed no worsening in patients treated with RISPERDAL® CONSTA® compared with patients treated with placebo: 0 (placebo group); -1 (25-mg group, significantly less than the placebo group); and 0 (50-mg group). *Dystonia: Class Effect:* Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups. **Changes in Body Weight:** In the 12-week double-blind, placebo-controlled trial, 9% of patients treated with RISPERDAL® CONSTA®, compared with 6% of patients treated with placebo, experienced a weight gain of >7% of body weight at endpoint. **Changes in ECG:** The electrocardiograms of 202 schizophrenic patients treated with 25 mg or 50 mg RISPERDAL® CONSTA® and 98 schizophrenic patients treated with placebo in the 12-week double-blind, placebo-controlled trial were evaluated. Compared with placebo, there were no statistically significant differences in QTc intervals (using Fridericia's and linear correction factors) during treatment with RISPERDAL® CONSTA®. **Pain Assessment and Local Injection Site Reactions:** The mean intensity of injection pain reported by patients using a visual analog scale (0 = no pain to 100 = unbearably painful) decreased in all treatment groups from the first to the last injection (placebo: 16.7 to 12.6; 25 mg: 12.0 to 9.0; 50 mg: 18.2 to 11.8). After the sixth injection (Week 10), investigator ratings indicated that 1% of patients treated with 25 mg or 50 mg RISPERDAL® CONSTA® experienced redness, swelling, or induration at the injection site. In a separate study to observe local-site tolerability in which RISPERDAL® CONSTA® was administered into the deltoid muscle every 2 weeks over a period of 8 weeks, no patient discontinued treatment due to local injection site pain or reaction. Clinician ratings indicated that only mild redness, swelling, or induration at the injection site was observed in subjects treated with 37.5 mg or 50 mg RISPERDAL® CONSTA® at 2 hours after deltoid injection. All ratings returned to baseline at the predose assessment of the next injection 2 weeks later. No moderate or severe reactions were observed in any subject. **Postmarketing Experience:** The following adverse reactions have been identified during postapproval use of risperidone; because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency: agranulocytosis, alopecia, anaphylactic reaction, angioedema, atrial fibrillation, diabetic ketoacidosis in patients with impaired glucose metabolism, inappropriate antidiuretic hormone secretion, hypothermia, intestinal obstruction, jaundice, mania, pancreatitis, priapism, QT prolongation, sleep apnea syndrome, thrombocytopenia, and water intoxication. In addition, the following adverse reactions have been observed during postapproval use of RISPERDAL® CONSTA®: cerebrovascular disorders, including cerebrovascular accidents, and diabetes mellitus aggravated. Retinal artery occlusion after injection of RISPERDAL® CONSTA® has been reported during postmarketing surveillance. This has been reported in the presence of abnormal arteriovenous anastomosis. Serious injection site reactions including abscess, cellulitis, cyst, hematoma, necrosis, nodule, and ulcer have been reported with RISPERDAL® CONSTA® during postmarketing surveillance. Isolated cases required surgical intervention.

DRUG INTERACTIONS: The interactions of RISPERDAL® CONSTA® with coadministration of other drugs have not been systematically evaluated. The drug interaction data provided in this section is based on studies with oral RISPERDAL®. **Centrally-Acting Drugs and Alcohol:** Given the primary CNS effects of risperidone, caution should be used when RISPERDAL® CONSTA® is administered in combination with other centrally-acting drugs or alcohol. **Drugs with Hypotensive Effects:** Because of its potential for inducing hypotension, RISPERDAL® CONSTA® may enhance the hypotensive effects of other therapeutic agents with this potential. **Levodopa and Dopamine Agonists:** RISPERDAL® CONSTA® may antagonize the effects of levodopa and dopamine agonists. **Amitriptyline:** Amitriptyline did not affect the pharmacokinetics of risperidone or of risperidone and 9-hydroxyrisperidone combined following concomitant administration with oral RISPERDAL®. **Cimetidine and Ranitidine:** Cimetidine and ranitidine increased the bioavailability of oral risperidone by 64% and 26%, respectively. However, cimetidine did not affect the AUC of risperidone and 9-hydroxyrisperidone combined, whereas ranitidine increased the AUC of risperidone and 9-hydroxyrisperidone combined by 20%. **Clozapine:** Chronic administration of clozapine with risperidone may decrease the clearance of risperidone. **Lithium:** Repeated doses of oral RISPERDAL® (3 mg twice daily) did not affect the exposure (AUC) or peak plasma concentrations (C_{max}) of lithium (n=13). **Valproate:** Repeated doses of oral RISPERDAL® (4 mg once daily) did not affect the pre-dose or average plasma concentrations and exposure (AUC) of valproate (1000 mg/day in three divided doses) compared to placebo (n=21). However, there was a 20% increase in valproate peak plasma concentration (C_{max}) after concomitant administration of oral RISPERDAL®. **Digoxin:** Oral RISPERDAL® (0.25 mg twice daily) did not show a clinically relevant effect on the pharmacokinetics of digoxin. **Topiramate:** Oral RISPERDAL® administered at doses from 1-6 mg/day concomitantly with topiramate 400 mg/day resulted in a 23% decrease in risperidone Cmax and a 33% decrease in risperidone $AUC_{0\text{-}12\ hour}$ at steady state. Minimal reductions in the exposure to risperidone and 9-hydroxyrisperidone combined, and no change for 9-hydroxyrisperidone were observed. This interaction is unlikely to be of clinical significance. There was no clinically relevant effect of oral RISPERDAL® on the pharmacokinetics of topiramate. **Drugs That Inhibit CYP 2D6 and Other CYP Isozymes:** Risperidone is metabolized to 9-hydroxyrisperidone by CYP 2D6, an enzyme that is polymorphic in the population and that can be inhibited by a variety of psychotropic and other drugs *[see Clinical Pharmacology in full PI]*. Drug interactions that reduce the metabolism of risperidone to 9-hydroxyrisperidone would increase the plasma concentrations of risperidone and lower the concentrations of 9-hydroxyrisperidone. Analysis of clinical studies involving a modest number of poor metabolizers (n≅70 patients) does not suggest that poor and extensive metabolizers have different rates of adverse effects. No comparison of effectiveness in the two groups has been made. *In vitro* studies showed that drugs metabolized by other CYP isozymes, including 1A1, 1A2, 2C9, 2C19, and 3A4, are only weak inhibitors of risperidone metabolism. Fluoxetine and Paroxetine: Fluoxetine (20 mg once daily) and paroxetine (20 mg once daily), CYP 2D6 inhibitors, have been shown to increase the plasma concentration of risperidone 2.5-2.8 fold and 3-9 fold respectively. Fluoxetine did not affect the plasma concentration of 9-hydroxyrisperidone. Paroxetine lowered the concentration of 9-hydroxyrisperidone by about 10%. When either concomitant fluoxetine or paroxetine is initiated or discontinued, the physician should re-evaluate the dose of RISPERDAL® CONSTA®. When initiation of fluoxetine or paroxetine is considered, patients may be placed on a lower dose of RISPERDAL® CONSTA® between 2 to 4 weeks before the planned start of fluoxetine or paroxetine therapy to adjust for the expected increase in plasma concentrations of risperidone. When fluoxetine or paroxetine is initiated in patients receiving the recommended dose of 25 mg RISPERDAL® CONSTA®, it is recommended to continue treatment with the 25-mg dose unless clinical judgment necessitates lowering the RISPERDAL® CONSTA® dose to 12.5 mg or necessitates interruption of RISPERDAL® CONSTA® treatment. When RISPERDAL® CONSTA® is initiated in patients already receiving fluoxetine or paroxetine, a starting dose of 12.5 mg can be considered. The efficacy of the 12.5 mg dose has not been investigated in clinical trials. *[See also Dosage and Administration in full PI]*. The effects of discontinuation of concomitant fluoxetine or paroxetine therapy on the pharmacokinetics of risperidone and 9-hydroxyrisperidone have not been studied. Erythromycin: There were no significant interactions between oral RISPERDAL® and erythromycin. **Carbamazepine and Other CYP 3A4 Enzyme Inducers:** Carbamazepine co-administration with oral RISPERDAL® decreased the steady-state plasma concentrations of risperidone and 9-hydroxyrisperidone by about 50%. Plasma concentrations of carbamazepine did not appear to be affected. Co-administration of other known CYP 3A4 enzyme inducers (e.g., phenytoin, rifampin, and phenobarbital) with risperidone may cause similar decreases in the combined plasma concentrations of risperidone and 9-hydroxyrisperidone, which could lead to decreased efficacy of RISPERDAL® CONSTA® treatment. At the initiation of therapy with carbamazepine or other known hepatic enzyme inducers, patients should be closely monitored during the first 4–8 weeks, since the dose of RISPERDAL® CONSTA® may need to be adjusted. A dose increase, or additional oral RISPERDAL®, may need to be considered. On discontinuation of carbamazepine or other CYP 3A4 hepatic enzyme inducers, the dosage of RISPERDAL® CONSTA® should be re-evaluated and, if necessary, decreased. Patients may be placed on a lower dose of RISPERDAL® CONSTA® between 2 to 4 weeks before the planned discontinuation of carbamazepine or other CYP 3A4 enzyme inducers to adjust for the expected increase in plasma concentrations of risperidone plus 9-hydroxyrisperidone. For patients treated with the recommended dose of 25 mg RISPERDAL® CONSTA® and discontinuing from carbamazepine or other CYP 3A4 enzyme inducers, it is recommended to continue treatment with the 25-mg dose unless clinical judgment necessitates lowering the RISPERDAL® CONSTA® dose to 12.5 mg or necessitates interruption of RISPERDAL® CONSTA® treatment. The efficacy of the 12.5 mg dose has not been investigated in clinical trials. *[See also Dosage and Administration in full PI]* **Drugs Metabolized by CYP 2D6:** *In vitro* studies indicate that risperidone is a relatively weak inhibitor of CYP 2D6. Therefore, RISPERDAL® CONSTA® is not expected to substantially inhibit the clearance of drugs that are metabolized by this enzymatic pathway. In drug interaction studies, oral RISPERDAL® did not significantly affect the pharmacokinetics of donepezil and galantamine, which are metabolized by CYP 2D6.

USE IN SPECIFIC POPULATIONS: Pregnancy: Pregnancy Category C.: The teratogenic potential of oral risperidone was studied in three embryofetal development studies in Sprague-Dawley and Wistar rats (0.63-10 mg/kg or 0.4 to 6 times the oral maximum recommended human dose [MRHD] on a mg/m² basis) and in one embryofetal development study in New Zealand rabbits (0.31-5 mg/kg or 0.4 to 6 times the oral MRHD on a mg/m² basis). The incidence of malformations was not increased compared to control in offspring of rats or rabbits given 0.4 to 6 times the oral MRHD on a mg/m² basis. In three reproductive studies in rats (two peri/post-natal development studies and a multigenerational study), there was an increase in pup deaths during the first 4 days of lactation at doses of 0.16-5 mg/kg or 0.1 to 3 times the oral MRHD on a mg/m² basis. It is not known whether these deaths were due to a direct effect on the fetuses or pups or to effects on the dams. There was no no-effect dose for increased rat pup mortality. In one peri/post-natal development study, there was an increase in stillborn rat pups at a dose of 2.5 mg/kg or 1.5 times the oral MRHD on a mg/m² basis. In a cross-fostering study in Wistar rats, toxic effects on the fetus or pups, as evidenced by a decrease in the number of live pups and an increase in the number of dead pups at birth (Day 0), and a decrease in birth weight in pups of drug-treated dams were observed. In addition, there was an increase in deaths by Day 1 among pups of drug-treated dams, regardless of whether or not the pups were cross-fostered. Risperidone also appeared to impair maternal behavior in that pup body weight gain and survival (from Days 1 to 4 of lactation) were reduced in pups born to control but reared by drug-treated dams. These effects were all noted at the one dose of risperidone tested, i.e., 5 mg/kg or 3 times the oral MRHD on a mg/m² basis. No studies were conducted with RISPERDAL® CONSTA®. Placental transfer of risperidone occurs in rat pups. There are no adequate and well-controlled studies in pregnant women. However, there was one report of a case of agenesis of the corpus callosum in an infant exposed to risperidone *in utero*. The causal relationship to oral RISPERDAL® therapy is unknown. Reversible extrapyramidal symptoms in the neonate were observed following postmarketing use of risperidone during the last trimester of pregnancy. RISPERDAL® CONSTA® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Labor and Delivery:** The effect of RISPERDAL® CONSTA® on labor and delivery in humans is unknown. **Nursing Mothers:** Risperidone and 9-hydroxyrisperidone are also excreted in human breast milk. Therefore, women should not breast-feed during treatment with RISPERDAL® CONSTA® and for at least 12 weeks after the last injection. **Pediatric Use:** RISPERDAL® CONSTA® has not been studied in children younger than 18 years old. **Geriatric Use:** In an open-label study, 57 clinically stable, elderly patients (≥ 65 years old) with schizophrenia or schizoaffective disorder received RISPERDAL® CONSTA® every 2 weeks for up to 12 months. In general, no differences in the tolerability of RISPERDAL® CONSTA® were observed between otherwise healthy elderly and nonelderly patients. Therefore, dosing recommendations for otherwise healthy elderly patients are the same as for nonelderly patients. Because elderly patients exhibit a greater tendency to orthostatic hypotension than nonelderly patients, elderly patients should be instructed in nonpharmacologic interventions that help to reduce the occurrence of orthostatic hypotension (e.g., sitting on the edge of the bed for several minutes before attempting to stand in the morning and slowly rising from a seated position). In addition, monitoring of orthostatic vital signs should be considered in elderly patients for whom orthostatic hypotension is of concern *[see Warnings and Precautions]*. Concomitant use with Furosemide in Elderly Patients with Dementia-Related Psychosis: In two of four placebo-controlled trials in elderly patients with dementia-related psychosis, a higher incidence of mortality was observed in patients treated with furosemide plus oral risperidone when compared to patients treated with oral risperidone alone or with oral placebo plus furosemide. No pathological mechanism has been identified to explain this finding, and no consistent pattern for cause of death was observed. An increase of mortality in elderly patients with dementia-related psychosis was seen with the use of oral risperidone regardless of concomitant use with furosemide. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis. *[See Boxed Warning and Warnings and Precautions]*

PATIENT COUNSELING INFORMATION: Physicians are advised to discuss the following issues with patients for whom they prescribe RISPERDAL® CONSTA®. **Orthostatic Hypotension:** Patients should be advised of the risk of orthostatic hypotension and instructed in nonpharmacologic interventions that help to reduce the occurrence of orthostatic hypotension (e.g., sitting on the edge of the bed for several minutes before attempting to stand in the morning and slowly rising from a seated position) *[see Warnings and Precautions]*. **Interference with Cognitive and Motor Performance:** Because RISPERDAL® CONSTA® has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that treatment with RISPERDAL® CONSTA® does not affect them adversely *[see Warnings and Precautions]*. **Pregnancy:** Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy and for at least 12 weeks after the last injection of RISPERDAL® CONSTA® *[see Use in Specific Populations]*. **Nursing:** Patients should be advised not to breast-feed an infant during treatment and for at least 12 weeks after the last injection of RISPERDAL® CONSTA® *[see Use in Specific Populations]*. **Concomitant Medication:** Patients should be advised to inform their physicians if they are taking, or plan to take, any prescription or over-the-counter drugs, since there is a potential for interactions *[see Drug Interactions]*. **Alcohol:** Patients should be advised to avoid alcohol during treatment with RISPERDAL® CONSTA® *[see Drug Interactions]*.

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Subthreshold Symptoms: Where Do They Lead?

Less may be more for architects, but sometimes it's enough for child psychiatrists assessing their young patients.

BY AARON LEVIN

Every child psychiatrist regularly sees orphans. No, not kids without parents but diagnostic orphans, troubled children with psychiatric symptoms that don't add up to a *DSM-IV* diagnosis for a specific disorder.

"Children come in with a little bit of a lot of things, especially rages, and they are significantly handicapped, even without a diagnosis, but they still need help," said Gabrielle Carlson, M.D. She was commenting on a discussion of subthreshold psychopathologies and their meaning at the annual meeting of the American Academy of Child and Adolescent Psychiatry in Chicago in October.

"We created diagnostic criteria in order to have a common language in psychiatry, and we had to simplify the terms in order to keep them useful," she said. "But things are just more complicated than we wish that they were."

Presenters at the symposium examined whether these subthreshold symptoms represented subsyndromal "noncases" or were precursors to full syndromes. The discussion, which included examples based on several disorders, also reflected the continuing dialogue between categorical and dimensional approaches to classifying illness.

William Copeland, Ph.D., of Duke University Medical Center began by citing data from the Great Smoky Mountains Study, covering 8,806 assessments of 1,420 participants who were followed from ages 9 to 13 until they turned 21.

He noted that at 473 assessment points, subjects recorded symptoms for oppositional defiant disorder (ODD), while also meeting duration criteria for the disorder at 470 of those points, making duration redundant.

Copeland also compared the *ICD-10* and *DSM-IV* criteria for ODD, noting that *DSM* lists separate criteria for ODD and conduct disorder (CD).

"Under the *DSM*, a child can have three ODD symptoms and two conduct disorder symptoms and would still not meet diagnostic criteria," he said. "Almost one-third of *ICD-10* disruptive behavior disorders [DBD] don't meet DBD criteria under *DSM-IV*, yet both groups are equally sick, judging by impairment or use of services."

Credit: Aaron Levin

Gabrielle Carlson, M.D.: "How do you trade off what is in front of you with what is down the road?"

Is Impairment Predictive Factor?

Investigators also looked at impairment as a predictive factor in the study. They found that subsyndromal CD with impairment does predict antisocial personality disorder later in adult life, but there was not much predictive difference between subthreshold ODD with and without impairment.

Looking at alcohol-related disorders, Christopher Martin, Ph.D., an associate professor of psychiatry and psychology at the University of Pittsburgh School of Medicine and the Pittsburgh Adolescent Alcohol Research Center, said, "The choice is not whether diagnostic criteria should be categorical or dimensional, but how to integrate both into our thinking."

The presence of at least three out of seven diagnostic symptoms is needed for a diagnosis of alcohol dependence, and at least one out of four symptoms is needed for a diagnosis of alcohol abuse, according to *DSM-IV*. *DSM* also says that abuse and dependence are mutually exclusive and dependence precludes a diagnosis of abuse.

"People with one or two symptoms may fall through the cracks, but they are more likely to have full-blown clinical symptoms one year later than if symptoms are absent," Martin said. These subclinical symptom ratings are therefore helpful in identifying persons at risk for future impairment or disorder, he said.

Role for Comorbid Disorders

Reporting on material gathered as part of the Oregon Adolescent Depression Project, Stewart Shankman, Ph.D., an assistant professor of psychology at the University of Illinois, Chicago, said that comorbid disorders are too often ignored in research studies. More attention to them might elucidate whether homotypic symptoms—ones associated with the corresponding full syndrome—predict escalation to those disorders.

The longitudinal study of 739 subjects at ages 16, 17, 24, and 30 found that subthreshold psychiatric symptoms observed at age 16 were initially associated at age 24 with anxiety, alcohol, and conduct disorder, but once adjusted for comorbidities, they were associated only with alcohol use and conduct disorders.

"It is important to understand why comorbidities exist and not just consider them nuisance variables," he said.

A second analysis from the same study found that subthreshold symptoms of major depressive disorder, bipolar disorder, anxiety, substance abuse, and conduct disorder were associated with familial risk and/or future development of the full syndrome disorders.

These subthreshold symptoms cannot be ignored, said Carlson, a professor of psychiatry and behavioral science at Stony Brook University School of Medicine in Stony Brook, N.Y., in her discussion of the panelists' talks.

please see ***Subthreshold*** *on page 34*

Substance-Abuse Risk Appears Less In Stimulant-Treated ADHD Patients

Girls with ADHD who had been treated with stimulants were less likely to develop substance use disorders in adolescence than were girls with ADHD who had never taken stimulants.

BY JUN YAN

Despite their potential for being abused, stimulants prescribed to treat children with attention-deficit/hyperactivity disorder (ADHD) do not increase the risks they will develop substance use disorder (SUD), alcohol use disorder, or begin smoking in adolescence, according to a study published in the October *Archives of Pediatric and Adolescent Medicine*.

In this observational study, the authors collected long-term health data and medical treatment histories on 114 young female patients with ADHD. The participants were aged 6 to 18 at the start of the study and followed for five years.

Twenty participants who had never taken stimulant medications were compared with the other 94 participants who had been treated with stimulants for ADHD in terms of each subject's use of cigarettes, alcohol, marijuana, and other substances.

The study data were derived from a longitudinal case-control study of adolescents with and without the disorder. The study was naturalistic and was not randomized. Nevertheless, the authors stated that the patients with and without stimulant exposure did not differ significantly in age, family status and SUD history, ADHD severity, and rate of conduct disorder.

The girls in the cohort who had a diagnosis of ADHD and no stimulant exposure generally did not receive other types of treatment, according to the study's lead author, Timothy Wilens, M.D., an associate professor of psychiatry at Harvard Medical School and director of substance abuse services in the Clinical and Research Program in Pediatric Psychopharmacology at Massachusetts General Hospital.

The ADHD patients who had taken stimulants had a 73 percent risk reduction for developing a subsequent SUD and a 72 percent risk reduction in taking up cigarette smoking compared with those who had never taken stimulants. Both reductions were statistically significant.

Stimulant-treated patients who did take up smoking did so at an older age on average than those not treated with stimulants. All the SUD diagnoses were made by blinded evaluators using *DSM-IV* criteria.

In addition, exposure to stimulant treatment was not associated with increased risk of substance dependence and alcohol abuse or dependence.

"The results of this study should calm the fears of both parents and clinicians that early stimulant treatment will lead to cigarette smoking or substance use in adolescence," said Wilens.

On the contrary, he continued, "the data showed a reduction in cigarette smoking and substance use risks [associated with stimulant use] at least in adolescence, which adds to a growing literature on the long-term positive effects of ADHD treatment on the development of these sequelae."

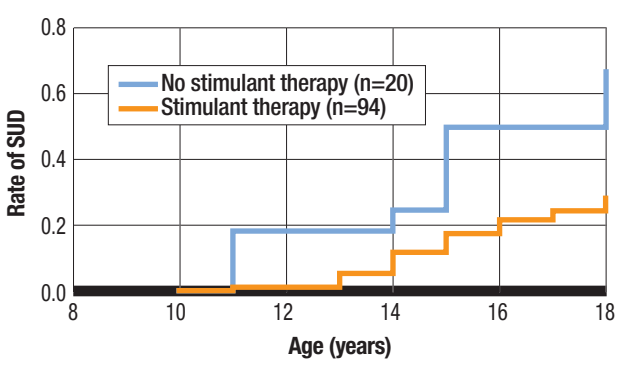
The study was funded by the National Institute of Health and the Lilly Foundation, the charitable arm of the pharmaceutical company.

Youngsters with untreated ADHD, especially adolescents, are at a significantly increased risk of developing substance use problems. Past research has shown that stimulant treatment does not increase the risk of smoking and substance use in boys with ADHD, the authors noted.

An abstract of "Effect of Prior Stimulant Treatment for Attention-Deficit/Hyperactivity Disorder on Subsequent Risk for Cigarette Smoking and Alcohol and Drug Use Disorders in Adolescents" is posted at <archpedi.ama-assn.org/cgi/content/abstract/162/10/916>. ■

SUD Less Common in Girls Given Stimulants for ADHD

In a five-year observational study of 114 girls with ADHD, the rate of substance use disorder (SUD) was significantly lower in the girls who had been treated with stimulants than in the girls who had never taken stimulants.



Source: Timothy Wilens, M.D., et al., *Arch Pediatr Adolesc Med*, October 2008


NEW
Introducing
A NEW SNRI therapy
for major depressive disorder in adults

IMPORTANT TREATMENT CONSIDERATIONS

PRISTIQ 50 mg is indicated for the treatment of major depressive disorder in adults.

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 PRISTIQ 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. PRISTIQ is not approved for use in pediatric patients.

Contraindications

- PRISTIQ is contraindicated in patients with a known hypersensitivity to PRISTIQ or venlafaxine.
- PRISTIQ must not be used concomitantly with an MAOI or within 14 days of stopping an MAOI. Allow 7 days after stopping PRISTIQ before starting an MAOI.

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 during 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, hypomania, mania, or suicidality that are severe, abrupt in onset, or were not part of the patient's presenting symptoms. **Families and caregivers of patients being treated with antidepressants should be alerted about the need to monitor patients.**
- Development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including PRISTIQ, particularly with concomitant use of serotonergic drugs, including triptans, and with drugs that impair the metabolism of serotonin (including MAOIs). If concomitant use is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. Concomitant use of PRISTIQ with serotonin precursors is not recommended.
- Patients receiving PRISTIQ should have regular monitoring of blood pressure since sustained increases in blood pressure were observed in clinical studies. Pre-existing hypertension should be controlled before starting PRISTIQ. Caution should be exercised in treating patients with pre-existing hypertension or other underlying conditions that might be compromised by increases in blood pressure. Cases of elevated blood pressure requiring immediate treatment have been reported. For patients who experience a sustained increase in blood pressure, either dose reduction or discontinuation should be considered.

For major depressive disorder in adults

New SNRI therapy. From the start: One dose. No titration.

- The major active metabolite of Effexor XR® (venlafaxine HCl)[1]
- One simple 50-mg dose, no need to titrate[1]
  - — Dosage adjustment is necessary in patients with severe renal impairment or end-stage renal disease and is recommended when discontinuing therapy
- PRISTIQ may help your patients with depression—emotionally, physically, and functionally[1-3]
- Discontinuation rate due to adverse events was comparable to placebo in clinical studies at 50 mg[1]

New Pristiq™ desvenlafaxine
EXTENDED-RELEASE TABLETS

- SSRIs and SNRIs, including PRISTIQ, may increase the risk of bleeding events. Concomitant use of aspirin, NSAIDs, warfarin, and other anticoagulants may add to this risk.
- Mydriasis has been reported in association with PRISTIQ; therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure glaucoma) should be monitored.
- PRISTIQ is not approved for use in bipolar depression. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine the risk of bipolar disorder.
- As with all antidepressants, PRISTIQ should be used cautiously in patients with a history or family history of mania or hypomania, or with a history of seizure disorder.
- Caution is advised in administering PRISTIQ to patients with cardiovascular, cerebrovascular, or lipid metabolism disorders. Increases in blood pressure and small increases in heart rate were observed in clinical studies with PRISTIQ. PRISTIQ has not been evaluated systematically in patients with a recent history of myocardial infarction, unstable heart disease, uncontrolled hypertension, or cerebrovascular disease.
- Dose-related elevations in fasting serum total cholesterol, LDL (low density lipoprotein) cholesterol, and triglycerides were observed in clinical studies. Measurement of serum lipids should be considered during PRISTIQ treatment.
- On discontinuation, adverse events, some of which may be serious, have been reported with PRISTIQ and other SSRIs and SNRIs. Abrupt discontinuation of PRISTIQ has been associated with the appearance of new symptoms. Patients should be monitored for symptoms when discontinuing treatment. A gradual reduction in dose (by giving 50 mg of PRISTIQ less frequently) rather than abrupt cessation is recommended whenever possible.
- Dosage adjustment (50 mg every other day) is necessary in patients with severe renal impairment or end-stage renal disease (ESRD). The dose should not be escalated in patients with moderate or severe renal impairment or ESRD.
- Products containing desvenlafaxine and products containing venlafaxine should not be used concomitantly with PRISTIQ.
- Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including PRISTIQ. Discontinuation of PRISTIQ should be considered in patients with symptomatic hyponatremia.
- Interstitial lung disease and eosinophilic pneumonia associated with venlafaxine (the parent drug of PRISTIQ) therapy have been rarely reported.

Adverse Reactions

- The most commonly observed adverse reactions in patients taking PRISTIQ vs placebo for MDD in short-term fixed-dose premarketing studies (incidence ≥5% and twice the rate of placebo in the 50-mg dose group) were nausea (22% vs 10%), dizziness (13% vs 5%), hyperhidrosis (10% vs 4%), constipation (9% vs 4%), and decreased appetite (5% vs 2%).

References: 1. Pristiq™ (desvenlafaxine) Prescribing Information, Wyeth Pharmaceuticals Inc. **2.** Data on file, Wyeth Pharmaceuticals Inc. **3.** Sheehan DV, Sheehan Disability Scale. In: Rush AJ Jr, Pincus HA, First MB, et al, eds. *Handbook of Psychiatric Measures*. 1st ed. Washington, DC: American Psychiatric Association; 2000:113-115.

Please see brief summary of Prescribing Information on adjacent page.

Pristiq™ desvenlafaxine

Wyeth®

Pristiq™ desvenlafaxine Extended-Release Tablets

BRIEF SUMMARY. See package insert for full Prescribing Information. For further product information and current package insert, please visit www.wyeth.com or call our medical communications department toll-free at 1-800-934-5556.

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 Pristiq 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. Pristiq is not approved for use in pediatric patients [*see Warnings and Precautions (5.1), Use in Specific Populations (8.4), and Patient Counseling Information (17.1 in the full prescribing information)*].

INDICATIONS AND USAGE: Pristiq, a selective serotonin and norepinephrine reuptake inhibitor (SNRI), is indicated for the treatment of major depressive disorder (MDD).

CONTRAINDICATIONS: Hypersensitivity- Hypersensitivity to desvenlafaxine succinate, venlafaxine hydrochloride or to any excipients in the Pristiq formulation. **Monoamine Oxidase Inhibitors-** Pristiq must not be used concomitantly in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days due to the risk of serious, sometimes fatal, drug interactions with SNRI or SSRI treatment or with other serotonergic drugs. Based on the half-life of desvenlafaxine, at least 7 days should be allowed after stopping Pristiq before starting an MAOI [*see Dosage and Administration (2.5) in the full prescribing information*].

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 studies 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 studies in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term studies of 9 antidepressant drugs in over 4,400 patients. The pooled analyses of placebo-controlled studies in adults with MDD or other psychiatric disorders included a total of 295 short-term studies (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 of the full prescribing information. No suicides occurred in any of the pediatric studies. There were suicides in the adult studies, 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 studies 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 Warnings and Precautions (5.9) and Dosage and Administration (2.3) in the full prescribing information for a description of the risks of discontinuation of Pristiq*]. 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 Pristiq 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 studies) 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 Pristiq is not approved for use in treating bipolar depression. **Serotonin Syndrome-** The development of a potentially life-threatening serotonin syndrome may occur with Pristiq treatment, particularly with concomitant use of other serotonergic drugs (including SSRIs, SNRIs and triptans) and with drugs that impair metabolism of serotonin (including MAOIs). The concomitant use of Pristiq and MAOIs is contraindicated [*see Contraindications (4.2)*]. If concomitant treatment with Pristiq and an SSRI, another SNRI or 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 Pristiq with serotonin precursors (such as tryptophan supplements) is not recommended. **Elevated Blood Pressure-** Patients receiving Pristiq should have regular monitoring of blood pressure since dose-dependent increases were observed in clinical studies. Pre-existing hypertension should be controlled before initiating treatment with Pristiq. Caution should be exercised in treating patients with pre-existing hypertension or other underlying conditions that might be compromised by increases in blood pressure. Cases of elevated blood pressure requiring immediate treatment have been reported with Pristiq. Sustained hypertension- Sustained blood pressure increases could have adverse consequences. For patients who experience a sustained increase in blood pressure while receiving Pristiq, either dose reduction or discontinuation should be considered [*see Adverse Reactions (6.1)*]. Treatment with Pristiq in controlled studies was associated with sustained hypertension, defined as treatment-emergent supine diastolic blood pressure (SDBP) ≥ 90 mm Hg and ≥ 10 mm Hg above baseline for 3 consecutive on-therapy visits. In clinical studies, regarding the proportion of patients with sustained hypertension, the following rates were observed: placebo (0.5%), Pristiq 50 mg (1.3%), Pristiq 100 mg (0.7%), Pristiq 200 mg (1.1%), and Pristiq 400 mg (2.3%). Analyses of patients in Pristiq controlled studies who met criteria for sustained hypertension revealed a dose-dependent increase in the proportion of patients who developed sustained hypertension. **Abnormal Bleeding-** SSRIs and SNRIs can increase the risk of bleeding events. Concomitant use of aspirin, other drugs that affect platelet function, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants can add to this risk. Bleeding events related to SSRIs and SNRIs have ranged from ecchymosis, hematoma, epistaxis, and petechiae to life-threatening hemorrhages. Patients should be cautioned about the risk of bleeding associated with the concomitant use of Pristiq and NSAIDs, aspirin, or other drugs that affect coagulation or bleeding. **Narrow-angle Glaucoma-** Mydriasis has been reported in association with Pristiq; therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure glaucoma) should be monitored. **Activation of Mania/Hypomania-** During all MDD and VMS (vasomotor symptoms) phase 2 and phase 3 studies, mania was reported for approximately 0.1% of patients treated with Pristiq. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorder who were treated with other marketed antidepressants. As with all antidepressants, Pristiq should be used cautiously in patients with a history or family history of mania or hypomania. **Cardiovascular/ Cerebrovascular Disease-** Caution is advised in administering Pristiq to patients with cardiovascular, cerebrovascular, or lipid metabolism disorders [*see Adverse Reactions (6.1)*]. Increases in blood pressure and heart rate were observed in clinical studies with Pristiq. Pristiq has not been evaluated systematically in patients with a recent history of myocardial infarction, unstable heart disease, uncontrolled hypertension, or cerebrovascular disease. Patients with these diagnoses, except for cerebrovascular disease, were excluded from clinical studies. **Serum Cholesterol and Triglyceride Elevation-** Dose-related elevations in fasting serum total cholesterol, LDL (low density lipoprotein) cholesterol, and triglycerides were observed in the controlled studies. Measurement of serum lipids should be considered during treatment with Pristiq [*see Adverse Reactions (6.1)*]. **Discontinuation of Treatment with Pristiq-** Discontinuation symptoms have been systematically and prospectively evaluated in patients treated with Pristiq during clinical studies in Major Depressive Disorder. Abrupt discontinuation or dose reduction has been associated with the appearance of new symptoms that include dizziness, nausea, headache, irritability, insomnia, diarrhea, anxiety, fatigue, abnormal dreams, and hyperhidrosis. In general, discontinuation events occurred more frequently with longer duration of therapy. During marketing of SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors) and SSRIs (Selective Serotonin 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., paresthesia, such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. 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 Pristiq. 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 (2.4) and Adverse Reactions (6.1) in full prescribing information*]. **Renal Impairment-** In patients with moderate or severe renal impairment or end-stage renal disease (ESRD) the clearance of Pristiq was decreased, thus prolonging the elimination half-life of the drug. As a result, there were potentially clinically significant increases in exposures to Pristiq [*see Clinical Pharmacology (12.6) in full prescribing information*]. Dosage adjustment (50 mg every other day) is necessary in patients with severe renal impairment or ESRD. The doses should not be escalated in patients with moderate or severe renal impairment or ESRD [*see Dosage and Administration (2.2) in full prescribing information*]. **Seizure-** Cases of seizure have been reported in premarketing clinical studies with Pristiq. Pristiq should be prescribed with caution in patients with a seizure disorder. **Hyponatremia-** Hyponatremia can occur as a result of treatment with SSRIs and SNRIs, including Pristiq. In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Elderly patients can be at greater risk of developing hyponatremia with SSRIs and SNRIs. Also, patients taking diuretics or who are otherwise volume depleted can be at greater risk [*see Use in Specific Populations (8.5) and Clinical Pharmacology (12.6) in full prescribing information*]. Discontinuation of Pristiq should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted. **Coadministration of Drugs Containing Desvenlafaxine and Venlafaxine-** Desvenlafaxine is the major active metabolite of venlafaxine. Products containing desvenlafaxine and products containing venlafaxine should not be used concomitantly with Pristiq. **Interstitial Lung Disease and Eosinophilic Pneumonia-** Interstitial lung disease and eosinophilic pneumonia associated with venlafaxine (the parent drug of Pristiq) therapy have been rarely reported. The possibility of these adverse events should be considered in patients treated with Pristiq who present with progressive dyspnea, cough, or chest discomfort. Such patients should undergo a prompt medical evaluation, and discontinuation of Pristiq should be considered.

ADVERSE REACTIONS: Clinical Studies Experience: The most commonly observed adverse reactions in Pristiq-treated MDD patients in short-term fixed-dose studies (incidence ≥5% and at least twice the rate of placebo in the 50- or 100-mg dose groups) were nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, and specific male sexual function disorders. Adverse reactions reported as reasons for discontinuation of treatment- The most common adverse reactions leading to discontinuation in at least 2% of the Pristiq-treated patients in the short-term studies, up to 8 weeks, were nausea (4%); dizziness, headache and vomiting (2% each); in the long-term study, up to 9 months, the most common was vomiting (2%). Common adverse reactions in placebo-controlled MDD studies- Table 3 in full PI shows the incidence of common adverse reactions that occurred in ≥2% of Pristiq-treated MDD patients at any dose in the 8-week, placebo-controlled, fixed-dose, premarketing clinical studies. In general, the adverse reactions were most frequent in the first week of treatment. Cardiac disorders: Palpitations; Tachycardia, Blood pressure increased; Gastrointestinal disorders: Nausea, Dry mouth, Diarrhea, Constipation, Vomiting; General disorders and administration site conditions: Fatigue, Chills, Feeling jittery, Asthenia; Metabolism and nutrition disorders: Decreased appetite, weight decreased; Nervous system disorders: Dizziness, Somnolence, Headache, Tremor, Paraesthesia, Disturbance in attention; Psychiatric Disorders: Insomnia, Anxiety, Nervousness, Irritability, Abnormal dreams; Renal and urinary disorders: Urinary hesitation; Respiratory, thoracic, and mediastinal disorders: Yawning; Skin and subcutaneous tissue disorders: Hyperhidrosis, Rash; Special Senses: Vision blurred; Mydriasis, Tinnitus, Dysgeusia; Vascular Disorders: Hot flush. Sexual function adverse reactions-Table 4 shows the incidence of sexual function adverse reactions that occurred in ≥2% of Pristiq-treated MDD patients in any fixed-dose group (8-week, placebo-controlled, fixed and flexible-dose, premarketing clinical studies). Men Only: Anorgasmia, Libido decreased, Orgasm abnormal, Ejaculation delayed, Erectile dysfunction, Ejaculation disorder, Ejaculation failure, Sexual dysfunction; Women Only: Anorgasmia Other adverse reactions observed in premarketing clinical studies: Other infrequent adverse reactions occurring at an incidence of <2% in MDD patients treated with Pristiq were: *Immune system disorders* – Hypersensitivity. *Investigations* – Liver function test abnormal, blood prolactin increased. *Nervous system disorders* – Convulsion, syncope, extrapyramidal disorder. *Psychiatric disorders* – Depersonalization, hypomania. *Respiratory, thoracic and mediastinal disorders* – Epistaxis. *Vascular disorders* – Orthostatic hypotension. In clinical studies, there were uncommon reports of ischemic cardiac adverse events, including myocardial ischemia, myocardial infarction, and coronary occlusion requiring revascularization; these patients had multiple underlying cardiac risk factors. More patients experienced these events during Pristiq treatment as compared to placebo [*see Warnings and Precautions (5.7)*]. Discontinuation events-Adverse events reported in association with abrupt discontinuation, dose reduction or tapering of treatment in MDD clinical studies at a rate of ≥5% include dizziness, nausea, headache, irritability, insomnia, diarrhea, anxiety, abnormal dreams, fatigue, and hyperhidrosis. In general, discontinuation events occurred more frequently with longer duration of therapy [*see Dosage and Administration (2.4) and Warnings and Precautions (5.9) in full prescribing information*]. Laboratory, ECG and vital sign changes observed in MDD clinical studies- The following changes were observed in placebo-controlled, short-term, premarketing MDD studies with Pristiq. *Lipids*-Elevations in fasting serum total cholesterol, LDL (low density lipoproteins) cholesterol, and triglycerides occurred in the controlled studies. Some of these abnormalities were considered potentially clinically significant [*see Warnings and Precautions (5.8)*]. *Proteinuria*-Proteinuria, greater than or equal to trace, was observed in the fixed-dose controlled studies (see Table 6 in full prescribing information). This proteinuria was not associated with increases in BUN or creatinine and was generally transient. *ECG changes*-Electrocardiograms were obtained from 1,492 Pristiq-treated patients with major depressive disorder and 984 placebo-treated patients in clinical studies lasting up to 8 weeks. No clinically relevant differences were observed between Pristiq-treated and placebo-treated patients for QT, QTc, PR, and QRS intervals. In a thorough QTc study with prospectively determined criteria, desvenlafaxine did not cause QT prolongation. No difference was observed between placebo and desvenlafaxine treatments for the QRS interval. *Vital sign changes*-Table 7 summarizes the changes that were observed in placebo-controlled, short-term, premarketing studies with Pristiq in patients with MDD (doses 50 to 400 mg). Relative to placebo, Pristiq was associated with mean increase of up to 2.1 mm Hg in systolic blood pressure, 2.3 mm Hg in diastolic blood pressure, and 4.1 bpm with supine pulse. At the final on-therapy assessment in the 6-month, double-blind, placebo-controlled phase of a long-term study in patients who had responded to Pristiq during the initial 12-week, open-label phase, there was no statistical difference in mean weight gain between Pristiq- and placebo-treated patients. **DRUG INTERACTIONS: Central Nervous System (CNS)-Active Agents-** The risk of using Pristiq in combination with other CNS-active drugs has not been systematically evaluated. Consequently, caution is advised when Pristiq is taken in combination with other CNS-active drugs [*see Warnings and Precautions (5.13)*]. **Monoamine Oxidase Inhibitors (MAOIs)-** Adverse reactions, some of which were serious, have been reported in patients who have recently been discontinued from a monoamine oxidase inhibitor (MAOI) and started on antidepressants with pharmacological properties similar to Pristiq (SNRIs or SSRIs), or who have recently had SNRI or SSRI therapy discontinued prior to initiation of an MAOI [*see Contraindications (4.2)*]. **Serotonergic Drugs-** Based on the mechanism of action of Pristiq and the potential for serotonin syndrome, caution is advised when Pristiq is coadministered with other drugs that may affect the serotonergic neurotransmitter systems [*see Warnings and Precautions (5.2)*]. **Drugs that Interfere with Hemostasis (e.g., NSAIDs, Aspirin, and Warfarin)-** Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of case-control and cohort design have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding. These studies 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 and SNRIs are coadministered with warfarin. Patients receiving warfarin therapy should be carefully monitored when Pristiq is initiated or discontinued. **Ethanol-** A clinical study has shown that desvenlafaxine does not increase the impairment of mental and motor skills caused by ethanol. However, as with all CNS-active drugs, patients should be advised to avoid alcohol consumption while taking Pristiq. **Potential for Other Drugs to Affect Desvenlafaxine-** Inhibitors of CYP3A4 (ketoconazole)- CYP3A4 is a minor pathway for the metabolism of Pristiq. Concomitant use of Pristiq with potent inhibitors of CYP3A4 may result in higher concentrations of Pristiq. Inhibitors of other CYP enzymes- Based on *in vitro* data, drugs that inhibit CYP isozymes 1A1, 1A2, 2A6, 2D6, 2C8, 2C9, 2C19, and 2E1 are not expected to have significant impact on the pharmacokinetic profile of Pristiq. **Potential for Desvenlafaxine to Affect Other Drugs-** Drugs metabolized by CYP2D6 (desipramine)- *In vitro* studies showed minimal inhibitory effect of desvenlafaxine on CYP2D6. Clinical studies have shown that desvenlafaxine does not have a clinically relevant effect on CYP2D6 metabolism at the dose of 100 mg daily. Concomitant use of desvenlafaxine with a drug metabolized by CYP2D6 can result in higher concentrations of that drug. Drugs metabolized by CYP3A4 (midazolam)- *In vitro*, desvenlafaxine does not inhibit or induce the CYP3A4 isozyme. Concomitant use of Pristiq with a drug metabolized by CYP3A4 can result in lower exposures to that drug. Drugs metabolized by CYP1A2, 2A6, 2C8, 2C9 and 2C19- *In vitro*, desvenlafaxine does not inhibit CYP1A2, 2A6, 2C8, 2C9, and 2C19 isozymes and would not be expected to affect the pharmacokinetics of drugs that are metabolized by these CYP isozymes. **P-glycoprotein Transporter-** *In vitro*, desvenlafaxine is not a substrate or an inhibitor for the P-glycoprotein transporter. The pharmacokinetics of Pristiq are unlikely to be affected by drugs that inhibit the P-glycoprotein transporter, and desvenlafaxine is not likely to affect the pharmacokinetics of drugs that are substrates of the P-glycoprotein transporter. **Electroconvulsive Therapy-** There are no clinical data establishing the risks and/or benefits of electroconvulsive therapy combined with Pristiq treatment. **USE IN SPECIFIC POPULATIONS: Pregnancy-** Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. Teratogenic effects – Pregnancy Category C- There are no adequate and well-controlled studies of Pristiq in pregnant women. Therefore, Pristiq should be used during pregnancy only if the potential benefits justify the potential risks. Non-teratogenic effects- Neonates exposed to SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors), or SSRIs (Selective Serotonin Reuptake Inhibitors), 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 (5.2)*]. When treating a pregnant woman with Pristiq during the third trimester, the physician should carefully consider the potential risks and benefits of treatment [*see Dosage and Administration (2.2)*]. **Labor and Delivery-** The effect of Pristiq on labor and delivery in humans is unknown. Pristiq should be used during labor and delivery only if the potential benefits justify the potential risks. **Nursing Mothers-** Desvenlafaxine (O-desmethylvenlafaxine) is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from Pristiq, a decision should be made whether or not to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Only administer Pristiq to breastfeeding women if the expected benefits outweigh any possible risk. **Pediatric Use-** Safety and effectiveness in the pediatric population have not been established [*see Box Warning and Warnings and Precautions (5.1)*]. Anyone considering the use of Pristiq in a child or adolescent must balance the potential risks with the clinical need. **Geriatric Use-** Of the 3,292 patients in clinical studies with Pristiq, 5% were 65 years of age or older. No overall differences in safety or efficacy were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. For elderly patients, possible reduced renal clearance of desvenlafaxine should be considered when determining dose [*see Dosage and Administration (2.2) and Clinical Pharmacology (12.6) in the full prescribing information*]. **Renal Impairment-** In subjects with renal impairment the clearance of Pristiq was decreased. In subjects with severe renal impairment (24-hr CrCl < 30 mL/min) and end-stage renal disease, elimination half-lives were significantly prolonged, increasing exposures to Pristiq; therefore, dosage adjustment is recommended in these patients [*see Dosage and Administration (2.2) and Clinical Pharmacology (12.6) in the full prescribing information*]. **Hepatic Impairment-** The mean $t_{1/2}$ changed from approximately 10 hours in healthy subjects and subjects with mild hepatic impairment to 13 and 14 hours in moderate and severe hepatic impairment, respectively. No adjustment in starting dosage is necessary for patients with hepatic impairment.

OVERDOSAGE: Human Experience with Overdosage- There is limited clinical experience with desvenlafaxine succinate overdosage in humans. In premarketing clinical studies, no cases of fatal acute overdose of desvenlafaxine were reported. The adverse reactions reported within 5 days of an overdose > 600 mg that were possibly related to Pristiq included headache, vomiting, agitation, dizziness, nausea, constipation, diarrhea, dry mouth, paresthesia, and tachycardia. Desvenlafaxine (Pristiq) is the major active metabolite of venlafaxine. Overdose experience reported with venlafaxine (the parent drug of Pristiq) is presented below; the identical information can be found in the *Overdosage* section of the venlafaxine package insert. In postmarketing experience, overdose with venlafaxine (the parent drug of Pristiq) has occurred predominantly in combination with alcohol and/or other drugs. The most commonly reported events in overdosage include tachycardia, changes in level of consciousness (ranging from somnolence to coma), mydriasis, seizures, and vomiting. Electrocardiogram changes (e.g., prolongation of QT interval, bundle branch block, QRS prolongation), sinus and ventricular tachycardia, bradycardia, hypotension, rhabdomyolysis, vertigo, liver necrosis, serotonin syndrome, and death have been reported. Published retrospective studies report that venlafaxine overdosage may be associated with an increased risk of fatal outcomes compared to that observed with SSRI antidepressant products, but lower than that for tricyclic antidepressants. Epidemiological studies have shown that venlafaxine-treated patients have a higher pre-existing burden of suicide risk factors than SSRI-treated patients. The extent to which the finding of an increased risk of fatal outcomes can be attributed to the toxicity of venlafaxine in overdosage, as opposed to some characteristic(s) of venlafaxine-treated patients, is not clear. Prescriptions for Pristiq should be written for the smallest quantity of capsules consistent with good patient management, in order to reduce the risk of overdose. **Management of Overdosage-** Treatment should consist of those general measures employed in the management of overdosage with any SSRI/SNRI. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients. Activated charcoal should be administered. Induction of emesis is not recommended. Because of the moderate volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. No specific antidotes for desvenlafaxine are known. In managing an overdose, 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. Telephone numbers for certified poison control centers are listed in the Physicians Desk Reference (PDR®).

This brief summary is based on Pristiq Prescribing Information W10529C002, revised April 2008.

Wyeth®

Combined Therapy Proves Superior For Pediatric Anxiety Disorder

If more clinicians were trained in both cognitive-behavioral therapy and pharmacotherapy, more children with anxiety disorders might experience better outcomes.

BY JUN YAN

Cognitive-behavioral therapy (CBT) combined with a selective serotonin-reuptake inhibitor is more effective than either treatment alone for pediatric anxiety disorders, a large randomized, controlled clinical trial funded by the National Institute of Mental Health has found.

The study recruited patients from December 2002 to May 2007. Results from phase 1 of the study, which evaluated the effectiveness of three active treatments compared with placebo in the first 12 weeks, were published online in the *New England Journal of Medicine* on October 30.

Researchers at six academic medical centers enrolled 488 children aged 7 to 17 who had a primary diagnosis of separation anxiety disorder, generalized anxiety disorder, or social phobia.

These patients were randomly assigned to one of four treatment groups: CBT only (n=139), sertraline only (n=133), combined CBT and sertraline (n=140), and an oral placebo (n=76). Patients in the placebo or sertraline-only groups did not know their treatment assignment, but those in the combination therapy group or CBT-only group knew they were not taking placebo.

At the end of the 12-week treatment, 80.7 percent of patients in the combination treatment group were rated as very much or much improved by independent evaluators who were unaware of treatment assignments. The assessment was made on the basis of the seven-point Clinician Global Impression–Improvement (CGI-I) scale, in which a score of 1 or 2 reflects "a substantial, clinical meaningful improvement in anxiety severity and normal functioning" compared with baseline, according to the authors.

The improvement of the combination treatment group was significantly greater than that of the monotherapy groups. Approximately 60 percent in the CBT-only group and 55 percent in the sertraline-only group were found to be "very much improved" or "much improved" at week 12. Both monotherapies were significantly superior to placebo, with only 24 percent of placebo patients very much or much improved.

CBT was provided in 14 60-minute sessions over the 12 weeks for both the CBT-only and the combination treatment groups. Pharmacotherapy began with 25 mg/day of sertraline, and the dose was adjusted up to 200 mg/day. Patients in the placebo and sertraline-only groups visited the study sites for eight 30- to 60-minute sessions to assess their symptoms and adverse events.

"The study shows that we have three really good treatment options," John Walkup, M.D., an associate professor of psychiatry and deputy director of the Division of Child and Adolescent Psychiatry at Johns Hopkins Medical Institutions and lead author of the study, told *Psychiatric News*. "In places where it is available, combination therapy is the way to go."

He pointed out that the effectiveness of CBT alone provides assurance to parents who are reluctant to put their children on medications. "In communities where CBT is not available, because we are not training enough clinicians to do manualized CBT, medication is not a bad idea." He noted that sertraline was relatively well tolerated even though the mean dosages were 133.7 mg/day in the combination treatment group and 146.0 mg/day in the sertraline-only group.

Fourteen patients dropped out of the study because of adverse events, including three in the combination-therapy group, eight in the sertraline-alone group, and three in the placebo group. CBT appeared to be better tolerated than the other treatments. The CBT-only group had the fewest dropouts—none withdrew because of adverse events or symptom worsening.

The average age of study patients was under 11 years, and most had moderate to severe anxiety and impairment. More than three-quarters were diagnosed with two or more primary anxiety disorders, and more than half had a secondary diagnosis of another psychiatric disorder that was less severe than the anxiety disorder. Patients with suicidal ideation at the time of enrollment were excluded from the study, but those with only a history of suicidal ideation were not.

No suicide attempt was made by any subject in the study. Five patients in the combination group, five in the CBT-only group, and one in the placebo group reported suicidal ideation; none did in the sertraline-only group.

The CBT approach used in the study was based on the Coping Cat program manual. It included teaching children anxiety-management skills, implementing behavioral exposure to anxiety-causing situations, and two parent-only sessions.

Because this study and previous research have demonstrated that CBT is generally as effective as medication alone, Walkup hoped the finding would encourage pediatric medicine, not just psychiatry, to incorporate training programs for this evidence-based intervention. "There aren't enough specialists to meet the needs of these anxious kids," he said. "We need to train more clinicians who can do both CBT and medication management to fulfill the promise of these treatments."

An abstract of "Cognitive Behavioral Therapy, Sertraline, or a Combination in Childhood Anxiety" is posted at <content.nejm.org/cgi/content/abstract/NEJMoa0804633v2>. ■

Monitor Suicide Risk After Surgery For Parkinson's, Clinicians Urged

Deep brain stimulation for advanced Parkinson's disease may be followed by increased suicide risk. The suicide risk in turn seems to be largely due to postoperative depression.

BY JOAN AREHART-TREICHEL

Deep stimulation of the subthalamic nucleus region of the brain is a well-established surgical procedure for treating advanced Parkinson's disease. It can dramatically improve patients' motor symptoms and quality of life. However, according to a new study in the October *Brain*, clinicians are advised to monitor such patients carefully for suicide risk following the procedure.

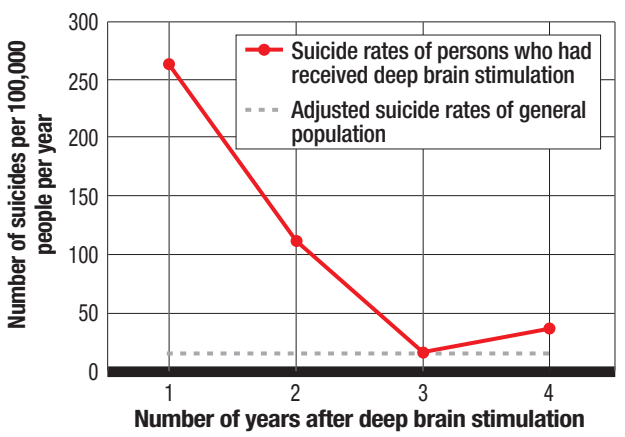
The international case-control study, nested within a retrospective survey of movement disorder, included more than 5,000 subjects. All had undergone deep stimulation of the subthalamic nucleus area to alleviate Parkinson's disease symptoms. The subjects had been treated at 55 centers in North America, South America, Europe, and Asia.

Their suicide rates after the procedure were compared with the age- and gender-adjusted suicide rates of the general population in their respective countries. (The authors cited literature showing that Parkinson's disease suicide rates ranged from the same as to as much as 10 times lower than the those of the general population.)

The suicide rate of the subjects who had received deep brain stimulation for Parkinson's disease was statistically, significantly much higher during the first year after the procedure compared with the country-specific adjusted general population suicide rates. The suicide rates of the Parkinson's patients during the second, third, and fourth years after the procedure were lower than during the first year, but still significantly elevated.

Suicide Risk Increases After Brain Stimulation

In an international study of about 5,000 subjects who underwent deep brain stimulation for advanced Parkinson's, the subjects' suicide rate was significantly higher during the four years after surgery compared with the suicide rate in the general population matched on age, gender, and country. The rate was highest in the first year after surgery.



Source: Valerie Voon, M.D., et al., *Brain*, October 2008

These results did not surprise the study's lead investigator, Valerie Voon, M.D., a staff psychiatrist at Toronto Western Hospital in Canada when the study was conducted. She told *Psychiatric News* that "there were early reports of very high, postoperative suicide rates based on single centers. This study [simply] helps establish that the rate is high."

Voon and her colleagues also tried to identify the reason or reasons for the increased risk of suicide in Parkinson's subjects who had received deep brain stimulation by comparing Parkinson's subjects who had received the procedure and had committed or attempted suicide to Parkinson's patients who had received the procedure but had not committed or attempted suicide. They found that being younger, having an earlier age at the onset of the disease, being single, having a history of impulse control disorders, and having made a previous suicide attempt seemed to be some of the reasons. However, the major reason appeared to be postoperative depression. But why?

"There is no evidence that subthalamic nucleus deep brain stimulation is associated with depression," said Voon, who is now affiliated with the U.S. National Institute of Neurological Diseases and Stroke. "On the contrary, the majority of studies note an overall improvement in mood symptoms [after the stimulation]." Thus, it is unlikely that the postoperative depression is due to the stimulation, she said.

However, two other possibilities may explain the postoperative depression, she noted: the depression was caused by Parkinson's disease or it existed prior to the procedure. Further analysis revealed that the postoperative depressed subjects had a significantly greater frequency of preoperative antidepressant use and a trend toward more frequent preoperative suicide attempts than the postoperative nondepressed subjects. This finding supports the possibility that the depression existed prior to surgery.

In any event, the findings suggest that psychiatrists involved in the selection of patients for deep brain stimulation for Parkinson's disease, or for other conditions, should carefully screen them for suicide risk, said Voon. Such an assessment "is not necessarily a contraindication to surgery," she explained. Furthermore, after patients receive deep brain stimulation, psychiatrists should evaluate them for depression, and if they are found to be depressed, the depression should be managed and followed.

The good news, she said, is that by treating postoperative depression, "the risk for postoperative suicide is clearly modifiable."

An abstract of "A Multicenter Study on Suicide Outcomes Following Subthalamic Stimulation for Parkinson's Disease" is posted at <http://brain.oxfordjournals.org/cgi/content/abstract/131/10/2720>. ■

Some With Depression Able To Get Assisted Suicide

Oregon's 11-year-old assisted-suicide law bars lethal prescriptions for people found to have a mental disorder causing impaired judgment.

BY RICH DALY

Although most terminally ill Oregonians who receive medical aid in dying under the state's assisted-suicide law do not have depressive disorders, some patients with depression did receive a prescription for a lethal drug, researchers found.

The findings by Linda Ganzini, M.D., a professor of psychiatry at Oregon Health and Science University, and her colleagues published October 27 in the online version of *BMJ (British Medical Journal)* are the most recent of several they have conducted on the state's assisted-suicide law.

The researchers examined 58 Oregonians, most terminally ill with cancer or amyotrophic lateral sclerosis, who either had requested aid in dying from a physician or contacted a right-to-die advocacy organization. A study psychologist administered the Structured Clinical Interview for *DSM-IV* Axis I Disorders (SCID-I). Then, a different psychologist reviewed the auddiotapes, interspersed with interviews of terminal patients not requesting aid in dying, and determined that 15 study participants met criteria for depression and 13 met criteria for anxiety disorders.

Although thoughts of death or suicide and suicidal plans or attempts are criteria for major depressive disorder in *DSM*, the researchers attributed suicidal ideation to a diagnosis of depression only if the patient endorsed suicidal thoughts or plans aside from their interest in pursuing physician-assisted suicide.

> **"The current practice of legalized aid in dying may allow some potentially ineligible patients to receive a prescription for a lethal drug."**

By the end of the study, 42 patients had died. Among these, 18 had received a prescription for a lethal drug, and nine had died by lethal ingestion of the prescribed medication. Three lethal-dose recipients met the criteria for depression and died by "legal ingestion," the study authors found.

"Our findings also indicate that the current practice of legalized aid in dying may allow some potentially ineligible patients to receive a prescription for a lethal drug," said Ganzini and her coauthors.

The 11-year-old law authorizes physicians to prescribe a lethal dosage of drugs—usually a short-acting barbiturate—to a competent adult who requests it. Safeguards in the law aim to ensure that patients are adult, competent, terminally ill, and choosing to end life voluntarily but not impulsively.

Oregon's Death With Dignity Act requires the prescribing or consulting physician to refer the requester of a fatal dose to a psychiatrist or psychologist if he or she is concerned that the patient's judgment is impaired by a mental disorder. The law bars prescribing a fatal dose until one of those clinicians determines that the patient does not have a mental disorder causing impaired judgment.

The recent research study comes as the debate continues over the influence of psychiatric illness on an ill person's desire for assisted suicide. "For people at the end of life, depression, hopelessness, and psychosocial distress are among the strongest correlates of a desire for hastened death," Ganzini and colleagues wrote.

Previous research has found that physicians, hospice professionals, and family members of patients who seek assisted suicide in Oregon generally do not believe that major depression was present in most patients who requested assisted suicide. In fact, caretakers never requested psychiatric evaluations for any of the people who died by assisted suicide in Oregon in 2007.

The authors pointed out that previous research has found that "health care professionals" often fail to recognize depression and its impact, particularly among medically ill patients.

A study conducted by Ganzini and colleagues and published in the September 2002 *Journal of Pain and Symptom Management* found that a feeling of hopelessness—but not a major depressive disorder—at the start of the study predicted a desire for assisted suicide later on. That ran counter to research by William Breitbart, M.D., chief of the psychiatry service at Memorial Sloan-Kettering Cancer Center. That study, published in the December 2000 *JAMA*, found that hopelessness and depression both contributed to terminally ill patients' desire for a hastened death (*Psychiatric News*, September 15, 2006).

Among the acknowledged limitations of the recent study was the inability to understand the extent of the impact that depression, even when it had been formally diagnosed, had on the patients' desire to end their lives. The authors said that even the three depressed patients who died by lethal ingestion could have satisfied the requirements of the Death With Dignity Act if the attending physician had determined that depression was present but not influencing their judgment.

"Although diagnosing depression can be relatively straightforward, determining its role in influencing decision making is more difficult, even by expert assessment," wrote Ganzini and colleagues.

A 1996 study published by Ganzini and colleagues in the *American Journal of Psychiatry*, for example, found that among 321 psychiatrists in Oregon, only 6 percent said they were very confident that a single evaluation would allow them to adequately determine whether a psychiatric disorder was impairing the judgment of a patient requesting assisted suicide.

The finding that some cases of depression in terminally ill patients requesting physician-assisted suicide are missed or overlooked led the study authors to conclude that the Oregon law may not adequately protect mentally ill individuals. They urged "increased vigilance and systematic examination for depression among patients who may access legalized aid in dying."

Future research also is needed, Ganzini and colleagues noted, to help determine the effect of treatment of depression on the choice to hasten death.

An abstract of "Prevalence of Depression and Anxiety in Patients Requesting Physicians' Aid in Dying: Cross-Sectional Survey" is posted at <www.bmj.com/cgi/content/abstract/337/oct07_2/a1682>. ■

Language

continued from page 2

Before adjustment of confounding variables, the Spanish speakers were less likely to achieve remission and took longer to get there, wrote Lesser and colleagues. However, adjustment for demographic, clinical, functional, and severity variables eliminated those differences, indicating that those factors may be just the ones standing in the way of better outcomes for these patients, they said.

"[T]he poorer response by Spanish speakers may be related to factors such as their more disadvantaged socioeconomic status or higher medical burden, rather than their language preference per se," wrote the authors.

The Spanish speakers tended to be older and less educated than their counterparts who preferred using English, with lower incomes and a first major depressive episode occurring later in life.

"These baseline differences are consistent with what we know about Latinos with mental illness" who prefer to speak Spanish, said Pumariega. "They have more socioeconomic and medical illness burdens, but also show more chronicity of mental illness and a longer time to seeking treatment."

Part of that disparity may be due not only to socioeconomic issues but to a preference among Latinos for obtaining mental health care from primary care providers, who ordinarily know less about mental illnesses than specialists do, said Pumariega.

"Primary care physicians do not have the same skills as psychiatrists in diagnosing and treating depression, leading to a less-skilled approach to management of depression and possibly contributing to some disparities of outcomes," he said.

Furthermore, a preference for primary care may have deep cultural roots. Among some Latinos, especially the less educated and the more recent arrivals in the United States, there is an added burden of stigma in seeking help, based on experiences in their ancestral countries. To them, seeing a psychiatrist is just the first step on a slippery slope to institutionalization, said Pumariega.

Another issue is the variation of subcultures collected under the single umbrella labeled "Hispanic" or "Latino." "A Cuban-American psychiatrist may well miss the meaning and context of a Mexican-American's story," said Pumariega.

Finally, many clinical trials may contain a subtle, invisible barrier despite all attempts to bridge the gap between researcher and subject, he said.

"It is assumed that Latinos have a clear conception of what depression means to the interviewer or psychiatrist," he said. "If they used culturally specific Spanish-language terms, the responses may have been different. You have to use terminology they use, not what is used in mainstream culture."

"Depression Outcomes of Spanish- and English-Speaking Hispanic Outpatients in STAR*D" is posted at <http://ps.psychiatryonline.org/cgi/content/full/59/11/1273>. ■

Minorities Avoid MH Care

An article in the November *Psychiatric Services* reported on nationally representative data from 8,762 people on disparities in access to mental health care. The study found that among the 1,032 people with some depressive disorder, 40 percent of non-Latino white individuals did not access mental health treatment in the previous year, while 64 percent of Latinos, 69 percent of Asians, and 59 percent of African Americans did not do so. African Americans and Asians were especially less likely than non-Latino whites to both have access to care and receive adequate care, wrote Margarita Alegría, Ph.D., who is with the Center for Multicultural Mental Health Research, Cambridge Health Alliance, and Harvard Medical School, and colleagues.

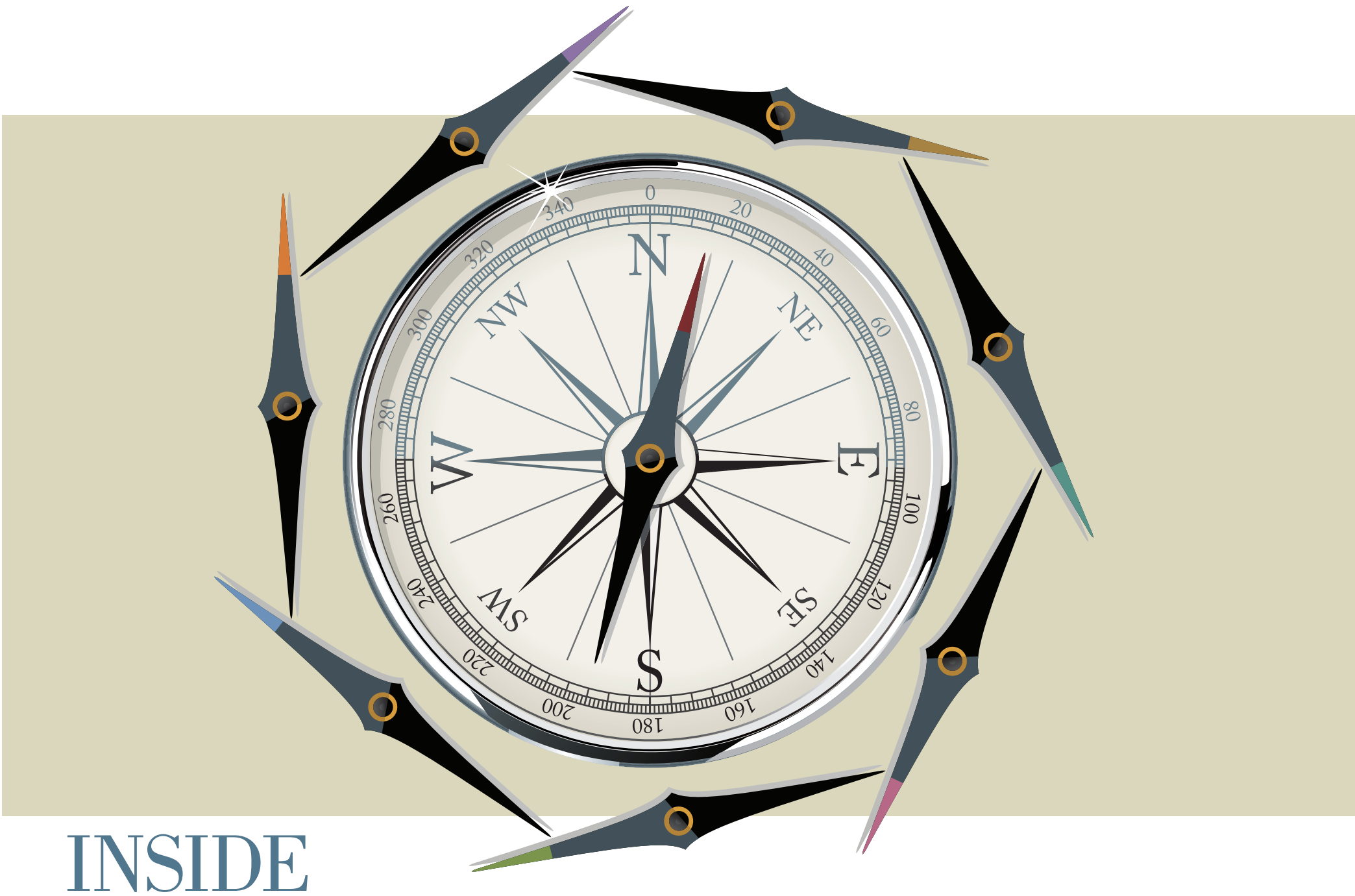
Clinicians may need more help in identifying depression among these groups, they wrote, citing several reasons. For one, minority patients may distrust the medical profession due to prior "mistreatment by mental health professionals." Minority families may also be less likely to recognize and report depression. Latinos and others are more likely to somaticize psychiatric symptoms or use terms like *ataques de nervios* (which overlaps panic disorder, anxiety disorder, and depression) rather than standard *DSM-IV* formulations. Stigma and economic factors such as losing half a day's pay to visit a mental health professional also take their toll.

"Simply relying on current systems, without considering the unique barriers to high-quality care that apply for underserved ethnic and racial minority populations, is unlikely to affect the pattern of disparities we observed," concluded Alegría.

"Disparity in Depression Treatment Among Racial and Ethnic Minority Populations in the United States" is posted at <http://ps.psychiatryonline.org/cgi/content/full/59/11/1264>.

APA Election 2009

This **SPECIAL ELECTION SECTION** provides information on the **17 CANDIDATES** running for office in the **ASSOCIATION'S 2009 ELECTION.**



INSIDE

For this section, the candidates in APA's 2009 election were asked to supply a biographical sketch and a statement in which they could discuss their views on any issues in psychiatry. This information is intended to help voters cast their ballots for the candidates they believe are best qualified for office. Also, candidates were asked to list by approximate percentages the primary professional activities on which they spend more than 5 percent of their time and approximate percentages of their sources of professional income that are greater than 5 percent. The deadline for candidates' information for this section was October 15. Here are a few more notes about this year's election:

- APA voting members can cast their ballots online. It is hoped that the ease offered by Internet voting will encourage more members to participate in the election. For more information about online voting, see "APA's Voting and Ballot Information" on page 27.

- On **December 22,** ballots will be mailed to all voting members, and instructions for voting online will be e-mailed to all members whose e-mail address is on file with APA. Mailed ballots must be received by Intelliscan Inc. no later than **February 5, 2009.** This is also the deadline for online voting.

ABOUT APA

How does APA's governance structure operate? What are the responsibilities of APA members who hold governing positions? The answers to these and similar questions may not be familiar to many APA members, yet they are vital to the smooth and successful functioning of the Association. The following article provides a brief description of the Association's purpose, its organizational structure, the duties of the officers and trustees, and the role of councils and other components. It is intended to help APA members make the best possible choice among the candidates running in the 2009 election.

PURPOSES AND OBJECTIVES OF THE ASSOCIATION

The purposes for which APA is organized are to

- promote the common professional interests of its members;
- improve the treatment, rehabilitation, and care of persons with mental disorders (including mental retardation and substance-related disorders);
- advance the standards of all psychiatric services and facilities;
- promote research, professional education in psychiatry and allied fields, and the prevention of psychiatric disabilities;
- foster the cooperation of all who are concerned with the medical, psychological, social, and legal aspects of mental health and illness;
- make psychiatric knowledge available to practitioners of medicine, to scientists, and to the public;
- promote the best interests of patients and those actually or potentially making use of mental health services; and
- advocate for its members.

ORGANIZATION

The key elements of APA's governance structure are the Board of Trustees, the Assembly, and the Joint Reference Committee. Standing committees (those named in APA's Bylaws) and topic councils and their components carry out the Association's work.

BOARD OF TRUSTEES

The Board of Trustees, composed of officers and trustees elected by the membership, governs the Association. The power to make policy is vested in the Board, and the Board's primary function is to formulate and implement the policies of the Association. The Board exercises all powers of the Association that are not otherwise assigned. Trustees are expected to attend all Board meetings and participate in the matters at hand, for they cannot delegate responsibility to govern or give a proxy vote. Area trustees are ex-officio members of their respective Area Councils.

These are the voting members of the Board of Trustees:

- President
- President-elect
- Vice president
- Secretary-treasurer
- Seven Area trustees, representing each of APA's seven geographic Areas
- Two trustees-at-large
- One early career psychiatrist (ECP) trustee-at-large
- Member-in-training trustee (MITT)
- Three immediate past presidents
- Speaker of the Assembly
- Speaker-elect of the Assembly

The nonvoting members of the Board are the member-in-training trustee-elect (MITTE) and the past presidents elected before the year 2000.

Candidates other than those for Area trustee are selected by the Nominating Committee or nominated by petition. They are elected by the entire voting membership, except for the MITTE, who is elected solely by members-in-training. The seven Area trustees are nominated by their Area Councils or by petition and elected by the members who belong to the district branches within the individual geographic regions (see page 29).

In the 2009 election, voters will elect the president-elect, vice president, ECP trustee-at-large (elected every three years), MITTE (serves one year without voting privileges and one year as MITT with voting privileges), and Area trustees in Areas 1, 4, and 7.

DUTIES OF OFFICERS AND TRUSTEES

- **President/President-Elect**—The president-elect chosen in the 2009 election will serve as president-elect from the close of the 2009 annual meeting through the close of the 2010 annual meeting and as president through the close of the 2011 annual meeting.

  The president-elect chairs the Joint Reference Committee and carries out any duties assigned by the president that are specifically designed to familiarize him or her with the duties to be assumed as president.

  If the president is unable to function because of absence or illness, the president-elect shall act for the president. If the president dies or resigns, the president-elect becomes president for the remainder of the term.

  The president prepares the agenda for and chairs all meetings of the Board and general meetings of the Association. The president (after election as president-elect) appoints the personnel of nearly all components except the Joint Reference Committee.

- **Vice President**—The vice president, who serves a two-year term, performs the duties assigned by the president. He or she may represent the president at official functions of APA, such as district branch meetings, national conferences, and other meetings.

- **Secretary-Treasurer**—The secretary-treasurer, who serves a two-year term, and his or her authorized agents are bonded in an amount determined by the Board. He or she receives, disburses, accounts for, and manages all monies of APA under the general direction of the Board. The secretary-treasurer submits financial statements each year to the Board and to the Assembly at the annual meeting. He or she also submits financial statements to the auditors, sends out annual dues bills, notifies members who are in arrears, and is responsible for investment of Association funds with the help of the Investment Oversight Committee and the medical director. The secretary-treasurer, by reason of office, is a voting member of the Finance and Budget Committee. The secretary-treasurer also keeps the records of the Association; receives petitions for nominating candidates or for referenda or to amend the Bylaws or for recall of officers or trustees and submits the recall ballot to the membership; certifies minutes of Board meetings; certifies the editions of the Bylaws; and chairs the Ethics Appeals Board.

- **Member-in-Training Trustee (MITT) and Trustee-Elect (MITTE)**—Each year an MITTE is elected and serves on the Board for one year without a vote and then advances to the MITT position for one year with a vote. The MITTE is elected by members-in-training only, instead of by the membership at large.

- **Other Trustees**—Other members of the Board are two trustees-at-large, one ECP trustee-at-large, trustees from each of the seven Areas, and the three immediate past presidents, all of whom serve three-year terms.

ASSEMBLY

The Assembly is composed of representatives from the Association's seven Area Councils and 74 district branches, minority/underrepresented groups, ECPs, MITs, and allied organizations. The Board and its components often refer issues to the Assembly for consideration and study. The Assembly elects its own officers each May.

Area Councils

The seven Area councils are regional links between the Assembly and the district branches. They consist of representatives from each of the district branches within the Area, an Area representative and deputy representative elected by the council itself, an Area ECP representative and deputy representative, an Area MIT representative and deputy representative, allied organization liaisons within the Area, and the Area trustee to the Board of Trustees. The Area councils promote relationships between organized psychiatry and state governments, coordinate a range of branch activities, hold scientific meetings and other programs in continuing education, and provide a forum for discussion of national and regional issues.

District Branches

Constituent parts of the Association, district branches work locally to foster the science of psychiatry, promote its progress as a healing profession, and maintain high professional standards. Most correspond to state or metropolitan areas. Each district branch collects dues from its members, elects its own officers, and arranges and funds its own programs. Each district branch elects its own representatives to the Assembly. An effective way for members to bring an issue to national attention is through their district branch representatives to the Assembly.

JOINT REFERENCE COMMITTEE

The Joint Reference Committee is a standing committee that acts as a liaison and screening mechanism for the Board, the Assembly, and the Association's supportive components. It refers issues for study to various components and coordinates their recommendations for further consideration by the Board or the Assembly. The president-elect serves as chair and the speaker-elect of the Assembly as vice chair.

OTHER COMPONENTS

Standing Committees

The Bylaws establish an Executive Committee of the Board of Trustees and eight committees to assist in conducting the business affairs of the Association: Ethics, Membership, Nominating, Bylaws, Budget, Tellers, Elections, and Joint Reference.

Councils and Components

There are currently 14 councils: Addiction Psychiatry; Advocacy and Public Policy; Aging; Children, Adolescents, and Their Families; Global Psychiatry; Health Care Systems and Financing; Medical Education and Lifelong Learning; Member and District Branch Relations; Minority Mental Health and Health Disparities; Psychiatry and Law; Psychosomatic Medicine; Quality Care; Research; and Social Issues and Public Psychiatry. Various committees, corresponding committees, task forces, and caucuses report to each council. Each council, composed of voting members, has authority to create and eliminate informal work groups, subject to the approval of the Board.

Several boards report directly to the Board of Trustees, such as the editorial boards of APA's newspaper and journals.

ABOUT THE CANDIDATES

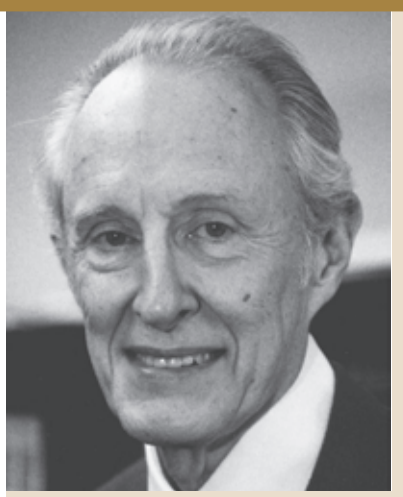
Candidates for President-Elect

Carol A. Bernstein, M.D.
Distinguished Fellow

Private Practice, 1984- ◆ APA Vice President, 2007- ◆ APA Treasurer, 2000-2004 ◆ APA Trustee-at-Large, 1995-98 ◆ Member, Chair, APA Committee on Graduate Medical Education, 1998-2000 ◆ APA Assembly Representative, New York County District Branch, 1989-95 ◆ New York University School of Medicine: Associate Professor of Psychiatry, 1993- ; Vice Chair, Education in Psychiatry, 2006- ; Associate Dean, Graduate Medical Education, 2004- ; Director, Psychiatry Residency, 1993-2007

Michael Blumenfield, M.D.
Distinguished Fellow

Private Practice of Adult Psychiatry, 1980- ◆ New York Medical College: Professor of Psychiatry, Medicine, Director of Medical Student Education, Director Consultation/Liaison Psychiatry, 1980-2007 ◆ Director, Outpatient Psychiatry, Kings County Hospital, 1977-80 ◆ APA Assembly Speaker, 2006-07 ◆ Chair, APA Joint Commission on Public Affairs, 2001 ◆ President, Psychiatric Society of Westchester County, 1992



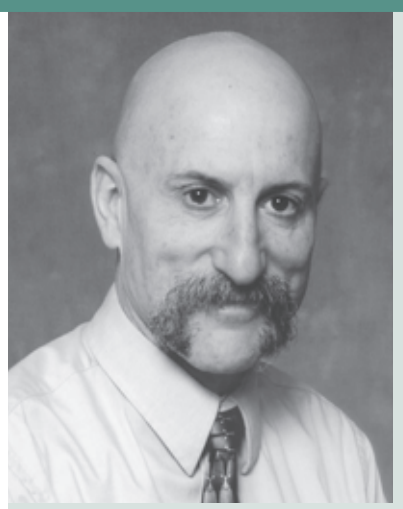
Roger Peele, M.D.
Distinguished Fellow

Chief Psychiatrist, Montgomery County, Md., 2001- ◆ Clinical Professor, George Washington ◆ Member, APA Board of Trustees, 1986-87, 1989-92, and 2001- ◆ Assembly, 1975- ◆ Speaker, 1986-87 ◆ Washington Psychiatric Society, Board of Directors, 1974 - ◆ *DSM-III* work groups, 1975-80 ◆ *DSM-III-R* Task Force, 1983-87 ◆ *DSM-IV* Task Force, 1989-1994 ◆ *DSM-V* Task Force, 2007- ◆ Co-author, *Clinical Manual of Supportive Psychotherapy*

Candidates for Vice President

Jeffrey Akaka, M.D.
Distinguished Fellow

Medical Director, Diamond Head Community Mental Health Center, 2003- ◆ Associate Clinical Professor of Psychiatry, University of Hawaii, 1999- ◆ APA Assembly Speaker, 2007-08 ◆ APA Board of Trustees, 2006-08 ◆ APA Finance and Budget Committee, 2006- ◆ Secretary, APA*PAC,* 2004-07 ◆ AMA Section Council on Psychiatry, 1998- ◆ Chair, Hawaii Medical Advisory Board, 1999-2001 ◆ Five-Time Ironman Triathlete, 1980-83



Jeffrey Geller, M.D., M.P.H.
Distinguished Fellow

Professor, Public Sector Psychiatry, University of Massachusetts, 1986- ◆ APA Service: Board of Trustees (Chair, Work Group on Financial Relationships Between APA and Pharmaceutical Industry), 2006- ; Assembly, 1993-2006; Components, 1983- ; *Psychiatric Services* Editorships, 1992- ◆ APA Awards: Van Ameringen, 2003; Ron Shellow, 2006 ◆ Current: therapy, psychopharmacology, mentor/training, forensics, research, consults, administration.

Sidney H. Weissman, M.D.
Distinguished Fellow

APA Area 4 Trustee, 2003- ◆ Private Practice ◆ Professor of Clinical Psychiatry, Northwestern University ◆ Faculty, Institute for Psychoanalysis, Chicago ◆ President, American Association of Directors of Psychiatric Residency Training, 1992 ◆ President, Illinois Psychiatric Society, 1998-99 ◆ APA Assembly, 1999-2003 ◆ President, American Society for Adolescent Psychiatry, 2002 ◆ Member, American Academy of Child and Adolescent Psychiatry, 2002-

ABOUT THE CANDIDATES

WANT TO KNOW MORE ABOUT THE CANDIDATES?

Some of the candidates in APA's 2009 election are sponsoring their own sites on the Internet. To access these sites, go to APA's homepage at **WWW.PSYCH.ORG** and then click on the 2009 election logo.

CANDIDATES FOR ECP TRUSTEE-AT-LARGE

Joyce Spurgeon, M.D.
General Member

Assistant Professor of Psychiatry, University of Louisville, 2005- ◆ Consultant Member, Scientific Program Committee, 2008- ◆ Early Career Psychiatrist Deputy Representative and Representative to Assembly, 2005-08 ◆ Member-in-Training Deputy Representative and Representative to Assembly, 2003-05 ◆ Director of Women's Mental Health, University of Louisville, 2007- ◆ Chair, Membership Committee, Kentucky Psychiatric Medical Association, 2006-

Harsh K. Trivedi, M.D.
General Member

Assistant Professor of Psychiatry, Brown Medical School, 2006- ◆ Site Training Director and Director of Adolescent Services, Bradley Hospital, 2007- ◆ Consulting Editor, *Child and Adolescent Psychiatric Clinics of North America*, 2007- ◆ APA Jeanne Spurlock, M.D., Congressional Fellow, 2004 ◆ Member, Board of Directors, APA*PAC*, 2004- ◆ APA Area 1 Public Affairs Representative, 2008- ◆ APA Council on Advocacy and Public Policy, 2007-

CANDIDATES FOR MEMBER-IN-TRAINING TRUSTEE-ELECT

Erick H. Cheung, M.D.
Member-in-Training

University of California at Los Angeles: Psychiatry Resident, 2007- ; Curriculum Committee Member, 2007- ; and Residents' Council Secretary, 2008- ◆ M.D., Distinction in Medical Ethics, Albany Medical College, 2007 ◆ Association of American Medical Colleges: Medical Student Chair, 2005-06; Member, Task Force on Industry Funding of Medical Education, 2006-08 ◆ Member-in-Training Representative, Southern California Psychiatric Society, 2008-

Laura K. Kent, M.D.
Member-in-Training

PGY-3 Psychiatry Resident, New York State Psychiatric Institute/ Columbia Presbyterian Medical Center, 2007- ◆ Hospitalist, Catholic Medical Center, Manchester, New Hampshire, 2006-07 ◆ Internal Medicine Residency, Columbia Presbyterian Medical Center, 2003-06 ◆ Medical School, Albert Einstein College of Medicine, 1999-2003 ◆ Dean's Recognition Award, 2003 ◆ Director, Einstein Community Health Outreach Free Clinic, 1999-2003

Kayla Pope, M.D., J.D.
Member-in-Training

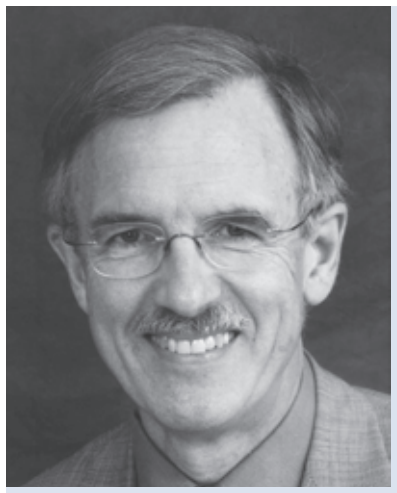
Child and Adolescent Psychiatry Research Fellow, Children's National Medical Center/National Institute of Mental Health, 2008- ◆ Adult Psychiatry, University of Maryland/ Sheppard Pratt ◆ APA: Leadership Fellow, 2008-09; Council on Psychiatry and Law, 2008-09 ◆ American Medical Association: American Academy of Child and Adolescent Psychiatry Resident Delegate, 2006- ◆ Psychiatry Residency Review Committee, 2007-

ABOUT THE CANDIDATES

CANDIDATES FOR AREA 1 TRUSTEE

Robert Feder, M.D.
Distinguished Fellow

Private Practice of Adult and Adolescent Psychiatry, 1981- ◆ Representative, New Hampshire Psychiatric Society, APA Assembly, 1996-2008 ◆ APA Nominating Committee, 2001, 2008 ◆ APA Assembly Nominating Committee, 2001-08 ◆ APA Council on Advocacy and Public Policy, 2006- ◆ New Hampshire Board of Medicine, 2001-08 ◆ National Alliance on Mental Illness Exemplary Psychiatrist Award, 1992, 1994



Frederick J. Stoddard Jr., M.D.
Distinguished Life Fellow

Associate Clinical Professor of Psychiatry, Massachusetts General Hospital, Harvard Medical School, 1998- ◆ Vice Chair, APA Council on Healthcare Systems and Financing, 2006-09 ◆ Representative, Massachusetts Psychiatric Society, APA Assembly, 2007- ◆ Disaster Representative for Area I, 2007- ◆ President, Massachusetts Psychiatric Society, 2000-01 ◆ Private Practice, Child and Adult Psychiatry, 1976-

CANDIDATES FOR AREA 4 TRUSTEE

Sul Ross Thorward, M.D.
Distinguished Fellow

Psychiatrist, Ohio Department of Mental Health, 2000- ◆ Clinical Assistant Professor, Psychiatry, Ohio State University, 1995- ◆ Ohio APA Assembly Representative, 2003- ◆ APA Council on Healthcare Systems and Financing, 2006- ◆ Chair, Ohio Government Relations, 2000-07 ◆ President, Mental Health Association Franklin County ◆ American Hospital Governing Council Psychiatry ◆ National Alliance on Mental Illness Exemplary Psychiatrist, 2008

John J. Wernert, M.D.
Distinguished Fellow

Private Practice of Adult and Geriatric Psychiatry, 1989-2008 ◆ Medical Director, Senior Adult Services, St. Francis Health Systems, 2000-07 ◆ Vice Speaker, House of Delegates, Indiana State Medical Association, 2008- ◆ President, Indianapolis Medical Society, 2005-06 ◆ Chair, APA Political Action Committee, 2003- ◆ APA Assembly Representative, Indiana Psychiatric Society, 2002- ◆ President, Indiana Psychiatric Society, 1994

CANDIDATES FOR AREA 7 TRUSTEE

Constance Powell, M.D.
General Member

Private Practice, 1989- ◆ APA Area 7 Representative, 2006- ◆ Assembly, 2001- ◆ APA Alternate Delegate, AMA Section Council on Psychiatry, 2005- ◆ President, Oregon Medical Association, 2002-03 ◆ President, Oregon Psychiatric Association, 1998-99 ◆ Chair, Mental Health Division Institutional Review Board, 1990-97 ◆ National Alliance on Mental Illness Oregon Award for Partners in Leadership, 2000

William Womack, M.D.
Distinguished Life Fellow

Associate Professor Emeritus, Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine, 2004- ◆ Attending Child Psychiatrist, Division of Child Psychiatry, Children's Hospital and Medical Center, 1981- ◆ Area 7 Trustee, 2006- ◆ Area 7 Council Representative, APA Assembly, 2003-06 ◆ Member, *Psychiatric News* Editorial Advisory Board, 2006- ◆ Member, *DSM-V* Task Force, 2006-

ABOUT THE CANDIDATES

CANDIDATES FOR PRESIDENT-ELECT

Carol A. Bernstein, M.D.

It is a privilege to be nominated for the position of president-elect of APA at this critical time for psychiatry and for national health care. We must capitalize on the medical advances in neuroscience, psychopharmacology, genetics, and psychotherapy in order to have a strong, accountable, and effective national organization which can provide leadership and direction in advocacy and education for our patients and our members.

I have been actively involved in APA for more than 25 years beginning as chair of the residents' committee of the N.Y. County District Branch. I served in the Assembly for six years, chaired components including the committees on medical student and graduate education and the Institute on Psychiatric Services, and have been elected to the Board of Trustees as trustee-at-large, treasurer, and vice president. As treasurer, I converted a $4 million budget deficit into a $5 million dollar surplus and assured that our organization would be fiscally stable. My work in so many aspects of APA in combination with my extensive career in psychiatry has prepared me exceptionally well to assume this leadership role.

APA must advocate for our patients and our members. To achieve this goal, I will:

- Forge close working relationships with allied organizations to improve advocacy nationwide.
- Collaborate with other medical organizations to improve funding for medical research, education, and clinical care.
- Develop more effective methods for assisting our local and state organizations in their legislative and educational initiatives.
- Increase opportunities for members to participate actively in APA using electronic technology to develop leadership in the next generation while preserving a work/life balance.
- Promote our diversity and encourage collaboration to increase the effectiveness of APA.

I will also continue to address the many challenges facing our profession and our patients including:

- The persistence of stigma.
- Discriminatory practices which restrict access to care.
- Continuing lack of appropriate reimbursement for mental health services despite the passage of the parity bill by Congress.
- Erosion of the confidentiality of the doctor-patient relationship.
- Encroachment by nonmedical professionals into the practice of psychiatric medicine.

I have been an active clinician for more than 20 years. As a clinician-educator, I have dedicated my career to the education and training of the next generation, directed medical student and residency training programs, and now oversee house staff education for all residency and fellowship programs as the associate dean for GME at NYU. I have been actively involved in numerous other significant national psychiatric organizations including AADPRT, ACP, GAP, AACP, and the ABPN. I pledge to:

- Advocate strenuously for our patients and our profession through effective interactions with the media and government.
- Work to recruit the best and brightest students to our field and provide them with the best education possible.
- Improve communication between APA leadership and our members.

Thank you for your support.

Primary Professional Activities and Sources of Income

Professional Activities
95%—Administration, education, and training
5%—Clinical, private practice

Income
100%—New York University School of Medicine

Michael Blumenfield, M.D.

It is a great honor to be nominated for president-elect of APA. I will not let you down if you choose me for this job.

The president leads APA in its interface with the public. My work in public affairs in my DB, Area, and as chair of the APA Joint Commission on Public Affairs has prepared me for this task as well as my experience in writing a syndicated newspaper column, having a local radio program, and recently having an Internet podcast. I also plan to work closely with APA experts and use local psychiatrists to speak with local media markets.

We have made great strides in reducing stigma, but it is still present regarding serious and persistent mental illness. This is one reason that it is inadequately funded. There is a need for hospital beds for the care of many patients who are housed in prisons, are waiting for transfer from our overcrowded medical emergency rooms, or are among the homeless in our communities. I would develop a Presidential Committee where I would meet with APA experts along with our communications and government divisions, with input from patient/family advocacy groups and others, with the goal of developing a major multiyear public relations plan to change the public's and lawmakers' attitude toward chronic and persistent mental illness.

I would facilitate a plan, that I suggested as speaker, to have local Town Hall Meetings where a panel of psychiatrists listens and questions interested parties on important topics such as access to care, treatment of veterans and their families, teenage drug use, etc. These meetings will get media coverage, establish psychiatrists as interested community leaders, and provide information leading to APA advocacy and other action.

APA has been preparing psychiatrists to be ready to respond at times of disaster and terrorism. I have co-edited a recent book, *Intervention and Resilience After Mass Trauma*; have co-taught courses on disaster at APA meetings; and in 2001 was a consultant to the State Department on terrorism. APA has some outstanding experts on these subjects, and I will work to expand the work that we are doing.

In order to grow APA, I would appoint small task forces of outstanding members who work in prisons, veterans or state hospitals, are psychoanalysts, MURs, ECPs, MITs, international members, as well as other specific groups. Each task force would develop recruitment methods for nonmembers of their group, including DVDs, outreach, incentives, etc. Success would be measured by increased membership in each category.

I would hold at least one Board of Trustees meeting as an interactive videocast. This would be an example to other components of effective economical technology. As speaker I tried to introduce electronic voting to the Assembly. The AEC wasn't ready for it yet because of cost. This can be revisited as well as videocasting the Assembly for members to see their APA in action. All APA members should be given templates to develop professional Web sites perhaps hosted by APA.

Other current issues which I feel are important are:

- Full parity and universal health care coverage.
- Be at the table to discuss any health care plan.
- Oppose scope of practice incursions.
- Assure transparency about Pharma, *DSM*, and in all other areas.
- Expand APA support to the district branches.

Please see my Web site for more discussion: <www.apayes.com>.

I am passionate about the care of our patients, our profession, and APA. I would like your vote so I can make a difference.

Primary Professional Activities and Sources of Income

Professional Activities
Since January 2008:
70%—Writing, editing, public education
30%—Private practice

Prior January 2008:
70%—Teaching and clinical care at N.Y. Medical College
25%—Private practice
5%—Writing, editing, public education

Income
Since January 2008:
100%—Private practice

Prior January 2008:
70%—N.Y. Medical College
30%—Private practice

ABOUT THE CANDIDATES

Roger Peele, M.D.

Will it make any difference if I am elected? Yes, it will. During a Peele presidency:

- **APA will expand membership involvement.** Doing more with less will be the major test for the 2010-11 president. No matter what happens to the U.S. economy, APA's revenues will decline in the near future. Some suggest that the budgetary challenge be met by decreasing member involvement. We must do the opposite. I will ask district branches and allied organizations to alert me to members willing to volunteer their knowledge and skills to help APA. Furthermore, increasing volunteers and allied organization ties, associated with bottom-up governance, will make APA more democratic.

- **APA's clinical publications will be more current.** Presidents have discretionary funds. Candidates for president-elect should be telling voters how they will use those funds. I will use those funds to keep our guidelines current. Our guidelines are old. This must change. An example of increased volunteerism: Since the Delirium Guide was developed, 1999, there have been over 4,000 publications about delirium. We should ask the Academy of Psychosomatic Medicine to keep that guide current so that the clinician can swim, not drown, in the vast scientific literature. APA was founded 164 years ago to explicate, to promulgate, and to advocate for the needs of people with psychiatric disorders. We all want greater advocacy. The degree to which we are seen as authoritative is the degree to which our advocacy is potent. To be authoritative, we must be current.

- **The Board will function for the full year of my presidency**. Under the current system, the first substantial Board meeting is in July, and the final substantial one is in March. During my presidency, the first substantial Board meeting will be in May 2010, and the final substantial Board meeting will be in May 2011. To save resources, there will be fewer face-to-face meetings and greater use of modern technology to assure timely, well-considered Board decisions.

All candidates favor nondiscrimination, confidentiality, limiting prescribing to physicians, and fair reimbursement for psychiatric treatments, etc. **For my statement to focus on policy positions, however, would show an ignorance as to the role of APA presidents**. Presidents do not decide policy except under rare circumstances: when the Board vote is tied. The Assembly and Board decide policy.

Instead of setting policy, the president oversees the governance process, sets priorities, and addresses communications daily from the media and policymakers. **I have a proven record of success as an advocate and spokesman at high levels of government and the media.** I am experienced with the media and have dealt many times with members of Congress and top-level government officials. Over the years, I have been on all four major networks and handled inquiries from the *New York Times* and the *Washington Post*. I have testified before Congressional committees (including testimony which helped obtain $65 million in capital expenditures for St. Elizabeths), before the FDA (about misuse of "suicidality"), and before Rep. Patrick Kennedy's subcommittee with Steve Sharfstein and Harold Eist about the need for nondiscrimination in health insurance plans. I have received a phone call from a U.S. president, while he was on Air Force One, and successfully dissuaded him from an action he wanted to take that, clinically, would have poorly served a patient.

APA members should be fully informed about candidates for president-elect. My record and my stances are laid out in detail on my Web site, including **fuller personal disclosures than ever seen in APA elections,** at <http://rogerpeele.com/apa_activities.asp>.

Primary Professional Activities and Sources of Income

Professional Activities

95%—County government
- 75%—Clinical
- 10%—Administration
- 5%—Teaching
- 5%—Health care policies

5%—Psychiatrist at a low-income primary care clinic; all clinical

Income

100%—County government ($164,000 plus about $30,000 in benefits) income

HOW APA'S PREFERENTIAL VOTING SYSTEM WORKS

There are three candidates for three races in APA's 2009 election: president-elect, vice president, and member-in-training trustee-elect (MITTE). The preferential voting system will be used for these races. The system avoids the cost and time of a run-off election by having members vote in a single ballot for all their choices in order of preference.

Please note that these instructions are for the printed ballot; members who choose to vote online will find instructions adapted for the computerized ballot once online. Also, only members-in-training will get ballots with the MITTE race included.

In the three-way races, next to each candidate's name are three boxes marked 1, 2, and 3 (see example at right). To mark your ballot, decide which candidate you want to win. Make a solid mark in the box marked 1 next to that candidate's name. Then decide which one of the remaining candidates you would want to win if your first choice received the lowest number of first-choice votes and was eliminated from the race. Make a solid mark in the box marked 2 next to that candidate's name. Indicate your last choice by making a solid mark in the box marked 3 next to the remaining candidate's name.

In preferential voting, voters must decide which candidate they would want to vote for if the candidate of their first choice receives the lowest number of first-choice votes and is therefore eliminated from the contest. The only second-choice votes that are distributed are those on the ballots of the candidate with the lowest number of first-choice votes. ***You are not helping your first-choice candidate in any way by not rank-ordering the remaining candidates.*** Conversely, you are not hurting your first-choice candidate in any way by rank-ordering the remaining candidates.

The procedures for counting preferential votes are as follows: All first-choice votes for each candidate are counted. If no candidate receives a majority vote, the candidate with the lowest number of first-choice votes is eliminated. His or her ballots are then redistributed to the remaining candidates based on voters' second choices and added to each of the remaining candidates' first-choice votes to determine which one has now received a majority vote.

The three-candidate races will appear on ballots as shown below.

IMPORTANT INSTRUCTIONS

1 2 3 Candidate A, MD
1 2 3 Candidate B, MD
1 2 3 Candidate C, MD

- Rank order the candidates. (1, 2, 3 with 1 being your first choice.)
- You need not rank order every candidate.
- You may vote for a single candidate by marking only one box containing a "1."

To be sure you get the most out of your APA voting privileges, rank-order all the candidates in the three-way races.

ABOUT THE CANDIDATES

CANDIDATES FOR VICE PRESIDENT

Jeffrey Akaka, M.D.

My mother was a Daughter of the American Revolution, a fourth-generation female graduate of Alfred University, the second university in the United States to admit women. My father, a Chinese–Native Hawaiian who escaped France to return to the United States just days after Hitler invaded Poland, was the first of his family to attend college and became a Kahu (spiritual shepherd) of the Hawaiian People. Despite concerns by many over their interracial relationship, she sailed across the Pacific in 1944 to marry him. Different races, different cultures, a raging world war. Yet their faithful partnership succeeded for the rest of their lives.

Our APA is also a partnership, of our members with each other and with our medical ancestors, a cherished inheritance, borne of the sacrifices of our predecessors, representing gains hard won despite forces beyond measure. Without APA, we would not have the science to support the best psychiatric education, care, and annual meeting in the world, nor the *DSM*, nor the *CPT* codes that provide the means, the reimbursements, and salary schedules by which we pay off our mortgages, our cars, and our college and medical school loans. APA is our lifeline to heal our afflicted.

For over 15 years, I have served APA, from the Committee of American Indian, Alaska Native, and Native Hawaiian Psychiatrists in 1992 to the Board of Trustees 2006-08. As speaker of the APA Assembly, I hosted the first-ever address to the Assembly by a sitting United States Senator, who announced his introduction of (ultimately passed) legislation to improve care of "Invisible" (PTSD) injuries in veterans. I appointed women to fill four of the seven openings on the restructured Assembly Committee on Planning. I lobbied for parity with the New Jersey Psychiatric Association in Trenton, mentored residents at Howard in Washington, D.C., and met with 13 more district branches.

As a member of the AMA Section Council on Psychiatry, I arranged for APA to host meetings since 1998 of the APA and AMA leadership with Hawaii's legislators, lieutenant governor, and governor. This led to our coalition successfully defeating crash-course prescribers in the home state of their chief national architect for over 15 years. Through this, we significantly raised the stature of psychiatry in the AMA, facilitating not only the AMA Scope of Practice Partnership to fight multiple inappropriate scope expansions, but expanding our influence via the election or appointment of APA members to nearly every council in the AMA, including Jeremy Lazarus, M.D., as speaker of the AMA. With the AMA's help, and through new partnerships with members of Congress via APA*PAC*, of which I was a founding board member in 2002 and secretary 2004-07, after 40 years of fighting discrimination against our patients, we actually won parity via the Medicare Reauthorization Act this year. Furthermore, we secured for APA more than $350,000 in savings on Hawaii Convention Center rental fees as well as hotel rates low enough to make up for anticipated airfare differences for the 2011 annual meeting. This is the kind of progress for you and our APA that powerful partnerships provide.

Please vote for me to continue serving you in this manner as your vice president. If elected, then as always, I will do everything I can to creatively and honorably accomplish what matters most to our dues-paying members, our patients, and our profession. In partnership with you, I will work to move APA from the Good organization that it is to the Remarkable organization it is to become.

Aloha and mahalo (thank you),
Jeffrey Akaka, M.D.

Primary Professional Activities and Sources of Income

Professional Activities

80%—Medical Director, Diamond Head Community Mental Health Center
- 75%—Patient care
- 25%—Administrative

5%—Medical Consultant
15%—Organized medicine and other volunteer advocacy activity
- 80%—APA
- 20%—HPMA, AMA, HMA, state/federal lobbying

Income

100%—State of Hawaii
- 90%—Department of Health
- 10%—Department of Human Services

Jeffrey Geller, M.D., M.P.H.

I am the first physician ever in my large extended family that has seen more than its share of psychiatric issues. My wife and I are parents of 3: the oldest with developmental disabilities, the youngest a medical student, the middle one an artist. My practice of psychiatry is influenced by personal encounters with Robert Kennedy; Anna Freud; Martin Luther King; Ms Thomas, my 5th grade teacher; Kathy W., Marybeth B., and hundreds of other patients with serious mental illness. I have assisted 26 states and territories in better meeting the needs of their psych patients (AZ, CA, CO, CT, DE, FL, GA, IL, HI, MD, MA, MI, NH, NJ, NY, NC, OK, OR, PA, TN, VT, VA, WA, WV, DC, PR). I am well aware of psychiatry's struggles across N. Amer.

With work experience in public sector and private practice; in academic medicine and forensics; on Capitol Hill, with state mental health authorities and with state attorneys general; and with volunteer experiences in Europe, Asia, and Africa, I am ready to work with APA members to move our patient care, political, and professional agendas.

Do you know in APA's history we've had periods with one VP (1844-1885, 2004-), two VPs (1958-2003) and no VP (1886-1958)?

What specifically is an APA vice president to do to provide a necessary, meaningful, maybe even memorable contribution?

First, comprehend contemporary problems in psychiatry:

Psychiatrists are too few in number, maldistributed within and amongst states and provinces, short on cultural competency, and under-compensated compared to other specialties. The fight against psychologists and others expanding their scope of practice must address these issues and be reframed into a fight for patients—in the trenches, not simply in the state houses.

Substance/alcohol abuse are addling the brains of America's teens. We must expand our efforts in preventing addictions.

You and I, and our patients, are beleaguered victims of a confounding (non)system of care and insurances. The uninsured choose between meds and meals; the underinsured can be bankrupted by a psych admission. Psychiatrists in private practice struggle, consumed by forms that result in inadequate payments delivered late. Those in the public sector labor with inadequate resources and appreciation. Not only isn't there a single payer, too often there's no payer at all!

Children are sitting and suffering in ERs—there are no child psychiatry beds because market forces don't support them.

Hospitals are being replaced by jails/prisons which now house 500% more mentally ill persons than do state hospitals.

Second, understand major issues facing APA:

Accountability to all our members is essential, particularly residents and early career psychiatrists.

Pharma support taints our profession. Moderating this calls for thoughtful belt-tightening by informed leaders.

Actions of APA need to address members wherever they work: private office, CMHC, academia, VA, inpatient, rural.

Third, take action on two major projects for the 2-year term with leadership endorsement: 1) external and 2) internal.

- Address unmet needs of veterans: facilitate their ability to get services wherever they seek them, improve VA and states' partnerships, keep struggling vets out of jails/prisons, and extend psychiatric care to veterans' families.
- Formalize relationships with groups to strengthen our mission, e.g., Canadian Psychiatric Association, American Academy of Family Physicians, American College of Emergency Physicians. In this way we create partners in medicine, refine our care, and solidify our unique scope of practice.

Is your practice better off than when you started it? Rather than wait in the wings, the APA Vice President can actually do something for North American psychiatrists and our patients.

Primary Professional Activities and Sources of Income

As professor and director of public sector psychiatry, I am full-time at the University of Massachusetts Medical School, where I do teaching, mentoring, and supervision; patient care; research and administration: 75% of income. On my own time I do state and agency consultation and other forensic work: 25% of income.

ABOUT THE CANDIDATES

Sidney H. Weissman, M.D.

For the last five years, I have had the privilege of serving as an APA Trustee. I am honored to be a candidate for APA vice president. APA today confronts a number of serious challenges and opportunities. I shall speak to these challenges. The passage of parity legislation and the phasing in of equality in Medicare payments position us to address from a strong platform the mental health care issues our nation must confront. My responses are informed and enriched by my ongoing medical education and broad work in academic psychiatry departments as a residency training director, clinical services director, educational researcher, and author and by providing direct patient care.

Today we must:

- **Enhance** the alliance between the various groups in our field. Academic psychiatrists, practitioners in varied practice settings, and subspecialists must all see APA as their home. In the absence of unity, we cannot impact on the various challenges we face.

  To attain this essential unity, we must reorganize the APA governance structure. With a revitalized governance, we will be able to more effectively address these challenges.

- **Position** APA to be the lead organization in developing programs for our members to maintain competency after residency training. They will need to meet the evolving requirements of the ABPN to maintain certification and down stream to potentially meet new requirements to maintain state licensure.

  To accomplish this, we need to reorganize the structure and direction of our annual meetings. We need to appoint a director of annual meetings who will direct them in a manner similar to the editors of our journals and our residencies.

- **Develop** a model and then implement it as to how APA should relate to Pharma. We need to further develop standards for our members and organizations as to how they can relate to Pharma.

- **Ensure** that as discussions of health care reform progress, mental health care is a cornerstone of any new or revised health care systems in the U.S.

- **Maintain** a vigilant stance to ensure that as varied scope-of-practice proposals are developed that impact on our patients and practice, they are clearly addressed and countered to protect our patients.

- **Work** for the funding of all health care to ensure affordable, available psychiatric care for all citizens in both the public and private sectors. In a parallel fashion, we must develop reimbursement models that protect our economic needs.

- **Require** in our practices and education sensitivity to the vast cultural diversity of our nation and our trainees. We must further ensure in our institutions sensitivity to the needs and diversity of all of us.

- **Demand** adequate and sustained funding for mental health research and education.

These are but a few of the challenges with responses that I feel we must address. I look forward to hearing from you and our working together. (**E-mail: s-weissman2@northwestern.edu**)

Primary Professional Activities and Sources of Income

Professional Activities
100%—Private practice

Income
100%—Private practice

A REMINDER TO CAMPAIGN SUPPORTERS

The Elections Committee urges that members who wish to undertake any activities on behalf of any candidate for APA office first contact the candidate to learn of any election guidelines that may apply. Information on election guidelines may also be obtained by sending an e-mail request to election@psych.org.

The APA Elections Committee wishes to emphasize that pledges of electoral support may be changed at any time, for any reason, and APA members who have pledged support to any candidate at any time may withdraw, reaffirm, or otherwise change such a pledge.

ABOUT THE CANDIDATES

CANDIDATES FOR ECP TRUSTEE-AT-LARGE

Joyce Spurgeon, M.D.

As an early career psychiatrist, I realize that my journey into the field of psychiatry is still in its early phases; however, I am aware that many of the experiences I have had through APA have helped shape me into the psychiatrist that I am today.

Advocacy for our patients and our profession is a core part of that identity. This is true not only because of the stigma attached to mental illness, but also because we represent a group of patients and their families who cannot always speak for themselves. Also, when APA advocates for the profession of psychiatry, it does something that none of us could do individually. As we face a world with questions of scope of practice, Medicare reimbursement issues, and treatment of our mentally traumatized returning veterans, the profession of psychiatry needs advocates as well.

I have had the privilege of being elected as a member of the Assembly for two years as an MIT and three years as an ECP. It was an honor to receive the Area 5 William Sorum Award as an MIT. These experiences have helped me gain a broad perspective about our Association and the field of psychiatry on a larger scale. This has included, in particular in the wake of Hurricane Katrina, an understanding of the critically important role of APA supporting the disaster relief work that continues to be a part of everyday life for the psychiatrists in those areas. I also participated in the development of a women's forum in Area 5 which focused on women in psychiatry across the lifespan of our careers. I have been gratified that my efforts have also enabled me to work with my colleagues in the Kentucky Psychiatric Medical Association, where I have had the opportunity to serve in various ways as a member of the executive council. In these and other experiences, I have developed a working knowledge of how to get things done within APA on a national, regional, and local level and have developed personal and professional relationships which will last a lifetime.

My faculty position at the University of Louisville also offers me the opportunity to serve the profession of psychiatry by working hard to train the next generation of physicians and psychiatrists. I serve as the associate training director for the adult residency training program and the director of our developing women's mental health center. In these roles, I not only have gained administrative skills which I use in my APA work, but also have the opportunity to recruit the next generation of APA members. I enjoy the teaching aspect of my job, and I am also dedicated to my patients. My patients continue to inspire me to continue my APA work as I have seen firsthand the need for even more advocacy efforts to gain more resources and a better organized system of mental health care for all patients.

I am asking for your vote for ECP trustee because I believe that I have a broad base of experience in both district branch and national APA activities which will allow me to hit the ground running. Early career psychiatrists represent the next generation in the ever-changing world of psychiatric care, and I have the drive and experience to both represent our views and work in an effective way within the system of APA. Thank you for your consideration, and I look forward with great anticipation to contributing to the important missions of APA.

Primary Professional Activities and Sources of Income

Professional Activities

100%—University of Louisville Department of Psychiatry and Behavioral Sciences
- 75%—Clinical service
- 25%—Teaching

Income

100%—University of Louisville Department of Psychiatry and Behavioral Sciences

Harsh K. Trivedi, M.D.

I am a child and adolescent psychiatrist practicing in Providence, R.I. I am currently the site training director and director of adolescent services at Brown Medical School–affiliated Bradley Hospital. I provide academic teaching and supervision to medical students, adult psychiatry residents, child and adolescent psychiatry fellows, and triple-board residents. I am responsible for the clinical care and administrative oversight of a 24-bed adolescent inpatient unit and a 10-bed adolescent partial hospital program. I am also the consulting editor of the *Child and Adolescent Psychiatric Clinics of North America* and president of the Rhode Island Council for Child and Adolescent Psychiatry.

It is an honor to be running for the ECP trustee position. Since becoming a medical student member of APA in 1999, I have had the pleasure of learning from and working with many of you. The opportunity to network with and receive mentorship from senior APA members has been critical as I developed my own professional identity and thought about what my own career path would be.

I cannot think of a more crucial time for APA to be on the mark with its policies and its actions. With questions regarding conflicts of interest with pharmaceutical companies, with Scientology's traveling road show about the horrors of our profession, with psychologists pushing scope-of-practice legislation in multiple states, with patients finding it harder to access our services, and with reimbursement rates ever diminishing—we need to elect people with **proven leadership**.

A transformative experience for me was being selected as the 2004 APA/APF Jeanne Spurlock, M.D., Congressional Fellow. My unfaltering interest in advocating for our patients and our profession was vastly augmented by the opportunity to hone my own advocacy skills while working in the Senate office of Jack Reed (D-R.I.). I helped to author the Garrett Lee Smith Memorial Act, which passed Congress and was signed into law. It has provided over $80 million for suicide prevention and college mental health programs.

Leadership alone will not suffice without having people who can strategically effect positive change. We must have people who can provide **practical stepwise solutions** to meet our challenges head on, to strengthen our profession, and to improve our APA.

As I transitioned back to my fellowship in child and adolescent psychiatry at Harvard Medical School–affiliated Children's Hospital Boston, I successfully lobbied the APA-*PAC* board about the importance of building a base of younger members—thus creating the first MIT position to the PAC board. With the step-by-step creation of the MIT Advisory Group, an ECP position to the APA*PAC* Board, and now the soon-to-be ECP Advisory Group—we have been able to strengthen and propel our PAC to a position where we can be influential in the legislative process. After 20+ years of an uphill battle in Congress, mental health parity has finally passed.

We need people who can lead our organization with the highest **professional integrity**. We need people without conflicts of interest who do not accept pharmaceutical funding. Our patients and the general public trust us because of our science and our ethics—we need to have people with **academic excellence** who can stand up for the strength of our evidence base and who can instill in others the unrelenting belief that we can be trusted to do no harm.

I know the importance of clear, concise communication, of representing our profession well, of partnering with other professional and patient advocacy organizations, and of having **an APA that truly represents and works for its members.**

I understand that this is a tall order—but I have risen to the task time and time again. We **must demand** that our officers have the conviction to stand up for **meaningful change**.

Primary Professional Activities and Sources of Income

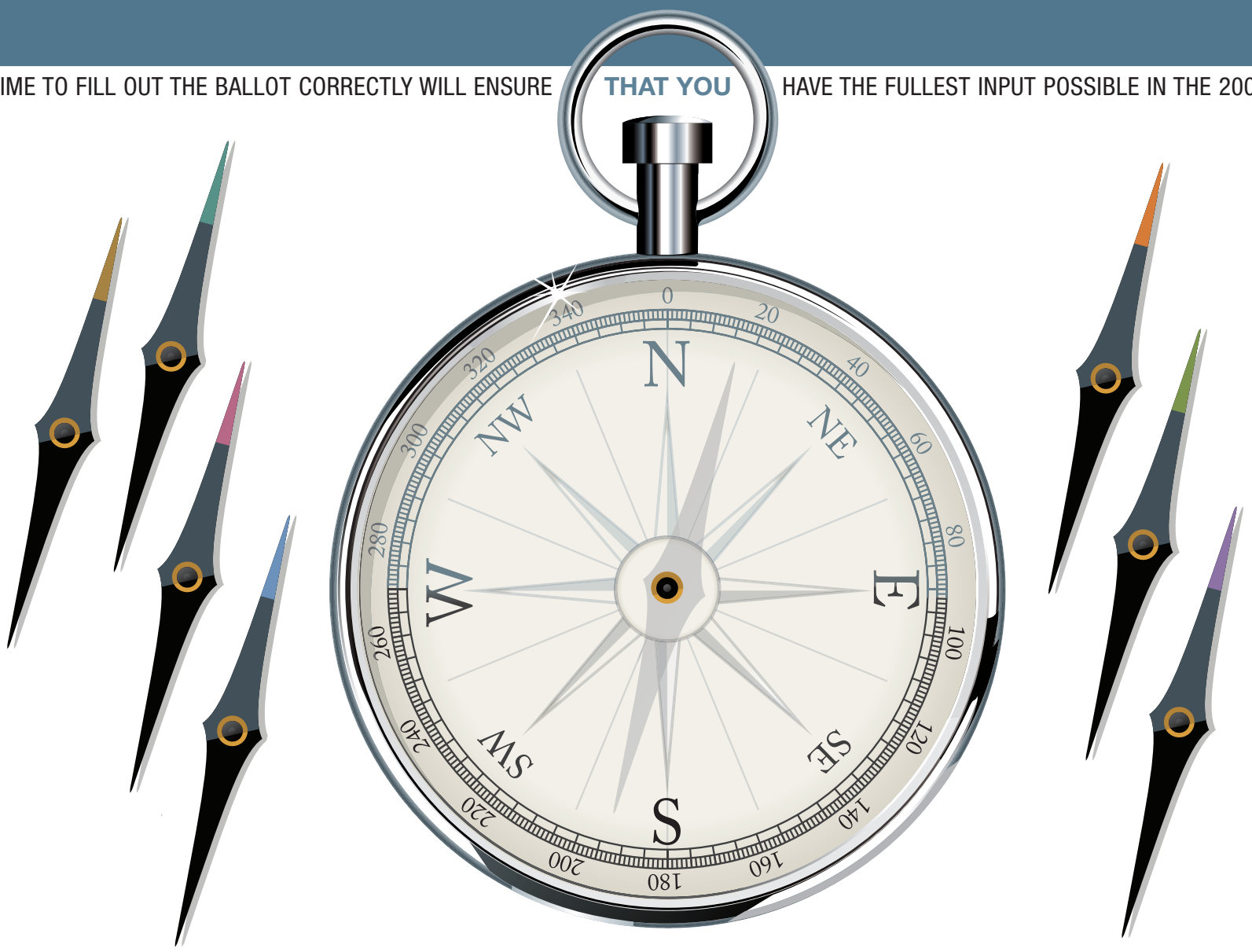
Professional Activities

75%—Patient care and administration, Bradley Hospital
20%—Training and education, Brown Medical School
5%—Volunteer work for professional organizations and advocacy groups

Income

90%—Bradley Hospital
7%—Cambridge Health Alliance, independent contractor
3%—Consulting editor of *Child Psychiatric Clinics*
Absolutely no income from pharmaceutical companies.

TAKING TIME TO FILL OUT THE BALLOT CORRECTLY WILL ENSURE **THAT YOU** HAVE THE FULLEST INPUT POSSIBLE IN THE 2009 ELECTION.



PREVIEW THE APA BALLOT

Once again, Intelliscan Inc., a professional election management firm, will conduct the vote count in the 2009 election. As in the past several elections, eligible voting members will have the opportunity to cast their votes online by visiting APA's Web site at <www.psych.org>, where they will find instructions for voting online. The eligible voting members are members-in-training, general members, fellows, life members, life fellows, distinguished fellows, and distinguished life fellows.

As a cost-saving measure, ballots will be sent using nonprofit postage, and to accommodate possible slight delays in delivery, the Board of Trustees approved an early mailing date of December 22, 2008. At about the time the ballots are mailed, Intelliscan Inc. will send e-mails to those members who indicated they wished to vote online and for whom APA has e-mail addresses, providing them with information on accessing the online ballot before they receive their paper ballot. Members who do not receive such e-mails may also vote online but need to wait for the paper ballot for their access information.

The paper ballot will be sent in an envelope along with a booklet containing the photographs and biographies of and brief statements by the candidates for national, member-in-training, and Area offices. The booklet contains information on all candidates, including those for member-in-training trustee-elect (MITTE) and Area trustees. The ballot you receive, however, includes only the offices for which you are eligible to vote. Thus, only members-in-training will receive ballots for voting for the MITTE, and only those members in Areas 1, 4, and 7 will receive ballots for voting for their respective Area trustees.

VOTING ON PAPER

- The votes on paper ballots are counted using optical scanning equipment. Be sure to mark your votes correctly. (See "Marking the Paper Ballot" below.)
- The ballot and the courtesy return envelope are separate from the booklet and may be lost easily. Voters are encouraged, but not required, to use the courtesy envelope to return their ballots. Members who misplace the courtesy return envelope may use their own envelopes to mail their ballots to American Psychiatric Association, c/o Intelliscan Inc., PO Box 783, Phoenixville, Pa. 19460-0783.
- Do not send completed ballots to APA.
- APA does not use a postmark deadline. To be counted, ballots must be **received** at Intelliscan by **5 p.m. Eastern Standard Time on February 5, 2009.**

MARKING THE PAPER BALLOT

- Use No. 2 pencil or blue or black ink pen only
- Do not use red ink or felt-tip pens
- Make solid marks that fill the box completely

INCORRECT MARKS	CORRECT MARK
☑ ☒ ⊙ ▬	■

- Make no stray marks on the ballot

VOTING ONLINE

- Each member will be able to access his/her online ballot using his/her last name and the ballot control number that appears at the top of the paper ballot or in the e-mail sent to members with addresses on file. (For security purposes, Intelliscan Inc. randomly assigns the ballot control number to each ballot. No one at APA knows or can access those numbers.)
- Each member's online ballot is a replica of his/her paper ballot; it includes photos, bios, and statements of the candidates and instructions for voting.
- Once the online ballot has been marked and submitted, votes cannot be changed.
- If a member returns a paper ballot *and* votes online, only the votes on the online ballot will be counted.
- The deadline for voting online is **5 p.m. Eastern Standard Time, February 5, 2009.**

Members should send an e-mail message to election@psych.org if they believe they are eligible to vote but did not receive a ballot or if they received a ballot and misplaced it. In the event of duplicate voting (paper and online), only the online ballot will be counted. Also, members are invited to send questions, complaints, or suggestions regarding the election process or improving the ballot packet to election@psych.org.

ABOUT THE CANDIDATES

CANDIDATES FOR MEMBER-IN-TRAINING TRUSTEE-ELECT

Erick H. Cheung, M.D.

Philosophical Drive: Psychiatry is about more than just the science and the patient; it is also about society and ethics, resources and business, policy and politics. The future of psychiatry is exciting but uncertain, and our generation of psychiatrists will practice in a time of revolutionary change.

The philosophy that has guided my engagement in health politics and organized medicine is a strong social conscience and the belief in a physician's duty to fulfill a public role. As your APA MIT trustee, I seek to serve on the behalf of residents by engaging nationally in health care reform and mental health advocacy, protecting and promoting research and education funding, and addressing the practical and ethical challenges at the interface of policy and mental health care.

Grassroots Reform: America's health care system is costly, inefficient, and unequal. When this reality struck me early in my medical training, I grew committed to advocacy for the uninsured and health care reform. Beginning with grassroots activism and eventually working with legislative staff, we ultimately introduced a bill for health care reform into the New York State legislature.

With hope, health care reform will be the legacy of our generation. One of my goals is to promote the development of APA principles and recommendations to ensure that when we reach the tipping point for true reform, our profession will have strong representation and our patients will have mental health parity and affordable access to services. Likewise, our work is never-ending in combating the stigma of mental illness. We should continue to build on the success of APA awareness campaigns such as "Healthy Minds. Healthy Lives."

National Leadership: As a former national chair for the Association of American Medical Colleges (AAMC), I have leadership experience with organized medicine and the analysis of issues including the U.S. physician workforce shortage, medical licensure and accreditation, conflicts of interest with industry, and diversity in medicine.

An area that remains of acute concern is the pharmaceutical industry's subsidization of "educational" activities. As a member of the AAMC's Task Force on Industry Funding of Medical Education, I can attest to the intensely polarizing nature of this issue. Rectifying this problem will be difficult but necessary for our patients' best interest and our profession's integrity and accountability. In APA's ongoing efforts, we must develop sensible guidelines for industry interactions and CME, while working to increase federal funding for education and research.

Education and Ethics in Psychiatry: In the midst of pioneering science and advancing technologies, psychiatry education must continually evolve. APA may soon need to address ethical questions surrounding the clinical use of neurotechnology, such as diagnostic functional imaging and invasive procedures as treatment for mental illness.

As part of the residency curriculum committee at UCLA, we are attempting to apply information technology in ways that will streamline the core curriculum and facilitate flexibility in subject matter and methods. I propose an APA education initiative that would identify and disseminate best practices in psychiatry education, address ethical concerns with neurotechnology, and develop methods for effective education of *DSM-V.*

I will follow the ideals above and use my practical experience to serve our best interests as psychiatry residents, to combat the health care inequality that jeopardizes the welfare of our patients, and to prepare our organization for the challenges ahead.

Primary Professional Activities and Sources of Income

Professional Activities

100%—Psychiatry Resident, PGY-2, at the University of California at Los Angeles, Semel Institute for Neuroscience and Human Behavior

Income

100%—University of California at Los Angeles, Semel Institute for Neuroscience and Human Behavior

Laura K. Kent, M.D.

I am deeply honored to have this opportunity to run for member-in-training trustee-elect (MITTE) of APA. As psychiatrists in training, we are the future of psychiatry. This means that we need to know what is happening on the front lines of the field—both in order to understand the challenges that lie ahead and to shape the decisions that will affect our patients and our careers for years to come. If elected to be your representative to APA, I will work to keep you as informed as possible about what is happening in APA and psychiatry—and conversely keep APA and psychiatry as informed as possible about what is happening with you.

This is a very exciting and pivotal time in psychiatry. With the recent passing of the mental health parity bill, a new era is unfolding that promises both tremendous opportunity and great challenge. As your MITTE, I will work to keep you aware of the latest developments in the field and of APA's involvement in these issues so that together we can be most effective in shaping the future of psychiatry.

In the age of e-mail and the Internet, we can develop ways in which we can truly work together. I believe that my training in medicine, psychiatry, social service, and the financial sector positions me to be able to effectively represent and communicate with you as your MITTE. As the former director of a 200-member, free outreach clinic in medical school, I have demonstrated that my management style is collaborative and based on good communication. As your MITTE, I will:

- Develop a collaborative network of residents nationwide through frequent two-way e-mail communication and focused discussions at national meetings.
- Work to increase resident representation in APA so that we can maximize resources identified for future psychiatrists to help with early career concerns including fellowship opportunities, growing a practice, and financing medical education.
- Be directly accessible to you throughout the two-year term to hear your concerns, to discuss the issues that you believe should be on the Board of Trustees agenda, and to brainstorm solutions.
- Invite any resident to contact me directly with their concerns and ideas.

You are the future of psychiatry, and we need your talent and input!

I come to psychiatry from a unique perspective because I completed an internal medicine residency prior to becoming a psychiatry resident. I chose to pursue psychiatry because I increasingly saw psychiatric issues as central to the lives of my patients. You and I know that psychiatry is essential to all of medicine and thus that psychiatry residents belong at the epicenter of medicine. I am eager to apply my experiences in both medicine and psychiatry as your MITTE to help increase communication and collaboration across all medical fields and organizations.

APA is a vital organization that advocates for us, educates us, and connects us as a nation of psychiatrists. There should be no question that being a psychiatry resident means being a member of APA and helping to shape APA's future. As your MITTE, I will use my diverse experience to represent your interests at the highest levels of the organization and to make you aware of the myriad opportunities that APA offers you.

In summary:

- I will vigorously represent your needs on APA's Board of Trustees and will advocate for those issues most important to you as residents and young psychiatrists.
- I will be accessible to you and keep you informed of important developments as they occur.
- I will work with you to shape the future of psychiatry, finding opportunity in these challenging times.
- I will work to place psychiatry firmly at the forefront of medicine where it belongs.

I look forward to working together to make APA work for you!

Primary Professional Activities and Sources of Income

Professional Activities

90%—Psychiatry Resident, New York State Psychiatric Institute
8%—Hospitalist, Catholic Medical Center, Manchester, N.H. (moonlighting)
2%—Internist, Burke Rehabilitation Hospital, White Plains, N.Y. (moonlighting)

Income

69%—Psychiatry Resident, New York State Psychiatric Institute
20%—Hospitalist, Catholic Medical Center, Manchester, N.H. (moonlighting)
11%—Internist, Burke Rehabilitation Hospital, White Plains, N.Y. (moonlighting)

ABOUT THE CANDIDATES

Kayla Pope, M.D., J.D.

I am a child and adolescent psychiatry research fellow, training at Children's National Medical Center and the National Institute of Mental Health. My path to psychiatry has been a nontraditional one. I began my professional life as an attorney and mediator, specializing in family law. The greatest sense of achievement I derived from that work was the time I spent advocating for children in abuse and neglect cases and juvenile delinquency proceedings. It was through this work that I discovered my true passion, advocating for those who cannot advocate for themselves. I began to take classes and conduct research in the area of child development and, through this work, came to realize my professional calling.

I attended medical school at George Washington University and then completed my adult psychiatry training at the University of Maryland/Sheppard Pratt. It was in medical school that I first became involved in organized medicine and developed an appreciation for the impact trainees can have when we pursue an issue with a unified voice. My first involvement was with the American Academy of Child and Adolescent Psychiatry, where I worked on developing ways to increase the number of child and adolescent psychiatrists to address the critical shortage. As a medical student, I was able to bring the trainee perspective to our discussions and helped to create solutions that would address the needs of medical students.

During residency, I was fortunate in befriending a child psychiatrist who encouraged me to become involved in the American Medical Association. Though hesitant at first, I have come to value this experience perhaps more than any of the other activities in which I have become involved. The Resident and Fellow Section of the AMA is the great melting pot of trainees, who are passionate, dedicated, and committed. Through my work with the AMA, I was again reminded of the importance of working in a unified way with the diverse voices in medicine. With this body, I have helped develop policy to maintain the quality of residency education and training, increase trainees' awareness of what to expect from training, and address quality-of-life issues during residency, including providing affordable child care.

Through my professional and organizational experiences, I have honed my skills as an advocate and have learned how to bring together people to create consensus and accomplish goals. If elected by my fellow trainees, I would use these skills to make your voice heard. I would want to hear your ideas, but will share with you what my priorities are:

- Increase resident, fellow, and early career psychiatrist involvement in the APA components.
- Advocate for maintaining quality education in residency and fellowship programs.
- Work to improve the quality of life of trainees including the provision of affordable, high-quality child care.
- Encourage collaboration of psychiatric residents and fellows with other specialties in medicine.
- Work to organize trainees to advocate for a system of health care that provides affordable and accessible mental health services for all.

We can accomplish great things if we have the courage to dream and the resolve to bring our ideas to fruition.

Primary Professional Activities and Sources of Income

Professional Activities
100%—Child and adolescent psychiatry research fellow

Income
100%—National Institute of Mental Health

DO YOU KNOW YOUR APA AREA?

This article serves as a guide to members who aren't sure about their Area affiliation.

The APA Bylaws stipulate that APA's district branches be grouped into Areas, not to exceed a total of 10 Areas, from which Area trustees shall be elected. Currently there are seven Areas; the district branches within each Area are listed at right.

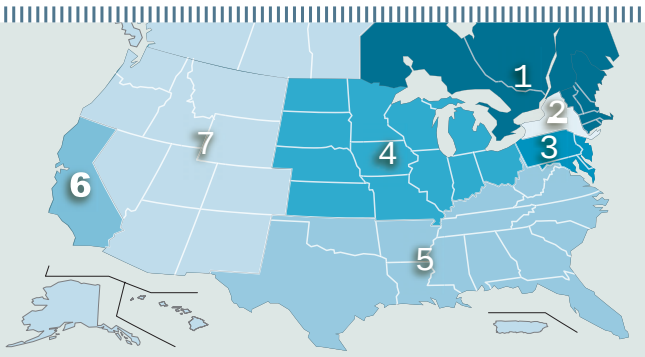
Area membership is determined by district branch membership; that is, one must be a member of a district branch in an Area to be a member of that Area and eligible to elect the Area trustee. Area trustees are elected every three years on a rotating schedule. Areas 1, 4, and 7 in 2009 will elect their Area trustees in 2009; Areas 3 and 6 in 2010; and Areas 2 and 5 in 2011.

All APA members, except medical student members, international members, international fellows, honorary fellows, and a small number designated as members-at-large, must belong to the district branch where they live or work. Members are expected to transfer district branch membership when they move their residence or practice from the jurisdiction of one district branch to another. Members who need to transfer should contact the APA Membership Office by phone at (888) 35-PSYCH or (888) 357-7924, or by e-mail at membership@psych.org.

AREA 1: NEW ENGLAND/ EASTERN CANADA
Connecticut
Maine
Massachusetts
New Hampshire
Ontario
Quebec & Eastern Canada
Rhode Island
Vermont

AREA 2: NEW YORK
Bronx
Brooklyn
Central New York
Genesee Valley
Greater Long Island
Mid-Hudson
New York County
New York State Capital
Northern New York
Queens County
Westchester County
Western New York
West Hudson

AREA 3: MIDDLE ATLANTIC
Delaware
Maryland
New Jersey
Pennsylvania
Washington, D.C.



AREA 4: NORTH CENTRAL
Central Missouri
Eastern Missouri
Illinois
Indiana
Iowa
Kansas
Michigan
Minnesota
Nebraska
North Dakota
Ohio
South Dakota
Western Missouri
Wisconsin

AREA 5: SOUTH
Alabama
Arkansas
Florida
Georgia
Kentucky
Louisiana
Mississippi
North Carolina
Oklahoma
Puerto Rico
Society of Uniformed Services Psychiatrists
South Carolina
Tennessee
Texas
Virginia
West Virginia

AREA 6: CALIFORNIA
Central California
Northern California
Orange County
San Diego
Southern California

AREA 7: WEST/ WESTERN CANADA
Alaska
Arizona
Colorado
Hawaii
Idaho
Montana
Nevada
New Mexico
Oregon
Utah
Washington State
Western Canada
Wyoming

ABOUT THE CANDIDATES

CANDIDATES FOR AREA 1 TRUSTEE

Robert Feder, M.D.

If elected Area 1 Trustee, I will focus my efforts on:

- **Ensuring that the needs and interests of Area 1 are acted on by the APA Board of Trustees**

  Area 1 has always been a leader in formulating APA policy and new initiatives. I plan to strongly support any Assembly action papers initiated by Area 1 reps that are brought to the Board for final approval. I will also be a strong advocate for the specific needs of our Area, including ongoing support to our fine academic institutions, help for our struggling community mental health systems, and help for our members in private practice who continue to struggle to maintain their existence in an era of managed care.

- **Increasing the role of Canadian members in APA**

  Our Canadian members have much to teach Americans about psychiatry in a single-payer system, as well as unique and fresh academic perspectives. Canadian membership is vital to APA as we strive to keep membership numbers up. I will strive to increase the Canadians' voice and to make sure that they are getting what they want from APA.

- **Ensuring the fiscal strength of APA**

  A strong future for psychiatry requires a strong APA. A strong APA requires fiscal strength in the organization. I will work to help identify new sources of income for APA and to reduce unnecessary expenditures related to redundancy and inefficiency.

- **Fighting nonphysician prescribing**

  I believe that allowing psychologists, nurse practitioners, and other nonphysicians to prescribe is the greatest current threat to our patients' safety and the greatest threat to the role of the psychiatric professional. I pledge to see that APA continues to do all it possibly can to fight this threat.

- **Ensuring that APA plays an important role in designing a new American health care system**

  Both patients and health care providers are becoming increasingly critical of our current for-profit insurance-based system. With such an increasing loss of faith, some change in the system is likely to happen in the near future. It is vitally important that physicians play a key role in designing any new system if it is to succeed. It is also vitally important that psychiatrists be involved in this effort, and that APA be the conduit for that representation.

- **Increasing support to community mental health systems**

  Community mental health systems in most states are in such dire need of support that they cannot wait for the overall redesign of the American health care system mentioned above. Community mental health systems serve our sickest and neediest patients and must get help now if they and their patients are to survive.

- **Restoring faith in clinical psychiatric research through increased academic control and government funding**

  With an increase in the proportion of psychiatric research funded by pharmaceutical companies has come a growing mistrust of clinical psychiatric research in general. We must strive to put academic control and federal funding back in the central roles they deserve to ensure unbiased research and safe and efficacious treatments.

I have the experience and training necessary to accomplish these goals. After graduating from the Yale residency program, I have practiced in a wide variety of clinical settings, including private and public inpatient, partial hospitalization, and outpatient programs. I also served as the medical director of a provider-owned behavioral health managed-care company and have a thorough knowledge of the economics of mental health treatment. Having served APA in various official capacities for over 25 years (including president of the New Hampshire District Branch, New Hampshire rep to the Assembly, member of the national and Assembly Nominating Committees, and member of the Council on Advocacy and Public Policy), I know how APA functions and how to make it function even better.

Primary Professional Activities and Sources of Income

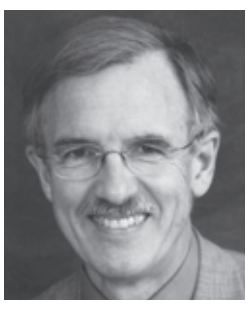
Professional Activities

100%—Private practice of adult and adolescent psychiatry

Income

100%—Private practice of adult and adolescent psychiatry

Frederick J. Stoddard Jr., M.D.



I am honored to be nominated and, if elected, look forward to further serving as Area 1 Trustee. My commitment is to our patients, to the science, and to our profession.

Strong and successful advocacy is essential, and I have sought to provide leadership for our district branch, APA, and our profession. I have advocated for children and families, for parity, for disaster psychiatry, and for partnerships between our district branch and APA, and between them both and other allied and advocacy organizations. The historic passage of the federal parity law is a major tribute to the success of APA advocacy. For this to be fully implemented, I will work for ongoing monitoring and advocacy, especially in this economic recession. The health care system requires comprehensive change if it is to provide universal access and improve quality. I would continue to work for improved care for the disadvantaged especially women and children, for our veterans, for the severely and persistently mentally ill and the disabled, and lasting solutions to the emergency room crisis. I will continue to encourage and mentor residents and early career psychiatrists in becoming active in APA. Within APA, I am an Assembly representative, vice chair of the Council on Healthcare Systems and Financing, a member of the Committee on Psychiatric Dimensions of Disasters, have served on many other components, and as president of the Massachusetts Psychiatric Society.

I have a limited private practice and am an administrator, researcher, teacher, and mentor. My commitment to Area 1 is deep, and I am familiar with the issues in each New England state and in the provinces of Eastern Canada. Most of my career has been in consultation psychiatry, and I am chief of psychiatry at the Shriners Burns Hospital, the pediatric division of the MGH Burn Center, as a member of the Department of Psychiatry at the Massachusetts General Hospital and Harvard Medical School. I received APA's Bruno Lima Award in Disaster Psychiatry in 1999.

APA is the organizational leader in our field. It is a uniquely effective advocate for our patients and our profession. It has successfully attracted you and many other highly competent and dedicated psychiatrists to be members, who benefit our patients and our field. I would like to serve on the APA Board in order to contribute to this effort.

My goals, in representing Area 1 for APA, are:

- To meet the needs of you, our members.
- To further coordinate with and support each of our district branches.
- To sustain its federal advocacy role with the executive, legislative, and judicial branches in a time of economic stress.
- To further improve APA's preparation for disasters.
- To assure ongoing monitoring of the implementation of the federal parity law, whose historic passage is a tribute to APA advocacy.
- To advocate for universal health care coverage.

Primary Professional Activities and Sources of Income

Professional Activities

75%—Massachusetts General Hospital
- 35%—Research
- 15%—Administration
- 15%—Patient care
- 10%—Teaching

15%—Private practice of child and adult psychiatry and forensic consultation

10%—Volunteer activities for professional associations and advocacy organizations

Income

70%—Massachusetts General Hospital

30%—Private practice and forensic consultation

ABOUT THE CANDIDATES

CANDIDATES FOR AREA 4 TRUSTEE

Sul Ross Thorward, M.D.

Psychiatry and its patients are affected by every current economic, medical, and political stressor active today. Most data indicate that psychiatric patients and care systems are affected to a greater extent than any other field of medicine. Active leadership and advocacy have never been more imperative. We must be team players as well as team leaders in order to promote universal access to current standards of care. I am very ready to represent Area 4 on our APA Board of Trustees to assure focus on urging our country forward in embracing and supporting resources for the best clinical knowledge and care for all our patients.

Our members have the knowledge, experience, ideas, creativity, and dedication to deliver the best psychiatric care in the world. As your representative, I will strive to gather all the ideas I can from you and take those ideas to the Board. Our organization should be driven from our membership up. Our Assembly, elected officers, and representatives should be active in taking the members' ideas and priorities forward. This is my primary goal—to be your active representative and advocate on the Board.

Experience:

- Medical school at San Antonio, my home town. Rotating Internship in Seattle—Providence Hospital. Residency in Chicago—Northwestern University. ABPN certified in general psychiatry in 1980.
- 30 years of clinical experience in private outpatient practice, as well as in private hospitals, community hospitals, state hospitals, university hospitals across the states of Texas, Illinois, Washington, and Ohio.
- Teaching—College students, paramedic students, police officers, medical students, and psychiatry residents. Advocacy and lay education—High school students, church groups, Rotary, NAMI, MHA, radio talk shows, TV and newspaper interviews.
- Administration—CEO Harding Hospital 1994–1996. Administrative Director OSU Harding Hospital 1996-2000. Board of Trustees OSU Harding Hospital 2000-2008.
- APA governance—Numerous officer positions and committee chairmanships at the local chapter, district branch, and national APA levels.

Goals:

- Advocate for standards of clinical practice which promote universal access at full parity to the most effective clinical interventions for all *DSM* disorders.
- Advocate for medical education that gives every medical student an understanding of psychiatric illness, diagnosis, and treatment. Medical education must recruit bright and talented residents who will be fully trained in broad-based clinical practice that spans dynamics, psychology, social situations, as well as biology.
- Advocate for full support and adequate resources for original, objective science and research.
- Reduce stigma by promoting education and providing information with every community partner and in every venue possible.
- Promote professionalism by standing for ethics that make it clear improper commercial influence and conflict are not acceptable. Misuse of clinical skills for coercive and brutal interrogation is not acceptable. Creeping scope of practice encroachments which empower inadequately trained clinicians are not acceptable.
- Stand for financial responsibility by budgeting that makes the most of every membership dues dollar. Outside revenues must pass the test of no improper commercial influence which degrades professional integrity. Eliminate activities which are not essential for our professional organizational growth.

Primary Professional Activities and Sources of Income

Professional Activities

70%—Inpatient psychiatry, Ohio Department Mental Health
15%—Outpatient private practice
15%—Teaching

Income

85%—Ohio Department Mental Health
10%—Outpatient private practice
5%—Teaching (Columbus State Community College)

John J. Wernert, M.D.

Times of uncertainty and turmoil present opportunities for healthy evolution. The stable professional environment we have known as the "American health care system" has shifted beneath our collective feet. Changing to meet these challenges is no longer optional.

It is an unfortunate reality that politicians and policymakers are driving the debate in health care reform. Definitions of "value-added" services, reimbursement rates, and medical decision making are more likely made by M.B.A.s rather than M.D.s. As the United States moves inevitably toward a single-payer, government-sponsored health care system, physician organizations must speak in a loud, clear, and unified voice to advocate for the services our patients need.

Our APA has been that clear voice representing psychiatry at the planning table. Yet, our organization must adapt itself to the demanding medical world we now live in, not pine for the constancy of yesteryears.

I am a candidate for the Area 4 trustee because I believe our APA is at a crossroad. The APA Board of Trustees has provided strong leadership over the years, but is frequently mired in administrative decisions of the present rather than strategic planning of our professional future.

My father was a lifelong member of APA. As a state hospital superintendant in the 1960s and a private practitioner in the 1970s, he was a role model for professional commitment and duty to my patients. My mother has been a psychiatric nurse for 49 years and continues to work part time with chronic mentally ill patients in our hometown of Louisville, Ky. My mother has demonstrated the compassion and civic involvement that have guided my life. I have been an APA member since 1985 and have served in all offices of our Indiana district branch including president in 1994-95. I have proudly served our state as an Indiana representative to the APA Assembly since 1998. I currently serve on the Assembly Committee on Planning and the Nominating Committee. I am particularly proud of my service on the APA Political Action Committee Board of Directors, serving as chairman since 2003. I have spent these five years speaking out to our members and leadership about the importance of political action and the financial investment we all must make to gain political access. With the hard work of our PAC members and staff, we have grown the PAC by over 250 percent, and have focused congressional contributions in concert with our Department of Government Relations. The results have been outstanding as evidenced by APA's role in passing the historic Medicare legislation, and most recently the long-awaited parity bill. Both of these monumental wins were clearly a team effort, and both will have a profound positive impact on our members and patients.

Our future successes are dependent upon standing with the House of Medicine. I have served as an APA alternate delegate to the AMA House of Delegates. I am currently vice speaker of the Indiana State Medical Association House of Delegates. I have served as president of the Indianapolis Medical Society and an alternate trustee of our state medical association. Enhancing our standing as psychiatrists in organized medicine is essential to our continued legislative success.

Most of all, I value my work with patients and students. As a 20-year clinician and volunteer faculty member, I feel nothing is more important than modeling compassionate and expert care. Our residents and early career colleagues deserve to "see" and "feel" all the benefits and professional rewards of being a psychiatrist. I work hard each day to project passion for our profession and enthusiasm about our future.

I am running for the APA Board of Trustees because I believe our experienced, actively practicing, mid-career psychiatrists must step forward and be active leaders. I have served our Association on the county, state, and national level, and I have the experience and gusto to push our professional agenda. I believe in our APA and respectfully ask all members of Area 4 to support my candidacy for Area trustee.

Primary Professional Activities and Sources of Income

Professional Activities

90%—Administrative: chief medical officer, MDwise Inc.
5%—Teaching
5%—Clinical

Income

95%—MDwise Inc.
5%—Consultation

ABOUT THE CANDIDATES

CANDIDATES FOR AREA 7 TRUSTEE

Constance Powell, M.D.

I am a grassroots advocate. I believe APA must support our members at the grassroots level. A measure of success for APA is the value we provide the psychiatrist in his or her work with patients across a range of settings. I have been a psychiatrist in private practice in Portland, Ore., for 20 years and truly love to see patients, some of whom I have known since I started practice.

As the Area 7 representative, I have had the privilege of working with an outstanding group of district branch representatives on a DB Sustainability Project. Our Area DBs have unique challenges because of expansive geography and limited workforce. The Council has developed, with the help of APA staff, an Area 7 Resource Handbook that is updated to reflect requests of the DBs. We hold joint meetings with DB Executive Committees and provide programs they request, making APA resources available to them, as they need them. Our Area 7 Council is effective because of our ongoing efforts to communicate with our district branches.

I have been active in my district branch since residency. I served as first chair of the Member Assistance Committee, which developed and followed protocols for responding to members in difficulty. I subsequently served as first chair of the Private Practice Committee and served on the Legislative Committee. Advocating for parity with the state legislature has been a focus of my district branch work. For this work, I was recognized with the Oregon Mental Health and Developmental Disabilities Services Award of Excellence and the NAMI Oregon Award for Partners in Leadership.

As chair of my State Medical Association Mental Heath Task Force, I conducted a survey of psychiatrists and primary care physicians, asking about the mental health needs of their patients. This work provided a platform for the unanimously supported House of Delegates resolution making mental health parity the first priority of the state association. We asked physicians what they needed to serve their patients, and tried to provide it. For this work, I was recognized with an Oregon Medical Association Presidential Citation for Mental Health Advocacy.

I was honored to be elected president of my state medical association, the second psychiatrist to serve in this position. As president, I recruited psychiatrists for committees and the governance structure. I held the first strategic planning effort in 35 years, beginning with the organizational priorities provided by the full House of Delegates. Implementation of this planning is ongoing and has given the broader membership greater voice. I believe we psychiatrists must actively advocate for all aspects of health for our patients. I have represented the medical association with legislative testimony on parity, tort reform, and scope of practice. I have just completed a second term on my county medical society board and continue to serve on my state medical society board. I am also an alternate delegate to the AMA Section Council on Psychiatry.

My work in the public sector has been volunteer. I chaired the Institutional Review Board of the Oregon State Mental Health Division for seven years. I have served as the physician representative on state and local task forces charged to recommend health system design: Governor's Safety Net Advisory Council, Governor's Mental Health Task Force, County Mental Health Task Force, County Mental Health Redesign Team.

APA represents diverse interests, each with a legitimate voice to be heard? and considered in determining policy and activities. I am confident I have the experience and skills needed to represent the unique position of Area 7 to our colleagues on the Board of Trustees. I would very much like the privilege of representing you. I ask for your vote.

Primary Professional Activities and Sources of Income

Professional Activities
100%—Private practice adult psychiatry

Income
100%—Private practice adult psychiatry

William Womack, M.D.

I am an academic child psychiatrist on the faculty of the University of Washington School of Medicine, Department of Psychiatry, Division of Child Psychiatry. I have a long involvement with APA at the state and district branch level, with the component system, and with Assembly governance as a district branch representative with progression to election as the Area 7 Council representative. I am currently the Area 7 trustee to the APA BOT.

The challenges and opportunities for our organization as the voice of physicians who care for and care about patients with mental health issues and who work in a multitude of settings—academic, clinical, research, and commmunity—continue to evolve, but also in many ways remain the same.

Health care coverage has become a major issue in this national election year, and we have every reason to be proud of our advocacy efforts which were successful in bringing parity for mental health and medical care, but it will be important for our organization to weigh in on what kind of health care reform would be best to provide a system of care for psychiatric and mental health services.

Scope of practice concerns are still with us, and we will continue to assist state associations and district branches in defense against psychologists prescribing, but we will need to expand our efforts and creativity to enlist medical partners who can help us with our own manpower shortage. We will also need to develop wider usage of technology such as telemedicine, and to improve our communication with organized medicine and sharpen our media messages to patients and families about the critical and unique roles psychiatrists play in medical care.

Fiscal strength and stability will need to be addressed at all levels of governance. We will need to look at size and efficiency and how to give the membership a real sense of ownership and voice in the organization. This will mean continuing the efforts to maintain the viability of small district branches, like many of those in Area 7.

The membership has had conflicting views about our relationship with the pharmaceutical industry for some time, but this issue has become a front and center concern. We are moving in the right direction to improve transparency and caution with regard to conflict of interest. However, not everything about Pharma is bad, and we need to find ways of building a transparent, collaborative relationship to be sure we can continue to learn new approaches to improve patient care.

Our greatest challenges continue to be in the area of making sure that all levels of our governance structure are on the **same page** with regard to goals and outcomes, **and** to make sure we are really taking care of our membership constituency.

I have extensive professional experience working with underserved populations, the public sector, and the juvenile justice system. I will continue to be supportive of those organizational activities that support inclusiveness, services to diverse populations, and ensuring that kids and families are included in our priorities.

Primary Professional Activities and Sources of Income

Professional Activities
100%—Attending child psychiatrist/Division of Child Psychiatry; Children's Hospital and Medical Center

Income
100%—University of Washington School of Medicine

APA's 100% Club Gains Two New Member Programs

Credit: Jamaica (NY) Hospital Medical Center's residency program

Staff and residents of the Jamaica Hospital Medical Center's psychiatry training program gather for photo. Seated, from left: Adam Chester, D.O. (psychosomatic fellowship director), Richard Deucher, M.D. (psychiatry residency director), Seeth Vivek, M.D. (Department of Psychiatry chair), Daniel Chen, M.D. (assistant residency director), and Salah Qureshi, M.D. (chief resident). Standing, from left: Khemdat Umadat, M.D., Mahmudur Rabbi, M.D., Jafar Bozorgmehr, M.D., Urmila Pai, M.D., Isheta Shahed, M.D., Pierre Joseph, M.D., Miriam Sevilla Saez-Benito, M.D., Binu Chacko, M.D., Padmaja Puppala, M.D., Deowchand Depoo, M.D., Saloni Wadia, M.D., Sachidanand Peteru, M.D., Sagarika Ray, M.D., Marion Georgiev, M.D., Larisa Kouperschmidt, M.D., Tariq Khwaja, M.D., Rose Michael, M.D., Kulwant Singh, M.D., and Satpal Rathour, M.D.

The psychiatry residency program at Jamaica Hospital Medical Center in Jamaica, Queens, N.Y., has joined APA's 100% Club. Another new member of the club, just 40 miles to the east, is the psychiatry residency program at Stony Brook University Medical Center.

"At Jamaica Hospital we are pleased to be in the 100% Club for several successive years," said Seeth Vivek, M.D., chair of the Department of Psychiatry. "We recognize the importance of APA in the professional identity of a psychiatrist. We are proud of training psychiatrists who are well rounded and competent professionals."

"We believe in teaching our residents that membership and involvement in APA is one of the most important personal commitments that each psychiatrist can make to professionalism and to the future of our medical specialty," said Michael Schwartz, M.D., an associate professor of clinical psychiatry in the Department of Psychiatry at Stony Brook and director of residency training.

APA's 100% Club was created to encourage the directors and chairs of psychiatric residency programs to promote APA membership to their residents. Today programs that reach the goal of having all residents (100%) join APA receive a group photo on a wooden plaque.

Also, each program in the 100% Club receives a major psychiatric textbook, and residents get a one-year subscription to *Focus: The Journal of Lifelong Learning* for each year all the residents become APA members. The textbook and journal are published by American Psychiatric Publishing Inc.

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

We are APA

Credit: Department of Psychiatry at Stony Brook University Medical Center, Stony Brook, New York.

These are residents and staff of the Stony Brook University Medical Center psychiatry training program. Kneeling, from left: Brenda Garro, M.D., Lavinia Bizeta, M.D., and Jane Lahr (residency coordinator). Standing, from left: Adi Virmani, M.D., Andrew Francis, M.D., Ph.D. (adult inpatient director), Kevin Kavookjian, M.D., Alex Dimitriu, M.D., Lara Quatinetz, D.O., Chenel Michel, M.D., Leilani Lee, M.D., Meera Joseph, M.D., Steve Kuruvilla, M.D., Rachel Schoolcraft, M.D., Maria German, M.D., Sharon Skariah, M.D., Thomas Vertrees, M.D., Suzy Krishnamoorthy, D.O., David Orbach, M.D., Lisa Changchien, M.D., Arun Singh, D.O., William Jangro, D.O., Simran Bagga, D.O., Philbert Chow, M.D., and Michael Schwartz, M.D. (training director). Residents not pictured are Mylan Kohler, D.O., Katya Stepanova, M.D., and Elizabeth Varghese, M.D.

DB Outreach Focuses on Vets' MH Issues

An education program organized by psychiatrists in the Albany, N.Y., area addresses the mental health needs of U.S. troops returning from overseas combat.

BY AARON LEVIN

The New York State Capital District Branch has launched a series of free seminars aimed at helping the region's mental health community improve care for members of the armed forces who return to the region after serving in Iraq or Afghanistan.

The first lecture in the series was September 24 and featured Matthew Friedman, M.D., director of the National Center for Posttraumatic Stress Disorder. He discussed crucial issues that confront men and women returning from a war zone.

The second talk was delivered in November by Col. Chris Williams, senior executive director for traumatic brain injury at the Department of Defense's Center of Excellence for Psychological Health and Traumatic Brain Injury.

Two sessions remain in the series, one to be held on January 28 and the other on March 25. The presentation in January will cover Department of Veterans Affairs' services for returning combat veterans and assessments of fitness for return to duty.

The March program will look at challenges facing military families. Scheduled speakers are the director of family programs for the New York State National Guard and two social workers from the posttraumatic stress disorder (PTSD) program at Albany Medical Center.

The first two programs were limited to psychiatrists and mental health professionals, but the remaining two are also open to veterans and their families.

Civilian mental health clinicians are needed to ensure that all troops who need help can get it, emphasized Anna Engel, M.D., president of the district branch, whose members are in the Albany area.

"The sessions are open not only to psychiatrists but also to psychologists, social workers, those who work with the homeless, and students in any of these fields," she said in an interview.

More than 100 people attended the first lecture in September, including psychiatry residents from Albany Medical Center, where the program is based. Vicki Balkowski, M.D., chief of psychiatry at that hospital, has included the lecture

please see ***Vets*** *on page 35*

From left: Anna Engel M.D., president of the N.Y. State Capital District Branch, and Vicki Balkowski, M.D., chair of the Department of Psychiatry at Albany Medical Center, helped organize the DB's seminar series on mental health among returning combat veterans. Speakers included Greg Miller, M.D., and Col. Chris Williams.

APA Announces New Member Benefit With Affinity Partner Merrill Lynch

APA has entered into a partnership with Merrill Lynch to provide free financial consultations to APA members as a member benefit. Merrill Lynch is offering APA members convenient access to customized, actionable financial advice from one of the world's leading wealth management firms.

A dedicated, nationwide team of Merrill Lynch Financial Advisors is ready to assist APA members with developing strategies around their personal financial needs supported by an illustrated report outlining specific investment strategies to help reach their goals.

APA members can call Merrill Lynch at 888-9ML-OFFER (965-6333) **between 8 a.m. and 6 p.m. (ET), Monday through Friday**. Members should reference their APA partner code 1844 to reach a Merrill Lynch financial advisor and to ask about other benefits available to APA members who become clients.

viewpoints

DSM-V Needs Mid-Course Correction

BY SEYMOUR GERS, M.D.

An article titled "Expert Appointments Key Step On Road to *DSM-V*" in the September 19 issue identifies the *DSM-V* Task Force members and the work group chairs and indicates that national and international researchers and clinicians will review and collaborate to produce the next *DSM*.

But, I hear a familiar refrain:

It's still the same old story,
Criteria seeking glory,
The fundamentals of
psychiatry are gone,
As *DSM* "revisions" move on!

DSM-III was a revolutionary departure from its predecessor in that it introduced specifically defined symptom-based criteria sets for each diagnosis. The intent was to make *DSM-III* "more scientific."

The inadvertent consequences of our "new" symptom-based diagnostic system are that our new *DSM* system is perfectly suited to the symptom-relief approach of the pharmaceutical industry, which has essentially captured psychiatric treatment with its "scientific studies" and "double-blind statistics" that have become the primary source for evidence-based treatment in psychiatry.

"Revisions" of *DSM-III*, namely *DSM-III-R* and *DSM-IV*, have resulted in criteria changes, but the diagnostic system remains a decision-tree approach that becomes a "shortcut" questionnaire primarily designed to get to the "criteria sets" that define each diagnosis. What has been sacrificed are almost all of the elements of the traditional basic psychiatric evaluation and mental status exam.

We now emphasize the chief complaint and present illness as we scrutinize the words of the patient to ascertain if the criteria sets have been fulfilled. The flaw in the scientific *DSM-III* "diagnostic system" was not in the establishment of specifically defined criteria sets for each diagnosis, but the deemphasis and essential elimination of traditional aspects of the basic psychiatric history taking and the examination of the psychiatric history, medical history, substance abuse history, family history of mental illness, and developmental, educational, and social history of the patient—that is, fundamental psychiatry.

This unrecognized flaw in the *DSM* diagnostic system has not been addressed in previous revisions of *DSM*, and we now appear poised to repeat it. The flawed diagnostic system needs to be revised, rather than the criteria sets for specific diagnoses.

I propose that *DSM-V* include a mid-course correction by creating a new multiaxial diagnostic scale that corresponds to the existing, well-established sections of the psychiatric examination. This would include the chief complaint and present illness sections, which are already being emphasized as we continue to examine for the presence of symptom criteria.

However, the currently neglected information and data obtained from the examination of the psychiatric history; family history of mental illness; developmental, educational, and social history; medical history; substance abuse history; legal history; and the patient's responses to the mental status examination will now all be entered on separate scales, to be added to the information obtained from the chief complaint and history of present illness so that each category of information is now included and used as part of the complete diagnostic profile. In addition, there should be added an informant reliability axis and scale to prompt the examiner to ascertain the reliability and validity of information obtained from all patients.

I do not believe that the mere addition of a multiaxial diagnostic scale to the symptom-based criteria will by itself bring about a change in the direction that psychiatry has taken as an unintended consequence of the introduction of the symptom-based criteria sets, the questionnaire-type evaluations, and decision-tree approach that has replaced clinical thinking and judgment in psychiatry over the past three decades. I do not know a remedy for this problem, but I believe that this proposal is, at least, a beginning and a mid-course correction for our *DSM* system.

This is too important an issue to allow this to be decided only by elected officials or a group of selected experts. If you agree, please contact me with your recommendations and/or criticisms at drsgers@rcn.com. (This article is an abbreviated version of a lengthier one on the same subject, which is available via e-mail upon request.) ■

Seymour Gers, M.D., teaches and practices in Brooklyn, N.Y.

letters to the editor

No Free Lunch

The column in the August 15 issue by APA President Nada Stotland, M.D., titled "Psychiatry Across the Pond" raises a number of issues worth discussing.

The first is the cost of registration at the Royal College of Psychiatrists' annual meeting, which in 2008 reached the astronomical level of $1,500 to $2,000. This effectively prevented many members and fellows of the college from attending and may well have discouraged APA members who might have been interested in attending. As a fellow of the college and an APA member, I can attest to this. Related to this cost factor was the college's policy decision to hold the annual meeting without pharmaceutical support. Clearly, this decision led to the high registration cost and the low attendance figures.

Involvement of pharmaceutical companies has been examined, criticized, and restricted in both the United States and Britain. Does this mean that APA might follow the example set by the Royal College? Should APA do so, the consequences might include the following outcomes:

- Reduced attendance at the APA annual and fall meetings.
- Reduced or terminated industry-supported symposia, which have formed an integral part of annual meetings for many years.
- Reduced or discouraged involvement of faculty from major medical schools; this is major source of continuing medical education for rank-and-file members who attend the meeting.
- Reduced income for academics and researchers who are compensated by pharmaceutical companies and who have acknowledged this kind of support. While this may be the aim of those who would reform the relationship with the pharmaceutical industry, are we risking throwing the baby out with the bathwater?

MICHAEL CLEARY, M.D.
Scottsdale, Ariz.

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

FDA Creates Web Site On Drug Safety Info

Health care professionals and the public can now go to a single page on the Food and Drug Administration's Web site to find a variety of safety information about prescription drugs. The Web page at <www.fda.gov/cder/drugSafety.htm> provides links to the following topics and more:

- Drug labeling, including patient labeling, professional labeling, and patient package inserts
- Drugs with a Risk Evaluation and Mitigation Strategy (REMS) for weighing benefits against risks
- A database of postmarket studies
- Clinicaltrials.gov
- Warning letters, recalls, market withdrawals, and safety alerts.
- Instructions how to report problems to the FDA through its MedWatch program

Establishing such a Web page is one of the requirements of the Food and Drug Administration Amendments Act of 2007. ■

clinical & research news

Subthreshold

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She noted the relevance of subthreshold symptoms to the controversy over diagnosing pediatric bipolar disorder. Despite that issue, she said, there is broad agreement on treating these children to improve their emotional regulation, create structure in their lives, and help with anger control.

"These approaches are good for most psychiatric disorders and will help produce better outcomes for kids with these problems," she said.

Children with subthreshold bipolar symptoms may not develop bipolar disorder but do have problems with mood dysregulation, expressed as depression and anxiety disorders, she said. However, many psychiatrists fear that treating these children for depression will raise the risk of triggering manic episodes.

"How do you trade off what is in front of you with what is down the road?" she said. "I've seen as many kids get an SSRI and do OK as become manic. And is having a manic episode the worst thing that can happen? We have treatments for manic episodes but not for major depression in bipolar disorder." ■

government news

Medicare

continued from page 8

The resolution also calls for imposing financial penalties on carriers for unjustified delays in enrollment and re-enrollment.

"We know how physicians are being imposed on by not getting their enrollment in a timely fashion and losing income," said AMA board member Peter Carmel, M.D., during reference committee hearings on the resolution. "The board suggests that we urge Congress and CMS that they must put more resources into the CMS payment process so you get your reimbursement within 30 to 40 days."

For reports on other actions taken at the AMA meeting, see page 1 and the next issue of *Psychiatric News*.

Actions taken by the AMA House of Delegates at its November meeting are posted at <www.ama-assn.org/ama/pub/category/20272.html>. ■

Executives

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Web site design and content. A good district branch Web site can help not only its members, she said, but also the public, the media, and other physicians through the information it provides on mental illness and its treatment.

"The members want this, but it is also a good connection to the community," De Mille said.

The wish to improve connections with other district branches and other groups concerned with mental health issues brought Valerie Lewis, executive director of the Vermont Psychiatric Association (VPA), to the meeting. The insights she gleaned on techniques for successful cooperation with other state advocacy groups and medical societies will be used to increase collaborations on a regional level. Such relationships help make up for shortages of a district branch's funding and time, she noted.

Lewis also hoped to learn more about effective state legislative lobbying during a session on that activity. The session included training on ways in which district branches can promote, oppose, or amend legislation. Lobbying insights are especially important to the VPA, she said. The VPA accepts no pharmaceutical industry funding that it can use for advocacy or other activities, and plans to push for legislation in 2009 requiring more open disclosure by drug and medical device makers of payments to physicians and hospitals.

Rebecca DeFilippo, executive director of the Eastern Missouri Psychiatric Society, described the November meeting as "motivating" because discussion of the model district branch taught her not only what organizational documents a district branch needs to keep but also provided her and the other executives with model forms for gathering and organizing such information. She cited the model ethics documents as an example of the type of valuable documents that APA provides.

DeFilippo, as well as other executives with whom *Psychiatric News* spoke, was effuse in her praise of APA for using its resources in lean economic times to continue to provide much-needed training through the November leadership conference. That assistance, she said, is an extension of the training APA provided when she first started in her position and guidance that APA staff continues to provide.

"I find it so helpful to be able to learn from my counterparts and do the job without having to reinvent the wheel," she said.

APA's "Model District Branch" document is posted at <www.psych.org/Resources/BranchesStateAssociations/ResourcesforDBSAs/Documents/ModelDB/ModelDB.aspx>. ■

Credit: Sylvia Johnson Photography 2008

DB executive directors Janet Shaw and Robin Huffman participate in a best-practice sharing workshop during APA's District Branch/State Association Leadership Conference.

Vets

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series among training options at the facility, said Engel.

"The war is no longer on the front page, and veterans' issues have gotten pushed to the side, especially now that people are more concerned with the financial crisis," said Engel.

Civilians need help understanding not only the diagnosis and treatment of PTSD and other disorders related to combat trauma, but also the range of care options available from the VA and military health systems.

"Often, the only information providers get is from the vets themselves, and that isn't always accurate," said Engel. "We also want to move professionals away from the stereotype of the VA as solely involved in chronic care, rather than the acute needs of younger people who we are now seeing."

Engel hopes that the lecture series will be a concrete demonstration that psychiatrists are involved and are providing advocacy and help to the surrounding community. The district branch also hopes to record the proceedings to share with other branches around the country, she said.

More information is available by sending an e-mail to DB28APA@gmail.com. ■

Volunteering

continued from page 1

of Social Workers to the program during the same press conference.

Give an Hour was developed to address needs not currently met by the Defense and Veterans Affairs departments.

"Americans respect our servicemen and women but few understand them," said Romberg, a clinical psychologist in private practice in Washington, D.C. "They are asking for our time, expertise, and compassion. The most important service we can provide is to hear their stories and learn what they have been through."

Those who wear the uniform of the nation earn a commitment from the nation, stated APA member and retired Brig. Gen. Stephen Xenakis, a U.S. Army medical corps officer for 28 years, who chaired the press conference.

"Combat changes everyone, and many need help coping," said Xenakis. "Many service members have not yet asked for help because of the stigma for the unseen wound. We need to remove the stigma, and seeking help should not be labeled as a disorder."

"Saying 'thanks' isn't enough," added retired Adm. Donald Arthur, a former Navy surgeon general who is now chief medical officer at Main Line Health System in Bryn Mawr, Pa. "We should honor their service with an hour of service—an hour a week to listen, helping to heal the absolutely normal effects of extraordinary circumstances."

Along with providing services, the professional organizations and the Department of Defense must do more to reduce the opprobrium attached to seeking help, the speakers said.

"Two-thirds of military people in one survey said that seeking help would have a negative effect on their careers," said Robinowitz. "We need more poster children—generals, colonels, admirals—to come forth and show that mental health treatment improves lives and careers."

More information about Give an Hour is posted at <www.giveanhour.org>. ■

Credit: Aaron Levin

Former APA President Carolyn Robinowitz, M.D., urges mental health professionals to support Give an Hour, which connects volunteer providers with returning troops and their families. With her are leaders of other major mental health professional organizations, including (left ro right) Mary Ragan, Ph.D., American Association of Pastoral Counselors; Elizabeth Clark, Ph.D., National Association of Social Workers; Randy Phelps, Ph.D., American Psychological Association; Brig. Gen. Stephen Xenakis (Ret.); Barbara Romberg, Ph.D., founder and president of Give an Hour; Adm. Donald Arthur (Ret.); U.S. Army veteran Jennifer Crane.

Parity

continued from page 1

"There are many ways to leverage resources to get this job done," agreed Kevin Sherin, M.D., of Orlando, president of the American Association of Public Health Physicians. "The mission is critical and affects all specialties."

John McIntyre, M.D., chair of the Section Council on Psychiatry, cited the "support and enthusiasm throughout the House of Delegates for the passage" of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008.

He added, "The AMA had lobbied along with APA for this for many years, and there was considerable celebration about its having passed. It's significant that the house thought it important that the impact be maximized by making sure that physicians and patients are fully informed."

McIntyre added that the section council agreed that existing technological resources should be used for dissemination of information and that an expensive national campaign "was not the right way to go."

Credit: Mark Moran

Psychiatrist Jerry Halvorson, M.D., a member of APA's delegation to the AMA, testifies during reference committee hearings on a resolution calling on the AMA to educate physicians and patients about the new federal mental health parity law.

TRICARE Under Scrutiny

In other house business of interest to psychiatrists, delegates approved a report by the AMA's Council on Medical Services outlining problems associated with physician payment under the military's TRICARE health care system and with recruitment of clinicians—especially mental health professionals.

After testimony from psychiatrists and other physicians about the importance of recruiting mental health clinicians, delegates approved the report with a resolution calling on the AMA to "encourage the TRICARE Management Activity and its contractors to continue and strengthen their efforts to recruit and retain mental health and addiction service providers in TRICARE networks, which should include providing adequate reimbursement for mental health and addiction services."

Also approved was a recommendation that the AMA "strongly urge the TRICARE Management Activity to implement significant increases in physician payment rates to ensure all TRICARE beneficiaries, including service members and their families, have adequate access to and choice of physicians."

APA President Nada Stotland, M.D., testified during reference committee hearings in support of the measure. "Service in the military has resulted in a devastating epidemic of mental illnesses, causing disability and pain to members and veterans of the armed services and their families. All too often these illnesses, when untreated, end tragically, in suicide.

"The American Psychiatric Association has conducted a membership survey," Stotland said. "Psychiatrists report payment obstacles and low reimbursement so severe that they either cannot participate or regard participation as charity care."

Stotland also informed the house that the American Psychiatric Foundation has supported the development of a program called Give an Hour, encouraging members to volunteer time to treating veterans. "Thousands of mental health professionals are donating an hour of direct service, consultation, or education each week," she said (see page 1).

She provided delegates written information about Give an Hour and urged physicians to visit the program's Web site at <www.giveanhour.org>.

McIntyre, who serves on the AMA Council on Medical Services, noted that the council had met with Maj. Gen. Elder Granger, M.C., a physician and deputy director and program executive office of TRICARE. He said that Granger was very welcoming of input from physicians about the matter of physician payment and manpower shortage areas and had vowed to continue being in contact with the council.

Credit: Mark Moran

Seated at the AMA House of Delegates meeting are Section Council on Psychiatry members (from right) Rodrigo Muñoz, M.D., Paul Wick, M.D., and Ken Certa, M.D.

Action Taken on Immunizations

APA representatives were also involved in shaping measures by the house to address misinformation about childhood vaccines and their alleged but unproven causal relationship with autism.

The house passed a resolution calling on the AMA to draft model legislation that states can pursue to enact more stringent requirements for parents and legal guardians to obtain personal-belief exemptions from state immunization requirements, develop educational materials that can be distributed to patients and their families articulating the benefits of immunizations and highlighting the exemplary safety record of vaccines, and communicate and work with other concerned organizations about effective ways to continue to support immunizations while rejecting claims that have no foundation in science.

The addition of a recommendation that the AMA develop educational materials was prompted by reference committee testimony from child psychiatrist and psychiatry section council member Louis Kraus, M.D.

"Time and time again I hear from families wondering if they should avoid vaccines," Kraus said. "Thousands of kids are not being vaccinated because of faulty information. One of the key components of this resolution is not just that we support the concept of vaccination but that we support the dissemination of information. There is repetitive research showing that vaccines are not a causative agent of autism." ■

Treat core symptoms[1,2]

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

*Lexapro Market Overview. Patient level report based on longitudinal analysis of US electronic pharmacy claims submitted for third-party reimbursement. Patients projected based on their activity in retail pharmacies.

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

Lexapro is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs), pimozide (see DRUG INTERACTIONS – Pimozide and Celexa), or in patients with hypersensitivity to escitalopram oxalate. As with other SSRIs, caution is indicated in the coadministration of tricyclic antidepressants (TCAs) with Lexapro. SSRIs and SNRIs (including Lexapro) and other psychotropic drugs that interfere with serotonin reuptake may increase the risk of bleeding events. Concomitant use of aspirin, NSAIDs, warfarin, and other anticoagulants may add to the risk. Patients should be cautioned about these risks. SSRIs and SNRIs have been associated with clinically significant hyponatremia. Elderly patients or 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. The most common adverse events with Lexapro versus placebo (approximately 5% or greater and approximately 2x placebo) were nausea, insomnia, ejaculation disorder, somnolence, increased sweating, fatigue, decreased libido, and anorgasmia.

Please see the accompanying brief summary of prescribing information for LEXAPRO.

References: 1. Burke WJ, Gergel I, Bose A. Fixed-dose trial of the single isomer SSRI escitalopram in depressed outpatients. *J Clin Psychiatry*. 2002;63: 331-336. **2.** Davidson JRT, Bose A, Korotzer A, Zheng H. Escitalopram in the treatment of generalized anxiety disorder: double-blind, placebo controlled, flexible-dose study. *Depress Anxiety*. 2004;19:234-240. **3.** LEXAPRO [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2008. **4.** Surveillance Data, Inc. (SDI), April 2008. **5.** Data on file, Forest Laboratories, Inc.

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

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

INDICATIONS AND USAGE Major Depressive Disorder Lexapro (escitalopram) is indicated for the treatment of major depressive disorder. The efficacy of Lexapro in the treatment of major depressive disorder was established in three, 8-week, placebo-controlled trials of outpatients whose diagnoses corresponded most closely to the DSM-IV category of major depressive disorder (see **CLINICAL PHARMACOLOGY**). 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. The efficacy of Lexapro in hospitalized patients with major depressive disorder has not been adequately studied. The efficacy of Lexapro in maintaining a response, in patients with major depressive disorder who responded during an 8-week, acute-treatment phase while taking Lexapro and were then observed for relapse during a period of up to 36 weeks, was demonstrated in a placebo-controlled trial (see **Clinical Efficacy Trials** under **CLINICAL PHARMACOLOGY**). Nevertheless, the physician who elects to use Lexapro for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient (see **DOSAGE AND ADMINISTRATION**). **Generalized Anxiety Disorder** Lexapro is indicated for the treatment of Generalized Anxiety Disorder (GAD). The efficacy of Lexapro was established in three, 8-week, placebo-controlled trials in patients with GAD (see **CLINICAL PHARMACOLOGY**). 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. The efficacy of Lexapro in the long-term treatment of GAD, that is, for more than 8 weeks, has not been systematically evaluated in controlled trials. The physician who elects to use Lexapro for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. **CONTRAINDICATIONS** Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated (see **WARNINGS**). Concomitant use in patients taking pimozide is contraindicated (see **Drug Interactions – Pimozide and Celexa**). Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Lexapro. **WARNINGS WARNINGS-Clinical Worsening and Suicide Risk Clinical Worsening and Suicide Risk** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in **Table 1. TABLE 1: Age Range and Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated**: 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 **PRECAUTIONS and DOSAGE AND ADMINISTRATION—Discontinuation of Treatment with Lexapro**, for a description of the risks of discontinuation of Lexapro). **Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers.** Prescriptions for Lexapro should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. **Screening Patients for Bipolar Disorder:** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Lexapro is not approved for use in treating bipolar depression. **Potential for Interaction with Monoamine Oxidase Inhibitors In patients receiving serotonin reuptake inhibitor drugs in combination with a monoamine oxidase inhibitor (MAOI), there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Furthermore, limited animal data on the effects of combined use of SSRIs and MAOIs suggest that these drugs may act synergistically to elevate blood pressure and evoke behavioral excitation. Therefore, it is recommended that Lexapro should not be used in combination with an MAOI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days should be allowed after stopping Lexapro before starting an MAOI. Serotonin syndrome has been reported in two patients who were concomitantly receiving linezolid, an antibiotic which is a reversible non-selective MAOI.** ***Serotonin Syndrome:*** The development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including Lexapro treatment, particularly with concomitant use of serotonergic drugs (including triptans) and with drugs which impair metabolism of serotonin (including MAOIs). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The concomitant use of Lexapro with MAOIs intended to treat depression is contraindicated (see **CONTRAINDICATIONS** and **WARNINGS - Potential for Interaction with Monoamine Oxidase Inhibitors**). If concomitant treatment of Lexapro with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **PRECAUTIONS - Drug Interactions**). The concomitant use of Lexapro with serotonin precursors (such as tryptophan) is not recommended (see **PRECAUTIONS - Drug Interactions**). **PRECAUTIONS General** Discontinuation of Treatment with Lexapro During marketing of Lexapro and other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with Lexapro. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (see **DOSAGE AND ADMINISTRATION**). Abnormal Bleeding 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 SSRI and SNRI 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. 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. Activation of Mania/Hypomania In placebo-controlled trials of Lexapro in major depressive disorder, activation of mania/hypomania was reported in one (0.1%) of 715 patients treated with Lexapro and in none of the 592 patients treated with placebo. One additional case of hypomania has been reported in association with Lexapro treatment. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorders treated with racemic citalopram and other marketed drugs effective in the treatment of major depressive disorder. As with all drugs effective in the treatment of major depressive disorder, Lexapro should be used cautiously in patients with a history of mania. Seizures Although anticonvulsant effects of racemic citalopram have been observed in animal studies, Lexapro has not been systematically evaluated in patients with a seizure disorder. These patients were excluded from clinical studies during the product's premarketing testing. In clinical trials of Lexapro, cases of convulsion have been reported in association with Lexapro treatment. Like other drugs effective in the treatment of major depressive disorder, Lexapro should be introduced with care in patients with a history of seizure disorder. Interference with Cognitive and Motor Performance In a study in normal volunteers, Lexapro 10 mg/day did not produce impairment of intellectual function or psychomotor performance. Because any psychoactive drug may impair judgment, thinking, or motor skills, however, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro therapy does not affect their ability to engage in such activities. Use in Patients with Concomitant Illness Clinical experience with Lexapro in patients with certain concomitant systemic illnesses is limited. Caution is advisable in using Lexapro in patients with diseases or conditions that produce altered metabolism or hemodynamic responses. Lexapro has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were generally excluded from clinical studies during the product's premarketing testing. In subjects with hepatic impairment, clearance of racemic citalopram was decreased and plasma concentrations were increased. The recommended dose of Lexapro in hepatically impaired patients is 10 mg/day (see **DOSAGE AND ADMINISTRATION**). Because escitalopram is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Until adequate numbers of patients with severe renal impairment have been evaluated during chronic treatment with Lexapro, however, it should be used with caution in such patients (see **DOSAGE AND ADMINISTRATION**). **Information for Patients** Physicians are advised to discuss the following issues with patients for whom they prescribe Lexapro. Patients should be cautioned about the risk of serotonin syndrome with the concomitant use of Lexapro and triptans, tramadol or other serotonergic agents. In a study in normal volunteers, Lexapro 10 mg/day did not impair psychomotor performance. The effect of Lexapro on psychomotor coordination, judgment, or thinking has not been systematically examined in controlled studies. Because psychoactive drugs may impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro therapy does not affect their ability to engage in such activities. Patients should be told that, although Lexapro has not been shown in experiments with normal subjects to increase the mental and motor skill impairments caused by alcohol, the concomitant use of Lexapro and alcohol in depressed patients is not advised. Patients should be made aware that escitalopram is the active isomer of Celexa (citalopram hydrobromide) and that the two medications should not be taken concomitantly. Patients should be advised to inform their physician if they are taking, or plan to take, any prescription or over-the-counter drugs, as there is a potential for interactions. Patients should be cautioned about the concomitant use of Lexapro and NSAIDs, aspirin, warfarin, or other drugs that affect coagulation since combined use of psychotropic drugs that interfere with serotonin reuptake and these agents has been associated with an increased risk of bleeding. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. Patients should be advised to notify their physician if they are breastfeeding an infant. While patients may notice improvement with Lexapro therapy in 1 to 4 weeks, they should be advised to continue therapy as directed. Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Lexapro and should counsel them in its appropriate use. A patient Medication Guide about "Antidepressant Medicines, Depression and other Serious Mental Illness, and Suicidal Thoughts or Actions" is available for Lexapro. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking Lexapro. **Clinical Worsening and Suicide Risk:** Patients, their families, and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to look for the emergence of such symptoms on a day-to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication. **Laboratory Tests** There are no specific laboratory tests recommended. **Concomitant Administration with Racemic Citalopram** Citalopram - Since escitalopram is the active isomer of racemic citalopram (Celexa), the two agents should not be coadministered. **Drug Interactions Serotonergic Drugs:** Based on the mechanism of action of SNRIs and SSRIs including Lexapro, and the potential for serotonin syndrome, caution is advised when Lexapro is coadministered with other drugs that may affect the serotonergic neurotransmitter systems, such as triptans, linezolid (an antibiotic which is a reversible non-selective MAOI), lithium, tramadol, or St. John's Wort (see **WARNINGS-Serotonin Syndrome**). The concomitant use of Lexapro with other SSRIs, SNRIs or tryptophan is not recommended (see **PRECAUTIONS - Drug Interactions**). **Triptans:** There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of Lexapro with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **WARNINGS - Serotonin Syndrome**). CNS Drugs - Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally-acting drugs. Alcohol - Although Lexapro did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by patients taking Lexapro is not recommended. Monoamine Oxidase Inhibitors (MAOIs) - See **CONTRAINDICATIONS** and **WARNINGS**. **Drugs That Interfere With Hemostasis (NSAIDs, Aspirin, Warfarin, etc.)** Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of the case-control and cohort design that have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding have also shown that concurrent use of an NSAID or aspirin 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. **Carcinogenesis, Mutagenesis, Impairment of Fertility** Carcinogenesis Racemic citalopram was administered in the diet to NMRI/BOM strain mice and COBS WI strain rats for 18 and 24 months, respectively. There was no evidence for carcinogenicity of racemic citalopram in mice receiving up to 240 mg/kg/day. There was an increased incidence of small intestine carcinoma in rats receiving 8 or 24 mg/kg/day racemic citalopram. A no-effect dose for this finding was not established. The relevance of these findings to humans is unknown. Mutagenesis Racemic citalopram was mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) in 2 of 5 bacterial strains (Salmonella TA98 and TA1537) in the absence of metabolic activation. It was clastogenic in the *in vitro* Chinese hamster lung cell assay for chromosomal aberrations in the presence and absence of metabolic activation. Racemic citalopram was not mutagenic in the *in vitro* mammalian forward gene mutation assay (HPRT) in mouse lymphoma cells or in a coupled *in vitro/in vivo* unscheduled DNA synthesis (UDS) assay in rat liver. It was not clastogenic in the *in vitro* chromosomal aberration assay in human lymphocytes or in two *in vivo* mouse micronucleus assays. Impairment of Fertility When racemic citalopram was administered orally to 16 male and 24 female rats prior to and throughout mating and gestation at doses of 32, 48, and 72 mg/kg/day, mating was decreased at all doses, and fertility was decreased at doses ≥32 mg/kg/day. Gestation duration was increased at 48 mg/kg/day. **Pregnancy** Pregnancy Category C In a rat embryo/fetal development study, oral administration of escitalopram (56, 112, or 150 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased fetal body weight and associated delays in ossification at the two higher doses (approximately ≥56 times the maximum recommended human dose [MRHD] of 20 mg/day on a body surface area [mg/m^2] basis). Maternal toxicity (clinical signs and decreased body weight gain and food consumption), mild at 56 mg/kg/day, was present at all dose levels. The developmental no-effect dose of 56 mg/kg/day is approximately 28 times the MRHD on a mg/m^2 basis. No teratogenicity was observed at any of the doses tested (as high as 75 times the MRHD on a mg/m^2 basis). When female rats were treated with escitalopram (6, 12, 24, or 48 mg/kg/day) during pregnancy and through weaning, slightly increased offspring mortality and growth retardation were noted at 48 mg/kg/day which is approximately 24 times the MRHD on a mg/m^2 basis. Slight maternal toxicity (clinical signs and decreased body weight gain and food consumption) was seen at this dose. Slightly increased offspring mortality was seen at 24 mg/kg/day. The no-effect dose was 12 mg/kg/day which is approximately 6 times the MRHD on a mg/m^2 basis. In animal reproduction studies, racemic citalopram has been shown to have adverse effects on embryo/fetal and postnatal development, including teratogenic effects, when administered at doses greater than human therapeutic doses. In two rat embryo/fetal development studies, oral administration of racemic citalopram (32, 56, or 112 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased embryo/fetal growth and survival and an increased incidence of fetal abnormalities (including cardiovascular and skeletal defects) at the high dose. This dose was also associated with maternal toxicity (clinical signs, decreased body weight gain). The developmental no-effect dose was 56 mg/kg/day. In a rabbit study, no adverse effects on embryo/fetal development were observed at doses of racemic citalopram of up to 16 mg/kg/day. Thus, teratogenic effects of racemic citalopram were observed at a maternally toxic dose in the rat and were not observed in the rabbit. When female rats were treated with racemic citalopram (4.8, 12.8, or 32 mg/kg/day) from late gestation through weaning, increased offspring mortality during the first 4 days after birth and persistent offspring growth retardation were observed at the highest dose. The no-effect dose was 12.8 mg/kg/day. Similar effects on offspring mortality and growth were seen when dams were treated throughout gestation and early lactation at doses ≥24 mg/kg/day. A no-effect dose was not determined in that study. There are no adequate and well-controlled studies in pregnant women; therefore, escitalopram should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Pregnancy-Nonteratogenic Effects** Neonates exposed to Lexapro and other SSRIs or SNRIs, late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome (see **WARNINGS**). Infants exposed to SSRIs in late pregnancy may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN). PPHN occurs in 1-2 per 1000 live births in the general population and is associated with substantial neonatal morbidity and mortality. In a retrospective, case-control study of 377 women whose infants were born with PPHN and 836 women whose infants were born healthy, the risk for developing PPHN was approximately six-fold higher for infants exposed to SSRIs after the 20th week of gestation compared to infants who had not been exposed to antidepressants during pregnancy. There is currently no corroborative evidence regarding the risk for PPHN following exposure to SSRIs in pregnancy; this is the first study that has investigated the potential risk. The study did not include enough cases with exposure to individual SSRIs to determine if all SSRIs posed similar levels of PPHN risk. When treating a pregnant woman with Lexapro during the third trimester, the physician should carefully consider both the potential risks and benefits of treatment (see **DOSAGE AND ADMINISTRATION**). Physicians should note that in a prospective longitudinal study of 201 women with a history of major depression who were euthymic at the beginning of pregnancy, women who discontinued antidepressant medication during pregnancy were more likely to experience a relapse of major depression than women who continued antidepressant medication. **Labor and Delivery** The effect of Lexapro on labor and delivery in humans is unknown. **Nursing Mothers** Racemic citalopram, like many other drugs, is excreted in human breast milk. There have been two reports of infants experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of citalopram by its mother and, in the second case, no follow-up information was available. The decision whether to continue or discontinue either nursing or Lexapro therapy should take into account the risks of citalopram exposure for the infant and the benefits of Lexapro treatment for the mother. **Pediatric Use** Safety and effectiveness in the pediatric population have not been established (see **BOXED WARNING** and **WARNINGS—Clinical Worsening and Suicide Risk**). One placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients. Anyone considering the use of Lexapro in a child or adolescent must balance the potential risks with the clinical need. **Geriatric Use** Approximately 6% of the 1144 patients receiving escitalopram in controlled trials of Lexapro in major depressive disorder and GAD were 60 years of age or older; elderly patients in these trials received daily doses of Lexapro between 10 and 20 mg. The number of elderly patients in these trials was insufficient to adequately assess for possible differential efficacy and safety measures on the basis of age. Nevertheless, greater sensitivity of some elderly individuals to effects of Lexapro cannot be ruled out. 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 **PRECAUTIONS**, 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. **ADVERSE REACTIONS** Adverse event information for Lexapro was collected from 715 patients with major depressive disorder who were exposed to escitalopram and from 592 patients who were exposed to placebo in double-blind, placebo-controlled trials. An additional 284 patients with major depressive disorder were newly exposed to escitalopram in open-label trials. The adverse event information for Lexapro in patients with GAD was collected from 429 patients exposed to escitalopram and from 427 patients exposed to placebo in double-blind, placebo-controlled trials. Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tables and tabulations that follow, standard World Health Organization (WHO) terminology has been used to classify reported adverse events. The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. **Adverse Events Associated with Discontinuation of Treatment Major Depressive Disorder** Among the 715 depressed patients who received Lexapro in placebo-controlled trials, 6% discontinued treatment due to an adverse event, as compared to 2% of 592 patients receiving placebo. In two fixed-dose studies, the rate of discontinuation for adverse events in patients receiving 10 mg/day Lexapro was not significantly different from the rate of discontinuation for adverse events in patients receiving placebo. The rate of discontinuation for adverse events in patients assigned to a fixed dose of 20 mg/day Lexapro was 10%, which was significantly different from the rate of discontinuation for adverse events in patients receiving 10 mg/day Lexapro (4%) and placebo (3%). Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice that of placebo, were nausea (2%) and ejaculation disorder (2% of male patients). **Generalized Anxiety Disorder** Among the 429 GAD patients who received Lexapro 10-20 mg/day in placebo-controlled trials, 8% discontinued treatment due to an adverse event, as compared to 4% of 427 patients receiving placebo. Adverse events that were associated with the discontinuation of at least 1% of patients treated with Lexapro, and for which the rate was at least twice the placebo rate, were nausea (2%), insomnia (1%), and fatigue (1%). **Incidence of Adverse Events in Placebo-Controlled Clinical Trials Major Depressive Disorder Table 2** enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred among 715 depressed patients who received Lexapro at doses ranging from 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The prescriber should be aware that these figures cannot be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and non-drug factors to the adverse event incidence rate in the population studied. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were insomnia, ejaculation disorder (primarily ejaculatory delay), nausea, sweating increased, fatigue, and somnolence (see **TABLE 2**). **TABLE 2: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Major Depressive Disorder* (Percentage of Patients Reporting Event) Body System/Adverse Event [Lexapro (N=715) and Placebo (N=592)]: Autonomic Nervous System Disorders:** Dry Mouth (6% and 5%); Sweating Increased (5% and 2%). **Central & Peripheral Nervous System Disorders:** Dizziness (5% and 3%). **Gastrointestinal Disorders:** Nausea (15% and 7%); Diarrhea (8% and 5%); Constipation (3% and 1%); Indigestion (3% and 1%); Abdominal Pain (2% and 1%). **General:** Influenza-like Symptoms (5% and 4%); Fatigue (5% and 2%). **Psychiatric Disorders:** Insomnia (9% and 4%); Somnolence (6% and 2%); Appetite Decreased (3% and 1%); Libido Decreased (3% and 1%). **Respiratory System Disorders:** Rhinitis (5% and 4%); Sinusitis (3% and 2%). **Urogenital:** Ejaculation Disorder[1,2] (9% and <1%); Impotence[2] (3% and <1%); Anorgasmia[3] (2% and <1%).*Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: headache, upper respiratory tract infection, back pain, pharyngitis, inflicted injury, anxiety. [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 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. The most commonly observed adverse events 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 (see **TABLE 3**). **TABLE 3: Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Generalized Anxiety Disorder* (Percentage of Patients Reporting Event) Body System/Adverse Event [Lexapro (N=429) and Placebo (N=427)]: Autonomic Nervous System Disorders:** Dry Mouth (9% and 5%); Sweating Increased (4% and 1%). **Central & Peripheral Nervous System Disorders:** Headache (24% and 17%); Paresthesia (2% and 1%). **Gastrointestinal Disorders:** Nausea (18% and 8%); Diarrhea (8% and 6%); Constipation (5% and 4%); Indigestion (3% and 2%); Vomiting (3% and 1%); Abdominal Pain (2% and 1%); Flatulence (2% and 1%); Toothache (2% and 0%). **General:** Fatigue (8% and 2%); Influenza-like symptoms (5% and 4%). **Musculoskeletal:** Neck/Shoulder Pain (3% and 1%). **Psychiatric Disorders:** Somnolence (13% and 7%); Insomnia (12% and 6%); Libido Decreased (7% and 2%); Dreaming Abnormal (3% and 2%); Appetite Decreased (3% and 1%); Lethargy (3% and 1%); Yawning (2% and 1%). **Urogenital:** Ejaculation Disorder[1,2] (14% and 2%); Anorgasmia[3] (6% and <1%); Menstrual Disorder (2% and 1%). *Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo ≥ Lexapro: inflicted injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. [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 Events** The potential dose dependency of common adverse events (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 events 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 Events* in Patients with Major Depressive Disorder Receiving 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%).*Adverse events with an incidence rate of at least 5% in either of the Lexapro groups and with an incidence rate in the 20 mg/day Lexapro group that was approximately twice that of the 10 mg/day Lexapro group and the placebo group. **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** shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-controlled trials. **TABLE 5: Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials** [In Males Only: **Adverse Event: Lexapro** (N=407) **and Placebo** (N=383)]: Ejaculation Disorder (primarily ejaculatory delay) (12% and 1%); Libido Decreased (6% and 2%); Impotence (2% and <1%). [In Females Only**: Lexapro** (N=737) **and Placebo** (N=636)]: Libido Decreased (3% and 1%); Anorgasmia (3% and <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 Events Observed During the Premarketing Evaluation of Lexapro** Following is a list of WHO terms that reflect 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. All reported events are included except those already listed in **Tables 2 & 3**, those occurring in only one patient, event terms that are so general as to be uninformative, and those that are unlikely to be drug related. It is important to emphasize that, although the events reported occurred during treatment with Lexapro, they were not necessarily caused by it. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring on one or more occasions in at least 1/100 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1000 patients. Cardiovascular - *Frequent:* palpitation, hypertension. *Infrequent:* bradycardia, tachycardia, ECG abnormal, flushing, varicose vein. Central and Peripheral Nervous System Disorders - *Frequent:* light-headed feeling, migraine. *Infrequent:* tremor, vertigo, restless legs, shaking, twitching, dysequilibrium, tics, carpal tunnel syndrome, muscle contractions involuntary, sluggishness, coordination abnormal, faintness, hyperreflexia, muscular tone increased. Gastrointestinal Disorders - *Frequent:* heartburn, abdominal cramp, gastroenteritis. *Infrequent:* gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult. General - *Frequent:* allergy, pain in limb, fever, hot flushes, chest pain. *Infrequent:* edema of extremities, chills, tightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. Hemic and Lymphatic Disorders - *Infrequent:* bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical. Metabolic and Nutritional Disorders - *Frequent:* increased weight. *Infrequent:* decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. Musculoskeletal System Disorders - *Frequent:* arthralgia, myalgia. *Infrequent:* jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness. Psychiatric Disorders - *Frequent:* appetite increased, lethargy, irritability, concentration impaired. *Infrequent:* jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, amnesia, anxiety attack, bruxism, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. Reproductive Disorders/Female* - *Frequent:* menstrual cramps, menstrual disorder. *Infrequent:* menorrhagia, breast neoplasm, pelvic inflammation, premenstrual syndrome, spotting between menses. *% based on female subjects only: N=905 Respiratory System Disorders - *Frequent:* bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. *Infrequent:* asthma, breath shortness, laryngitis, pneumonia, tracheitis. Skin and Appendages Disorders - *Frequent:* rash. *Infrequent:* pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodule. Special Senses - *Frequent:* vision blurred, tinnitus. *Infrequent:* taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste. Urinary System Disorders - *Frequent:* urinary frequency, urinary tract infection. *Infrequent:* urinary urgency, kidney stone, dysuria, blood in urine. **Events Reported Subsequent to the Marketing of Escitalopram** - Although no causal relationship to escitalopram treatment has been found, the following adverse events have been reported to have occurred in patients and to be temporally associated with escitalopram treatment during postmarketing spontaneous and clinical trial experience and were not observed during the premarketing evaluation of escitalopram: Blood and Lymphatic System Disorders: hemolytic anemia, leukopenia, thrombocytopenia. Cardiac Disorders: atrial fibrillation, cardiac failure, myocardial infarction, torsade de pointes, ventricular arrhythmia, ventricular tachycardia. Endocrine Disorders: diabetes mellitus, hyperprolactinemia, SIADH. Eye Disorders: diplopia, glaucoma. Gastrointestinal Disorders: gastrointestinal hemorrhage, pancreatitis, rectal hemorrhage. General Disorders and Administration Site Conditions: abnormal gait. Hepatobiliary Disorders: fulminant hepatitis, hepatic failure, hepatic necrosis, hepatitis. Immune System Disorders: allergic reaction. Investigations: electrocardiogram QT prolongation, INR increased, prothrombin decreased. Metabolism and Nutrition Disorders: hypoglycemia, hypokalemia. Musculoskeletal and Connective Tissue Disorders: rhabdomyolysis. Nervous System Disorders: akathisia, choreoathetosis, dysarthria, dyskinesia, dystonia, extrapyramidal disorders, grand mal seizures (or convulsions), hypoaesthesia, myoclonus, neuroleptic malignant syndrome, nystagmus, seizures, serotonin syndrome, tardive dyskinesia. Pregnancy, Puerperium and Perinatal Conditions: spontaneous abortion. Psychiatric Disorders: acute psychosis, aggression, anger, delirium, delusion, nightmare, paranoia, visual hallucinations. Renal and Urinary Disorders: acute renal failure. Reproductive System and Breast Disorders: priapism. Respiratory, Thoracic and Mediastinal Disorders: pulmonary embolism. Skin and Subcutaneous Tissue Disorders: angioedema, ecchymosis, erythema multiforme, photosensitivity reaction, Stevens Johnson Syndrome, toxic epidermal necrolysis, urticaria. Vascular Disorders: deep vein thrombosis, hypotension, orthostatic hypotension, phlebitis, thrombosis.

Nurses

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based practice into the community settings," England told *Psychiatric News*. "So they are very patient focused."

As part of the FNINR's psychiatric nursing focus, the organization is creating a short film featuring psychiatric nurse researchers that will provide nursing students insight into the "depth and strength" of the research the mental health nurses conduct on delivery of patient care. The film is part of the FNINR's effort to boost the number of nurse researchers, an effort that also includes providing financial assistance to doctoral nursing students.

A psychiatric nurse researcher was among the nurse researchers honored for their achievements at the FNINR awards banquet. Deborah Gross, D.N.Sc., R.N., a professor of mental health and psychiatric nursing at Johns Hopkins University School of Nursing, has focused her research on the mental health and well-being of young children living in low-income urban areas. Funding from the NINR has helped her develop and test a cost-effective program to strengthen parenting competence and confidence among families from diverse backgrounds.

Gross's program used video vignettes of challenging parental situations to educate parents of young children about techniques that succeed in correcting child misbehavior and prevent the development of behavior disorders in their offspring. ■

Applicants Invited for Fellowship Program

Psychiatry residents are invited to apply for APA's Minority Fellowships Program (MFP). The MFP provides educational opportunities not only to minority residents, but to any resident interested in providing quality and effective service to minorities and the underserved.

The fellowships provide funds for psychiatry residents to experience a specialized educational program geared toward building leaders in psychiatry to improve the quality of mental health care for the following federally recognized ethnic minority groups: American Indians, Native Alaskans, Asian Americans, Native Hawaiians, Native Pacific Islanders, African Americans, and Hispanics/Latinos.

The MFP fellows are classified into three groups: APA/SAMHSA Fellows (funded by the Substance Abuse and Mental Health Services Administration), APA/SAMHSA Substance Abuse Fellows (funded by the Centers for Substance Abuse Treatment and Substance Abuse Prevention), and APA/AstraZeneca Fellows (funded by AstraZeneca).

SAMHSA and SAMHSA/Substance Abuse Fellows receive a stipend based on their postgraduate year and the availability of federal funds. AstraZeneca fellows do not receive stipends, but travel funds are available for specific APA meetings and special projects. AstraZeneca fellows serve for two years.

Psychiatry residents must be at least a PGY-2 in July 2009 and remain in training during the entire academic year. Applicants must be APA members. SAMHSA applicants must be U.S. citizens or permanent residents at the time of application. Federal employees are ineligible. AstraZeneca applicants do not have to be U.S. citizens or permanent residents or graduates of a U.S. medical school. SAMHSA Substance Abuse applicants must be in their PGY-5 of training in July 2009 and in a substance abuse training program approved by the affiliated medical school or agency in which a significant number of substance abuse patients are from minority and underserved groups.

All residents are welcome to apply regardless of race, ethnicity, gender, national origin, religion, sexual orientation, or disability.

The deadline for applications is January 30, 2009. Applications are posted at <www.psych.org/Resources/OMNA/MFP.aspx>. More information is available from Marilyn King at (703) 907-8653 or mking@psych.org. ■

Depression Care

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by Cartreine, was slated to begin in October at Beth Israel Deaconess and would assess the program's effectiveness in 100 volunteers with mild to moderate depression.

Both Cartreine and Buckey noted that this self-treatment program may be useful for not only astronauts but also the general patient population, and that NASA is interested in spinning off its technology for civilian use.

"It does not replace a psychologist or a psychiatrist," said Buckey. "But it can guide the user to identify [his or her] problems" and then provide instructions on how the user can take steps to solve those problems. "Even people who are not depressed can find it helpful," he said. Cartreine added that it also can be used in conjunction with in-person therapies and medications.

"The field of computer-based psychotherapy is still very new," Cartreine noted. "Research has shown that people are more willing to admit embarrassing problems to a computer than to a live person—[problems] such as suicidal or homicidal ideations, certain sexual behaviors, and addictions." In other words, he said, a computer is often perceived in patient interviews as being less judgmental than a live person.

A description of the Self-Guided Depression Treatment on Long-Duration Spaceflights is posted at <www.nsbri.org/Research/Projects/viewsummary.epl?pid=155>. ■

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GHS, a tertiary healthcare system with 1,268 beds on five campuses serving upstate South Carolina and surrounding regions, is affiliated with the University of South Carolina School of Medicine.

Greenville, located on the I-85 Boom Belt between Atlanta and Charlotte, enjoys a diverse thriving economy, excellent cultural and educational opportunities, a mild climate, and close proximity to mountains, lakes and beaches.

Contact Linda McCarthy: (864) 797-6116, fax (864) 797-6199, lmccarthy@ghs.org.

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Broughton Hospital, which provides quality psychiatric care to the citizens of western North Carolina, is seeking **psychiatrists** to help expand and enhance its inpatient services. Generalists, sub-specialists, new graduates and recent retirees are all welcome to apply. In addition to adolescent, adult and geriatric services Broughton has recently opened a statewide psychiatric and substance abuse service for deaf citizens, and will open a forensic treatment unit covering the western half of the state in 2008.

Broughton is located in Morganton, NC in Burke County. Morganton has a vibrant downtown and is convenient by car to Hickory (20 minutes), Asheville (60 minutes), and the rest of the planet via Douglas Airport in Charlotte (85 minutes). Major league sports and some of the best hiking, skiing, trout fishing, and kayaking on the East Coast are just as close. Some staff reside on the shore of Lake James, just 20 minutes to the west. Burke County was voted as one of the 10 best places to raise a family by *Reader's Digest*.

Salary and benefits are competitive. Flexible or part-time schedules are negotiable. On-campus housing is available. Opportunities exist for additional income via paid call. The hospital has academic affiliation with a nationally known residency program. Broughton hosts medical students and voluntary participants in the clinical clerkship earn paid CME. Physicians here are eligible to apply for a State student loan repayment program. EOE

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Sherrie Kappa
Broughton Hospital
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Morganton, NC 28655

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This position offers a highly competitive VA salary and a faculty appointment at Harvard Medical School commensurate with experience. Please send a letter of interest, CV, and contact information for three references to:

DR. GARY KAPLAN, DIRECTOR,
MENTAL HEALTH SERVICE
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Ena Casas
Department of Psychiatry
University of Illinois
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Chicago, Illinois 60612.
E-mail: ecasas@psych.uic.edu

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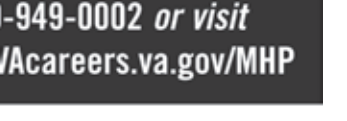

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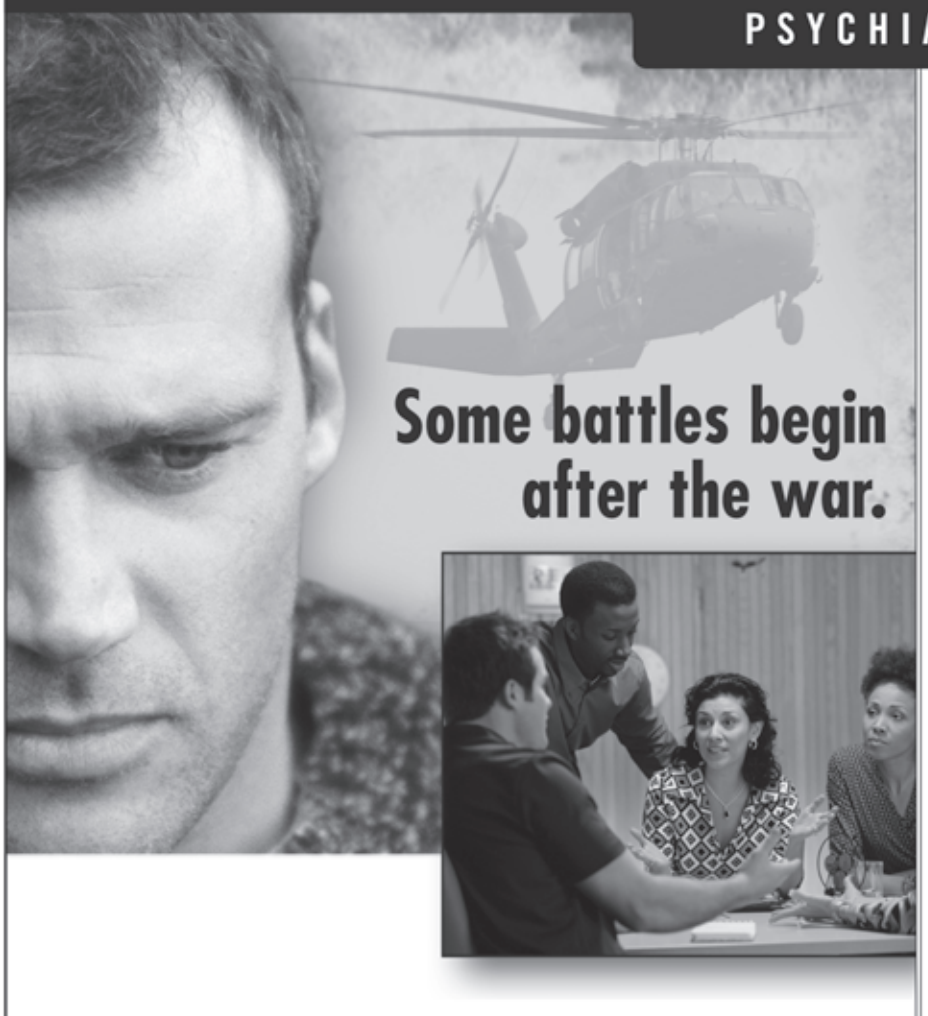

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Coalinga State Hospital is the first new State psychiatric hospital built in California in over 50 years. With its 1,500 beds, almost exclusively devoted to the treatment of sexually violent predators, it is a state-of-the-art facility. It is closely affiliated with the University of California, Irvine School of Medicine, and will train medical students and residents. A forensic fellowship program is being developed.

This is an excellent opportunity for a Board Certified or Board Eligible clinician interested in general adult psychiatry as well as forensic psychiatry. Coalinga State Hospital's salary package is competitive and we offer job security, flexible work schedules, and a generous California State benefit package, including paid leave, medical insurance, and CalPERS Retirement. J-1 visa applicants accepted.

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If you are interested in discussing any of our psychiatric positions, please contact.

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CALIFORNIA DEPARTMENT OF Mental Health

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ADULT PSYCHIATRISTS
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Scott & White and Texas A&M College of Medicine is seeking outstanding candidates to join our nationally recognized Department of Psychiatry. Currently, we have openings for Adult Psychiatrists at our College Station Clinic. The division in College Station includes 2 full-time Psychiatrists and 4 full-time Psychologists, offering a wide variety of preclinical and clinical teaching opportunities as the College of Medicine expands its campus in College Station. We are a full service Psychiatric Department with specialty clinics and programs. We have a diverse faculty with a close sense of collegiality.

The S&W College Station Clinic is the largest of our twenty regional clinics system, with more than 80 physicians from all specialties networked to the main campus and hospital in Temple. College Station is 90 minutes west of Houston, 90 minutes east of Austin, and 3 hours south of Dallas, and is home to Texas A&M University.

Led by physicians with a commitment to patient care, education and research, Scott & White is listed among the "Top 100 Hospitals" in America in several categories, and has been listed as a Solucient Top 15 Teaching Hospital for the past three years. All staff are full-time Texas A&M medical school faculty. The health system and medical school are investing heavily in basic, translational and clinical research, with appropriate support.

Scott & White offers a competitive salary and comprehensive benefit package, which begins with four weeks vacation, three weeks CME and a generous retirement plan. For additional information regarding these positions, please contact: Jason Culp, Physician Recruiter, Scott & White Clinic, 2401 S. 31st, Temple, TX 76508. (800) 725-3627 jculp@swmail.sw.org Scott & White is an equal opportunity employer. A formal application must be completed to be considered for these positions. For more information on Scott & White, please visit our web site at: www.sw.org

S&W SCOTT&WHITE

TEXAS A&M HEALTH SCIENCE CENTER COLLEGE OF MEDICINE

DARTMOUTH MEDICAL SCHOOL

THE DEPARTMENT OF PSYCHIATRY IS EXPANDING AND WE ARE LOOKING TO HIRE FOR THE FOLLOWING POSITIONS:

ADULT OUTPATIENT PSYCHIATRIST TO JOIN OUR FACULTY AT THE MONADNOCK FAMILY SERVICES IN KEENE, NH.

The position entails interdisciplinary team care of adults and older adults in an outpatient setting. The successful candidate will have a strong interest in working with adults who experience severe and persistent mental illnesses and be willing to participate in an on-call pool.

Monadnock Family Services is an innovative behavioral health agency with a 100-year history of providing high-quality services in a creative and supportive climate. The agency is a leader in area of health and social services, alliances, and partnerships. The beautiful Monadnock region of N.H. (90 miles from Boston) offers many excellent recreational and cultural activities.

Academic duties may include teaching and supervision of medical students and residents. Candidates should be board certified or eligible in Psychiatry. This position will include a faculty appointment at Dartmouth Medical School at a rank and salary commensurate with experience.

INPATIENT AND CONSULTATION-LIAISON PSYCHIATRIST TO JOIN OUR FACULTY AT THE CHESHIRE MEDICAL CENTER IN KEENE, NH.

The position involves delivering clinical care and oversight for Cheshire's inpatient adult psychiatric program, providing consultation-liaison services to hospitalized, medically ill inpatients throughout the hospital and offering outpatient triage evaluations, consultation, and short term care for patients who are served by non-psychiatric outpatient physicians. He or she will serve as an ambassador for behavioral health to non-psychiatric colleagues, working closely with them to develop an efficient and effective outpatient model for delivering integrated psychiatric and general medical care.

Academic duties may include teaching and supervision of medical students and residents. Candidates should be board certified or eligible in Psychiatry. This position will include a faculty appointment at Dartmouth Medical School at a rank and salary commensurate with experience.

AFFECTIVE DISORDERS PSYCHIATRIST TO JOIN OUR FACULTY AT DARTMOUTH-HITCHCOCK MEDICAL CENTER IN LEBANON, NH.

The position, Director of the Affective Disorders Service, involves developing and leading an affective disorders program for the Department. The successful applicant will provide clinical consultation and ongoing care of adults with affective illnesses, oversee the Electroconvulsive Treatment program, and lead the medical student teaching and resident training on treatment of affective illnesses. Over time, he or she will be expected to build an affective disorders research program.

The ideal candidate will be a strong clinician and dynamic teacher with experience in conducting research in the treatment of affective illness or a strong interest in developing these skills. Candidates should be board certified or eligible in Psychiatry. This position will include a faculty appointment at Dartmouth Medical School at a rank and salary commensurate with experience.

Curriculum vitae and three letters of reference should be e-mailed to: William.C.Torrey@Dartmouth.edu.
Dr. Torrey is the Medical Director for the Department of Psychiatry and chair of these searches.
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The VA Boston Healthcare System

&

Senior Associate Director of Residency Training

Harvard South Shore Psychiatry Residency Training Program

Department of Psychiatry Harvard Medical School

VA Boston Healthcare System and Harvard Medical School are recruiting a Senior Associate Director of the Harvard South Shore Psychiatry Residency Training Program (HSS) to work with the current Training Director and Associate Training Director team. We are seeking a psychiatrist with strong academic credentials, residency training program administration experience, and demonstrated scholarly ability in the field of medical education to take a leadership role in program development, administration, and teaching.

The applicant must be board-certified in psychiatry with a minimum of 5 years of experience post-residency, and must qualify for a Harvard Medical School appointment at the Assistant or Associate Professor level. Experience as a residency director or associate director and a demonstrated track record of scholarly productivity are required.

HSS is sponsored by VA Boston and functions as a consortium that draws on strengths of multiple Harvard-affiliated healthcare systems. The program trains a total of 32 residents over four years and is fully accredited by the ACGME. HSS emphasizes development of academic leaders who are well trained in biopsychosocial assessment and evidence-based pharmacotherapy and psychotherapy, and has strong links to federally sponsored research programs and several VA Clinical Centers of Excellence.

Comprehensive program description can be found at

www.harvardsouthshorepsychiatry.org

This position offers a highly competitive federal salary and benefits. VA Boston is an Affirmative Action / Equal Opportunity Employer, and women and individuals from health-underserved minority populations are encouraged to apply.

To apply, candidates should send a letter of interest, CV, and the names of three persons to contact for references to: **Human Resources: vhabhsjobs@med.va.gov, Drs. Mark Bauer & Gary Kaplan, Search Committee Co-Chairs, 940 Belmont Street, Brockton, MA 02301; or email: Mary.Tarantino@va.gov**

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Faculty – General Psychiatrist

University Hospitals Case Medical Center, in Cleveland, OH, is the 947-bed primary teaching affiliate of Case Western Reserve University and includes the NCI-designated Case Comprehensive Cancer Center, Rainbow Babies and Children's Hospital and MacDonald Woman's Hospital. Expansion of our current facilities includes a new cancer hospital and emergency room.

Due to the expansion of the Department of Psychiatry's Ambulatory Care division, we are seeking additional full-time board-certified or board-eligible Academic Psychiatrists (adult certified) to join one of the premier Adult Psychiatry programs in the country. The openings are for tenure and non-tenure track.

Candidates with academic and research interests and teaching experience are preferred.

Responsibilities include a varied mix of inpatient and outpatient services, possibly including medication management and/or investigational treatments, as well as training and supervising skilled health professionals and psychiatric residents. Salary and academic rank are highly competitive and commensurate with qualifications.

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Assistant/Associate Professor (Director; Inpatient Academic Teaching Unit)

The Department of Psychiatry at the **University of Illinois (Chicago Campus)** is seeking an innovative clinician-educator (tenured or non-tenured) with experience and interest in clinical research to lead a 36 bed adult inpatient unit. This unit has specialty services in women's mental health, psychotic disorders, mood and anxiety disorders, neuropsychiatry and some active clinical research. Interest in clinical research is highly desirable. In addition to work on the inpatient service, a limited amount of clinical work in the ambulatory setting is expected.

This is a full time position on our clinician-educator track. The successful candidate will have had a minimum of three to five years experience providing clinical inpatient care, supervising other attending physicians and staff, building therapeutic milieus and working in a multidisciplinary setting. Experience in clinical administrative activities on an inpatient service or in another clinical milieu is desirable. Interest in teaching and supervising medical students and residents is essential.

Candidates should be Board Certified or Board Eligible in Psychiatry. The successful candidate will be appointed as a faculty member of the Dept of Psychiatry, College of Medicine, rank and salary commensurate with qualifications and experience. Please submit your CV and all contact information along with four letters of recommendation by **12/15/08** to:

Ena Casas
Department of Psychiatry
University of Illinois
1601 W. Taylor Street
Chicago, Illinois 60612
E-mail: ecasas@psych.uic.edu

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The North Carolina Department of Health and Human Services is recruiting for Psychiatrists!

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The University of Louisville School of Medicine
Department of Psychiatry and Behavioral Sciences

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The Department of Psychiatry and Behavioral Sciences is seeking dynamic, academically-oriented psychiatrists to join our expanding faculty in a rapidly growing medical center complex with five hospitals. There are 150 medical students per year and a total of 40 general and specialty residency positions. The city of Louisville is a metropolitan area with nearly one million people. The cost of living is low, cultural amenities are extensive, schools are excellent, and outdoor and family oriented activities abound.

Clinical duties for these faculty positions generally include a combination of inpatient, outpatient, or work in our psychiatric emergency services or consult/liaison service. The successful candidate will have a demonstrated interest in teaching residents and medical students. In addition, there are opportunities to collaborate in ongoing clinical and basic science research. Candidates should be Board Certified or Board Eligible in Psychiatry. These positions are full-time faculty appointments in the Department of Psychiatry and Behavioral Sciences in the University of Louisville School of Medicine. Academic rank and salary are commensurate with qualifications and experience, and a comprehensive benefits package is included.

Interested candidates should mail or e-mail a curriculum vitae and a letter of interest to:

Kelly Moore, Faculty Affairs Coordinator
Department of Psychiatry and Behavioral Sciences
University of Louisville School of Medicine
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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Contact:

Pamela Trujillo
703.907.7330 or ptrujillo@psych.org

APA JOB BANK

Psychiatric Clinicians and Hospitalists
Scott & White Healthcare - Central Texas

Department of Mental Health Services

Scott & White and Texas A&M College of Medicine are seeking outstanding BC/BE individuals for the positions of Psychiatric Clinicians and Hospitalists within the Department of Mental Health Services at our main campus in Temple, TX. Candidates for this position should have strong credentials in clinical care and education, with inpatient psychiatric patient care experience. Academic responsibilities will include opportunities to mentor medical students and residents in basic psychiatric concepts, as well as delivering high quality health care to all population groups.

Led by physicians with a commitment to patient care, education and research, Scott & White is listed among the "Top 100 Hospitals" in America. Scott & White Health System serves as the clinical educational site for The Texas A&M University System Health Science Center College of Medicine.

Scott & White offers a competitive salary and comprehensive benefit package, which begins with four weeks vacation, three weeks CME and a generous retirement plan. For additional information, please call or send your CV to: Kathryn Kotrla, MD, Chair, Department of Mental Health Services, c/o Jason Culp, Physician Recruiter, Scott & White Clinic, 2401 S. 31st, Temple, TX 76508. Phone: (800) 725-3627; email: jculp@swmail.sw.org. A formal application must be completed to be considered for this position.

For more information on Scott & White, please visit our web site at: www.sw.org. Scott & White is an equal opportunity employer.

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TEXAS A&M HEALTH SCIENCE CENTER COLLEGE OF MEDICINE

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The **first and only** adjunctive therapy to antidepressants for Major Depressive Disorder in adults.[1]

ABILIFY®
(aripiprazole)
2 mg, 5 mg Tablet

HELP ILLUMINATE THE PERSON WITHIN

ABILIFY is indicated for use as an adjunctive therapy to antidepressants for the acute treatment of Major Depressive Disorder in adults.

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 and other psychiatric disorders. 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, especially during the initial few months of therapy, or at times of dose changes. ABILIFY is not approved for use in pediatric patients with depression (see Boxed WARNING).

Please see IMPORTANT SAFETY INFORMATION, including **Boxed WARNINGS**, on next page.

www.abilify.com

IMPORTANT SAFETY INFORMATION and INDICATION for ABILIFY® (aripiprazole)

INDICATION

- ABILIFY (aripiprazole) is indicated for use as an adjunctive therapy to antidepressants for the acute treatment of Major Depressive Disorder in adults

IMPORTANT SAFETY INFORMATION

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Although the causes of death were varied, most of the deaths appeared to be cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. ABILIFY is not approved for the treatment of patients with dementia-related psychosis.

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 adjunctive ABILIFY or another antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increased risk of suicidality in adults beyond age 24. 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. ABILIFY is not approved for use in pediatric patients with depression.

See Full Prescribing Information for complete Boxed WARNINGS

Contraindication – Known hypersensitivity reaction to ABILIFY. Reactions have ranged from pruritus/urticaria to anaphylaxis.

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

Orthostatic Hypotension – ABILIFY may be associated with orthostatic hypotension and should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

Seizures/Convulsions – As with other antipsychotic drugs, ABILIFY should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

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

Body Temperature Regulation – Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotics. Appropriate care is advised for patients who may exercise strenuously, be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or be subject to dehydration.

Suicide – The possibility of a suicide attempt is inherent in psychotic illnesses, Bipolar Disorder, and Major Depressive Disorder, and close supervision of high-risk patients should accompany drug therapy. Prescriptions should be written for the smallest quantity consistent with good patient management in order to reduce the risk of overdose.

Dysphagia – Esophageal dysmotility and aspiration have been associated with antipsychotic drug use, including ABILIFY; use caution in patients at risk for aspiration pneumonia.

Physicians should advise patients to avoid alcohol while taking ABILIFY.

Strong CYP3A4 (eg, ketoconazole) or CYP2D6 (eg, fluoxetine) inhibitors will increase ABILIFY drug concentrations; reduce ABILIFY dose by one-half when used concomitantly, except when used as adjunctive treatment with antidepressants in adults with Major Depressive Disorder.

CYP3A4 inducers (eg, carbamazepine) will decrease ABILIFY drug concentrations; double ABILIFY dose when used concomitantly.

Commonly observed adverse reactions (≥5% incidence and at least twice the rate of placebo for adjunctive ABILIFY vs adjunctive placebo, respectively):

- Adult patients (with Major Depressive Disorder): akathisia (25% vs 4%), restlessness (12% vs 2%), insomnia (8% vs 2%), constipation (5% vs 2%), fatigue (8% vs 4%), and blurred vision (6% vs 1%)

Dystonia is a class effect of antipsychotic drugs. Symptoms of dystonia may occur in susceptible individuals during the first days of treatment and at low doses.

Reference:

1. *PDR® Electronic Library™* (n.d.). Greenwood Village, CO: Thomson Micromedex. http://www.thomsonhc.com. Accessed October 16, 2007.

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

ABILIFY® (aripiprazole)
2 mg, 5 mg Tablet

Bristol-Myers Squibb Otsuka Otsuka America Pharmaceutical, Inc.

570U508AB16203 September 2008 0508A-1461 Printed in USA Printed on recycled paper.

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ABILIFY® (aripiprazole) Tablets
ABILIFY DISCMELT® (aripiprazole) Orally Disintegrating Tablets
ABILIFY® (aripiprazole) Oral Solution

℞ ONLY

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

WARNINGS: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDALITY AND ANTIDEPRESSANT DRUGS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (eg, heart failure, sudden death) or infectious (eg, pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. ABILIFY (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis [see *Warnings and Precautions*].

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 adjunctive ABILIFY 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. ABILIFY is not approved for use in pediatric patients with depression [see *Warnings and Precautions*].

INDICATIONS AND USAGE: ABILIFY (aripiprazole) is indicated for use as an adjunctive therapy to antidepressants for the acute treatment of Major Depressive Disorder in adults [see *Clinical Studies (14.3) in Full Prescribing Information*].

CONTRAINDICATIONS: Known hypersensitivity reaction to ABILIFY. Reactions have ranged from pruritus/urticaria to anaphylaxis [see *Adverse Reactions*].

WARNINGS AND PRECAUTIONS: Use in Elderly Patients with Dementia-Related Psychosis - Increased Mortality: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ABILIFY is not approved for the treatment of patients with dementia-related psychosis [see *Boxed Warning*].

Cerebrovascular Adverse Events, Including Stroke: In placebo-controlled clinical studies (two flexible dose and one fixed dose study) of dementia-related psychosis, there was an increased incidence of cerebrovascular adverse events (eg, stroke, transient ischemic attack), including fatalities, in aripiprazole-treated patients (mean age: 84 years; range: 78-88 years). In the fixed-dose study, there was a statistically significant dose response relationship for cerebrovascular adverse events in patients treated with aripiprazole. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis [see also *Boxed Warning*].

Safety Experience in Elderly Patients with Psychosis Associated with Alzheimer's Disease: In three, 10-week, placebo-controlled studies of aripiprazole in elderly patients with psychosis associated with Alzheimer's disease (n=938; mean age: 82.4 years; range: 56-99 years), the treatment-emergent adverse events that were reported at an incidence of ≥3% and aripiprazole incidence at least twice that for placebo were lethargy [placebo 2%, aripiprazole 5%], somnolence (including sedation) [placebo 3%, aripiprazole 8%], and incontinence (primarily urinary incontinence) [placebo 1%, aripiprazole 5%], excessive salivation [placebo 0%, aripiprazole 4%], and lightheadedness [placebo 1%, aripiprazole 4%]. The safety and efficacy of ABILIFY in the treatment of patients with psychosis associated with dementia have not been established. If the prescriber elects to treat such patients with ABILIFY, vigilance should be exercised, particularly for the emergence of difficulty swallowing or excessive somnolence, which could predispose to accidental injury or aspiration [see also *Boxed Warning*].

Clinical Worsening of Depression 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) were reported as: **Increases compared to placebo**: <18 (14 additional cases); 18-24 (5 additional cases); and **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, ie, 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.

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 healthcare providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for ABILIFY 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 ABILIFY is not approved for use in treating depression in the pediatric population.

Neuroleptic Malignant Syndrome (NMS) - A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) may occur with administration of antipsychotic drugs, including aripiprazole. Rare cases of NMS occurred during aripiprazole treatment in the worldwide clinical database. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to exclude cases where the clinical presentation includes both serious medical illness (eg, pneumonia, systemic infection) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology.

The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

Tardive Dyskinesia - A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and, thereby, may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, ABILIFY (aripiprazole) should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms of tardive dyskinesia appear in a patient on ABILIFY, drug discontinuation should be considered. However, some patients may require treatment with ABILIFY despite the presence of the syndrome.

Hyperglycemia and Diabetes Mellitus - Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia in patients treated with ABILIFY [see *Adverse Reactions*]. Although fewer patients have been treated with ABILIFY, it is not known if this more limited experience is the sole reason for the paucity of such reports. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with Schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies which did not include ABILIFY suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics included in these studies. Because ABILIFY was not marketed at the time these studies were performed, it is not known if ABILIFY is associated with this increased risk. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (eg, obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Orthostatic Hypotension - Aripiprazole may cause orthostatic hypotension, perhaps due to its α_1-adrenergic receptor antagonism. The incidence of orthostatic hypotension-associated events from short-term, placebo-controlled trials of adult patients on oral ABILIFY (n=2467) included (aripiprazole incidence; placebo incidence): orthostatic hypotension (1%, 0.3%), postural dizziness (0.5%, 0.3%), and syncope (0.5%, 0.4%). The incidence of a significant orthostatic change in blood pressure (defined as a decrease in systolic blood pressure ≥20 mmHg accompanied by an increase in heart rate ≥25 when comparing standing to supine values) for aripiprazole was not meaningfully different from placebo (aripiprazole incidence; placebo incidence): in adult oral aripiprazole-treated patients (4%, 2%).

Aripiprazole should be used with caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease, or conditions which would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications).

Seizures/Convulsions - In short-term, placebo-controlled trials, seizures/convulsions occurred in 0.1% (3/2467) of adult patients treated with oral aripiprazole. As with other antipsychotic drugs, aripiprazole should be used cautiously in patients with a history of seizures or with conditions that lower the seizure threshold, eg, Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older.

Potential for Cognitive and Motor Impairment - ABILIFY, like other antipsychotics, may have the potential to impair judgment, thinking, or motor skills. For example, in short-term, placebo-controlled trials, somnolence (including sedation) was reported as follows (aripiprazole incidence; placebo incidence): in adult patients (n=2467) treated with oral ABILIFY (11%, 6%). Somnolence (including sedation) led to discontinuation in 0.3% (8/2467) of adult patients on oral ABILIFY in short-term, placebo-controlled trials. Despite the relatively modest increased incidence of these events compared to placebo, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that therapy with ABILIFY does not affect them adversely.

Body Temperature Regulation - Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing aripiprazole for patients who will be experiencing conditions which may contribute to an elevation in core body temperature (eg, exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration) [see *Adverse Reactions*].

Suicide - The possibility of a suicide attempt is inherent in psychotic illnesses, Bipolar Disorder, and Major Depressive Disorder, and close supervision of high-risk patients should accompany drug therapy. Prescriptions for ABILIFY should be written for the smallest quantity consistent with good patient management in order to reduce the risk of overdose [see *Adverse Reactions*].

In two 6-week, placebo-controlled studies of aripiprazole as adjunctive treatment of Major Depressive Disorder, the incidences of suicidal ideation and suicide attempts were 0% (0/371) for aripiprazole and 0.5% (2/366) for placebo.

Dysphagia - Esophageal dysmotility and aspiration have been associated with antipsychotic drug use, including ABILIFY. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia. Aripiprazole and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia [see *Warnings and Precautions* and *Adverse Reactions*].

Use in Patients with Concomitant Illness - Clinical experience with ABILIFY in patients with certain concomitant systemic illnesses is limited [see *Use in Specific Populations*]. ABILIFY has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies [see *Warnings and Precautions*].

ADVERSE REACTIONS: Overall Adverse Reactions Profile - The following are discussed in more detail in other sections of the labeling (see *Boxed Warning* and *Warnings and Precautions*): Use in Elderly Patients with Dementia-Related Psychosis; Clinical Worsening of Depression and Suicide Risk; Neuroleptic Malignant Syndrome (NMS); Tardive Dyskinesia; Hyperglycemia and Diabetes Mellitus; Orthostatic Hypotension; Seizures/Convulsions; Potential for Cognitive and Motor Impairment; Body Temperature Regulation; Suicide; Dysphagia; Use in Patients with Concomitant Illness.

The most common adverse reactions in adult patients in clinical trials (≥10%) were nausea, vomiting, constipation, headache, dizziness, akathisia, anxiety, insomnia, and restlessness.

Aripiprazole has been evaluated for safety in 13,543 adult patients who participated in multiple-dose, clinical trials in Schizophrenia, Bipolar Disorder, Major Depressive Disorder, Dementia of the Alzheimer's type, Parkinson's disease, and alcoholism, and who had approximately 7619 patient-years of exposure to oral aripiprazole. A total of 3390 patients were treated with oral aripiprazole for at least 180 days and 1933 patients treated with oral aripiprazole had at least 1 year of exposure. 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.

Clinical Studies Experience - *Adult Patients Receiving ABILIFY as Adjunctive Treatment of Major Depressive Disorder:* The following findings are based on a pool of two placebo-controlled trials of patients with Major Depressive Disorder in which aripiprazole was administered at doses of 2 mg to 20 mg as adjunctive treatment to continued antidepressant therapy.

Adverse Reactions Associated with Discontinuation of Treatment: The incidence of discontinuation due to adverse reactions was 6% for adjunctive aripiprazole-treated patients and 2% for adjunctive placebo-treated patients.

Commonly Observed Adverse Reactions: The commonly observed adverse reactions associated with the use of adjunctive aripiprazole in patients with Major Depressive Disorder (incidence of 5% or greater and aripiprazole incidence at least twice that for placebo) were: akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision.

Less Common Adverse Reactions: The following treatment-emergent reactions reported at an incidence of ≥2%, rounded to the nearest percent, with adjunctive aripiprazole (doses ≥2 mg/day), and at a greater incidence with adjunctive aripiprazole than with adjunctive placebo during short-term (up to 6 weeks), placebo-controlled trials (aripiprazole + ADT n=371; placebo + ADT n=366; respectively, were: akathisia (25%, 4%), restlessness (12%, 2%), fatigue (8%, 4%), insomnia (8%, 2%), somnolence (6%, 4%), upper respiratory tract infection (6%, 4%), blurred vision (6%, 1%), tremor (5%, 4%), constipation (5%, 2%), arthralgia (4%, 3%), dizziness (4%, 2%), sedation (4%, 2%), increased appetite (3%, 2%), weight increased (3%, 2%), disturbance in attention (3%, 1%), feeling jittery (3%, 1%), myalgia (2%, 1%), and extrapyramidal disorder (2%, 0%). ADT = Antidepressant Therapy.

Dose-Related Adverse Reactions:

Extrapyramidal Symptoms: In the short-term, placebo-controlled trials in Major Depressive Disorder, the incidence of reported EPS-related events, excluding events related to akathisia, for adjunctive aripiprazole-treated patients was 6% vs. 5% for adjunctive placebo-treated patients; and the incidence of akathisia-related events for adjunctive aripiprazole-treated patients was 25% vs. 4% for adjunctive placebo-treated patients. Objectively collected data from those trials was collected on the Simpson Angus Rating Scale (for EPS), the Barnes Akathisia Scale (for akathisia), and the Assessments of Involuntary Movement Scales (for dyskinesias). In the Major Depressive Disorder trials, the Simpson Angus Rating Scale and the Barnes Akathisia Scale showed a significant difference between adjunctive aripiprazole and adjunctive placebo (aripiprazole, 0.31; placebo, 0.03 and aripiprazole, 0.22; placebo, 0.02). Changes in the Assessments of Involuntary Movement Scales were similar for the adjunctive aripiprazole and adjunctive placebo groups.

Dystonia: *Class Effect:* Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups.

Laboratory Test Abnormalities: In the 6-week trials of aripiprazole as adjunctive therapy for Major Depressive Disorder, there were no clinically important differences between the adjunctive aripiprazole-treated and adjunctive placebo-treated patients in the median change from baseline in prolactin, fasting glucose, HDL, LDL, or total cholesterol measurements. The median % change from baseline in triglycerides was 5% for adjunctive aripiprazole-treated patients vs. 0% for adjunctive placebo-treated patients.

Weight Gain: In the trials adding aripiprazole to antidepressants, patients first received 8 weeks of antidepressant treatment followed by 6 weeks of adjunctive aripiprazole or placebo in addition to their ongoing antidepressant treatment. The mean weight gain with adjunctive aripiprazole was 1.7 kg vs. 0.4 kg with adjunctive placebo. The proportion of patients meeting a weight gain criterion of ≥7% of body weight was 9% with adjunctive aripiprazole compared to 1% with adjunctive placebo.

ECG Changes: Between group comparisons for a pooled analysis of placebo-controlled trials in patients with Major Depressive Disorder revealed no significant differences between oral aripiprazole and placebo in the proportion of patients experiencing potentially important changes in ECG parameters. Aripiprazole was associated with a median increase in heart rate of 2 beats per minute compared to no increase among placebo patients.

Other Adverse Reactions Observed During the Premarketing Evaluation of Aripiprazole: Following is a list of MedDRA terms that reflect adverse reactions as defined in *Adverse Reactions* reported by patients treated with oral aripiprazole at multiple doses ≥ 2 mg/day during any phase of a trial within the database of 13,543 adult patients, oral aripiprazole excluding those events already listed as adverse reactions in other parts of Full Prescribing Information, or those considered in *Warnings and Precautions*. Although the reactions reported occurred during treatment with aripiprazole, they were not necessarily caused by it.

Adults: Oral Administration - *Blood and Lymphatic System Disorders: ≥ 1/1000 patients and < 1/100 patients* - leukopenia, neutropenia, thrombocytopenia; *Cardiac Disorders: ≥ 1/1000 patients and < 1/100 patients* - bradycardia, palpitations, cardiopulmonary failure, myocardial infarction, cardio-respiratory arrest, atrioventricular block, extrasystoles, sinus tachycardia, atrial fibrillation, angina pectoris, myocardial ischemia; *< 1/1000 patients* - atrial flutter, supraventricular tachycardia, ventricular tachycardia; *Eye Disorders: ≥ 1/1000 patients and < 1/100 patients* - photophobia, diplopia, eyelid edema, photopsia; *Gastrointestinal Disorders: ≥ 1/1000 patients and < 1/100 patients* - gastro-esophageal reflux disease, swollen tongue, esophagitis; *< 1/1000 patients* - pancreatitis; *General Disorders and Administration Site Conditions: ≥ 1/100 patients* - asthenia, peripheral edema, irritability, chest pain; *≥ 1/1000 patients and < 1/100 patients* - face edema, thirst, angioedema; *< 1/1000 patients* - hypothermia; *Hepatobiliary Disorders: < 1/1000 patients* - hepatitis, jaundice; *Immune System Disorders: ≥ 1/1000 patients and < 1/100 patients* - hypersensitivity; *Injury, Poisoning, and Procedural Complications: ≥ 1/100 patients* - fall; *≥ 1/1000 patients and < 1/100 patients* - self mutilation; *< 1/1000 patients* - heat stroke; *Investigations: ≥ 1/100 patients* - weight decreased, creatine phosphokinase increased; *≥ 1/1000 patients and < 1/100 patients* - hepatic enzyme increased, blood glucose increased, blood prolactin increased, blood urea increased, electrocardiogram QT prolonged, blood creatinine increased, blood bilirubin increased; *< 1/1000 patients* - blood lactate dehydrogenase increased, glycosylated hemoglobin increased, gamma-glutamyl transferase increased; *Metabolism and Nutrition Disorders: ≥ 1/100 patients* - decreased appetite; *≥ 1/1000 patients and < 1/100 patients* - hyperlipidemia, anorexia, diabetes mellitus (including blood insulin increased, carbohydrate tolerance decreased, diabetes mellitus non-insulin-dependent, glucose tolerance impaired, glycosuria, glucose urine, glucose urine present), hyperglycemia, hypokalemia, hyponatremia, hypoglycemia, polydipsia; *< 1/1000 patients* - diabetic ketoacidosis; *Musculoskeletal and Connective Tissue Disorders: ≥ 1/100 patients and < 1/100 patients* - muscle rigidity, muscular weakness, muscle tightness, mobility decreased; *< 1/1000 patients* - rhabdomyolysis; *Nervous System Disorders: ≥ 1/100 patients* - coordination abnormal; *≥ 1/1000 patients and < 1/100 patients* - speech disorder, parkinsonism, memory impairment, cogwheel rigidity, cerebrovascular accident, hypokinesia, tardive dyskinesia, hypotonia, myoclonus, hypertonia, akinesia, bradykinesia; *< 1/1000 patients* - Grand Mal convulsion, choreoathetosis; *Psychiatric Disorders: ≥ 1/100 patients* - suicidal ideation; *≥ 1/1000 patients and < 1/100 patients* - aggression, loss of libido, suicide attempt, hostility, libido increased, anger, anorgasmia, delirium, intentional self injury, completed suicide, tic, homicidal ideation; *< 1/1000 patients* - catatonia, sleep walking; *Renal and Urinary Disorders: ≥ 1/1000 patients and < 1/100 patients* - urinary retention, polyuria, nocturia; *Reproductive System and Breast Disorders. ≥ 1/1000 patients and < 1/100 patients* - menstruation irregular, erectile dysfunction, amenorrhea, breast pain; *< 1/1000 patients* - gynecomastia, priapism; *Respiratory, Thoracic, and Mediastinal Disorders: ≥ 1/100 patients* - nasal congestion, dyspnea, pneumonia aspiration; *Skin and Subcutaneous Tissue Disorders: ≥ 1/100 patients* - rash (including erythematous, exfoliative, generalized, macular, maculopapular, papular rash; acneiform, allergic, contact, exfoliative, seborrheic dermatitis, neurodermatitis, and drug eruption), hyperhydrosis; *≥ 1/1000 patients and < 1/100 patients* - pruritus, photosensitivity reaction, alopecia, urticaria; *Vascular Disorders: ≥ 1/100 patients* - hypertension; *≥ 1/1000 patients and < 1/100 patients* - hypotension.

Postmarketing Experience - The following adverse reactions have been identified during post-approval use of ABILIFY (aripiprazole). Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to establish a causal relationship to drug exposure: rare occurrences of allergic reaction (anaphylactic reaction, angioedema, laryngospasm, pruritus/urticaria, or oropharyngeal spasm), and blood glucose fluctuation.

DRUG INTERACTIONS: Given the primary CNS effects of aripiprazole, caution should be used when ABILIFY is taken in combination with other centrally-acting drugs or alcohol. Due to its alpha adrenergic antagonism, aripiprazole has the potential to enhance the effect of certain antihypertensive agents.

Potential for Other Drugs to Affect ABILIFY - Aripiprazole is not a substrate of CYP1A1, CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, or CYP2E1 enzymes. Aripiprazole also does not undergo direct glucuronidation. This suggests that an interaction of aripiprazole with inhibitors or inducers of these enzymes, or other factors, like smoking, is unlikely.

Both CYP3A4 and CYP2D6 are responsible for aripiprazole metabolism. Agents that induce CYP3A4 (eg, carbamazepine) could cause an increase in aripiprazole clearance and lower blood levels. Inhibitors of CYP3A4 (eg, ketoconazole) or CYP2D6 (eg, quinidine, fluoxetine, or paroxetine) can inhibit aripiprazole elimination and cause increased blood levels.

Ketoconazole and Other CYP3A4 Inhibitors: Coadministration of ketoconazole (200 mg/day for 14 days) with a 15 mg single dose of aripiprazole increased the AUC of aripiprazole and its active metabolite by 63% and 77%, respectively. The effect of a higher ketoconazole dose (400 mg/day) has not been studied. When ketoconazole is given concomitantly with aripiprazole, the aripiprazole dose should be reduced to one-half of its normal dose. Other strong inhibitors of CYP3A4 (itraconazole) would be expected to have similar effects and need similar dose reductions; moderate inhibitors (erythromycin, grapefruit juice) have not been studied. When the CYP3A4 inhibitor is withdrawn from the combination therapy, the aripiprazole dose should be increased.

Quinidine and Other CYP2D6 Inhibitors: Coadministration of a 10 mg single dose of aripiprazole with quinidine (166 mg/day for 13 days), a potent inhibitor of CYP2D6, increased the AUC of aripiprazole by 112% but decreased the AUC of its active metabolite, dehydro-aripiprazole, by 35%. Aripiprazole dose should be reduced to one-half of its normal dose when quinidine is given concomitantly with aripiprazole. Other significant inhibitors of CYP2D6, such as fluoxetine or paroxetine, would be expected to have similar effects and should lead to similar dose reductions. When the CYP2D6 inhibitor is withdrawn from the combination therapy, the aripiprazole dose should be increased. When adjunctive ABILIFY is administered to patients with Major Depressive Disorder, ABILIFY should be administered without dosage adjustment as specified in *Dosage and Administration (2.3)* in Full Prescribing Information.

Carbamazepine and Other CYP3A4 Inducers: Coadministration of carbamazepine (200 mg twice daily), a potent CYP3A4 inducer, with aripiprazole (30 mg/day) resulted in an approximate 70% decrease in C_{max} and AUC values of both aripiprazole and its active metabolite, dehydro-aripiprazole. When carbamazepine is added to aripiprazole therapy, aripiprazole dose should be doubled. Additional dose increases should be based on clinical evaluation. When carbamazepine is withdrawn from the combination therapy, the aripiprazole dose should be reduced.

Potential for ABILIFY to Affect Other Drugs - Aripiprazole is unlikely to cause clinically important pharmacokinetic interactions with drugs metabolized by cytochrome P450 enzymes. *In in vivo* studies, 10 mg/day to 30 mg/day doses of aripiprazole had no significant effect on metabolism by CYP2D6 (dextromethorphan), CYP2C9 (warfarin), CYP2C19 (omeprazole, warfarin), and CYP3A4 (dextromethorphan) substrates. Additionally, aripiprazole and dehydro-aripiprazole did not show potential for altering CYP1A2-mediated metabolism *in vitro*. No effect of aripiprazole was seen on the pharmacokinetics of lithium or valproate.

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

Drugs Having No Clinically Important Interactions with ABILIFY - Famotidine: Coadministration of aripiprazole (given in a single dose of 15 mg) with a 40 mg single dose of the H_2 antagonist famotidine, a potent gastric acid blocker, decreased the solubility of aripiprazole and, hence, its rate of absorption, reducing by 37% and 21% the C_{max} of aripiprazole and dehydro-aripiprazole, respectively, and by 13% and 15%, respectively, the extent of absorption (AUC). No dosage adjustment of aripiprazole is required when administered concomitantly with famotidine.

Valproate: When valproate (500 mg/day-1500 mg/day) and aripiprazole (30 mg/day) were coadministered, at steady-state the C_{max} and AUC of aripiprazole were decreased by 25%. No dosage adjustment of aripiprazole is required when administered concomitantly with valproate.

When aripiprazole (30 mg/day) and valproate (1000 mg/day) were coadministered, at steady-state there were no clinically significant changes in the C_{max} or AUC of valproate. No dosage adjustment of valproate is required when administered concomitantly with aripiprazole.

Lithium: A pharmacokinetic interaction of aripiprazole with lithium is unlikely because lithium is not bound to plasma proteins, is not metabolized, and is almost entirely excreted unchanged in urine. Coadministration of therapeutic doses of lithium (1200 mg/day-1800 mg/day) for 21 days with aripiprazole (30 mg/day) did not result in clinically significant changes in the pharmacokinetics of aripiprazole or its active metabolite, dehydro-aripiprazole (C_{max} and AUC increased by less than 20%). No dosage adjustment of aripiprazole is required when administered concomitantly with lithium. Coadministration of aripiprazole (30 mg/day) with lithium (900 mg/day) did not result in clinically significant changes in the pharmacokinetics of lithium. No dosage adjustment of lithium is required when administered concomitantly with aripiprazole.

Lamotrigine: Coadministration of 10 mg/day to 30 mg/day oral doses of aripiprazole for 14 days to patients with Bipolar I Disorder had no effect on the steady-state pharmacokinetics of 100 mg/day to 400 mg/day lamotrigine, a UDP-glucuronosyltransferase 1A4 substrate. No dosage adjustment of lamotrigine is required when aripiprazole is added to lamotrigine.

Dextromethorphan: Aripiprazole at doses of 10 mg/day to 30 mg/day for 14 days had no effect on dextromethorphan's O-dealkylation to its major metabolite, dextrorphan, a pathway dependent on CYP2D6 activity. Aripiprazole also had no effect on dextromethorphan's N-demethylation to its metabolite 3-methoxymorphinan, a pathway dependent on CYP3A4 activity. No dosage adjustment of dextromethorphan is required when administered concomitantly with aripiprazole.

Warfarin: Aripiprazole 10 mg/day for 14 days had no effect on the pharmacokinetics of R-warfarin or S-warfarin or on the pharmacodynamic end point of International Normalized Ratio, indicating the lack of a clinically relevant effect of aripiprazole on CYP2C9 and CYP2C19 metabolism or the binding of highly protein-bound warfarin. No dosage adjustment of warfarin is required when administered concomitantly with aripiprazole.

Omeprazole: Aripiprazole 10 mg/day for 15 days had no effect on the pharmacokinetics of a single 20 mg dose of omeprazole, a CYP2C19 substrate, in healthy subjects. No dosage adjustment of omeprazole is required when administered concomitantly with aripiprazole.

Lorazepam: Coadministration of lorazepam injection (2 mg) and aripiprazole injection (15 mg) to healthy subjects (n=40; 35 males and 5 females; ages 19-45 years old) did not result in clinically important changes in the pharmacokinetics of either drug. No dosage adjustment of aripiprazole is required when administered concomitantly with lorazepam. However, the intensity of sedation was greater with the combination as compared to that observed with aripiprazole alone and the orthostatic hypotension observed was greater with the combination as compared to that observed with lorazepam alone *[see Warnings and Precautions]*.

Escitalopram: Coadministration of 10 mg/day oral doses of aripiprazole for 14 days to healthy subjects had no effect on the steady-state pharmacokinetics of 10 mg/day escitalopram, a substrate of CYP2C19 and CYP3A4. No dosage adjustment of escitalopram is required when aripiprazole is added to escitalopram.

Venlafaxine: Coadministration of 10 mg/day to 20 mg/day oral doses of aripiprazole for 14 days to healthy subjects had no effect on the steady-state pharmacokinetics of venlafaxine and O-desmethylvenlafaxine following 75 mg/day venlafaxine XR, a CYP2D6 substrate. No dosage adjustment of venlafaxine is required when aripiprazole is added to venlafaxine.

Fluoxetine, Paroxetine, and Sertraline: A population pharmacokinetic analysis in patients with Major Depressive Disorder showed no substantial change in plasma concentrations of fluoxetine (20 mg/day or 40 mg/day), paroxetine CR (37.5 mg/day or 50 mg/day), or sertraline (100 mg/day or 150 mg/day) dosed to steady-state. The steady-state plasma concentrations of fluoxetine and norfluoxetine increased by about 18% and 36%, respectively, and concentrations of paroxetine decreased by about 27%. The steady-state plasma concentrations of sertraline and desmethylsertraline were not substantially changed when these antidepressant therapies were coadministered with aripiprazole. Aripiprazole dosing was 2 mg/day to 15 mg/day (when given with fluoxetine or paroxetine) or 2 mg/day to 20 mg/day (when given with sertraline).

USE IN SPECIFIC POPULATIONS: In general, no dosage adjustment for ABILIFY (aripiprazole) is required on the basis of a patient's age, gender, race, smoking status, hepatic function, or renal function *[see Dosage and Administration (2.5)* in Full Prescribing Information*]*.

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

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

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

Pediatric Use - Safety and effectiveness in pediatric patients with Major Depressive Disorder has not been established. The efficacy of adjunctive ABILIFY with concomitant lithium or valproate in the treatment of manic or mixed episodes in pediatric patients has not been systematically evaluated. However, such efficacy and lack of pharmacokinetic interaction between aripiprazole and lithium or valproate can be extrapolated from adult data, along with comparisons of aripiprazole pharmacokinetic parameters in adult and pediatric patients.

Geriatric Use - In formal single-dose pharmacokinetic studies (with aripiprazole given in a single dose of 15 mg), aripiprazole clearance was 20% lower in elderly (≥65 years) subjects compared to younger adult subjects (18 to 64 years). Also, the pharmacokinetics of aripiprazole after multiple doses in elderly patients appeared similar to that observed in young, healthy subjects. No dosage adjustment is recommended for elderly patients *[see also Boxed Warning and Warnings and Precautions]*.

Of the 13,543 patients treated with oral aripiprazole in clinical trials, 1073 (8%) were ≥65 years old and 799 (6%) were ≥75 years old. The majority (81%) of the 1073 patients were diagnosed with Dementia of the Alzheimer's type.

Placebo-controlled studies of oral aripiprazole in Major Depressive Disorder did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Renal Impairment - In patients with severe renal impairment (creatinine clearance <30 mL/min), C_{max} of aripiprazole given in a single dose of 15 mg and dehydro-aripiprazole increased by 36% and 53%, respectively, but AUC was 15% lower for aripiprazole and 7% higher for dehydro-aripiprazole. Renal excretion of both unchanged aripiprazole and dehydro-aripiprazole is less than 1% of the dose. No dosage adjustment is required in subjects with renal impairment.

Hepatic Impairment - In a single-dose study (15 mg of aripiprazole) in subjects with varying degrees of liver cirrhosis (Child-Pugh Classes A, B, and C), the AUC of aripiprazole, compared to healthy subjects, increased 31% in mild HI, increased 8% in moderate HI, and decreased 20% in severe HI. None of these differences would require dose adjustment.

Gender - C_{max} and AUC of aripiprazole and its active metabolite, dehydro-aripiprazole, are 30% to 40% higher in women than in men, and correspondingly, the apparent oral clearance of aripiprazole is lower in women. These differences, however, are largely explained by differences in body weight (25%) between men and women. No dosage adjustment is recommended based on gender.

Race - Although no specific pharmacokinetic study was conducted to investigate the effects of race on the disposition of aripiprazole, population pharmacokinetic evaluation revealed no evidence of clinically significant race-related differences in the pharmacokinetics of aripiprazole. No dosage adjustment is recommended based on race.

Smoking - Based on studies utilizing human liver enzymes *in vitro*, aripiprazole is not a substrate for CYP1A2 and also does not undergo direct glucuronidation. Smoking should, therefore, not have an effect on the pharmacokinetics of aripiprazole. Consistent with these *in vitro* results, population pharmacokinetic evaluation did not reveal any significant pharmacokinetic differences between smokers and nonsmokers. No dosage adjustment is recommended based on smoking status.

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

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

OVERDOSAGE: 76 cases of deliberate or accidental overdosage with oral aripiprazole alone or in combination with other substances were reported worldwide [44 cases with known outcome, 33 recovered without sequelae and one recovered with sequelae (mydriasis and feeling abnormal)]. Additionally, 10 of these cases were in children (age 12 and younger) involving oral aripiprazole ingestions up to 195 mg with no fatalities. The largest known acute ingestion was 1080 mg of oral aripiprazole (36 times maximum recommended daily dose) in a patient who fully recovered. Common adverse reactions (reported in at least 3% of all overdose cases) were vomiting, somnolence, and tremor. **For more information on symptoms of overdose, see Full Prescribing Information.**

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

PATIENT COUNSELING INFORMATION: Information for Patients - Physicians are advised to discuss the following issues with patients for whom they prescribe ABILIFY: [See Medication Guide (17.2) in Full Prescribing Information.]

Increased Mortality in Elderly Patients with Dementia-Related Psychosis - Advise patients and caregivers of increased risk of death *[see Warnings and Precautions]*.

Clinical Worsening of Depression and Suicide Risk - Alert families and caregivers of patients to monitor for the emergence of agitation, irritability, unusual changes in behavior, suicidality, and other symptoms as described in *Warnings and Precautions* and to report such symptoms immediately. Advise patients and their families and caregivers to read the Medication Guide and assist them in understanding its contents *[see Warnings and Precautions]*.

Interference with Cognitive and Motor Performance - Because aripiprazole may have the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that aripiprazole therapy does not affect them adversely *[see Warnings and Precautions]*.

Pregnancy - Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy with ABILIFY *[see Use in Specific Populations]*.

Nursing - Patients should be advised not to breast-feed an infant if they are taking ABILIFY *[see Use in Specific Populations]*.

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

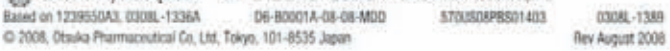
Alcohol - Patients should be advised to avoid alcohol while taking ABILIFY *[see Drug Interactions]*.

Heat Exposure and Dehydration - Patients should be advised regarding appropriate care in avoiding overheating and dehydration *[see Warnings and Precautions]*.

Sugar Content - Patients should be advised that each mL of ABILIFY Oral Solution contains 400 mg of sucrose and 200 mg of fructose.

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

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



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Rev August 2008

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A community-oriented healthcare system seeks a **BC/BE Adult Psychiatrist**. Provider would join an established Psychiatric and Counseling Services team and enjoy an **outpatient only** practice with **limited call** requirements. Opportunity offers chance to pursue individual medical interests while balancing personal and professional life.

Provider would join the medical staff of Community Memorial Hospital, which is linked to area healthcare providers by a community-wide Electronic Medical Record.

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855 Mankato Avenue • Winona, MN 55987
800.944.3960, ext. 4301 • *winonahealth.org*

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– Alisa A. Sabshin, M.D.
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Roderick Shaner, M.D., Medical Director
Los Angeles County
Department of Mental Health
550 S. Vermont Avenue, 12th Floor
Los Angeles, CA 90020
omd@dmh.lacounty.gov

PSYCHIATRISTS - VA BOSTON HEALTHCARE SYSTEM

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

Emergency Services Psychiatrist – West Roxbury campus: VABHS is recruiting a board certified (board eligible if less than 2 years post-residency) psychiatrist with at least 2 years full-time (or equivalent) experience in an ED setting to provide direct services and clinical supervision of psychiatry residents on evenings and weekends in the Emergency Department. This individual would join an established, highly regarded Psychiatry Consultation-Liaison team that trains residents and fellows from both medical schools. Academic appointment is through HMS and/or BUSM, commensurate with qualifications.

Medical Director, Consultation-Liaison Psychiatry – West Roxbury campus: VABHS is recruiting a Medical Director for the Psychiatry Consultation-Liaison service, West Roxbury campus. We seek a board certified academic psychiatrist with at least 3 years' post-residency experience full time (or equivalent) on an academic C-L service, demonstrated excellence in clinical teaching, strong administrative skills, and the motivation and ability to lead this outstanding clinical teaching service. The C-L service receives more than 1200 consultation requests per year, and is an integral part of a vibrant and exceptional academic environment that features nationally recognized training and research programs, and several VA Clinical Centers of Excellence. Academic appointment is through HMS, commensurate with qualifications. The Medical Director oversees the VA-Brigham Women's Hospital Psychosomatic Fellowship and BUSM and HMS resident and medical student C-L rotations.

Geropsychiatrist – Brockton/Boston campuses: VABHS is recruiting a geropsychiatrist to provide clinical services to outpatient geriatric mental health clinics and geriatric extended care bed programs, and to supervise advanced psychiatry residents rotating to these programs. We are seeking an academically oriented individual to participate in our vibrant research programs in geriatrics, neurology, and mental health. This individual would join an established multidisciplinary clinical team with an active and productive research program. Academic appointment is through BUSM and/or HMS, commensurate with qualifications.

Substance Use Disorders Psychiatrist – Jamaica Plain campus: VABHS is recruiting an outstanding, board-certified (board eligible if less than 2 years post-residency) psychiatrist with a demonstrated commitment to academic psychiatry. This individual will oversee a well-staffed and clinically excellent 18-bed residential substance use disorder rehabilitation program on the Jamaica Plain campus. The position includes direct services and clinical supervision of psychiatry residents in an outpatient setting. This residential program is part of an outstanding academic environment with prominent BUSM and VA substance abuse research programs. Academic appointment through Boston University School of Medicine (BUSM) Division of Psychiatry. If you are interested in any of these positions, please send a letter of interest, CV, and contact information for three references to:

Dr. Gary Kaplan, Director • Mental Health Service • VA Boston Healthcare System
940 Belmont Street Brockton • MA • 02301
Phone: 774-826-2473; email: Gary.Kaplan@va.gov

VA Boston is an Affirmative Action/Equal Opportunity Employer with a strong institutional commitment to diversity in all areas. Applicants selected for this position can be eligible to apply for an award up to the maximum limitation under the provisions of the Education Debt Reduction Program.

Build your future at South Bay

At South Bay, our strategy is simple: hire talented, dedicated individuals and provide them with the training and resources necessary to develop new skills and pursue professional goals.

Our supportive organization provides a competitive and comprehensive benefits package and numerous professional development opportunities.

Medical Director of Children's Services

As our growth continues, we seek to hire a board-certified Child Psychiatrist who can focus on the needs of our children, adolescents and families. Full time preferred, but will consider part time.

Psychiatrist

Full- and part-time, board-certified Psychiatrist. Immediate openings in our Brockton, Weymouth, Worccester and South Yarmouth, MA offices.

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or fax to (508)580-5162
www.SouthBayMentalHealth.com

South Bay Mental Health

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FELLOWSHIP OPENINGS

2009 - 2010 Fellowship in Public Services Psychiatry

The University of Pennsylvania Department of Psychiatry announces the creation of The Center of Excellence and Innovation in Public Psychiatry. The Center is offering subspecialty training for psychiatrists who plan careers in the public sector. Two one- or two-year post residency fellowships are available annually beginning in July 2009. The core of the fellowship consists of supervised work at collaborating public sector agencies in Philadelphia. Field placement is complemented by an academic curriculum that teaches clinical, leadership and administrative / management skills that will provide fellows with the tools and expertise to become part of the next generation of leaders in public psychiatry. Independent research projects are an integral part of this fellowship. In addition there are opportunities to earn MS and MPH degrees as part of the fellowship experience.

Faculty: Cordula Holzer, MD, Medical Director of Horizon House and Clinical Associate Professor at the University of Pennsylvania is Director of the Center of Excellence and Innovation in Public Psychiatry. Trevor Hadley, PhD, Director of the Center for Mental Health Policy and Services Research (CMHPSR) serves as the primary mentor for fellows' research activities along with other investigators at CMPHSR. Anthony Rostain, MD, MA, Director of Education for the Department of Psychiatry, serves as primary liaison to departmental and medical school teaching programs. Additional clinical supervision will be provided by mentors recruited from the ranks of Philadelphia community psychiatrists.

Salary for the first year of the fellowship will be $75,000 plus benefits. Additional funding is available for conference and educational activities. Interested applicants should contact Dr. Cordula Holzer at holzerc@mail.med.upenn.edu

Further information and applications are available at the website of the CMHPSR: http://www.med.upenn.edu/cmhpsr/fellowship.html.

University of Pennsylvania School of Medicine

OPENINGS FOR PSYCHIATRISTS

Southwestern Virginia Mental Health Institute (SWVMHI), located on 85 acres of tranquility in Marion, Virginia invites applications for our Psychiatrist openings. We are a progressive Joint Commission-accredited psychiatric hospital, with 172 beds serving adolescent, adult, geriatric and forensic patients. We offer a team oriented environment based on recovery principles, university affiliation, and an excellent compensation and benefits package.

For our Psychiatrist positions, we seek candidates who are board certified or eligible in psychiatry to work with adult patients (ages 18-64), geriatric patients (ages 65 and older), and adolescent patients (ages 13-17).

The chosen candidates for these positions will possess or be eligible for licensure to practice medicine in Virginia. Candidates may qualify for loan repayment with the Virginia Department of Health.

You may call the Human Resource Office at 276-783-1204 or visit our website **www.swvmhi.dmhmrsas.virginia.gov** for more information.

Southwestern Virginia Mental Health Institute
340 Bagley Circle
Marion, VA 24354

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Bd. Cert in Psychiatry by American Bd. of Psychiatry & Neuro., Eligible for or licensed by AL Bd. Of Medical Ex., MD; Possess Fed & State Controlled Substance Cert.

Psychiatrist III - Clinical Director – ($125,316.00 - $191,044.80 Annually)
Bd. Cert in Psychiatry by American Bd. of Psychiatry & Neuro. Eligible for licensed by AL Bd. of Medical Ex. MD; Possess Fed & State controlled Substance Cert.; 72 mons professional medical exp. in Psychiatry with 48 mons exp. in administration.

Benefits include 13 paid holidays, 13 paid vacation days, free employee health and dental insurance, sick leave, retirement, and more!

Send resume'/vitae or contact:

Searcy Hospital, Office of Human Resources, P.O. Box 1090, Mt. Vernon, AL 36560,
Telephone -251-662-6732, Fax—251-829-9075,
E-mail: human.resources@searcy.mh.alabama.gov
website: www.mh.alabama.gov EOE

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Issue	Deadline (Friday, 2 p.m. E.T.)
January 2	Thursday, December 18
January 16	January 2

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ARIZONA

University of Arizona

The University of Arizona's **Psychiatry Department** is recruiting adult and child psychiatrists to join a progressive and growing academic department located in the beautiful Southwest. Candidates must have current credentials to practice medicine in the United States and be Board-certified or -eligible in Psychiatry.

Child Psychiatrist / Assistant or Associate Professor or Professor, Clinical Psychiatry Job # 39689-Responsibilities include child and adolescent services for outpatient care and in a correction/residential treatment setting. Other duties include providing a significant contribution to the didactic and supervisory component for training programs. Individuals must be Board-certified or -eligible in Child and Adolescent Psychiatry. Salary: DOE

For additional information and/or to apply visit www.uacareertrack.com and reference specific job # from above. If you have questions, please contact: Ashley Lott, Human Resources, Dept. of Psychiatry, 1501 N. Campbell Avenue, P.O. Box 245002, Tucson, AZ 85724-5002; (520) 626-3819; or aelott@email.arizona.edu. Review of applications is ongoing until positions are filled. The University of Arizona is an EEO/AA Employer-M/W/D/V

CALIFORNIA

COUNTY OF SANTA BARBARA
Alcohol, Drug, and Mental Health Services

is recruiting for

PSYCHIATRIST
BOARD CERTIFIED
$183,666 - $210,761/YR.

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Job location is Santa Maria

Call Ratio:
Only one weekend every three months!

For immediate consideration, contact Dr. Edwin Feliciano, Medical Director, at 805-681-5235, or apply online at **www.sbcountyjobs.com**

The County of Santa Barbara strongly promotes diversity and equality in the workplace.

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GREATER BAY AREA - Modesto, California

General & Child Psychiatrists needed, for unique, stable County Mental Health system in a welcoming community. Serve both public & private sector patients, in both inpatient/outpatient settings that have been benchmarked for their quality. Possibilities for Resident teaching & consultation with a full range of providers. When patients require hospitalization, inpatient & outpatient staff work **TOGETHER** to optimize care. Stanislaus County is located only 1 1/2 hours from both San Francisco and Yosemite, enjoying the best of both worlds.

Excellent salary scale, with steps from $171K to $208K; **PLUS** full benefits; **PLUS** 5% additional for Inpatient, and General Boards or Child Boards; **PLUS** extra for limited On-Call; **PLUS** Union-negotiated increases already set for next few years. Negotiable hourly contract also an option. Fax CV to Uday Mukherjee, MD, 209-525-6291 or call 209-525-6121.

Karl E. Douyon, M.D., Inc.
Psychiatrists are needed as independent contractors for Locum Tenens positions in California. Pay is $175 to $250.00 per hour depending on location. On call pay is extra. Hours are flexible for weekdays and some weekends. Call 805-644-4093. Fax resumes to 805-830-6300. karledouyonmd.com

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SOUTHERN CALIFORNIA

The Department of Psychiatry at Arrowhead Regional Medical Center is seeking full time teaching faculty for our residency training program in addition to staffing our acute inpatient psychiatric program. Our hospital is located in Colton, CA, approximately 50 miles east of downtown LA. We are an easy reverse traffic commute from a large portion of the LA Basin. Position salary is compatible with local City, County, and State positions with additional benefits that include a fully vested 401K retirement plan, malpractice, health insurance, 6 weeks paid vacation and an additional 13 paid county holidays. Additional income can be earned through voluntary sign up on our ER schedule.

Please contact the Dept. of Psychiatry for additional information at: (909) 580-3830.

UC DAVIS SCHOOL OF MEDICINE DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

Health Sciences Assistant/Associate Clinical Professor. The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting an Assistant/Associate Clinical Professor to serve in our Outpatient Psychiatry Clinic, a growing general psychiatry residency program with 32 approved positions. The program is distinguished by excellence in 1) Clinical experiences in the academic, public sector, and private sector settings; 2) Innovative combined training program in psychiatry-family practice and psychiatry-internal medicine; 3) Specialized tracks in research and teaching for residents and a diverse patient population, residents and faculty. The academic series for this appointment is the teacher/clinician series. The individual selected will also supervise residents and treat patients in the department's outpatient clinic. The successful candidate should be board certified in general psychiatry, be eligible for a California Medical license, should have a passion for residency education and teaching and be committed to pursuing an academic career.

For full consideration, applications must be received by December 31, 2008. Position is open until filled, but no later than February 28, 2009. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-03R-09 to Juli Koeberlein, Academic Personnel Coordinator at juli.koeberlein@ucdmc.ucdavis.edu or UCDMC Department of Psychiatry and Behavioral Sciences, 2230 Stockton Blvd. Sacramento, CA 95817. In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

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

Shasta Community Health Center

Psychiatry Position in Northern California
NHSC Loan Repayment Approved Site/
J1 Waiver Available

Opportunity
Shasta CHC, a not for profit community health center is a leader in the development of the Consultation and Liaison (C/L) Outpatient paradigm in beautiful Redding, Northern California and is currently seeking a Psychiatrist to join our professional team.

Job Description
This position would provide psychiatric services to patients with serious and chronic mental illnesses throughout our facilities. A vital aspect of the position is providing consultations to our medical providers regarding mental, behavioral and emotional disorders to help assist with proper diagnosis, treatment plans and referrals.

- 100% Outpatient
- Monday to Friday Position
- Competitive Salary
- Full Benefits

Interested applicants should contact Katrina Delevati, Human Resources Manager at (530) 246-5977 or via E-Mail at kdelevati@shastahealth.org

Healthy And Happy America (HAHA) Corporation

We have limited contract psychiatrist positions available at Coalinga State Hospital, CA for $180 per hour and at Atascadero State Hospital, CA for $190 per hour.

Interested candidates should call 800-758-7012 or fax CV to 800-758-7013 or e-mail C.V. to hahacorp@gmail.com. California state license is a requirement.

CONNECTICUT

OUTPATIENT ADULT PSYCHIATRIST CENTRAL CONNECTICUT

Flexible options available for BC psychiatrist in adult outpatient mental health and addictions center associated with a community hospital offering a comprehensive mental health continuum that serves over 1600 adult patients annually. This position offers leadership potential for the candidate who can bring their skills and expertise to provide clinical and medical oversight to serve a chronic psychiatric and addictions patient clientele. You'll work with a multidisciplinary team of highly experienced therapists, nurse practitioner and other providers in a fast-paced environment. This is a hospital-based position offering competitive salary and benefits and adaptable hours for the right individual.

Our central Connecticut location offers easy access to all the amenities of the New England region, including first-rate schools and a choice of family-oriented suburban communities. Close proximity to urban living with professional sporting events, concerts, ballet, theatres, easy access to skiing and shoreline. 2 hours to NYC and Boston.

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 cdoughti@bristolhospital.org
Visit our website at www.bristolhospital.org

EEO

Inpatient and Ambulatory Services at Yale/CMHC

The Yale University School of Medicine seeks psychiatrists for full-time faculty positions in Inpatient and Ambulatory Services of the Connecticut Mental Health Center [CMHC] for July 2009 that will carry academic appointments at the Assistant or Associate Professor level in the Department of Psychiatry. Outstanding clinical and teaching skills are required for roles in patient care as well as supervision of psychiatry residents and other trainees at CMHC, a core site for training and research within Yale's Department of Psychiatry. The positions include protected time for participation in a variety of Departmental research and educational activities. Applicants must be board certified or eligible in psychiatry, licensed to practice in CT and be legally employable. Please send a CV and 3 references by January 1, 2009 to Jeanne Steiner, D.O., Medical Director CMHC, 34 Park St., New Haven, CT, 06519. Direct inquiries to jeanne.steiner@yale.edu. Yale University is an affirmative action/equal opportunity employer; applications from women and minority group members are specifically invited.

GENERAL PSYCHIATRY-CT

Busy two-person provider of behavioral healthcare services seeks a BE/BC psychiatrist to join their private practice providing adult psychiatric services. Practice is affiliated with a suburban community hospital offering a full continuum of mental health services. The practice is offering a competitive salary and benefits package and partnership potential.

ATTRACTIVE SOUTHERN NEW ENGLAND LIVING

Our central CT location offers a choice of upscale suburban communities with first-rate schools and is a short distance from professional sporting events, concerts, ballet, gourmet dining, and theatre. The coastal beaches of Long Island Sound are within easy reach and in just two hours, you can enjoy Boston, New York and the ski slopes of Vermont.

To learn more about this opportunity, call toll-free, Christine Bourbeau, Director of Physician Recruitment at 800.892.3846/860.714.1090 or fax/email your resume to 860.714.8894. EOE.

Email address: cbourbeau@brishosp.chime.org

DISTRICT OF COLUMBIA

Community Connections is a nationally recognized private, not-for-profit mental health agency in Washington, D.C. providing comprehensive services to mentally ill adults, children and their families many with histories of trauma, substance abuse, HIV and homelessness. We are seeking to employ board certified Psychiatrists. New grads and contract positions considered.
The prospective employee provides consumer care including psychiatric assessment, crisis emergency intervention, assessment of medical activity, and psychiatric medical treatment and documentation.
Duties involve formulating a DSM-IV multiaxial diagnosis and providing psychiatric treatment working as a member of a multi-disciplinary treatment team. Assignments may involve occasional local travel.
Must have a current, unrestricted District of Columbia license to practice medicine.

Submit CV and cover letter to:
jcullinan@ccdc1.org
Joseph Cullinan, Associate Director
801 Pennsylvania Ave SE, Suite 201
Washington, DC 20003
www.ccdc1.org

FLORIDA

Part-time Geriatric Psychiatrist needed in Aventura office with interest in long term care. Contact us @ 305-932-5500 or fax resume to 305-935-0466.

DAYTONA - MELBOURNE - ORLANDO - MIAMI - FORT LAUDERDALE - PALM BEACH - OCALA - GAINESVILLE - FORT MYERS - SARASOTA - PENSECOLA - JACKSONVILLE - 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 administrator, Christy, at 866-936-5250.

BC/BE Psychiatrist (Multiple Openings Available): Must have Medical Degree & completion of Residency in Psychiatry. Must possess FL state medical license. Location: Jacksonville, FL. If interested, mail resume to: Robert Sommers, Ph.D., President/CEO, Renaissance Behavioral Health Systems, Inc., P.O. Box 19249, Jacksonville, FL 32245.

Adult psychiatrist wanted for an outpatient practice in West Palm Beach Florida, this is a contract position for 10-15 hours per week, you would be responsible for providing psychiatric evaluation and med management, there are multiple offices, call (561) 967-2566

Vero Beach - Beautiful Coastal Location - Seeking Board Certified (or just recently finished training) Adult and Child/Adolescent psychiatrists to work in an impressive general hospital. Services consist of adult, C/A and future geriatric beds and IOPs. Come be part of this friendly, top notch mental health team and live, work, play and enjoy the coastal lifestyle of this lovely area. Please call **Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

MIAMI AREA (Aventura, FL): PSYCHIATRIST, FT; FL LICENSE REQ'D; also hiring ARNP and/or P.A.; private practice (adoles/adult/geriatric pts); Office/SNF/IP; Excellent Salary & Benefits; **FAX CV** to Dusty: **305-935-1717** or **EMAIL:** aventuraoffices@bellsouth.net

GEORGIA

PSYCHIATRIST OPPORTUNITY:
Floyd Behavioral Health
We have an outstanding opportunity for a hospital-based psychiatrist to provide coverage for 53-bed, adult behavioral health center where all patients are admitted on a voluntary basis. Programs include adult psychiatry, chemical dependency and geriatrics. Located in Northwest Georgia, within an hour of Atlanta and Chattanooga, Rome is unique small city that has been recognized as the "Number One Small City in the Southeast." Rome boasts a flourishing health care community with more than 350 practicing physicians. Our area enjoys a mild climate and offers impressive educational and cultural opportunities. Floyd offers a competitive salary with great benefits and bonus opportunity. The on-call schedule would include every 6th weekend and every 5th working day.

Learn about Floyd by visiting www.floyd.org

For more information email Stacie Davis, sdavis@floyd.org or call 706.509.3966

PSYCHIATRISTS

New Horizons Community Service Board in Columbus, Georgia is seeking an Adult psychiatrist for its outpatient and residential programs. This growing community offers a pleasing climate and is situated within a short distance to Atlanta and the Gulf Coast. The qualified applicant will possess or be eligible for a valid physician's license from the State of Georgia and have completed a three-year residency in an accredited facility. Excellent salary with a comprehensive benefits package. Interested parties should fax their curriculum vitae to the attention of Shannon Robertson at 706/317-5004.
No phone calls, please.

Clinical Director

Skyland Trail is a non-profit behavioral health organization in Atlanta, GA and one of the leading providers of behavioral health treatment, fully accredited by the Joint Commission on the Accreditation of Healthcare Organizations.

We are currently seeking a highly motivated, creative individual to direct a comprehensive array of community-based clinical services. Reporting to the Medical Director, the Clinical Director will lead in Program planning, development, and implementation of programs and services to maintain cutting-edge therapeutic interventions. Day-to-day responsibilities include supervision, program development and outcomes research evaluation, and training. The ideal candidate will possess supervisory and clinical management expertise, crisis management skills (including 1013 assessments), and a commitment to state-of-the-art, quality care. The position requires active clinical licensure in Georgia (Ph.D., LCSW, or Psychiatric NP), 5 years direct care experience, and 2 years administrative or supervisory experience.

Skyland Trail offers competitive salary & benefits packages. To apply, please visit www.skylandtrail.org or contact Human Resources at (404) 315-8333 ext. 6000. You may also send resumes via fax at (678) 686-5919.

Psychiatrist - Metro-Atlanta

Cobb-Douglas Community Services Board, a behavioral healthcare organization in metro Atlanta (Marietta, GA), seeks a full-time or part-time BC/BE Adult Psychiatrist for Community Outpatient Behavioral Health clinic. Please send CV to cholt@cobbcsb.com or fax to Cheryl Holt at 770-948-6147.

ATLANTA: General or Geriatric Psychiatrist. Inpatient & partial programs. Fulltime positions - salary & benefits. **SAVANNAH: General Psychiatrist** - inpatient & partial programs. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

ILLINOIS

PSYCHIATRIST-EDUCATORS: Univ. of Illinois Coll. of Medicine at Peoria, Dept. of Psychiatry & Behav. Medicine is seeking Board Cert/elig Adult (2) and Child-Adol (1) Psychiatrists to join a rapidly growing, collegial, psychiatry department. Primary responsibilities include classroom/clinical teaching and clinical care. The department has been recruiting successfully in recent years, expanding its faculty ranks, services, and affiliations. Its offices are soon to be relocated to a new state-of-the-art facility currently under construction. We are looking for psychiatrists that value providing high quality clinical care and teaching within a collegial environment. Salary is competitive. Rank is commensurate with experience. Applications accepted until position is filled. Reply to: Peter Alahi, M.D., Chair, Psychiatry Search Committee, Dept. of Psychiatry & Behav. Medicine, UIC College of Medicine at Peoria, 221 NE Glen Oak Ave., 7 West, Peoria, IL 61636; Phone (309) 671-2165; FAX (309) 671-8384 e-mail: palahi@uic.edu The University of Illinois is an AA/EO Employer.

Edward Hines VA Medical Center is seeking a full-time Chief of Psychiatry for the Mental Health Service Line located near Chicago. This position reports to the Chief/Manager Mental Health Service Line. This is a unique, exciting opportunity. The right person can meld Hines excellent quality Psychiatrists to make the Hines/Loyola Psychiatry Residency Program one of the best in the country. A minimum of 10 years training and experience in mental health are required. Proven productivity and administrative/clinical/research work history in a VA medical center and an academic environment are highly desirable. A proven ability to work well with others is essential. This key Board Certified position includes an academic appointment with the Department of Psychiatry and Behavioral Neurosciences at Loyola University Medical Center, Chicago. Responsibilities include clinical and administrative duties, oversight of Psychiatrists, oversight of training Residents and Medical Students. Clinical research is encouraged and available. Salary is commensurate with qualifications and experience and includes an excellent benefits package. Submit letter of interest and CV to Edward Hines, Jr. VA Hospital, ATTN: Marilyn Boughton; PO Box 5000 South 5th Avenue; Hines, Illinois 60141. Inquires contact Katheryn Mansell, 708 202 8387 extension 24978.

CHAMPAIGN (East Central IL) Staff Psychiatrist - inpatient & partial programs. Salaried employment & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

IOWA

The University of Iowa Roy J. and Lucille A. Carver College of Medicine, Department of Psychiatry is currently recruiting Associate(s), Assistant Professor(s), Associate Professor(s), or Professor(s) for Clinical (Non-Tenure) and Tenure Track positions in Adult and Child Psychiatry. These positions may also have a joint appointment with the Iowa City Veterans Affairs (VA) Medical Center within the Mental Health Service Line. Opportunities exist in general outpatient and inpatient settings as well as in a telemental health clinic, a collaborative women's health clinic, and Medicine/Psychiatry unit.

Requirements: Physicians who hold MD or DO degrees and have completed a psychiatry residency. Applicants must be board eligible or board certified and have a commitment to patient care, teaching, and research. Dual board with Internal Medicine preferred for Medicine/Psychiatry unit opportunities. Tenure track positions require post-residency fellowship or comparable experience in research.

The Department of Psychiatry at the University of Iowa Hospitals and Clinics has a wide range of clinical programs as well as residency and research programs. Iowa City provides the unique combination of a safe, small, and attractive college town with the opportunity to take advantage of abundant local and world-class cultural events. The school system is ranked among the best in the nation.

To apply for the positions, visit our website at http://jobs.uiowa.edu, requisition 56245.

The University of Iowa is an Affirmative Action/Equal Opportunity Employer. Women and minorities are strongly encouraged to apply.

KENTUCKY

LOUISVILLE AREA - General or Child Psychiatrist - Inpatient and Outpatient services. Full-time position - salary, benefits & limited call. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

LOUISIANA

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

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

The Department of Psychiatry and Neurology at Tulane University School of Medicine is recruiting for a Medical Director of Southeast Louisiana Hospital (SELH) in Mandeville, LA. This is a full-time faculty position. Teaching responsibilities would include the supervision of trainees and medical students at SELH and contributions to the psychiatry residency didactic series, as well as participation in CME conferences sponsored by the Department. The person selected for this position must be professionally competent and be board eligible/certified in general psychiatry. She/he must be eligible for medical licensure in the State of Louisiana and have a current state and federal narcotics number. In addition, candidates must be eligible for clinical privileges at Tulane University Hospital and Clinic and SELH under the appropriate staff category and must agree to abide by those privileges as outlined by the current bylaws of the institutions. Salary will be competitive and commensurate with the level of the candidate's academic appointment. We will continue to accept applications for this position until a suitable qualified candidate is identified. Qualified applicants should send email, updated CV and list of references to Daniel K. Winstead, MD, Heath Professor and Chair, at winstead@tulane.edu or letter of interest to Department of Psychiatry and Neurology, Tulane University School of Medicine TB48, 1440 Canal Street, Suite 1000, New Orleans, LA 70112. Tulane is strongly committed to policies of non-discrimination and affirmative action in student admissions and in employment.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY, TULANE UNIVERSITY SCHOOL OF MEDICINE in New Orleans, LA, is recruiting for several general and forensic psychiatrists (clinical track) for our growing department, at the Assistant/Associate Professor level. Candidates must have completed an approved general psychiatry residency and be board certified/eligible in general psychiatry and forensic psychiatry, respectively. Responsibilities will include direct patient care, teaching of medical students and house officers (including those in our accredited forensic psychiatry fellowship program), and research (clinical and basic science) at various state hospitals, state correctional institutions, and at Tulane University Health Sciences Center. Time allocations will be based upon individual situations. Applicants must be eligible to obtain a Louisiana medical license. Applications will be accepted until suitable qualified candidates are found. Send CV and list of references to John W. Thompson, Jr., M.D., Vice Chair, Adult Psychiatry and Director, Division of Forensic Neuropsychiatry, Tulane University School of Medicine, Department of Psychiatry and Neurology, 1440 Canal Street TB53, New Orleans, LA 70112. For further information onsite, please contact Dan Winstead, MD, Chair of Psychiatry and Neurology, at 504-473-5246 or winstead@tulane.edu. Tulane is strongly committed to policies of non-discrimination and affirmative action in student admission and in employment.

The Department of Psychiatry and Neurology at Tulane University School of Medicine is recruiting for a Director of Residency Training in Psychiatry. This is a full-time faculty position with half-time devoted to the residency training program and half-time to other academic pursuits. An associate director is available to assist with program leadership and administration. The person selected for this position must be professionally competent and be board eligible/certified in general psychiatry. She/he must be eligible for medical licensure in the State of Louisiana and have a current state and federal narcotics number. In addition, candidates must be eligible for clinical privileges at Tulane University Hospital and Clinic under the appropriate staff category and must agree to abide by those privileges as outlined by the current bylaws of the institution. This is a fully accredited psychiatry program for up to 39 general residents, 10 triple board trainees, 6 child fellows and 3 forensic fellows. We also offer combined programs in med-psych and in psych-neuro. Salary will be competitive and commensurate with the level of the candidate's academic appointment. We will continue to accept applications for this position until a suitable qualified candidate is identified. Qualified applicants should send email of interest, updated CV and list of references to Daniel K. Winstead, MD, Heath Professor and Chair, at winstead@tulane.edu or letter to Department of Psychiatry and Neurology, Tulane University School of Medicine TB48, 1440 Canal Street, Suite 1000, New Orleans, LA 70112. Tulane is strongly committed to policies of non-discrimination and affirmative action in student admissions and in employment.

MAINE

Adult and Child/Adolescent Psychiatrists
Nation's 1st Psychiatric Magnet Hospital seeking BC/BE psychiatrists for both our adult and child/adolescent inpatient and outpatient programs. We are a thriving, non-profit, private community-based hospital offering acute psychiatric care for adults and children, as well as chemical dependency programs. One of only two private psychiatric hospitals in Maine. We offer physicians clinical practice in a highly collaborative, multi-disciplinary setting. Competitive salary/benefit package. Send CV to: VP of Medical Affairs, The Acadia Hospital, P.O. Box 422, Bangor, ME 04402-0422.
www.acadiahospital.org

MARYLAND

"THE MARYLAND PLAN" is a nationally acclaimed program in public psychiatry. Positions are available for child and adult psychiatrists. Academic involvement with med. schools in your area of interest is encouraged. Please e-mail CV with area of interest and geographic preference to: GJordanRandolph@dhmh.state.md.us or mail to: Gayle Jordan-Randolph, M.D., Mental Hygiene Administration, Spring Grove Hospital, Dix Building, 55 Wade Avenue, Catonsville, MD 21228.

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

PSYCHIATRIST - Part-time

The Calvert County Health Department Mental Health Clinic is seeking a part-time Psychiatrist (12 - 20 hours per week). Psychiatrist's duties include performing Medication Evaluations and providing Medication Management to mental health patients. This is an hourly contractual position which is not contingent on patients keeping their appointments.
Respond by: December 15, 2008

Please send resume and 3 references to:

Mental Health Clinic
Calvert County Health Department
PO BOX 980
Prince Frederick, MD 20678
Attn: J.D. Everette
or
FAX to: 410-414-9413

NURSE PRACTITIONER - Part-time

The Calvert County Health Department Mental Health Clinic is seeking a part-time Nurse Practitioner (12 - 20 hours per week). Applicant must be Certified Registered Nurse Practitioners with Psychiatry Specialty (CRNP-P). Nurse Practitioner's duties include performing Medication Evaluations and providing Medication Management. This is an hourly contractual position which is not contingent on patients keeping their appointments.
Respond by: December 15, 2008

Please send resume and 3 references to:

Mental Health Clinic
Calvert County Health Department
PO BOX 980
Prince Frederick, MD 20678
Attn: J.D. Everette
or
FAX to: 410-414-9413

MASSACHUSETTS

BOSTON & SUBURBs - Brookline, Jamaica Plain, Westwood, & Lowell! Full time & part-time positions for **Child and General Psychiatrists.** Inpatient/partial programs - **NO CALL.** Administrative/clinical positions for qualified candidates. Salary, benefits & incentive plans offered. Outpatient only positions in area counseling centers for all specialties AND week night & weekend call coverage/moonlighting shifts also available.
Contact Courtney Williams @ 866-227-5415 or email courtney.williams@uhsinc.com

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The Edith Nourse Rogers Memorial Veterans Hospital is currently seeking candidates for the following position:

PSYCHIATRIST-MENTAL HEALTH
SERVICE LINE MANAGER

The Mental Health Service Line Manager oversees our Mental Health clinical, research and teaching program. This Veterans Hospital conducts approximately $10 million per year in bench to bedside research each year in Mental Health, Alzheimers and Health Services Outcomes. It is a major teaching facility for Boston University School of Medicine Division of Psychiatry and is academically affiliated with University of Massachusetts School of Medicine. We are situated in a pleasant suburban environment in Bedford, Massachusetts 25 miles northwest of downtown Boston. An academic appointment commensurate with qualifications preferred. License and a US citizenship required. Interested candidates please direct inquiries with CV to:

Gregory K. Binus, M.D.
Chief of Staff
Edith Nourse Rogers Memorial Veterans Hospital
Bedford, MA 01730
781 687-2363
Gregory.Binus2@.va.gov

Veterans who served on active duty for a period of more than 180 consecutive days during a specific timeframe and were discharged or released from active duty under honorable conditions or Veterans who are preference eligible or who have been separated from the armed forces under honorable conditions after 3 years or more of continuous are encouraged to apply.

SELECTEE MAY BE SUBJECT TO
PHYSICAL AND RANDOM
DRUG TESTING
For other career opportunities in the VA New England Healthcare System, log onto www.vacareers.va.gov or www.usajobs.gov

Equal Opportunity Employer

CAMBRIDGE: Adult Psychiatry

Positions available at Cambridge Health Alliance, Harvard Medical School. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School with excellent residencies in adult and child psychiatry. 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. Academic appointment, as determined by the criteria of Harvard Medical School, is available for qualified candidates.

Adult Inpatient Psychiatrist - We are seeking a psychiatrist to join a collegial team and become an active member of a rich clinical department. This opportunity is a full-time inpatient psychiatrist position with clinical responsibility for a 9 patient team on an active community service. Clinical care is provided through a multidisciplinary team approach with psychiatrist leadership.

Adult Outpatient Psychiatrists - Full and Part Time: Opportunities in adult outpatient services. Ambulatory programs consist of multidisciplinary practice teams located at outpatient psychiatry program settings and at local neighborhood medical clinics throughout the Alliance, including specialized services for Latino, Portuguese, Asian, and Haitian patients.

Weekend Moonlighting Psychiatrists: Lucrative and flexible opportunities available for attending psychiatrists to provide weekend/holiday coverage of inpatient units.

Qualifications: BE/BC, demonstrated commitment to public sector populations, strong clinical skills, team oriented, problem solver. Interest and/or experience with dual diagnosis patients a plus. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. CV & letter to Derri Shtasel, MD, Dept. of Psychiatry, 1493 Cambridge Street, Cambridge, MA 02139. Fax 617-665-2521. **Email preferred: DShtasel@challiance.org.**

CAMBRIDGE HEALTH ALLIANCE: Inpatient Child/Adolescent Psychiatry Position

Cambridge Health Alliance, Division of Child and Adolescent Psychiatry, Harvard Medical School. Full time Medical Director or Staff Psychiatrist for Child Assessment Unit at our Cambridge campus. Work in a dynamic setting with multidisciplinary teams using a nationally recognized program for restraint reduction. Opportunities to teach child psychiatry fellows, general psychiatry residents, medical students, and other trainees. Academic appointment, as determined by the criteria of Harvard Medical School, is anticipated.

Qualifications: BE/BC, demonstrated commitment to public sector populations, strong clinical skills, strong leadership and management skills, team oriented, problem solver. Bilingual and/or bicultural abilities are desirable. Interest and experience with dual diagnosis and/or substance use disorders preferred. Competitive compensation, excellent benefit package. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. **CV & letter to Joel Goldstein, MD, Dept. of Psychiatry, 1493 Cambridge Street, Cambridge, MA 02139. Fax 617-665-1204. Email: JoGoldstein@challiance.org** (email preferred).

The Department of Psychiatry at Mount Auburn Hospital, affiliated with Harvard Medical School, is recruiting for a half-time position in our Outpatient Psychiatry Service. Responsibilities include evaluation and treatment of adult patients with a variety of psychiatric disorders, including dual diagnosis patients, and coordination of care with other psychiatric clinicians and with primary care and specialty physicians. There are opportunities to work with our Dept. of OB/GYN and the women's mental health program. Position includes participating in the teaching activities of the Department. Academic appointment to the clinical faculty at Harvard Medical School is anticipated. Please send letter of interest and cv to: Joseph D'Afflitti, M.D., Chair, Department of Psychiatry, Mount Auburn Hospital, 330 Mount Auburn Street, Cambridge, MA 02138; tel: 617 499-5008; email: jdafflit@mah.harvard.edu.

Chairman, Department of Psychiatry

MetroWest Medical Center is seeking a dynamic, creative psychiatrist to lead the Department of Psychiatry. The Chairman will be responsible for providing clinical and administrative leadership to an active department that includes 28 psychiatrists practicing in a 469-bed, two-hospital system, located in the Western suburbs of Boston.

The ideal candidate will possess:

- A strong, demonstrated track record in Physician leadership
- Board certification in psychiatry
- Current experience in clinical practice with exceptional clinical skills and commitment to quality
- Administrative experience in a hospital setting
- Ability to foster collaborative relationships with local physicians
- Vision to develop outstanding inpatient and outpatient psychiatric services

The Department of Psychiatry provides a broad range of psychiatric services in a community setting. The hospital has 48 beds devoted to Child, Adult, and Geriatric inpatient care; Evaluation and Referral Services; ECT Services; and a Partial Hospital Program.

MetroWest Medical Center is a fiscally strong medical system that is highly regarded for its commitment to psychiatric care. The MetroWest region of Massachusetts is an attractive and growing area with excellent school systems and convenient access to Boston.

Interested Candidates should send their curriculum vitae in confidence to:

Rebecca Woods, Market VP, Physician Recruitment and Retention
Vanguard Health Systems/MetroWest Medical Center
132 Turnpike Road, Suite 200
Southborough, MA 01772
Inquiries: 508-363-9921
tmcadams@vhsnewengland.com

CHILD AND ADOLESCENT PSYCHIATRIST

St. Ann's Home is seeking a part-time Child and Adolescent Psychiatrist (BE/BC) to provide services to children, ages 5-18, and families in our residential, educational, hospital diversion, and outpatient programs . The Child and Adolescent Psychiatrist will be part of our dynamic multi-disciplinary team. St. Ann's Home is known and respected for our holistic and multifaceted approach to providing psychiatric care.

Interested candidates please contact:
Susan Perry, St. Ann's Home and School
100A Haverhill St., Methuen, MA 01844
sperry@st.annshome.org
Phone: (978)682-5276; FAX: (978)688-4932

www.st.annshome.org
EOE

Beautiful South Shore near Cape Cod - General Psychiatrist - Inpatient adult services. NO CALL. Salary, benefits & incentive package offered. Flexible call coverage/moonlighting also available. **Contact:** Courtney Williams @ 866-227-5415 or email courtney.williams@uhsinc.com

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WORCESTER, MA - The University of Massachusetts Medical School, Public Sector Division has new opportunities in inpatient and outpatient positions. Work in a collegial setting where a career focused on clinical care; education; supervision and mentoring; and research is valued. We offer a generous salary, excellent benefits, and a faculty appointment. Come live and work in the epicenter of Massachusetts. 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

MICHIGAN

Associate Medical Director
Alpena, MI

Horizon Health, in partnership with **Alpena Regional Medical Center** in **Alpena, MI**, seeks an **Associate Medical Director** for a 15-bed Adult Inpatient Psychiatric Program.

Alpena overlooks Lake Huron's picturesque Thunder Bay in northern Michigan, and is located on the Sunrise Side Coastal Highway, a 200-mile stretch of US 23 graced with scenic views, undeveloped wild areas, roomy beaches and recreational areas for hiking, biking, cross-country skiing and snowmobiling. Excellent practice and income opportunity.

Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. EOE.

7:30 a.m. to 4:30 p.m. Position - Seeking Psychiatrist to work on adult psychiatric unit in a medical facility that houses behavioral health, extended care, and medical rehabilitation in Saginaw, MI. No E.R. Can live in Bay City right on Lake Huron or in Flint if you so choose. Please call **Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

Grand Rapids - Staff Psychiatrist for inpatient and partial day services. Fulltime position offering excellent compensation and benefits plan. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

NEVADA

Las Vegas - BC/BE Psychiatrist/Medical Director. Nevada licensed, 5 years exp. required. In-patient/outpatient acute psychiatric setting. Excellent salary/benefits. Contact: Claire @ 801-327-9947 or claire@professionalrecruiterinc.com www.professionalrecruiterinc.com

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- **Effectively treats acute manic and mixed episodes**
- **Well-established tolerability profile**
- **Target 120–160 mg/day on Day 2**
- **Initiate dosing at 80 mg/day with meals**

GEODON is indicated for the treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic symptoms.

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

GEODON is contraindicated in patients with a known history of QT prolongation, recent acute myocardial infarction, or uncompensated heart failure, and should not be used with certain other QT-prolonging drugs. **GEODON has been associated with prolongation of the QT_c interval. In some drugs, QT prolongation has been associated with torsade de pointes, a potentially fatal arrhythmia. Patients who are at risk for electrolyte disturbances should have baseline measurements performed before initiating GEODON. Patients on diuretics should be monitored.**

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

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

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

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

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

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

Individual results may vary.

Please see brief summary of prescribing information on adjacent page.

For more information, please visit www.pfizerpro.com/GEODON

GEODON®
(ziprasidone HCl) **Capsules**

BRIEF SUMMARY See package insert for full prescribing information.

Increased Mortality in Elderly Patients with Dementia-Related Psychosis—Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. Geodon (ziprasidone) is not approved for the treatment of patients with Dementia-Related Psychosis (see WARNINGS).

INDICATIONS—GEODON Capsules is indicated for the treatment of schizophrenia and acute manic or mixed episodes associated with bipolar disorder with or without psychotic features. GEODON® (ziprasidone mesylate) for Injection is indicated for acute agitation in schizophrenic patients.

CONTRAINDICATIONS — ***QT Prolongation:*** Because of GEODON's dose-related prolongation of the QT interval and the known association of fatal arrhythmias with QT prolongation by some other drugs, GEODON is contraindicated in patients with a known history of QT prolongation (including congenital long QT syndrome), with recent acute myocardial infarction, or with uncompensated heart failure (see **WARNINGS**). Pharmacokinetic/pharmacodynamic studies between GEODON and other drugs that prolong the QT interval have not been performed. An additive effect of GEODON and other drugs that prolong the QT interval cannot be excluded. Therefore, GEODON should not be given with dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol, or tacrolimus. GEODON is also contraindicated with drugs that have demonstrated QT prolongation as one of their pharmacodynamic effects and have this effect described in the full prescribing information as a contraindication or a boxed or bolded warning (see **WARNINGS**). GEODON is contraindicated in individuals with a known hypersensitivity to the product. **WARNINGS** — ***Increased Mortality in Elderly Patients with Dementia-Related Psychosis:*** **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. GEODON (ziprasidone) is not approved for the treatment of patients with dementia-related psychosis (see BOXED WARNING).** ***QT Prolongation and Risk of Sudden Death:*** **GEODON use should be avoided in combination with other drugs that are known to prolong the QT$_c$ interval. Additionally, clinicians should be alert to the identification of other drugs that have been consistently observed to prolong the QT$_c$ interval. Such drugs should not be prescribed with GEODON. A study directly comparing the QT/QT$_c$-prolonging effect of GEODON with several other drugs effective in the treatment of schizophrenia was conducted in patient volunteers. The mean increase in QT$_c$ from baseline for GEODON ranged from approximately 9 to 14 msec greater than for four of the comparator drugs (risperidone, olanzapine, quetiapine, and haloperidol), but was approximately 14 msec less than the prolongation observed for thioridazine. In this study, the effect of GEODON on QT$_c$ length was not augmented by the presence of a metabolic inhibitor (ketoconazole 200 mg bid). In placebo-controlled trials, GEODON increased the QT$_c$ interval compared to placebo by approximately 10 msec at the highest recommended daily dose of 160 mg. In clinical trials the electrocardiograms of 2/2503 (0.08%) GEODON patients and 1/440 (0.23%) placebo patients revealed QT$_c$ intervals exceeding the potentially clinically relevant threshold of 500 msec. In the GEODON patients, neither case suggested a role of GEODON. Some drugs that prolong the QT/QT$_c$ interval have been associated with the occurrence of torsade de pointes and with sudden unexplained death. The relationship of QT prolongation to torsade de pointes is clearest for larger increases (20 msec and greater) but it is possible that smaller QT/QT$_c$ prolongations may also increase risk, or increase it in susceptible individuals, such as those with hypokalemia, hypomagnesemia, or genetic predisposition. Although torsade de pointes has not been observed in association with the use of GEODON at recommended doses in premarketing studies, experience is too limited to rule out an increased risk. A study evaluating the QT/QT$_c$ prolonging effect of intramuscular GEODON, with intramuscular haloperidol as a control, was conducted in patient volunteers. In the trial, ECGs were obtained at the time of maximum plasma concentration following two injections of GEODON (20 mg then 30 mg) or haloperidol (7.5 mg then 10 mg) given four hours apart. Note that a 30 mg dose of intramuscular GEODON is 50% higher than the recommended therapeutic dose. The mean change in QT$_c$ from baseline was calculated for each drug using a sample-based correction that removes the effect of heart rate on the QT interval. The mean increase in QT$_c$ from baseline for GEODON was 4.6 msec following the first injection and 12.8 msec following the second injection. The mean increase in QT$_c$ from baseline for haloperidol was 6.0 msec following the first injection and 14.7 msec following the second injection. In this study, no patient had a QT$_c$ interval exceeding 500 msec. As with other antipsychotic drugs and placebo, sudden unexplained deaths have been reported in patients taking GEODON at recommended doses. The premarketing experience for GEODON did not reveal an excess of mortality for GEODON compared to other antipsychotic drugs or placebo, but the extent of exposure was limited, especially for the drugs used as active controls and placebo. Nevertheless, GEODON's larger prolongation of QT$_c$ length compared to several other antipsychotic drugs raises the possibility that the risk of sudden death may be greater for GEODON than for other available drugs for treating schizophrenia. This possibility needs to be considered in deciding among alternative drug products. Certain circumstances may increase the risk of the occurrence of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QT$_c$ interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QT$_c$ interval; and (4) presence of congenital prolongation of the QT interval. GEODON should also be avoided in patients with congential long QT syndrome and in patients with a history of cardiac arrhythmias (see CONTRAINDICATIONS, and see *Drug Interactions* under PRECAUTIONS). It is recommended that patients being considered for GEODON treatment who are at risk for significant electrolyte disturbances, hypokalemia in particular, have baseline serum potassium and magnesium measurements. Hypokalemia (and/or hypomagnesemia) may increase the risk of QT prolongation and arrhythmia. Hypokalemia may result from diuretic therapy, diarrhea, and other causes. Patients with low serum potassium and/or magnesium should be repleted with those electrolytes before proceeding with treatment. It is essential to periodically monitor serum electrolytes in patients for whom diuretic therapy is introduced during GEODON treatment. Persistently prolonged QT$_c$ intervals may also increase the risk of further prolongation and arrhythmia, but it is not clear that routine screening ECG measures are effective in detecting such patients. Rather, GEODON should be avoided in patients with histories of significant cardiovascular illness, eg, QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. GEODON should be discontinued in patients who are found to have persistent QT$_c$ measurements >500 msec.** ***Neuroleptic Malignant Syndrome (NMS):*** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported. ***Tardive Dyskinesia (TD):*** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients undergoing treatment with antipsychotic drugs. Although the prevalence of TD appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop TD. If signs and symptoms of TD appear in a patient on GEODON, drug discontinuation should be considered. ***Hyperglycemia and Diabetes Mellitus:*** Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON, and it is not known if GEODON is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia. **PRECAUTIONS** — ***General:*** Rash: In premarketing trials, about 5% of GEODON patients developed rash and/or urticaria, with discontinuation of treatment in about one-sixth of these cases. The occurrence of rash was dose-related, although the finding might also be explained by longer exposure in higher-dose patients. Several patients with rash had signs and symptoms of associated systemic illness, e.g., elevated WBCs. Most patients improved promptly upon treatment with antihistamines or steroids and/or upon discontinuation of GEODON, and all patients were reported to recover completely. Upon appearance of rash for which an alternative etiology cannot be identified, GEODON should be discontinued. Orthostatic Hypotension: GEODON may induce orthostatic hypotension associated with dizziness, tachycardia, and, in some patients, syncope, especially during the initial dose-titration period, probably reflecting its α_1-adrenergic antagonist properties. Syncope was reported in 0.6% of GEODON patients. GEODON should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Seizures: In clinical trials, seizures occurred in 0.4% of GEODON patients. There were confounding factors that may have contributed to seizures in many of these cases. As with other antipsychotic drugs, GEODON should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older. Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia, and GEODON and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. **(See also Boxed WARNING. WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis).** Hyperprolactinemia: As with other drugs that antagonize dopamine D$_2$ receptors, GEODON elevates prolactin levels in humans. Tissue culture experiments indicate that approximately one third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans, the available evidence is considered too limited to be conclusive at this time. Potential for Cognitive and Motor Impairment: Somnolence was a commonly reported adverse event in GEODON patients. In the 4- and 6-week placebo-controlled trials, somnolence was reported in 14% of GEODON patients vs 7% of placebo patients. Somnolence led to discontinuation in 0.3% of patients in short-term clinical trials. Since GEODON has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about performing activities requiring mental alertness, such as operating a motor vehicle (including automobiles) or operating hazardous machinery until they are reasonably certain that GEODON therapy does not affect them adversely. Priapism: One case of priapism was reported in the premarketing database. Body Temperature Regulation: Although not reported with GEODON in premarketing trials, disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Suicide: The possibility of a suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. GEODON prescriptions should be written for the smallest quantity of capsules consistent with good patient management to reduce overdose risk. Use in Patients with Concomitant Illness: Clinical experience with GEODON in patients with certain concomitant systemic illnesses is limited. GEODON has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies. Because of the risk of QT$_c$ prolongation and orthostatic hypotension with GEODON, caution should be observed in cardiac patients (see ***QT Prolongation and Risk of Sudden Death*** in **WARNINGS** and Orthostatic Hypotension in **PRECAUTIONS**). ***Information for Patients:*** To ensure safe and effective use of GEODON, the information and instructions in the *Patient Information* Section should be discussed with patients. ***Laboratory Tests:*** Patients being considered for GEODON treatment who are at risk of significant electrolyte disturbances, should have baseline serum potassium and magnesium measurements. Low serum potassium and magnesium should be repleted before treatment. Patients who are started on diuretics during GEODON therapy need periodic monitoring of serum potassium and magnesium. Discontinue GEODON in patients who are found to have persistent QT$_c$ measurements >500 msec (see **WARNINGS**). ***Drug Interactions:*** (1) GEODON should not be used with any drug that prolongs the QT interval. (2) Given the primary CNS effects of GEODON, caution should be used when it is taken in combination with other centrally acting drugs. (3) Because of its potential for inducing hypotension, GEODON may enhance the effects of certain antihypertensive agents. (4) GEODON may antagonize the effects of levodopa and dopamine agonists. Effect of Other Drugs on GEODON: Carbamazepine, 200 mg bid for 21 days, resulted in a decrease of approximately 35% in the AUC of GEODON. Ketoconazole, a potent inhibitor of CYP3A4, 400 mg od for 5 days, increased the AUC and C_{max} of GEODON by about 35%–40%. Cimetidine, 800 mg qd for 2 days, did not affect GEODON pharmacokinetics. Coadministration of 30 mL of Maalox did not affect GEODON pharmacokinetics. Population pharmacokinetic analysis of schizophrenic patients in controlled clinical trials has not revealed any clinically significant pharmacokinetic interactions with benztropine, propranolol, or lorazepam. Effect of GEODON on Other Drugs: In vitro studies revealed little potential for GEODON to interfere with the metabolism of drugs cleared primarily by CYP1A2, CYP2D1, CYP2C19, CYP2D6, and CYP3A4, and little potential for drug interactions with GEODON due to displacement. GEODON 40 mg bid administered concomitantly with lithium 450 mg bid for 7 days did not affect the steady-state level or renal clearance of lithium. GEODON 20 mg bid did not affect the pharmacokinetics of concomitantly administered *oral contraceptives*, ethinyl estradiol (0.03 mg) and levonorgestrel (0.15 mg). Consistent with in vitro results, a study in normal healthy volunteers showed that GEODON did not alter the metabolism of dextromethorphan, a CYP2D6 model substrate, to its major metabolite, dextrorphan. There was no statistically significant change in the urinary dextromethorphan/dextrorphan ratio. ***Carcinogenesis, Mutagenesis, Impairment of Fertility:*** Lifetime carcinogenicity studies were conducted with GEODON in Long Evans rats and CD-1 mice. In male mice, there was no increase in incidence of tumors relative to controls. In female mice there were dose related increases in the incidences of pituitary gland adenoma and carcinoma, and mammary gland adenocarcinoma at all doses tested. Increases in serum prolactin were observed in a 1-month dietary study in female, but not male, mice. GEODON had no effect on serum prolactin in rats in a 3-week dietary study at the doses that were used in the carcinogenicity study. The relevance for human risk of the findings of prolactin-mediated endocrine tumors in rodents is unknown (see Hyperprolactinemia). Mutagenesis: There was a reproducible mutagenic response in the Ames assay in one strain of *S. typhimurium* in the absence of metabolic activation. Positive results were obtained in both the in vitro mammalian cell gene mutation assay and the in vitro chromosomal aberration assay in human lymphocytes. Impairment of Fertility: GEODON increased time to copulation in Sprague-Dawley rats in two fertility and early embryonic development studies at doses of 10 to 160 mg/kg/day (0.5 to 8 times the MRHD of 200 mg/day on a mg/m^2 basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m^2 basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m^2 basis). The fertility of female rats was reduced. ***Pregnancy—Pregnancy Category C:*** There are no adequate and well-controlled studies in pregnant women. GEODON should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. ***Labor and Delivery:*** The effect of GEODON on labor and delivery in humans is unknown. ***Nursing Mothers:*** It is not known whether, and if so in what amount, GEODON or its metabolites are excreted in human milk. It is recommended that women receiving GEODON should not breast feed. ***Pediatric Use:*** The safety and effectiveness of GEODON in pediatric patients have not been established. ***Geriatric Use:*** Of the approximately 4500 patients treated with GEODON in clinical studies, 2.4% (109) were 65 years of age or over. In general, there was no indication of any different tolerability for GEODON or of reduced clearance of GEODON in the elderly compared to younger adults. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to GEODON, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients. **ADVERSE REACTIONS** — ***Adverse Findings Observed in Short-term, Placebo-Controlled Trials:*** The following findings are based on the short-term placebo-controlled premarketing trials for schizophrenia (a pool of two 6-week, and two 4-week fixed-dose trials) and bipolar mania (a pool of two 3-week flexible-dose trials) in which GEODON was administered in doses ranging from 10 to 200 mg/day. ***Adverse Events Associated with Discontinuation:*** Schizophrenia: Approximately 4.1% (29/702) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 2.2% (6/273) on placebo. The most common event associated with dropout was rash, including 7 dropouts for rash among GEODON patients (1%) compared to no placebo patients (see **PRECAUTIONS**). Bipolar Mania: Approximately 9.5% (18/2/9) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 3.7% (5/136) on placebo. The most common events associated with dropout in the GEODON-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash, and vomiting, with 2 dropouts for each of these events among GEODON patients (1%) compared to one placebo patient each for dystonia and rash (1%) and no placebo patients for the remaining adverse events.

Adverse Events at an Incidence ≥ 5% and at Least Twice the Rate of Placebo: The most commonly observed adverse events associated with GEODON in schizophrenia trials were somnolence (14%) and respiratory tract infection (8%). The most commonly observed adverse events associated with the use of GEODON in bipolar mania trials were somnolence (21%), extrapyramidal symptoms (21%), dizziness (16%), akathisia (10%), abnormal vision (8%), asthenia (8%), and vomiting (5%). The following list enumerates the treatment-emergent adverse events that occurred during acute therapy, including only those events that occurred in 2% of GEODON patients and at a greater incidence than in placebo. Schizophrenia: Body as a Whole—asthenia, accidental injury, chest pain. Cardiovascular—tachycardia. Digestive—nausea, constipation, dyspepsia, diarrhea, dry mouth, anorexia. Nervous—extrapyramidal symptoms, somnolence, akathisia, dizziness. Respiratory—respiratory tract infection, rhinitis, cough increased. Skin and Appendages—rash, fungal dermatitis. Special Senses—abnormal vision. Bipolar Mania: Body as a Whole—headache, asthenia, accidental injury. Cardiovascular—hypertension. Digestive—nausea, diarrhea, dry mouth, vomiting, increased salivation, tongue edema, dysphagia. Musculoskeletal—myalgia. Nervous—somnolence, extrapyramidal symptoms, dizziness, akathisia, anxiety, hyperthesia, speech disorder. Respiratory—pharyngitis, dyspnea. Skin and Appendages—fungal dermatitis. Special Senses—abnormal vision. ***Dose Dependency:*** An analysis for dose response in the schizophrenia trials revealed an apparent relation of adverse event to dose for the following: asthenia, postural hypotension, anorexia, dry mouth, increased salivation, arthralgia, anxiety, dizziness, dystonia, hypertonia, somnolence, tremor, rhinitis, rash, and abnormal vision.

Extrapyramidal Symptoms (EPS): The incidence of reported EPS for GEODON patients in the short-term, placebo-controlled schizophrenia trials was 14% vs 8% for placebo. Objectively collected data from those trials on the Simpson-Angus Rating Scale and the Barnes Akathisia Scale did not generally show a difference between GEODON and placebo. ***Dystonia:*** Prolonged abnormal contractions of muscle groups may occur in susceptible individuals during first few days of treatment. Dystonia may occur at any dose level but with greater frequency and severity with high potency, and at higher doses of first generation antipsychotic drugs. Elevated risk is observed in males and younger age groups. ***Vital Sign Changes:*** GEODON is associated with orthostatic hypotension (see **PRECAUTIONS**). ***Weight Gain:*** In short-term schizophrenia trials, the proportions of patients meeting a weight gain criterion of ≥7% of body weight were compared, revealing a statistically significantly greater incidence of weight gain for GEODON patients (10%) vs placebo patients (4%). A median weight gain of 0.5 kg was observed in GEODON patients vs 0.0 kg in placebo patients. Weight gain was reported as an adverse event in 0.4% of both GEODON and placebo patients. During long-term therapy with GEODON, a categorization of patients at baseline on the basis of body mass index (BMI) showed the greatest mean weight gain and the highest incidence of clinically significant weight gain (≥7% of body weight) in patients with a low BMI (<23) compared to normal (23-27) or overweight (>27) patients. There was a mean weight gain of 1.4 kg for patients with a "low" baseline BMI, 0.0 kg for patients with a "normal" BMI, and a 1.3 kg mean weight loss for patients with a "high" BMI. ***ECG Changes:*** GEODON is associated with an increase in the QT$_c$ interval (see **WARNINGS**). In schizophrenia trials, GEODON was associated with a mean increase in heart rate of 1.4 beats per minute compared to a 0.2 beats per minute decrease among placebo patients. ***Other Adverse Events Observed During the Premarketing Evaluation of GEODON:*** Frequent adverse events are those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. Schizophrenia: Body as a Whole—*Frequent:* abdominal pain, flu syndrome, fever, accidental fall, face edema, chills, photosensitivity reaction, flank pain, hypothermia, motor vehicle accident. Cardiovascular System—*Frequent:* tachycardia, hypertension, postural hypotension; *Infrequent:* bradycardia, angina pectoris, atrial fibrillation; *Rare:* first-degree AV block, bundle branch block, phlebitis, pulmonary embolus, cardiomegaly, cerebral infarct, cerebrovascular accident, deep thrombophlebitis, myocarditis, thrombophlebitis. Digestive System—*Frequent:* anorexia, vomiting; *Infrequent:* rectal hemorrhage, dysphagia, tongue edema; *Rare:* gum hemorrhage, jaundice, fecal impaction, gamma glutamyl transpeptidase increased, hematemesis, cholestatic jaundice, hepatitis, hepatomegaly, leukoplakia of mouth, fatty liver deposit, melena. Endocrine—*Rare:* hypothyroidism, hyperthyroidism, thyroiditis. Hemic and Lymphatic System—*Infrequent:* anemia, ecchymosis, leukocytosis, leukopenia, eosinophilia, lymphadenopathy; *Rare:* thrombocytopenia, hypochromic anemia, lymphocytosis, monocytosis, basophilia, lymphedema, polycythemia, thrombocythemia. Metabolic and Nutritional Disorders—*Infrequent:* thirst, transaminase increased, peripheral edema, hyperglycemia, creatine phosphokinase increased, alkaline phosphatase increased, hypercholesteremia, dehydration, lactic dehydrogenase increased, albuminuria; *Rare:* BUN increased, creatinine increased, hyperlipemia, hypocholesteremia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hyperchloremia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. Musculoskeletal System—*Frequent:* myalgia; *Infrequent:* tenosynovitis; *Rare:* myopathy. Nervous System—*Frequent:* agitation, extrapyramidal syndrome, tremor, dystonia, hypertonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, hyperthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, buccoglossal syndrome, choreoathetosis, diplopia, incoordination, neuropathy; *Infrequent:* paralysis; *Rare:* myoclonus, nystagmus, torticollis, circumoral paresthesia, opisthotonos, reflexes increased, trismus. Respiratory System—*Frequent:* dyspnea; *Infrequent:* pneumonia, epistaxis; *Rare:* hemoptysis, laryngismus. Skin and Appendages—*Infrequent:* maculopapular rash, urticaria, alopecia, eczema, exfoliative dermatitis, contact dermatitis, vesiculobullous rash. Special Senses—*Frequent:* fungal dermatitis; *Infrequent:* conjunctivitis, dry eyes, tinnitus, blepharitis, cataract, photophobia; *Rare:* eye hemorrhage, visual field defect, keratitis, keratoconjunctivitis. Urogenital System—*Infrequent:* impotence, abnormal ejaculation, amenorrhea, hematuria, menorrhagia, female lactation, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; *Rare:* pyelonephritis, vaginal hemorrhage, nocturia, oliguria, female sexual dysfunction, uterine hemorrhage. **Adverse Finding Observed in Trials of Intramuscular GEODON:** In these studies, the most commonly observed adverse events associated with the use of intramuscular GEODON (≥5%) and observed at a rate on intramuscular GEODON (in the higher dose groups) at least twice that of the lowest intramuscular GEODON group were headache (13%), nausea (12%), and somnolence (20%). **Adverse Events at an Incidence >1% in Short-Term Fixed-Dose Intramuscular Trials:** The following list enumerates the treatment-emergent adverse events that occurred in ≥1% of GEODON patients (in the higher dose groups) and at least twice that of the lowest intramuscular GEODON group. Body as a Whole—headache, injection site pain, asthenia, abdominal pain, flu syndrome, back pain. Cardiovascular—postural hypotension, hypertension, bradycardia, vasodilation. Digestive—nausea, rectal hemorrhage, diarrhea, vomiting, dyspepsia, anorexia, constipation, tooth disorder, dry mouth. Nervous—dizziness, anxiety, insomnia, somnolence, akathisia, agitation, extrapyramidal syndrome, hypertonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. Respiratory—rhinitis. Skin and Appendages—furunculosis, sweating. Urogenital—dysmenorrhea, priapism.

DRUG ABUSE AND DEPENDENCE — ***Controlled Substance Class:*** GEODON is not a controlled substance. **OVERDOSAGE**—In premarketing trials in over 5400 patients, accidental or intentional overdosage of GEODON was documented in 10 patients. All patients survived without sequelae. In the patient taking the largest confirmed amount (3240 mg), the only symptoms reported were minimal sedation, slurring of speech, and transitory hypertension (BP 200/95).

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Bellevue Hospital Center is seeking board certified/eligible psychiatrists for several positions in our expanding and exciting Department of Psychiatry. Qualified candidates are eligible for faculty appointment at a suitable rank at New York University School of Medicine. Positions are available on the following services:

Forensic and General Inpatient Services
The 68-bed inpatient service is the cornerstone of Bellevue's Division of Forensic Psychiatry and is the central provider of acute inpatient care for the New York City Police Department and the Department of Corrections. Our general inpatient units provide compassionate, culturally sensitive care to patients with a range of diagnoses and psychosocial complexities. Chinese and/or Spanish speaking psychiatrists are especially sought.

Assisted Outpatient Treatment Program
Forensic experience is ideal but not required for attending psychiatrists who would assess and coordinate treatment planning for court-mandated outpatient treatment.

Comprehensive Psychiatric Emergency Program
Psychiatrists lead a multidisciplinary team assessing and treating patients at one of the most exciting emergency services in the New York City area.

Internal Medicine
We are also seeking board certified internists to treat the medical needs of our patients on inpatient psychiatry.

Position inquiries should be sent to:
Mary Anne Badaracco, M.D.
Chief of Psychiatry, Bellevue Medical Center,
Department of Psychiatry
462 First Avenue, A Building, Room 648A,
New York, NY 10016
Phone: 212.263.6220,
Mary.Badaracco@nyumc.org

A Facility of the New York City Health and Hospitals Corporation

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Child Psychiatrist, Part-Time

Prestigious child and family services agency is seeking a Part Time Psychiatrist for its mental health clinics in Westchester. Consult and collaborate with professional staff. Evaluate clients and manage medication. Desire to work as a team player and in a diverse environment. Competitive salary and excellent benefits. Board eligible or certified is preferred . Andrus Children's Center, 1156 North Broadway, Yonkers, NY 10701, Attn: PN/PSY, Fax: 914-965-3883, email: andrusjobs@jdam.org , http://www.andruschildren.org/. EOE

PSYCHIATRISTS
PER DIEM/MOONLIGHTING

Rare blocks of weekend, night & weekend shifts are available for NYS licensed PGY4's, Fellows, and career psychiatrists to cover hospital ED/CL/Detox Services and/or Adult Psych Unit on a variety of shifts. Hourly rate based on BE/BC and years of experience, with enhanced Holiday weekend rates. Partial to full reimbursement of a Part Time malpractice policy premium offered. For consideration, please fax 718-630-8594, email: bgoff@lmcmc.com, or send resume/CV to: Bradford M. Goff, M.D., Chairman, Dept. of Psychiatry, Lutheran Medical Center, Ste. 2-45, 150 55th St., Brooklyn, NY 11220. EOE/AA M/F/D/V

LUTHERAN MEDICAL CENTER
www.LutheranMedicalCenter.com

PSYCHIATRISTS
Full time positions available at Kirby Forensic Psychiatric Center, a New York State Office of Mental Health facility specializing in the treatment of a wide range of patients with forensic concerns. The psychiatrist leads a multi-disciplinary team with, opportunities to utilize clinical, administrative and teaching skills. Prior forensic training is not expected, but opportunities exist to develop forensic skills. Kirby is affiliated with the NYU residency and forensic fellowship programs. We are conveniently located near the Triboro Bridge.

Please fax or mail resume to:
Kirby Forensic Psychiatric Center
Wards Island Complex
Wards Island, NY 10035
Dr. Michal Kunz, Clinical Director
Fax 646-672-6893
Kirby Forensic Psychiatric Center is an equal opportunity employer

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Part Time / Flexible hours, Consultation/Liaison Psychiatrist: excellent opportunity for general psychiatrist available at Long Island College Hospital in Brownstone Brooklyn. Position has benefits and 403B, also has many opportunities for moonlighting. We're looking for a highly motivated and committed physician. Please fax your CV to Camille Munch at 718-780-1236.

Consulting Psychiatrists & Psychologists

BC/BE **Psychiatrists** to provide Consultation-Liaison services and **Psychologists** to provide Psychotherapy and Behavioral Management in Long Term Care settings (NH, SNF).
Facilities Located in NYC Metro area and Westchester, Putnam, Dutchess, Rockland, Orange and Ulster Counties. PT/FT Well above average salaries/benefits, flexible hours.
Recent graduates encouraged to apply.

Please contact: Carlos Rueda, M.D. at Tel: 718-239-0030 or via fax: 718-239-0032
E-mail: crueda@neuropsych-services.com

NEW YORK STATE

Ulster County Mental Health, an outpatient clinic with a wide range of services, has two full or part-time (28 hours minimum) psychiatry positions in the Kingston clinic. We are looking for recovery-oriented board certified or board-eligible community psychiatrists to treat adult patients. Kingston is located in the beautiful Hudson Valley, two hours north of NYC. Competitive salary, good benefits, on-site psychopharmacology supervision and collegial atmosphere. No on-call or weekends. Full time 35 hours. Send CV to JuLita Adamczak, MD, Medical Director, FAX #845-340-4094. Telephone #845-340-4173.

NORTH CAROLINA

Winston-Salem - General Psychiatrist position. Option for employment with hospital with salary & benefits or join a private practice. Residential/inpatient programs. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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The Department of Psychiatric Medicine at the Brody School of Medicine at ECU is now accepting applications for a full-time psychiatrist faculty position. The successful candidate will provide direct clinical services, both face-to-face and via telepsychiatry, at clinical sites covering 13 county region in eastern North Carolina; provide consultation and support for other clinical staff on complicated cases; interface with mobile crisis teams; assist in teaching and clinical supervision of medical students, residents, physician extenders, and other health professionals/trainees; collaborate with other faculty members, performing such duties as are appropriate to academic rank and position. The faculty member will spend approximately 85% of his/her time in providing clinical care supervision at multiple sites. Tenure track appointment possible. Requirements include MD or equivalent degree, completion of accredited psychiatric residency training in psychiatry and board eligibility in Psychiatry. Salary and academic rank commensurate with experience and academic background. Please send letter of interest and a CV to Dr. Richard Bloch, Chair, Search Committee, Department of Psychiatric Medicine, Brody School of Medicine, 4E-65 Brody Building, 600 Moye Blvd., Greenville, NC 27834, e-mail: **blochri@ecu.edu** Additionally, applicants should submit an on-line application to **www.jobs.ecu.edu** (position #966055) with attached cover letter, CV, and list of references. East Carolina University is an AAEO Employer

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Eastern NC - Convenient to Outer Banks, NC and Norfolk/VA Beach - A very attractive salaried position with benefits & bonus plan in a general hospital located in an area that is becoming one of THE places to retire in NC. This position can be inpatient or outpatient or both. Student loan repayment plan available. Work with a great group of people that make work a pleasure every day. What could be better: low stress small town living with an easy drive to the coast. Can commute from Edenton, NC or Suffolk, VA. Please **call Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

BE YOUR OWN BOSS - FANTASTIC PRACTICE OPPORTUNITY RIGHT NEAR RALEIGH - Live in Raleigh and work in Rocky Mount in a very impressive general hospital with adult and chemical dependency inpatient/outpatient services. Offering 3 year income guarantee and opportunity to join our Medical Director's very successful practice. You won't need the guarantee long in this area! Area has some of the finest golf courses. In the middle of everything NC has to offer. Contact **Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; terry.good@horizonhealth.com.

OHIO

30 Minutes from Dayton Suburbs - easy drive to Indianapolis - Expanding adult and geropsych services in an extremely impressive med/surg hospital. Brand new facility just opened. Services include inpatient, outpatient and IOP. Offering very attractive salary with benefits & bonus plan & possible sign-on bonus. Please call **Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com. EOE

OREGON

Portland, OR - Enjoy all the benefits of living in Portland without the congestion, high cost of living and competition.
Please see our ad under Washington state.
Southwest Washington Medical Center, Vancouver, WA.

A psychiatrist is sought to join a busy outpatient and inpatient practice. Inpatient work is about two hours/day. Most of our physicians choose to work four days/week in their outpatient practice, which is primarily commercial insurance with some Medicare. No Medicaid.

Weekend call is every one in five weekends, but we are considering models that would require no weekend call at all.

The inpatient units are primarily adult-20 beds total, with consult/liaison services. We are jointly recruiting with St. Charles Medical Center, the largest medical center east of the Cascades. The hospital is offering a practice guarantee, interview and moving expenses.

We are located in Bend, Oregon which is nestled in the beautiful Cascades three hours driving time from Portland.

From visitbend.com:
"Bend is a land of extremes and contrasts - desert and forest, lava and snow, volcanoes and plains, rustic and urban hip. Everyone here mixes and mingles in a big happy soup pot of snowboarders and professionals, families in shorts and sandals and couples in casual chic, locals and visitors. Maybe that´s why people in Bend are so friendly - because most of them were visitors first, too. You'll find fun for the entire family in Bend, Oregon. Enjoy spectacular outdoor activities including world-class golfing, skiing, hiking and much more."

USA Today calls Bend 'the new Boulder' click here to learn more:
http://www.usatoday.com/travel/destinations/road/2008-05-22-bend-oregon_N.h

A few other links to enjoy:
http://www.visitcentraloregon.com/
http://www.ci.bend.or.us/

CONTACT:
Email CV to Magnus Lakovics, MD, Medical Director, Behavioral Health Services, St. Charles Medical Center at mlakovics@msn.com or call 541-390-4418.

PENNSYLVANIA

Faculty Openings
Inpatient, Consultation and Liaison

Temple University School of Medicine, Department of Psychiatry and Behavioral Science, has faculty openings in Inpatient, Consultation and Liaison. Responsibilities include providing clinical care and teaching residents and medical students. The selected individual will also have the opportunity to participate in research. Candidate must be board-eligible or board-certified (preferred). Rank and salary commensurate with experience.

To apply, submit curriculum vitae to Dr. David Baron, Chair, TUSM Department of Psychiatry and Behavioral Science C/O Scott Caldie, Director, Physician/Faculty Recruitment & Retention. Temple University School of Medicine, 3401 North Broad Street, 6th Floor Parkinson Pavilion, Suite 640, Philadelphia, PA 19140.

Temple University is an affirmative action/equal opportunity employer and strongly encourages applications from women and minorities.

School of Medicine
TEMPLE UNIVERSITY®

Pittsburgh PA Metro

Butler Memorial Hospital and P.B.S. Mental Health Associates, P.C. are recruiting a psychiatrist to lead our 20 bed general psychiatry unit.

Be part of a physician owned psychiatric group with opportunities for outpatient, clinic and nursing home practice. First year salary guarantee; 1:4 call; excellent benefits; productivity with robust earning potential.

For further information please contact Debby Solari, Practice Administrator at 724-282-1627.

The Philadelphia VA Medical Center (PVAMC) and the Department of Psychiatry at the University of Pennsylvania School of Medicine seeks candidates for an Assistant, Associate, and/or Full Professor position in the non-tenure clinician-educator track. Rank will be commensurate with experience. The successful applicant will have experience in the field of Psychiatry with a focus on Addiction Psychiatry. Responsibilities include taking care of patients with substance abuse disorders, development of a comprehensive rehabilitation treatment program integrating pharmacology with evidence-based psychological treatments, clinical research, and teaching of residents and fellows. Applicants must have an M.D or M.D./Ph.D. degree and have demonstrated excellent qualifications in Education, Research, and Clinical Care. Board Certification or Board Eligibility in Psychiatry, and unrestricted PA license required.
The successful applicant must have completed a fellowship in Addiction Psychiatry.

The PVAMC Behavioral Healthcare Service provides a full range of high quality, restorative and preventative behavioral health services to the veteran population. Research opportunities exist with both the PVAMC Centers of Excellence that focus on addictions research (the CESTATE and the MIRECC). The University of Pennsylvania's Department of Psychiatry is recognized nationally for clinical, education and research excellence.

This position is full-time with primary duty location being the Philadelphia VA Medical Center. The PVAMC is an equal opportunity, affirmative action employer. Women and minority candidates are strongly encouraged to apply.

Please submit curriculum vitae, a cover letter, and references to:
Ken Sullivan, MD, Acting ACOS of PVAMC Behavioral Health Services; Dwight L. Evans, MD, Ruth Meltzer Professor and Chair, Department of Psychiatry, University of Pennsylvania School of Medicine; REF#112; c/o Diane Daniels, Office of Human Resources (05), Philadelphia VA Medical Center, 3900 Woodland Avenue, Philadelphia, PA 19104
diane.daniels@va.gov
The University of Pennsylvania is an equal opportunity, affirmative action employer. Women and minority candidates are strongly encouraged to apply.

Horizon Health and St. Vincent Health System
Staff Psychiatrist
Erie, PA

Horizon Health, in partnership with **St. Vincent Health Center (Voted 5th Best Place to work in Pennsylvania!)**, a 436-bed tertiary care hospital in **Erie, PA**, has an exciting opportunity for a **Staff Psychiatrist** for a **32-bed** Adult and Geriatric Inpatient Psychiatric Program. Census runs 18-29 (75%), average LOS is 11-12 days. General patient population - depression, bipolar, secondary chemical dependency and schizophrenia

Call: 1 in 5. If on call for the weekend take Monday off. Weekends do daily rounds and then phone calls. Call is from Fridays at 4pm til Mondays at 8am.

Opportunities for input and growth, tertiary care, teaching opportunities in FP residency program and LECOM medical school. Work well with neurologists. Excellent compensation package with full benefits.

Located on the shores of **Lake Erie** with 7 miles of beaches, Erie is the **fourth largest city** in Pennsylvania with a metropolitan population of 280,000. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

Horizon Health and Lancaster General Hospital
Psychiatrists
Lancaster, PA

Horizon Health, in partnership with **Lancaster General Hospital** in **Lancaster, PA,** has exciting opportunities for **Psychiatrists** for a newly managed, 25-bed, Adult Inpatient Psychiatric Program. Great work environment, family friendly, and excellent compensation! For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

VA Medical Center
Wilkes-Barre, PA
Champions Caring for Veterans

DEPARTMENT OF VETERANS AFFAIRS
MEDICAL CENTER
1111 East End Boulevard
Wilkes-Barre, PA 18711

CHIEF, MENTAL HEALTH & BEHAVIORAL SERVICE

The VA Medical Center, Wilkes-Barre, PA (VAMCWB) is currently accepting applications for one (1) full-time Chief, Mental Health & Behavioral Service. This position will be responsible for the supervision of the Mental Health & Behavioral Service to include the Community Based Outpatient Clinics. Management experience a plus.
VAMCWB is an acute care, general medical, surgical and psychiatric facility consisting of 79 operating hospital beds, with an attached 100 bed nursing home care unit.
Interest in and ability to assume a leadership/administrative role to include organization stewardship and the following responsibilities: supervision of psychiatrists and mid level practitioners; consultation liaison to other services; oversight for inpatient adherence to performance measures, treatment planning, utilization review and management guidelines, joint commission and other regulatory body standards; monitoring inpatient/outpatient provider productivity and clinical care efficiencies. Incumbent will report directly to the Chief of Staff for Mental Health and Behavioral Services.
Board certified/board eligible preferred. Salary is commensurate with credentials and experience. Salary range: $93,818-$200,000. Relocation/Recruitment incentives may be authorized. In addition to an attractive salary, we offer paid malpractice insurance, vacation/sick leave, health and life insurance coverage and an attractive retirement package including a tax deferred savings plan.
The applicant selected for this position may be eligible to apply for an education loan reimbursement award under the provisions of the Education Debt Reduction Program (EDRP).
Interested applicants must submit an Application for Physicians, Dentists, Podiatrists and Optometrists, VA Form 10-2850, Declaration for Federal Employment, OF-306, Curriculum Vitae, and a copy of your current license. Applications may be obtained online at www.usajobs.opm.gov or by calling Beth Nealon, Human Resources Service at (570)824-3521, Extension 4962.

VA IS AN EQUAL OPPORTUNITY EMPLOYER

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.

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

Child/Adolescent and Adult Psychiatrists: Positions available in the scenic Laurel Highlands of Southwestern Pennsylvania (60 minutes SE of Pittsburgh/3 hours NW of D.C.). Join team of 11 psychiatrists in a progressive community-based behavioral health program. Full-time and part-time positions available in a comprehensive outpatient service. Treatment provided in concert with a team of PA's, CRNP's, certified psychiatric nurses and professional counselors. Crisis Intervention team provides 24/7 on-call coverage. Competitive salary and excellent benefit package. **J-1/H-1 positions available**. Please forward CV to: Mike Quinn, CEO, Chestnut Ridge Counseling Services, Inc., 100 New Salem Road, Uniontown, PA 15401 FAX: 724 439-2779. EMAIL: mquinn@crcsi.org. To learn more about Chestnut Ridge Counseling please visit our website at www.crcsi.org.

VA Medical Center
Wilkes-Barre, PA
Champions Caring for Veterans

DEPARTMENT OF VETERANS AFFAIRS
MEDICAL CENTER
1111 East End Boulevard
Wilkes-Barre, PA 18711-0026

STAFF PSYCHIATRISTS

The VA Medical Center, Wilkes-Barre, PA is currently accepting applications for Full-Time Staff Psychiatrists (BC/BE preferred) in our Mental Health & Behavioral Service.
As a member of a multidisciplinary team he/she will focus on the assessment/evaluation and medication management of veterans who suffer from a variety of mental health conditions, including, but not limited to: Post Traumatic Stress Disorder (PTSD), substance abuse, depression, anxiety and other related conditions. The incumbent will work with veterans from all theaters of service including Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF). This position provides clinical assessment/evaluation of veterans with difficult and complex mental health issues and then selects treatment from a variety of resources and clinical approaches including non-direct and cognitive behavior therapy, behavior modification, insight oriented methods, family therapy, relaxation training, medication management, etc. Serves as a consultant and advisor to other professional staff and the community on the assessment, education and treatment of veterans with complex clinical problems such as PTSD and war zone related stress reaction. This position also provides support in meeting the suicide prevention initiative, local recovery initiative, and the rapid response for mental health service initiative. May be involved in outreach activities for OIF and OEF veterans and may engage in individual and cooperative research projects directly connected with PTSD or related conditions.
Salary is commensurate with credentials and experience. Salary range: $93,818 - $175,000. In addition to an attractive salary, we offer paid malpractice insurance, vacation/sick leave, health and life insurance coverage and an attractive retirement package including a tax deferred savings plan. A recruitment bonus may be offered, at the discretion of the medical center, which may be up to 25% of the annual salary. Applicants selected for these positions may be eligible to apply for an education loan reimbursement award under the provisions of the Education Debt Reduction Program (EDRP).
Interested applicants must submit *VA Form 10-2850, Application for Physicians, Dentists, Podiatrists and Optometrists, OF-306, Declaration for Federal Employment, Curriculum Vitae* and a copy of your current license. Applications may be obtained online at www.usajobs.opm.gov or by calling Beth Nealon, Human Resources Service, at 570-824-3521, extension 4962.

VA IS AN EQUAL OPPORTUNITY EMPLOYER

PHILADELPHIA - Child Psychiatrist for Residential & Inpatient Treatment Center in Bucks County. **STATE COLLEGE** - Inpatient and Outpatient - General or Child Psychiatrist. **CLARION** - General Psychiatrist for Adult services. Positions can be fulltime or part-time (both Mon-Fri schedule) - salary & benefits. Contact Joy Lankswert @ 866-227-5415; OR email joy.lankswert@uhsinc.com

SOUTH CAROLINA

HOSPITALIST - Employment model. 5-day week; call 1:5. Good comp / benefits. 25-bed adult in-patient unit of 600-bed AnMed Health System. Program development; leadership opportunities available.

Northwest SC town of nearly 50K; 200,000 medical draw. 30 miles from Greenville; on I-85 and Lake Hartwell. Midway Atlanta / Charlotte.

Sherry Chastain, Medical Staff Development
AnMed Health Medical Center
Anderson, SC
sherry.chastain@anmedhealth.org
800 226 3103

GREENVILLE, SC

Opportunity for general or child psychiatrist (who is also willing to treat adult patients) to join respected, established private practice in growing upstate South Carolina. 100% outpatient with quality lifestyle and sizeable income potential. Health and malpractice insurance and 401K plan. Contact Guy Louthian at 1-803-261-1123 or guy@physicianservicessc.com.

AIKEN - minutes from Augusta GA & Columbia, SC. General Psychiatrist - inpatient & partial programs. Fulltime position - salary & benefits. LOAN REPAYMENT ELIGIBLE. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

TENNESSEE

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

TEXAS

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

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

Harris County Jail
Day shift at 24/7 facility
Perform psychiatric evaluations & medication management
Some on call

LEAD PSYCHIATRIST
Provides medical leadership, direction & supervision for professionals engaged in administering mental health program in correctional facility and performs psychiatric evaluations and treatment interventions.

Texas licensure is required for all positions

MHMRA offers competitive salary plus a generous benefit package. Houston offers excellent quality of life, lower than average cost of living, no state sales tax and exciting cultural, entertainment, sporting and tourists venues.
Contact Charlotte Simmons at (713) 970-7397, or submit your C.V. to charlotte.simmons@mhmraharris.org or fax: 713-970-3386

AUSTIN area - Salaried employment & benefits. Child Psychiatrist for Residential treatment Center working with child & adolescent services.
WEST TEXAS - San Angelo - Private practice opportunity. Income guarantee & practice start-up support. Family oriented community - good schools, housing, economy & activities.
Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Come to beautiful San Antonio, Texas!!

Psychiatrists

The Center for Health Care Services, a 2006 APA Gold Award winner, is actively seeking full-time/part-time/contract psychiatrists for our Adult & Child Programs. The Center Psychiatrists are at the leading edge of the delivery of community mental health service, providing assessment and treatment of clients, and leadership of a team of skilled and dedicated mental health professionals. Must be board eligible or board certified.

The Center offers:
- *Attractive salary*
- *Excellent benefits package, including retirement benefits*

San Antonio offers:
- *Great climate year round*
- *Ranked among the best value cost of living*
- *Arts, Theatre, Sports and Entertainment, Amusement parks and more*
- *Easy access to beaches, Mexico, the Texas Hill Country, more*

If you are interested in learning more about service at The Center, please submit your C.V. in confidence to:

The Center for Health Care Services
Attn: HR Director
3031 IH 10 West
San Antonio, Texas 78201
Fax: 210-731-1310
staffing@chcsbc.org

EOE

MEDICAL DIRECTOR, ADDICTION TREATMENT PROGRAM

Join us as Medical Director of an innovative and growing VA addiction program. Administrative leadership will be shared and supported by the team co-leader, Dr. Stacy McCord, Ph.D. The Amarillo Veterans Health Care System (AVAHCS) addiction program currently includes intensive outpatient care and a more intensive day treatment program coordinated with a therapeutic half-way house. The program is a training site for Texas Tech Health Sciences Center School of Medicine medical students and residents, with strong potential for academic development. A residential treatment program is under development. The addiction program is moving into a new state-of-the-art facility next year. AVAHCS is nationally recognized for high levels of patient satisfaction and a culture of compassion and caring among the staff and administration.

Amarillo is a pleasant surprise - a warm friendly city with progressive cultural and artistic offerings including a fine symphony orchestra and one of the best established community theatres in the country. The VA sits in the best part of town, 5 minutes from the finest schools and residential neighborhoods. Amarillo is near incredible outdoor spectacles including Palo Duro Canyon (25 minutes) and the Rocky Mountains (3.5 hours).

Requirements:
- Unrestricted licensure as a physician in any state or territory
- Board Certified/Eligible in Psychiatry
- Excellent communication and interpersonal skills

Contact:
Ms. Helen Jefferson
Amarillo VA Human Resources (05)
6010 Amarillo Blvd. West
Amarillo, Texas 79106
Fax: (806) 354-7828

University Behavioral Health of Denton is seeking two Board Certified or Board Eligible Psychiatrists for adult and youth inpatient programs. UBH of Denton is the area's only private freestanding psychiatric hospital specializing in mental health and chemical dependency care. Located in Denton and convenient to surrounding counties (30 minutes north of Dallas/Fort Worth), UBH provides inpatient and outpatient psychiatric services for children, adolescents, adults, and seniors.

Candidates should forward their Curriculum Vitae to:

Human Resources
2026 W. University Drive
Denton, TX 76201
Henry.in@ubhdenton.com
Fax 940-239-0007

The Department of Psychiatry at The University of Texas Health Science Center at San Antonio seeks a Director of the Division of Mood Disorders. The position is a full-time tenure-track faculty position at the Associate or Full Professor level supported in part through a named endowed professorship. The successful applicant will be a board-certified or board-eligible academic psychiatrist with a track record of independent research funding in the area of mood disorders. Psychiatry currently has over 15 million dollars per year in extramural research funding. Areas of greatest research strength include translational research on etiology and treatment of mood disorders, substance use disorders, childhood disorders, geriatrics and executive function, schizophrenia, and genetics. Additionally, the department has strong educational and clinical programs in an attractive, culturally rich city situated on the edge of the Texas Hill Country, with a pleasant climate, an excellent public school system and abundant recreational activities. Interested individuals should forward their curriculum vitae to Pedro L. Delgado, M.D., Professor and Chairman, Department of Psychiatry, Mail Code 7792, The University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, San Antonio TX 78229-3900, phone 210-567-5391, FAX 210-567-6941. The University of Texas Health Science Center at San Antonio is an Equal Employment Opportunity/Affirmative Action Employer. All faculty appointments are designated as security sensitive positions.

UTAH

IMMEDIATELY SEEKING A PSYCHIATRIST to join Valley Mental Health in Salt Lake City, one of the largest community mental health centers in the country. Our physicians enjoy working with interesting and challenging patients, value the support and camaraderie found in the clinics and enjoy a very flexible schedule. Experience and interest in severely mentally ill adults and community mental health encouraged. We are a training site for the University of Utah Dept. of Psychiatry and offer generous benefits which include membership in Utah's State Retirement system. Salt Lake City also offers the enjoyment of world-class skiing only 20 minutes away. Please complete an on-line application by visiting our Website at: www.vmh.com. and applying for Job #100. For further information, please contact Dr. Joseph Yau, Clinical Director, at 801-263-7106.

VERMONT

Middlebury, VT - Psychiatrist

Psychiatrist to join our innovative interdisciplinary practice. Our highly regarded nonprofit community mental health center is centrally located in Middlebury, a unique New England small college community. Our diverse practice includes consultation with Middlebury College. Responsibilities include shared back-up outpatient coverage of our experienced Emergency Team. This position is full time with excellent benefits. Qualifications: BC/BE. Child/adolescent psychiatry experience would ideally complement adult expertise. The Middlebury-Burlington area offers excellent schools and outstanding cultural and four season recreational resources.

We are people helping people.

Please submit cover letter and resume to Cheryl Huntley via email at chuntley@csac-vt.org, fax at (802) 388-8183, or mail to 89 Main Street, Middlebury, VT 05753. For more information you may call her at (802) 388-0302 ext. 493. Visit our website: www.csac-vt.org.

VIRGINIA

Exciting Opportunity with a large behavioral health company nestled in the heart of Southwest Virginia. Full-time outpatient Psychiatrist needed to work with adult patients in Lee, Scott & Wise Co. Communities. Comprehensive array of services available with Case Workers, Nurse Practitioners and licensed Clinicians. Salaried position with full benefit package. For more information, please contact Andra Savage @ 423.844.5062 or Andra_R_Savage@Wellmont.org.

Come Work & Play in the Mountains

Centra Health, in beautiful Lynchburg, Virginia, is seeking a board certified/eligible child psychiatrist and a general/adult psychiatrist for its expanding mental health services. Duties include maintaining an outpatient practice, facilitating admissions to the acute inpatient programs and sharing call with the psychiatric team. The child psychiatrist has the opportunity to practice at our 102-bed residential treatment center. Centra provides the most comprehensive array of mental health programs for children and adolescents in the Commonwealth.

Comprised of Virginia Baptist, Lynchburg General, and Southside Community Hospitals, Centra provides a competitive, guaranteed base salary and an incentive bonus along with an excellent benefit package.

Lynchburg is located in Central Virginia on the James River in the foothills of the Blue Ridge Mountains. The area offers a great climate, excellent schools, and a wide variety of activities and amenities with a high quality of life. For more information, contact Bill Semones, Vice President, Mental Health Services, at 434-200-4514 or bill.semones@centrahealth.com

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Psychiatrist
UVA School of Medicine/Psychiatry and Neurobehavioral Sciences

The Department of Psychiatry and Neurobehavioral Sciences at the University of Virginia is seeking one psychiatrist to provide clinical care as an attending on inpatient psychiatric services, consult liaison, or outpatient clinic services, teach and supervise residents, and provide on call services. Must have an M.D. degree in psychiatry, board certification in adult psychiatry, and a valid VA medical license. A strong interest in scholarship and research is preferred. Faculty appointment as an Assistant/Associate Professor will be commensurate with training and experience. Send Application to: Genya Saunders, University of Virginia Health System, P O Box 800623, Charlottesville, VA 22908 or genya@virginia.edu

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VIRGINIA COMMONWEALTH UNIVERSITY, Department of Psychiatry, School of Medicine, is re-advertising the recruitment of a BE/BC psychiatry educator, to serve as Chair, Division of Ambulatory Psychiatry. Duties include development of new programs, ambulatory care research, ambulatory resident and student education, and direction of general and specialty clinics. Significant experience in academic ambulatory care, psychiatric education, administration and clinical research desired. Ambulatory Care Clinics are located at the VCU Medical Campus, and have an estimated 16,000 patient visits/year. Department of Psychiatry employs over 70 fulltime faculty, is financially stable, and is nationally ranked in federally funded research. Richmond, the State Capital, has moderate climate and rich mix of history, a diverse multicultural community, excellent housing and public/private schools. Internet provides comparative cost of living. Send CV to Search Committee Chair, Joel J. Silverman, MD, c/o Marie Roach at VCU, Department of Psychiatry, PO 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.

Come to the creative arts capital of the East Coast in Virginia! Hospital expansion creates need for additional general psychiatrist and child psychiatrist to join 11 others. Jim Ault at St. John Associates, jault@stjohnjobs.com or 1-800-737-2001. Visit www.stjohnjobs.com for psychiatry positions nationwide.

WASHINGTON

PSYCHIATRIC PRACTICE OPPORTUNITY IN THE BEAUTIFUL SOUTH PUGET SOUND AREA

Thriving outpatient psychiatric practice in Olympia, WA , with well established referral base has a unique opportunity for board certified or board eligible psychiatrists wishing to start or relocate an outpatient private practice. Beautiful brand new facility with experienced support staff. Interested? Please contact us at 360 357 4313 or email KristenM@pinelclinic.com for more details.

Western Washington State: Adult/Geriatric/Forensic Psychiatrist (BE/BC with a WA state license) applications considered. Western State Hospital is a fully accredited (JCAHO) and certified (CMS) 997 bed hospital serving adult, geriatric and forensic populations. Annual salary up to $158,304 DOQ. Excellent benefits, including hospitalization/medical insurance, retirement and vacation leave, plus optional deferred income plan. Send CV to Leah Muasau, Medical Staff Coordinator; Western State Hospital; 9601 Steilacoom Blvd. SW; Lakewood, WA 98498-7213. E-Mail: MUASALL@DSHS.WA.GOV.

Vancouver, WA/Portland, OR

Your professional fulfillment is assured upon joining our group of 4 psychiatrists and 5 NPs. The inpatient/outpatient private practice includes active consultation/liaison, emergency services, EAP and day treatment. Due to demand for services, you can have as varied and busy private practice as you desire.

The generous base salary, comprehensive benefit package and income from our efficiently run private practice will provide you the financial security to focus on developing your practice to support your interests.
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For additional information contact:
Michael Bernstein, MD, c/o Bill Kohut
Southwest Washington Heath System
800-409-3147
bkohut@sw-health.org

The University of Washington and Harborview Medical Center (HMC) in Seattle, WA is accepting applications for a psychiatrist at the rank of Instructor or Assistant Professor (without tenure). This position is 1.0 FTE and will do a mix of consultation and inpatient psychiatry. Two half days a week will be spent working in psychiatry outpatient service settings. The position requires an MD and includes responsibility for teaching residents and medical students. University of Washington faculty engage in teaching, research, and service. Please send application and CV to Peter Roy-Byrne MD, Chief Psychiatry, Harborview Medical Center 325 9th Ave. Box 359911, Seattle, WA 98104. The UW is building a culturally diverse faculty and strongly encourages applications from females and minority candidates. The UW is an EOE/AA employer.

WEST VIRGINIA

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

Inpatient/Outpatient Position - Lovely Area Near Marietta, Ohio - 1 hour north of Charleston - Seeking psychiatrist to work on adult unit with top-notch behavioral health team in a very impressive hospital. Great schools, affordable housing and a low cost of living. Enjoy laid-back lifestyle in this family-oriented community. 2 hours from Columbus & 3 hours from Pittsburgh. **J1/H1B applicants welcome. Please call Terry B. Good, Horizon Health, at 1-804-684-5661**, Fax #: 804-684-5663; email: terry.good@horizonhealth.com.

WISCONSIN

The University of Wisconsin Department of Psychiatry is a financially strong academic Psychiatry department undergoing an aggressive faculty growth plan. We are seeking BC/BE Child and Adolescent Psychiatrists and BC/BE Adult Psychiatrists to join in the expansion of innovative clinical programming and services. We have opportunities for both inpatient and outpatient practice settings and provide compensation equivalent to that found in private practice settings, paired with the stimulation of an academic environment. Participation in teaching activities is expected and rewarded. For more information, please e-mail a letter of interest and CV to:

Roderick J. Hafer, Ph.D.
Vice Chair of Clinical Serivces
RHAFER@WISC.EDU

Wisconsin - Lifestyle opportunity. 5-day workweek with minimal call. Our client seeks BE/BC psychiatrists for two positions: a blended hospitalist/outpatient psychiatrist and an outpatient adult psychiatrist. Large behavioral health center that is part of an integrated health system with 4 psychiatrists, neuropsychologist and NP. Excellent salary and benefit package. Lakefront living nestled away in Wisconsin's rolling countryside. This city offers a plethora of amenities. The schools are among the best in the nation, recreation is abundant, and the people are neighborly. Enjoy an easy drive to Madison, Milwaukee, Chicago, or Minneapolis/St. Paul. It's worth checking out! Contact Bob Bregant at bbregant@hortonsmithassociates.com or call 800.398.2923. Job #1185

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Fellowships

Psychiatric Epidemiology Program

Columbia University Psychiatric Epidemiology Training Program announces openings for pre- and postdoctoral fellows beginning September 2009. The program provides social scientists, epidemiologists, psychologists, and psychiatrists with research skills in psychiatric epidemiology. Training involves course work in substantive issues and research methods, and participation in an affiliated research unit. Postdoctoral stipends range from $36,996 to $51,036, depending on years of experience. Predoctoral stipends are $20,772. Application deadline: February 15, 2009. Contact: Training Coordinator, Columbia University, School of Public Health, 722 West 168th Street, Room 720-B, New York, NY 10032; e-mail: PET@Columbia.edu
Columbia University is an affirmative action/equal opportunity employer.

Fellowship in Addiction Psychiatry
University of Massachusetts Medical School

NEWLY ACCREDITED Fellowship in Addiction Psychiatry in a department with a major focus on addictions, including psychopharmacology, multiculturalism, basic neuroscience, psychosomatic medicine (working with primary care medicine's addiction faculty), and state-of-the-art psychosocial interventions. Major public and private sector affiliations including 120-bed private sector addiction hospital, a first-of-its-kind 16-bed public sector adolescent detoxification & rehabilitation unit, a new general hospital buprenorphine clinic with an intensive outpatient program for co-occurring disorders, organizational-wide tobacco cessation program, and a continuum of care for opioid dependent patients from detoxification through substitution therapy to community rehabilitation. We are in the midst of a major expansion of clinical and research services in the addictions, and the establishment of an academic Center of Excellence in Addiction Psychiatry. There are many clinical and translational research opportunities for trainees. This is an exciting time to join the UMass Addiction Psychiatry Program. Interested persons should contact: Gerardo Gonzalez, MD, Director of Addiction Psychiatry Fellowship Program, Department of Psychiatry, University of Massachusetts Medical School, 55 Lake Avenue North, Worcester, MA 01655. Call Diana Langford (508) 334-0577 or email gerardo.gonzalez@umassmed.edu AA/EOE

Addiction Psychiatry/Medicine Fellowships
Univ. of Cincinnati top teaching, clinical sites. VA Nat'l Center of Excellence. NIDA CTN, NIAAA trials. 1 (ACGME-accredited) or 2 yr. Robust benefits/pay. Dir: Shannon Miller, MD. www.psychiatry.uc.edu, kathleen.peak@va.gov

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Fellowship in Psychosomatic Medicine
M. D. Anderson Cancer Center and Baylor College of Medicine

Applications are currently being accepted for a unique Fellowship Program in Psychosomatic Medicine jointly sponsored by the Departments of Psychiatry at The University of Texas M. D. Anderson Cancer Center and the Baylor College of Medicine.

Based at M. D. Anderson Cancer Center and St. Luke's Episcopal Hospital at the Texas Medical Center, the program provides Fellows with clinical and didactic opportunities in all areas of psychosomatic medicine. In addition to clinical rotations with the medical psychiatry services at both hospitals, the Fellow will have an opportunity to work with the world-renowned palliative medicine and integrative medicine programs at M. D. Anderson Cancer Center.

The M. D. Anderson Cancer Center, rated as the number one comprehensive cancer center in the United States, is located within the Texas Medical Center - one of the largest and most interactive biomedical research communities in the world. The Texas Medical Center provides Fellows with a remarkably wide range of educational and research opportunities. As the fourth-largest city in the United States, Houston is a vibrant cultural center that offers an affordable and cosmopolitan lifestyle.

The one-year clinical Fellowship can be extended to a second research-oriented year during which time the Fellow will have an opportunity to develop research skills relevant to psychosomatic medicine.

Applicants must have completed an ACGME accredited Psychiatric Residency program and must meet requirements for board-eligibility in Adult Psychiatry for the American Board of Psychiatry and Neurology.

To apply, please complete the M D Anderson general fellowship "Discover" application form at http://discoverpostoffice.mdanderson.org. For further information, applicants should contact Dr. James Duffy, Fellowship Director, at UT M. D. Anderson Cancer Center; Department of Psychiatry - Unit 453; Post Office Box 301402, Houston, TX 77230-1402; (713) 563-4157. jduffy@mdanderson.org

M. D. Anderson Cancer Center is an equal opportunity employer and does not discriminate on the basis of race, color, national origin, gender, sexual orientation, age, religion, disability or veteran status except where such distinction is required by law. All positions at The University of Texas M. D. Anderson Cancer Center are security sensitive and subject to examination of criminal history record information. Smoke-free and drug-free environment.

Augusta, Georgia
Research Fellowship in Psychotic Disorders

The Medical College of Georgia, Department of Psychiatry and Health Behavior, has 1-2 year PGY-5 Schizophrenia Research Fellowship position, starting July, 2009. The fellow will be a psychiatrist who has completed residency and is eligible for Georgia license. Fellow will participate in psychopharmacological, genetic and epidemiological studies of schizophrenia with competitively funded mentors, attend national/international meetings and learn neurobiology research methods, statistics, and scientific writing. Augusta is an inexpensive and superb place to live.
See http://mcg.edu/som/psychiatry/fellowship.htm for more information. MCG is an equal employment, equal access and equal educational opportunity and affirmative action institution. It is the policy of the University to recruit, hire, train, promote and educate persons without regard to age, disability, gender, national origin, race, religion, sexual orientation or veteran status. Contact: Brian Kirkpatrick, M.D., bkirkpatrick@mail.mcg.edu.

INFANT PSYCHIATRY FELLOWSHIP. The Section of Child and Adolescent Psychiatry at Tulane University School of Medicine is seeking a full-time Fellow in Infant Psychiatry. This one or two year fellowship includes clinical and research experiences with the multidisciplinary Infant Mental Health group at Tulane. MD/DO required. Completion of a fellowship in Child and Adolescent Psychiatry preferred. Faculty appointment at the Instructor level with very competitive salary is possible. Applications will be accepted until a suitable qualified candidate is found. Applicants should send letter of interest, updated CV and list of references to Charles Zeanah MD, Vice Chair and Director of Child and Adolescent Psychiatry, 1440 Canal Street TB52, New Orleans, LA 70112. Interested eligible applicants may obtain further information regarding this position by contacting Dr. Zeanah at 504-988-5402 or czeanah@tulane.edu. Tulane is strongly committed to policies of nondiscrimination and affirmative action in student admission and in employment.

PSYCHOSOMATIC MEDICINE FELLOWSHIPS

2009-2010
NY Medical College/Westchester Med. Ctr.

FLEXIBLE STARTING TIME

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

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USF HEALTH

Geriatric Psychiatry Fellowship
with Emphasis on
Memory Disorder and Neuroscience Research

The Department of Psychiatry at the University of South Florida College of Medicine in Tampa, Florida, announces the availability of an innovative ACGME-accredited geriatric psychiatry fellowship position starting July 2009. With eight board certified geriatric psychiatrists, the geriatric psychiatry fellow will have dedicated experience in geriatric inpatient, long-term care, outpatient, ECT and memory disorders clinic at the James A. Haley VA Hospital and the Johnnie B. Byrd Sr. Alzheimer's Center and Research Institute. Located within the new USF Byrd Center and the James A. Haley VA Hospital, fellows in geriatric psychiatry will participate in a clinical milieu emphasizing understanding of the psychiatric aspects of medical conditions, along with special emphases on cognitive disorders. Fellows have the unusual opportunity through collaborative relationships to develop expertise working closely with faculty in the Florida ADRC, the Suncoast Gerontology Center, Department of Psychiatry, Geriatric Medicine and Neurology.

To apply for the position, please go to our website at http://health.usf.edu/medicine/psychiatry and download an application. Please fax your application, your personal statement, your CV and three letters of reference to 813-974-2478 or email at kisaac@health.usf.edu.

Or send by mail to
Maria Caserta, M.D., Ph.D.
Director, Geriatric Psychiatry
Training Program
Medical Director of the
Memory Disorders Clinic
Dept. of Psychiatry and Behavioral Medicine
University of South Florida
3515 E. Fletcher Ave, MDC14
Tampa, FL 33613

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 2, 2009 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/

Issue Deadlines:

Issue	Deadline
January 2	December 18
January 16	January 2
February 6	January 23
February 20	February 6
March 6	February 20
March 20	March 6
April 3	March 20
April 17	April 3
May 1	April 17
May 15	May 1

Contact: Pamela Trujilo,
703.907.7330 or classads@psych.org

DEPARTMENT OF VETERANS AFFAIRS SPECIAL FELLOWSHIP PROGRAM IN ADVANCED PSYCHIATRY

The Office of Academic Affiliations, Department of Veterans Affairs (VA), is now accepting applications for its two-year special Fellowship training program in Advanced Psychiatry. The ten Fellowship positions, one for each of ten VA Mental Illness Research, Education and Clinical Centers (MIRECC), begin between July 1st and Sept 1st, 2009. Each MIRECC Center is affiliated with an academic institution. This interdisciplinary program aims to train psychiatrists to become outstanding clinical researchers in high priority areas of mental health. Individualized, mentored research and clinical training is combined with a state-of-the-art curriculum that emphasizes research methods, statistics, epidemiology, mental health systems, quality improvement methods, education, and service delivery. Fellowship sites are linked electronically for didactic, academic, and research efforts. Fellows devote 75% of their time to research and education activities and 25% to clinical training. In collaboration with their mentors, Fellows will develop and implement a research project, publish and present findings, participate in grant writing, and utilize the latest technology for educational activities and clinical service delivery. Applicants must have completed ACGME accredited residency training, be board eligible or board certified, and have an active, unrestricted U.S. license to practice. International medical graduates must also have a current visa and an ECFMG certificate that is valid indefinitely. Applicants on a J-1 visa must have current ECFMG sponsorship as well. The VA funds Fellows' stipends in amounts based on previously completed ACGME accredited residency training. To apply for this post-residency Fellowship, contact the Fellowship Program Director at one of the following ten sites:

Bruce Rounsaville, MD, New Haven, CT - (203) 932-5711 x7401 or Bruce.Rounsaville@yale.edu
Bruce Levine, MD, The Bronx, NY - (718) 584.9000 x5204 or Bruce.Levine@va.gov
David Oslin, MD, Philadelphia, PA - (215) 823-5800 x5894 or Dave.Oslin@med.va.gov
Paul Ruskin, MD, Baltimore, MD - (410) 605-7000 x7354 or Paul.Ruskin@med.va.gov
Christine Marx, MD, Durham, NC - (919) 286-0411 x5112 or Christine.Marx@va.gov
Mark Kunik, MD, Houston, TX - (713) 794-8639 or Kunik.MarkE@va.gov
Hal Wortzel, MD, Denver, CO - (303) 399-8020 x5644 or Hal.Wortzel@va.gov
Elaine Peskind, MD, Seattle, WA - (206) 277-3965 or Elaine.Peskind@va.gov
J. Wesson Ashford, MD, Palo Alto, CA - (650) 493-5000 x64059 or Wes.Ashford@va.gov
Jonathan M. Meyer, MD, San Diego, CA - (858) 642-3570 or Jonathan.Meyer@va.gov

For other information, please contact Ruth O'Hara, Ph.D. or Sherry Beaudreau, Ph.D., at the Fellowship hub site, (650) 493-5000 x64119 or Sherry.Beaudreau@va.gov.

Residencies

R-4 OPENING

Albert Einstein College of Medicine at North Shore-LIJ Health Center, The Zucker Hillside Hospital, has an opening for an R-4 Resident beginning July 1, 2009.

To learn more about our program,
see our web site:
www.northshorelij.com/doaa.cfm?ID=10730

To inquire further about the position, please e-mail your Curriculum Vitae to Dorothy Winheim, Coordinator, at **dwinheim@lij.edu**. EOE.

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PGY-2, 4 & 5 TRAINING POSITIONS

Every year the Residency Program at **Yale University Department of Psychiatry** admits 4-6 residents at the **PGY-2** level. Additionally, we have several **PGY-4** and **PGY-5** level training positions. Start Date: July 1, 2009. Sites include the Connecticut Mental Health Center, Silver Hill Hospital, VA Connecticut Healthcare System, Yale New Haven Hospital and Yale University Health Service. Positions include inpatient, outpatient, ER and C-L. Each offers clinical and academic opportunities. For further information please call Ann Cohen DePalma at 203-785-2095.

Practice for Sale

Busy Adult and Geriatric psychiatric practice for sale: East Brunswick, NJ 08816 near medical school. 2 office condominiums for sale. Please call 732-257-9599 or 732-556-0836. Calls will be returned within 24 hours.

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Meetings & Conferences

The Northern California Psychiatric Society invites you to its **50th Annual Meeting and Scientific Program** to be held **Feb. 27 - Mar. 1, 2009 in Monterey, CA. Bob Post, MD** will speak on BDNF in affective disorders, **Terence Ketter, MD** will present on Bipolar Affective Disorder, and **Renée Binder, MD** will discuss the relationship between violence and mental illness. Other lectures include: Schizophrenia and Delusional Disorders, New Biology of Depression, Care of Psychiatrists and a panel discussion with **Nada Stotland, MD, MPH** about the relationship between medicine and the pharmaceutical industry.
For more information, call (415) 334-2418 ext. 105, or email rgeorgulas@ncps.org.

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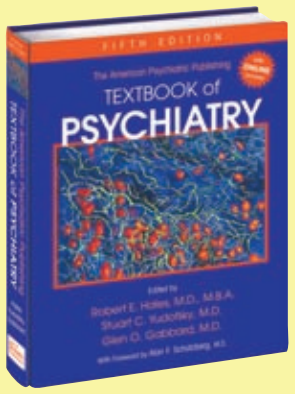

The American Psychiatric Publishing Textbook of Psychiatry

Edited by Robert E. Hales, M.D., M.B.A., Stuart C. Yudofsky, M.D., and Glen O. Gabbard, M.D.

With Foreword by Alan F. Schatzberg, M.D.

The American Psychiatric Publishing Textbook of Psychiatry has been meticulously revised to maintain its preeminence as an accessible and authoritative educational reference and clinical compendium. More than 100 contributors–65 new to this edition–summarize the latest developments in psychiatry, with new chapters on cellular and molecular biology; neuroanatomy; human sexuality and sexual dysfunctions; nonpharmacological somatic treatments; supportive psychotherapy; combined psychotherapy and pharmacotherapy; treatment of gay, lesbian, bisexual, and transgender patients; and assessment of dangerousness.

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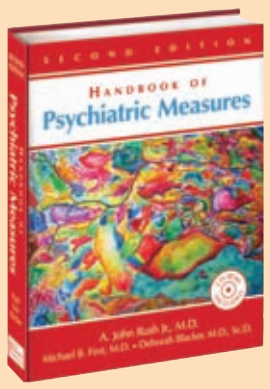

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Edited by A. John Rush Jr., M.D., Michael B. First, M.D., and Deborah Blacker, M.D., Sc.D.

This book offers a concise summary of key evaluations that clinicians can use to enhance the quality of patient care. It contains more than 275 rating methods, from the Abnormal Involuntary Movement Scale to the Zung Self-Rating Depression Scale.

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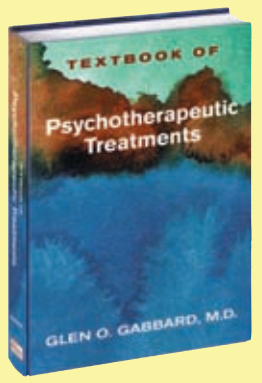

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Edited by Glen O. Gabbard, M.D.

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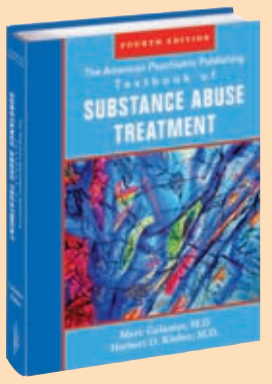

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Edited by Marc Galanter, M.D., and Herbert D. Kleber, M.D.

This book has been fully updated to present the most current scientific and clinical information on a wide range of substance use disorders, from tobacco and alcohol to methamphetamine and "club drug" abuse. It is a comprehensive guide to treatment written at a level appropriate to both experienced and new clinicians, reflecting the expertise of leading addiction specialists in psychiatry and allied fields. With most chapters extensively revised by new authors, it incorporates the latest biomedical research findings as well as recent advances in treatment modalities and the growth of pharmacotherapies.

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INDICATIONS AND USAGE ARICEPT® is indicated for the treatment of dementia of the Alzheimer's type. Efficacy has been demonstrated in patients with mild to moderate Alzheimer's Disease, as well as in patients with severe Alzheimer's Disease. **CONTRAINDICATIONS** ARICEPT® is contraindicated in patients with known hypersensitivity to donepezil hydrochloride or to piperidine derivatives. **WARNINGS *Anesthesia:*** ARICEPT®, as a cholinesterase inhibitor, is likely to exaggerate succinylcholine-type muscle relaxation during anesthesia. ***Cardiovascular Conditions:*** Because of their pharmacological action, cholinesterase inhibitors may have vagotonic effects on the sinoatrial and atrioventricular nodes. This effect may manifest as bradycardia or heart block in patients both with and without known underlying cardiac conduction abnormalities. Syncopal episodes have been reported in association with the use of ARICEPT®. ***Gastrointestinal Conditions:*** Through their primary action, cholinesterase inhibitors may be expected to increase gastric acid secretion due to increased cholinergic activity. Therefore, patients should be monitored closely for symptoms of active or occult gastrointestinal bleeding, especially those at increased risk for developing ulcers, e.g., those with a history of ulcer disease or those receiving concurrent nonsteroidal anti-inflammatory drugs (NSAIDS). Clinical studies of ARICEPT® have shown no increase, relative to placebo, in the incidence of either peptic ulcer disease or gastrointestinal bleeding. ARICEPT®, as a predictable consequence of its pharmacological properties, has been shown to produce diarrhea, nausea and vomiting. These effects, when they occur, appear more frequently with the 10 mg/day dose than with the 5 mg/day dose. In most cases, these effects have been mild and transient, sometimes lasting one to three weeks, and have resolved during continued use of ARICEPT®. ***Genitourinary:*** Although not observed in clinical trials of ARICEPT®, cholinomimetics may cause bladder outflow obstruction. ***Neurological Conditions:*** Seizures: Cholinomimetics are believed to have some potential to cause generalized convulsions. However, seizure activity also may be a manifestation of Alzheimer's Disease. ***Pulmonary Conditions:*** Because of their cholinomimetic actions, cholinesterase inhibitors should be prescribed with care to patients with a history of asthma or obstructive pulmonary disease. **PRECAUTIONS Drug-Drug Interactions** (see Clinical Pharmacology: Clinical Pharmacokinetics: Drug-drug Interactions) ***Effect of ARICEPT® on the Metabolism of Other Drugs:*** No *in vivo* clinical trials have investigated the effect of ARICEPT® on the clearance of drugs metabolized by CYP 3A4 (e.g. cisapride, terfenadine) or by CYP 2D6 (e.g. imipramine). However, *in vitro* studies show a low rate of binding to these enzymes (mean K_i about 50-130 μM), that, given the therapeutic plasma concentrations of donepezil (164 nM), indicates little likelihood of interference. Whether ARICEPT® has any potential for enzyme induction is not known. Formal pharmacokinetic studies evaluated the potential of ARICEPT® for interaction with theophylline, cimetidine, warfarin, digoxin and ketoconazole. No effects of ARICEPT® on the pharmacokinetics of these drugs were observed. ***Effect of Other Drugs on the Metabolism of ARICEPT®:*** Ketoconazole and quinidine, inhibitors of CYP450, 3A4 and 2D6, respectively, inhibit donepezil metabolism *in vitro*. Whether there is a clinical effect of quinidine is not known. In a 7-day crossover study in 18 healthy volunteers, ketoconazole (200 mg q.d.) increased mean donepezil (5 mg q.d.) concentrations (AUC_{0-24} and C_{max}) by 36%. The clinical relevance of this increase in concentration is unknown. Inducers of CYP 2D6 and CYP 3A4 (e.g., phenytoin, carbamazepine, dexamethasone, rifampin, and phenobarbital) could increase the rate of elimination of ARICEPT®. Formal pharmacokinetic studies demonstrated that the metabolism of ARICEPT® is not significantly affected by concurrent administration of digoxin or cimetidine. ***Use with Anticholinergics:*** Because of their mechanism of action, cholinesterase inhibitors have the potential to interfere with the activity of anticholinergic medications. ***Use with Cholinomimetics and Other Cholinesterase Inhibitors:*** A synergistic effect may be expected when cholinesterase inhibitors are given concurrently with succinylcholine, similar neuromuscular blocking agents or cholinergic agonists such as bethanechol. **Carcinogenesis, Mutagenesis, Impairment of Fertility** No evidence of a carcinogenic potential was obtained in an 88-week carcinogenicity study of donepezil hydrochloride conducted in CD-1 mice at doses up to 180 mg/kg/day (approximately 90 times the maximum recommended human dose on a mg/m² basis), or in a 104-week carcinogenicity study in Sprague-Dawley rats at doses up to 30 mg/kg/day (approximately 30 times the maximum recommended human dose on a mg/m² basis). Donepezil was not mutagenic in the Ames reverse mutation assay in bacteria, or in a mouse lymphoma forward mutation assay *in vitro*. In the chromosome aberration test in cultures of Chinese hamster lung (CHL) cells, some clastogenic effects were observed. Donepezil was not clastogenic in the *in vivo* mouse micronucleus test and was not genotoxic in an *in vivo* unscheduled DNA synthesis assay in rats. Donepezil had no effect on fertility in rats at doses up to 10 mg/kg/day (approximately 8 times the maximum recommended human dose on a mg/m² basis). **Pregnancy *Pregnancy Category C:*** Teratology studies conducted in pregnant rats at doses up to 16 mg/kg/day (approximately 13 times the maximum recommended human dose on a mg/m² basis) and in pregnant rabbits at doses up to 10 mg/kg/day (approximately 16 times the maximum recommended human dose on a mg/m² basis) did not disclose any evidence for a teratogenic potential of donepezil. However, in a study in which pregnant rats were given up to 10 mg/kg/day (approximately 8 times the maximum recommended human dose on a mg/m² basis) from day 17 of gestation through day 20 postpartum, there was a slight increase in still births and a slight decrease in pup survival through day 4 postpartum at this dose; the next lower dose tested was 3 mg/kg/day. There are no adequate or well-controlled studies in pregnant women. ARICEPT® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers** It is not known whether donepezil is excreted in human breast milk. ARICEPT® has no indication for use in nursing mothers. **Pediatric Use** There are no adequate and well-controlled trials to document the safety and efficacy of ARICEPT® in any illness occurring in children. **Geriatric Use** Alzheimer's disease is a disorder occurring primarily in individuals over 55 years of age. The mean age of the patients enrolled in the clinical studies with ARICEPT® was 73 years; 80% of these patients were between 65 and 84 years old and 49% of the patients were at or above the age of 75. The efficacy and safety data presented in the clinical trials section were obtained from these patients. There were no clinically significant differences in most adverse events reported by patient groups ≥65 years old and <65 years old. **ADVERSE REACTIONS *Mild To Moderate Alzheimer's Disease* Adverse Events Leading to Discontinuation** The rates of discontinuation from controlled clinical trials of ARICEPT® due to adverse events for the ARICEPT® 5 mg/day treatment groups were comparable to those of placebo-treatment groups at approximately 5%. The rate of discontinuation of patients who received 7-day escalations from 5 mg/day to 10 mg/day, was higher at 13%. The most common adverse events leading to discontinuation, defined as those occurring in at least 2% of patients and at twice the incidence seen in placebo patients, are shown in Table 1. **Table 1. Most Frequent Adverse Events Leading to Withdrawal from Controlled Clinical Trials by Dose Group (Placebo, 5 mg/day ARICEPT®, and 10 mg/day ARICEPT®, respectively); Patients Randomized (355, 350, 315); Event/% Discontinuing:** Nausea (1%, 1%, 3%); Diarrhea (0%, <1%, 3%); Vomiting (<1%, <1%, 2%). **Most Frequent Adverse Clinical Events Seen in Association with the Use of ARICEPT®.** The most common adverse events, defined as those occurring at a frequency of at least 5% in patients receiving 10 mg/day and twice the placebo rate, are largely predicted by ARICEPT®'s cholinomimetic effects. These include nausea, diarrhea, insomnia, vomiting, muscle cramp, fatigue and anorexia. These adverse events were often of mild intensity and transient, resolving during continued ARICEPT® treatment without the need for dose modification. There is evidence to suggest that the frequency of these common adverse events may be affected by the rate of titration. An open-label study was conducted with 269 patients who received placebo in the 15 and 30-week studies. These patients were titrated to a dose of 10 mg/day over a 6-week period. The rates of common adverse events were lower than those seen in patients titrated to 10 mg/day over one week in the controlled clinical trials and were comparable to those seen in patients on 5 mg/day. See Table 2 for a comparison of the most common adverse events following one and six week titration regimens. **Table 2. Comparison of rates of adverse events in patients titrated to 10 mg/day over 1 and 6 weeks (No titration: Placebo [n=315], No titration: 5 mg/day [n=311], One week titration: 10 mg/day [n=315], Six week titration: 10 mg/day [n=269], respectively):** Nausea (6%, 5%, 19%, 6%); Diarrhea (5%, 8%, 15%, 9%); Insomnia (6%, 6%, 14%, 6%); Fatigue (3%, 4%, 8%, 3%); Vomiting (3%, 3%, 8%, 5%); Muscle cramps (2%, 6%, 8%, 3%); Anorexia (2%, 3%, 7%, 3%). **Adverse Events Reported in Controlled Trials** The events cited reflect experience gained under closely monitored conditions of clinical trials in a highly selected patient population. In actual clinical practice or in other clinical trials, these frequency estimates may not apply, as the conditions of use, reporting behavior, and the kinds of patients treated may differ. Table 3 lists treatment emergent signs and symptoms that were reported in at least 2% of patients in placebo-controlled trials who received ARICEPT® and for which the rate of occurrence was greater for ARICEPT® assigned than placebo assigned patients. In general, adverse events occurred more frequently in female patients and with advancing age. **Table 3. Adverse Events Reported in Controlled Clinical Trials in Mild to Moderate Alzheimer's Disease in at Least 2% of Patients Receiving ARICEPT® and at a Higher Frequency than Placebo-treated Patients (Body System/Adverse Event: Placebo [n=355], ARICEPT® [n=747], respectively): Percent of Patients with any Adverse Event: 72, 74. Body as a Whole:** Headache (9, 10); Pain, various locations (8, 9); Accident (6, 7); Fatigue (3, 5). **Cardiovascular System:** Syncope (1, 2). **Digestive System:** Nausea (6, 11); Diarrhea (5, 10); Vomiting (3, 5); Anorexia (2, 4). **Hemic and Lymphatic System:** Ecchymosis (3, 4). **Metabolic and Nutritional Systems:** Weight Decrease (1, 3). **Musculoskeletal System:** Muscle Cramps (2, 6); Arthritis (1, 2). **Nervous System:** Insomnia (6, 9); Dizziness (6, 8); Depression (<1, 3); Abnormal Dreams (0, 3); Somnolence (<1, 2). **Urogenital System:** Frequent Urination (1, 2). **Other Adverse Events Observed During Clinical Trials.** ARICEPT® has been administered to over 1700 individuals during clinical trials worldwide. Approximately 1200 of these patients have been treated for at least 3 months and more than 1000 patients have been treated for at least 6 months. Controlled and uncontrolled trials in the United States included approximately 900 patients. In regards to the highest dose of 10 mg/day, this population includes 650 patients treated for 3 months, 475 patients treated for 6 months and 116 patients treated for over 1 year. The range of patient exposure is from 1 to 1214 days. Treatment emergent signs and symptoms that occurred during 3 controlled clinical trials and two open-label trials in the United States 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 a modified COSTART dictionary and event frequencies were calculated across all studies. These categories are used in the listing below. The frequencies represent the proportion of 900 patients from these trials who experienced that event while receiving ARICEPT®. All adverse events occurring at least twice are included, except for those already listed in Tables 2 or 3, COSTART terms too general to be informative, or events less likely to be drug caused. 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 ARICEPT® treatment and in most cases were observed at a similar frequency in placebo-treated patients in the controlled studies. No important additional adverse events were seen in studies conducted outside the United States. **Body as a Whole:** *Frequent:* influenza, chest pain, toothache; *Infrequent:* fever, edema face, periorbital edema, hernia hiatal, abscess, cellulitis, chills, generalized coldness, head fullness, listlessness. **Cardiovascular System:** *Frequent:* hypertension, vasodilation, atrial fibrillation, hot flashes, hypotension; *Infrequent:* angina pectoris, postural hypotension, myocardial infarction, AV block (first degree), congestive heart failure, arteritis, bradycardia, peripheral vascular disease, supraventricular tachycardia, deep vein thrombosis. **Digestive System:** *Frequent:* fecal incontinence, gastrointestinal bleeding, bloating, epigastric pain; *Infrequent:* eructation, gingivitis, increased appetite, flatulence, periodontal abscess, cholelithiasis, diverticulitis, drooling, dry mouth, fever sore, gastritis, irritable colon, tongue edema, epigastric distress, gastroenteritis, increased transaminases, hemorrhoids, ileus, increased thirst, jaundice, melena, polydipsia, duodenal ulcer, stomach ulcer. **Endocrine System:** *Infrequent:* diabetes mellitus, goiter. **Hemic and Lymphatic System:** *Infrequent:* anemia, thrombocythemia, thrombocytopenia, eosinophilia, erythrocytopenia. **Metabolic and Nutritional Disorders:** *Frequent:* dehydration; *Infrequent:* gout, hypokalemia, increased creatine kinase, hyperglycemia, weight increase, increased lactate dehydrogenase. **Musculoskeletal System:** *Frequent:* bone fracture; *Infrequent:* muscle weakness, muscle fasciculation. **Nervous System:** *Frequent:* delusions, tremor, irritability, paresthesia, aggression, vertigo, ataxia, increased libido, restlessness, abnormal crying, nervousness, aphasia; *Infrequent:* cerebrovascular accident, intracranial hemorrhage, transient ischemic attack, emotional lability, neuralgia, coldness (localized), muscle spasm, dysphoria, gait abnormality, hypertonia, hypokinesia, neurodermatitis, numbness (localized), paranoia, dysarthria, dysphasia, hostility, decreased libido, melancholia, emotional withdrawal, nystagmus, pacing. **Respiratory System:** *Frequent:* dyspnea, sore throat, bronchitis; *Infrequent:* epistaxis, post nasal drip, pneumonia, hyperventilation, pulmonary congestion, wheezing, hypoxia, pharyngitis, pleurisy, pulmonary collapse, sleep apnea, snoring. **Skin and Appendages:** *Frequent:* pruritus, diaphoresis, urticaria; *Infrequent:* dermatitis, erythema, skin discoloration, hyperkeratosis, alopecia, fungal dermatitis, herpes zoster, hirsutism, skin striae, night sweats, skin ulcer. **Special Senses:** *Frequent:* cataract, eye irritation, vision blurred; *Infrequent:* dry eyes, glaucoma, earache, tinnitus, blepharitis, decreased hearing, retinal hemorrhage, otitis externa, otitis media, bad taste, conjunctival hemorrhage, ear buzzing, motion sickness, spots before eyes. **Urogenital System:** *Frequent:* urinary incontinence, nocturia; *Infrequent:* dysuria, hematuria, urinary urgency, metrorrhagia, cystitis, enuresis, prostate hypertrophy, pyelonephritis, inability to empty bladder, breast fibroadenosis, fibrocystic breast, mastitis, pyuria, renal failure, vaginitis. ***Severe Alzheimer's Disease* Adverse Events Leading to Discontinuation:** The rates of discontinuation from controlled clinical trials of ARICEPT® due to adverse events for the ARICEPT® patients were approximately 12% compared to 7% for placebo patients. The most common adverse events leading to discontinuation, defined as those occurring in at least 2% of ARICEPT® patients and at twice the incidence seen in placebo patients, were anorexia (2% vs 1% placebo), nausea (2% vs <1% placebo), diarrhea (2% vs 0% placebo), and urinary tract infection (2% vs 1% placebo). **Most Frequent Adverse Clinical Events Seen in Association with the Use of ARICEPT®** The most common adverse events, defined as those occurring at a frequency of at least 5% in patients receiving ARICEPT® and twice the placebo rate, are largely predicted by ARICEPT®'s cholinomimetic effects. These include diarrhea, anorexia, vomiting, nausea, and ecchymosis. These adverse events were often of mild intensity and transient, resolving during continued ARICEPT® treatment without the need for dose modification. **Adverse Events Reported in Controlled Trials** Table 4 lists treatment emergent signs and symptoms that were reported in at least 2% of patients in placebo-controlled trials who received ARICEPT® and for which the rate of occurrence was greater for ARICEPT® assigned than placebo assigned patients. **Table 4. Adverse Events Reported in Controlled Clinical Trials in Severe Alzheimer's Disease in at Least 2% of Patients Receiving ARICEPT® and at a Higher Frequency than Placebo-treated Patients (Body System/Adverse Event: Placebo [n=392], ARICEPT® [n=501], respectively): Percent of Patients with any Adverse Event: 73, 81. Body as a Whole:** Accident (12, 13); Infection (9, 11); Headache (3, 4); Pain (2, 3); Back Pain (2, 3); Fever (1, 2); Chest Pain (<1, 2). **Cardiovascular System:** Hypertension (2, 3); Hemorrhage (1, 2); Syncope (1, 2). **Digestive System:** Diarrhea (4, 10); Vomiting (4, 8); Anorexia (4, 8); Nausea (2, 6). **Hemic and Lymphatic System:** Ecchymosis (2, 5). **Metabolic and Nutritional Systems:** Creatine Phosphokinase Increased (1, 3); Dehydration (1, 2); Hyperlipemia (<1, 2). **Nervous System:** Insomnia (4, 5); Hostility (2, 3); Nervousness (2, 3); Hallucinations (1, 3); Somnolence (1, 2); Dizziness (1, 2); Depression (1, 2); Confusion (1, 2); Emotional Lability (1, 2); Personality Disorder (1, 2). **Skin and Appendages:** Eczema (2, 3). **Urogenital System:** Urinary Incontinence (1, 2). **Other Adverse Events Observed During Clinical Trials** ARICEPT® has been administered to over 600 patients with severe Alzheimer's Disease during clinical trials of at least 6 months duration, including 3 double blind placebo controlled trials, one of which had an open label extension. All adverse events occurring at least twice are included, except for those already listed in Table 4, COSTART terms too general to be informative, or events less likely to be drug caused. Events are classified by body system using the COSTART dictionary 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 ARICEPT® treatment and in most cases were observed at a similar frequency in placebo-treated patients in the controlled studies. **Body as a Whole:** *Frequent:* abdominal pain, asthenia, fungal infection, flu syndrome; *Infrequent:* allergic reaction, cellulitis, malaise, sepsis, face edema, hernia. **Cardiovascular System:** *Frequent:* hypotension, bradycardia, ECG abnormal, heart failure; *Infrequent:* myocardial infarction, angina pectoris, atrial fibrillation, congestive heart failure, peripheral vascular disorder, supraventricular extrasystoles, ventricular extrasystoles, cardiomegaly. **Digestive System:** *Frequent:* constipation, gastroenteritis, fecal incontinence, dyspepsia; *Infrequent:* gamma glutamyl transpeptidase increase, gastritis, dysphagia, periodontitis, stomach ulcer, periodontal abscess, flatulence, liver function tests abnormal, eructation, esophagitis, rectal hemorrhage. **Endocrine System:** *Infrequent:* diabetes mellitus. **Hemic and Lymphatic System:** *Frequent:* anemia; *Infrequent:* leukocytosis. **Metabolic and Nutritional Disorders:** *Frequent:* weight loss, peripheral edema, edema, lactic dehydrogenase increased, alkaline phosphatase increased; *Infrequent:* hypercholesteremia, hypokalemia, hypoglycemia, weight gain, bilirubinemia, BUN increased, B_{12} deficiency anemia, cachexia, creatinine increased, gout, hyponatremia, hypoproteinemia, iron deficiency anemia, SGOT increased, SGPT increased. **Musculoskeletal System:** *Frequent:* arthritis; *Infrequent:* arthrosis, bone fracture, arthralgia, leg cramps, osteoporosis, myalgia. **Nervous System:** *Frequent:* agitation, anxiety, tremor, convulsion, wandering, abnormal gait; *Infrequent:* apathy, vertigo, delusions, abnormal dreams, cerebrovascular accident, increased salivation, ataxia, euphoria, vasodilatation, cerebral hemorrhage, cerebral infarction, cerebral ischemia, dementia, extrapyramidal syndrome, grand mal convulsion, hemiplegia, hypertonia, hypokinesia. **Respiratory System:** *Frequent:* pharyngitis, pneumonia, cough increased, bronchitis; *Infrequent:* dyspnea, rhinitis, asthma. **Skin and Appendages:** *Frequent:* rash, skin ulcer, pruritus; *Infrequent:* psoriasis, skin discoloration, herpes zoster, dry skin, sweating, urticaria, vesiculobullous rash. **Special Senses:** *Infrequent:* conjunctivitis, glaucoma, abnormal vision, ear pain, lacrimation disorder. **Urogenital System:** *Frequent:* urinary tract infection, cystitis, hematuria, glycosuria; *Infrequent:* vaginitis, dysuria, urinary frequency, albuminuria. **Postintroduction Reports** Voluntary reports of adverse events temporally associated with ARICEPT® that have been received since market introduction that are not listed above, and that there is inadequate data to determine the causal relationship with the drug include the following: abdominal pain, agitation, cholecystitis, confusion, convulsions, hallucinations, heart block (all types), hemolytic anemia, hepatitis, hyponatremia, neuroleptic malignant syndrome, pancreatitis, and rash. **OVERDOSAGE Because strategies for the management of overdose are continually evolving, it is advisable to contact a Poison Control Center to determine the latest recommendations for the management of an overdose of any drug.** As in any case of overdose, general supportive measures should be utilized. Overdosage with cholinesterase inhibitors can result in cholinergic crisis characterized by severe nausea, vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, collapse and convulsions. Increasing muscle weakness is a possibility and may result in death if respiratory muscles are involved. Tertiary anticholinergics such as atropine may be used as an antidote for ARICEPT® overdosage. Intravenous atropine sulfate titrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV with subsequent doses based upon clinical response. Atypical responses in blood pressure and heart rate have been reported with other cholinomimetics when co-administered with quaternary anticholinergics such as glycopyrrolate. It is not known whether ARICEPT® and/or its metabolites can be removed by dialysis (hemodialysis, peritoneal dialysis, or hemofiltration). Dose-related signs of toxicity in animals included reduced spontaneous movement, prone position, staggering gait, lacrimation, clonic convulsions, depressed respiration, salivation, miosis, tremors, fasciculation and lower body surface temperature.

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START AND STAY WITH ARICEPT®

Indicated for
MILD · MODERATE · SEVERE
Alzheimer's

Proven Efficacy for Patients...

- Improved behavior in mild to moderate AD[1]*
- Persistent treatment helped delay nursing home placement[2†]

and Benefits for Caregivers

- Caregivers of ARICEPT patients with mild to moderate AD experienced significantly less distress from patient behavioral problems[1]*

*The primary end point was the Neuropsychiatric Inventory (NPI); secondary measures included the Neuropsychiatric Inventory-Distress (NPI-D).
†As with observational follow-up studies of this type, results may be attributable to various factors. ARICEPT treatment was one such factor.

Important safety information

Cholinesterase inhibitors have the potential to increase gastric acid secretion. Patients at risk for developing ulcers, including those receiving concurrent NSAIDs, should be monitored closely for gastrointestinal bleeding.

In clinical trials, syncopal episodes have been reported (2% for ARICEPT versus 1% for placebo).

In clinical trials, the most common adverse events seen with ARICEPT were nausea, diarrhea, insomnia, vomiting, muscle cramps, fatigue, anorexia, and ecchymosis. In studies, these were usually mild and transient.

Please see brief summary of prescribing information on adjacent page.

References: 1. Holmes C, Wilkinson D, Dean C, et al. The efficacy of donepezil in the treatment of neuropsychiatric symptoms in Alzheimer disease. *Neurology*. 2004;63:214-219. **2.** Geldmacher DS, Provenzano G, McRae T, Mastey V, Ieni JR. Donepezil is associated with delayed nursing home placement in patients with Alzheimer's disease. *J Am Geriatr Soc*. 2003;51:937-944.

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