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Newspaper of the
American
Psychiatric
Association

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TIME-SENSITIVE MATERIALS

Credit: Capital Area Human Services District

Louisiana's Capital Area Human Services District maintained delivery of services after Hurricane Gustav despite losing the roof over its adult and child mental health clinic, developmental disabilities site, and administrative offices in suburban Baton Rouge. See story on page 14.

APA Announces Candidates For 2009 Election

APA members may have to show more due diligence than usual in deciding on their choices in the 2009 election, as several positions feature three-way races.

BY KEN HAUSMAN

The APA Nominating Committee last month announced the candidates who will compete in the 2009 election and, in a rare move, set up three-way candidate races for president-elect and vice president. There are also three candidates running for member-in-training trustee-elect, who are chosen through a different process.

APA Vice President Carol Bernstein, M.D., of New York, N.Y.; former Assembly Speaker Michael Blumenfield, M.D., of Woodland Hills, Calif.; and Trustee-at-Large Roger Peele, M.D., of Rockville, Md., will vie for the president-elect post.

Competing to replace Bernstein as vice president will be Jeffrey Akaka, M.D., of Honolulu; Jeffrey Geller, M.D., of Worcester, Mass.; and Sidney Weissman, M.D., of Chicago. Akaka is the immediate past speaker of the Assembly, Geller is the Area 1 representative on the Board of Trustees, and Weissman is the Board's Area 4 representative.

Each year one of the Board's three at-large trustee positions is up for election, and this year it is the one designated for an early career psychiatrist. The candidates for this post are Joyce Spurgeon, M.D., of Sellersburg, Ind., and Harsh Trevedi, M.D., of Riverside, R.I. Spurgeon is chair of the Kentucky district branch's Membership Committee and a consultant to the Scientific Program Committee. Trevedi is on the Board of Directors of APA's political action committee, APA*PAC*, and a consultant to the Council on Advocacy and Public Policy.

Areas 1, 4, and 7 will each also choose a trustee in the 2009 election. The nominees for Area trustee positions are chosen by their Area councils, rather than the APA Nominating Committee.

The Area 1 Council has nominated Robert Feder, M.D, of Manchester, N.H., and Frederick Stoddard, M.D., of Boston.

Area 4's nominees are John Wernert, M.D., of Indianapolis and Sul Ross Thorward, M.D., of Columbus, Ohio.

Vying to be Area 7 trustee are Con-

please see ***Candidates*** *on page 10*

Spike in Youth Suicides Spurs Search for Causes

The national rate of suicide deaths among 10- to 19-year-olds in 2005 confirms that the uptick in 2004 was not a random phenomenon but may be a troubling trend.

BY JUN YAN

The suicide rate of U.S. youth remains elevated after a decade of decline that ended in 2003, according to a study in the September 3 *Journal of the American Medical Association*.

In this study, researchers led by Jeffrey Bridge, Ph.D., a principal investigator at the Research Institute at Nationwide Children's Hospital and an assistant professor at the Ohio State University College of Medicine, analyzed 1996-2005 data on suicide deaths of youngsters aged 10 to 19 and found, after the spike in 2004, that the suicide rate dropped slightly but remained significantly higher than the trend in previous years.

The estimated rate of suicide deaths in 10- to 19-year-olds was 4.49 per 100,000 in 2005, a small reduction from 4.74 per 100,000 in 2004 but still significantly higher than the projected rate based on the steadily declining trend from 1996 to 2003.

The analysis used data from the National Center for Injury Prevention and Control, a division of the Centers for Disease Control and Prevention (CDC).

After years of decline, the suicide death rate in youth rose in 2003 and more sharply in 2004, according to the CDC's announcement last year (*Psychiatric News*, October 5, 2007). The 18 percent increase from 2003 to 2004 had been the highest one-year jump in the previous 15 years. The unexpected spike caused heated debates over its causes, and many, including the Food and Drug Administration (FDA), were unsure whether this was an isolated incident. The new study suggests that the elevated trend persisted in 2005 and thus may not be an anomaly.

please see ***Suicides*** *on page 23*

Petition Reminder

APA members thinking about running by petition in APA's 2009 election are asked to contact Mary Histing by e-mail at mhisting@psych.org or phone at (703) 907-8557. Petitions must by received by **Wednesday, October 15.**

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PSYCHIATRIC NEWS

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Ethics Experts Challenge Army's Interrogation Participation Memo

A recently revealed Army memo on psychiatrists' role in interrogation does not reflect APA's position on the subject.

BY AARON LEVIN

Psychiatrists and other physicians must not take part in interrogations of persons detained by military authorities, according to both an APA position statement and AMA ethics guidelines, but a recently revealed Department of Defense policy memorandum "seeks to undermine the positions taken by the AMA and APA concerning physicians' monitoring of interrogations," said a Perspective in the September 11 *New England Journal of Medicine*.

The memorandum was signed by the then-Army Surgeon General Lt. Gen. Kevin Kiley, M.C., in October 2006, but it applies to all branches of the armed services.

The Army memo "fails to mention the APA statement and provides a permissive gloss on the AMA's policy, at some points contradicting it outright," wrote Jonathan H. Marks, M.A., B.C.L., and M. Gregg Bloche, M.D., J.D. Marks is an associate professor of bioethics, humanities, and law at the Pennsylvania State University at University Park and at the College of Medicine in Hershey, and a barrister and academic member of Matrix Chambers, London. Bloche is a professor of law at Georgetown University and a nonresident senior fellow at the Brookings Institution in Washington, D.C., and an adjunct professor at the Bloomberg School of Public Health at Johns Hopkins University.

The APA statement, approved by APA's Board of Trustees in May 2006, states, in part: "No psychiatrist should participate directly in the interrogation of persons held in custody by military or civilian investigative or law enforcement authorities, whether in the United States or elsewhere. Direct participation includes being present in the interrogation room, asking or suggesting questions, or advising authorities on the use of specific techniques of interrogation with particular detainees."

While Marks and Bloche credited the Army with prohibiting torture or other illegal treatment of detainees, they argued that the Army memo's wording introduces confusion about the ethical obligations of health professionals—including psychiatrists—who function as consultants during interrogations (see box on page 27).

The confusion is most explicit in the contrast between the organizations' statements against involvement in interrogation and the Army memo, which says: "[Psychologists and psychiatrists] must regularly monitor their behavior and remain within professional ethical boundaries as established by their professional associations, by their licensing State, and by the military."

"Such consulting undermines their role as physicians," said Marks in an interview.

Through a Freedom of Information Act request, the authors asked the Army to provide documents relating to health professionals' role on Behavioral Science Consultation Teams, the military term for "operational psychologists and psychiatrists . . . essential in developing integrated interrogation strategies and assessing interrogation intelligence production."

please see ***Interrogation*** *on page 27*

Nominations Invited

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

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

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

APA RESOURCES

- ***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
- **APA Web Site:** www.psych.org
- **APA Job Bank:** www.psych.org/jobbank
- **Managed Care Help Line:** (800) 343-4671
- **Member2Member List Serve (M2M):** www.psych.org/apa_members/list serves.cfm
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Feelings About Pharma

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

Credit: David Hathcox

In the September 5 *Psychiatric News*, I described APA's response to Sen. Charles Grassley's request for information about every kind of revenue that APA has received from the pharmaceutical industry, and I asked for your opinions. (Unfortunately, the APA members-only Web site link to the cover letter that accompanied the 50-page report to Sen. Grassley, which outlines the issues and the contents, was not functional at the time of that column; you can read that letter now at <http://psych.org/MainMenu/Newsroom/APAMemberDBSAResources/GrassleyLetter.aspx>. I heard from many of you. This is not a random sample; probably those with the strongest feelings took the time to write. Nevertheless, the messages reflect the wide range of attitudes among our members. I thought I would give you a sampling from those messages. Although these were not confidential communications, members were not advised that their messages might be printed, and therefore I have omitted their names. I have also corrected the occasional typographical error.

A few members expressed indignation over what they considered to be prejudicial and unwarranted criticism of psychiatrists and APA.

The predominant view is reflected in the following quotes:

• "I would be in favor of eliminating all sources of income from the pharmaceutical companies even if this meant eliminating fellowships, antistigma campaigns, education funding, etc. I believe that we as a profession would do well to eliminate even the potential appearance of a conflict of interest."

• "The APA annual meeting provides a great chance to take courses which are not industry sponsored. As a private practitioner I have to pay for my own CMEs . . . and feel free to make decisions regarding medications based on scientific evidence . . . but have felt like the lone voice in the wilderness.

"I am dismayed that so many colleagues I know rely on 'free' CME courses, feel entitled to gifts from industry, continue to believe they prescribe without bias. . . .

"Let's go back to training ourselves. . . . The ties to industry were the most important reason why I did not belong to the APA for almost 20 years . . . and I joined back up when I saw that the APA was moving away from that position."

Several members urged moderation. For example, two messages reminded us to consider context.

• "In considering guidelines, please consider rural psychiatrists without access to grand rounds."

• "When you see many people who are 'dumped out' of the . . . hospital or jail, . . . the samples that the . . . pharmacy companies provide are a gift from God . . . . If Sen. Grassley or others want to really help, fix this and we will all come out ahead. . . . Please keep hammering this point to all the politically correct people who only talk about one side of this dynamic relationship. . . ."

One message asserted that the profit motive is part of human nature, that physicians are not immune, and that medicine's relationships with pharma can be beneficial.

• "APA must work with the drug companies . . . to make sure the work benefits the patients, . . . research, and care . . . . If not for the industry-supported symposia and activities, APA convention . . . activities would not have attracted the attention they have. . . . Make sure we do not destroy the relationship to foster a quasi-ethical relationship . . . . Medicine . . . will not survive or grow if deprived of all the financial . . . frills, bells, and whistles. . . . How can we take financial . . . incentives from medicine, . . . government, or any human venture?"

Another writer saw the situation as an opportunity to broaden, or perhaps refresh, our vision:

• " . . . Having to reflect on how much we depend on . . . pharmaceutical companies can be taken as an opportunity to consider what else besides . . . medication psychiatrists have to offer. . . . We could research a lot more on prevention of mental illness and fostering mental health if our mindset was more focused on the whole individual rather than the brain . . . . Using medication alone is limiting our possibilities of . . . helping a patient master his/her difficulties in life. We can take this opportunity to learn to give medication its proper place in the treatment of a patient."

Thanks to everyone who wrote. I am proud, but not surprised, that every message focused on the welfare of our patients. I am heartened that many of you think APA is heading in the right direction. Our healthy self-examination preceded any inquiry from outside. As one member proclaimed:

• "Let's be bold. Let's make the rules. Let's not wait for the drug companies or the Congress to tell us what to do." ■

Become an APA Distinguished Fellow

APA Distinguished Fellowship is a nationally recognized honor and is awarded to members who not only have achieved distinction in special areas of psychiatry, but also whose depth of knowledge and breadth of skills are recognized and highly respected. More information regarding the nomination and selection process is available from your district branch.

Response to Allegations and Call For Open Discussion of Pharmaceutical Funding

BY ALAN SCHATZBERG, M.D.

I am writing to address briefly the misperceptions and false statements about my research and ethics that have circulated in various forums. I have posted a more complete response on the Member-to-Member Listserv.

My integrity is important to me, and I have always taken steps to report and avoid any potential conflict throughout my career. Moreover, I have never improperly used my position at Stanford or my involvement with various research studies for my personal gain. I have tried to fairly and honestly report on all my research and subjected all the studies at issue to peer review.

Let me also assure everyone that I did not conceal any pertinent information during the recent APA election process. It was several months after I was recruited to run and the slate was announced that Sen. Charles Grassley first wrote to the president of Stanford University seeking information. Sen. Grassley never contacted me, and to this date has not contacted me, seeking any information or clarification. It was my understanding that Stanford had provided all the requested information and was dealing with the senator to clarify any issues. I did not become aware of any specific concerns until late June of this year, over four months after the APA election results were announced, when the senator publicly questioned Stanford about my disclosures.

The senator's initial contentions were based on some confusion regarding the information we provided. For example, the senator contended that I had not reported payments from Johnson & Johnson, not realizing that my disclosures had specified payments from the company's subsidiary, Janssen.

The senator also alleged that I had failed to report the extent of my holdings in Corcept Therapeutics, a company I cofounded. This allegation was based on reviewing an annual disclosure form that I had correctly filled out but does not provide specificity on stock above $100,000. Other forms, providing more detailed descriptions, were available and were provided once Sen. Grassley raised the issue. In addition, my Corcept stock holdings have been publicly available on financial Web sites for several years.

Over the past 25 years, my colleagues and I have studied psychotic major depression and developed a hypothesis that excessive activity of the hypothalamic-pituitary axis plays a role in the development of psychosis of this often lethal illness. We hypothesized that blocking cortisol activity in the brain could produce relief and, from 1995 to 1997, we studied mifepristone, a progesterone and glucocorticoid receptor antagonist. In accord with the Bayh-Dole Act, Stanford applied for a use patent for the use of mifepristone in psychotic depression, which was issued at the end of 2000. When the university was unable to license the drug to any pharmaceutical companies, my colleagues and I founded a biotech company, Corcept Therapeutics, to develop mifepristone to help treat psychotic depression.

We informed NIMH of a possible conflict of interest on a grant on which I had been the principal investigator and agreed that I would abstain from involvement with the conduct of the mifepristone component of the grant. I am one of the authors on the NIMH-sponsored study that was reported in 2006 because I was instrumental in the study design before the conflict, in obtaining the funding, and in helping to write the paper. Moreover, the results of all of our mifepristone studies have been published in peer-reviewed publications in a totally transparent manner for others to review. Stanford double-blind data are totally independent of Corcept and will not be used for an FDA submission for approval. The plan for dealing with the conflict of interest, including my involvement with Concept Therapeutics, had been agreed to by NIMH and had been audited independently by NIH pursuant to its "Targeted Site Review for Financial Conflict of Interest." Nonetheless, Stanford and I have agreed that I would temporarily withdraw my involvement in the entire NIMH study given the concern recently raised by Sen. Grassley.

I remain proud of my efforts to develop a new treatment for a lethal disorder that has no approved pharmacological therapy and remain hopeful that this treatment will be effective. Patients, their families, and practitioners may all benefit from a dramatically innovative therapy. That is my goal and one shared by all psychiatrists who treat such patients.

I am also proud of what APA does to defend the rights of psychiatric patients and the professional interests of its members. APA takes pride in allowing all of its members to voice their opinions and is currently addressing the very complex issues regarding pharmaceutical funding. This issue will require all interested parties and all views to be expressed and considered, whether they believe that all funding from the pharmaceutical industry should be banned and the government should fund all research, that such funding is essential to continuing development and research, or that limits need to be imposed on the funding. I share the belief that all voices need to be heard to address these issues, and I look forward to working with you all as your president-elect and next year's president. ■

professional news

CDC Finds Most With Depression Fail to Seek Specialized Care

Only 29 percent of people with depression reported contact with a psychiatrist or mental health professional in the prior year; in a subset with severe depression, only 39 percent reported such contact.

BY RICH DALY

More than 1 in 20 Americans older than age 11 may have depression, according to an analysis from the Centers for Disease Prevention and Control (CDC). That's about 5 percent of individuals in this age group.

Researcher Laura Pratt, Ph.D., of the Office of Analysis and Epidemiology at the CDC's National Center for Health Statistics, and CDC colleague Deborah Brody, M.P.H., based their finding on a data analysis of the National Health and Nutrition Examination Survey (NHANES) from 2005-2006. The NHANES used a nine-item screening tool to ask those surveyed in face-to-face interviews about "depressive symptoms" they had experienced during the prior two weeks. The analysis was released in September.

The researchers found depression rates were higher in people aged 40 to 59, women, and non-Hispanic black people than in other demographic groups. Rates of depression were higher among low-income individuals than among those with higher incomes.

"Depression is a major public health problem, and increasing the number of Americans with depression who receive treatment is an important public health goal and a national objective of Healthy People 2010," wrote Pratt and Brody, referring to the federal health goals for the nation. Brody works in the CDC's Division of Health and Nutrition Examination Surveys.

NHANES is a continuous cross-sectional survey of the civilian, noninstitutionalized U.S. population designed to assess the health and nutrition of Americans. The survey participants completed a face-to-face "household interview" and had an examination in a mobile examination center that included a private interview. More than 5,000 people were included in the 2005 to 2006 NHANES, which also oversampled blacks and Mexican Americans, adults over age 60, and individuals of low income in order to "improve the statistical reliability of the estimates for these groups," according to the researchers.

The depression rates found in the CDC analysis are lower than those found in some previous research. For example, major depression was estimated to affect about 9 percent of adolescents aged 12 through 17 and 7.6 percent of adults over the preceding year in data released by the Substance Abuse and Mental Health Services Administration in June 2007 (*Psychiatric News*, August 3, 2007).

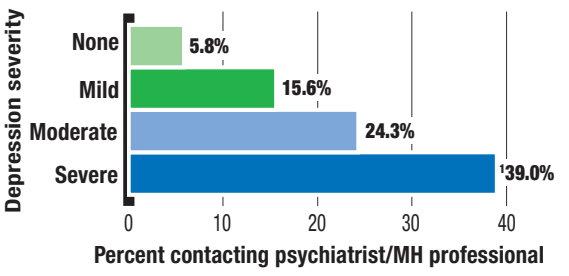
The CDC report also found that 80 percent of people who reported symptoms of depression also reported some degree of "functional impairment" due to their depression; and 27 percent reported "serious difficulties" in work and home life. About 35 percent of male respondents and 22 percent of female respondents with depression symptoms reported that their symptoms made it "very or extremely difficult" for them to work, get things done at home, or get along with other people. More than half of the people with mild depressive symptoms also reported some difficulty in daily functioning attributable to their symptoms.

Among the most startling findings for psychiatrists and mental health professionals was that only 29 percent of respondents with depression symptoms reported contacting a mental health clinician in the prior year. In a subset of respondents with severe depres-

please see ***Depression*** *on page 10*

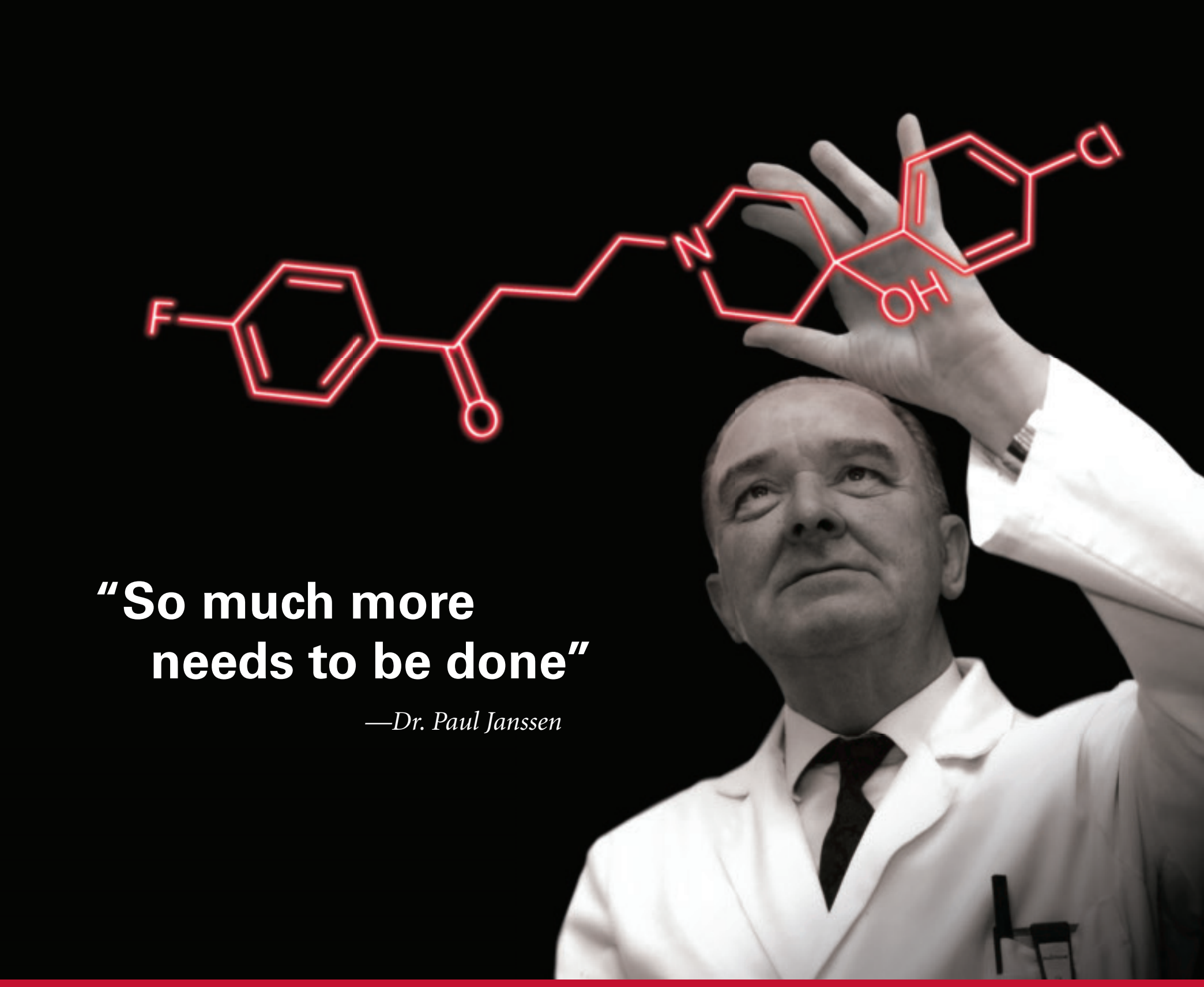
Most People Do Not Seek Care for Depression

A CDC analysis of a national survey of about 5,000 people found that most people with depression symptoms did not seek care from a psychiatrist or mental health professional, although those with the most severe depression symptoms were most likely to have contacted a psychiatrist or mental health worker.



[1]Statistically significant trend.
NOTE: Moderate/severe indicate depression, while mild indicates mild depressive symptoms.

Source: NCHS Data Brief, Centers for Disease Control and Prevention, September 2008



“So much more needs to be done”

—Dr. Paul Janssen

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Psychiatrists Find Home In the Blogosphere

Blogging is now technically easy, but keeping a good blog going over the long run requires that the author have a passionate interest in the blog's subject.

BY MARK MORAN

Last year medical ethicist Howard Brody, M.D., published a book, *Hooked: Ethics, the Medical Profession, and the Pharmaceutical Industry*, about a subject that would quickly become a moving target.

"The scene was changing rapidly," Brody said of the mounting public and professional concern about medicine's relationship with the pharmaceutical industry. "It seemed to me that the minute the book was in print, it would be out of date in two weeks. So I thought, What would be a mechanism for keeping me abreast of new developments while also sharing new information with the public?"

The answer was a Weblog, or "blog," a real-time, online, running commentary on all matters related to the subject of medical-pharmaceutical relationships. He named the blog "Hooked: Ethics, Medicine and Pharma."

"I set up the blog with one intention—to serve as an update to the book," said Brody, who is chair of family medicine and director of the Institute for the Medical Humanities at the University of Texas Medical Branch at Galveston.

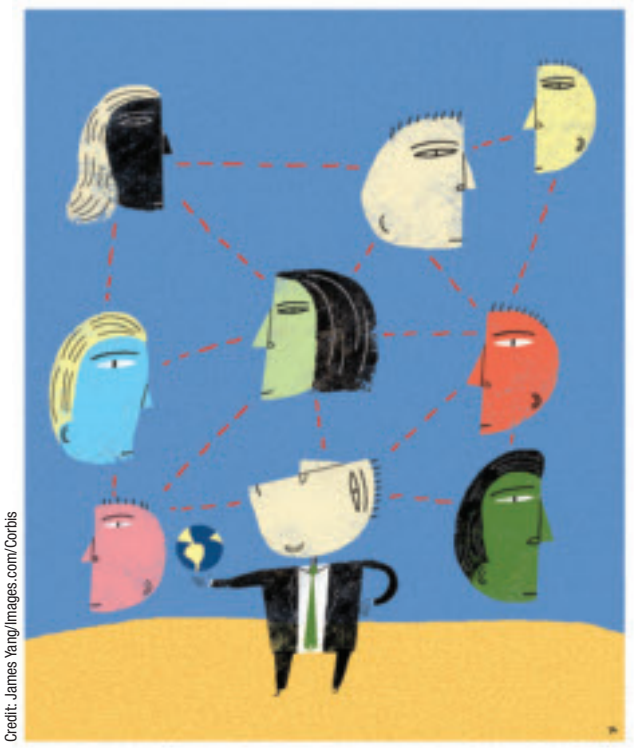
At about the same time, his friend and colleague, psychiatrist Jim Sabin, M.D., also began writing a blog called "Healthcare Organizational Ethics."

"I had been thinking about writing a blog for a few years, but I put it off thinking that I didn't have the technical expertise to do it," Sabin said. "Then a year ago I made the decision to end my clinical practice. When I really bit the bullet and started to come to terms with the end of clinical practice, all of a sudden instead of dithering about doing a blog, I decided that the only way I would learn about it is by doing it.

"In retrospect I can see there was a connection between the very emotionally meaningful decision to wind up my clinical practice and starting the blog," Sabin said. "It struck me that there is a deep underlying connection in the area of reaching out to people and making connections. Clinical practice, of course, is about making connections. And in its own way, blogging has something of the same structure."

Sabin's and Brody's experience underscores two features of blogging—the ability to stay with an evolving subject on a daily basis over time and the capacity to connect in a new way with a universe of Internet surfers looking for thoughtful discourse. These features may account for the popularity of blogging and for turning the medical and health care "blogosphere" into a new force for shaping public opinion.

Putting a figure on the number of blogs that are written by psychiatrists and other doctors or are focused on medicine, science, and health is impossible; but it is emblematic, perhaps, that *Webster's Dictionary*—the old-fashioned one you hold in your hands—has an entry for "blog" and defines it thus: "a Web site that contains an online personal journal with reflections, comments, and often hyperlinks provided by the writer."



Credit: James Yang/Images.com/Corbis

It is telling as well that Health and Human Services Secretary Mike Leavitt has his own blog on government policies related to health care.

"We live in an era when information has made a basic change," said Leavitt in an online symposium titled "The Health Blogosphere: What It Means for Policy Debates and Journalism," sponsored by the Kaiser Family Foundation. "It used to be we would go to libraries and universities because. . . they stored and passed on and enhanced information. In the information age, information goes where people are, and public policymakers need to do the same."

Jim Sabin, M.D.: "In retrospect I can see there was a connection between the very emotionally meaningful decision to wind up my clinical practice and starting the blog."

"Do I expect that blogs are going to be a significant part of public policy in government in the future?" he asked. "Absolutely. How? I think we are all figuring that out."

Even Aunt Min Can Do It

One fact that has certainly contributed to the growth of the blogosphere is that starting a Weblog now requires next to no technical expertise. Many Web sites offer blog-starting tools that can be employed by the most naïve computer owner.

"Basically, it's set up in such a way that Aunt Min can start her own blog and put up pictures of her family," said Brody about Blogspot at <www.blogger.com>, the Web site that hosts Hooked. "If it were technically difficult, I wouldn't be doing it."

"If you can use e-mail, you should be able to start your own blog," agreed "Roy," a clinician who is one of three psychiatrists anonymously hosting a blog called Shrink Rap. "It is devoted to everyday issues in psychiatry, ranging from private practice to forensics to general-hospital psychiatry—what Roy, who asked to remain anonymous for the purposes of this article, called the nuts and bolts of practicing psychiatry.

The psychiatric threesome also produces a podcast called My Three Shrinks.

A sample of the topics posted on Shrink Rap includes "When Lawyers Call," "*CPT* Billing Codes for Psychiatrists and Psychotherapy," "Why Docs Don't Like Xanax," and "Write on that Slate?"—a posting that addressed the concept of the therapist as a "blank slate" and asked such questions as the following:

"How exactly does it damage the patient's treatment if he knows some information about a psychotherapist's personal life? Do we really truly believe that there is a difference in treatment outcomes if a therapist wears a wedding ring or doesn't? If he answers a question about where he went on vacation or if he has children?"

"The goal was to make the blog a place where psychiatrists could talk about issues that affect them on a daily basis," Roy told *Psychiatric News*.

It Takes Passion

Weblog writers agreed that blogging can be pleasurable, but "it's demanding," Sabin said. "It's absolutely clear that the more you post, the more readers you get. The blogs with the highest readership have postings once or twice a day. My aspiration is to post three times a week, and I don't accomplish that week in and week out. So it's fun, but it's work."

Sabin, who has written books including *Setting Limits Fairly* and *No Margin, No Mission: Health Care Organizations and the Quest for Ethical Excellence*, has devoted a career to exploring how medical resources can be ethically allocated across a population (*Psychiatric News*, June 3, 2005).

He is director of the ethics program at Harvard Pilgrim Health Care and a clinical professor in the departments of ambulatory care/prevention and psychiatry at Harvard Medical School.

"One of my missions on the blog is to contribute to detoxifying the topic of including cost as a component when we think about the ethics of health care," Sabin said. "So there are a lot of postings dealing with cost that have in common the theme of encouraging or delineating ethically robust ways of addressing the topic."

Postings on Sabin's blog include "Why We're so Ineffective in Controlling Healthcare Costs," "Learning How to Ration," "Technology Running Amok," and "Avastin 1/Cost Control 0."

The last of them was a posting on July 8 about the anticancer drug Avastin: "Only in the U.S. is it possible to ask 'When, if ever, should cost come into the equation?' with regard to a drug that produces ambiguous benefits at best for which billions of dollars are spent."

Psychiatrist Daniel Carlat, M.D., who writes "The Carlat Psychiatry Blog: Supporting the Search for Honesty in Medical Education," agreed that without an abiding interest in the subject matter, the Weblogger will have a difficult time sustaining a successful site.

"Unless you feel passionately about your blog subject, chances are you are not going to continue to be successful," said Carlat, an assistant clinical professor of psychiatry at Tufts University School of Medicine and cochair of the CME Committee of the Massachusetts Psychiatric Society.

Bloggers who spoke with *Psychiatric News* said that there are countless Weblogs given over entirely to spleen; the Internet is a safe haven for all manner of rants and raves.

But thoughtful, articulate bloggers typically find each other in cyberspace, trading posts and building up a community of readers and writers.

"The thing that's interesting is that out in the blogosphere there is a club, and I'm now a member of it," said Brody. "I have these fellow bloggers, and we exchange things. If one of us posts something that attracts interest, someone else may use it. These are careful, thoughtful people doing their blogs. They are not just being incendiary, but are trying to back up what they say." ■

Sample of Medical Blogs on Web

- "Hooked: Ethics, Medicine and Pharma": http://brodyhooked.blogspot.com
- "Healthcare Organizational Ethics": http://healthcareorganizationalethics.blogspot.com
- "Shrink Rap": http://psychiatrist-blog.blogspot.com
- "Secretary Mike Leavitt's Blog": http://secretarysblog.hhs.gov
- "The Carlat Psychiatry Blog": http://carlatpsychiatry.blogspot.com
- Transcript, video, and podcast of the Kaiser symposium on the health blogosphere: www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=2847

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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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Psychiatric Patients Fare Well In Australia's Health System

Unlike America's Medicare, Australia's Medicare covers people of all ages. Nonetheless, the Australian government encourages its citizens to purchase private health insurance to supplement their Medicare coverage.

BY JOAN AREHART-TREICHEL

When Americans think of life "Down Under," that is, in Australia, they often envision cowboys roaming the outback and encountering kangaroos, dingos, and laughing kookaburras or young adults in splendid health playing on Sydney's beaches. And indeed, life is very good for many Aussies; their life expectancy is among the highest in the world.

When it comes to health insurance, however, Aussies do not emphasize rugged individualism as much as Americans do. Australia has had a publicly funded universal health insurance system since 1975—first called "Medibank" and then renamed "Medicare" in 1984. As Ken Kirkby, M.D., president of the Royal Australian and New Zealand College of Psychiatrists, explained in an interview, "The philosophy of Medicare is communitarian; we all chip in to help those less fortunate." Kirkby is also chief psychiatrist of mental health services in the Department of Health and Human Services in Tasmania.

Under Australia's Medicare, all citizens are entitled to treatment in a public hospital at no charge. "Many people who can't afford treatment or who need extensive treatment are treated in public hospitals," Kirkby explained.

Medicare will also pay 85 percent of the going Medicare fee for outpatient visits with physicians in private practice; patients then pay the remaining 15 percent as well as anything beyond that when doctors do not accept the Medicare fee as payment in full. A Medicare fee accepted as payment in full is called "bulk billing."

"Anywhere from 70 to 90 percent of psychiatrists bulk bill sometimes, but a lot of them don't do it most of the time," said Kirkby. When psychiatrists do bulk bill, he added, it is often for patients who are incapacitated by depression or psychosis and not working. Also, there is a limit on patients' out-of-pocket costs for outpatient care; Medicare picks up the tab for any care beyond the limit.

Australia also offers people of few means outpatient care—including outpatient psychiatric care—in public clinics. "For example, we have outpatient clinics in country towns that are free to the user," Kirkby said.

Medicare is funded by a 1.5 percent tax levy. An exemption applies to low-income earners and the unemployed. In practice, the levy raises only a fraction of the money required to cover the program. If the levy were to cover it fully, then it would need to be about 8 percent. Moreover, Medicare does not fund public hospitals; they are financed by federal tax revenue through grants to the states.

The Australian government also encourages citizens to purchase private health insurance to supplement their Medicare hospital coverage (see box).

System's Pluses Add Up

In Kirkby's opinion, "Australia's Medicare system is one of the world's best health care coverage systems." One of the features he likes best about it, he said, is that it provides "universal coverage of the population."

Alexander McFarlane, M.D., a professor of psychiatry at the University of Adelaide, concurred: "The system provides invaluable access by all members of the community to general practice and specialist health care independent of their personal wealth. Furthermore, medications are provided at marginal cost to patients, which ensures that treatment is available to all. The fact that Australia has the second longest life expectancy [in the world] may, in part, arise from the accessibility of health care."

The system's strong safety net, Kirkby added, is especially beneficial to psychiatric patients who are "one of the most socially disadvantaged groups." Not only do psychiatric patients have access to free or subsidized care in public hospitals, public outpatient clinics, and the offices of private medical practitioners, but also their psychotropic medication costs are subsidized by Medicare. Medicare recently started covering psychotherapy by psychologists.

Yet another benefit of Australia's Medicare is that it treats mental illnesses like other illnesses without discrimination, Harvey Whiteford, M.D., a professor of psychiatry at the University of Queensland and an adviser to the Australian government on mental health policy and financing, told *Psychiatric News*. For example, Medicare pays 85 percent of the cost of a psychiatric outpatient visit for up to 50 visits a year.

Still another positive aspect of Australia's Medicare "is that it greatly reduces the financial barrier to appropriate professional health care for young people with mental health problems," Michael Sawyer, Ph.D., a professor of child and adolescent psychiatry at Women's and Children's Hospital in North Adelaide, South Australia, said. "This is an important issue because many young people with mental health problems live in families with very limited financial resources. As such, they cannot afford to pay for expensive health services."

Picture Not all Rosy

However, Australia's Medicare is not without flaws.

One of the things that Whiteford does not like about it, he said, is that "procedural medicine (for example, surgery, invasive procedures such as endoscopies) is reimbursed much better than is nonprocedural medicine (for example, internal medicine, psychiatry)."

Kirkby agreed that this is one aspect of the system that he doesn't like—and so did McFarlane, who added, "The differential fees where proceduralists are overpaid for their work. . .conspire to encourage interventions and investigations when less-invasive approaches would be appropriate."

Another weakness of Medicare, Kirkby pointed out, is that it has no way of correcting physician shortages if they occur. True, he said, the Australian government essentially controls the number of people who receive a medical education in Australia, yet the numbers are largely historically based rather than need based.

Yet another "limitation of the system is its focus on payment for specific treatments or interventions delivered by medical and nonmedical specialists to young people who have existing mental health problems," Sawyer noted. "There is a need for a funding system that gives equal weight to universal and targeted prevention programs designed to reduce the incidence (that is, reduce the number of new 'cases') of mental health problems among young people."

Ian Hickie, M.D., a professor of psychiatry at the University of Sydney, has called for an overhaul in the way that Medicare pays psychiatrists to lure them to work in more remote areas of the country.

Any Lessons for Americans?

So in view of the advantages and disadvantages of Australia's Medicare, and with health insurance reform being a hot election issue in the United States this fall, are there any aspects of Australia's Medicare that Americans should perhaps consider?

"Given the different economic doctrine in the United States, particularly the emphasis on individualism, this is a complex question to answer," Kirkby replied. However, "with the U.S. government already providing ample medical coverage to seniors through the American Medicare, it is not a radical departure to envisage extending the safety net to younger Americans as well. But it is for the United States to work out how this would best be accommodated in a system dominated by employer-funded health insurance and health maintenance organizations (HMOs), neither of which are significant factors in Australia."

"I feel it would be a little presumptuous of me to make suggestions for the United States to adopt," Sawyer said. "However, all countries need to ensure that young people with mental health problems, regardless of the wealth or poverty of their parents, have access to appropriate professional health care. Furthermore, all countries need to adopt universal and targeted approaches to reduce the incidence of mental health problems among young people. This is important because mental health problems among young people are relatively common, they are associated with significant comorbidity. . .[and], once established, they are often chronic or recurring with a significant proportion persisting into adulthood."

"You need a national health insurance system with parity coverage for mental illness as a basic financing system for all

please see ***Australia*** *on facing page*

Private Health Insurance Purchased as Supplement

In Australia, people can purchase private health insurance to supplement their in-hospital coverage under Medicare. Currently, some 40 percent of Australians have such coverage.

Private health insurance plans offer perks that Medicare does not. For example, people who are treated in public hospitals can choose their doctor, which is not otherwise the case. Also, people can be treated in a private hospital instead of in a public hospital. Certain surgical procedures—coronary bypass surgery or a hip replacement—can be obtained more quickly if patients have private insurance to supplement their Medicare coverage. And for people who elect to be treated in a private hospital, private insurance helps cover the gap between Medicare reimbursement and out-of-pocket costs.

The Australian government promotes the purchase of private health insurance because it wants a hybrid public-private health insurance system and because it wants to take some of the strain off public hospitals. For instance, if people in higher-income brackets do not purchase private health insurance, they have to pay a penalty tax. And if people purchase private health insurance, they receive a 30 percent rebate from the government.

The rebates were introduced in 1999. Some Australians believe that the rebate might be better invested in the Medicare system. And as Denzil Fiebig, a professor of economics at the University of New South Wales, reported on the university's Web site on July 17, 2006: "While private health insurance coverage in Australia has increased by 50 percent as a result of the rebate, that is not necessarily easing pressure on the public hospital system."

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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.

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BRIEF SUMMARY. See package insert for full prescribing information.

Increased Mortality in Elderly Patients with Dementia-Related Psychosis—Elderly patients with dementia-related psychosis treated with 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 2/2988 (0.06%) GEODON patients and 1/440 (0.23%) placebo patients revealed QT_c intervals exceeding the potentially clinically relevant threshold of 500 msec. In the GEODON patients, neither case suggested a role of GEODON. Some drugs that prolong the QT/QT_c interval have been associated with the occurrence of torsade de pointes and with sudden unexplained death. The relationship of QT prolongation to torsade de pointes is clearest for larger increases (20 msec and greater) but it is possible that smaller QT/QT_c prolongations may also increase risk, or increase it in susceptible individuals, such as those with hypokalemia, hypomagnesemia, or genetic predisposition. Although torsade de pointes has not been observed in association with the use of GEODON at recommended doses in premarketing studies, experience is too limited to rule out an increased risk. A study evaluating the QT/QT_c prolonging effect of intramuscular GEODON, with intramuscular haloperidol as a control, was conducted in patient volunteers. In the trial, ECGs were obtained at the time of maximum plasma concentration following two injections of GEODON (20 mg then 30 mg) or haloperidol (7.5 mg then 10 mg) given four hours apart. Note that a 30 mg dose of intramuscular GEODON is 50% higher than the recommended therapeutic dose. The mean change in QT_c from baseline was calculated for each drug using a sample-based correction that removes the effect of heart rate on the QT interval. The mean increase in QT_c from baseline for GEODON was 4.6 msec following the first injection and 12.8 msec following the second injection. The mean increase in QT_c from baseline for haloperidol was 6.0 msec following the first injection and 14.7 msec following the second injection. In this study, no patient had a QT_c interval exceeding 500 msec. As with other antipsychotic drugs and placebo, sudden unexplained deaths have been reported in patients taking GEODON at recommended doses. The premarketing experience for GEODON did not reveal an excess of mortality for GEODON compared to other antipsychotic drugs or placebo, but the extent of exposure was limited, especially for the drugs used as active controls and placebo. Nevertheless, GEODON's larger prolongation of QT_c length compared to several other antipsychotic drugs raises the possibility that the risk of sudden death may be greater for GEODON than for other available drugs for treating schizophrenia. This possibility needs to be considered in deciding among alternative drug products. Certain circumstances may increase the risk of the occurrence of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QT_c interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QT_c interval; and (4) presence of congenital prolongation of the QT interval. GEODON should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias (see CONTRAINDICATIONS, and see *Drug Interactions* under PRECAUTIONS). It is recommended that patients being considered for GEODON treatment who are at risk for significant electrolyte disturbances, hypokalemia in particular, have baseline serum potassium and magnesium measurements. Hypokalemia (and/or hypomagnesemia) may increase the risk of QT prolongation and arrhythmia. Hypokalemia may result from diuretic therapy, diarrhea, and other causes. Patients with low serum potassium and/or magnesium should be repleted with those electrolytes before proceeding with treatment. It is essential to periodically monitor serum electrolytes in patients for whom diuretic therapy is introduced during GEODON treatment. Persistently prolonged QT_c intervals may also increase the risk of further prolongation and arrhythmia, but it is not clear that routine screening ECG measures are effective in detecting such patients. Rather, GEODON should be avoided in patients with histories of significant cardiovascular illness, eg, QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. GEODON should be discontinued in patients who are found to have persistent QT_c measurements >500 msec.** ***Neuroleptic Malignant Syndrome (NMS):*** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported. ***Tardive Dyskinesia (TD):*** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients undergoing treatment with antipsychotic drugs. Although the prevalence of TD appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop TD. If signs and symptoms of TD appear in a patient on GEODON, drug discontinuation should be considered. ***Hyperglycemia and Diabetes Mellitus:*** Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON, and it is not known if GEODON is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia. **PRECAUTIONS**—***General:*** Rash: In premarketing trials, about 5% of GEODON patients developed rash and/or urticaria, with discontinuation of treatment in about one-sixth of these cases. The occurrence of rash was dose related, although the finding might also be explained by longer exposure in higher-dose patients. Several patients with rash had signs and symptoms of associated systemic illness, e.g., elevated WBCs. Most patients improved promptly upon treatment with antihistamines or steroids and/or upon discontinuation of GEODON, and all patients were reported to recover completely. Upon appearance of rash for which an alternative etiology cannot be identified, GEODON should be discontinued. Orthostatic Hypotension: GEODON may induce orthostatic hypotension associated with dizziness, tachycardia, and, in some patients, syncope, especially during the initial dose-titration period, probably reflecting its α_1-adrenergic antagonist properties. Syncope was reported in 0.6% of GEODON patients. GEODON should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Seizures: In clinical trials, seizures occurred in 0.4% of GEODON patients. There were confounding factors that may have contributed to seizures in many of these cases. As with other antipsychotic drugs, GEODON should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older. Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia, and GEODON and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. **(See also Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis).** Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, GEODON elevates prolactin levels in humans. Tissue culture experiments indicate that approximately one third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time. Potential for Cognitive and Motor Impairment: Somnolence was a commonly reported adverse event in GEODON patients. In the 4- and 6-week placebo-controlled trials, somnolence was reported in 14% of GEODON patients vs 7% of placebo patients. Somnolence led to discontinuation in 0.3% of patients in short-term clinical trials. Since GEODON has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about performing activities requiring mental alertness, such as operating a motor vehicle (including automobiles) or operating hazardous machinery until they are reasonably certain that GEODON therapy does not affect them adversely. Priapism: One case of priapism was reported in the premarketing database. Body Temperature Regulation: Although not reported with GEODON in premarketing trials, disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Suicide: The possibility of a suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. GEODON prescriptions should be written for the smallest quantity of capsules consistent with good patient management to reduce overdose risk. Use in Patients with Concomitant Illness: Clinical experience with GEODON in patients with certain concomitant systemic illnesses is limited. GEODON has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies. Because of the risk of QT prolongation and orthostatic hypotension with GEODON, caution should be observed in cardiac patients (see ***QT Prolongation and Risk of Sudden Death*** in **WARNINGS** and Orthostatic Hypotension in **PRECAUTIONS**). ***Information for Patients:*** To ensure safe and effective use of GEODON, the information and instructions in the *Patient Information* section should be discussed with patients. ***Laboratory Tests:*** Patients being considered for GEODON treatment who are at risk of significant electrolyte disturbances should have baseline serum potassium and magnesium measurements. Low serum potassium and magnesium should be repleted before treatment. Patients who are started on diuretics during GEODON therapy need periodic monitoring of serum potassium and magnesium. Discontinue GEODON in patients who are found to have persistent QT_c measurements >500 msec (see **WARNINGS**). ***Drug Interactions:*** (1) GEODON should not be used with any drug that prolongs the QT interval. (2) Given the primary CNS effects of GEODON, caution should be used when it is taken in combination with other centrally acting drugs. (3) Because of its potential for inducing hypotension, GEODON may enhance the effects of certain antihypertensive agents. (4) GEODON may antagonize the effects of levodopa and dopamine agonists. Effect of Other Drugs on GEODON: Carbamazepine, 200 mg bid for 21 days, resulted in a decrease of approximately 35% in the AUC of GEODON. Ketoconazole, a potent inhibitor of CYP3A4, 400 mg qd for 5 days, increased the AUC and C_{max} of GEODON by about 35%-40%. Cimetidine, 800 mg qd for 2 days, did not affect GEODON pharmacokinetics. Coadministration of 30 mL of Maalox did not affect GEODON pharmacokinetics. Population pharmacokinetic analysis of schizophrenic patients in controlled clinical trials has not revealed any clinically significant pharmacokinetic interactions with benztropine, propranolol, or lorazepam. Effect of GEODON on Other Drugs: In vitro studies revealed little potential for GEODON to interfere with the metabolism of drugs cleared primarily by CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4, and little potential for drug interactions with GEODON due to displacement. GEODON 40 mg bid administered concomitantly with *lithium* 450 mg bid for 7 days did not affect the steady-state level or renal clearance of lithium. GEODON 20 mg bid did not affect the pharmacokinetics of concomitantly administered *oral contraceptives*, ethinyl estradiol (0.03 mg) and levonorgestrel (0.15 mg). Consistent with in vitro results, a study in normal healthy volunteers showed that GEODON did not alter the metabolism of *dextromethorphan*, a CYP2D6 model substrate, to its major metabolite, dextrorphan. There was no statistically significant change in the urinary dextromethorphan/dextrorphan ratio. ***Carcinogenesis, Mutagenesis, Impairment of Fertility.*** Lifetime carcinogenicity studies were conducted with GEODON in Long Evans rats and CD-1 mice. In male mice, there was no increase in incidence of tumors relative to controls. In female mice there were dose-related increases in the incidences of pituitary gland adenoma and carcinoma, and mammary gland adenocarcinoma at all doses tested. Increases in serum prolactin were observed in a 1-month dietary study in female, but not male, mice. GEODON had no effect on serum prolactin in rats in a 5-week dietary study at the doses that were used in the carcinogenicity study. The relevance for human risk of the findings of prolactin-mediated endocrine tumors in rodents is unknown (see Hyperprolactinemia). Mutagenesis: There was a reproducible mutagenic response in the Ames assay in one strain of *S. typhimurium* in the absence of metabolic activation. Positive results were obtained in both the in vitro mammalian cell gene mutation assay and the in vitro chromosomal aberration assay in human lymphocytes. Impairment of Fertility: GEODON increased time to copulation in Sprague-Dawley rats in two fertility and early embryonic development studies at doses of 10 to 160 mg/kg/day (0.5 to 8 times the MRHD of 200 mg/day on a mg/m^2 basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m^2 basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m^2 basis). The fertility of female rats was reduced. ***Pregnancy—Pregnancy Category C:*** There are no adequate and well-controlled studies in pregnant women. GEODON should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. ***Labor and Delivery:*** The effect of GEODON on labor and delivery in humans is unknown. ***Nursing Mothers:*** It is not known whether, and if so in what amount, GEODON or its metabolites are excreted in human milk. It is recommended that women receiving GEODON should not breast feed. ***Pediatric Use:*** The safety and effectiveness of GEODON in pediatric patients have not been established. ***Geriatric Use:*** Of the approximately 4500 patients treated with GEODON in clinical studies, 2.4% (109) were 65 years of age or over. In general, there was no indication of any different tolerability for GEODON or of reduced clearance of GEODON in the elderly compared to younger adults. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to GEODON, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients. **ADVERSE REACTIONS**—***Adverse Findings Observed in Short-term, Placebo-Controlled Trials:*** The following findings are based on the short-term placebo-controlled premarketing trials for schizophrenia (a pool of two 6-week, and two 4-week fixed-dose trials) and bipolar mania (a pool of two 3-week flexible-dose trials) in which GEODON was administered in doses ranging from 10 to 200 mg/day. ***Adverse Events Associated with Discontinuation:*** Schizophrenia: Approximately 4.1% (29/702) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 2.2% (6/273) on placebo. The most common event associated with dropout was rash, including 7 dropouts for rash among GEODON patients (1%) compared to no placebo patients (see **PRECAUTIONS**). Bipolar Mania: Approximately 6.5% (18/279) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 3.7% (5/136) on placebo. The most common events associated with dropout in the GEODON-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash, and vomiting, with 2 dropouts for each of these events among GEODON patients (1%) compared to one placebo patient each for dystonia and rash (1%) and no placebo patients for the remaining adverse events. ***Adverse Events at an Incidence ≥5% and at Least Twice the Rate of Placebo:*** The most commonly observed adverse events associated with GEODON in schizophrenia trials were somnolence (14%) and respiratory tract infection (8%). The most commonly observed adverse events associated with the use of GEODON in bipolar mania trials were somnolence (31%), extrapyramidal symptoms (31%), dizziness (16%), akathisia (10%), abnormal vision (6%), asthenia (6%), and vomiting (5%). The following list enumerates the treatment-emergent adverse events that occurred during acute therapy, including only those events that occurred in 2% of GEODON patients and at a greater incidence than in placebo. Schizophrenia: Body as a Whole—asthenia, accidental injury, chest pain. Cardiovascular—tachycardia. Digestive—nausea, constipation, dyspepsia, diarrhea, dry mouth, anorexia. Nervous—extrapyramidal symptoms, somnolence, akathisia, dizziness. Respiratory—respiratory tract infection, rhinitis, cough increased. Skin and Appendages—rash, fungal dermatitis. Special Senses—abnormal vision. Bipolar Mania: Body as a Whole—headache, asthenia, accidental injury. Cardiovascular—hypertension. Digestive—nausea, diarrhea, dry mouth, vomiting, increased salivation, tongue edema, dysphagia. Musculoskeletal—myalgia. Nervous—somnolence, extrapyramidal symptoms, dizziness, akathisia, anxiety, hypesthesia, speech disorder. Respiratory—pharyngitis, dyspnea. Skin and Appendages—fungal dermatitis. Special Senses—abnormal vision. ***Dose Dependency:*** An analysis for dose response in the schizophrenia trials revealed an apparent relation of adverse event to dose for the following: asthenia, postural hypotension, anorexia, dry mouth, increased salivation, arthralgia, anxiety, dizziness, dystonia, hypertonia, somnolence, tremor, rhinitis, rash, and abnormal vision. ***Extrapyramidal Symptoms (EPS):*** The incidence of reported EPS for GEODON patients in the short-term, placebo-controlled schizophrenia trials was 14% vs 8% for placebo. Objectively collected data from those trials on the Simpson-Angus Rating Scale and the Barnes Akathisia Scale did not generally show a difference between GEODON and placebo. ***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, 0.6 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, hyperthermia, 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, hypercholesterolemia, dehydration, lactic dehydrogenase increased, albuminuria, hypokalemia; *Rare:* BUN increased, creatinine increased, hyperlipemia, hypocholesterolemia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hypercalciuremia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. Musculoskeletal System—*Frequent:* myalgia; *Infrequent:* tenosynovitis; *Rare:* myopathy. Nervous System—*Frequent:* agitation, extrapyramidal syndrome, tremor, dystonia, hypertonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, hypesthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, buccoglossal syndrome, choreoathetosis, diplopia, incoordination, neuropathy; *Infrequent:* paralysis; *Rare:* myoclonus, nystagmus, torticollis, circumoral paresthesia, opisthotonos, reflexes increased, trismus. Respiratory System—*Frequent:* dyspnea; *Infrequent:* pneumonia, epistaxis; *Rare:* hemoptysis, laryngismus. Skin and Appendages—*Infrequent:* maculopapular rash, urticaria, alopecia, eczema, exfoliative dermatitis, contact dermatitis, vesiculobullous rash. Special Senses—*Frequent:* fungal dermatitis; *Infrequent:* conjunctivitis, dry eyes, tinnitus, blepharitis, cataract, photophobia; *Rare:* eye hemorrhage, visual field defect, keratitis, keratoconjunctivitis. Urogenital System—*Infrequent:* impotence, abnormal ejaculation, amenorrhea, hematuria, menorrhagia, female lactation, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; *Rare:* gynecomastia, vaginal hemorrhage, nocturia, oliguria, female sexual dysfunction, uterine hemorrhage. **Adverse Finding Observed in Trials of Intramuscular GEODON:** In these studies, the most commonly observed adverse events associated with the use of intramuscular GEODON (≥5%) and observed at a rate on intramuscular GEODON (in the higher dose groups) at least twice that of the lowest intramuscular GEODON group were headache (13%), nausea (12%), and somnolence (20%). **Adverse Events at an Incidence >1% in Short-Term Fixed-Dose Intramuscular Trials:** The following list enumerates the treatment-emergent adverse events that occurred in ≥1% of GEODON patients (in the higher dose groups) and at least twice that of the lowest intramuscular GEODON group. Body as a Whole—headache, injection site pain, asthenia, abdominal pain, flu syndrome, back pain. Cardiovascular—postural hypotension, hypertension, bradycardia, vasodilation. Digestive—nausea, rectal hemorrhage, diarrhea, vomiting, dyspepsia, anorexia, constipation, tooth disorder, dry mouth. Nervous—dizziness, anxiety, insomnia, somnolence, akathisia, agitation, extrapyramidal syndrome, hypertonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. Respiratory—rhinitis. Skin and Appendages—furunculosis, sweating. Urogenital—dysmenorrhea, priapism. **DRUG ABUSE AND DEPENDENCE**—***Controlled Substance Class:*** GEODON is not a controlled substance. **OVERDOSAGE**—In premarketing trials in over 5400 patients, accidental or intentional overdosage of GEODON was documented in 10 patients. All patients survived without sequelae. In the patient taking the largest confirmed amount (3240 mg), the only symptoms reported were minimal sedation, slurring of speech, and transitory hypertension (BP 200/95).

Revised August 2008

Shattered MH System Not Easy to Repair

North Carolina's public mental health system was dysfunctional, so it was fixed and then fixed again.

BY AARON LEVIN

The road to mental health reform may be paved with the best of intentions, but when the potholes get bigger after the repairs, people start to wonder.

North Carolina is bumping along through another upheaval in its public mental health system as citizens, patients, legislators, psychiatrists, and mental health professionals try to recover from the previous upheaval.

Legislators and policymakers shook up the system about seven years ago, but the resulting reforms proved at least as problematic as the conditions they were intended to cure.

"We tried to fix it, and we broke it," said one legislator, according to news reports.

Now the state is trying again to pick up the pieces and patch together a functional system.

Until 2001, North Carolina's system tied four large psychiatric hospitals scattered across the state with 39 area mental health, developmental disability, and substance abuse programs, supplemented by contracts with private agencies.

"The clinic-based area programs were local, safety-net operations with state funding," Debra Dihoff, M.A., executive director of the North Carolina branch of the National Alliance on Mental Illness and a former executive in the system, told *Psychiatric News*. Many were overwhelmed by growing caseloads after Medicaid and managed care were introduced.

The state was late in adopting many of the changes developed in public mental health and managed them badly in the process. It mishandled the Medicaid transition, and staffing, record-keeping, and physical-plant problems in the hospitals drew the attention of the Department of Justice in 2001.

Faced with a system on the verge of collapse, the Office of the State Auditor produced a report in 2000.

Among other things, the auditor's report called for cutting 667 beds from the 2,400-bed state hospital system, developing specialized outpatient services for targeted populations, and creating a separate developmental-disabilities division.

The most significant change, however, came in the creation of local management entities (LMEs) to administer, fund, and oversee—but not provide—services in each county. In theory, psychiatrists, social workers, psychologists, and other clinicians would leave the shrinking state system and reassemble into private-practice groups. Proponents argued that privatization would be more efficient and less costly and permit more rapid innovation than the public system.

Children, the elderly, the severely mentally ill, and substance-using populations would receive state-funded treatment, while others would use the county-based community support services.

Psychiatric Input Overlooked

"[The plan] didn't look too bad, but it left out a lot of input from professional groups," said Stephen Kramer, M.D., a professor of psychiatry at Wake Forest University School of Medicine and president of the North Carolina Psychiatric Association, in an interview.

The auditor's report was handled at arm's length by politicians, said Marvin Swartz, M.D., a professor of psychiatry and chief of the Division of Social and Community Psychiatry at Duke University. "There was no visionary leader with influence."

Gov. Mike Easley (D) employed a delegating management style and had little personal interest in mental health, Swartz said. State legislators had a poor grasp of the complexity surrounding mental health and simply said: "Fix it—just tell us what you want."

Whatever its intentions, the new system didn't work, said Swartz, who served as a consultant to the state auditor.

"Implementation was poor," Swartz said. "There were not enough people or knowledge or cash flow to implement a plan that was poorly designed."

"It was supposed to be budget neutral, but funding was inadequate before the reforms and more inadequate afterward," said Kramer.

Privatization also exacerbated an existing shortage of psychiatrists, said Swartz. Psychiatrists had always been "loss leaders" in the state system. Not all the work they did with complex patients was reimbursable, but cost-shifting under the area programs kept the system in balance. That couldn't be sustained with the reforms.

There was another factor as well. "People who work in the public sector are not entrepreneurs," said Swartz. "Some former public psychiatrists joined provider groups, but many left the field or the state because their income stream became too uncertain."

Fewer Psychiatrists Available

The supply of psychiatrists declined in about half of North Carolina's 100 counties during the period, according to a report by Swartz and his colleagues.

"Between 1999 and 2004, five counties lost all their psychiatrists, 48 counties experienced a decline in their supply relative to population growth, and 12 counties had no psychiatrists in either 1999 or 2004," they wrote.

The role of psychiatrists was undercut further because of the "quasi-fraudulent" system that developed in the early years of reform.

Provider organizations were paid a flat $61-an-hour fee to provide services, regardless of who treated the patient. Some (although not all) dispatched low-level (and low-paid) paraprofessionals to perform ill-defined "community support" services and pocketed the difference. The state had no mechanism to monitor these practices until the system went hundreds of millions of dollars over budget, said Swartz.

"The mental health plan did not carry clear lines of accountability," said Vicki Smith, M.S., executive director of Disability Rights North Carolina, in an interview. "It was built on the assumption that all entities would do the right thing. You have to build community capacity first, but they didn't do that."

It's a Long and Winding Road

"I wouldn't say reform failed, but it certainly has taken longer than expected to get it right," said psychiatrist Michael Lancaster, M.D., who in January was named codirector of the state's Division of Mental Health, Developmental Disabilities, and Substance Abuse Services.

Service definitions from the Centers for Medicare and Medicaid Services were approved only in 2006, two years later than expected, said Lancaster. The wholesale privatization of the system was clearly too radical, he said. "You need a public/private partnership to maintain a safety net."

Community support, said Lancaster, was intended to get people connected with services, build skills, and promote recovery, not serve as a substitute for long-term outpatient care.

"But community support became the norm, and the paraprofessionals were providing the maximum amount of services, whether they were needed or not," he said. "The money drove everything. Overutilization of community support meant other services weren't developed."

Now the division requires preauthorization for services other than outpatient treatment and requires national accreditation for providers to weed out the marginally qualified.

"We've seen a decrease in the use of community support and increase in other services," said Lancaster. He pushed in 2004 for the state to stop divesting the public system and halt the outflow of professionals, but the process was hard to stop, he said.

Legislative support will help. The state now offers psychiatrists a tuition-loan repayment program even if they are not working in federally approved health professional shortage areas. Lawmakers authorized funds last spring for 30 mobile treatment teams, 30 psychiatrists, and 30 walk-in clinics, along with expanded telepsychiatry services. Money has been allocated to develop inpatient beds in community hospitals, said Lancaster.

Perhaps because they have no other choice, most observers of the system hold out hope that the future will bring needed improvements.

"There are many naysayers who feel the system is irrevocably broken, but I don't feel that way," said Swartz. The legislature has made a "down payment" to get the system back on its feet, he said, while consumers, professionals, and others continue to pressure the politicians.

"I'm less concerned about the 'why' than in moving forward and ensuring that there is an accountability mechanism now," said Smith.

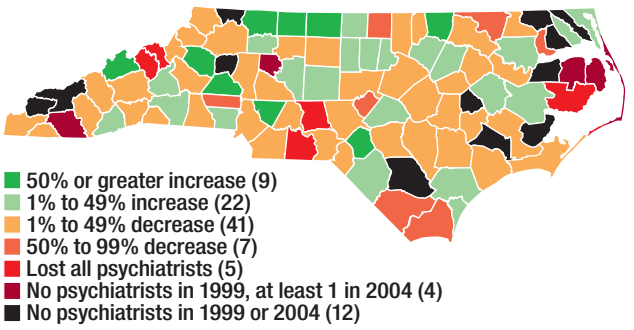
Dihoff expects consolidation of the local management entities and consequent improvement in efficiency, accompanied by development of family- and peer-support approaches.

"We have funding now for clinics and mobile teams, although they will take two years to put in place," said Lancaster. "We want to improve recruitment and retention, move treatment closer to home and families, and have institutions focus on the most severe cases."

Information about the North Carolina Division of Mental Health, Developmental Disabilities, and Substance Abuse Services and its programs is posted at <www.ncdhhs.gov/mhddsas/>. ■

Psychiatrists' Availability Declines in North Carolina

The number of full-time equivalent psychiatrists per 10,000 population declined from 1999 to 2004 (or were never available) in just over half of North Carolina's 100 counties.



Source: North Carolina Health Professions Data System, with data derived from the North Carolina Medical Board, 1999-2004; LINC, 2000 and 2005

Australia

continued from facing page

Americans," Whiteford advised. "If physicians want to charge above that, they should be allowed, and the market will determine who can and who chooses to pay. It will not bankrupt the country. Australia has had this system since 1984, and we spend 9.5 percent of our gross domestic product on health compared to 14 percent-plus in the United States."

McFarlane commented, "I understand that Sen. [Hillary] Clinton got to know about the Australian system from contact with senior government officials who were traveling with our prime minister to meet President Clinton. She got a number of her ideas [for health insurance reform] from these conversations. A system of universal health insurance that is based on a taxation levy provides social equity and protects those disadvantaged by ill health. This system underpins social stability and allows children to get good quality health care independent of the resources available to their parents. The system provides access to good quality mental health care without the restrictions that have come about in HMOs. This means that psychiatrists can deliver both good quality psychotherapy and pharmacotherapy." ■

Drug Prevention Needs to Be Extended to Baby Boomers

People who obtain pain relievers for nonmedical reasons usually get them from a single physician, which highlights the need for continuous patient and physician education.

BY RICH DALY

Efforts to curtail a surge in drug and alcohol abuse among youth in the 1990s appear to be rolling back their usage rates, while older Americans are showing increasing rates of such abuse, according to new federal data.

Results from the 2007 National Survey on Drug Use and Health (NSDUH), released in September, included a finding that illicit drug use overall declined among adolescents aged 12 to 17, from 11.6 percent in 2002 to 9.5 percent in 2007. ("Current use" is defined as use in the past month.) The rate of current marijuana use among adolescents aged 12 to 17 dropped from 8.2 percent in 2002 to 6.7 percent in 2007. In addition, the estimated number of American adolescents aged 12 or older who used methamphetamine for the first time dropped from 299,000 in 2002 to 157,000 in 2007.

"Drug use among youth and young people is shockingly down," said Eric Broderick, acting administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA), at a press conference marking the release of the drug-use data.

The reductions in drug use were touted by federal officials as a major improvement from the rising rates of drug use among adolescents found in previous research.

The findings of the SAMHSA survey (formerly called the Household Survey) are based on interviews of a random sample of 67,500 people. The survey results are considered the primary-source data on the extent of illicit drug, alcohol, and tobacco use in the noninstitutionalized U.S. population aged 12 and older, according to federal health officials.

In contrast, the survey also found that illicit drug use in the month prior to the survey interview among Americans aged 50 to 54 had increased from 3.4 percent in 2002 to 5.7 percent in 2007. Similarly, among people aged 55 to 59, illicit drug use in the month before the subjects were surveyed increased from 1.9 percent in 2002 to 4.1 percent in 2007.

The increase among people in their 50s was attributed to the rising numbers of the post-World War II population cohort dubbed the Baby Boomers. They have historically had high rates of substance abuse, starting in the 1960s.

"We had the largest exposure to underage illicit drug and alcohol use of any age cohort before or since," Broderick said about his fellow boomers.

Tackling this generation's early exposure and lingering acceptance of substance abuse as a "legitimate" recreational activity requires increased effort to integrate substance abuse and mental health screening and treatment into primary health care, according to federal health officials. Broderick emphasized that there are effective treatments available for substance abusers of any age, and at any age family, friends, and clinicians need to help them seek the care they need.

Increased intervention efforts by clinicians and those who know people with untreated substance abuse problems also can help convince the large number who need help to seek it. The survey estimated that 19.5 million people with substance use problems don't plan to seek assistance.

"That is something we have to address moving forward," said John Walters, director of the White House Office on National Drug Control Policy.

Prescription Pain Killers More Popular

Although most categories of drug use declined, the nonmedical use of pain relievers slightly increased in the study period. The survey results estimated that 4.4 million people aged 12 and older were current nonmedical users of prescription pain killers in 2002, which increased to 5.2 million people in 2007.

In addition to prescription pain reliever abuse among adolescents, young adults also were affected. The survey found current use of prescription pain relievers among young adults aged 18 to 25 increased from 4.1 percent to 4.6 percent over the same five years.

The increases in the abuse of pain killers was particularly troubling, according to federal antidrug officials, because the survey found that most nonmedical users of pain relievers reported obtaining the drugs from a single physician.

"Clearly we have work to do among doctors and patients to stem the tide of illicit use of prescription drugs," Walters said.

The problem is complex. Among the 57 percent of survey respondents who described nonmedical use of a prescription pain reliever stolen from a friend or relative, 80 percent said the friend or relative had obtained the drug from a single doctor. The finding indicated to federal officials that doctor-shopping by painkiller abusers may be a smaller problem than theft of legitimately prescribed pain relievers.

H. Westley Clark, M.D., director of SAMHSA's Center for Substance Abuse Treatment, said physicians could help stem the increase in the nonmedical abuse of pain relievers through increased efforts to limit prescriptions and amounts of prescriptions to appropriate conditions. Patients also should be encouraged to promptly dispose of unneeded medications in an "environmentally appropriate" manner that prevents drugs from ending up in the water supply.

Meanwhile, among the troubling trends revealed by the survey was that adolescent girls aged 12 to 17 have pulled even with boys in their rates of substance abuse. Educators need to address this trend by tailoring their prevention messages to address the specific peer-acceptance and dieting-related pressures that push girls into substance abuse, Walters told *Psychiatric News*.

Treatment Rate Stable

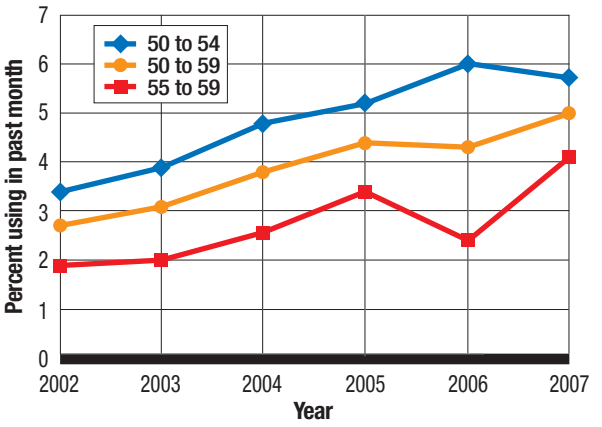
The mental health section of the annual survey found that the rate of adults seeking mental health care has remained fairly stable since 2002. About 13 percent of adults reported seeking any type of psychiatric treatment in the five years beginning in 2002, while 10 percent to 11 percent obtained prescription medication to treat psychiatric illness, and about 7 percent used outpatient treatment.

The rate of adults seeking care for depression dropped significantly from 2006 to 2007. Included in this reduction was the rate of adult women who had a "major depressive episode" and sought care, which dropped from 74 percent in 2006 to 68 percent in 2007. However, Clark told *Psychiatric News* that the finding was likely a statistical anomaly that was not a trend seen in the preceding years and won't be borne out over a longer time period.

The NSDUH report is posted at <http://oas.samhsa.gov/nsduh/2k7nsduh/2k7Results.cfm>. ■

Boomer Drug Use Grows

Drug abuse rates among Americans in their 50s have steadily increasec over the last five years. This presents a unique challenge to clinicians to recognize drug abuse and encourage treatment.



Source: The 2007 National Survey on Drug Use and Health: National Findings, SAMHSA, September 2008

Candidates

continued from page 1

stance Powell, M.D., of Portland, Ore., and incumbent William Womack, M.D., of Seattle.

The candidates for the Board's member-in-training trustee-elect (MITTE) position are Erick Cheung, M.D., a resident at the University of California at Los Angeles; Kayla Pope, M.D., a resident at the University of Maryland/Sheppard Pratt; and Laura Kent, M.D., a resident at the New York State Psychiatric Institute/Columbia University. The winner of the MITTE election will serve one year as an ex officio Board member, and the following year will step up to the member-in-training trustee position, which is a voting position.

Paper ballots will be mailed out on December 22, the same day on which members for whom APA has an e-mail address will receive, via e-mail, instructions for voting online. Members who would like to receive an online ballot only, an option that can be selected in the Members Corner of the APA Web site, will receive an e-mail with a ballot-control number and online voting instructions. The address for indicating that choice is <http://onlineapa.psych.org/OnlineBallot/aspx>.

The deadline for receipt of both paper and online ballots is 5 p.m. Eastern time on February 5, 2009. ■

Depression

continued from page 4

sion scores, only 39 percent made contact with a psychiatrist, psychologist, psychiatric nurse, or clinical social worker.

"There are many reasons people with depression do not receive treatment," said Pratt and Brody. "Some do not realize they have an illness that can be treated. Others do not believe treatment works. Other barriers to treatment include the stigma surrounding mental illness and mental health treatment and lack of insurance coverage for mental health care."

The survey's findings of "contact" rates may not reflect actual treatment rates, because the respondents who contacted a psychiatrist or mental health professional were not asked if they actually began treatment for depression. Also, the survey did not ask about mental health treatment received from primary care providers.

The survey's findings on rates of depression generally reflect those of previous research, Laurence Miller, M.D., chair of APA's Committee on Public Funding for Psychiatric Services, told *Psychiatric News*.

The finding that few with mental illness seek care from psychiatrists and mental health professionals probably reflects the common dependence of most Americans on general practice physicians for their health care. Unfortunately, many of these physicians do not look for signs of mental illness in their patients, he said.

"Unless [general practice physicians] provide depression screening, most of these cases are missed because of their focus on physical health care," Miller said.

Depression was measured in the NHANES using the Patient Health Questionnaire (PHQ–9), a nine-item screening instrument that asks questions about the frequency of symptoms of depression over the two weeks prior to the interview. Depression was defined as a PHQ–9 score of 10 or higher, a well-validated cutoff point commonly used in clinical studies that measure depression, according to the CDC authors.

The CDC analysis of the NHANES is posted at <www.cdc.gov/nchs/data/databriefs/db07.htm>. ■

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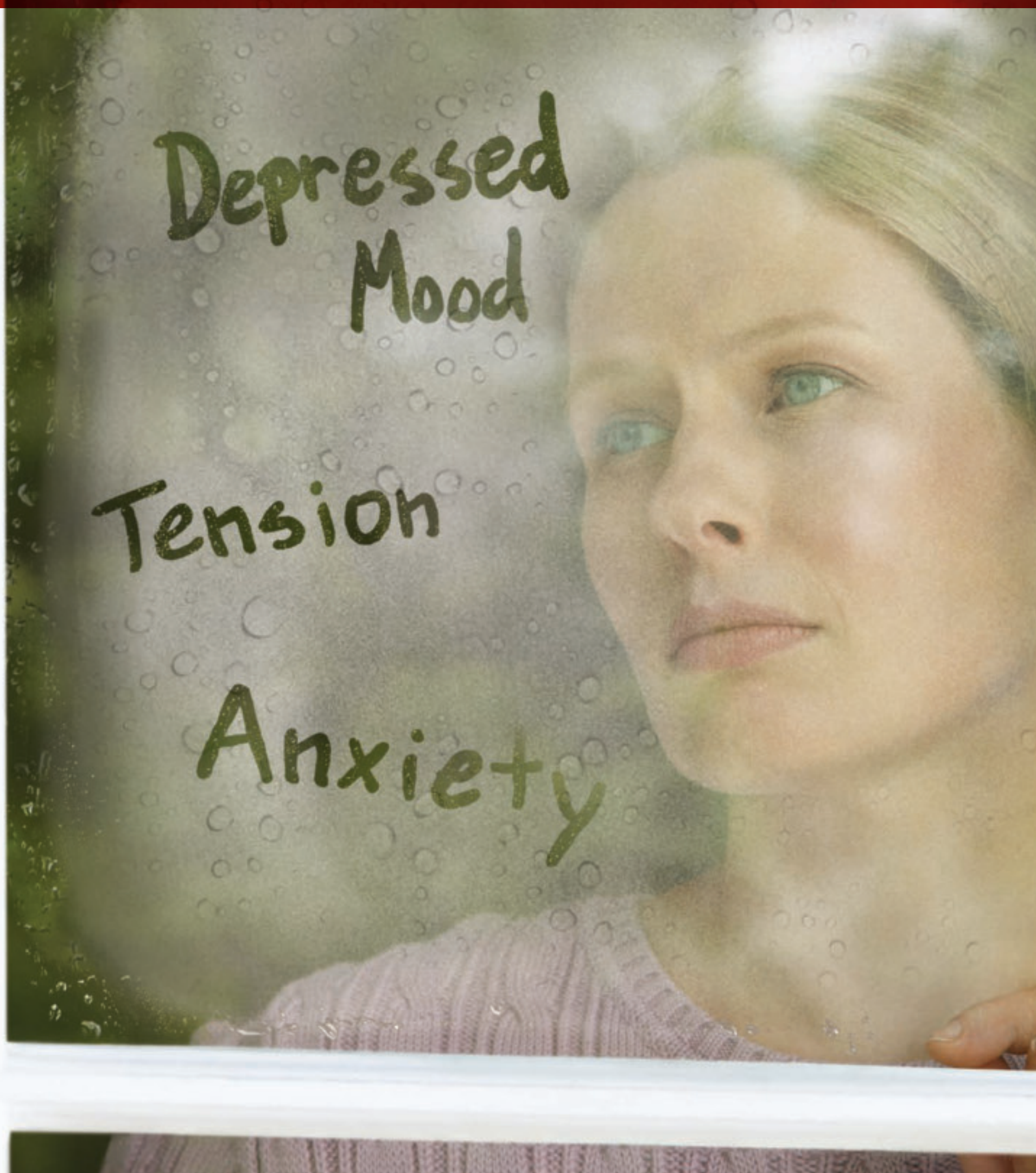

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- **Symptom relief starting as early as week 1*[7]**
- **Widely available on health plan formularies without restrictions[9]**

*Full antidepressant/anxiolytic effect may take 4 to 6 weeks.

Lexapro escitalopram oxalate

POWER TO ENJOY LIFE™

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.

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Please see accompanying brief summary of prescribing information for LEXAPRO.

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

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

CONTRAINDICATIONS Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated (see **WARNINGS**). Concomitant use in patients taking pimozide is contraindicated (see **Drug Interactions – Pimozide and Celexa**). Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Lexapro. **WARNINGS WARNINGS-Clinical Worsening and Suicide Risk Clinical Worsening and Suicide Risk** Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressants compared to placebo in adults aged 65 and older. The pooled analyses of placebo-controlled trials in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4400 patients. The pooled analyses of placebo-controlled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk differences (drug vs placebo), however, were relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in **Table 1. TABLE 1: Age Range and Drug-Placebo Difference in Number of Cases of Suicidality per 1000 Patients Treated:** 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 health care providers. Such monitoring should include daily observation by families and caregivers.** Prescriptions for Lexapro should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. **Screening Patients for Bipolar Disorder:** A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Lexapro is not approved for use in treating bipolar depression. **Potential for Interaction with Monoamine Oxidase Inhibitors In patients receiving serotonin reuptake inhibitor drugs in combination with a monoamine oxidase inhibitor (MAOI), there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Furthermore, limited animal data on the effects of combined use of SSRIs and MAOIs suggest that these drugs may act synergistically to elevate blood pressure and evoke behavioral excitation. Therefore, it is recommended that Lexapro should not be used in combination with an MAOI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days should be allowed after stopping Lexapro before starting an MAOI. Serotonin syndrome has been reported in two patients who were concomitantly receiving linezolid, an antibiotic which is a reversible non-selective MAOI.** ***Serotonin Syndrome:*** The development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including Lexapro treatment, particularly with concomitant use of serotonergic drugs (including triptans) and with drugs which impair metabolism of serotonin (including MAOIs). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The concomitant use of Lexapro with MAOIs intended to treat depression is contraindicated (see **CONTRAINDICATIONS** and **WARNINGS - Potential for Interaction with Monoamine Oxidase Inhibitors**.) If concomitant treatment of Lexapro with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases (see **PRECAUTIONS - Drug Interactions**).The concomitant use of Lexapro with serotonin precursors (such as tryptophan) is not recommended (see **PRECAUTIONS - Drug Interactions**). **PRECAUTIONS General** Discontinuation of Treatment with Lexapro During marketing of Lexapro and other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with Lexapro. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (see **DOSAGE AND ADMINISTRATION**). Abnormal Bleeding 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). Cases with serum sodium lower than 110 mmol/L have been reported and appeared to be reversible when Lexapro was discontinued. Elderly patients may be at greater risk of developing hyponatremia with SSRIs and SNRIs. Also, patients taking diuretics or who are otherwise volume-depleted may be at greater risk (see 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/m²] 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/m² basis. No teratogenicity was observed at any of the doses tested (as high as 75 times the MRHD on a mg/m² 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/m² 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/m² 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 post marketing 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.

Buildings Were Battered, But Not MH Services

Louisiana knows Katrina, and Gustav was no Katrina, but the recent hurricane was difficult enough for clinicians trying to provide uninterrupted mental health care services.

BY AARON LEVIN

Hurricane Gustav may have treated Louisiana less harshly than Katrina, but the lessons learned from the catastrophic 2005 storm kept Baton Rouge's public mental health services in operation despite widespread damage.

"In Katrina, we were providers" of care for storm victims from New Orleans, said Jan Kasofsky, Ph.D., executive director of the region's Capitol Area Human Services District (CAHSD). "In Gustav, we were providers and victims."

Gustav left Louisiana's capital city struggling under a burden of broken tree limbs, downed power lines, and wind-damaged buildings. Electric power still hadn't been restored throughout much of the city a week after the storm.

Baton Rouge was hit harder than New Orleans this time, at least in part because the storm's path collided with major power lines feeding the city.

The CAHSD took steps to ensure continuity of its services even before the storm made landfall.

"We printed out all appointments and telephone numbers ahead of time and called clients to tell them when and where they could be seen," said Kasofsky. "We also contracted with Walgreens Pharmacy so we could call in all prescriptions, which are prepaid and can be picked up at the location closest to the patient."

Perhaps chastened by Katrina, residents of New Orleans and the Louisiana coast headed inland ahead of Gustav as ordered, said Harold Ginzburg, M.D., J.D., disaster coordinator for the Louisiana Psychiatric Medical Association. Transportation by bus or rail was provided this time for institutionalized or incarcerated persons and for those without cars. Most evacuees had to keep moving on to Mississippi or Texas to find places to ride out the storm, although Baton Rouge churches did provide some space for those who couldn't make it to out-of-state destinations.

"Everyone was anxious until the storm passed," said Ginzburg of his enforced stay at Jacob's Camp in Mississippi, his place of refuge during both Katrina and Gustav. Afterward, some saw this storm as a positive, even therapeutic experience, he said. One patient told Ginzburg of his new-found resiliency in the face of the hurricane.

However, Ginzburg worried that lighter-than-expected damage in New Orleans coupled with heavy traffic and eight-hour travel times during the evacuation would dissuade residents from evacuating the next time a big hurricane looms.

Medical Shelters Established

Baton Rouge, still home to thousands of people dislocated by Katrina, faced a different set of problems with Gustav.

"There were no nonmedical shelters set up in the state," said Kasofsky. "Along with the Office of Public Health and LSU [Louisiana State University], we set up a medical special-needs shelter in the Pete Maravich Center on the LSU campus."

Medical-needs shelters were set up in neighboring states too.

The CAHSD teams were responsible for all mental health support for its main shelter and 66 other sites in the region, she said. The LSU shelter took in 330 patients, many of whom had been homebound. Medical care was provided by Earl K. Long Hospital, and nurses were sent from the Department of Public Health. Kasofsky's staff went on 12-hour shifts to provide round-the-clock service and remained on that schedule for over a week.

"In a disaster, you can't stop serving clients," she said. "Patients were here asking to see their doctors."

Her team played another role as well. Critics of disaster planning in the United States have complained in the past that mental health considerations have been left out of the disaster-response infrastructure. The Baton Rouge incident command team not only included a mental health liaison 24 hours a day, but Kasofsky or a member of her staff also served rotating tours of duty as team commanders.

Credit: Capital Area Human Services District

Mobile clinics run by the Children's Health Foundation are parked in front of the Capital Area Human Services District's storm-wrecked building to keep existing appointments and offer triage services to the public after Hurricane Gustav.

Credit: Capital Area Human Services District

Wind and water damage to Louisiana's Capital Area Human Services District's main facilities was so extensive that the building will be out of use for a year while repairs are made.

About 60 patients were on oxygen when the power in the shelter went out and the backup generator malfunctioned and died. Fortuitously, the blackout happened just before the arrival of Gov. Bobby Jindal (R), who placed a call to the power company, which provided a new generator. Eventually the patients needing oxygen were transferred to a hospital for further care.

Damage Leaves Staff Scrambling

But problems at the shelter were manageable compared with the storm's effects on the CAHSD's headquarters building and main clinic.

"The roof of our largest facility was peeled off, and the building sustained water damage," said Kasofsky. The agency's largest adult and child mental health facilities, its developmental disabilities services, and all administrative offices are unusable and will be closed for a year.

The staff scrambled to find temporary and then long-term alternative office and clinic spaces and began moving in within a week after the storm. They also transferred $3 million worth of pharmaceuticals into a temperature-controlled building.

The quick response by the staff had clinical benefits, said CAHSD medical director Gerald Heintz, M.D.

"Because we made it known that we were in operation and taking walk-ins, we prevented a lot of decompensation—and hospital beds were in pretty short supply to begin with," said Heintz in an interview.

The experience reinforced the lessons of prior hurricanes.

"Decision makers have to be on the ground to see for themselves what's going on," Kasofsky emphasized. "Management must be visible as well. Let the staff troubleshoot, give them input and feedback and honest answers to questions. You have to be clear and give direction, but you also have to be flexible." ■

SAMHSA Web Site Links Professionals Who Study, Work With Homeless

The federal agency creates a Web site to help clinicians and others address problems of homeless people with mental health problems.

BY EVE BENDER

To create a virtual community for clinicians, policymakers, and researchers working with homeless people who have a mental illness, the Substance Abuse and Mental Health Services Administration has launched a new Web site.

The Homelessness Resource Center Web site is designed to facilitate education and communication among those who work with or conduct research involving people who are homeless and have mental health and substance abuse problems.

Features on the site include information from caseworkers about how to reach out to the homeless, get medical care for homeless people, and obtain housing for them. It also has a section discussing recovery-oriented mental health services.

In addition, the Web site lists facts about homelessness in different populations, such as children, adolescents, and ethnic and racial minorities, for example. There is also information about federal programs for homeless people and supportive housing programs.

The new site "provides a platform for creating an interactive community of providers, consumers, policymakers, researchers, and public agencies at federal, state, and local levels working to prevent and end homelessness," said SAMHSA Administrator Terry Cline, Ph.D., in a press release announcing the new Web site.

The Homelessness Resource Center Web site can be accessed at <www.homeless.samhsa.gov>. ■

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Parity Compromise Overcomes Most DB Objections

The compromise parity bill now before Congress would not undercut stronger state parity laws, as many feared an earlier Senate-passed version might.

BY RICH DALY

APA district branches that previously opposed terms in a Senate-passed mental health parity bill are supporting a compromise measure that addresses a number of their key concerns.

Several district branches (DBs) had contacted APA's Department of Government Relations over the last year to voice opposition to a federal parity bill that passed the Senate in September 2007. The Mental Health Parity Act of 2007 (S 558) would have required insurers to apply the same treatment limitations and cost-sharing requirements to treatment of mental illness, including substance abuse, as they did for other medical services. Similarly, day and visit maximums, copays, and deductibles, would have had to be applied equally.

The Senate bill—arrived at after years of negotiations among Senate parity supporters, business groups, and the insurance industry—drew opposition for language that many psychiatrists in states with strong mental health parity laws said would create a "ceiling," or national limit, on the maximum parity benefits that insurers could be required to provide.

Some state parity laws go beyond the requirements of the Senate bill or even a stronger House measure (HR 1424), with provisions such as those requiring insurers to allow any licensed mental health or substance abuse treatment provider willing to meet the insurer's terms and conditions into the insurer's network or list of authorized providers.

"Vermont has a broad-based parity bill, which was passed in 1997, with active support from" the Vermont Psychiatric Association (VPA), David Fassler, M.D., VPA's legislative representative and secretary-treasurer of APA, told *Psychiatric News*. "We were concerned that early drafts of the federal parity bill, specifically the Senate version, contained a preemption clause designed to override such existing state legislation."

Like several other DBs, the VPA contacted APA and its state congressional delegation to voice its concerns about the Senate bill.

Oregon DB Registers Concerns

John McCulley, executive director of the Oregon Psychiatric Association, said that the DB also had voiced concerns to APA about the Senate bill, because its member psychiatrists were concerned that Oregon's strong parity law, which was enacted in 2005, could be undermined by the federal measure.

"Any time we can provide parity for more people, it will be helpful," McCulley said.

Many other mental health advocacy groups and state officials also contacted members of Congress to voice their preemption concerns stemming from the Senate bill. For example, Vermont's Department of Banking, Insurance, Securities, and Health Care Administration sent House Speaker Nancy Pelosi (D-Calif.) an analysis that also outlined areas of its state parity law that the Senate bill might override. Advocates for a stronger mental health parity bill called for federal legislation that would establish a base level of mental health parity requirements and allow states to add onto that with their own laws.

The DB opposition to the Senate parity bill was in contrast to other mental health advocates who supported it as the most politically realistic option at this time. Mental health advocates who supported the Senate version were concerned that changes to the carefully negotiated Senate measure, which marked the first time that business and insurance-industry leaders had supported a parity expansion, would keep any parity measure from passing in the current Congress.

Compromise Gains Support

A parity measure that was more popular with mental health advocates and provided only a floor for mental health and substance abuse benefits passed the House of Representatives in March. Congressional negotiators wrestled with differences in the House and Senate versions of parity until a compromise was announced in June. The compromise language dropped the Senate's ceiling on benefits, while retaining other less-controversial components of the Senate bill (*Psychiatric News*, September 19).

The compromise language has drawn widespread support from previously critical DBs primarily because it allows their stronger state provisions to continue while broadening access to parity coverage, even within those states, by applying to insurance plans that federal law has long barred states from regulating. The federal compromise measure would require equal coverage for both mental and physical health in those plans that provide a mental health benefit, and it would affect coverage of nearly 113 million people. Nearly 82 million of those people affected are insured through plans that fall under the Employee Retirement Income Security Act (ERISA), which are not subject to state parity law requirements. The compromise bill would provide the first expansion in parity requirements for ERISA plans—principally the insurance plans of large, self-insured companies—since a limited federal parity law was enacted in 1996.

"To have comprehensive parity outside of the government [health care insurance] systems, you have to have both state and federal parity," said Barry Perlman, M.D., chair of APA's Committee on Government Relations and legislative director for the New York State Psychiatric Association, which also had raised concerns about the earlier Senate parity measure. "They really complement each other."

Fassler said that the compromise bill "represents progress, particularly with respect to ERISA," although it is not the ideal federal legislation that some parity advocates would like to have. Many parity advocates were hoping for strong federal legislation that would include such measures as requiring all health insurance plans to offer an option with mental health coverage and cover all conditions listed in *DSM-IV*.

The compromise also "could have a significant impact in Vermont where many larger employers are self-insured and not subject to state insurance regulations," Fassler noted.

To finally obtain parity for mental health treatment, including that for substance abuse, supporters will need to advocate for the compromise measure's passage in the final weeks of the current Congress. Senate and House supporters are scrambling to find funding offsets for the bill's $3.8 billion, 10-year cost before the compromise can be voted on in both houses.

The text of the parity compromise can be accessed at <http://thomas.loc.gov> by searching on the bill number, S 3334. ■

Financial Aid for Part D Recipients Difficult to Obtain

A government report finds eligibility denials common in a program that is supposed to offer Medicare Part D payment assistance to low-income beneficiaries.

BY RICH DALY

The Part D Medicare drug program rejected over half of the seniors who applied for payment assistance based on either their income or the amount of assets they reported, according to a new federal agency report.

The report by the Government Accountability Office (GAO), released in September, examined the Low-Income Subsidy (LIS) or Extra Help program included in Part D when Congress approved the Medicare prescription-assistance plan in 2003. The LIS program was designed to help defray the cost of prescription drugs for beneficiaries with "limited means" and restricted the assistance program to beneficiaries whose assets and income were less than the thresholds established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Social Security Administration is responsible for determining eligibility for the LIS.

In a report mandated by the 2003 Medicare Part D law, the GAO found that more than half of the 4.5 million beneficiaries who applied for LIS assistance in Fiscal 2006 were denied the subsidy. The report also found that about 56 percent, or 336,183 applicants, were denied the extra help in Fiscal 2007. The continued high rejection rate and other LIS findings indicate that many more seniors need help than are qualifying for assistance based on federal standards, according to critics of those standards.

"This GAO report shows that there continues to be problems with low-income beneficiaries getting the help they need with high drug costs," said Rep. Henry Waxman (D-Calif.), chair of the House Oversight and Government Reform Committee, in a written statement following release of the report. "We need to take a hard look at the Part D asset test and make the necessary reforms so that the Medicare program is working effectively for our nation's seniors and ensuring they get the assistance they need."

There were no reported findings that the LIS rejections were erroneous or that administrators did not follow the federal eligibility guidelines in denying applications.

To qualify for the LIS, applicants must be below the Part D income and asset thresholds, which for 2008 are $15,600 in income for individuals and $21,000 for couples, and assets of $11,990 for individuals and $23,970 for couples.

The LIS help can amount to substantial financial assistance. Generally, Part D beneficiaries are responsible for paying monthly premiums, an annual deductible, and copayments. Those who qualify for full LIS assistance pay no deductible or monthly premiums, and they are not subject to Part D's "donut hole" or coverage gap in prescription-drug costs between $2,510 and $5,726.

The high rejection rate in the LIS program has helped limit the growth of the benefit.

The Centers for Medicare and Medicaid Services (CMS) reported that 9.38 million beneficiaries were receiving the LIS as of January, but most qualified automatically because they are recipients of Medicaid or Supplemental Security Income or because they are enrolled in a Medicare Savings Program. Only 1.53 million of the LIS recipients (about 16 percent) had applied for the subsidy and cleared its income and asset limits. CMS estimated that there were 2.6 million additional beneficiaries who were eligible for the LIS as of January but were not receiving it because they had failed to apply.

The report noted that although the rate of LIS rejection remained at over 50 percent in Fiscal 2006 and Fiscal 2007, the percentage of beneficiaries rejected because of income alone rose from 50 percent to 70 percent over those two years.

"Both assets and income were important factors in LIS denials, but more applicants were denied the subsidy because their income was too high than were denied it because their assets were too high," according to the GAO.

Among those who were denied based on their assets, many exceeded the asset

please see ***Financial Aid*** *on page 22*

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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.

62-1012588R 03/08

Namenda
memantine HCl

Tablets/Oral Solution
Rx Only

Brief Summary of Prescribing Information.

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

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

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

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

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

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

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

Renal Impairment
No dosage adjustment is needed in patients with mild or moderate renal impairment. A dosage reduction is recommended in patients with severe renal impairment (see CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION in Full Prescribing Information).

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

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

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

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

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

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

Carcinogenesis, Mutagenesis and Impairment of Fertility
There was no evidence of carcinogenicity in a 113-week oral study in mice at doses up to 40 mg/kg/day (10 times the maximum recommended human dose [MRHD] on a mg/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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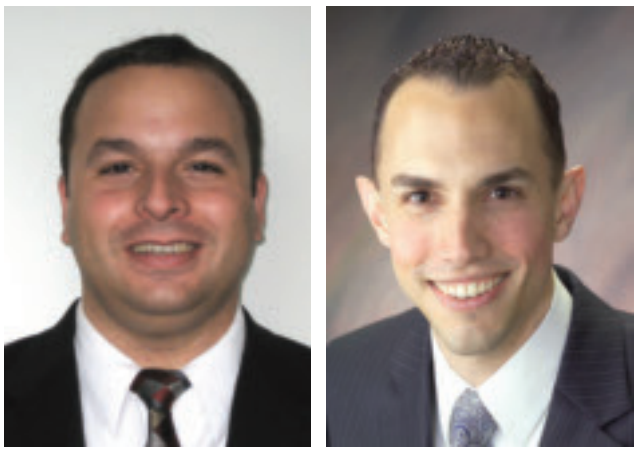
Want Your Voice to Count? Join Us at the AMA

BY CARLOS RODRIGUEZ, M.D.
KEITH STOWELL, M.D., M.S.P.H.



Carlos Rodriguez, M.D., and Keith Stowell, M.D., M.S.P.H.

The AMA's Resident and Fellow Section, the largest national organization of graduate medical trainees, has a membership of nearly 30,000 individuals from all states and specialties. The group advocates for resident and fellow physicians within the AMA and has an influential voice in reforming the health care system, improving medical education, and helping trainees on a professional and personal level.

APA has a highly involved and very effective delegation—the Section Council on Psychiatry—that works within the AMA. Currently led by Dr. Jack McIntyre, chair of the Section Council on Psychiatry and a past president of APA, and Dr. David Fassler, vice chair of the Section Council on Psychiatry and APA secretary-treasurer, the delegation is influential in the AMA annual and interim meetings.

The delegation introduces and advocates for resolutions important to psychiatrists, their patients, and the mental health of Americans in general. Within the section council are a delegate and alternate delegate to the Resident and Fellow Section (RFS) whose job is to represent the interests of psychiatric trainees and patients.

Several issues discussed by the AMA House of Delegates at its annual meeting in June were highly relevant to psychiatrists and others who treat people with mental illness. Psychiatrists were, for example, involved in submitting a resolution related to concerns about therapeutic equivalence (or potential lack thereof) of generic medications, which may particularly affect drugs used to treat psychiatric and neurologic conditions.

Another resolution focused on the difficulty patients have in accessing psychiatric beds, which has resulted in overcrowding in emergency departments, and the need to improve access to inpatient and outpatient psychiatric care (*Psychiatric News*, July 18).

In addition the section council was involved in advocating for resolutions related to medical education. The AMA Council on Medical Education had prepared a report, "Improving Parental Leave Policies for Residents," with recommendations that included encouraging the Accreditation Council for Graduate Medical Education to "study the feasibility of requiring training institutions to offer paid FMLA [Family and Medical Leave Act]-qualified leave for residents of no less than six weeks' duration, and to permit unpaid FMLA-qualified leave of an additional six weeks." The section council backed this recommendation, which resulted in a resolution proposing that the member boards of the American Board of Medical Specialties standardize policies regarding leave, including not requiring residents to make up any more time than they took for FMLA-qualified leave.

In response to the crucial need for physicians to receive training in public-health issues, the AMA Council on Medical Education also recommended that the AMA participate in planning to implement recommendations in the Institute of Medicine report titled "Training Physicians for Public Health Careers," which calls for expansion of physician enrollment in postresidency public-health fellowships. Proponents hoped that this would allow for trainees in all specialties to participate in public-health training, perhaps leading to a master's degree in public health. Given the significant need for input from psychiatrists and mental health professionals in the public health sphere, this resolution was supported by the section council.

With young physicians increasingly struggling with debt from their medical education, numerous resolutions were submitted on medical-school debt and financial aid. The House of Delegates approved supporting medical-school policies that require financial-aid officers to disclose any incentives received from lenders designated as "preferred lenders" to allow for greater transparency in educational-loan processing. The AMA also agreed to support standardizing disclosure practices that require medical schools to explain reasons for tuition increases and the planned use of income generated by those increases.

Further, a resolution was approved to have the AMA research solutions to the ongoing debt crisis faced by medical students, residents, and fellows. Unfortunately, issues of educational debt and loan repayment have been shown to play significant roles in the career choices of medical students and residents, making some less likely to choose careers in psychiatry or certain areas of psychiatry because of a perception that these are lower paying than other specialty fields. The section council was a strong supporter of efforts to reduce the loan burden from medical education costs.

While both time and money for graduate medical trainees are often limited, membership in the AMA is a good way to ensure that your voice and your concerns are heard by your colleagues in all medical fields. The AMA's activities have been influential in changing key policies at local and national levels to the benefit of physicians and the people they treat. Membership and participation also afford residents a valuable opportunity to meet trainees and practicing physicians in all specialties and all areas of the country, helping to make personal and professional connections that can last a lifetime.

Additional information about the AMA RFS is posted at <www.ama-assn.org/ama/pub/category/15.html>. Information on joining the AMA or renewing membership is posted at <https://membership.ama-assn.org/JoinRenew>. ■

Carlos Rodriguez, M.D., is APA's delegate to the AMA Resident and Fellow Section and a child psychiatry fellow at the University of Florida. Keith Stowell, M.D., is APA's alternate delegate and a geriatric psychiatry fellow at the University of Pittsburgh Medical Center's Western Psychiatric Institute and Clinic.

Forensic Coverage; Documentation Crucial

Q. I am currently in private practice. Recently I was asked to provide expert witness testimony. When I mentioned this offer to a colleague, she advised me to check my professional liability insurance policy to verify that I have coverage for forensic activities. Don't all policies cover forensic services? If not, do I really need to be concerned since only a small percentage of my practice would be focused in this area?

A. Many insurance carriers classify forensic services as nonmedical because this professional activity by a psychiatrist does not involve the direct treatment or care of a patient. Thus, these insurance carriers do not cover claims arising out of forensic services. This could be problematic as courts are imposing greater duties and liability on physicians performing forensic services, such as expert witness testimony. A policy with the Psychiatrists' Program defines psychiatric services as medical services directly related to the practice of psychiatry or behavioral health care with respect to evaluating, diagnosing, or treating a mental disorder and routine medical care incidental to the provision of such services to patients. With the Psychiatrists' Program, forensic psychiatric activities are covered at no additional charge.

Q. I am a psychiatrist who recently graduated from residency. I have opted to start a private practice, but I'm concerned about the risks of practicing without the supports that hospital staff psychiatrists automatically have at their disposal. How can I avoid being sued for medical malpractice without resorting to practicing "defensive" medicine?

A. Because the primary goal of risk management is to provide for adequate patient care, the most effective way to reduce your risk of being successfully sued is to practice good medicine while documenting the same.

Practicing good medicine entails remaining focused on patients' clinical needs, carefully monitoring medications, being diligent with follow-up care, and staying current with advances in the field. As a treating psychiatrist, you are obligated to obtain an adequate medical and psychiatric history, conduct an appropriate examination, and follow up at reasonable intervals to assure that treatment is progressing as desired.

Medication levels and appropriate physiologic functions should be monitored regularly along with patient compliance. If you are prescribing medications, be sure to consult reputable treatment guidelines (for example, APA's practice guidelines, AACAP's practice parameters). Useful information for patients, as well as physicians, about medication is accessible at the Food and Drug Administration's Web site at <www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm>.

Don't forget to document carefully and contemporaneously your clinical care and decision-making processes. Remember the adage, "If it wasn't documented, it wasn't done." This is a useful reminder that the purpose of documentation is to provide for good patient care. In short, the medical records you create will serve as your best tangible defense in the event that a patient sues or makes a medical board complaint.

Maintaining competency is imperative for psychiatrists. Avenues to achieve this include consulting with other colleagues, joining APA and your state medical society, attending continuing medical education courses, and consulting professional literature. APA provides myriad resources, one of which is *Practice Management for Early Career Psychiatrists: A Reference Guide.* This 2008 publication is a handy reference guide for any psychiatrist thinking of starting a practice.

Participants in the Psychiatrists' Program have access to additional resources such as detailed articles and tips on specific topics of interest and phone consultations through the Risk Management Consultation Helpline at (800) 527-9181. The Helpline operates from 8:30 a.m. to 5:30 p.m. Eastern time.

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

Newer Antipsychotics Don't Show Superiority in Children, Teens

Weight gain was a significant problem with risperidone and olanzapine; the older molindone was associated with more self-reports of akathisia.

BY MARK MORAN

Two second-generation antipsychotic agents typically prescribed to children and teens with early-onset schizophrenia were not more efficacious than an older first-generation drug, according to a report in the *American Journal of Psychiatry*.

The findings appear to replicate in early-onset schizophrenia what was found for adults in the landmark Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study: that newer second-generation drugs, marketed as better as a class than the older drugs, are not necessarily superior.

In the Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS) study, risperidone and olanzapine did not demonstrate superior efficacy over molindone for treating patients with early-onset schizophrenia and schizoaffective disorder. Adverse effects were frequent but differed among medications, and dropout was substantial in all groups.

Weight gain was particularly prominent in the group receiving risperidone and olanzapine.

The report was posted September 15 on *AJP in Advance*. It will appear in the November print edition of the journal.

Lead author Lin Sikich, M.D., said that most antipsychotic prescriptions written for children and teens—as high as 98 percent—are for second-generation antipsychotics. The TEOSS study should prompt a reconsideration of that pattern, she said. Sikich is an associate professor of psychiatry at the University of North Carolina.

"Clinicians should give serious consideration to using midpotency, low weight-gain-inducing, first-generation drugs early in the treatment of kids with early-onset schizophrenia," Sikich told *Psychiatric News*. "It becomes a big issue because weight gain is so much more problematic in kids than in adults."

In the study, 116 youth aged 8 to 19 were identified at four academic medical centers and randomized to olanzapine (2.5 mg/day–20 mg/day), risperidone (0.5 mg/day–6 mg/day), or molindone (10 mg/day–140 mg/day plus 1 mg/day of benztropine) for eight weeks. The four centers were the University of North Carolina at Chapel Hill, McLean Hospital and Cambridge Health Alliance at Harvard Medical School, University of Washington, and Case Western Reserve University.

The primary outcome was response to treatment, defined as a Clinical Global Impression improvement score of 1 or 2, and at least a 20-percent reduction in the total score on the Positive and Negative Syndrome Scale after eight weeks of treatment.

No significant differences were found among treatment groups in response rates (molindone: 50 percent; olanzapine: 34 percent; risperidone: 46 percent) or magnitude of symptom reduction. Olanzapine and risperidone were associated with significantly greater weight gain. Olanzapine showed the greatest risk of weight gain and significant increases in fasting cholesterol, low-density lipoprotein, insulin, and liver transaminase levels.

Sikich said that the issue of antipsychotic-induced weight gain is especially problematic in children. They are more likely to experience weight gain associated with antipsychotic use than adults are—80 percent to 90 percent of children and teens treated with olanzapine or risperidone experience weight gain of 70 percent or more of their baseline weight—and they also gain more weight both proportionately and absolutely.

Additionally, even youth who were obese during childhood and return to a normal weight are believed to be at greater risk for cardiovascular and other health effects later in life, Sikich said.

She added that reports that children are more susceptible to extrapyramidal symptoms (EPS) have caused clinicians to shy away from using first-generation drugs. But she stressed that EPS can be controlled with anticholinergic drugs—such as benzotropine, which was used in the trial with youth receiving molindone—and propanolol.

Molindone led to more self-reports of akathisia, but was not associated with more Parkinsonian or dystonic symptoms than olanzapine or risperidone, likely because of prophylactic benztropine treatment, Sikich and colleagues wrote.

Those children who experienced akathisia were treated with propanolol. "One question the study raises is whether clinicians should use propanolol prophylactically when treating children or teenagers with a first-generation antipsychotic," Sikich said.

"Although it is difficult to rank the clinical importance of different adverse effects, those associated with olanzapine and risperidone are likely to have persistent effects on long-term physical health, while those associated with molindone seem more likely to impact adherence to antipsychotic medication," the authors wrote. "However, in this trial, there was no greater attrition in the molindone group, despite more reports of akathisia."

William Carpenter, M.D., director of the Maryland Psychiatric Research Center and a frequent critic of industry marketing of second-generation drugs, said the TEOSS study confirms that what was found by CATIE applies as well at the earliest point of treatment initiation.

"Clinicians' hope and industry marketing have made second-generation antipsychotic drugs the first choice for patients at or near their first episode of psychotic illness," Carpenter told *Psychiatric News*. "Overlooked was the reasonable expectation that drugs with the same therapeutic mechanism would have the same efficacy profile. Important differences in adverse-effect profiles should guide drug selection, but recognition of efficacy similarity and adverse-effect differences has been slow in influencing practice."

The study was supported by the National Institute of Mental Health and National Institutes of Health. Janssen and Eli Lilly and Co. provided risperidone and olanzapine, respectively, at no cost for the study.

"Double-Blind Comparison of First- and Second-Generation Antipsychotics in Early-Onset Schizophrenia and Schizoaffective Disorder: Findings From the Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS) Study" can be accessed at <http://ajp.psychiatryonline.org/pap.dtl>. ■

Gene Study Reveals Clues To Bipolar Disorder Physiology

Genetic findings converge with previous research to reveal what goes wrong in the nervous system of bipolar patients.

BY JUN YAN

A large genomic study suggests that defective sodium and calcium channels in neurons may explain an important part of the physiological mechanism of bipolar disorder.

A group of researchers in the United States, United Kingdom, and Canada found significant association between bipolar disorder and genetic variations in two genes involved in the formation of a sodium channel and a calcium channel, ANK3 and CACNA1C.

The study, the largest genomic study on bipolar disorder to date, tested 1.8 million genetic polymorphisms in 4,387 bipolar patients and 6,209 control subjects from three studies to identify genetic variations that may be significantly associated with the illness.

Sodium and calcium channels are "ion gates" made of proteins embedded in cell membranes. They regulate the amount of electrically charged sodium and calcium ions flowing in and out of nerve cells as they open and close. This process is a fundamental part of generating and transmitting signals throughout the nervous system.

please see ***Gene Study*** *on facing page*

FGAs Not Necessarily Safer Than SGAs in Elderly

Although initial warnings have been directed at second-generation antipsychotics, elderly patients face similar risks with first-generation ones as new evidence points to cardiovascular side effects as the main culprit.

BY JUN YAN

Although regulatory warnings have been issued about the use of second-generation antipsychotics (SGAs) in elderly patients, recent studies indicate that first-generation antipsychotics (FGAs) pose similar or possibly higher risk of death, especially death related to cardiovascular disease. Evidence also suggests that dementia is associated with a higher risk of stroke in elderly patients taking antipsychotics.

In a large observational study published in the August 6 *Journal of the American Society for Geriatric Psychiatry*, Harvard Medical School researchers Soko Setoguchi, M.D., Dr.P.H., and colleagues analyzed medical records and causes of death of 12,882 elderly patients who were started on FGAs and 24,359 started on SGAs. All subjects were residents of British Columbia, Canada, from 1996 through 2004 and aged 65 or older.

The researchers found that cardiovascular causes accounted for almost half (49 percent) of patient deaths within the first 180 days of initiating treatment with an antipsychotic drug. FGAs were associated with statistically significantly higher risks than SGAs in terms of all noncancer deaths, with a hazard ratio of 1.27.

Patients who were started on FGAs had significantly higher risks for cardiovascular, respiratory (excluding pneumonia), and nervous-system-related deaths, but not infection- and mental disorder-related deaths, compared with those initiated on SGAs.

FGAs are considered more likely to prolong the QTc interval and repolarization in the heart than are SGAs (except for ziprasidone), which may explain the higher risk of cardiovascular deaths associated with FGAs, the researchers suggested. The increased risk of respiratory deaths, however, has not been studied before. They hypothesized that the reason may be that greater "anticholinergic side effects of [FGAs] in elderly patients with severe chronic respiratory disorders might cause worsening of symptoms and choking through drying secretions and difficulty in clearing mucus."

The patients in the study, which looked at deaths from all causes, were on average about 80 years old when they started taking an antipsychotic drug. About 10 percent of them had dementia.

The study was funded by the U.S. Agency for Healthcare Research and Quality.

Higher Stroke Risk With SGAs

Although the risk of death appears to be higher in elderly patients taking FGAs than in those taking SGAs, SGAs were associated with a higher risk of stroke than were FGAs in elderly patients, especially those with dementia, according to a study posted August 28 on the *British Medical Journal* Web site.

The study was conducted by Ian Douglas, M.D., and Liam Smeeth, Ph.D., of the London School of Hygiene and Tropical Medicine. They analyzed medical data from the U.K. General Practice Research Database and identified 6,790 patients who had at least one prescription for an antipsychotic drug and a recorded incident of stroke between January 1988 and the end of 2002.

Using the patients as their own controls before and after they were prescribed an antipsychotic drug, the researchers found an increased risk of stroke associated with antipsychotic use, and this risk was "slightly higher" in patients given SGAs (risk ratio 2.32 after treatment compared with before) than FGAs (risk ratio 1.69). In addition, the antipsychotic-associated risk of stroke in patients with dementia was more than twice as high as that in patients without dementia.

As in the Canadian study, the patients in this study also had an average age of approximately 80 at the time they were started on an antipsychotic drug. Unlike the Canadian sample, however, this study focused on stroke, not death, and a third of the patients had dementia.

Antipsychotics for Elderly Still Popular

Regulatory agencies in the United States, Canada, and the United Kingdom have issued warnings about the increased risk of death associated with SGA use in elderly dementia patients. The warnings are based on epidemiological data. And the U.S. Food and Drug Administration recently required that the package inserts for FGAs have the same black-box warning as the SGAs concerning use in elderly people (*Psychiatric News*, July 18).

Regulatory agencies began warning physicians and the public about SGA-associated risks starting in 2002, but elderly patients continued to receive these medications to treat agitation and other behavioral symptoms, a group of Canadian researchers found.

Using prescription-drug claims data from the Ontario government's drug-benefits program, the authors analyzed the number of antipsychotics prescribed for dementia patients from May 1, 2000, to February 28, 2007. They found that the number of SGA prescriptions for elderly dementia patients continued to rise after Health Canada issued three advisories to warn health care professionals of the associated risks.

Overall, the prescription rates of antipsychotics increased by 20 percent from September 2002, immediately before the first regulatory warning, to the end of the study period. The authors concluded that the regulatory warnings had "limited impact" on physicians' prescribing of antipsychotics for elderly patients with dementia.

This study was funded by the Canadian Institutes of Health Research and published in the August 26 *Canadian Medical Association Journal*.

An abstract of "Potential Causes of Higher Mortality in Elderly Users of Conventional and Atypical Antipsychotic Medications" is posted at <www3.interscience.wiley.com/journal/121371905/abstract>. An abstract of "Exposure to Antipsychotics and Risk of Stroke: Self-Controlled Case Series Study" is posted at <www.bmj.com/cgi/content/full/337/aug28_2/a1227>. An abstract of "Effect of Regulatory Warnings on Antipsychotic Prescription Rates Among Elderly Patients With Dementia: A Population-Based Time-Series Analysis" is posted at <www.cmaj.ca/cgi/content/abstract/179/5/438>. ■

Gene Study

continued from facing page

The ANK3 gene is expressed as the ankyrin G protein, a type of protein involved in regulating the sodium channels in nerve cell membranes that open and close according to electrical impulses. They are known as voltage-gated channels because they open and close depending on the difference in electric charges within and outside of the cell membrane. Several single nucleotide polymorphisms across the chromosomal region for the ANK3 gene were found to be strongly associated with bipolar disorder ($p=9.1\times10^{-9}$), meaning that bipolar patients are much more likely to have defects in this protein than those without the illness.

The second strongest genetic association with the illness was found in a noncoding region (the third intron) of the CACNA1C gene, which codes for a subunit of the L-type voltage-gated calcium channel protein. Additional regions associated with bipolar disorder were also identified.

Scientists have already suspected ion channel problems in the mechanism of bipolar disorder, as both ANK3 and subunits of the calcium channel are downregulated in the brain in mice after lithium treatment. The findings in this genomic study have provided strong and independent corroboration for this theory.

The study was published online in *Nature Genetics* on August 17 and supported by grants from a number of government agencies in the United States, Australia, the United Kingdom, and Ireland and several private sources.

An abstract of "Collaborative Genome-wide Association Analysis Supports a Role for ANK3 and CACNA1C in Bipolar Disorder" is posted at <www.nature.com/ng/journal/v40/n9/abs/ng.209.html>. ■

Misdiagnoses Common in Cases Of Depression With Psychosis

A comment such as "My thoughts are not quite right" or irrational worries such as "Bad things are about to happen" may suggest that a patient has psychotic depression.

BY JOAN AREHART-TREICHEL

The diagnosis of major depression with psychotic features is often missed in patients, especially in the emergency room, a study reported in the August *Journal of Clinical Psychiatry* pointed out.

The study, which was headed by Anthony Rothschild, M.D., chair of psychiatry at the University of Massachusetts, included 65 inpatients at four academic medical centers. Subjects were recruited from a larger study called the National Institute of Mental Health Study of Pharmacotherapy of Psychotic Depression (STOP-PD), and STOP-PD researchers had determined that all of them had psychotic depression.

Moreover, to be in their study, Rothschild explained to *Psychiatric News*, "all subjects were required to have at least one delusion, and some also had hallucinations. The delusions were most typically somatic delusions, paranoid delusions, delusions of guilt, delusions of poverty, and nihilistic delusions that bad things are about to happen."

Rothschild and his colleagues then gathered each patient's hospital records from the time preceding their enrollment in the STOP-PD study to see what types of diagnoses he or she had received in the hospital emergency room or hospital psychiatric unit. The 65 inpatients had received, altogether, 130 diagnoses, meaning that some had received several diagnoses. Finally Rothschild and his team looked to see whether these 130 diagnoses had been made correctly.

Over one-fourth had not, the researchers found. The three most common misdiagnoses were major depressive disorder without psychotic features, depression not otherwise specified, and mood disorder not otherwise specified. Misdiagnoses made less often included delirium, anxiety disorder not otherwise specified, and alcohol dependence.

The erroneous diagnoses were more common in emergency rooms than on inpatient psychiatric units, and as Rothschild and his colleagues pointed out, "It is quite striking that none of the patients with missed diagnoses were considered to have a psychotic disorder. This finding suggests that the physicians are missing the psychosis rather than the mood disorder. In many cases, it may be that the physician does not miss the symptom (for example, guilt, poverty, persecution), but does not recognize that the symptom is a delusion. In particular, the distinction between delusional and nondelusional guilt is frequently difficult."

These findings have important clinical implications, the researchers believe, since major depression with psychotic features often entails considerable morbidity and mortality, and its treatment differs from that for major depression alone. According to the APA 2000 practice guideline on the disorder, either an antipsychotic with an antidepressant or electroconvulsive therapy should be used, they noted.

"As the process for *DSM-V* is beginning," they continued, "it will be important to revisit the issue of whether 'major depression with psychotic features' should be a separate illness in *DSM-V*, as was recommended (but rejected) for *DSM-IV*, rather than a specifier of 'major depressive disorder,' a position where it can more easily be overlooked. The hope would be that if 'major depression with psychotic features' were a separate illness in *DSM-V*, it would result in greater awareness and more accurate diagnosis among practitioners."

Meanwhile, Rothschild offered the following tips on how psychiatrists can better detect psychotic depression:

- Develop a therapeutic relationship with patients so that they feel comfortable confiding their thoughts to you.
- Since patients are often guarded, use nonthreatening terms such as "irrational worries" instead of "paranoia" or "psychosis."
- Listen carefully for clues of psychosis—for example, a patient saying something such as "My thoughts are not quite right."
- Involve family members in the assessment process of the patient. They may have observed strange behavior or speech that might indicate psychosis.

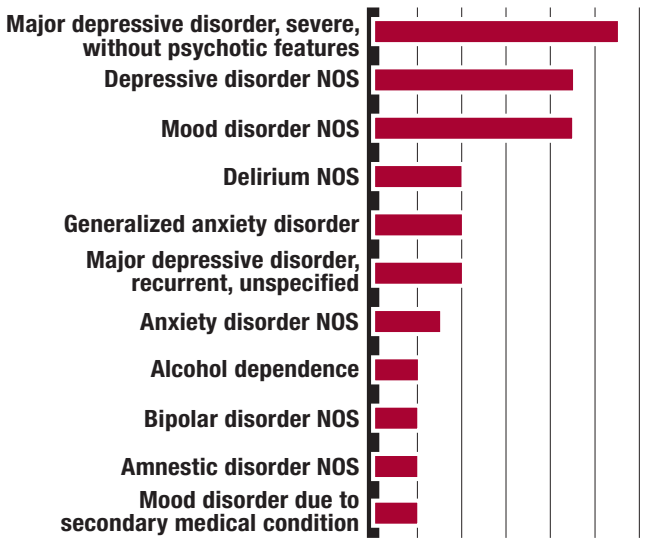
Also, Rothschild has written a book, *Clinical Manual for the Diagnosis and Treatment of Psychotic Depression*, to help physicians better diagnose the disorder. It will be available through American Psychiatric Publishing Inc. in November.

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

An abstract of "Missed Diagnosis of Psychotic Depression at Four Academic Medical Centers" is posted at <www.psychiatrist.com/abstracts/200808/080813.htm>. ■

Psychotic Depression Missed

In a study of 65 inpatients with psychotic depression who had received a total of 130 diagnoses, many of the diagnoses were incorrect. The erroneous diagnoses were more commonly made in emergency rooms than in inpatient psychiatric units.



Source: Anthony Rothschild, M.D., et al., *Journal of Clinical Psychiatry*, August 2008

Overlap Found Between Autism, Schizophrenia-Spectrum Disorders

Some patients may have traits of both autism and schizophrenia because the autism-spectrum and schizophrenia-spectrum disorders share some of the same susceptibility genes.

BY JOAN AREHART-TREICHEL

Although autism and schizophrenia are now generally recognized as two separate illnesses, there is reason to believe that autistic traits and schizophrenia traits co-occur in some individuals.

For instance, some children with autism disorder have been found to develop schizophrenia later in life, the negative symptoms of schizophrenia have been found to co-vary with autistic traits in certain schizophrenia subjects, and a link between autistic traits and schizophrenia traits was found in a sample of college students.

Now certain individuals with schizotypal personality disorder—considered the mildest schizophrenia-spectrum illness—have been found to possess an unusual preponderance of autistic traits. The results of the study, which was led by Michelle Esterberg, M.P.H., of Emory University, were published in the September *Schizophrenia Research*.

The study included 121 adolescent subjects—35 with schizotypal personality disorder; 38 with other types of personality disorders (antisocial, avoidant, borderline, narcissistic, obsessive-compulsive, paranoid, or schizoid); and 48 with no personality disorders. The subjects were evaluated for various autistic characteristics, and the results for each group were then compared.

The schizotypal group scored significantly higher than the other two groups on a number of autistic traits. They included being socially anxious, having no close friends, using a limited number of facial expressions, not showing affection, being unaware of social cues, having circumscribed or unusual interests, and being resistant to change. Furthermore, the schizotypal group scored especially high on deficits in the social-functioning domain.

"The present findings indicate significant. . .overlap between autism-spectrum and schizophrenia-spectrum disorders," Esterberg and her colleagues concluded.

Why might autistic traits and schizophrenia traits coexist in certain persons? Esterberg and her group suspect that it is because the autism-spectrum disorders and the schizophrenia-spectrum disorders share some of the same susceptibility genes or because some of the susceptibility genes contributing to each spectrum are occasionally inherited together.

For instance, individuals who lack genes on a particular stretch of chromosome 22—called the 22q11 chromosomal deletion—are known to be at heightened risk for both the autistic-spectrum and schizophrenia-spectrum disorders, they pointed out, suggesting that some genes located in this stretch are complicit in both disorders (*Psychiatric News*, September 19).

But one point they are quite sure about, as are many other investigators, is that autism and schizophrenia are not identical illnesses. One reason is because 10 of their schizotypal subjects, as well as two other subjects from the "other personality disorder" category, developed schizophrenia during a three-year follow-up period. Yet the researchers could find no link between having autistic traits and subsequently developing schizophrenia.

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

An abstract of "Childhood and Current Autistic Features in Adolescents With Schizotypal Personality Disorder" can be accessed at <www.sciencedirect.com> by clicking on "Browse A-Z," "S," and then "Schizophrenia Research." ■

Suspension

Stephen C. Schellhase, M.D., of Baltimore has been suspended for five years from APA and the Maryland Psychiatric Society. Schellhase was found to have violated Section 1, Annotation 1, and Section 2, Annotation 1, of the *Principles of Medical Ethics With Annotations Especially Applicable to Psychiatry* by the ethics committees of the Maryland Psychiatric Society and APA. He was found to have committed a boundary violation with a patient. ■

Exposure to Media Violence: Controlling It a Losing Battle

Clinicians should educate patients who are parents—especially parents of adolescents—about the health risks linked to excessive exposure to violence in the media.

BY RICH DALY

Millions of younger adolescents watch movies with extreme violence—including scenes of beheadings, rape, and torture, according to first-time research gauging the extent of such viewing across the country.

The national sampling of young adolescents found that the rate of violent-movie viewing ranged from less than 2 percent for the least-watched film on a list of violent films to nearly 50 percent, representing those who said they saw the particularly violent film "Scary Movie." A median of 12 percent of these youths had seen the "extremely violent" movies the researchers asked them about.

The study, "Exposure of U.S. Adolescents to Extremely Violent Movies," was published in the August *Pediatrics*. It was based on telephone interviews of a random sampling of 6,522 10- to 14-year-olds who were asked about viewing any of what several sources rated as the 40 most violent popular movies released from 1998 to 2002.

The findings echo previous research that also found widespread exposure of adolescents to violent television and video-game content.

"No expert in child development would advocate for subjecting children as young as 10 to this level of violence, yet the study shows that such exposure is commonplace in this country," James Sargent, M.D., a professor of pediatrics at Dartmouth Medical School and one of the study's authors, said in a statement accompanying release of the findings.

According to the study, the most likely children to have seen highly violent movies were boys, as well as minorities, those with low socioeconomic status, and those with poor school performance. The study authors found a strong relationship between exposure to violent movies and race, with black adolescents at particularly high risk for exposure.

The extent of exposure to movies with extreme violence raises concerns, according to the researchers, because of the growing body of research that documents a link between exposure to media violence and increased violent thoughts, emotions, and behavior and even, perhaps, more permissive attitudes toward other risk behaviors unrelated to violence.

Those dangers should encourage parents to limit such exposure, and health care professionals, including physicians, should urge such limits, the authors said.

"Although all mechanisms of the connection between exposure and behavior are not yet understood, it is clear that parents of adolescents should be aware of the negative consequences of this exposure and encouraged to limit it," said study coauthor Keilah Worth, Ph.D., a fellow in the Department of Pediatrics at Dartmouth Medical School.

Among the troubling aspects of violent-media exposure, the researchers said, are the findings of previous neurological research that determined that even if children, on a conscious level, report knowing the difference between entertainment violence and real violence, their brains respond as though they were being exposed to a real threat.

Michael Houston, M.D., chair of APA's Council on Children, Adolescents, and Their Families, noted that children and adolescents with preexisting emotional, cognitive, and neurodevelopmental difficulties are significantly more likely to confuse events that they witness in violent movies with real events than are youngsters without such conditions.

Houston agreed with the authors that physicians—including psychiatrists—need to take an active role in educating parents on the importance of limiting children's exposure to media violence.

The study highlights the importance of clinicians taking a complete media history when working with children, adolescents, and their families, Houston told *Psychiatric News*.

"This would include the general psychiatrist working with parents," he said.

It is, however, becoming more difficult for parents to limit their children's violent media exposure due to the increasing number of ways children have to access movie content, including DVDs, television movie channels, pay-per-view channels, and Web-based movie downloads, according to the researchers. Even when parents limited DVD rentals to movies rated appropriate for children, those often contain unrated "director's cuts" that may include violent material that was edited out of the theatrically released version.

Parents can better control violent-movie exposure by limiting the use of televisions and DVD players in their children's bedrooms, the researchers noted. They also can make use of blocking technology, such as television V-chips.

The film industry also must do a better job in limiting the marketing of such ultra-violent films from other entertainment likely viewed by children, said Sargent and colleagues. The idea of relying on the 40-year-old U.S. film-rating system also was found wanting: it allows adults to take children into theaters to watch highly violent films, which reflects the outdated view that these types of movies won't adversely affect children.

The researchers pointed out that much of the previous research on the impact of exposure to movie violence has focused on teenagers. They urged that future studies of media violence examine the impact of the apparently widespread exposure to violent movies on young adolescents such as those whose viewing habits were assessed in the current study.

An abstract of "Exposure of U.S. Adolescents to Extremely Violent Movies" is posted at <http://pediatrics.aappublications.org/cgi/content/abstract/122/2/306>. ■

APA's 100% Club Gains Two New Member Programs

Residency programs at Wake Forest University in Winston-Salem, N.C., and at the University of South Carolina in Columbia have been inducted into APA's 100% Club for 2008.

BY STEPHANIE WHYCHE

Two psychiatry residency programs inducted this year into APA's 100% Club are located in two bordering states: they are Wake Forest University School of Medicine in Winston-Salem, N.C., and the University of South Carolina in Columbia.

"We are very pleased and fortunate that our educational fund supports our residents joining the APA," said Harold Elliott, M.D., director of Wake Forest's resident psychiatry program in the Department of Psychiatry and Behavioral Medicine. "Through this fund, we are now able to finance 100 percent participation in APA for members in training. Here at Wake Forest we believe that APA is an integral part of becoming an active participant in the psychiatry community."

The University of South Carolina's (USC) School of Medicine was one of the first of three general psychiatry residency programs to join the 100% Club back in 2002, the year the program started. "I am proud to now have 100 percent membership of not only our general program, but our geriatric, forensic, and child and adolescent fellowships as well," said Richard Harding, M.D., chair of USC medical school's Department of Neuropsychiatry and Behavioral Science.

APA's 100% Club was created to encourage the directors and chairs of psychiatric residency programs to promote APA membership to their residents. Today, all programs that reach that goal receive a group photo of their residents, mounted on a wooden plaque. Each program also receives a major psychiatric textbook, and residents get a one-year subscription to *Focus: The Journal of Lifelong Learning*, both 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: Wake Forest University School of Medicine psychiatry residency programs

The Wake Forest University School of Medicine psychiatry training program. Front row, from left: Tommy Harris, D.O., Hal Elliott, M.D. (director of psychiatry resident education), Guy Palmes, M.D. (director of the child fellowship program), Matt Hough, D.O. (director child outpatient clinics), and James Kimball, M.D. (associate director of the general psychiatry training program); second row, from left: Jennifer Beckman, M.D., Rasheed Onafuye, M.D., Shannon Pitts, M.D., Mohammed Iqbal, M.D., Asha Davis, M.D., Brenda Harris, M.D., Jennifer Wildpret, D.O., and Frantz Pierre, M.D.; and third row, from left: Vaughn McCall, M.D. (department chair), Kara Emerson, M.D., Lance Fuller, M.D., Joseph Williams, M.D., Noah Richason, M.D., Bryan Smith, M.D., Dan Cotoman, M.D. (chief resident), Obinna Ikwechegh, M.D., Amy Singleton, M.D., Curtis Rollins, M.D., Maripat Moore, M.D., and Gene Mindel, M.D. (assistant professor).

Credit: University of South Carolina psychiatry residency and fellowship programs

The University of South Carolina psychiatry residency and psychiatry fellowship training program. Front row, from left: Nioaka Campbell, M.D. (training director, general psychiatry), Mac Madden, M.D., April Morciglio, M.D., Wendi Woods, M.D., Melissa Kannady, M.D., Kristin Clary, D.O., Marie McGough, M.D., Donna Smith (coordinator, general psychiatry), Megan Howard, M.D., and Eric Williams, M.D.; second row, from left: Ruhksana Mirza, M.D., Garrianne Gunter, M.D., Ashley Jones, M.D., Christian Neal, M.D., Kristin Arthur, M.D., Laurie Harden, M.D., Kara Sieverdes, M.D., April Carpenter, M.D., and Leslie Frinks, M.D.; third row, from left: Butch Mazumder, M.D., Jason Buckland, D.O., Jim Bouknight, M.D., Ph.D. (director, geriatric psychiatry fellowship), Pressley Warrick, M.D., Jamae Campbell, M.D., Shilpa Srinivasan, M.D., Jennifer Pender, M.D., Carnetha Mathews, M.D., LaKeisha Watson, M.D., Angelia Powell (child and geriatric fellowships coordinator), and Michelle Widener, M.D.; and fourth row, from left: John Bragg, M.D., Chad Pollock, M.D., Douglas Morris, M.D., Micah Baxley, M.D., Richard Frierson, M.D. (forensic psychiatry fellowship training director), Richard Harding, M.D. (department chair), Brian Dundas, M.D., Craig Stuck, M.D. (child and adolescent psychiatry training director), Jesse Raley, M.D., and Brad Freeman, M.D.

government news

Financial Aid

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threshold by a relatively small amount. In both Fiscal 2006 and Fiscal 2007, more than a quarter of assistance applicants exceeded the asset threshold by less than $5,000.

Laura Summer, a senior research scholar at Georgetown University's Health Policy Institute, testified before a congressional committee in May that the LIS offers great potential for low-income beneficiaries to receive substantial help with Part D premiums and cost sharing.

"Although they are entitled to this financial assistance, however, millions of beneficiaries do not receive it," she said.

Summer called for the elimination of the asset test in determining LIS eligibility. This would make the application process simpler and less time consuming for beneficiaries, as well as for those who assist them and those who process applications.

People who are rejected for LIS assistance also may seek help from some state and drug-manufacturer programs created to help low-income Medicare beneficiaries obtain prescription drugs. However, the report found that the availability of these programs and the assistance they offer are "uneven."

Twenty-three states offer state pharmaceutical assistance programs, which can supplement Part D benefits. Patient assistance programs offered by drug manufacturers also assist low-income individuals in obtaining prescription drugs, but the drugs are limited to those produced by the sponsoring manufacturers.

The GAO report is posted at <www.gao.gov/docsearch/abstract.php?rptno=GAO-08-824>. ■


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®

Disclosure Controversy

I read my August 15 *Psychiatric News*. An important contribution is Dr. Nada Stotland's column, "From the President," in which she describes her experience at the annual meeting, without pharmaceutical company support, of the Royal College of Psychiatrists in London.

In the same issue is coverage of APA President-elect Alan Schatzberg, M.D.'s happenings, describing point by point Stanford University's responses to Sen. Charles Grassley's congressional charges and to questions from *Psychiatric News*. Stanford's removal of Dr. Schatzberg as principal investigator is not reported. I accept the reportage as accurate and clarifying about these events and about relationships our federal statutes encourage.

In my recent posting to APA's Member-to-Member Listserv, I called for Dr. Schatzberg to step aside [as president-elect]. My comment has triggered considerable discussion, as I had intended. If Dr. Schatzberg disclosed these events during the APA election, I missed it and apologize. His responses to *Psychiatric News*—"I don't relish the publicity" and "I have nothing to hide"—need to be augmented by a statement from him describing these events as he sees them to the membership. With his impending assumption of the presidency, it is still timely.

It is past time that APA begins to move toward self-reliance in its activities. It is clear that others as well as I have been uncomfortable with the symbiotic nature of our relationship with the pharmaceutical industry. Our statement of ethics cautions against doing business with our patients; we also need a statement of ethics about our relationships with patient-related industry. Many actions that are not against the law and some that are sanctioned by the law do not serve well our profession or our patients.

I appreciate and congratulate Dr. Stotland's description of the Royal College's self-financed meeting. I call on her and the president-elect to provide leadership to APA to move to a similar clarification and exploration of self-reliance of the organization and its members.

NICHOLAS E. STRATAS, M.D.
Raleigh, N.C.

Editor's note: See Dr. Schatzberg's statement on page 4 regarding issues arising from the investigation by Sen. Grassley of the pharmaceutical industry's ties to medicine.

I don't often disagree with Herbert Peyser, M.D., but I take issue with his suggestion in the September 5 issue that all colleagues who are willing to be candidates for "high APA office" should be required to disclose every "potential" conflict-of-interest connection that they may have in non-APA entities.

If this kind of harassment continues, we may end up not only having our least-qualified members running for office, but, worse, demanding such information from applicants for membership in our APA.

Enough is enough! Let's not destroy our organization.

ABRAHAM HALPERN, M.D.
Mamaroneck, N.Y.

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.

Suicides

continued from page 1

The suicide death rate in 2005 was significantly higher than the 1996-2003 trend predicts in both male and female teenagers and in both the younger (10 to 17) and older (18 and 19) subpopulations.

Many experts have suspected a connection between the rise in suicide deaths and the black-box warning on suicidal ideation and behavior in young patients associated with antidepressant drugs that was imposed by the FDA in 2004 and the accompanying publicity (*Psychiatric News*, October 5 and June 15, 2007). Studies have shown that the use of antidepressants declined or stopped increasing, especially among children and adolescents, after the FDA issued the warning (*Psychiatric News*, February 1).

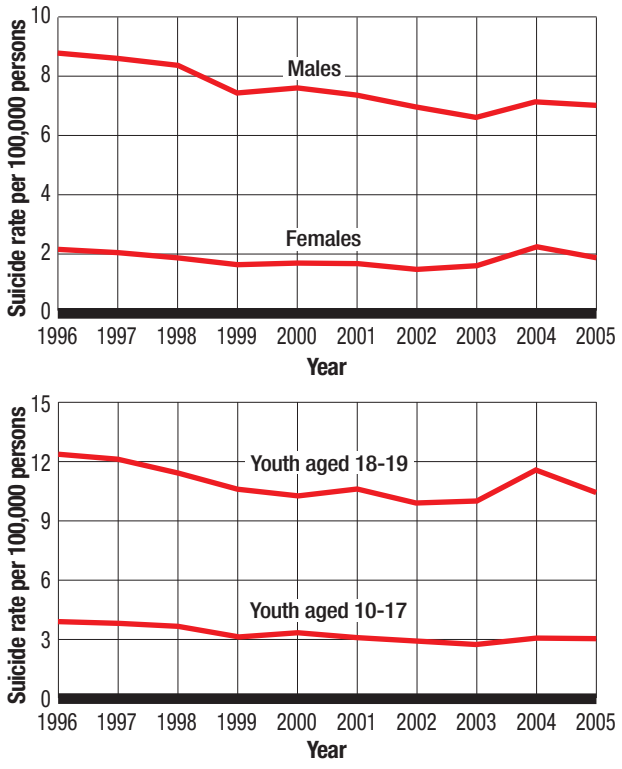
These observations have raised concerns by psychiatrists and others about inadequate treatment for depression in young patients that may pose a greater risk of suicide than the antidepressant-triggered suicidal ideation and behaviors.

"The fact that the adolescent suicide rate remains elevated is very disturbing," David Fassler, M.D., a pediatric psychiatrist and a clinical professor of psychiatry at the University of Vermont and APA secretary-treasurer, commented. "After over a decade of steady decline, we're seeing a definite and sustained increase." Meanwhile, "we've seen a significant reduction in prescriptions for young people since the FDA imposed a black-box warning."

The temporal parallel, however, cannot prove a correlation between the black-box warning and the rise in youth suicide rates.

Suicide Rates in Teens Rise After Steady Decline

The annual rate of death by suicide among youths aged 10 to 19 reversed the declining trend in the previous decade and rose significantly in 2004. The reversal was significant for both male and female as well as for younger (10-17 years) and older (18-19 years) youth.



Source: Jeffrey Bridge, Ph.D., *JAMA*, September 3, 2008

The study authors proposed several possible explanations for the observed trend such as changes in alcohol use or firearm access, influence of Internet social networks, and increased suicide among military personnel in this age category, as well as more patients with untreated depression after the black-box warning was issued.

"Attention must now be directed toward understanding whether this increase in the youth suicide rate . . . reflects an emerging public health crisis," they wrote.

"It is very difficult to prove a causal relationship between the increase in the youth suicide rate and the decrease of antidepressant prescribing," Darrel Regier, M.D., M.P.H., director of APA's Division of Research and the American Psychiatric Institute for Research and Education, told *Psychiatric News*. "One finding is very clear—the black-box warning did not reduce completed suicides, which should have been the ultimate goal of the FDA action."

He pointed out that, because of ethical reasons, researchers cannot conduct a randomized, controlled experiment to assess whether a link exists between completed suicide and decreased availability of treatment. "One possibility is to conduct a quasi-experiment and withdraw the black-box warning to see if there is a subsequent reduction in suicide rate," he said.

Regier explained that the FDA had relied on relative rates of spontaneously reported suicidal ideation or behavior from depressed people on medication compared with those on placebo in clinical trials in the agency's decisions about whether to require the black-box warning for antidepressants.

"Epidemiologists, FDA staff, and psychiatric experts have identified many methodological problems of relying on spontaneous reports of suicidal ideation in randomized clinical trials," Regier pointed out. "The FDA now advocates using prospective systematic assessments of suicidal risk in future clinical trials for all medications that may be associated with such risks." However, the black-box warning for antidepressants remains standing.

"In the recent FDA hearing on suicidal risks of antiseizure and mood-stabilizing medications, we heard testimonies suggesting that the societal effects of black-box warnings go beyond informing physicians for better monitoring and vigilance, but may be more complex and unpredictable than expected," Regier noted.

Earlier this year, the FDA intended to require a black-box warning for antiseizure medications based also on spontaneous reports of suicidal ideation and behavior in clinical trials (*Psychiatric News*, August 15). The experts on the advisory committee, however, voted to recommend against a black-box warning, citing concerns that patients' fear of taking these medications would lead to far more deaths from untreated seizures and bipolar disorder than from the possible drug-related suicidal ideation.

"Not all children and adolescents with depression need medication, but for those who do, it can be extremely effective and even lifesaving," said Fassler. He urged the FDA to monitor the consequences of its regulatory decisions and modify its actions if evidence suggests it is necessary.

"The question now for the FDA is what epidemiological evidence would be enough to prompt the agency to reconsider its previous decision about the black-box warning because of these reported signs of unintended consequences," said Regier.

"Suicide Trends Among Youths Aged 10 to 19 Years in the United States, 1996-2005" is posted at <jama.ama-assn.org/cgi/content/full/300/9/1025>. ■

Drop Contested Elections

APA is facing serious challenges from outside agencies and internal budgetary pressures. It is absurd to have contested elections in this situation. Such contests, which sometimes have three candidates, for the topmost positions, take up time and foster some dissension among winners and losers and their backers.

The reality is that those running have basically the same agenda with minor differences depending upon their career setting. We all want better health care for psychiatric patients and more support for our clinical, educational, and research endeavors. It makes no sense to fool ourselves that such elections allow the membership to voice their concerns and choices. The low election turnout demonstrates this.

Can't we trust a nominating committee and allow an option for a write-in process for other nominees? We strongly recommend reevaluation of this process to eliminate a wasteful exercise that does little good.

THOMAS WISE, M.D.
Falls Church, Va.
CHESTER SCHMIDT JR., M.D.
Glen Burnie, Md.

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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 seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. 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.

Commonly Observed Adverse Events for RISPERDAL® CONSTA®: Treatment-emergent adverse events with an incidence of 5% or greater in at least one of the RISPERDAL® CONSTA® groups (25 mg or 50 mg) and at least twice that of placebo were: somnolence, akathisia, Parkinsonism, dyspepsia, constipation, dry mouth, fatigue, and weight increase.

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.

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.

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.

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 treating these patients.

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 (2%, 9%, 4%), Parkinsonism* (4%, 10%, 3%) and tremor (0%, 3%, 0%). *Bradykinesia, extrapyramidal disorder, and hypokinesia.

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®.

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.

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

01CS1030

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

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

October 2008 01CS994CR1

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LONG-ACTING INJECTION

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

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

INDICATIONS AND USAGE: RISPERDAL® CONSTA® (risperidone) is indicated for the treatment of schizophrenia.

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

WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of dementia-related psychosis (see Boxed Warning). Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability. Other signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Management should include: discontinuation of the antipsychotic and other drugs not essential to therapy; intensive symptomatic treatment and medical monitoring; and treatment of other serious medical problems. If a patient requires antipsychotic drugs after recovery from NMS, the reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences have been reported. **Tardive Dyskinesia:** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. The risk of developing and likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose. However, tardive dyskinesia can develop, after brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although it may remit, partially or completely, if the antipsychotic is withdrawn. Prescribing should be in a manner to minimize the occurrence. In patients who require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms should appear drug discontinuation should be considered. **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, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis.**) **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 who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment.

PRECAUTIONS: General: Administration: RISPERDAL® CONSTA® should be injected into the 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 – Postintroduction Reports [retinal artery occlusion].) **Orthostatic Hypotension:** RISPERDAL® CONSTA® (risperidone) may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, 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. **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, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis.**) **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 under PRECAUTIONS, Carcinogenicity, Mutagenesis, Impairment of Fertility. The relevance of these findings to human risk is unknown. **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. **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. **Priapism:** Rare cases of priapism have been reported in patients treated with RISPERDAL® CONSTA®. **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. **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. **Body Temperature Regulation:** Disruption of body temperature regulation has been attributed to antipsychotic agents. **Suicide:** The possibility of a suicide attempt is inherent in schizophrenia, and close supervision of high-risk patients should accompany drug therapy. **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. 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 – Dosage in Special Populations in full PI). **Information for Patients:** 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). **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. **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®. **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®. **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. **Alcohol:** Patients should be advised to avoid alcohol during treatment with RISPERDAL® CONSTA®. **Drug Interactions:** The interactions of RISPERDAL® CONSTA® and other drugs have not been systematically evaluated. 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. Because of its potential for inducing hypotension, RISPERDAL® CONSTA® may enhance the hypotensive effects of other therapeutic agents with this potential. RISPERDAL® CONSTA® may antagonize the effects of levodopa and dopamine agonists. Amitriptyline did not affect the pharmacokinetics of risperidone or the active moiety. Cimetidine and ranitidine increased the bioavailability of risperidone by 64% and 26%, respectively. However, cimetidine did not affect the AUC of the active moiety, whereas ranitidine increased the AUC of the active moiety by 20%. Chronic administration of clozapine with risperidone may decrease the clearance of risperidone. **Carbamazepine and Other CYP 3A4 Enzyme Inducers:** In a drug interaction study in schizophrenic patients, 11 subjects received oral risperidone titrated to 6 mg/day for 3 weeks, followed by concurrent administration of carbamazepine for an additional 3 weeks. During co-administration, the plasma concentrations of risperidone and its pharmacologically active metabolite, 9-hydroxyrisperidone, were decreased 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 CYP 3A4 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. (See also DOSAGE AND ADMINISTRATION in full PI.) The efficacy of the 12.5 mg dose has not been investigated in clinical trials. **Fluoxetine and Paroxetine:** Fluoxetine (20 mg QD) and paroxetine (20 mg QD), 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. **Lithium:** Repeated oral doses of risperidone (3 mg BID) did not affect the exposure (AUC) or peak plasma concentrations (C_{max}) of lithium (n=13). **Valproate:** Repeated oral doses of risperidone (4 mg QD) 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 risperidone. **Digoxin:** RISPERDAL® (0.25 mg BID) did not show a clinically relevant effect on the pharmacokinetics of digoxin. **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. There were no significant interactions between risperidone and erythromycin (see CLINICAL PHARMACOLOGY 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 risperidone did not significantly affect the pharmacokinetics of donepezil and galantamine, which are metabolized by CYP 2D6. **Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis - Oral:** Carcinogenicity studies were conducted in Swiss albino mice and Wistar rats. Risperidone was administered in the diet at doses of 0.63, 2.5, and 10 mg/kg for 18 months to mice and for 25 months to rats. These doses are equivalent to 2.4, 9.4, and 37.5 times the oral maximum recommended human dose (MRHD) for schizophrenia (16 mg/day) on a mg/kg basis, or 0.2, 0.75, and 3 times the oral MRHD (mice) or 0.4, 1.5, and 6 times the oral MRHD (rats) on a mg/m^2 basis. A maximum tolerated dose was not achieved in male mice. There was a significant increase in pituitary gland adenomas in female mice at doses 0.75 and 3 times the oral MRHD on a mg/m^2 basis. There was a significant increase in endocrine pancreatic adenomas in male rats at doses 1.5 and 6 times the oral MRHD on a mg/m^2 basis. Mammary gland adenocarcinomas were significantly increased in female mice at all doses tested (0.2, 0.75, and 3 times the oral MRHD on a mg/m^2 basis), in female rats at all doses tested (0.4, 1.5, and 6 times the oral MRHD on a mg/m^2 basis), and in male rats at a dose 6 times the oral MRHD on a mg/m^2 basis. **Carcinogenesis - IM:** RISPERDAL® CONSTA® was evaluated in a 24-month carcinogenicity study in which SPF Wistar rats were treated every 2 weeks with IM injections of either 5 mg/kg or 40 mg/kg of risperidone. These doses are 1 and 8 times the MRHD (50 mg) on a mg/m^2 basis. A control group received injections of 0.9% NaCl, and a vehicle control group was injected with placebo microspheres. There was a significant increase in pituitary gland adenomas, endocrine pancreas adenomas, and adrenomedullary pheochromocytomas at 8 times the IM MRHD on a mg/m^2 basis. The incidence of mammary gland adenocarcinomas was significantly increased in female rats at both doses (1 and 8 times the IM MRHD on a mg/m^2 basis). A significant increase in renal tubular tumors (adenoma, adenocarcinomas) was observed in male rats at 8 times the IM MRHD on a mg/m^2 basis. Plasma exposures (AUC) in rats were 0.3 and 2 times (at 5 and 40 mg/kg, respectively) the expected plasma exposure (AUC) at the IM MRHD. The relevance for human risk of the findings of prolactin-mediated endocrine tumors in rodents is unknown (see PRECAUTIONS - Hyperprolactinemia). **Mutagenesis:** No evidence of mutagenic potential for oral risperidone was found. In addition, no evidence of mutagenic potential was found in the *in vitro* Ames reverse mutation test for RISPERDAL® CONSTA®. **Impairment of Fertility:** Oral risperidone (0.16 to 5 mg/kg) was shown to impair mating, but not fertility, in Wistar rats in three reproductive studies at doses 0.1 to 3 times the oral maximum recommended human dose. No mating and fertility studies were conducted with RISPERDAL® CONSTA®. **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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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/m^2 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:** In animal studies, risperidone and 9–hydroxyrisperidone are excreted in milk. 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 PRECAUTIONS, DOSAGE AND ADMINISTRATION and CLINICAL PHARMACOLOGY in full PI). **Concomitant use with Furosemide in Elderly Patients with Dementia-Related Psychosis:** In 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, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis.**)

ADVERSE REACTIONS: Associated with Discontinuation of Treatment: In the 12-week, placebo-controlled trial, the incidence of schizophrenic patients who discontinued treatment due to an adverse event was lower with RISPERDAL® CONSTA® (11%; 22/202 patients) than with placebo (13%; 13/98 patients). **Incidence in Controlled Trials: Commonly Observed Adverse Events in Controlled Clinical Trials:** Spontaneously reported, treatment-emergent adverse events with an incidence of 5% or greater in at least one of the RISPERDAL® CONSTA® groups (25 mg or 50 mg) and at least twice that of placebo were: somnolence, akathisia, parkinsonism, dyspepsia, constipation, dry mouth, fatigue, weight increase. **Dose Dependency of Adverse Events:** ***Extrapyramidal Symptoms:*** The overall incidence of EPS-related adverse events (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 events was higher in patients treated with 50 mg RISPERDAL® CONSTA®. **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. **Vital Sign Changes:** RISPERDAL® is associated with orthostatic hypotension and tachycardia (see PRECAUTIONS). In the placebo-controlled trial, orthostatic hypotension was observed in 2% of patients treated with 25 mg or 50 mg RISPERDAL® CONSTA® (see PRECAUTIONS). **Weight Changes:** In the 12-week, 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. **Laboratory Changes:** The percentage of patients treated with RISPERDAL® CONSTA® who experienced potentially important changes in routine serum chemistry, hematology, or urinalysis parameters was similar to or less than that of placebo patients. Additionally, no patients discontinued treatment due to changes in serum chemistry, hematology, or urinalysis parameters. **ECG Changes:** The electrocardiograms of 202 schizophrenic patients treated with 25 mg or 50 mg RISPERDAL® CONSTA® and 98 schizophrenic patients treated with placebo in a 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. **Other Events Observed During the Premarketing Evaluation of RISPERDAL® CONSTA®:** During its premarketing assessment, RISPERDAL® CONSTA® was administered to 1499 patients in multiple-dose studies. The conditions and duration of exposure to RISPERDAL® CONSTA® varied greatly, and included (in overlapping categories) open-label and double-blind studies, uncontrolled and controlled studies, inpatient and outpatient studies, fixed-dose and titration studies, and short-term and long-term exposure studies. The following reactions were reported: (Note: 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. It is important to emphasize that, although the reported events occurred during treatment with RISPERDAL® CONSTA®, they were not necessarily caused by it.) **Psychiatric Disorders:** *Frequent:* anxiety, psychosis, depression, agitation, nervousness, paranoid reaction, delusion, apathy. *Infrequent:* anorexia, impaired concentration, impotence, emotional lability, manic reaction, decreased libido, increased appetite, amnesia, confusion, euphoria, depersonalization, paroniria, delirium, psychotic depression. **Central and Peripheral Nervous System Disorders:** *Frequent:* hypertonia, dystonia. *Infrequent:* dyskinesia, vertigo, leg cramps, tardive dyskinesia[a], involuntary muscle contractions, paraesthesia, abnormal gait, bradykinesia, convulsions, hypokinesia, ataxia, fecal incontinence, oculogyric crisis, tetany, apraxia, dementia, migraine. *Rare:* neuroleptic malignant syndrome. [a]In the integrated database of multiple-dose studies (1499 patients with schizophrenia or schizoaffective disorder), 9 patients (0.6%) treated with RISPERDAL® CONSTA® (all dosages combined) experienced an adverse event of tardive dyskinesia. **Body as a Whole/General Disorders:** *Frequent:* back pain, chest pain, asthenia. *Infrequent:* malaise, choking. **Gastrointestinal Disorders:** *Frequent:* nausea, vomiting, abdominal pain. *Infrequent:* gastritis, gastroesophageal reflux, flatulence, hemorrhoids, melena, dysphagia, rectal hemorrhage, stomatitis, colitis, gastric ulcer, gingivitis, irritable bowel syndrome, ulcerative stomatitis. **Respiratory System Disorders:** *Frequent:* dyspnea. *Infrequent:* pneumonia, stridor, hemoptysis. *Rare:* pulmonary edema. **Skin and Appendage Disorders:** *Frequent:* rash. *Infrequent:* eczema, pruritus, erythematous rash, dermatitis, alopecia, seborrhea, photosensitivity reaction, increased sweating. **Metabolic and Nutritional Disorders:** *Infrequent:* hyperuricemia, hyperglycemia, hyperlipemia, hypokalemia, glycosuria, hypercholesterolemia, obesity, dehydration, diabetes mellitus, hyponatremia. **Musculo-Skeletal System Disorders:** *Frequent:* arthralgia, skeletal pain. *Infrequent:* torticollis, arthrosis, muscle weakness, tendinitis, arthritis, arthropathy. **Heart Rate and Rhythm Disorders:** *Frequent:* tachycardia. *Infrequent:* bradycardia, AV block, palpitation, bundle branch block. *Rare:* T-wave inversion. **Cardiovascular Disorders:** *Frequent:* hypotension. *Infrequent:* postural hypotension. **Urinary System Disorders:** *Frequent:* urinary incontinence. *Infrequent:* hematuria, micturition frequency, renal pain, urinary retention. **Vision Disorders:** *Infrequent:* conjunctivitis, eye pain, abnormal accommodation. **Reproductive Disorders, Female:** *Frequent:* amenorrhea. *Infrequent:* nonpuerperal lactation, vaginitis, dysmenorrhea, breast pain, leukorrhea. **Resistance Mechanism Disorders:** *Infrequent:* abscess. **Liver and Biliary System Disorders:** *Frequent:* increased hepatic enzymes. *Infrequent:* hepatomegaly, increased SGPT. *Rare:* bilirubinemia, increased GGT, hepatitis, hepatocellular damage, jaundice, fatty liver, increased SGOT. **Reproductive Disorders, Male:** *Infrequent:* ejaculation failure. **Application Site Disorders:** *Frequent:* injection site pain. *Infrequent:* injection site reaction. **Hearing and Vestibular Disorders:** *Infrequent:* earache, deafness, hearing decreased. **Red Blood Cell Disorders:** *Frequent:* anemia. **White Cell and Resistance Disorders:** *Infrequent:* lymphadenopathy, leucopenia, cervical lymphadenopathy. *Rare:* granulocytopenia, leukocytosis, lymphopenia. **Endocrine Disorders:** *Infrequent:* hyperprolactinemia, gynecomastia, hypothyroidism. **Platelet, Bleeding and Clotting Disorders:** *Infrequent:* purpura, epistaxis. *Rare:* pulmonary embolism, hematoma, thrombocytopenia. **Myo-, Endo-, and Pericardial and Valve Disorders:** *Infrequent:* myocardial ischemia, angina pectoris, myocardial infarction. **Vascular (Extracardiac) Disorders:** *Infrequent:* phlebitis. *Rare:* intermittent claudication, flushing, thrombophlebitis. **Postintroduction Reports:** The following adverse drug reactions have been identified during postapproval use of risperidone: agranulocytosis, anaphylactic reaction, angioedema, atrial fibrillation, diabetic ketoacidosis in patients with impaired glucose metabolism, hypothermia, inappropriate antidiuretic hormone secretion, intestinal obstruction, jaundice, mania, pancreatitis, priapism, QT prolongation, sleep apnea syndrome, and water intoxication. Adverse events reported since market introduction which were temporally (but not necessarily causally) related to oral RISPERDAL® therapy include the following: apnea, cerebrovascular disorder, including cerebrovascular accident, diabetes mellitus aggravated, hyperglycemia, Parkinson's disease aggravated, and pituitary adenomas. There have been rare reports of sudden death and/or cardiopulmonary arrest in patients receiving oral RISPERDAL®. A causal relationship with oral RISPERDAL® has not been established. It is important to note that sudden and unexpected death may occur in psychotic patients whether they remain untreated or whether they are treated with other antipsychotic drugs. 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.

DRUG ABUSE AND DEPENDENCE
Controlled Substance Class: RISPERDAL® CONSTA® (risperidone) is not a controlled substance.
For more information on symptoms and treatment of overdosage, see full Prescribing Information.
7519512B - US Patent 4,804,663 Revised May 2008

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

01CS990B

Interrogation

continued from page 2

Among those documents was the Army memo, which the authors did not know existed prior to receiving it. The document is not classified.

The Army contends that it avoids any conflict of interest or violation of professional ethics by separating psychiatrists and psychologists who provide clinical care for detainees or U.S. personnel from those who serve as behavioral science consultants, said Col. Elspeth Cameron Ritchie, M.C., a psychiatrist and medical director of strategic communication in the Army Medical Department, in an interview.

"The Army uses only experienced forensic psychiatrists specially trained for this role, and then only if a psychologist is not available," said Ritchie.

An American Psychological Association resolution passed in 2007 does not prevent psychologists from taking part in interrogations in which torture is not used (*Psychiatric News*, December 21, 2007).

"There is a real clash of values between military convenience and professional ethics."

However, at press time, that organization passed a measure prohibiting psychologists from taking part in interrogations in settings where "persons are held outside of, or in violation of, either International Law (e.g., the U.N. Convention Against Torture and the Geneva Conventions) or the U.S. Constitution, where appropriate," unless they represent a detainee or an independent third party.

The Army requires psychiatrists to complete a 136-hour course before taking part in interrogations. Ritchie has taught parts of that program and said that four psychiatrists have attended it so far.

"The big question is, Should forensic psychiatrists participate as subject-matter experts and not in a treatment role, like they do in the civilian world?" said Ritchie.

The Army may be pinning too much emphasis on this distinction, according to APA experts on the matter.

"We should not be a part of interrogation under any conditions," said former APA President Steven Sharfstein, M.D., president and chief executive officer of the Sheppard Pratt Health System in Baltimore. "Taking part in interrogations is just not part of our medical ethics." Sharfstein was APA president when APA's position statement on interrogation of detainees was approved.

At APA's 2006 annual meeting in Toronto, Kiley appeared on a panel with members to discuss the Association's statement.

"He said unequivocally that the Army would abide by APA's position and not put psychiatrists in situations where they would have to go against APA's position unless there was absolutely no alternative," said Paul Appelbaum, M.D., another former APA president and former chair of the Council on Law and Psychiatry. "The Army memo appears to violate the assurances we were given then."

The Army policy was developed after the expansion of Guantanamo Bay as a detention center and the exposure of mistreatment of prisoners at the Abu Ghraib prison in Iraq, said Ritchie.

"We needed to be explicit about what the rules should be," she said. She cited the value of health professionals' assisting interrogators.

"Psychologists and psychiatrists are experts at enhancing rapport," she said. "They also can counteract behavioral drift, the spiraling down of interrogation into a culture of coercion" that can lead to mistreatment of detainees.

Such interrogations have revealed weapons caches, identified the remains of U.S. troops, and have saved the lives of American soldiers, she said.

While Ritchie envisions these specially trained psychiatrists putting the brakes on illegal or unethical treatment of detainees, others see an inevitable pressure to remain in step with one's unit.

"The Army is being naïve in thinking that physicians will magically be able to resist the tendencies that everyone else is susceptible to," said Appelbaum.

Marks agreed it would be hard for a member of an interrogation team to act independently and report colleagues who go beyond the bounds of professional ethics.

"You don't want to seem unpatriotic or to be crying wolf," he said in an interview. "So you wait for egregious cases, but that signals that other cases are OK."

The Army memo does not refer to APA's statement of May 2006, although it does refer to an AMA report by the Council on Ethical and Judicial Action issued a month later. The AMA does not distinguish between treating and nontreating physicians, and the report became a part the AMA's code of ethics in November 2006.

APA members are bound by the nine principles of the AMA's ethics code but not by its more specific set of opinions.

The lack of reference to APA's statement was no oversight, said Ritchie.

"APA's was a position statement, not an ethical guideline," she said. "My understanding is that if you violate ethical guidelines, there are measures that the Association can take, but not if it's a position statement."

That may be where things stand at the moment, said Spencer Eth, M.D., who was chair of APA's Ethics Committee when it developed its annotation addressing torture. The annotation prohibits psychiatrists from participating in "cruel and degrading treatment" of prisoners, that is, torture.

"However, the position statement opposing a role in interrogation binds APA as an organization, but is not actionable against individual members," said Eth in an interview.

Only if the position statement against interrogation were passed as an ethics annotation could action be taken against a psychiatrist who was found to have violated it, he said. That is unlikely to happen soon.

"There is a real clash of values between military convenience and professional ethics," said Lawrence Hartmann, M.D., chair of APA's Council on Global Psychiatry. "The Army should embrace the [APA and AMA] statements, but let's be realistic: we don't have the power to enforce our views on the government and the military. We can influence but not enforce."

The Army is now reviewing the 2006 memo, which expires on October 20, and it may be revised before it is reissued. Changes are possible, said Ritchie. "But we expect there will continue to be differences of opinion."

"The Ethics of Interrogation—The U.S. Military's Ongoing Use of Psychiatrists" is posted at: <http://content.nejm.org/cgi/content/full/359/11/1090>. The Department of the Army's "Behavioral Science Consultation Policy" is posted at the* New England Journal of Medicine's *Web site at <http://content.nejm.org/cgi/data/359/11/1090/DC1/1>. ■

Army Document at Odds With Ethics

The following statements are excerpted from the Army's OTSG/MEDCOM Policy Memo 06-029, dated October 20, 2006. The memo sets out Department of Defense standards for actions by psychologists and psychiatrists during interrogation of detainees. APA and the AMA have stated their opposition to such activity by psychiatrists and other physicians, but the memo indicates ". . . that the Department of Defense still wants doctors to be involved in interrogations and continues to resist the positions taken by medicine's professional associations," according to a recent Perspective in the *New England Journal of Medicine.* The full memorandum is posted at the journal's Web site (see URL below).

- [T]he events of September 11, 2001 and the ongoing Global War on Terrorism (GWOT) have required the unprecedented and sustained involvement of Behavioral Science Consultants (BSCs) in support of both detention operations and intelligence interrogations and detainee debriefing operations.

- BSCs are psychologists and psychiatrists, not assigned to clinical practice functions, but to provide consultative services to support authorized law enforcement or intelligence activities. . . .

- The mission of a BSC is to provide psychological expertise and consultation, or to assist the command in conducting safe, legal, ethical, and effective detention operations, intelligence interrogations, and detainee debriefing operations.

- BSCs must regularly monitor their behavior and remain within professional ethical boundaries as established by their professional associations, by their licensing State, and by the military.

- BSCs are authorized to make psychological assessments of the character, personality, social interactions, and other behavioral characteristics of detainees. . . .

- BSCs may observe interrogations.

- Psychologists and psychiatrists are bound by both legal and ethical constraints when supporting detention operations, intelligence interrogations, and detainee debriefings.

Also, the document quotes guidelines in the AMA's 2006 report "Physician Participation in Interrogation" and then adds commentary from the Army memo. Here are excerpts from that portion of the document.

- **Second AMA guideline:** Physicians must neither conduct nor directly participate in an interrogation, because a role as physician-interrogator undermines the physician's role as healer and thereby erodes trust in the individual physician-interrogate and in the medical profession.

  Memo Commentary: Although physicians who provide medical care to detainees should not be involved in decisions whether or not to interrogate because such decisions are unrelated to medicine or the health interests of an individual, physicians who are not providing medical care to detainees may provide such information if warranted by compelling security interests.

- **Third AMA guideline:** Physicians must not monitor interrogations with the intention of intervening in the process, because this constitutes direct participation in interrogation.

  Memo Commentary: The presence of a physician at an interrogation, particularly an appropriately trained psychiatrist, may benefit the interrogates because of the belief held by many psychiatrists that kind and compassionate treatment of detainees can establish rapport that may result in eliciting more useful information.

The Department of the Army's "Behavioral Science Consultation Policy" is posted on the Web site of the* New England Journal of Medicine *at <http://content.nejm.org/cgi/data/359/11/1090/DC1/1>.

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Dartmouth Medical School

The Department of Psychiatry is seeking an **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. Salary consistent 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 this search. Dartmouth College is an Equal Opportunity/Affirmative Action Employer and encourages applications from women and members of minority groups.

Psychiatric Clinicians and Hospitalists
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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.

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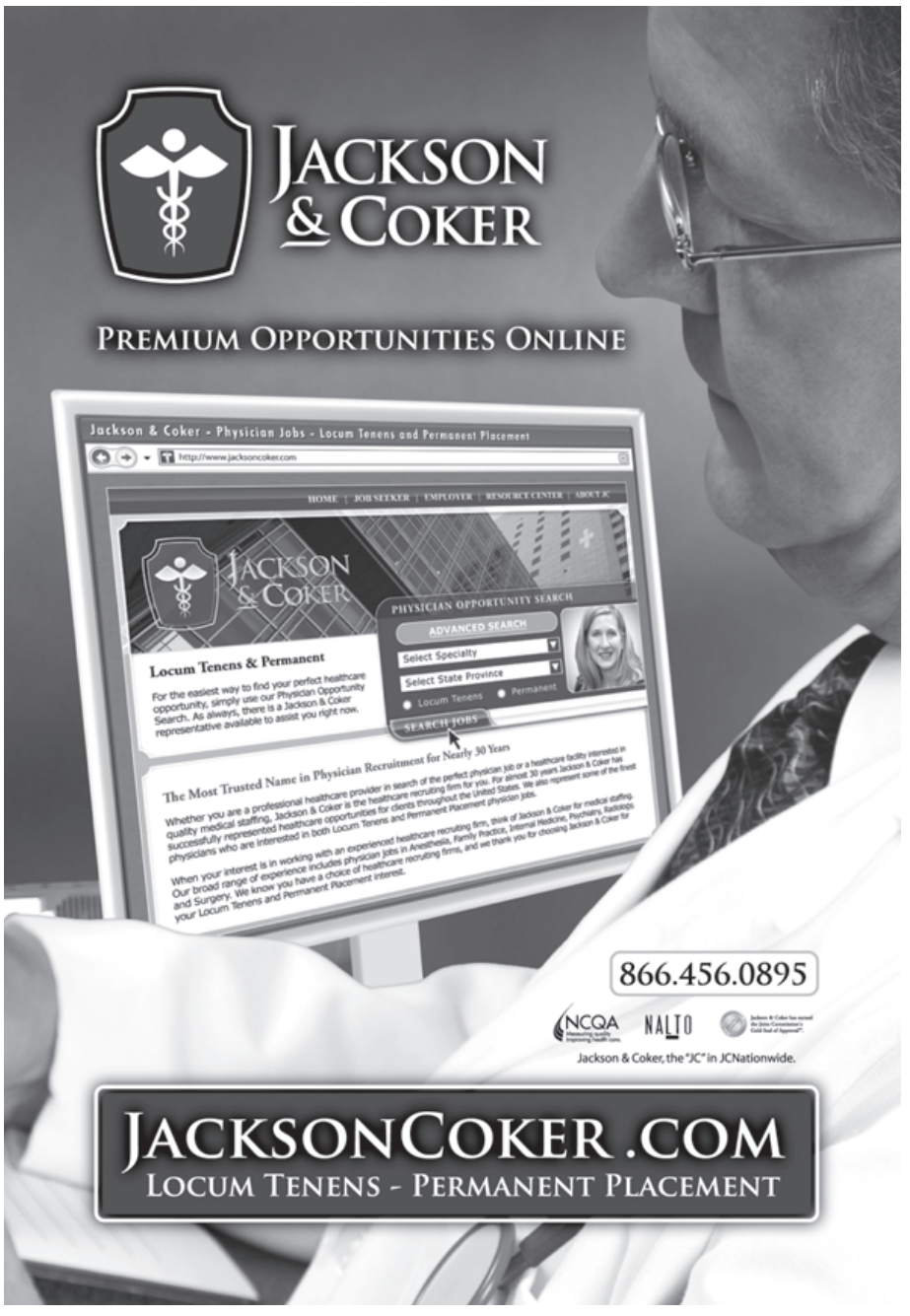

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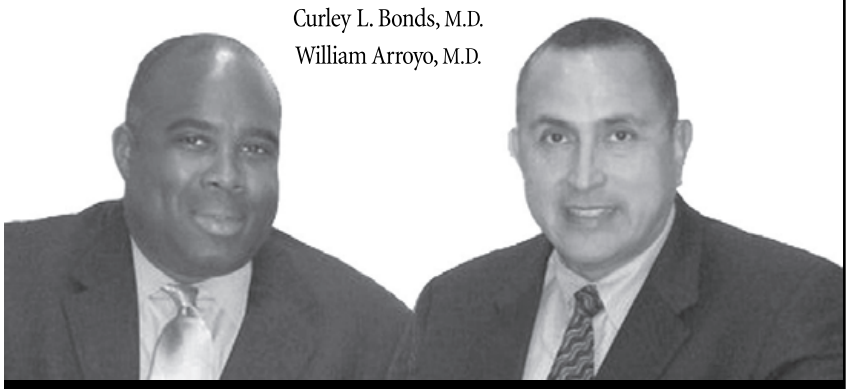

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CHAIR, DEPARTMENT OF PSYCHIATRY

John H. Stroger Jr. Hospital of Cook County (JHSH), formerly Cook County Hospital, is seeking candidates for the Chair of the Department of Psychiatry. JHSH is a newly constructed 464-bed tertiary care general hospital, and is the flagship of the Cook County Bureau of Health Services, an integrated health care system with three major hospitals and affiliated community-based clinics.

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Previous experience in a multicultural healthcare system and in addiction medicine is preferred. Applicants must have current licensure and specialty board certification. JHSH is an equal opportunity employer and actively solicits applications from women and underrepresented minorities. **Send CV and 3 references to:**

Maria L. Torres, M.D.
Chair, Search Committee for the Psychiatry Department Chair
Department of Anesthesiology and Pain Management
John H. Stroger, Jr. Hospital of Cook County
1901 West Harrison Street, Clinic B, Suite 1233
Chicago, Illinois 60612
Phone: (312) 864-1903 Fax: (312) 864-9536
Email: mltorres1@msn.com

DARTMOUTH MEDICAL SCHOOL

The Department of Psychiatry is seeking an 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. Salary consistent 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 this search. Dartmouth College is an Equal Opportunity/Affirmative Action Employer and encourages applications from women and members of minority groups.

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The Department of Psychiatry is seeking an
AFFECTIVE DISORDERS PSYCHIATRIST
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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. Academic rank and salary consistent 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 this search.

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CALIFORNIA DEPARTMENT OF Mental Health

Child and Adolescent Consultation Psychiatrist

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The initial focus is to build a psychiatric consultation service serving this institution with some 700 beds, nearly 1,500 medical staff, and 180 residents in 12 specialties. An immediate need is for a child and adolescent psychiatrist to establish a new consultation service for pediatric patients at SJHMC/BNI.

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Jason P. Caplan, M.D.
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Issue	Deadline (Friday, 2 p.m. E.T.)
November 7	October 24
November 21	November 7

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ALABAMA

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The Department of Psychiatry at UAB invites applications for a full-time faculty position for a BC/BE psychiatrist in the Division of Adult Psychiatry. Rank, tenure status and salary commensurate with experience and qualifications. Major regional medical center with excellent resources and benefits. Responsibilities include care of adult psychiatric patients primarily in an outpatient setting. Some participation in departmental teaching, research and administrative activities also expected.
Applications should be sent to Daniel C. Dahl, M.D., Associate Professor, UAB Department of Psychiatry, 1713 6th Avenue South, Birmingham, AL 35294-0018. UAB is an affirmative action/equal opportunity employer.

ARIZONA

University of Arizona

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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

PSYCHIATRIC JOB FAIR!
The Northern California Psychiatric Society's **24th Annual JOB FAIR** for residents and all psychiatrists seeking full or part-time positions to be held **Saturday, January 24, 2008** 8:30 am in the Millberry Union Conference Center of UCSF in San Francisco. This established event connects more than 30 employers and 100 job seekers throughout the western US. For further information, call (415) 334-2418, ext. 105; FAX (415) 239-2533; or email rgeorgulas@ncps.org.

UC DAVIS SCHOOL OF MEDICINE DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES

CHILD PSYCHIATRIST TEACHING ATTENDING. The University of California, Davis, Department of Psychiatry and Behavioral Sciences is recruiting a Health Sciences Assistant/Associate Clinical Professor for the Child Psychiatry Division which is directed by Professor Robert Hendren. The position is in the clinician/teaching academic series. The individual will provide outpatient psychiatry services and teaching at either the UC Davis Department of Psychiatry's child psychiatry outpatient clinic or at the Child and Adolescent Psychiatry Clinic operated by the County of Sacramento. Both clinics serve as teaching sites for general psychiatry residents, child psychiatry residents, postdoctoral psychology fellows and medical students. The successful candidate should be licensed or license eligible in the State of California and board eligible or certified in general psychiatry and child and adolescent psychiatry, and have an interest in psychiatric education and training. The successful candidate will lecture in seminars and case conferences, and provide group and individual supervision of clinical cases. The candidate will also provide clinical teaching for child and general psychiatry residents, psychology fellows, medical students and other mental health professionals including timely and appropriate evaluation of trainee performance.

For full consideration, applications must be received by December 31, 2008. Position is open until filled but not later than June 30, 2009. Interested candidates should email a curriculum vitae and letter of interest in response to Position #PY-01R-09 to Juli Koeberlein at juli.koeberlein@ucdmc.ucdavis.edu. In conformance with applicable law and University policy, the University of California, Davis, is an equal opportunity/affirmative action employer.

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

VA Long Beach Healthcare System is recruiting for a full time psychiatrist to join our PTSD Clinical Team. The PTSD Clinical Team is staffed by 2 psychologists, a social worker, and nurse case manager. The ideal candidate will provide excellent clinical care, teach, and be an active member of our medical staff. LBVA is integrated with UC-Irvine and provides a substantial amount of teaching. Faculty appointments are available. The medical center is about 1 mile from the ocean in Long Beach and has many desirable features of So Cal urban life (restaurants, boating, great recreation facilities, pedestrian areas and an art district). This is a great opportunity to be involved in the development of a specialty program.
We can offer administrative, clinical and research mentorship. Research time can be negotiated depending on qualifications.

Interested applicants should contact Larry Albers, MD, Chief of Mental Health
At (562) 826-8000 Ext. 2150 or via E-Mail at larry.albers@med.va

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.

Northern California Opportunities

Have an outstanding Adult Psychiatrist position that is available in one of California's fastest growing communities. It is located 45 minutes south of Sacramento with a population of over 260,000. The position is a highly sought after Adult Psychiatrist employed outpatient opportunity with no call! Or, work with a superb medical group in a city of over 200,000 population in developing the psychiatric service with strong support from the primary care referrals and medical group. Have a guaranteed salary for the first two years with option to become a shareholder thereafter. **Send your CV to Tina Wilkins at MD-Jobs@TinaWilkins.com; fax to 916-536-9281; call 1-888-229-9495.**

COUNTY OF SANTA BARBARA
Alcohol, Drug, and Mental Health Services

is recruiting for

PSYCHIATRIST
BOARD CERTIFIED
$183,666 - $210,761/YR.

PLUS new hire incentives, excellent benefits, and cash allowances. See the job bulletin at www.sbcountyjobs.com for detailed information.

Job location is Santa Maria

Call Ratio:
Only one weekend every three months!

Call Vivian P. Smith, 805-568-2812, or apply on-line at **www.sbcountyjobs.com**

The County of Santa Barbara strongly promotes diversity and equality in the workplace.

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

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GREAT OPPORTUNITY
TO PRACTICE
IN SANTA BARBARA

Immediate opening for a well-trained
BC/BE Psychiatrist to join busy department

Sansum Clinic is the largest and oldest multispecialty group between San Francisco and Los Angeles with 150 physicians, surgeons, and a staff of healthcare professionals in over 30 specialized areas of medicine, two specialty clinics, plus ten satellite offices. We offer a competitive salary, full benefits package and an excellent living and practice environment. This is a unique opportunity to practice with a progressive and professionally stimulating multi-specialty group on the West Coast. Email CV to ngong@sansumclinic.org or Fax (805) 681-7710. www.sansumclinic.org

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Southern, CA - CORONA: General Psychiatrist. Private practice - outpatient, inpatient, & C/L. Income guarantee and practice start up expenses offered. Contact Kimberly Lanzillotti @ 866-227-5415 ext: 223 or email kimberly.lanzillotti@uhsinc.com

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Assoc. Medical Director Position/ the Beautiful Northwest - Be your own boss - An incredible lucrative inpatient/outpatient practice opportunity awaits you in Chico where the cost of living/housing is lower than most cities in CA. Live/work/play in this culture-rich college town only minutes from the gorgeous Sierra foothills. Only an hour and a half from Napa Valley and Sacramento; two hours from San Francisco. Please **call Terry B. Good, Horizon Health, at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

The UCSD Department of Psychiatry is seeking to recruit board certified/board eligible psychiatrists to join the faculty of the UCSD Owen Clinic, the multidisciplinary adult HIV clinic at UCSD Medical Center in San Diego. Individuals must be able to become licensed in the State of California and board eligible in psychiatry and/or designated sub-specialty. Those who apply should have a strong track record in clinical, teaching and administrative expertise in clinical psychiatry settings. The successful candidate would be appointed as an Assistant Clinical professor with a career path as a clinician-educator in the Department of Psychiatry. Opportunities for scholarly activity related to HIV psychiatry and mentoring by senior faculty will be provided. Bilingual (Spanish-English) is desirable. The candidates' appointment will be determined by their individual qualifications and achievements, and salary is based on University of California staff psychiatrists pay scales. Candidates who wish to be considered for immediate employment should send curriculum vitae and other supporting documents to Search Committee K, UCSD Department of Psychiatry, 9500 Gilman Drive, La Jolla, CA 92093-0603. Attn: Dr. Lohr and Dr. Soliman. The University of California, San Diego, is an equal opportunity employer.

Faculty Positions - UCSD

The Dept. of Psychiatry at the University of California, San Diego, is currently recruiting for contracted positions at the assistant or associate clinical professor level. We are seeking board-certified or board-eligible psychiatrists with a California medical license to practice in our community outpatient clinics. Preference will be given to candidates with a strong track record in clinical care, teaching experience and an interest or experience in clinical research. The positions offer flexible scheduling, along with potential teaching and research opportunities. The appointment level will be determined by the candidate's qualifications, and the salary is based on UC staff psychiatrist pay scales. Applicants should send their curriculum vitae and other supporting documents to: Attn: Dr. Lohr and Dr. Soliman, Search Committee K, UCSD Dept. of Psychiatry, 9500 Gilman Drive, La Jolla, CA 92093-0603. UCSD is an equal-opportunity employer.

PSYCHIATRIST - SAN FRANCISCO STATE
UNIVERSITY STUDENT HEALTH SERVICE
JOB #1743
Full-time Position
Providing outpatient psychiatric care for diverse community of 30,000 students.

MINIMUM QUALIFICATIONS: Completion of a psychiatry residency, valid California medical license, DEA Cert, CPR cert. Board certification in Psychiatry or ability to obtain within two years of hire.
Strong background/current knowledge of psychopharmacologic agents and psychological methodologies; experience with adolescents and young adults care.

For further information please visit https://cmsweb.sfsu.edu/psp/HSFPRDF/EMPLOYEE/HRMS/c/HRS_HRAM.HRS_CE.GBL & send res. w/ Job #1743 to HR Dept, 1600 Holloway Ave, Room 252, SF, CA 94132-4252. Open until filled. Please call 415-338-1351 if you would like an application packet emailed to you. EEO/ADA.

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

COLORADO

EMERGENCY PSYCHIATRIST

Denver Health, Denver's premier and growing safety net hospital system, is seeking a career emergency psychiatrist to join a state-of-the-art Psychiatric Emergency Service (PES). Qualified applicants will be board-certified or board-eligible in Psychiatry. Interest or added qualifications in addictions or forensic psychiatry a plus. This is a full-time academic position, with faculty appointment through the University of Colorado School of Medicine, Department of Psychiatry. Teaching of psychiatry residents and medical students is an expectation. Denver Health offers a competitive salary and benefits package. This position allows for a perfect balance between a career in emergency psychiatry and life at the foot of the Rocky Mountains. Interested applicants should email douglas.ikelheimer@dhha.org with attached CV and cover letter.

Aspire Behavioral Health of Colorado, LLC
A Geriatric Psychiatric Hospital

Come Join our Team!
- Innovative new gero-psych hospital
- Beautiful 24 bed facility in Denver (Lowry)
- Excellent salary and benefits package

Opening for Medical Director (Full-time)

Openings for Psychiatrists
(Part-time positions available)

We provide innovative inpatient behavioral healthcare for seniors age 65 and older, who are experiencing acute psychiatric symptoms.

Fax CV to: (800) 525-4072
Phone: (303) 790-8888

www.aspirebehavioralhealth.com

Aspire Behavioral Health of Colorado, LLC
A Geriatric Psychiatric Hospital

Come Join our Team!
- Innovative new gero-psych hospital
- Beautiful 24 bed facility in Denver (Lowry)
- Excellent salary and benefits package

Openings for Psychiatrists
Experienced in Administering ECT

We provide innovative inpatient behavioral healthcare for seniors age 65 and older, who are experiencing acute psychiatric symptoms.

Fax CV to: (800) 525-4072

Phone: (303) 790-8888

www.aspirebehavioralhealth.com

CONNECTICUT

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

CONSULTATION/LIAISON PSYCHIATRIST - CENTRAL CONNECTICUT

Opportunity for part-time or full-time (20 or 32 hour position) for CL psychiatrist at Saint Francis Hospital and Medical Center, a 617-bed tertiary hospital located in Hartford, Connecticut. Expertise in working with the interface of psychiatric and medical patients is desirable. As consultation/liaison psychiatrist, you would be part of a multidisciplinary team of psychiatrists, psychiatric nurse practitioners, licensed clinical social workers and licensed professional counselors. Our psychiatric services at Saint Francis Hospital also include four inpatient units and a large outpatient psychiatric program. Enjoy flexibility and well-defined scheduling so you can pursue other career or life interests. Additional work hours are available through the other components of our psychiatric service, for candidates that have interest in such an arrangement.

Our central Connecticut location offers a wide range of upscale suburban living choices and all the amenities of the New England region, including first-rate schools, and the pleasures of country and coastal environments. Close proximity to professional sporting events, concerts, ballet, theatres, skiing and boating, and less than 2 hours to Boston and New York.

For more information about this opportunity, please contact Christine Bourbeau in the Recruitment Office at 800.892.3846 or fax/email your CV to 860.714.8894.

Email address: CBourbea@stfranciscare.org
Visit our Website at:
www.saintfranciscare.com

EEO/AA-M/F/D/V, Pre-employment drug testing

Large psychiatric practice with offices in Fairfield and Trumbull is seeking a psychiatrist, general or child/adolescent, full or part-time possible. We offer competitive salary, benefits, an excellent atmosphere and partnership plan. Reply via email to mway@optonline.net or via fax at (203) 255-3126.

CHILD PSYCHIATRISTS- Connecticut

Opportunities for Inpatient and Outpatient Child Psychiatrists to join Behavioral Health Services affiliated with Saint Francis Hospital and Medical Center, a major teaching hospital distinguished as a leader in clinical excellence.

Outpatient opportunity includes working with psychiatrists, psychiatric nurse practitioners, clinical neuropsychologists, psychologists, licensed clinical social workers, and licensed professional counselors providing psychopharmacological and psychotherapeutic treatment in behavioral health centers located throughout the greater Hartford area. You'll be part of our innovative Rapid Psychiatric Assessment and Stabilization Service. Service includes primary care (pediatric and family medicine) collaboration.

Inpatient opportunity includes working with a multidisciplinary team on a 12-bed Acute Behavioral Child Unit for children ages 5-12 located on the Mount Sinai Campus in Hartford, Connecticut. On-site fully accredited school supports the educational needs of our young patients.

Our central Connecticut location offers a wide range of upscale suburban living choices and all the amenities of the New England region, including first-rate schools, and the pleasures of country and coastal environments. Close proximity to professional sporting events, concerts, ballet, theatres, skiing and boating, and less than 2 hours to Boston and New York.

For more information about this opportunity, please contact Christine Bourbeau in the Recruitment Office at 800.892.3846 or fax/email your CV to 860.714.8894.

Email address CBourbea@stfranciscare.org
Visit our website at www.saintfranciscare.com

EEO/AA-M/F/D/V, Pre-employment drug testing

Psychiatrist

Psychiatrist position - 3 part-time opportunities, could be combined into a full-time position. 20 hour in-patient unit, 20 bed community hospital; 20 hour in-patient consultation psychiatrist on med/surg floors of community hospital; 20 hour out-patient clinic. Work with a collegial, experienced multidisciplinary team in a state of the art hospital system. Competitive salary & benefits. Contact Robert Grillo, MD, Psychiatry Chairman, Middlesex Hospital. Robert_Grillo_MD@midhosp.org

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CMHC Director

Yale University, School of Medicine, Department of Psychiatry and the State of Connecticut, Department of Mental Health and Addiction Services are seeking a Director for the Connecticut Mental Health Center (CMHC). Since 1967, the CMHC has served as an exemplary community mental health center excelling in its combined missions of research, education, and the provision of recovery-oriented services to those experiencing serious psychiatric and/or substance use disorders. An enduring model of public-academic collaboration for Connecticut and the nation, the CMHC has consistently produced national leaders, outstanding clinical and rehabilitative care, and ground breaking research.

Successful candidates must qualify for an academic appointment as an Associate or Full Professor of Psychiatry at the Yale University, School of Medicine. Candidates must also be board certified in psychiatry, eligible for Connecticut licensure for the practice of medicine, and eligible for medical staff appointments at Yale-New Haven Hospital as well as at the CMHC. Extensive leadership in complex mental health systems required, as is an outstanding track record as a clinician, educator, and scholar.

Closing date for applications is expected to be Dec 1, 2008, for a hire/start date of July 1, 2009. Applications should include an introductory letter expressing interest and a C.V., sent to: William H. Sledge, MD, Medical Director, Yale-New Haven Psychiatric Hospital, 184 Liberty Street, LV113, New Haven, CT 06519. Yale University is an Equal Opportunity, Affirmative Action Employer. Applications from women and minority group members are invited.

FLORIDA

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.

18-YR PSYCHIATRIC/MENTAL HEALTH PRACTICE: VENICE/ SARASOTA, FLA. REVENUES: 1.13 MILLION- Retiring doc can stay for negotiated period to assure seamless transition. Price: MARKET BASED: Call med consultant at 301-704-3244

MIAMI AREA (Aventura, FL): PSYCHIATRIST, FT; FL LICENSE REQ'D; also hiring ARNP and/or P.A.; private practice (adoles/adult/geriatric pts); Office/SNF/IP; Excellent Salary & Benefits; **FAX CV** to Dusty: **305-935-1717** or **EMAIL:** aventuraoffices@bellsouth.net

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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.

PSYCHIATRIST - Full time for busy public receiving facility in Pinellas County, FL. Prev. exp. in community mental health preferred but not required. Competitive comp.
Resumes only
Email: hr@pemhs.org
FAX: 727-552-2464

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.

Adult Psychiatrist Needed
in Florida
(between Tampa and Orlando)

Excellent opportunity for a BC/BE psychiatrist to join a child psychiatrist, a psychologist and mental health therapist in well-established multispecialty group.

- Physician-owned practice of 200 Physicians in 40 specialties
- Monday-Friday, 8:00am-5:00pm
- Exceptional suburban setting provides a varied patient mix
- Year-round outdoor activities: tennis, golf, boating, fishing; 500+ lakes, numerous parks & access to beaches, museums, sports events & attractions
- Salary guarantee + bonus the 1st year; Partnership after 2 years.
- NO STATE INCOME TAX!

WATSON CLINIC LLP
1600 Lakeland Hills Blvd.
Lakeland, FL 33805
(800) 854-7786 Fax (863) 680-7951
Email: mstephens@watsonclinic.com

LEAD PSYCHIATRIST / MEDICAL DIRECTOR

Daniel Memorial, Inc. (daniel), a private nonprofit agency located in Jacksonville, Florida, is seeking a BE/BC Child and Adolescent Psychiatrist to become an active member of our senior executive team and to provide administrative and clinical oversight over agency services, including our Residential Treatment Center/Statewide Inpatient Psychiatric Program. daniel offers a competitive compensation package, including benefits, paid malpractice insurance, and compensation for on-call responsibilities. For more information, please see our website: http://www.danielkids.org or contact HR by email: hr@danielkids.org or fax your CV to (904) 296-1953.

Psychiatrist for CSU and Recovery Center

Punta Gorda is an attractive waterfront community on Charlotte Harbor leading to the Gulf of Mexico. CBHC is a private non-profit agency, which has operated independently in Charlotte County since 1969.

CBHC is seeking a full-time and/or part time FL Licensed Psychiatrist(s) to provide psychiatric medical services to consumers in an 18-bed crisis stabilization unit (adults and adolescents) and a 15-bed adult detox facility, as well as providing some outpatient services for a community mental health center. This position reports to the Chief Medical Officer. Work schedule is full time Monday through Friday. Responsibilities include working closely with the treatment team(s) and documenting to an electronic medical record. Prefer exp treating a consumer population with co-occurring disorders; exp. in inpatient setting is also preferred. CBHC prefers that candidates be bc ~ adults and children. Competitive pay and good benefits.

For consideration, please email mail or FAX your CV. For more information, call Dr. Matthews-Ferrari @ (941) 639-8300

Charlotte Behavioral Health Care, Inc.
1700 Education Avenue
Punta Gorda, FL 33950
Phone: (941) 639-8300
Fax: (941) 639-6831
Email: jvanderweele@cbhcfl.org
www.cbhcfl.org
An Equal Opportunity Employer

GEORGIA

Adult Psychiatry - NW Georgia

Harbin Clinic seeks Adult Psychiatrist to join a dynamic Behavioral Sciences team. High volume, primarily outpatient practice using advanced EMR and electronic prescribe. Call 1:6. Competitive compensation; 2 year partnership. Rome, GA, one hour NW of Atlanta, named one of "Forbes Best Places" in 2007. Progressive, economically diverse and thriving community. Contact Sarah King, (706) 378-8130; sking@harbinclinic.com; www.harbinclinic.com. Sorry no visa waivers.

CHILD AND ADOLESCENT PSYCHIATRIST - Position available for second physician to join a busy outpatient practice in a growing community 30 minutes south of Atlanta. This is an opportunity to provide quality treatment in a setting that offers flexible scheduling and options for designing a practice that suits your interests. All outpatient with minimal call; salary is percentage-based at competitive rates with partnership consideration. Interested parties may fax CV to Dr. Neale at 770-253-3175 or call at 770-253-3510.

Tired of managed care and spending less time with patients and more on paperwork? Dwight D. Eisenhower Army Medical Center (Joint Commission accredited) at Fort Gordon, Georgia is seeking Board Eligible and Board Certified Psychiatrists with an active and valid medical license for Department of Defense positions. A medical license in Georgia is not required for this federal position. Outpatient positions for the evaluation and treatment of active duty service members with Posttraumatic Stress Disorder and other psychiatric disorders are available. A position as Medical Director for an inpatient substance abuse unit and a position with an outpatient Traumatic Brain Injury program are also available. Full benefits include a competitive salary, health benefits, vacation, 401K and malpractice coverage. Calls taken from home are currently approximately 1 in 7, with psychology "first call" support for a significant number of the call nights. Fort Gordon is located in Augusta, Georgia, which has been designated as the most affordable city for housing in the US. It is home to the Masters and is the second largest city in Georgia, providing the amenities of a much larger city in a smaller setting. To apply, contact Ms. Beam @ 706-787-6377, or via e-mail @ trish.beam@us.army.mil. Fax # 706-787-1458.

ATLANTA area: General/Geriatric Psychiatrist or Child. Inpatient & partial programs. Fulltime position - salary & benefits.
SAVANNAH: Child or General Psychiatrist - inpatient & partial programs. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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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.

Psychiatrist - Metro-Atlanta

Cobb-Douglas Community Services Board, a behavioral healthcare organization in metro Atlanta (Marietta, GA), seeks a 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.

ILLINOIS

Outpatient Psychiatry Opportunity

4-Day work week! Loan forgiveness available; Limited consults. Impressive base salary, signing bonus, benefits, 401K with matching; 35-days off annually. University Community with medical school and residencies. **Contact Mark Nolen 888.260.4242 x 227 mnolen@medicuspartners.com** fax 972-759-0336

Visa Sponsor!

CHAMPAIGN (East Central IL) Staff Psychiatrist - inpatient & partial programs. Salaried employment & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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Immediately seeking child/adolescent psychiatrist for Summit Clinical Services, a well-established multidisciplinary mental health practice, composed of M.D.s, Licensed Psychologists, Licensed Clinical Social Workers, and Licensed Clinical Professional Counselors, in Chicago's western suburbs. The position offers an excellent opportunity to quickly build a practice among experienced professionals known for providing quality mental health services in a caring and respectful manner. Willingness to also be on staff at nearby hospital is desirable. Must be comfortable working with a conservative Christian patient population.

Flexible hours, set by individual clinician, and generous compensation based on the number of hours worked. Benefits include health insurance and Flexible Spending Account; disability insurance; 401K; and opportunity for partnership and profit sharing.

For more information about our practice, see our Website at www.summitclinical.com.

Contact Dan Wyma, M.D., at Summit Clinical Services, (630) 260-0606.

INDIANA

Visa candidates - still looking? Practice two hours from Chicago in a lakes resort area. Not for profit agency offers full continuum of care. Salaried position with benefits. Contact John Ault at St. John Associates, jault@stjohnjobs.com or 800-737-2001. Visit www.stjohnjobs.com for psychiatry opportunities nationwide.

IOWA

The No. 3 best city in the United States to "live, work and play"-*Kiplingers* - 2008

Medical Director

Horizon Health, in partnership with Jennie Edmundson Memorial Hospital and Alegent Healthcare System - Bergen Mercy in Council Bluffs, IA and Omaha, NE seeks a **Medical Director** for a **20-bed Adult Inpatient** Psychiatric Program. **Jennie Edmundson Memorial Hospital** is a 255-bed regional health center.

Omaha (**& Council Bluffs**) rest(s) on the Missouri River. The metro area population exceeds 1.2 million.
The city is the home to **five** *Fortune 500 companies.*
In **2001** *Newsweek* identified Omaha as one of the **Top 10 high-tech havens** in the nation.
Omaha also boasts a rich culture to satisfy most any form of entertainment.

For more information contact David Hamm at: 972-420-4083, 800.817.6652, or by e-mail david.hamm@horizonhealth.com

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Psychiatrist

Broadlawns Medical Center is a publicly funded hospital and clinic system serving the citizens of Polk County and affiliated with the University of Iowa Hospitals and Clinics. We are seeking a full time Board Eligible or Board Certified Psychiatrist. License eligible to practice in Iowa. M.D. or D.O. with four years of approved psychiatric residency required. Successful candidates will join a multidisciplinary team providing inpatient and/or outpatient serves.

Broadlawns offers a very competitive salary, relocation package and excellent benefits to include State of Iowa retirement. Academic & teaching appointments possible.

Des Moines' Midwest living offers affordable housing, good schools with high ACT scores and a great place to raise a family.

Interested candidates should forward CV to Human Resources for review by Chief Medical Officer.

Post offer pre-employment physical & drug screen required.

Broadlawns Medical Center

1801 Hickman Road
Des Moines, IA 50314
www.broadlawns.org
E.O.E.

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

Issue Deadlines:

Issue	Deadline
November 7	October 24
November 21	November 7
December 5	November 21
December 19	December 5
January 2 '09	December 18
January 16 '09	January 2 '09
February 6 '09	January 23 '09

Contact: Pamela Trujilo, 703.907.7330 or classads@psych.org

LOUISIANA

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY, TULANE UNIVERSITY SCHOOL OF MEDICINE in New Orleans, LA, is recruiting for several general and forensic psychiatrists (clinical track) for our growing department, at the Assistant/Associate Professor level. Candidates must have completed an approved general psychiatry residency and be board certified/eligible in general psychiatry and forensic psychiatry, respectively. Responsibilities will include direct patient care, teaching of medical students and house officers (including those in our accredited forensic psychiatry fellowship program), and research (clinical and basic science) at various state hospitals, state correctional institutions, and at Tulane University Health Sciences Center. Time allocations will be based upon individual situations. Applicants must be eligible to obtain a Louisiana medical license. Applications will be accepted until suitable qualified candidates are found. Send CV and list of references to John W. Thompson, Jr., M.D., Vice Chair, Adult Psychiatry and Director, Division of Forensic Neuropsychiatry, Tulane University School of Medicine, Department of Psychiatry and Neurology, 1440 Canal Street TB53, New Orleans, LA 70112. For further information onsite, please contact Dan Winstead, MD, Chair of Psychiatry and Neurology, at 504-473-5246 or winstead@tulane.edu. Tulane is strongly committed to policies of nondiscrimination and affirmative action in student admission and in employment.

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.

Ochsner Health System

BC/BE Psychiatrist

OCHSNER ST. ANNE GENERAL HOSPITAL is seeking:

- A BC/BE Psychiatrist for an employed position in Raceland, Louisiana
- Located 40 miles from New Orleans with a population of approximately 40,000
- Not-for-profit critical access hospital providing inpatient & outpatient services with high quality, cost-effective emergency, medical & surgical care
- Part of nationally renowned health system of 7 hospitals, 600+ member physician group, and 33 health centers
- Very competitive salary and benefits
- Family-oriented community with year-round outdoor activities
- Favorable malpractice environment in Louisiana
- J-1 visa candidates are welcome to apply
- Ochsner Health System is an equal opportunity employer.

Please email CVs to: profrecruiting@ochsner.org or call (800) 488-2240.
Ref# APSYN4.

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

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

Faculty Position
Assistant Professor (Tenure Track)
Department of Psychiatry

The Department of Psychiatry at the Uniformed Services University of the Health Sciences, Bethesda, MD is seeking to fill an Assistant Professor, tenure-track, teaching and research position. The Department is comprised of twenty full-time faculty and has active research interests in PTSD, disaster psychiatry, mental health services in primary care, neurobiological and behavioral aspects of stress response and substance abuse. The successful candidate will teach medical students and residents, provide clinical care and join the department's Center for the Study of Traumatic Stress research team.

Individuals who hold an M.D., have completed an approved psychiatric residency, are board eligible/certified and have present matching research interests or interest in developing research skills are invited to apply. Previous research experience is desirable, but not required. Send curriculum vitae, description of current and anticipated research interests and the names and addresses of four references to: Robert J. Ursano, M.D., Chairman, Department of Psychiatry, Uniformed Services University, 4301 Jones Bridge Road, Bethesda, MD 20814 (psychiatry @usuhs.mil). Review of applications is ongoing. The University is an affirmative action/equal opportunity employer.

"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.

Practice for sale - Gaithersburg managed care practice open in Montgomery County for over 25 years. Has excellent reputation and huge referral base from primary care practices and mental health professionals. Practice is 95% managed care and many sweetheart contracts will convey. Current billings are $1.4 mil. per year with a 97% collection ratio. The office building is also available for rent or sale. If interested, please e-mail psychiatricpractice@gmail.com.

MASSACHUSETTS

The Edith Nourse Rogers Memorial Veterans Hospital (ENRMVH) in Bedford, Massachusetts is looking for psychiatrists for newly authorized positions in order to address the needs of veterans returning from Iraq and Afghanistan. We have new positions for two outpatient psychiatrists interested in treatment of PTSD, substance abuse, depression and other disorders. We also have a new position for an innovative psychiatrist who would like to assume leadership of our 30 bed acute inpatient unit and help lead a reconfiguration of that unit to a best practice inpatient milieu. This inpatient unit already has two psychiatrists assigned as well as a full complement of experienced mental health staff. Residents from Boston University School of Medicine Division of Psychiatry rotate on the unit for their PGY1 and 2 experiences. The ENRMVH is a teaching hospital with research in Mental Health, Alzheimers Disease and Health Services Outcomes. It has a highly supportive and collegial environment in a delightful suburban setting. Academic appointments available commensurate with qualifications. ENRMVH is an Equal Opportunity Employer. Applicants are subject to an employment physical examination and drug testing.

Interested candidates please contact
Gregory K. Binus, M.D.
Mental Health Service Line Manager
Edith Nourse Rogers Memorial Veterans Hospital
Bedford, MA 01730
781 687-2363
Gregory.Binus2@med.va.gov

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

The Edith Nourse Rogers Memorial Veterans Hospital (ENRMVH) is recruiting for a Mental Health Service Line Manager to oversee our Mental Health clinical, research and teaching program. The Mental Health Service Line provides an exceptionally comprehensive continuum of psychiatric services which include but are not limited to acute inpatient, long term inpatient, a Domiciliary for Homeless Veterans, a crisis stabilization program, a full spectrum Substance Abuse Treatment Program, a Transitional Housing Program for veterans in vocational rehabilitation treatment, standard outpatient clinic services at the facility and in four Community Based Outpatient Clinics, a Day Activities Center, a Veterans Community Care Center, an Intensive Case Management Program, a Community Residential Care Program, and a comprehensive program offering a variety of services to homeless veterans. There is a major emphasis on treatment of PTSD, psychosocial rehabilitation and recovery. ENRMVH conducts approximately $10 million 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, its main academic affiliate, for PGY 1, 2 and 4 residents as well as 3rd year medical students in psychiatry. The facility also has a new academic affiliation with University of Massachusetts School of Medicine. ENRMVH has an outstanding, supportive and collegial staff in all disciplines and is situated in a pleasant suburban environment in Bedford, Massachusetts 25 miles northwest of downtown Boston, next to Lexington and Concord. An academic appointment commensurate with qualifications is expected. The Veterans Health Administration is an Equal Opportunity Employer. Applicants are subject to a physical examination and drug testing. Please direct inquiries and CV by June 2, 2008 to:

Gregory K. Binus, M.D.
Edith Nourse Rogers Memorial Veterans Hospital
Bedford, MA 01730
781 687-2363
Gregory.Binus2@med.va.gov

BOSTON & SUBURBS - Jamaica Plain, Westwood, & Lowell! Full time & part-time positions. Inpatient/partial programs - child/adol, adult & addiction. **NO CALL**. Salary, benefits & incentive plan 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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MASSACHUSETTS: Hallmark Health System

Melrose Wakefield Hospital is seeking a BC/BE Adult Psychiatrist for a full time hospital-based inpatient position. Melrose Wakefield Hospital is located in a congenial community setting just 8 miles north of Boston, and the position provides the opportunity to work in a highly collaborative general hospital setting which has been rated as "one of Boston's Best Places to Work". We are able to offer a **new** and highly competitive salary package with full benefits, including excellent malpractice and relocation reimbursement. **Night and weekend call is optional, and provides the opportunity for enhanced income**. Please contact jfarrar@hallmarkhealth.org; fax: 781.338.7531.

PSYCHIATRIST — BROCKTON, MA

24-hr position for BC/BE* psychiatrist in Joint Commission accredited CMHC just south of Boston with comprehensive outpatient, PACT, case management, residential services, and 24-hour on-site emergency services. CMHC is part of MA DMH Southeastern Area. Active medical staff and Harvard-affiliated psychiatry residency training program. Responsibilities include outpatient psychiatric evaluations, psychopharm. mgmt., treatment planning, consultation to treatment teams. Competitive salary, benefits, daytime, flex schedule, no night call. Board certification required (*can accept BE only if plan in place for board cert exams). Transitional age youth or forensic experience, and/or Spanish speaking desirable. Resident teaching and Harvard appointment available for qualified applicant if interested. Send CVs to Elaine Carmen, MD, Brockton Multi-Service Center, 165 Quincy St., Brockton, MA 02302 or email to elaine.carmen@state.ma.us with cc to robert.buckland @state.ma.us

STAFF PSYCHIATRIST

Opportunity for a Board-Certified/Board-Eligible Psychiatrist to join the expanding Mental Health Service at the Northampton VA Medical Center. Northampton is an active, diversified Medical Center, with 3 satellite outpatient clinics, a 16-bed substance abuse/compensated work therapy Psycho-social Residential Rehabilitation Treatment Program, 85 psychiatric inpatient beds, and 66 nursing home care unit beds. Specialized programs include PTSD, substance abuse, chronically mentally ill, and acute psychiatry. Opportunities are currently available for teaching residents as well as psychology and social work interns. Congenial work atmosphere, stimulating colleagues, and minimal night and weekend duties make this a very pleasant place to work. Northampton is located in the heart of the "five college" area of Western Massachusetts and abounds in cultural attractions. Two hours from Boston, three hours from Times Square, yet in its own cultural base, the area is ideal for raising a family. This Medical Center is affiliated to the Dartmouth Medical School. Competitive salary and federal benefits. EOE employer.

Send CV to: Michelle Zehelski, Human Resource Staffing Clerk (05-HR), Northampton VA Medical Center, 421 North Main Street, Leeds, MA 01053, (413) 584-4040, ext. 2124; FAX (413) 582-3146.

Adolescent Psychiatrist needed in Boston!

Caritas Carney Hospital in Dorchester is seeking a BC/BE adolescent psychiatrist for their short-term, 14-bed, secure inpatient unit. The unit accepts adolescents age 12-18 and is staffed by an interdisciplinary team including nurses, social workers, group therapists and teachers. Caritas Carney Hospital Behavioral Health Services offers a full range of inpatient and outpatient treatment services for adults and adolescents. The Department of Psychiatry had more than 1300 total discharges in 2007, with 273 of them being adolescent. In addition to the 14-bed adolescent unit, there is a 16-bed adult unit, and a 14-bed geriatric unit. The opportunity to be an integral part of our Consult and Liaison team and interface with a busy Emergency Department is available. Career advancement and enhanced income opportunities are available. The new physician will be part of an experienced and collegial team. An academic appointment is available at Tufts University School of Medicine to qualified candidates.

The offer includes competitive compensation and benefits. The benefits package includes: health, dental, retirement plan, disability coverage, malpractice coverage and more.

Caritas Carney Hospital is a member of Caritas Christi Health Care, the second largest health care system in New England. Dorchester is part of a diverse community, and minorities are encouraged to apply. It is only 15 minutes from downtown Boston and it allows easy access to public transportation, suburban communities, outstanding public and private schools, as well as many social and cultural amenities. H1B opportunities available.

Please send a copy of your CV and
Cover Letter to:
Christine Kady, Physician Recruiter
Caritas Christi Health Care
736 Cambridge St., OLH #509,
Boston, MA 02135
ph: (617) 562-7717, fax: (617) 789-2573
christine.kady@caritaschristi.org

Learn more about us at www.caritaschristi.org.

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.

Caritas Christi Health Care
Psychiatry Opportunities in Massachusetts

CARITAS CHRISTI HEALTH CARE, the second largest system in New England has exceptional clinical and academic opportunities for BC/BE inpatient, outpatient and adolescent psychiatrists. Academic affiliation is available at Tufts University School of Medicine for qualified candidates. Positions are available immediately at the following hospitals:

- Caritas St Elizabeth's Medical Center in Boston
- Caritas Carney Hospital in Dorchester
- Caritas Holy Family Medical Center in Methuen

System-wide, Caritas Christi Health Care includes 164 adult, 85 geriatric, and 14 adolescent beds along with a variety of outpatient, consult-liaison, emergency and partial hospital settings. Residency education and research opportunities are available at Caritas St. Elizabeth's Medical Center. Offers include competitive compensation and benefits. Boston and its environs offer world-class cultural, academic and recreational activities.

For more information about these opportunities, please submit a CV and cover letter to:

Christine Kady, Physician Recruitment
Caritas Christi Health Care
736 Cambridge St., OLH #509,
Boston, MA 02135
Email: christine.kady@caritaschristi.org
Phone: 617-562-7717
Learn more about us at: www.caritaschristi.org

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 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.**

The Berkshires~ Western Massachusetts

Adult Psychiatrist
Berkshire Medical Center, in Pittsfield, MA, is currently seeking BC/BE Adult Psychiatrists, with interest in substance-abuse treatment, consultations and brief treatments for primary care practices and/or interests in community mental health; needed for integrated mental health and substance abuse treatment network. Teaching/supervision opportunities and academic appointment possible through affiliation with UMASS Medical School. Competitive salary and benefits package, including relocation. The Berkshires is a 4-season resort community with endless cultural and recreational opportunities. Excellent public and private schools make this an ideal family location, just 2 ½ hours from both Boston and New York City.
Please send CV, or contact: Alex Sabo, MD Phone: 413-447-2162, asabo@bhs1.org, Fax: 413-447-2041 www.berkshirehealthysystems.org

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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).

RESIDENCY TRAINING DIRECTOR IN CHILD & ADOLESCENT PSYCHIATRY:

University of Massachusetts Medical School / UMass Memorial Health Care's Department of Psychiatry is recruiting a full-time faculty member at their qualified academic rank to serve as Child & Adolescent Psychiatry Training Director. The role includes 50% support for the training director role and 50% time dedicated to clinical, research, or other activities depending on the applicant's experience and interests. Led by Dr. Jean Frazier, a large and growing cadre of 40 child and adolescent psychiatry faculty work in a wide range of clinical settings, including University, Community, Consultation / ER, State Hospital, and Criminal Justice System. Current research teams focus on developmental disabilities (Shriver Center), schizophrenia, mood disorders, neuroimaging, addictions, psychopharmacology, behavioral therapy development, transitional youth, forensics, health services research, and primary care psychiatry. There are outstanding collaborations with pediatrics and family medicine. The Communities of Care and MCPAP programs are state and national models for wraparound and child psychiatric consultation to primary care, respectively. Candidates must be board certified in Child and Adolescent Psychiatry. Previous administrative and training experience highly desired. Competitive salary, excellent benefits and a UMMS faculty appointment. UMMS/UMMHC is an AA/EOE. Send letter of interest and CV to: Jean A. Frazier MD, Vice Chair, Division of Child and Adolescent Psychiatry, UMASS Memorial Medical Center, Department of Psychiatry, 55 Lake View North, Worcester, MA 01655. Phone: 508-856-6580, FAX: 508-856-6426, or email: Jean.Frazier@umassmed.edu

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.

Rochester Hills, MI - Very Lucrative Practice Opportunity - Please call me if you have plans to open an adult/gero inpatient and outpatient private practice in the Detroit area. Or if you have a practice already, adding our inpatient component to your income could be extremely rewarding. We will help market your practice in the area. Can offer an income guarantee to help get practice started. Please call **Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

FULL-TIME, PART-TIME AND PER DIEM POSITIONS AVAILABLE
OUTPATIENT PSYCHIATRISTS NEEDED
DETROIT MICHIGAN

Management company seeks physicians for Outpatient Programs within a Community Mental Health Center. Currently offering full-time, part-time and per diem assignments for board-eligible or board-certified Adult and Child Psychiatrists that offer a high level of collaboration within a multidisciplinary team. Competitive compensation. Progressive and rapidly growing management company also has locum and/or temporary assignments. Forward/send CV to: Management Company, churskin@bhrcorp.org or FAX to: (925) 520-0010. Or call us at: (925) 520-0005, ext 102. Visit us **www.bhrcorp.org**

MISSOURI

CHILD PSYCHIATRIST

A Board Certified, or Board Eligible Child Psychiatrist to provide psychiatric services to children, adolescents, and their families is being sought by Community Treatment, Inc. COMPREA is a comprehensive not for profit mental health and chemical abuse treatment center located a few minutes south of St. Louis, MO. This full time position requires proven ability to work as a member of a treatment team, monitor client care, and skills to document client contacts, interventions and medications of clients. Apply on line at www.comtrea.org or email resume to hrs@comtrea.org. E.O.E.

MEDICAL DIRECTOR/EXECUTIVE VICE PRESIDENT

Community Treatment, Inc., a comprehensive not for profit mental health and chemical abuse treatment center located minutes south of St. Louis, MO, is seeking a Medical Director to carry out the purpose, policies and programs of their Medical Services Division. Will be involved in administration and management, facilitate program development, participate in community/public relations and perform direct psychiatric services. This full time position requires Board Certification, five years experience in psychiatric service delivery and three years supervisory experience. Apply on line at www.comtrea.org or email resume to hrs@comtrea.org. E.O.E.

NEBRASKA

The No. 3 best city in the United States to "live, work and play." - *Kiplingers* - 2008

Staff Psychiatrist

DUE TO GROWTH, Horizon Health seeks a **Psychiatrist** for a NEW free-standing psychiatric hospital located in **Omaha, Nebraska.** This position includes an attractive stipend, employment benefits, and paid relocation. A spectrum of sub-acute, acute, regular and intensive care is provided. Call is better than 1:5.

Omaha rests on the Missouri River. The metro area population exceeds 1.2 million.
The city is the home to **five** *Fortune 500 companies.*
In **2001** *Newsweek* identified Omaha as one of the **Top 10 high-tech havens** in the nation.
Omaha also boasts a rich culture to satisfy most any form of entertainment.

For more information contact David Hamm at: 972-420-4083, 800.817.6652, or by e-mail david.hamm@horizonhealth.com

NEVADA

Associate Residency Training Director

The University of Nevada School of Medicine Department of Psychiatry and Behavioral Sciences is seeking an Associate Residency Training Director. Clinical services covered by this position include Consult Liaison work at University Medical Center, and outpatient care at the University clinic. Academic responsibilities include aiding the Residency Director, curriculum development, teaching lectures for residents, supervision of residents, aiding residents with required academic projects, and interaction with medical students. Las Vegas, Nevada, has numerous cultural and recreational events for the entire family and is quickly becoming recognized as a mecca for fine dining. Nevada citizens do not pay state income taxes. For a job description, please visit our website at www.unrsearch.com/applicants/Central?quickFind=53375. AA/EEO.

Clinical Academic Psychiatrist

The University of Nevada School of Medicine Psychiatry department in Las Vegas, Nevada, is seeking a full-time Assistant/Associate Clinical Academic Psychiatrist to provide Consult Liaison services to University Medical Center (UMC), and see outpatient cases in the University outpatient clinic. Academic duties would include teaching classes to all four levels of residents as well as supervising both residents and medical students, and aiding residents with required academic projects.
Las Vegas, Nevada, has a variety of recreational, cultural events and dining experiences including fine dining, shopping, hiking and shows. The climate is excellent with over 300 days of sun. Nevada citizens do not pay state income taxes. For a complete job description and to apply, please visit our web site at: www.unrsearch.com/applicants/Central?quickFind=53361. AA/EOE.

NEW HAMPSHIRE

Child & Adolescent Psychiatrist

Our dynamic comprehensive community mental health center located in scenic New England is seeking a FT or PT child psychiatrist (BE/BC) to join our medical staff. Responsibilities include providing psychiatric evaluations, on going psychiatric service and staff consultation, in a child and adolescent outpatient clinic setting. Research opportunities available. Paid call is shared with other physicians. We offer an attractive compensation and benefits package. Located 45 minutes from Boston, in tax free NH, Nashua, NH and surrounding communities are easily accessible to major airports, mountain and lake regions. Send CV to:

Human Resources
Community Council of Nashua, NH
7 Prospect St. Nashua, NH 03060
hr@ccofnashua.org

NEW JERSEY

PSYCHIATRIST, Adult

Princeton House Behavioral Health is an affiliate of Princeton HealthCare System and a leading provider of behavioral healthcare. Our team provides a full continuum of services and programs for individuals who need psychiatric support and have chemical dependency problems.

Our multidisciplinary **Women's Program** is expanding to **Hamilton, NJ.** Our growth has created a full time position for a BC/BE Psychiatrist with an interest in women's issues to work in innovative gender specific IOP and PHP programs for trauma, trauma and addiction and patients in life transition. This position will require on-call coverage approximately ten weekend days per year (additionally compensated).

We offer excellent benefits including pension plan. **If interested, please email a resume to egarrity@princetonhcs.org.** EOE.

PSYCHIATRIST OPPORTUNITIES

Princeton House Behavioral Health is an affiliate of Princeton HealthCare System and a leading provider of behavioral healthcare. Our team provides a full continuum of services and programs for individuals who need psychiatric support and have chemical dependency problems.

OUTPATIENT PROGRAMS
Full Time, Part Time and Locum positions are available for NJ licensed, BC/BE Psychiatrists (Suboxone experience is a plus) at the following locations:

Hamilton, NJ
Full Time: Women's Program
Full & Part Time: Child & Adolescent Program

Cherry Hill, NJ
Full Time: Child & Adolescent Program

North Brunswick, NJ
Full & Part Time: Child & Adolescent Program
Full time or 32 hrs/week: Adult Program

Princeton, NJ (Mt. Lucas Site)
Full Time: Adult Program

INPATIENT PROGRAMS
The following opportunities require a minimum of five years general psychiatry experience; experience in substance abuse preferred.

Princeton, NJ (Main Campus)
Full Time & Locum: Adult Programs
On Call: Approximately 10 weekend days per year (additionally compensated).

We offer excellent benefits including pension plan. **If interested, please email a resume to egarrity@princetonhcs.org.** EOE.

Westampton: Cherry Hill / Philadelphia area. General/Geriatric Psychiatrist. Inpatient & partial programs. **No call**. Part-time or fulltime - salary and benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

Busy psychiatric practice is seeking 2-3 part-time psychiatrists to assist with initial evaluation and follow-up for Med Management. Great atmosphere and team spirit. Located in Hamilton, NJ 08690. Flexible hours, competitive salary. Fax CV to 215-885-7197 or call 215-872-4451.

P/T Adolescent/Adult Psychiatrist for small non-profit counseling center - 5 hours per week - doing psychiatric evaluations and medication monitoring. Please send CV to: Irvcounseling@aol.com or Irvington Counseling Ctr, 21-29 Wagner Pl, Irv, NJ 07111 or fax 973-399-7552

Child/Adol. or Adult Psychiatrists

Child/Adol. or Adult Psychiatrists - needed for multi-disciplinary group in affluent community in North/Central N.J. NO Managed Care! Call Dr. S. Reiter at 908-598-2400 x1 and fax CV to 908-598-2408.

NEW YORK CITY & AREA

Psychiatrist - Outpatient

The highly regarded **Pederson-Krag Center** offers positions at our **Huntington** site in the following programs:
Assertive Community Treatment (ACT) to provide supervision and treatment on and off-site as part of a multi disciplinary team (17.5 hrs.)
Mental Health Clinic to provide assessments, consultation and treatment services (17.5 hrs.)
The positions can be combined for a full-time position.
Flexible schedule. Excellent benefits. Competitive salary.
Mail CV to **Roger Kallhovd, M.D., Pederson-Krag Center, 55 Horizon Drive, Huntington, N.Y. 11743 or fax 631-920-8165**
EOE/AA

ALBERT EINSTEIN COLLEGE OF MEDICINE Of Yeshiva University Department of Psychiatry and Behavioral Sciences

The Sound View Throgs Neck Community Mental Health Center

PSYCHIATRIST - Full-Time - Continuing Day Treatment and MICA Program.
This Program seeks psychiatrist experienced in diagnostic evaluation and psychopharmacology to provide clinical care, supervise a team and teach medical students, psychiatry residents and clinical fellows. New York State License, Board Certified/Board Eligible in Psychiatry. DEA Registration. This position carries a faculty appointment. Knowledge of Spanish a plus.

In return for your expertise, we offer a competitive salary, outstanding benefits package and a professional work environment offering career growth potential. For consideration, please submit your CV with salary history to: **Thomas F. Betzler, M.D., Executive Director, Sound View Throgs Neck Community Mental Health Center, 2527 Glebe Avenue, Room 304, Bronx, NY 10461; Fax: (718) 931-7307; Email: tbetzler@aecom.yu.edu Equal Opportunity Employer.**

On Call Psychiatrists: Psychiatrists, Fellows and Senior Residents to cover days, nights, weekends and Holidays in the Psychiatric Emergency Department at the Long Island College Hospital. Please send resume to Alina Bustamante, MD fax# 718-780-1827, phone # if you have any questions 718-780-1159.

MANHATTAN
Child/Adolescent Assoc Medical Director
Inpt academic clinical care with leadership, admin and teaching duties. Daytime hrs- no call, wkends or evenings. 25 day LOS, little mg'd care, great staff. Unique new opportunity/attractive salary. AdolMD@gmail.com or 917-710-2456

Premier HealthCare

BC/BE Psychiatrists

Child/Adolescent & Adult Brooklyn, Bronx & Manhattan Part Time/Fee for Service

YAI/Premier HealthCare is a nationally recognized, well-established NYC diagnostic & treatment center for people with developmental disabilities and their families.
Brooklyn Heights or Sheepshead Bay, Brooklyn, Throgs Neck, Bronx & Midtown Manhattan.
This is an opportunity to work with a professional staff of doctors and nurses in a multi-cultural, team environment. Growing field for learning. Send CV to: Karen Meyers, Clinical Recruiter, Premier HealthCare, 460 West 34 Street, N.Y., N.Y. 10001 Fax 212-563-4836 Email: kmeyers@yai.org

NEW YORK STATE

Psychiatrist - Upstate New York. $2,500 sign-on bonus. Relocation allowance. Excellent pay and Benefits. EOE. Private psychopharmacology practice in Albany, New York. Driving distance to New York City, Montreal, Boston. Enjoy the great Adirondack region for hiking, boating, golfing, site seeing. Resume: POB 5324, Albany, NY 12205 or info@psychopharmconsultants.com.

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.

Psychiatrists

BryLin Hospitals, Upstate New York's only private psychiatric hospital, is looking to hire NYS BE/BC psychiatrists. Located in Buffalo, NY, BryLin is a licensed 88 bed inpatient psychiatric hospital that provides acute mental health care for ages five and up.

We have dedicated programs for children, adolescents, adults and older adults. Specialized programs include: Dual diagnosis treatment (MICA); Inpatient and ambulatory Electroconvulsive Therapy (ECT); outpatient substance abuse care; and soon to open, an outpatient mental health program.

The applicant should be interested in working half time as an inpatient psychiatrist and half time in private practice. The private practice, Niagara Frontier Psychiatric Associates (NFPA), is one of the largest groups in the region. This unique hospital/practice model allows for flexibility in one's schedule while providing a diversified work day.

Please email or fax your letter of interest and CV to:
Mark Nowak
Director of Marketing & Physician Recruitment
mnowak@brylin.com
Phone: 716-886-8200 ext. 2201
Fax: 716-886-1986
BryLin Hospitals has a history of providing quality compassionate care for over 50 years.

NORTH CAROLINA

Private Practice Opportunities in North Carolina.

Carolina Partners in Mental HealthCare, PLLC is seeking BE/BC psychiatrists for our practices in Raleigh, Chapel Hill and Wake Forest, NC. Child/adolescent and/or adult psychiatrists welcome. Private outpatient practices, full partnership from day one - no investment required. FT, PT flexible. Carolina Partners has seven offices in Raleigh, Durham, Chapel Hill , Pitt sboro and Wake Forest, North Carolina. Good opportunity to control your life and clinical practice, while making a good income! Contact Executive Director or send CV to: Carolina Partners in Mental HealthCare, 1502 W. Hwy 54, Suite 103, Durham, NC 27707. Phone 919-967-9567; Fax 801-729-9867; EMail carolinapartners@bellsouth.net.

Adult Staff Psychiatrists
Emergency Room Psychiatrists
Charlotte, North Carolina

Carolinas HealthCare System has unique opportunities for Adult Staff Psychiatrists at its Behavioral Health Center. The center is part of a 861- bed regional teaching facility nestled in the heart of Charlotte. Join an outstanding team of psychiatrists in a very collegial working environment.

Adult Staff Position
Inpatient and outpatient position
Starting at $155k and up with experience
Emergency Room Psychiatry Positions
Work in the facility's in-house emergency department.
Several positions available. Rotating shifts
Starting at $175k and up with experience
There is a merit increase to the salary every year

Excellent benefits package which includes:
*Two weeks off for CME's per year
$4,500 stipend for CME's
19 days for vacation per year in addition to 6 Holidays
*Short and long-term disability
*401K, 457B and pension plan
Life insurance equal to three times your salary

Opportunity for extra income by seeing private patients or by taking shifts in the ER

Interested applicants should fax their CV to 704-355-5033 attention: Elaine Haskell, or for more information call 800-847-5084, or email elaine.haskell@carolinashealthcare.org

EOE/AA

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 a wonderful climate and an easy drive to the coast. Commuting from Suffolk, VA is also an option. Please **call Terry B. Good at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

STAFF PSYCHIATRIST POSITION - GREAT LOCATION - Live in Raleigh and work in Rocky Mount in a very impressive general hospital with adult and chemical dependency inpatient/outpatient services. 45 min. drive to Raleigh or Greenville. Offering very attractive salary w/benefits & bonus plan, or practice guarantee if you prefer to be your own boss. 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

Staff Psychiatrist

Full-time position with community mental health center offering inpatient, outpatient, partial hospital, and community support programs. Located in a family-friendly community between Columbus and Dayton with access to various natural, cultural, educational and entertainment activities. Must be board-certified or board-eligible with adult and adolescent psychiatric experience. Competitive salary and comprehensive benefit package. Relocation assistance available. Visit www.mhscc.org to download a brochure. Please send letter of interest and vita to J. Marenberg, HR Director, Mental Health Services for Clark & Madison Cos. 1345 N. Fountain Blvd. Springfield, OH 45504, fax 937 342-4254. or email Jo.Marenberg@mhscc.org.

Equal Opportunity Employer.

North Central Ohio near Cleveland & Columbus. Child Psychiatrist - Adolescent Residential Treatment & Outpatient services. Salaried employment & benefits. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

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CINCINNATI SUBURB - Seeking Psychiatrist to work on inpatient and outpatient services in a very impressive general hospital. Services consist of an adult unit and a geropsych unit. Additional possibilities here if you have an interest in nursing home consults or teaching Family Practice residents. Offering excellent salary/benefits. Please **call Terry B. Good, Horizon Health, at 1-804-684-5661**, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

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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

Adult Psychiatry - Want Variety? Portland, Oregon

Northwest Permanente, P.C., a stable, physician-managed, multi-specialty group providing care to 480,000 members of Kaiser Permanente in Oregon and Southwest Washington, is seeking a BC/BE psychiatrist for our acute care residential facility. The unit is housed in a new building, architecturally designed to provide mental health care based on the "Sanctuary Model."

New associates will work with our adult voluntary patients in an environment that supports a sense of community and is without the use of seclusion or restraints. The center has private rooms with views, comfortable seating areas, and patient access to an open-air atrium. Candidates must be comfortable working as part of an interdisciplinary team, and those with interest/experience in consult-liaison/ECT/addiction psychiatry are encouraged to apply.

The department of mental health regionwide consists of a multi-disciplinary staff of over 130 mental health professionals who provide a full range of professional services to Kaiser Permanente patients.

Northwest Permanente offers a collegial and professionally stimulating practice in one of the most successful managed care programs in the country. In addition to the lifestyle associated with the Pacific Northwest, we provide a predictable work schedule and a competitive salary/benefit package.

To submit your CV and learn more about this opportunity, please visit our Web site at http://physiciancareers.kp.org/nw/ and click on Career Opportunities. For more information please call 1-800-813-3763. No J1 opportunities. We are an Equal Opportunity Employer and value diversity within our organization.

physiciancareers.kp.org/nw
Kaiser Permanente

CHILD PSYCHIATRISTS Salem and Portland, Oregon

Northwest Permanente, P.C., a stable, physician-managed multispecialty group providing care to 480,000 members of Kaiser Permanente in Oregon and southwest Washington, has two excellent opportunities for BC Child Psychiatrists with our group in Salem, Oregon, 45 miles south of Portland in the lush Willamette Valley, and in Portland.

The majority of these practices will include children and teens, but there is also a small percentage of adult work. Position requires experience in medication consultation, crisis intervention, and all treatment modalities. Involves direct clinical work with outpatients as well as providing consultation to other mental health professionals and medical specialists. The Department of Mental Health regionwide consists of a multidisciplinary staff of over 130 mental health professionals who provide a full range of professional services to Kaiser Permanente patients.

We offer a collegial and professionally stimulating practice in one of the most successful managed care programs in the country. In addition to the lifestyle associated with the Pacific Northwest, we provide a predictable work schedule and a generous salary/benefit package.

To submit your CV and learn more about this opportunity, please visit our Web site http://physiciancareers.kp.org/nw/ and click on Career Opportunities. For more information please call 800-813-3763. No J1 opportunities. We are an Equal Opportunity Employer and value diversity within our organization.

PENNSYLVANIA

PHILADELPHIA - Child Psychiatrist for Residential and Inpatient Treatment Center in Bucks County. Fulltime or part-time - salary & benefits. Contact Joy Lankswert @ 866-227-5415; OR email joy.lankswert@uhsinc.com

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PITTSBURGH - Assertive Community Treatment and Outpatient Opportunities. Mercy Behavioral Health is experiencing tremendous growth with starting our fourth ACT program, development of new residentials and expansion of outpatient. MBH offers competitive compensation and an excellent benefits package, all with a flexible schedule that will fit your needs. Contact Jim Jacobson, M.D., Medical Director, Mercy Behavioral Health, 330 S. 9th St., Pittsburgh, PA 15203. Phone 412-488-4927, Fax: 412-488-4929, e-mail: JJacobson@mercybh.org

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Part time psychiatrist sought for busy, insurance-based practice in Philadelphia suburbs. Medication management, some psychotherapy possible. Please see our website at www.PsychChoices.com. If interested fax your resume, with references, to 610-626-8032 or email to office.drfreedman@gmail.com. Preference given to doctors who are already credentialed with Magellan, Aetna, etc.

Physician-Psychiatrist

The Philadelphia VA Medical Center is seeking full and part-time Psychiatrists for our outpatient clinical program. Positions are available with a focus on PTSD, Addictions, General Psychiatry, and Urgent care. The PVAMC Behavioral Healthcare Service provides a full range of high quality, restorative and preventative behavioral health services to the veteran population. Research opportunities and faculty appointments exist with both the PVAMC Centers of Excellence that focus on addictions research (the CESTATE and the MIRECC).

Applications 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 an unrestricted license required.

The PVAMC is an equal opportunity, affirmation action employer. Women and minority candidates are strongly encouraged to apply. We offer a salary commensurate with education and experience and an exceptional benefits package.

Please submit curriculum vitae, a cover letter, and references to:
David Oslin, MD,
ACOS of PVAMC Behavioral Health Services
3900 Woodland Avenue,
Philadelphia, PA 19104
dave.oslin@va.gov

Medical and Education Director

The Philadelphia VA Medical Center is seeking full and/or part-time Psychiatrist to provide oversight for the clinical services and medical education programs in Behavioral Health Services. This includes clinical and administrative management, either directly or through delegated authority of the following: Behavioral Health Outpatient Services, Addictions Recovery Unit, Inpatient Psychiatry Wards, Opiod Treatment Program, Community Based Care, Emergency and Consultative Services and Medical Education Programs. The incumbent provides direct patient care in outpatient clinics and/or inpatient ward and will participate in the on-call schedule. They will also oversee all medical education programs and activities including medical students, residents and post-doctoral fellowship training programs. Research opportunities and faculty appointments exist with both the PVAMC Centers of Excellence that focus on addictions research (the CESTATE and the MIRECC).

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 an unrestricted license required.

The PVAMC is an equal opportunity, affirmative action employer. Women and minority candidates are strongly encouraged to apply. We offer a salary commensurate with education and experience and an exceptional benefits package.

Please submit curriculum vitae, a cover letter, and references to:
David Oslin, MD,
ACOS of PVAMC Behavioral Health Services
3900 Woodland Avenue
Philadelphia, PA 19104
dave.oslin@va.gov

Medical Director - Psychiatrist

When you join CIGNA, you play an important role in improving the health, well-being and security of the people we serve. CIGNA is the fastest growing disability carrier in the industry.

We are seeking a full-time Medical Director to provide expert medical analysis of complex claims files; participate in developing and conducting training curricula to nurses and non-clinical team members; interact with the claimant's attending healthcare provider; and participate in special projects.

Job Qualifications:
- MD or DO required
- Board Certified in Psychiatry with a current unrestricted US medical license
- 5 years clinical experience in psychiatry; experience in private disability insurance or other corporate environment preferred

Benefits
Bonus Opportunity - Stock - Pension Plan - 401K - 23 Paid Days of Vacation - 8 Paid Holidays - No On-Call/Weekends - Casual Business Dress - Free Parking - Flexible Work Schedule

For all questions and inquiries please contact Ngina Muhammad, Physician Talent Manager @ ngina.muhammad@cigna.com.

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.

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

Medical Director & Staff Psychiatrist Erie, PA

Horizon Health, in partnership with **St. Vincent Health Center**, a 436-bed tertiary care hospital in **Erie, PA**, seeks a **Medical Director** and **Staff Psychiatrist** for a **32-bed** Adult and Geriatric Inpatient Psychiatric Program and Outpatient Services.

Medical Director of Behavioral Services (responsibilities include 10-15% administrative with outpatient oversight and remainder is inpatient work including consultation liaison services). Three to five years experience desired. Interest in ECT would be welcomed. **Outpatient position** includes psychiatric evaluations and medication management, crisis services, consultation liaison services and contracted to community programs. Call is 1:5.

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 and a referral base of 750,000.

Contact: Mark Blakeney, Horizon Health, 972-420-7473, fax CV: 972-420-8233, or email mark.blakeney@horizonhealth.com. EOE.

RHODE ISLAND

LIFESPAN PSYCHIATRY

Rhode Island Hospital
The Miriam Hospital

Affiliated Hospitals of the Brown University Department of Psychiatry & Human Behavior

These full-time clinical positions are part of an academic medical center program. These positions are eligible to be considered for Clinical Faculty appointments at Brown University. There are possibilities for some research participation for applicants with appropriate background and interests.

Outpatient (Adult): Interests should include working with medical populations as well as general psychiatry patients. The position includes a component of inpatient consultation-liaison as a member of a teaching service.

Emergency: Assistant Director (Adult) of a comprehensive regional psychiatric emergency program in a new hospital-based facility.

Inpatient (Adult): General psychiatry, inpatients. Some other clinical component may be combined with inpatient work.

Applicants must be Board Certified in Psychiatry or Board eligible (within three years of training completion). Salary and benefits commensurate with level of training and experience. Please send CV's along with a letter of interest to Richard J. Goldberg, M.D., Psychiatrist-in-Chief, APC-9, Rhode Island Hospital, 593 Eddy Street, Providence, RI 02903 and/or email: rjgoldberg@lifespan.org.

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

AIKEN - minutes from Augusta GA & Columbia, SC. General or Child Psychiatrist - inpatient & partial programs. Fulltime position - salary with benefits. J1 VISA SPONSORSHIP - LOAN REPAYMENT ELIGIBLE. Contact Joy Lankswert @ 866-227-5415 or email joy.lankswert@uhsinc.com

TENNESSEE

Parthenon Pavilion at Centennial
TRI STAR HEALTH SYSTEM.

$150 Per Hour - Medical Director Opportunity

Parthenon Pavilion, a 132-bed psychiatric hospital in Nashville, TN, is seeking a Medical Director to oversee the quality, appropriateness of services and treatment provided to patients. Responsibilities include 20-hours per week for Medical Directorship duties, leaving the remainder for private practice. Board Certification in adult and geriatric psychiatry with concentration in geriatric psychiatry preferred. Please contact Debbi Church with HCA Physician Services at 888-543-1314 x 3 or Debbi.Church@HCAHealthcare.com for more information. Also visit PracticeWithUs.com!

TEXAS

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

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

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

UTAH

DAVIS BEHAVIORAL HEALTH INC

In the heart of the American West

Full-time Adult Psychiatrist

Davis Behavioral Health, a progressive private non-profit CMHC located at the site of the 2002 Winter Olympics, 20 minutes north of Salt Lake City, is seeking an outpatient adult psychiatrist. We are located within 45 minutes of 8 world-class ski resorts along the Wasatch front, and for serious wilderness lovers, we are within a days drive of the Grand Canyon to the south, Yellowstone National Park to the north, and the best wilderness Whitewater in the lower 48 states: the Main and Middle forks of the Salmon River.

Utah is a unique balance of modern sophistication and natural wonder; from alpine terrain in the north to desert moonscape in the south, it is an outdoor enthusiast's dream. The average elevation of Utah's tallest peaks is 11,222 ft. above sea level, higher than the same average in any other state, making Utah the rooftop of the nation. The western fringe of the Rocky Mountains surrounds the Wasatch Front valley, nestling cities and towns where trailheads dot the foothills.

Utah's economy continues to experience strong growth. The Wasatch Front has one of the largest concentrations of biomedical, high technology and software firms in the country and a variety of education opportunities are available throughout the state in a network of five universities.

Davis Behavioral Health is a relatively compact organization that offers competitive salaries as well as an unmatched benefits plan including pension and 401(k) retirement accounts through Utah Retirement Systems, medical and dental insurance, cafeteria plan, paid holiday, vacation, and sick leave, and life insurance. The position is primarily outpatient, but provides opportunities to broaden skills, including on-call to the crisis team and crisis unit, commitment hearings, and other specialized services.

We are a progressive organization, located in a county with a population of 300,000, providing services in both the public, private, and unfunded sectors, with a commitment to evidence-based practices, in a collegial clinical community.

Davis Behavioral Health is an Equal Opportunity Employer.

Tim London, Human Resources Director
Davis Behavioral Health, Inc.
934 South Main Street
Layton, Utah 84041
(801) 589-5918
www.dbhutah.org

VERMONT

PSYCHIATRIST

Northwestern Counseling & Support Services, Inc. is seeking a BE/BC full-time outpatient Psychiatrist to join our CMHC. We are located near beautiful Lake Champlain and the Green Mountains, between Burlington, VT and Montreal. Experience with adult SPMI population and child/adolescent psychiatry is preferred but not required. Salaried with generous benefits and paid time off to enjoy VT! May qualify for National Health Service Loan Repayment assistance. Responses:

Ted Mable, Ed.D., Executive Director
NCSS, Inc.
107 Fisher Pond Road
St. Albans, VT 05478
(802) 524-6554
www.ncssinc.org

Medical Director

Medical Director sought for CARF-accredited Southern Vermont Community Mental Health Center on the edge of the Green Mountains. United Counseling Service is a private, non-profit agency with a wide range of programs and a staff of 300 serving a single county with a population of approx. 30,000. Responsibilities include: Providing medication management to a diverse outpatient population supervising one other psychiatrist and a physician's assistant; ensuring appropriate clinical treatment for clients; and providing liaison with the community and other physicians. Full-time salaried position with good benefits as part of the Senior Management team responsible for a blend of direct service & administrative duties. Call is phone back-up only. Live and relax in a 4-season environment with a high quality work/life balance and within easy commute to Albany (one hour), or New York, Boston, and Montreal (3 hours.) Board Certification or eligibility required. For more information visit our website at www.ucsvt.org. or contact Pamela Nemlich, Director of Human Resources at United Counseling Service of Bennington County, Inc. PO Box 588 Bennington, VT 05201. Tel: 802-442-5491. Fax: 802-442-3363 or e-mail pnemlich@ucsvt.org.

Middlebury, VT - Psychiatrist

Psychiatrist to join our innovative interdisciplinary practice. Our highly regarded non-profit 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

Virginia Licensed Psychiatrist to join a large multi-disciplinary group of providers w/ several locations in the Virginia Beach area. Excellent compensation & benefits. Fax Resume to: Christian Psychotherapy Service, 757-497-1327 or call 757-490-0377.

VIRGINIA COMMONWEALTH UNIVERSITY: Department of Psychiatry, School of Medicine, is recruiting BE/BC psychiatrists for these faculty positions: (1) Academic Geropsychiatrist to provide clinical care, training of fellows, residents and medical students, and research activities at Piedmont Geriatric Hospital and the University campus. Teaching, research experience and geropsychiatry fellowship preferred. J-1 AVAILABLE. PGH is specialty geriatric state hospital located in Burkeville, VA, 35 minutes from Richmond. (2) Community Psychiatrist with academic career interests to provide outpatient clinical care and supervise/teach residents/medical students. The clinical experiences include: community psychiatry and hospital-based teaching clinics, and (3) Ambulatory Psychiatry Chair duties will include development of new programs, ambulatory care research, ambulatory resident and student education, and direction of general and specialty clinics and staff supervision. Significant experience in academic ambulatory care, teaching, administration and clinical research required. Faculty with funded research preferred. Ambulatory Care Clinics are located at the VCU Medical Campus, and have an estimated 16,000 patient visits/year. Department of Psychiatry employs over 80 fulltime faculty and is nationally ranked in federally funded research. VCU is a large urban university with robust health science campus and 750-bed university hospital. Department of Psychiatry employs over 80 full time faculty and is nationally ranked in federally funded research. Richmond, the State Capital, has moderate climate and rich mix of history with modern facilities. Excellent suburban housing and quality public/private schools. Send CV to Marie Roach, Human Resources, Department of Psychiatry, VCU/MCV, Box 980710, Richmond, VA 23298. VCU is an EEO/AA employer. Women, minorities, persons with disabilities encouraged to apply.

Psychiatrist Virginia

Per Diem - $150/hr

Join a team of Internists, Psychologists and Counselors in collaboration with Correctional officers. It is a rewarding experience for a Psychiatrist who is interested in the "continuity of care and positive outcome" of treatment. Work in the safest environment one can imagine at two local prisons, and enjoy the outdoor activities in SW Virginia. The position requires 20hrs/wk work at each facility. Work is available as of January 1st, 2009. Malpractice coverage is provided. **Send CV to HCCI, PO Box 308, Pennington Gap, VA 24277 or email at neuro-psych @usa.net**

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

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.

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Please contact Ron Cohen, MD at 425.656.5424 or via e-mail at ron_cohen@valleymed.org. For more information about VMC, please visit www.valleymed.org.

LIVE AND WORK IN SEATTLE - A high quality of life can be offered by Fairfax Hospital, a 133 licensed bed facility providing psychiatric and dual disorders treatment for children, adolescents and adults. We also operate two alternative school programs, as well as a growing CD program. The successful hospital, located in a quiet residential neighborhood on the Eastside of Seattle, enjoys the largest market share in the state of WA for inpatient behavioral health services.

Our services are growing and in response we are seeking Board Certified or eligible **Psychiatrists for our Adult Services as well as Child, Adolescent Services.** Strong compensation package to be negotiated consistent with the candidates needs. All of our current 10 active psychiatrists have an interesting mix of inpatient and outpatient practices.

Fairfax Hospital offers an excellent time off plan, medical, dental, vision, employee assistance program, life and long term disability benefits for full time and part time employees. 401(k) plan available for all employees. Company sponsored fitness membership discount. Fairfax Hospital is an equal opportunity employer. For additional information about our facility please visit our web site at www.FairfaxHospital.com or contact us at Human Resources at 425-284-1715 or via email to anne.schreiber@psysolutions.com

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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.

PSYCHIATRIST

The VA Medical Center, Spokane, WA, is seeking a full time psychiatrist to join our clinical team. The psychiatrist will join seven psychiatrist colleagues in providing a full range of clinical services in our Behavioral Health Service.

The person selected for this position will provide assessment and management of psychiatric inpatients on our 8 bed ward, which is slated for expansion to 12 beds in the near future. The incumbent will also provide psychiatric consultation to medical and surgical inpatients in the general hospital.

On call duties are shared among the eight Behavioral Health Service psychiatrists.

Located in the heart of the Pacific Northwest, Spokane is a vibrant community with a metro population of approximately 400,000. Spokane offers exceptional recreational, educational, and cultural opportunities in a four-season climate.

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Gregory Winter, MD
Chief, Behavioral Health Service
Spokane VA Medical Center
4815 N. Assembly
Spokane, WA 99205-6197
Telephone: 509-434-7260
Fax: 509-434-7113

The VA is an Equal Opportunity Employer.

WEST VIRGINIA

PSYCHIATRISTS

The VA Medical Center, Huntington, WV is seeking board-certified/eligible **Psychiatrists** to join our Mental Health Clinic staff. Full-time positions located at the Huntington Medical Center. The incumbent will perform general psychiatric assessment and treatment in a multidisciplinary setting. Experience and competence in treating Post Traumatic Stress is required. The medical center is a fully accredited 80-bed acute medical and surgical care facility offering primary and subspecialty outpatient care. Candidate must qualify for an academic appointment with the Joan C. Edwards School of Medicine at Marshall University. Huntington, the home of Marshall University, is located in a Tri-State location on the borders of WV, KY and OH with easy access to the major cities in the region. Comprehensive benefit package including: malpractice coverage, Federal Retirement System, health insurance, life insurance, Thrift Savings Plan (401K); Salary commensurate with experience. Applicant selected for these positions will be eligible to apply for an Education Loan Reduction Program (EDRP) to assist in the payback of student loans. **Qualifications required:** Successful completion of a MD degree from an accredited college or university in the field of psychiatry. Must possess a current, full, unrestricted license to practice medicine in any US State/Territory/Commonwealth or District of Columbia. Must successfully complete a background security investigation and pass a pre employment medical examination. J-1 Visa applicants encouraged to apply. Please mail CV to Huntington VA Medical Center, Attn: Denise Littlejohn, Human Resources, 1540 Spring Valley Drive, Huntington, WV 25704. Phone inquiries: (304) 429-6741, ext. 2721 or 2716. VHA is an equal opportunity employer.

Outpatient Position - Lovely Area Near Marietta, Ohio - For the psychiatrist who wants an outpatient Mental Health Center position in a beautiful, growing community about an hour from Charleston. Great schools, affordable housing and a low cost of living. Will need to be on call for inpatient unit one weekend per month and occasionally vacation days. 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.

PSYCHIATRIST - William R. Sharpe, Jr. Hospital, a 150-bed, JCAHO-accredited, state psychiatric hospital and winner of APA Award for state/university collaboration, is searching for a BE/BC psychiatrist. This is a full time faculty position with West Virginia University with regionally competitive salaries and excellent benefits. Position will remain open until filled. Email CV's to Laura Blake at blakel@wvuh.com. WVU is an AA/EO employer.

Virgin Islands

Medical Director/Psychiatrist position is available immediately in an Adult Correctional Facility in the Virgin Islands. The selected candidate will be responsible for overseeing all medical services and providing psychiatric services to inmates in a low and medium security prison. Position includes medical and retirement package. Please call Dr. Denese Marshall for more information at (340) 773-0295 ext 212 or send CV to dmarshall@usvidoj.vi

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Fellowships

MGH Schizophrenia Fellowship

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

Qualified applicants will have completed an accredited psychiatry residency in the US and have passed all necessary exams to obtain a medical license in Massachusetts. Applications are now being accepted for the 2009/2010 academic year.

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

PSYCHOSOMATIC MEDICINE FELLOWSHIP

One year exciting, well-established, fellowship program, one of the first accredited by the ACGME, in a 750-bed university hospital, accepting applications for July 1, 2009. Advanced training offered to psychiatrists who have completed residency. Please write or call: James L. Levenson, M.D., Chairman, C-L Division, VCU Health System, Department of Psychiatry, Box 980268, Richmond, VA. 23298-0268, jlevenson @mcvh-vcu.edu (804) 828-0762; Yaacov R. Pushkin, M.D. ypushkin@mcvh-vcu.edu, or Sherif Meguid, M.D. aabdel-meguid@mcvh-vcu .edu

Yale University School of Medicine
Yale Child Study Center
NIMH Postdoctoral Research Fellowships

The Yale Child Study Center invites applications for postdoctoral positions in the NIMH sponsored, multidisciplinary postdoctoral research training program in Childhood Neuropsychiatric Disorders. Active areas of research include: 1) evidence based treatments of child mental disorders in the clinic and in the community; 2) community-based epidemiological studies; 3) phenomenology and treatment studies of autism, obsessive-compulsive disorder, dyslexia, Tourette's syndrome, and Post-traumatic stress disorder; 4) molecular biological studies involved in cortical development as well as signaling mechanisms in learning and memory; 5) neuroimaging studies of autism, Tourette's syndrome and other disorders; and 6) genetic studies of autism, Tourette's syndrome, mental retardation and dyslexia. Positions are available for 24 months, beginning July 2009. Applications should be submitted by November 15, 2008. Applicants will be notified of decision by January 31, 2009. Send curriculum vitae, any published research papers, three letters of reference and a brief statement of research goals to: James F. Leckman, M.D., Director of Research, Yale University Child Study Center, 230 So. Frontage Road, SHM, I-383, P.O. Box 207900, New Haven, CT 06520-7900. ***Please note that this is a U.S. Government sponsored fellowship and is only open to citizens or permanent residents of the United States.***

Yale University is an Affirmative Action/Equal Opportunity Employer and Welcomes applications from women and minority candidates.

Psychosomatic Medicine Fellowship, Portland, Oregon. Recruiting for 07/01/09 ACGME-accredited PGY5 level, at Oregon Health & Science Univ and Portland VA Med Center. Flexible program with clinical and research opportunities. Training sites include ambulatory care, specialty services, and consultation to inpatient med/surg. Research and clinical strengths in health services, mental disorders in primary care, pain, end-of-life/palliative care, ethics, mood disorders, Parkinson's disease, and substance abuse. Contact Dr. Steven Dobscha, Portland VA Med. Ctr., PO Box 1034 (R&D 66), Portland, OR 97207; at steven.dobscha@va.gov or (503) 220-8262, Ext. 56444. EOE.

Washington, DC
George Washington University School of Medicine

Entering its 32nd year, this ACGME-accredited fellowship in Psychosomatic Medicine is currently accepting applications for three PGY-V positions to start July 1, 2009. Under the guidance of **Thomas N. Wise, MD** and **Catherine C. Crone, MD**, the fellowship offers consultation-liaison training in a wide variety of medical specialties in both inpatient and outpatient settings. This includes: oncology, Ob-Gyn, HIV, trauma, internal medicine, organ transplantation, pulmonary rehabilitation and cardiology. Seminars include clinical, biological and psychodynamic approaches to understanding the medically ill. Opportunities in teaching, research, and outpatient psychotherapy are readily available and strongly encouraged. Training is tailored according to the fellow's area of interest and career goals. The fellowship is based at Inova Fairfax Hospital, an 850-bed tertiary care teaching facility located in the suburbs of Washington, D.C.

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

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
PUBLIC PSYCHIATRY at YALE

The Connecticut Mental Health Center - Yale University School of Medicine is accepting applications for a one-year Fellowship in Public Psychiatry for July 2009. CMHC is a major site for training, research and clinical service within the Yale and State systems. As a state-funded, academic, urban mental health center it provides a unique setting for psychiatrists to obtain advanced training as they pursue careers as leaders in the field. Fellows spend 50% time in seminars, supervision, and administrative/policy meetings of CMHC and the CT Dept. of Mental Health and Addiction Services; and up to 50% effort providing direct clinical service and/or consultation within public mental health settings in New Haven. Candidates must be eligible for board certification and CT licensure. Minority applicants are encouraged to apply. For further information contact Jeanne Steiner, D.O. Medical Director, CMHC - Yale Univ., 34 Park St New Haven, CT 06519 or Jeanne.Steiner@yale.edu.

VA Medical Center/University of Pennsylvania
Postdoctoral positions in Behavioral Health

We have several 2-3 year research or clinical Postdoctoral fellowship positions in Behavioral Health Areas for physicians or psychologists. Potential areas of specialty for these positions include late-life mental health, integrated behavioral health/primary care, genetics/pharmacology, substance abuse, and psychosocial factors in chronic illness. Fellowships are VA or NIMH supported. Every applicant must be a U.S. citizen or permanent resident.

Physician applicants must have an unrestricted medical license. Psychologist applicants must be a graduate of an APA-accredited doctoral program in clinical or counseling psychology, and an APA accredited internship. Other requirements vary depending on the focus on the fellowship, and whether the applicant is seeking a research or clinical fellowship. Salary is commensurate with experience.

Visit our Website (http://www/gov/oaa/specialfellows) to obtain a fellowship application, or contact Madeline Loftus, Coordinator at VA Medical Center, 2nd floor (116), 3900 Woodland Avenue, Philadelphia, PA 19104. tele: (215) 823-4690. email: Madeline.Loftus@med.va.gov

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Geriatric Psychiatry Fellowship with Emphasis on Integrated Consultation-Liaison Psychiatry

The Department of Psychiatry and Behavioral Science at Stony Brook announces the availability of an innovative ACGME-accredited geriatric psychiatry fellowship position starting July 2009 with the option for special emphasis on consultation-liaison psychiatry. With eight board certified geriatric psychiatrists on the faculty, the geriatric psychiatry fellow will have dedicated experience in geriatric inpatient, long-term care, outpatient, ECT, and consultation-liaison psychiatry at the University Hospital as well as several community settings. Located within the new Stony Brook "Division of Medical and Geriatric Psychiatry," fellows in geriatric psychiatry will participate in a clinical milieu emphasizing understanding of the psychiatric aspects of medical conditions, along with the medical aspects of psychiatric conditions. Fellows have the unusual opportunity, through collaborative consultation-liaison work, to develop added clinical expertise and professional relationship skills working closely with trainees and faculty in geriatric medicine, neurology, and family medicine. To apply for the position, fax (631) 444-7534 or email *steven.cole@stonybrook.edu* your letter of interest, your CV, and three letters of reference. Or send by mail to Steven Cole, MD, Head, Division of Medical and Geriatric Psychiatry Health Sciences Center, 10th Floor, Room 042, Stony Brook NY 11794-8101. Equal opportunity/affirmative action employer.

PSYCHOSOMATIC MEDICINE FELLOWSHIP AT YALE UNIVERSITY

This ACGME-accredited one-year fellowship has five Psychosomatic Medicine Fellowship positions available at the PGY-V level or above, starting July 1, 2009. The program offers training in inpatient and outpatient consultation-liaison psychiatry at Yale New Haven Hospital and at the VA Connecticut Healthcare System, with multiple specialty electives. An Equal Opportunity employer. Please contact Paul Desan, MD, PhD, Yale New Haven Hospital, 20 York St CB2039, New Haven, CT 06504, paul.desan@yale.edu, (203) 785-2618.

Residencies

You can make a difference: Louisiana State University Health Science Center (LSUHSC) at New Orleans, Division of Child/Adolescent Psychiatry has come back stronger than ever Post-Katrina. Additional funds have been made available to support and expand our Child/Adolescent Psychiatry Resident Training Program. Now accepting applications and interviewing for Jan. 2009 and July 2009.

Programs in Public/Community Psychiatry Systems of Care with training through LSU's Harris Center in Infant/Early Childhood Psychiatry, and opportunities for collaboration on clinical trials. Rotations include Crisis Intervention, Inpatient Child/Adolescent Psychiatry, School Consultation, Pediatric Consultations, Forensic Child Psychiatry and a Mobile Mental Health Unit. Comprehensive didactics include individual therapy, integrative and family systems—all clinical rotations at or close to main teaching site.

Salaries competitive with other USA Residency Programs and there are opportunities for moonlighting within the program. Financial incentives available if after residency completion the child psychiatrist stays to practice in State.

Candidates must be qualified for a Louisiana License. Contact Child Psychiatry Residency coordinator, Mrs. Dee Bonvillian at 1-504-897-4673 for details or contact:

Bert Quintana, M.D.
Director of the Child/Adolescent Psychiatry Residency Training Program
c/o New Orleans Adolescent Hospital,
3rd Floor, LSU Child/Adolescent Psychiatry
210 State Street
New Orleans, LA 70118
Email Hquint@lsuhsc.edu &
Fax 1-504-897-4781

Positions Wanted

Child Psychiatrist in Chicago seeks to join private practice.
Board Certified, 8 years experience, additional fellowship in Infant psychiatry. Seeking outpatient or residential only, no inpatient, no call. E-mail rumenslavkov@gmail.com

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Brief Summary—see package insert for full prescribing information.

ARICEPT® (Donepezil Hydrochloride Tablets)

ARICEPT® ODT (Donepezil Hydrochloride) Orally Disintegrating Tablets

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 ($AUC_{0\text{-}24}$ 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/m^2 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/m^2 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/m^2 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/m^2 basis) and in pregnant rabbits at doses up to 10 mg/kg/day (approximately 16 times the maximum recommended human dose on a mg/m^2 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/m^2 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.

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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