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PSYCHIATRIC NEWS

The First and Last Word in Psychiatry

ISSN 0033-2704

Agapito Sanchez Jr., Baylor College of Medicine

Researcher and psychopharmacologist Sanjay Mathew, M.D., says that ketamine, a glutamate receptor antagonist, may accelerate clinical advancement in depression therapeutics beyond the monoaminergic system. See story below.

Ketamine Shows Rapid Action In Treatment-Resistant Depression

Instead of targeting postsynaptic monoamine transporters, ketamine inhibits N-methyl-D-aspartate (NMDA) receptors to alter glutamatergic signaling.

BY VABREN WATTS

From "switching" and "combining" antidepressant prescriptions to electroconvulsive therapy, choosing an effective therapy for treatment-resistant depression can be challenging for both patients and clinicians. A report published August 28 in *AJP in Advance* described an alternative that could bring hope to those with the more severe form of depression and the physicians who treat them.

In a collaborative effort, scientists from Michael E. Debakey VA Medical Center in Houston, Baylor College of Medicine, and the Icahn School of Medicine at Mount Sinai conducted the largest study to date on the rapid effects of the anesthetic drug ketamine.

"Almost all current options to treat depression target the monoamine neurotransmitter system [such as selective serotonin reuptake inhibitors (SSRIs)]," said Sanjay Mathew, M.D., chair of the Psychopharmacology of Mood Disorders Program at Baylor, "so we wanted to focus on molecular targets outside the monoamine system that would accelerate clinical advancement in depression therapeutics."

Ketamine has a mechanism different from that of SSRIs and other monoaminergic reuptake inhibitors. Instead of targeting presynaptic monoamine transporters, it inhibits the postsynaptic glutamate binding protein, N-methyl-D-aspartate (NMDA) receptor. Glutamate elicits excitatory responses in neurons,

see **Ketamine** on page 23

Government Seeks Uninsured To Sign Up for Health Exchanges

Though the parity law applies to plans in the exchanges, there is nothing to indicate the breadth of benefits, and clinicians should also be alert to cost-sharing features of their patients' health exchange plans.

BY MARK MORAN

The federal government is mounting a major campaign to get uninsured individuals to sign up for an insurance plan through the new health exchanges, established by the Affordable Care Act (ACA), when enrollment begins October 1 this year.

In a briefing at the White House for approximately 150 invited representatives of mental health advocacy groups—including APA—staff at the White House, the Department of Health and Human Services (HHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA) described a multifaceted strategy to get at least 7 million uninsured individuals to sign up this year for a plan through the new health exchanges.

Steffanie Valencia, special assistant to the president and principal deputy director of the White House Office of Public Engagement, said that the ultimate goal is enrollment of all 40 million uninsured individuals (some of whom will be eligible for Medicaid under new eligibility rules in the ACA). But she said a more realistic target for the first year of the

see **Health Exchanges** on page 12

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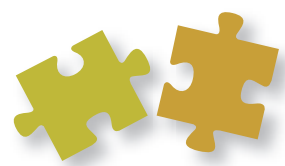

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Psychiatric News, ISSN 0033-2704, is published bi-weekly on the first and third Friday of each month by the American Psychiatric Association, 1000 Wilson Boulevard, Arlington, Va. 22209-3901. Periodicals postage paid at Arlington, Va., and additional mailing offices. Postmaster: send address changes to *Psychiatric News,* APA, Suite 1825, 1000 Wilson Boulevard, Arlington, Va. 22209-3901. Online version: ISSN 1559-1255.

SUBSCRIPTIONS
U.S.: individual, $123. International: APA member, $167; nonmember, $184. Single issues: U.S., $24; international, $41. Institutional subscriptions are tier priced. For site licensing and pricing information, call (800) 368-5777 or e-mail institutions@psych.org.

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Register Now for Institute!

Rudy Balasko/Shutterstock

APA's 2013 Institute on Psychiatric Services is being held October 10 to 13 in Philadelphia. The meeting is often referred to as APA's "little gem" because of its high quality and smaller size than the annual meeting. The theme of this year's institute is "Transforming Psychiatric Practice, Reforming Health Care Delivery." To register, go to www.psychiatry.org/ips. The preliminary program and housing information can also be accessed at that site. Also, see related articles **on pages 4 and 13.**

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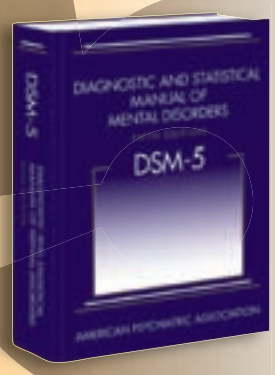

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FROM THE PRESIDENT

IPS to Feature Patrick Kennedy, Celebrate Community Psychiatry

BY JEFFREY LIEBERMAN, M.D.

I am pleased to share highlights of APA's 2013 Institute on Psychiatric Services with you in this *Psychiatric News* column as we get ready to meet in Philadelphia from October 10 to 13. The conference theme is "Transforming Psychiatric Practice, Reforming Health Care Delivery," and I am very excited about this year's meeting for many reasons. As APA president, I had the privilege of selecting the theme and have worked closely with the Scientific Program Committee in planning a learning experience that is innovative, diverse, comprehensive, and professionally fulfilling. In this column I want to share my thoughts on how this year's theme is particularly relevant given the changes we are experiencing in the profession and some of the exciting program events that I hope will support APA's goal of being in the forefront of changes in the profession under health care reform.

I am also very excited to announce two special events planned for this year's attendees. Thanks to the support of the American Psychiatric Foundation, former Rep. Patrick Kennedy, a strong advocate for improved access to mental health services as part of health care reform, will join me for a session in the "Conversations" format, where we will discuss changes in psychiatric practice, stigma, and the need for increased advocacy to improve access to psychiatric treatment. I am also chairing a special symposium on the role of psychiatrists in the transformed health care system with esteemed colleagues Ellen Katz, Ann Sullivan, and Grant Mitchell.

These are among other offerings at this year's IPS:

- Over 120 workshops, lectures, symposia, innovative programs, and forums and a new course: "*DSM-5*: What Clinicians Need to Know and Practical Applications."

- An expanded track on integration of behavioral health and primary care that includes numerous interactive sessions in which psychiatrists, other mental health professionals, and primary care providers can learn and talk about our different clinical cultures and how to effectively collaborate and integrate to provide the highest-quality services to our mutual patients.

- Several sessions on mental health recovery, including how psychiatrists can be involved. The Opening Session keynote will be presented by Estelle Richman, a pioneer in the integration of funding for behavioral health systems and a recipient of a Kennedy School of Government Innovation Award for the transformation of the Philadelphia behavioral health system.

- A special session commemorating a half century of community mental health, featuring community psychiatrists representing each decade since the signing of the Community Mental Health Centers Act of 1963.

- A special track organized by OMNA on Tour (APA's Office of Minority/National Affairs) on the impact of psychological trauma on minority and underserved communities and families.

I congratulate the IPS Scientific Program Committee for developing a diverse program agenda to address the many issues facing the membership related to health care reform, including scope of practice, integrated service models, new payment mechanisms, and the changing role of psychiatrists and psychiatric practice under health care reform. Also, I want to offer a special thanks to the American Association of Community Psychiatrists for its continued support of this meeting—it remains the "must-attend" professional meeting for community and public mental health psychiatrists and other mental health professionals. See you in Philadelphia! For registration information, see the box on page 3. PN

Nominations Invited for APA's 2014 Election

APA invites members to suggest candidates for APA's 2014 election. Nominations are being sought for the national offices of president-elect, treasurer, trustee-at-large, and member-in-training trustee-elect. Members who live in Area 2 or Area 5 are also invited to suggest candidates for their respective Area trustee. Nominations and letters of recommendation should be forwarded by **October 1** to election@psych.org.

More information on the APA elections process and eligibility information is posted on APA's election Web site at http://www.psychiatry.org/network/board-of-trustees/apa-national-elections.

Pioneer Extends Integration To Community-Based Aging Services

Conwell says a more fundamental line than the one between mental health care and other medical care is the barrier between medical care and community-based human and social services. This is the fifth in a series of profiles of leaders in integrated care.

BY MARK MORAN

Psychiatrist Yeates Conwell, M.D., is a pioneer in what might be called "collaborative care plus."

A researcher and leader in developing innovative service system models, Conwell is pushing forward the frontiers of the emerging integrated care movement. Leaders in that movement sometimes speak about degrees of integration—there is the original consultation-liaison model practiced by many in the hospital setting; there is co-located care where primary and mental health services are offered at the same site; and there is what some consider the most advanced model of "collaborative care": a psychiatrist works as a consultant to primary care physicians for an entire caseload of patients in a population.

But Conwell, director of the geriatric psychiatry program at the University of Rochester Medical Center (URMC), is extending the model to integrate medical care with human and social services in the community for elders with depression, dementia, and other mental disorders. Central to his unique vision is the insight, supported by years of research and practice, that social and cultural factors affecting the lives of elders in the community, especially social isolation and social connectedness, are critical to health and well-being—and are important variables in health care utilization and costs.

"A lot of my work, both in terms of research and service system development, has been directed specifically to the integration not just of mental health, primary care, and other medical specialties, but also reaching out to incorporate community-based aging services as a geriatric psychiatrist into that mix," Conwell told *Psychiatric News*. In December 2011, Conwell was chosen to be one of 73 "innovators" (and the only psychiatrist) in the Innovation Advisors Program (IAP) sponsored by the federal Centers for Medicare and Medicaid Innovation; that program is designed to recognize innovative health system service design.

"So many of our systems function in silos," he said. "The siloed mental health versus primary care dichotomy is one barrier, but far more ubiquitous is the barrier between health and human services. Population health allows us to [break down that barrier] if we get to a place where we recognize that community contextual factors influence health care use and expenditures tremendously and that there are these experts in the community that manage morbidities in the community very well."

Yeates Conwell

Yeates Conwell, M.D., says psychiatrists will be welcomed by colleagues in general medicine "worn out" from trying to work across artificial boundaries of a fragmented health care system.

Biopsychosocial Tradition 'Inherited'

As vice chair of the Department of Psychiatry at the University of Rochester, Conwell occupies an office where once sat George Engel, M.D., considered by many to be the father of the "biopsychosocial" model of care. So his vision for how to care for elders living in the community is a natural outgrowth of a long tradition at URMC of stretching the traditional biomedical model to incorporate—as Engel said in a seminal 1977 article in *Science*—"the patient and the social context in which he lives."

> "What I have tried to do with colleagues is bring representatives of the aging services network into our clinic so they can work collaboratively in the assessment and ongoing care of patients and families struggling with dementia."

But his work is also informed by a more personal witness to the strengths and resiliencies of older people. "What brought me into geriatric psychiatry, aside from its being a fascinating field that draws on medical training in neurology and psychiatry, were early influences in which I learned firsthand that older people who age successfully are drawing on remarkable reserves of strength and resilience," Conwell said. "Our older citizens are survivors, and our models of care for them need to draw on their strengths and resiliencies rather than deficits."

As director of a partnership between URMC and a community services provider network called the Senior Health and Research (SHARE) Alliance, Conwell has sought to develop collaborative systems of care integrating primary care, mental health care, and community senior service agencies in the care of seniors in the community with mental disorders.

Among his projects is a dementia care program that will link memory disorder specialty services (geriatric psychiatry, psychology, neurology, medicine, and nursing) with social work and other community-based care to optimize independent functioning and quality of life for people with dementia and their families, while reducing overall costs.

"What I have tried to do with colleagues is bring representatives of the aging services network into our clinic so they can work collaboratively in the assessment and ongoing care of patients and families struggling with dementia," he said. "You might have a depressed older person who has some underlying brain disease and may be brittle on that basis, has partial response to the treatment you provide, and then looks a little bit better and goes home. But if they are going home to a place where they are isolated and socially disconnected, don't have the stimulus they need, can't afford their medication, have to worry about keeping their heat on—any number of potential social problems—the treatment we have simply isn't going to work, or as effectively."

Like many leaders in integrated care, Conwell says the movement to bring together mental health care, medical care, and human and social services in the community is a remarkable opportunity for psychiatrists. He urges psychiatrists to seek out their own community health centers and hospitals for ways they can contribute their special expertise to the care of patients in primary care and those with chronic medical conditions, and he said they will be welcomed by colleagues in general medicine.

"I know it to be true that so many people in the primary practice community are just worn out by their inability to work effectively across these kinds of boundaries that have been artificially imposed by the way our service systems have evolved over time," he said. "To be able [to work across those boundaries] in some sort of population health service model is more satisfying and more fun—and not just for the psychiatrist, but for the primary care doctors who need and want our help." PN

A *Psychiatric News* audio interview with Conwell can be accessed at http://www.psychnews.org/update/audio/conwell.mp3. Also, resources on integrated care for members can be accessed on APA's website at http://www.psychiatry.org/practice/professional-interests/integrated-care.

EXCLUSIVE ONLINE CONTENT

APA Honors Deceased Members

The names of members whose deaths were reported to APA from April 1, 2012, to June 30, 2013, can be accessed at http://psychnews.psychiatryonline.org//newsArticle.aspx?articleid=1725787. In the future, this information will be posted on the *Psychiatric News* Web site on a quarterly basis. The link to the list will be published in the print and e-newsletter versions of *Psychiatric News*.

PROFESSIONAL NEWS

Industry Influence Can Be Mediated by Understanding Theory Behind It

If doctors can approach the food, flattery, and friendship that underlie pharmaceutical marketing with sufficient skepticism, its biasing effects may decrease.

BY AARON LEVIN

Social science research can help understand the marketing practices of pharmaceutical and medical device manufacturers, but might also plausibly be used to help doctors form independent judgments about therapies and diagnostic tools, according to two Georgetown University physicians.

However, doctors must first understand the techniques used to influence their choices.

"Industry uses principles of social psychology to manipulate prescribing behavior; physicians unaware of such subtle influences will not try to avoid the resulting conflicts of interest," wrote Sunita Sah, M.D., M.B.A., Ph.D., an assistant professor of business ethics at Georgetown and a research fellow at the Ethics Center at Harvard University; and Adriane Fugh-Berman, M.D., an assistant professor of pharmacology and physiology and of family medicine at the Georgetown University Medical Center. Their article appears in the August issue of the *Journal of Law, Medicine, and Ethics.*

Aaron Levin

New norms within the medical profession that keep industry at arm's length might lessen conflict of interest, said Adriane Fugh-Berman, M.D., of Georgetown University Medical Center.

Earlier studies showed that physicians believe they are not personally influenced by industry but their colleagues are.

"Physicians think they are making their own independent choice of therapeutics for their patients and don't realize the extent to which they are affected by drug reps," said Fugh-Berman in an interview. She is also director of PharmedOut, a Georgetown University Medical Center project that advocates evidence-based prescribing and educates health care professionals about pharmaceutical marketing practices. "Overconfidence and naiveté are a dangerous combination."

One understanding of the industry's techniques may lie in the principles of influence and persuasion set out by social psychologists like Robert Cialdini, Ph.D., a professor emeritus of psychology and marketing at Arizona State University, as cited by Sah and Fugh-Berman.

For a start, reciprocity might be the tenet most familiar to medical professionals. That pizza or fancy dinner provided by the drug rep sets up an implicit obligation to return the favor.

Commitment to even a small goal (like prescribing that new drug to just a few patients) is amplified by a desire later to justify that choice with future consistency.

Conformity (or "social proof") is doing what others do, especially those with more prestige or authority. Industry's use of "high-status, respected, academic physicians" to act as "key opinion leaders" is such a time-tested tactic.

"The effect on trainees of observing trusted mentors accepting hospitality and funds from industry may be more powerful than the influence of institutional policies or formal curricula," said Sah and Fugh-Berman.

However, Fugh-Berman said she has noticed a change in the last five years as attitudes toward speakers with heavy industry support have become less favorable, especially among medical students.

Finally, there's simple likeability. Drug reps are hired at least as much for their social skills as for their scientific knowledge. And flattery, whether it's a pleasant conversation over that archetypal pizza or an invitation to speak at a prestigious meeting, gets them everywhere.

"Some of that social science thinking might be turned around to help medical students and trainees think the way they have already learned to read the peer-reviewed literature," said former APA President Carolyn Robinowitz, M.D., special associate provost for health science at George Washington University in Washington, D.C. "They could learn to recognize marketing techniques and begin to question more critically drug reps or speakers at those dinner meetings."

Like Sah and Fugh-Berman, Robinowitz believes that educating physi-

see **Industry** on page 21

RESIDENTS' FORUM

Educator Has Mastered Art of 'Cerebral Jujitsu'

BY MICHELLE MARLBOROUGH, M.D.

The Psychiatric Emergency Service (PES) at St. Michael's Hospital in Toronto is a unique entity within the postgraduate training program. This site is part of a departmental focus on meeting the needs of a diverse inner-city population. Patients seen in crisis often have complex issues spanning substance abuse, homelessness, HIV infection, and poor access to services.

It is in this often chaotic environment that Dr. Mara Goldstein thrives. She is full of enthusiasm, passion, and humor. Medical students and residents consistently rate their time at the St. Michael's Hospital PES as one of the highlights of their training.

Dr. Goldstein knew she wanted to be a doctor at age 9, but it was a role-playing exercise focusing on personality disorders during medical school and a subsequent elective in emergency psychiatry with Dr. Mimi Israel that piqued her interest in psychiatry.

Michelle Marlborough, M.D., B.Sc.N. (right), and Mara Goldstein, M.D.

After completing her undergraduate medical training at McGill University, she went to New York University for her psychiatry residency and pursued a fellowship in forensic psychiatry. Dr. Goldstein reflected in an interview on the influence of her mentors during residency, in particular Dr. Carol Bernstein, the late Dr. Wendy Reeves, and the various dedicated psychoanalytic supervisors who frequently held supervision in obscure bars and restaurants in Manhattan.

Following graduation, she joined the staff at St. Michael's Hospital, where she has worked for 10 years, with her primary area of interest being acute-care psychiatry. In addition, Dr. Goldstein served as director of undergraduate electives at the University of Toronto from 2007 to 2013 and recently began a part-time position as medical advisor at the College of Physicians and Surgeons of Ontario.

Dr. Goldstein's contributions to psychiatric education at the University of Toronto have been recognized with two recent honors. She received the 2012 Robin Hunter Award for Excellence in Postgraduate Teaching (which she likens to "winning an Oscar") and the 2013 APA Irma Bland Award for Excellence in Teaching Residents. "I believe I can provide a balanced view of psychiatry with healthy skepticism, and after having had such good teachers myself, there was

see **Residents' Forum** on page 10

Michelle Marlborough, M.D., is a PGY-3 psychiatry resident at the University of Toronto.

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WARNINGS AND PRECAUTIONS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group.

Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis.

Cerebrovascular Adverse Reactions, Including Stroke in Elderly Patients with Dementia-Related Psychosis: In placebo-controlled clinical studies (two flexible dose and one fixed dose study) of dementia-related psychosis, there was an increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, in oral aripiprazole-treated patients (mean age: 84 years; range: 78-88 years). In the fixed-dose study, there was a statistically significant dose response relationship for cerebrovascular adverse reactions in patients treated with oral aripiprazole. ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome: A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) may occur with administration of antipsychotic drugs, including ABILIFY MAINTENA. Rare cases of NMS occurred during aripiprazole treatment in the worldwide clinical database.

Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to exclude cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology.

The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS.

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

Tardive Dyskinesia: A syndrome of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

There is no known treatment for established tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and, thereby, may possibly mask the underlying process. The effect of symptomatic suppression on the long-term course of the syndrome is unknown.

Given these considerations, ABILIFY MAINTENA should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that 1) is known to respond to antipsychotic drugs and 2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient treated with ABILIFY MAINTENA drug discontinuation should be considered. However, some patients may require treatment with ABILIFY MAINTENA despite the presence of the syndrome.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain. While all drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile. Although the following metabolic data were collected in patients treated with oral formulations of aripiprazole, the findings pertain to patients receiving ABILIFY MAINTENA as well.

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with diabetic ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with aripiprazole. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse reactions is not completely understood. However, epidemiological studies suggest an increased risk of hyperglycemia-related adverse reactions in patients treated with atypical antipsychotics. Because aripiprazole was not marketed at the time these studies were performed, it is not known if aripiprazole is associated with this increased risk. Precise risk estimates for hyperglycemia-related adverse reactions in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes), who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the atypical antipsychotic drug.

  In an analysis of 13 placebo-controlled monotherapy trials in adults, primarily with schizophrenia or bipolar disorder, the mean change in fasting glucose in aripiprazole-treated patients (+4.4 mg/dL; median exposure 25 days; N=1057) was not significantly different than in placebo-treated patients (+2.5 mg/dL; median exposure 22 days; N=799). Table 1 shows the proportion of aripiprazole-treated patients with normal and borderline fasting glucose at baseline (median exposure 25 days) that had high fasting glucose measurements compared to placebo-treated patients (median exposure 22 days).

Table 1: Changes in Fasting Glucose From Placebo-controlled Monotherapy Trials in Adult Patients

	Category Change (at least once) from Baseline	Treatment Arm	n/N	%
Fasting Glucose	Normal to High (<100 mg/dL to ≥126 mg/dL)	Aripiprazole	31/822	3.8
		Placebo	22/605	3.6
	Borderline to High (≥100 mg/dL and <126 mg/dL to ≥126 mg/dL)	Aripiprazole	31/176	17.6
		Placebo	13/142	9.2

At 24 weeks, the mean change in fasting glucose in aripiprazole-treated patients was not significantly different than in placebo-treated patients [+2.2 mg/dL (n=42) and +9.6 mg/dL (n=28), respectively].

- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

  There were no significant differences between aripiprazole- and placebo-treated patients in the proportion with changes from normal to clinically significant levels for fasting/nonfasting total cholesterol, fasting triglycerides, fasting LDLs, and fasting/nonfasting HDLs. Analyses of patients with at least 12 or 24 weeks of exposure were limited by small numbers of patients.

  Table 2 shows the proportion of adult patients, primarily from pooled schizophrenia and bipolar disorder monotherapy placebo-controlled trials, with changes in total cholesterol (pooled from 17 trials; median exposure 21 to 25 days), fasting triglycerides (pooled from eight trials; median exposure 42 days), fasting LDL cholesterol (pooled from eight trials; median exposure 39 to 45 days, except for placebo-treated patients with baseline normal fasting LDL measurements, who had median treatment exposure of 24 days) and HDL cholesterol (pooled from nine trials; median exposure 40 to 42 days).

Table 2: Changes in Blood Lipid Parameters From Placebo-controlled Monotherapy Trials in Adults

	Treatment Arm	n/N	%
Total Cholesterol Normal to High (<200 mg/dL to ≥240 mg/dL)	Aripiprazole	34/1357	2.5
	Placebo	27/973	2.8
Fasting Triglycerides Normal to High (<150 mg/dL to ≥200 mg/dL)	Aripiprazole	40/539	7.4
	Placebo	30/431	7.0
Fasting LDL Cholesterol Normal to High (<100 mg/dL to ≥160 mg/dL)	Aripiprazole	2/332	0.6
	Placebo	2/268	0.7
HDL Cholesterol Normal to Low (≥40 mg/dL to <40 mg/dL)	Aripiprazole	121/1066	11.4
	Placebo	99/794	12.5

In monotherapy trials in adults, the proportion of patients at 12 weeks and 24 weeks with changes from Normal to High in total cholesterol (fasting/nonfasting), fasting triglycerides, and fasting LDL cholesterol were similar between aripiprazole- and placebo-treated patients: at 12 weeks, Total Cholesterol (fasting/nonfasting), 1/71 (1.4%) vs. 3/74 (4.1%); Fasting Triglycerides, 8/62 (12.9%) vs. 5/37 (13.5%); Fasting LDL Cholesterol, 0/34 (0%) vs. 1/25 (4.0%), respectively; and at 24 weeks, Total Cholesterol (fasting/nonfasting), 1/42 (2.4%) vs. 3/37 (8.1%); Fasting Triglycerides, 5/34 (14.7%) vs. 5/20 (25%); Fasting LDL Cholesterol, 0/22 (0%) vs. 1/18 (5.6%), respectively.

- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended. In an analysis of 13 placebo-controlled monotherapy trials, primarily from pooled schizophrenia and bipolar disorder, with a median exposure of 21 to 25 days, the mean change in body weight in aripiprazole-treated patients was +0.3 kg (N=1673) compared to –0.1 kg (N=1100) in placebo-controlled patients. At 24 weeks, the mean change from baseline in body weight in aripiprazole-treated patients was –1.5 kg (n=73) compared to –0.2 kg (n=46) in placebo-treated patients.

  Table 3 shows the percentage of adult patients with weight gain ≥7% of body weight in the 13 pooled placebo-controlled monotherapy trials.

Table 3: Percentage of Patients From Placebo-controlled Trials in Adult Patients with Weight Gain ≥7% of Body Weight

	Indication	Treatment Arm	N	n (%)
Weight gain ≥7% of body weight	Schizophrenia[a]	Aripiprazole	852	69 (8.1)
		Placebo	379	12 (3.2)
	Bipolar Mania[b]	Aripiprazole	719	16 (2.2)
		Placebo	598	16 (2.7)

[a]4-6 weeks' duration. [b]3 weeks' duration.

Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension, perhaps due to its α_1-adrenergic receptor antagonism. Orthostasis occurred in 4/576 (0.7%) patients treated with ABILIFY MAINTENA during the stabilization phase, including abnormal orthostatic blood pressure (1/576, 0.2%), postural dizziness (1/576, 0.2%), presyncope (1/576, 0.2%) and orthostatic hypotension (1/576, 0.2%).

In the stabilization phase, the incidence of significant orthostatic change in blood pressure (defined as a decrease in systolic blood pressure ≥20 mmHg accompanied by an increase in heart rate ≥25 when comparing standing to supine values) was 0.2% (1/575).

Leukopenia, Neutropenia, and Agranulocytosis: *Class Effect:* In clinical trials and post-marketing experience, leukopenia and neutropenia have been reported temporally related to antipsychotic agents, including oral aripiprazole. Agranulocytosis has also been reported.

Possible risk factors for leukopenia/neutropenia include pre-existing low white blood cell count (WBC) and history of drug-induced leukopenia/neutropenia. In patients with a history of a clinically significant low WBC or drug-induced leukopenia/neutropenia perform a complete blood count (CBC) frequently during the first few months of therapy. In such patients, consider discontinuation of ABILIFY MAINTENA at the first sign of a clinically significant decline in WBC in the absence of other causative factors.

Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue ABILIFY MAINTENA in patients with severe neutropenia (absolute neutrophil count <1000/mm^3) and follow their WBC counts until recovery.

Seizures: As with other antipsychotic drugs, use ABILIFY MAINTENA cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older.

Potential for Cognitive and Motor Impairment: ABILIFY MAINTENA, like other antipsychotics, may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery, including automobiles, until they are reasonably certain that therapy with ABILIFY MAINTENA does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing ABILIFY MAINTENA for patients who will be experiencing conditions which may contribute to an elevation in core body temperature, (e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration).

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use, including ABILIFY MAINTENA. ABILIFY MAINTENA and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia.

ADVERSE REACTIONS: The following adverse reactions are discussed in more detail in other sections of the labeling in the *Full Prescribing Information:*

- Increased Mortality in Elderly Patients with Dementia-Related Psychosis *[see Boxed Warning and Warnings and Precautions (5.1)]*
- Cerebrovascular Adverse Reactions, Including Stroke in Elderly Patients with Dementia-Related Psychosis *[see Boxed Warning and Warnings and Precautions (5.2)]*
- Neuroleptic Malignant Syndrome *[see Warnings and Precautions (5.3)]*
- Tardive Dyskinesia *[see Warnings and Precautions (5.4)]*
- Metabolic Changes *[see Warnings and Precautions (5.5)]*
- Orthostatic Hypotension *[see Warnings and Precautions (5.6)]*
- Leukopenia, Neutropenia, and Agranulocytosis *[see Warnings and Precautions (5.7)]*
- Seizures *[see Warnings and Precautions (5.8)]*
- Potential for Cognitive and Motor Impairment *[see Warnings and Precautions (5.9)]*
- Body Temperature Regulation *[see Warnings and Precautions (5.10)]*
- Dysphagia *[see Warnings and Precautions (5.11)]*

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Safety Database of ABILIFY MAINTENA and Oral Aripiprazole: Aripiprazole has been evaluated for safety in 16,114 adult patients who participated in multiple-dose, clinical trials in schizophrenia and other indications, and who had approximately 8,578 patient-years of exposure to oral aripiprazole. A total of 3,901 patients were treated with oral aripiprazole for at least 180 days, 2,259 patients were treated with oral aripiprazole for at least 360 days, and 933 patients continuing aripiprazole treatment for at least 720 days.

ABILIFY MAINTENA 300-400 mg every 4 weeks has been evaluated for safety in 1,287 adult patients in clinical trials in schizophrenia, with approximately 1,281 patient-years of exposure to ABILIFY MAINTENA. A total of 832 patients were treated with ABILIFY MAINTENA for at least 180 days (at least 7 consecutive injections) and 630 patients treated with ABILIFY MAINTENA had at least 1 year of exposure (at least 13 consecutive injections).

The conditions and duration of treatment with ABILIFY MAINTENA included double-blind and open-label studies. The safety profile of ABILIFY MAINTENA is expected to be similar to that of oral aripiprazole. Therefore, most of the safety data presented below are derived from trials with the oral formulation. In patients who tolerated and responded to treatment with oral aripiprazole and single-blind ABILIFY MAINTENA and were then randomized to receive ABILIFY MAINTENA or placebo injections under double-blind conditions, the incidence of adverse reactions was similar between the two treatment groups.

Adverse Reactions of ABILIFY MAINTENA and Oral Aripiprazole: *Adverse Reactions Associated with Discontinuation of Oral Aripiprazole:* Based on a pool of five placebo-controlled trials (four 4-week and one 6-week) in which oral aripiprazole was administered to adults with schizophrenia in doses ranging from 2 mg/day to 30 mg/day, the incidence of discontinuation due to adverse reactions was 7% in oral aripiprazole-treated and 9% in placebo-treated patients. The types of adverse reactions that led to discontinuation were similar for the aripiprazole-treated and placebo-treated patients.

Commonly Observed Adverse Reactions of Oral Aripiprazole: Based on a pool of five placebo-controlled trials (four 4-week and one 6-week) in which oral aripiprazole was administered to adults with schizophrenia in doses ranging from 2 mg/day to 30 mg/day, the only commonly observed adverse reaction associated with the use of oral aripiprazole in patients with schizophrenia (incidence of 5% or greater and aripiprazole incidence at least twice that for placebo) was akathisia (aripiprazole 8%; placebo 4%).

Less Common Adverse Reactions in Adults Treated with Oral Aripiprazole: Table 4 enumerates the pooled incidence, rounded to the nearest percent, of adverse reactions that occurred during acute therapy (up to 6 weeks in schizophrenia and up to 3 weeks in bipolar mania), including only those reactions that occurred in 2% or more of patients treated with oral aripiprazole (doses ≥2 mg/day) and for which the incidence in patients treated with aripiprazole was greater than the incidence in patients treated with placebo in the combined dataset.

"It was so hard to watch my brother return to the hospital after his relapse."

"My mom's really scared I'm headed for another relapse."

FOR PATIENTS WITH SCHIZOPHRENIA,

DELAYING RELAPSE IS A MAJOR CHALLENGE.[1]

"What can I do to help my son keep his symptoms under control?"

"I'm feeling a little better; how can I keep this going?"

"Is there any way I can reach my treatment goals?"

INDICATION and IMPORTANT SAFETY INFORMATION for Abilify Maintena™ (aripiprazole) for extended-release injectable suspension

INDICATION

Abilify Maintena is an atypical antipsychotic indicated for the treatment of schizophrenia.

- Efficacy was demonstrated in a placebo-controlled, randomized-withdrawal maintenance trial in patients with schizophrenia and additional support for efficacy was derived from oral aripiprazole trials.

IMPORTANT SAFETY INFORMATION

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Abilify Maintena is not approved for the treatment of patients with dementia-related psychosis.

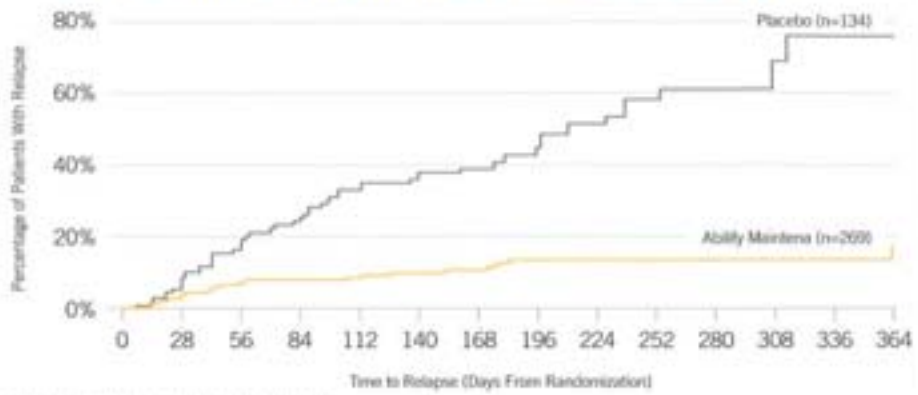
Please see IMPORTANT SAFETY INFORMATION continued, and BRIEF SUMMARY of FULL PRESCRIBING INFORMATION, including **Boxed WARNING**, on the following pages.

IN PATIENTS WITH SCHIZOPHRENIA

Challenge relapse with once-monthly

Abilify Maintena significantly delayed time to relapse* vs placebo[3]

PRIMARY ENDPOINT: SIGNIFICANTLY DELAYED TIME TO RELAPSE VS PLACEBO[3,a]



P<0.0001 (log-rank test) (HR: 5.03, 95% CI = 3.15-8.02)
[a]This figure is based on a total of 88 relapse events.
HR = Hazard Ratio; CI = Confidence Interval

The Abilify Maintena clinical trial had a multiphase design: patients were stabilized on oral aripiprazole 10-30 mg/day (phase 2); then converted to 400 mg Abilify Maintena and stabilized (oral aripiprazole 10-20 mg/day was continued for the first 2 weeks following initial Abilify Maintena dose); then patients were randomized 2:1 to either remain on 400 mg Abilify Maintena or be converted to IM placebo. A decrease to 300 mg Abilify Maintena was permitted for tolerability in phases 3 and 4.

Patients in the placebo group had a 5-times-higher risk (hazard ratio 5.03) for relapse than patients in the Abilify Maintena group[3]

*Relapse was defined as the first occurrence of one or more of the following criteria:

1) CGI-I of ≥5 (minimally worse) and
   a) an increase on any of the following individual Positive and Negative Syndrome Scale (PANSS™) items (conceptual disorganization, hallucinatory behavior, suspiciousness, unusual thought content) to a score >4 with an absolute increase of ≥2 on that specific item since randomization or
   b) an increase on any of the following individual PANSS items (conceptual disorganization, hallucinatory behavior, suspiciousness, unusual thought content) to a score >4 and an absolute increase ≥4 on the combined 4 PANSS items (conceptual disorganization, hallucinatory behavior, suspiciousness, unusual thought content) since randomization
2) Hospitalization due to worsening of psychotic symptoms (including partial hospitalization), but excluding hospitalization for psychosocial reasons
3) CGI-SS of 4 (severely suicidal) or 5 (attempted suicide) on Part 1 and/or 6 (much worse) or 7 (very much worse) on Part 2, or
4) Violent behavior resulting in clinically significant self-injury, injury to another person, or property damage

PANSS™ (Positive and Negative Syndrome Scale) is a trademark of Multi-Health Systems, Inc.

IMPORTANT SAFETY INFORMATION for Abilify Maintena™ (aripiprazole) for extended-release injectable suspension [*continued*]

Contraindication: Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Cerebrovascular Adverse Events, Including Stroke: Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, have been reported in clinical trials of elderly patients with dementia-related psychosis treated with oral aripiprazole.

Abilify Maintena™ (aripiprazole)

Safety profile is expected to be similar to that of oral aripiprazole

- The only commonly observed adverse reaction (≥5% incidence and at least twice the rate of placebo) was akathisia (oral aripiprazole 8% vs placebo 4%)
- The percentage of patients reporting any injection site-related adverse reaction was 6.3% for Abilify Maintena-treated patients in the open-label stabilization phase

Reasons to prescribe Abilify Maintena include:

- Proven to help protect patients from relapse[1] for up to 1 year[2]
- Once-monthly formulation of aripiprazole
- Dedicated patient and caregiver support through Assure-Programs.com

For information on dosing and administration, visit AbilifyMaintena.com

IMPORTANT SAFETY INFORMATION [*continued*]

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including Abilify Maintena. Rare cases of NMS occurred during aripiprazole treatment. Signs and symptoms of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (e.g., irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Continued on next page.

Please see IMPORTANT SAFETY INFORMATION continued, and BRIEF SUMMARY of FULL PRESCRIBING INFORMATION, including **Boxed WARNING**, on the following pages.

ONCE-MONTHLY

400mg

Abilify Maintena

(aripiprazole) for extended release injectable suspension

IMPORTANT SAFETY INFORMATION for Abilify Maintena™ (aripiprazole) for extended-release injectable suspension [*continued*]

Metabolic Changes (continued):

- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics. There were no significant differences between aripiprazole- and placebo-treated patients in the proportion with changes from normal to clinically significant levels for fasting/nonfasting total cholesterol, fasting triglycerides, fasting low-density lipoproteins (LDLs), and fasting/nonfasting high-density lipoproteins (HDLs).
- **Weight Gain:** Weight gain has been observed. Clinical monitoring of weight is recommended.

Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension. Abilify Maintena should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis have been reported. Patients with a history of clinically significant low white blood cell (WBC) count or drug-induced leukopenia/neutropenia should have their complete blood count monitored frequently during the first few months of therapy while receiving Abilify Maintena. In such patients, consider discontinuation of Abilify Maintena at the first sign of a clinically significant decline in WBC count in the absence of other causative factors.

Seizures/Convulsions: Abilify Maintena should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: Abilify Maintena may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery including automobiles until they are certain Abilify Maintena does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Dysphagia: Esophageal dysmotility and aspiration have been associated with Abilify Maintena; use caution in patients at risk for aspiration pneumonia.

Alcohol: Advise patients to avoid alcohol while taking Abilify Maintena.

Concomitant Medication: Dosage adjustments are recommended in patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for greater than 14 days. If the CYP3A4 inhibitor or CYP2D6 inhibitor is withdrawn, the Abilify Maintena dosage may need to be increased. Avoid the concomitant use of CYP3A4 inducers with Abilify Maintena for greater than 14 days because the blood levels of aripiprazole are decreased and may be below the effective levels. Dosage adjustments are not recommended for patients with concomitant use of CYP3A4 inhibitors, CYP2D6 inhibitors or CYP3A4 inducers for less than 14 days.

Most commonly observed adverse reaction: The safety profile of Abilify Maintena is expected to be similar to that of oral aripiprazole. In patients who tolerated and responded to oral aripiprazole and single-blind Abilify Maintena and were then randomized to receive Abilify Maintena or placebo injections, the incidence of adverse reactions was similar between the two treatment groups. The adverse reaction ≥ 5% incidence and at least twice the rate of placebo for oral aripiprazole vs. placebo, respectively, was:

- Akathisia (8% vs 4%) in adult patients with schizophrenia.

Injection Site Reactions: In the open-label, stabilization phase of a study with Abilify Maintena in patients with schizophrenia, the percent of patients reporting any injection site-related adverse reaction was 6.3% for Abilify Maintena-treated patients.

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

Pregnancy/Nursing: Based on animal data, may cause fetal harm. Abilify Maintena should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Aripiprazole is excreted in human breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Please see brief summary of FULL PRESCRIBING INFORMATION, including **Boxed WARNING**, on adjacent pages.

References: **1.** American Psychiatric Association. Practice Guideline for the Treatment of Patients With Schizophrenia. 2nd ed. 2004:1-114. doi:10.1176/appi.books.9780890423363.45859. **2.** Kane JM, Sanchez R, Perry PP, et al. Aripiprazole intramuscular depot as maintenance treatment in patients with schizophrenia: a 52-week, multicenter, randomized, double-blind, placebo-controlled study. *J Clin Psychiatry*. 2012;73(5):617-624. **3.** Data on file. ABIMAI-002.

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Table 4: Adverse Reactions in Short-term, Placebo-controlled Trials in Adult Patients Treated with Oral Aripiprazole		
	Percentage of Patients Reporting Reaction[a]	
System Organ Class Preferred Term	Oral Aripiprazole (n=1843)	Placebo (n=1166)
Eye Disorders		
Blurred Vision	3	1
Gastrointestinal Disorders		
Nausea	15	11
Constipation	11	7
Vomiting	11	6
Dyspepsia	9	7
Dry Mouth	5	4
Toothache	4	3
Abdominal Discomfort	3	2
Stomach Discomfort	3	2
General Disorders and Administration Site Conditions		
Fatigue	6	4
Pain	3	2
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal Stiffness	4	3
Pain in Extremity	4	2
Myalgia	2	1
Muscle Spasms	2	1
Nervous System Disorders		
Headache	27	23
Dizziness	10	7
Akathisia	10	4
Sedation	7	4
Extrapyramidal Disorder	5	3
Tremor	5	3
Somnolence	5	3
Psychiatric Disorders		
Agitation	19	17
Insomnia	18	13
Anxiety	17	13
Restlessness	5	3
Respiratory, Thoracic, and Mediastinal Disorders		
Pharyngolaryngeal Pain	3	2
Cough	3	2

[a]Adverse reactions reported by at least 2% of patients treated with oral aripiprazole, except adverse reactions which had an incidence equal to or less than placebo.

An examination of population subgroups did not reveal any clear evidence of differential adverse reaction incidence on the basis of age, gender, or race.

Dose-Related Adverse Reactions of Oral Aripiprazole: Dose response relationships for the incidence of treatment-emergent adverse events were evaluated from four trials in adult patients with schizophrenia comparing various fixed oral doses of aripiprazole (2 mg/day, 5 mg/day, 10 mg/day, 15 mg/day, 20 mg/day, and 30 mg/day) to placebo. This analysis, stratified by study, indicated that the only adverse reaction to have a possible dose response relationship, and then most prominent only with 30 mg, was somnolence [including sedation]; (incidences were placebo, 7.1%; 10 mg, 8.5%; 15 mg, 8.7%; 20 mg, 7.5%; 30 mg, 12.6%).

Injection Site Reactions of ABILIFY MAINTENA: In the open-label, stabilization phase of a study with ABILIFY MAINTENA in patients with schizophrenia, the percent of patients reporting any injection site-related adverse reaction was 6.3% for ABILIFY MAINTENA-treated patients. The mean intensity of injection pain reported by subjects using a visual analog scale (0=no pain to 100=unbearably painful) was minimal and improved in subjects receiving ABILIFY MAINTENA from the first to the last injection in the open-label, stabilization phase (6.1 to 4.9).

Investigator evaluation of the injection site for pain, swelling, redness and induration following injections of ABILIFY MAINTENA in the open-label, stabilization phase were rated as absent for 74%-96% of subjects following the first injection and 77%-96% of subjects following the last injection.

Extrapyramidal Symptoms of Oral Aripiprazole: In short-term, placebo-controlled trials in schizophrenia, the incidence of reported EPS-related events, excluding events related to akathisia, for oral aripiprazole-treated patients was 13% vs. 12% for placebo; and the incidence of akathisia-related events for aripiprazole-treated patients was 8% vs. 4% for placebo.

Objectively collected data from those trials was collected on the Simpson Angus Rating Scale (for EPS), the Barnes Akathisia Scale (for akathisia), and the Abnormal Involuntary Movement Scale (for dyskinesias). In the schizophrenia trials, the objectively collected data did not show a difference between aripiprazole and placebo, with the exception of the Barnes Akathisia Scale (aripiprazole, 0.08; placebo, –0.05).

Similarly, in a long-term (26-week), placebo-controlled trial of schizophrenia in adults, objectively collected data on the Simpson Angus Rating Scale (for EPS), the Barnes Akathisia Scale (for akathisia), and the Abnormal Involuntary Movement Scale (for dyskinesias) did not show a difference between aripiprazole and placebo.

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.

Adverse Reactions in Long-Term, Double-Blind, Placebo-Controlled Trials of Oral Aripiprazole: The adverse reactions reported in a 26-week, double-blind trial comparing oral aripiprazole and placebo in patients with schizophrenia were generally consistent with those reported in the short-term, placebo-controlled trials, except for a higher incidence of tremor [8% (12/153) for oral aripiprazole vs. 2% (3/153) for placebo]. In this study, the majority of the cases of tremor were of mild intensity (8/12 mild and 4/12 moderate), occurred early in therapy (9/12 ≤49 days), and were of limited duration (7/12 ≤10 days). Tremor infrequently led to discontinuation (<1%) of oral aripiprazole. In addition, in a long-term, active-controlled study, the incidence of tremor was 5% (40/859) for oral aripiprazole.

Other Adverse Reactions Observed During the Premarketing Evaluation of Oral Aripiprazole: Following is a list of MedDRA terms that reflect adverse reactions reported by patients treated with oral aripiprazole at multiple doses ≥2 mg/day during any phase of a trial within the database of 13,543 adult patients. All events assessed as possible adverse drug reactions have been included with the exception of more commonly occurring events. In addition, medically/clinically meaningful adverse reactions, particularly those that are likely to be useful to the prescriber or that have pharmacologic plausibility, have been included. Events already listed in other parts of *Adverse Reactions (6),* or those considered in *Warnings and Precautions (5) or Overdosage (10)* have been excluded. Although the reactions reported occurred during treatment with aripiprazole, they were not necessarily caused by it.

Events are further categorized by MedDRA system organ class and listed in order of decreasing frequency according to the following definitions: those occurring in at least 1/100 patients (only those not already listed in the tabulated results from placebo-controlled trials appear in this listing); those occurring in 1/100 to 1/1000 patients; and those occurring in fewer than 1/1000 patients.

Blood and Lymphatic System Disorders: ≥1/1000 patients and <1/100 patients - thrombocytopenia; *Cardiac Disorders:* ≥1/1000 patients and <1/100 patients - palpitations, cardiopulmonary failure, myocardial infarction, cardio-respiratory arrest, atrioventricular block, extrasystoles, angina pectoris, myocardial ischemia; <1/1000 patients - atrial flutter, supraventricular tachycardia, ventricular tachycardia; *Eye Disorders:* ≥1/1000 patients and <1/100 patients - photophobia, diplopia, eyelid edema, photopsia; *Gastrointestinal Disorders:* ≥1/1000 patients and <1/100 patients - gastroesophageal reflux disease, swollen tongue, esophagitis; <1/1000 patients - pancreatitis; *General Disorders and Administration Site Conditions:* ≥1/100 patients - asthenia, peripheral edema, chest pain; ≥1/1000 patients and <1/100 patients - face edema, angioedema; <1/1000 patients - hypothermia; *Hepatobiliary Disorders:* <1/1000 patients - hepatitis, jaundice; *Immune System Disorders:* ≥1/1000 patients and <1/100 patients - hypersensitivity; *Injury, Poisoning, and Procedural Complications:* ≥1/100 patients - fall; <1/1000 patients - heat stroke; *Investigations:* ≥1/1000 patients and <1/100 patients - blood prolactin increased, blood urea increased, blood creatinine increased, blood bilirubin increased; <1/1000 patients - blood lactate dehydrogenase increased, glycosylated hemoglobin increased; *Metabolism and Nutrition Disorders:* ≥1/1000 patients and <1/100 patients - anorexia, hyponatremia, hypoglycemia, polydipsia; <1/1000 patients - diabetic ketoacidosis; *Musculoskeletal and Connective Tissue Disorders:* ≥1/1000 patients and <1/100 patients - muscle rigidity, muscular weakness, muscle tightness, mobility decreased; <1/1000 patients - rhabdomyolysis; *Nervous System Disorders:* ≥1/100 patients - coordination abnormal; ≥1/1000 patients and <1/100 patients - speech disorder, hypokinesia, hypotonia, myoclonus, akinesia, bradykinesia; <1/1000 patients - choreoathetosis; *Psychiatric Disorders:* ≥1/100 patients - suicidal ideation; ≥1/1000 patients and <1/100 patients - loss of libido, suicide attempt, hostility, libido increased, anger, anorgasmia, delirium, intentional self injury, completed suicide, tic, homicidal ideation; <1/1000 patients - catatonia, sleepwalking; *Renal and Urinary Disorders:* ≥1/1000 patients and <1/100 patients - urinary retention, polyuria, nocturia; *Reproductive System and Breast Disorders:* ≥1/1000 patients and <1/100 patients - menstruation irregular, erectile dysfunction, amenorrhea, breast pain; <1/1000 patients - gynecomastia, priapism; *Respiratory, Thoracic, and Mediastinal Disorders:* ≥1/100 patients - nasal congestion, dyspnea; *Skin and Subcutaneous Tissue Disorders:* ≥1/100 patients - rash (including erythematous, exfoliative, generalized, macular, maculopapular, papular rash; acneiform, allergic, contact, exfoliative, seborrheic dermatitis, neurodermatitis, and drug eruption), hyperhydrosis; ≥1/1000 patients and <1/100 patients - pruritus, photosensitivity reaction, alopecia, urticaria.

Postmarketing Experience: The following adverse reactions have been identified during post-approval use of oral aripiprazole. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: rare occurrences of allergic reaction (anaphylactic reaction, angioedema, laryngospasm, pruritus/urticaria, or oropharyngeal spasm).

DRUG INTERACTIONS: Carbamazepine or Other CYP3A4 Inducers: Concomitant use of ABILIFY MAINTENA with carbamazepine or other CYP3A4 inducers decreases the concentrations of aripiprazole. Avoid use of ABILIFY MAINTENA in combination with carbamazepine and other inducers of CYP3A4 for greater than 14 days *[see Indications and Usage, Dosage and Administration (2.3) and Clinical Pharmacology (12.3)]*.

Ketoconazole or Other Strong CYP3A4 Inhibitors: Concomitant use of ABILIFY MAINTENA with ketoconazole or other CYP3A4 inhibitors for more than 14 days increases the concentrations of aripiprazole and reduction of the ABILIFY MAINTENA dose is recommended *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)]*. Due to prolonged-release characteristics of ABILIFY MAINTENA, short-term co-administration of ketoconazole or other inhibitors of CYP3A4 with ABILIFY MAINTENA does not require a dose adjustment.

Quinidine or Other Strong CYP2D6 Inhibitors: Concomitant use of ABILIFY MAINTENA with quinidine or other CYP2D6 inhibitors increases the concentrations of aripiprazole after longer-term use (i.e., over 14 days) and reduction of the ABILIFY MAINTENA dose is recommended *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)]*. Due to prolonged-release characteristics of ABILIFY MAINTENA, short-term co-administration of quinidine or other CYP2D6 inhibitors with ABILIFY MAINTENA does not require a dose adjustment.

CNS Depressants: Given the CNS depressant effects of aripiprazole, use caution when ABILIFY MAINTENA is taken in combination with other centrally-acting drugs or alcohol.

Anti-Hypertensive Agents: Due to its α_1-adrenergic antagonism, aripiprazole has the potential to enhance the effect of certain antihypertensive agents.

USE IN SPECIFIC POPULATIONS: Pregnancy: *Pregnancy Category C: Risk Summary:* Adequate and well controlled studies with aripiprazole have not been conducted in pregnant women. Neonates exposed to antipsychotic drugs (including ABILIFY MAINTENA) during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. In animal studies, aripiprazole demonstrated developmental toxicity, including possible teratogenic effects in rats and rabbits at doses 1-10 times the oral maximum recommended human dose [MRHD] of 30 mg/day based on a mg/m^2 body surface area. ABILIFY MAINTENA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Clinical Considerations: Fetal/Neonatal Adverse Reactions: Monitor neonates exhibiting extrapyramidal or withdrawal symptoms. Some neonates recover within hours or days without specific treatment; others may require prolonged hospitalization.

Animal Data: Pregnant rats were treated with oral doses of 3 mg/kg/day, 10 mg/kg/day, and 30 mg/kg/day (1 times, 3 times, and 10 times the oral maximum recommended human dose [MRHD] of 30 mg/day on a mg/m^2 body surface area) of aripiprazole during the period of organogenesis. Gestation was slightly prolonged at 30 mg/kg. Treatment caused a slight delay in fetal development, as evidenced by decreased fetal weight (30 mg/kg), undescended testes (30 mg/kg), and delayed skeletal ossification (10 mg/kg and 30 mg/kg). There were no adverse effects on embryofetal or pup survival. Delivered offspring had decreased body weights (10 mg/kg and 30 mg/kg), and increased incidences of hepatodiaphragmatic nodules and diaphragmatic hernia at 30 mg/kg (the other dose groups were not examined for these findings). A low incidence of diaphragmatic hernia was also seen in the fetuses exposed to 30 mg/kg. Postnatally, delayed vaginal opening was seen at 10 mg/kg and 30 mg/kg and impaired reproductive performance (decreased fertility rate, corpora lutea, implants, live fetuses, and increased post-implantation loss, likely mediated through effects on female offspring) was seen at 30 mg/kg. Some maternal toxicity was seen at 30 mg/kg; however, there was no evidence to suggest that these developmental effects were secondary to maternal toxicity.

In pregnant rats receiving aripiprazole injection intravenously (3 mg/kg/day, 9 mg/kg/day, and 27 mg/kg/day) during the period of organogenesis, decreased fetal weight and delayed skeletal ossification were seen at the highest dose, which also caused some maternal toxicity.

Pregnant rabbits were treated with oral doses of 10 mg/kg/day, 30 mg/kg/day, and 100 mg/kg/day (2 times, 3 times, and 11 times human exposure at the oral MRHD of 30 mg/day based on AUC and 6 times, 19 times, and 65 times the oral MRHD of 30 mg/day based on mg/m^2 body surface area) of aripiprazole during the period of organogenesis. Decreased maternal food consumption and increased abortions were seen at 100 mg/kg. Treatment caused increased fetal mortality (100 mg/kg), decreased fetal weight (30 mg/kg and 100 mg/kg), increased incidence of a skeletal abnormality (fused sternebrae at 30 mg/kg and 100 mg/kg), and minor skeletal variations (100 mg/kg).

In pregnant rabbits receiving aripiprazole injection intravenously (3 mg/kg/day, 10 mg/kg/day, and 30 mg/kg/day) during the period of organogenesis, the highest dose, which caused pronounced maternal toxicity, resulted in decreased fetal weight, increased fetal abnormalities (primarily skeletal), and decreased fetal skeletal ossification. The fetal no-effect dose was 10 mg/kg, which produced 5 times the human exposure at the oral MRHD based on AUC and is 6 times the oral MRHD of 30 mg/day based on mg/m^2 body surface area.

In a study in which rats were treated with oral doses of 3 mg/kg/day, 10 mg/kg/day, and 30 mg/kg/day (1 times, 3 times, and 10 times the oral MRHD of 30 mg/day on a mg/m^2 body surface area) of aripiprazole perinatally and postnatally (from day 17 of gestation through day 21 postpartum), slight maternal toxicity and slightly prolonged gestation were seen at 30 mg/kg. An increase in stillbirths and decreases in pup weight (persisting into adulthood) and survival were seen at this dose.

In rats receiving aripiprazole injection intravenously (3 mg/kg/day, 8 mg/kg/day, and 20 mg/kg/day) from day 6 of gestation through day 20 postpartum, an increase in stillbirths was seen at 8 mg/kg and 20 mg/kg, and decreases in early postnatal pup weights and survival were seen at 20 mg/kg. These doses produced some maternal toxicity. There were no effects on postnatal behavioral and reproductive development.

Nursing Mothers: Aripiprazole is excreted in human breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of ABILIFY MAINTENA in patients <18 years of age have not been evaluated.

Geriatric Use: Safety and effectiveness of ABILIFY MAINTENA in patients >60 years of age have not been evaluated. In oral single-dose pharmacokinetic studies (with aripiprazole given in a single oral dose of 15 mg), aripiprazole clearance was 20% lower in elderly (≥65 years) subjects compared to younger adult subjects (18 to 64 years). There was no detectable age effect, however, in the population pharmacokinetic analysis of oral aripiprazole in schizophrenia patients. Also, the pharmacokinetics of oral aripiprazole after multiple doses in elderly patients appeared similar to that observed in young, healthy subjects. No dosage adjustment of ABILIFY MAINTENA is recommended for elderly patients *[see also Boxed Warning and Warnings and Precautions (5.1)]*.

CYP2D6 Poor Metabolizers: Approximately 8% of Caucasians and 3–8% of Black/African Americans cannot metabolize CYP2D6 substrates and are classified as poor metabolizers (PM). Dosage adjustment is recommended in CYP2D6 poor metabolizers due to high aripiprazole concentrations *[see Dosage and Administration (2.3), Clinical Pharmacology (12.3)]*.

OVERDOSAGE: Human Experience: The largest known case of acute ingestion with a known outcome involved 1260 mg of oral aripiprazole (42 times the maximum recommended daily dose) in a patient who fully recovered.

Common adverse reactions (reported in at least 5% of all overdose cases) reported with oral aripiprazole overdosage (alone or in combination with other substances) include vomiting, somnolence, and tremor. Other clinically important signs and symptoms observed in one or more patients with aripiprazole overdoses (alone or with other substances) include acidosis, aggression, aspartate aminotransferase increased, atrial fibrillation, bradycardia, coma, confusional state, convulsion, blood creatine phosphokinase increased, depressed level of consciousness, hypertension, hypokalemia, hypotension, lethargy, loss of consciousness, QRS complex prolonged, QT prolonged, pneumonia aspiration, respiratory arrest, status epilepticus, and tachycardia.

Management of Overdosage: In case of overdosage, call the Poison Control Center immediately at 1-800-222-1222.

PATIENT COUNSELING INFORMATION: Physicians are advised to discuss the FDA-approved patient labeling (Medication Guide) with patients for whom they prescribe ABILIFY MAINTENA.

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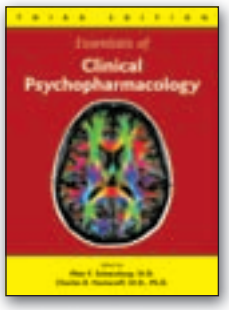

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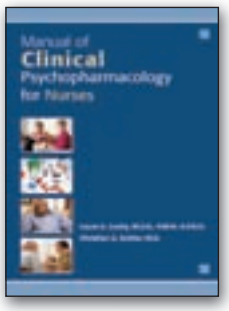

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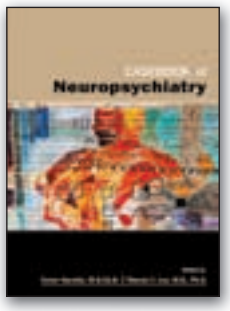

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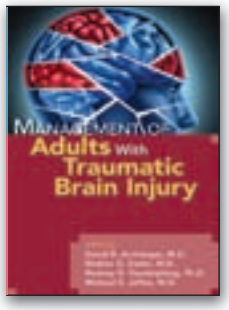

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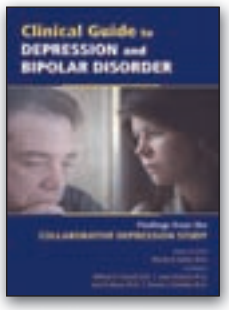

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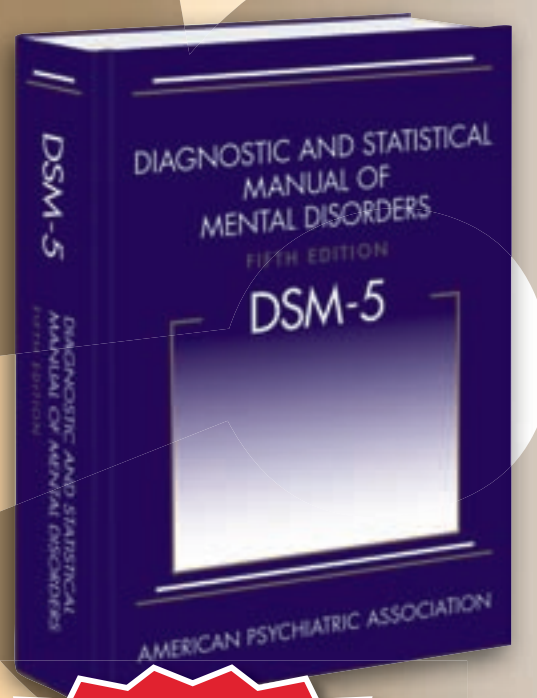

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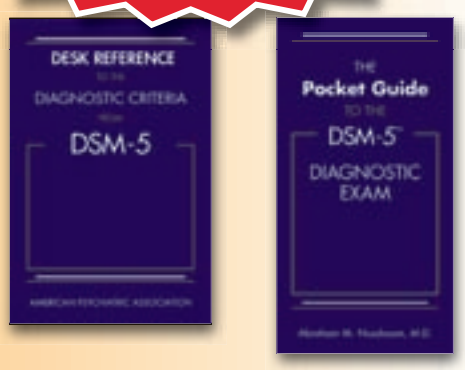

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Challenges Arise as Psychiatry's Ethics Landscape Changes

Thirty years ago, boundary crossing was the major ethical danger that psychiatrists faced. Today, other ethical challenges have cropped up, and they don't always have easy answers.

BY JOAN AREHART-TREICHEL

Psychiatrists have always been challenged about "doing the right thing" for their patients. And some of the same ethical hurdles that existed 30 years ago, such as boundary crossings, still exist today. But all things considered, the ethical landscape of today is quite different from that of that era, members of the APA Ethics Committee tend to concur.

For example, "Your primary job is to be the patient's doctor," Richard Milone, M.D., an associate clinical professor of psychiatry at New York Medical College and chair of the APA Ethics Committee, pointed out. "Any time you start being something else to a patient, it's the start of trouble. What are some of the other things? Lending a patient money. You are not the patient's banker. Borrowing money from your patient. The patient is not your banker. We've had psychiatrists who asked recently, 'Can I be a guardian for a patient who is not thoroughly competent? He likes me; I like him.' Well, you can't do that because as a guardian you would have the responsibility of doling out money and giving an allowance to the patient. And if he were dissatisfied with how much you gave him, it could erode your doctor-patient relationship."

"An ethical issue I'm coping with right now are the recent changes in CPT codes," Claire Zilber, M.D., a Denver, Colo., psychiatrist and an APA Ethics Committee member, commented "One insurance company is requesting a patient's entire chart before it will pay for every visit by the patient. Although technically the company is allowed to do that under HIPAA, I don't think that it's ethical."

The new CPT codes present yet another ethical dilemma, said Mark Komrad, M.D., an instructor in psychiatry at Johns Hopkins Medical Institutions and also an APA Ethics Committee member. "There are now so many nuances in coding. Spending just one extra minute or two with a patient can bring you to a whole new code, which could get more reimbursement for the patient or for you. Should you shift the encounter one minute to maximize reimbursement?"

Psychiatrists May Work as 'Double Agents'

A new ethical quandary for psychiatrists has appeared in the wake of the Newtown, Conn., school shootings last December, Milone suggested, as psychiatrists in some situations will both serve their patients and protect society from dangerous patients. Or as Komrad put it, "Society expects us to be their protectors, to work as double agents."

Sergey Ivanov

"It is a longstanding principle in psychiatry that when a patient presents a serious and imminent danger to either himself or others, the psychiatrist has the duty to report it," Milone explained. "This is the well-known *Tarasoff* rule. We psychiatrists accept that, we're comfortable with it, and we employ it without hesitation. But some states—for instance, New York and Connecticut—have now passed gun laws that say that when a psychiatrist or therapist believes that a patient is *likely* to engage in conduct that would render serious harm to self or others, then it is the psychiatrist's or therapist's duty to report that patient. *Likely* is much weaker than *imminent.*

We psychiatrists are therefore concerned [that these laws can lead to] overreporting and a breach of patient confidentiality. The New York State Psychiatric Association and the APA Council on Psychiatry and Law are grappling with this conflict we are facing."

Yet the greatest ethical hurdles psychiatrists have to cross these days are posed by the new information technology and use of social media, Elissa Benedek, M.D., a former APA president, an adjunct professor of psychiatry at the University of Michigan, and a member of the APA Ethics Committee, asserted. She believes that psychiatrists are facing more ethical challenges than ever before because of such technology.

For example, when, if ever, should you use e-mail with your patients? To schedule appointments only, Milone contended, and that is all that he uses it for.

Is it ethical to defend your professional reputation online when patients have negative things to say about you on doctor-rating sites? "What appears on such sites is more likely to come from disgruntled patients," Komrad remarked. "But how can doctors defend themselves within the bounds of preserving patient confidentiality? Would it be appropriate to ask patients to make positive comments about you to balance the negative comments?" Komrad thinks probably not.

And when, if ever, is it ethical to Google patients?

see **Ethics** on page 24

Ethical Dilemmas Vary by Subspecialty

Do certain types of psychiatrists face more ethical challenges than others? Members of the APA Ethics Committee hold different opinions on the matter.

Perhaps younger psychiatrists do, "because they are more likely to use social media than the older ones," said Elissa Benedek, M.D.

"I think that military psychiatrists face more ethical challenges than other types of psychiatrists, because they have the dual responsibility of answering to a commander and maintaining patient confidentiality," said Stephen Scheiber, M.D.

"I don't think that certain types of psychiatrists face more ethical challenges than others, but I do think that the types of challenges can vary depending on the type of psychiatrist," opined William Arroyo, M.D., a Los Angeles child psychiatrist. "For example, a child psychiatrist needs to seek informed consent about treatment from a child's legal guardian, but also assent from the child." In other words, "It is strongly recommended that getting an assent from a child is the standard for older children, especially teens, but many 8- to-10-year-olds may also participate in such an interchange."

Claire Zilber, M.D., agreed with Arroyo. For example, forensic psychiatrists are probably faced more often than other types of psychiatrists with requests from the media to comment on the mental state of someone on whom they have not conducted an evaluation, she said. "Yet it can sometimes be hard for not just a forensic psychiatrist, but any psychiatrist, to always abide by the rule because it is so compelling to say something."

As for Mark Komrad, M.D., he suggested that psychiatrists are more vulnerable to ethical breaches at certain stages of their careers than at others. For example, "Research has shown that sexual-boundary violations are more common in later-career psychiatrists than in early-career ones."

Ethics Problems: Don't Go It Alone

"Ethics is not strictly about common sense," Ethics Committee member Mark Komrad, M.D., pointed out. "It is about a process of thinking through a situation in light of some principles."

If you are faced with an ethical dilemma, you could discuss it with a trusted colleague, Richard Milone, M.D., chair of the APA Ethics Committee, noted. Or you could ask the APA Ethics Committee for guidance.

Here is how it works, he explained. You send your question via e-mail to Linda Hughes, director of APA's Office of Ethics and District Branch/State Association Relations, at lhughes@psych.org. "If it is a fairly easy, straightforward question, she will send it to me as committee chair, and I'll give her a few sentences to answer it, and she'll then forward the answer to you. But if the question is more complex—and we do get some interesting complex questions—we have a rotation of at least two psychiatrists on the Ethics Committee who will work together on an answer. They will then pass their answer on to me, as chair, to review it, and the three of us will arrive at a decision and get back to you."

HelpLine Resolves Member's Nightmare On Repayment Demands

Psychiatrists know all too well that dealing with insurance companies can be not only time consuming, but sometimes harrowing. Here's a happy ending for one member's frustrating tale.

BY ELLEN JAFFE

Bacho/Shutterstock

Through its Practice Management HelpLine, staff of APA's Office of Healthcare Systems and Financing (OHSF) frequently hear from members who are thinking about opting out of Medicare because they're fearful about falling into legal jeopardy if they fail to follow all of Medicare's complex rules. Generally our policy is to reassure these callers that if they code and document appropriately, they should not encounter any problems.

Nonetheless, the Centers for Medicare and Medicaid Services' (CMS's) rules can be extremely confusing, and when APA members do encounter problems, they often find it difficult to reach the level of authority within the Medicare system that has the ability to resolve their issue. When that happens, a good place to turn is APA's HelpLine.

Earlier this year, an APA member in Alabama started receiving what he described as "mountains" of letters from Cahaba GBA, his Medicare administrative contractor. Each letter stated that he had been paid erroneously for a claim and was required to return the payment. His office manager called Cahaba's customer service number and was eventually put in touch with a supervisor who explained there had been a computer glitch that led to the generation of the letters. She said that the company was unable to correct the problem at the moment, but told him to disregard any further dunning letters he received.

To his relief, he received a letter from Cahaba in April stating that 11 of the requests for repayment had been rescinded. Although a few repayment requests continued to trickle in, neither he nor his staff were concerned. Then, at the end of June, a letter came from Cahaba stating that the psychiatrist owed more than $23,000 (which included $808.60 in accrued interest) and that his case was going to be turned over to the Department of Treasury for collection. The first week of July brought another letter with the same information, but for a far lesser sum—$1,148.11. The psychiatrist called the HelpLine for assistance and faxed the letters he had received. He was concerned about how having to pay this chunk of money would affect his practice.

Because the HelpLine maintains working relationships with most Medicare contractors, we were able to contact Cahaba's medical director and send him a summary of what had occurred. Within two hours, the situation was resolved, and later that day the psychiatrist received an e-mail from Cahaba that the two most recent letters had been "incorrect," no money would be recouped, and no referral for recoupment would be made to the Department of Treasury.

We have heard from members in similar cases who immediately hired an attorney (at great expense) to seek a resolution on their behalf. Certainly that is an option, and indeed sometimes legal assistance is necessary, but the HelpLine is often able to serve successfully as the first line of defense. PN

APA's Practice Management HelpLine can be reached by phone at (800) 343-4671 or by e-mail at hsf@psych.org.

Ellen Jaffe is a Medicare specialist in APA's Office of Healthcare Systems and Financing.

EXCLUSIVE ONLINE CONTENT

Q&As From APA's Practice Management HelpLine

APA's Practice Management HelpLine provides practical assistance to APA members on a wide variety of day-to-day issues that arise in managing a practice: reimbursement, relationships with managed care companies, coding, documentation, Medicare, Medicaid, establishing a private practice, closing a practice, etc. Below are three of the recent questions that HelpLine staff have handled. To read the answers, go to http://psychnews.psychiatryonline.org/newsArticle.aspx?doi=10.1176/appi.pn.2013.9b26 or scan the QR code at left. APA members can submit their questions to the HelpLine by phone at (800) 343-4671 and e-mail at hsf@psych.org.

Q *I employ a social worker who provides psychotherapy to patients under my direction. Should the services she provides be billed under my National Provider Identifier? Does it matter whether the social worker is an employee or an independent contractor?*

Q *I am an out-of-network provider. My patients pay me directly and file for reimbursement from their insurers. Several patients have been denied payment because although I am now using two codes—an E/M code for medical management and a time-based psychotherapy add-on code—I list the two codes with one total fee, which is the same as before the CPT code changes went into effect. The insurer says I cannot be paid for my care unless I divide my fee between the two codes. Can you provide me with some rational way to do this?*

Q *I have been told that if counseling and coordination of care account for more than 50 percent of the time I spend with a patient for whom I am providing E/M services, I can select the appropriate E/M code based on the time of the encounter and its match to the typical time CPT assigns to the code rather than on the elements of the history, exam, and medical decision making the patient required. Why can't I just define my psychotherapy with E/M sessions as counseling with E/M sessions and bill based on the time? It seems like the pay would probably be better and the documentation requirements less onerous.*

Residents' Forum

continued from page 6

never a question of whether to be involved in education," said Dr. Goldstein.

She stated that her greatest reward is participating in the creation and development of psychiatrists as both professionals and people. Within emergency psychiatry, Dr. Goldstein maintains that "the cerebral jujitsu one has to master in order to be an effective teacher and clinician" keeps her on her toes and coming back day after day.

Outside of the hospital, Dr. Goldstein summons her creative and innovative teaching methods to deliver informative seminars on topics such as human sexuality and pop culture, blending issues in psychiatry with media-related ones. Recent notable sessions have included "Dysfunctional Families and 'Arrested Development' " and "Narcissism in 'Tropic Thunder.' " Dr. Goldstein has a natural ability to bring challenging clinical concepts to life in meaningful and memorable ways.

In the next 10 years, she envisions shifting her focus to public policy related to mental illness and aspires to one day be director of a psychiatry residency program. Along the way, she continually reminds residents of the importance of taking care of the self as "no one else is going to do it for you." She is a keen proponent of "the art of doing nothing" during down time and balances her role as a devoted mother to three children with her professional life as a psychiatrist.

I am grateful for Dr. Goldstein's mentorship, and my clinical experiences with her have been the most formative aspects of my training thus far. She has a unique ability to verbalize her decision-making process and takes time out from working in a stressful environment to explain her understanding of complex patients. She is always mindful of the ways in which clinical experiences can affect residents and creates an open and supportive space in which to reflect.

Her investment in my professional and personal success is without equal. When the end of residency arrives and I walk out the door, it will be Dr. Goldstein who helped me to put on my coat. PN

District Branch Finds Key To Recruiting Residents

Although many young professionals today aren't joining organizations, the Indiana Psychiatric Society is bucking the trend by enrolling enthusiastic young members. What is its secret?

BY JOAN AREHART-TREICHEL

When it comes to acquiring enthusiastic young members, the Indiana Psychiatric Society (IPS) is on a roll.

A few years ago, only about 10 percent of Indiana psychiatry residents at most attended IPS meetings. Today, there is so much of a culture of resident involvement in the IPS that nearly 80 percent of residents attended its annual symposium last fall in Indianapolis, 50 percent traveled 100 miles to attend the IPS's Integrative Medicine Conference in southern Indiana, and about 30 percent attended the APA annual meeting in San Francisco in May.

Today it is not unusual to have as many residents as general members attend the IPS Executive Council meetings. "It is really exciting to see," David Diaz, M.D., immediate past president of the IPS and an assistant professor of clinical psychiatry at Indiana University, told *Psychiatric News*. "Four or five years ago, you could shoot a cannon through the room and not hit anybody. Now it's hard to find a seat at our council meetings because we have so many people participating!"

How has the IPS achieved this dramatic turnaround?

Through a number of steps—many of which could be replicated by other district branches, Diaz and other IPS members believe.

First off, the psychiatry residency program at Indiana University—the only psychiatry residency program in the state—automatically enrolls all of its residents in the IPS and APA and pays their dues during all of their years of training. "This is a relatively rare but exceptionally important gesture" in getting residents to become members of the IPS and APA, Brian Hart, M.D., a fourth-year resident member, said in an interview.

Emily McKillip, M.D., a second-year resident member of the IPS, agreed: "Our residency program graciously pays for our membership dues during our training years, so removing this financial commitment is helpful."

"Yet making something free does not really guarantee involvement," she pointed out. So what has the IPS done to get residents involved?

For one thing, IPS members roll out the red carpet for residents, Diaz reported. "We invite them in person to attend meetings, and we make an attempt at every meeting to extend a special welcome to them. These are things that you can do that don't cost money. It is a lot different from when I was a resident. The approach was, 'You are welcome to come and get involved.' But there was no special attempt to involve residents."

Emily McKillip, M.D.: "Our Indiana Psychiatric Society leaders do a fantastic job of keeping us in the loop, asking our opinion, and going forward with ideas that residents suggest."

Brian Hart, M.D.: "At the start of this academic year, eight residents held Executive Council positions, and two of our just-graduated residents joined the council as early career psychiatrists."

Hart concurred: "The IPS has a number of members who have been very warm and welcoming to us residents when we come to IPS meetings."

And once residents attend IPS meetings, they find that they are strongly encouraged to participate and contribute, said Diaz. "Last year one of our residents was heavily involved as a representative to our legislative committee. We also have a resident involved with membership and retention and recruitment, and yet another involved with an integrative medicine committee we recently started. It looks at ways to integrate our specialty with other medical specialties in the state."

Crucial Decision Expands Involvement

Indeed, "the IPS's Executive Council made the important and ingenious decision to expand council committees to allow for every committee to have a resident member," Hart remarked.

Danny Hackman, M.D.: "This was a great experience, and I told other residents about it and encouraged them to apply for a fellowship or to find their own niche within APA."

Stephanie Price, D.O.: "I had senior colleagues who were passionate about their work in the Indiana Psychiatric Society, and it was contagious."

Creating council positions for residents "not only makes residents feel involved and important and looks good on their resumes, but is an incredibly valuable 'carrot' for getting them involved and keeping them involved," Danny Hackman, M.D., observed. "No resident should ever be declined a position on his or her district branch Executive Council for any reason. Let residents make up positions if need be." Hackman, who just graduated from the Indiana University psychiatry residency program, is a fervent member of the IPS.

And the ebullience that Hackman and other more senior residents have displayed for the IPS and APA has kindled similar enthusiasm in their younger peers, Diaz observed. "If you show incoming residents that involvement in organized psychiatry is expected of them, that it benefits their careers, and that it is an essential part of their training, you can literally change the culture of a residency program in two years," Hackman said. His advice to other district branches is to "find some senior residents to take the lead, target the incoming class, and have the senior residents practice what they preach by attending meetings themselves. And stay on that message of the importance of staying involved throughout the residency academic year. It will pay off."

Tangible Benefits Also Help

Seeing that there are tangible benefits to being involved in the IPS and APA has likewise helped cement residents' positive regard for both, Hackman noted. "I was fortunate to receive an APA Leadership Fellowship in which I got to travel to Washington, D.C., and to the APA annual meeting and meet many amazing residents from across the country," he said. "This was a great experience, and I told other residents about it and encouraged them to apply for a fellowship or to find their own niche within APA."

Jess Levy, M.D., a third-year resident and IPS member, shared this advice with other district branches trying to increase resident membership: "Make it easy for residents to get involved, and get them involved early! The IPS has been very supportive of residents, including financially, through scholarships to IPS events and donations to the resident retreat, as well as encouraging resident involvement. As a result, high regard for the IPS is simply part of the residency culture."

Finally, Stephanie Price, D.O., another third-year resident and IPS member, suggested that district branches "select one or two residents who are enthusiastic about involvement to be liaisons to the residency class and to update their fellow residents about meetings, dinners, and conferences and how to get involved at the local and national levels to impact change." PN

APA has made a number of resources available for members-in-training and fellows on APA's website. They can be accessed at http://www.psychiatry.org/residents.

GOVERNMENT NEWS

Health Exchanges

continued from page 1

new exchanges, as established by the Congressional Budget Office, is 7 million.

Enrollment begins October 1, 2013, and ends March 31, 2014, leaving a window of approximately 180 days for the government to accomplish its task.

Valencia described a strategy whereby she expected young people to be surrounded by messages—from physicians, religious leaders, teachers, family members, and community leaders—explaining the benefits of health insurance. "We want people to be hearing about this everywhere they turn," she said.

She was joined during the briefing by Howard Koh, M.D., the HHS assistant secretary for health; Christen Linke-Young, director of coverage policy in the HHS Office of Health Reform; and Pamela Hyde, administrator of SAMHSA, which is part of HHS.

The briefing was a follow-up to the National Conference on Mental Health, hosted by President Obama at the White House in June, to talk about raising awareness of mental health issues. At last month's briefing, Valencia and other administration officials said they were counting on advocacy and provider groups to help in enlisting enrollment in the new exchanges.

They drew attention to a website, http://marketplace.cms.gov, which is designed for mental health professionals wishing to help patients get enrolled.

The opening of the exchanges, along with the expansion of Medicaid, will extend mental health benefits to millions of Americans. States were given the choice to build a fully state-based exchange, enter into a state-federal partnership exchange, or default into a federally facilitated exchange; the ACA directs the secretary of HHS to establish and operate a federally facilitated exchange in any state that is not able or willing to establish a state-based exchange (see website at end of article for state information).

But Irvin "Sam" Muszynski, director of APA's Office of Healthcare Systems and Financing, told *Psychiatric News* that there are a number of unknowns regarding what the plans in the health exchanges will look like.

Because of the requirement that all plans offer a mental health benefit, the plans will have to comply with the terms of the 2008 Mental Health Parity and Addiction Equity Act. States have been assigned the task of designing the essential health benefits (EHBs) that will be offered by the plans in their exchanges, with the stipulation that these benefits may not fall below those provided by a benchmark plan chosen in the state. HHS has said the EHB benchmark plan that a state may use must be one of the following:

- The largest plan by enrollment in any of the three largest small-group insurance plans in the state's small-group market.
- Any of the three largest state employee health benefit plans by enrollment.
- Any of the three largest plans by enrollment in the Federal Employees Health Benefits Program (FEHBP).
- The largest insured commercial non-Medicaid HMO operating in the state.

The state's benchmark plan comprises the state's EHBs, plus whatever state benefit mandates that state had on its books by December 2011. The plan types must include 10 health service categories, and if the plan type selected by a state—say, a small-group employer plan—lacks one of these categories, it has to take a category from another HHS-approved plan type, perhaps a Medicaid HMO plan or a plan from the FEHBP, and supplement its benchmark plan type.

Muszynski cautioned that nothing in the ACA indicates the breadth of services that will be covered within a particular required essential health benefit category—that is, plans could offer a benefit for, say, substance abuse treatment, but pay only for a narrow range of treatment services.

Moreover, clinicians treating patients enrolled in the exchanges need to be alert to cost-sharing features of the plans. The exchanges offer plans in four levels of premiums, with varying deductibles at each level; the lowest-level plan covering a family of four may have a deductible as high as $5,000.

Finally—and crucially—Muszynski stressed that clinicians need to review contracts they have signed with health plans to determine if those plans will be part of the exchanges, and if so, whether existing contractual arrangements will continue or need to be renewed.

Some states have outlawed so-called "all-products clauses"—contractual clauses that require a physician in a provider network for one company to be in the network for all of the insurance company's products. Other states allow all-products clauses for provider contracts, so clinicians are advised to inquire about all-products clauses that may affect their status as providers within a health exchange plan.

"Clinicians need to know where they stand under current payer contracts and whether they are considered part of these exchanges," he said. PN

A complete listing of state decisions with regard to health exchanges and Medicaid expansion is posted on Kaiser Family Foundation News at http://kff.org/health-reform/state-indicator/state-decisions-for-creating-health-insurance-exchanges-and-expanding-medicaid/decisions-for-creating-health-insurance-exchanges-and-expanding-medicaid/.

Key Points

The opening of new health exchanges under the Affordable Care Act will extend mental health benefits to millions of uninsured individuals, but clinicians should be alert to several important points:

- Though the mental health parity law applies to plans in the health exchanges, there is nothing in the Affordable Care Act concerning the scope of services to be offered.
- Clinicians should be alert to the cost-sharing features of the health exchange plans their patients are enrolled in; deductibles may vary and could be as high as $5,000.
- Clinicians should review existing contractual arrangements they have with health plans to determine if those plans will be part of the exchanges, and if so whether existing contractual arrangements will continue or need to be renewed.

Bottom Line: Members with questions about the health exchanges should contact APA's Practice Management HelpLine by phone at (800) 343-4671 or e-mail at hsf@psych.org.

VIEWPOINTS

What Has APA Done for You Lately?

BY MARIA OQUENDO, M.D.

I was nothing short of astonished by my experience at the APA Board of Trustees (BOT) meeting in July in Arlington, Va. I certainly anticipated that the BOT would sit indoors for long hours reviewing reams of material. Having prepared for the meeting by reading those reams beforehand alerted me to that. There was debate, sometimes passionate, and lots of humor. That too was expected since I knew several, though not all, of the BOT members. Close attention was paid to parliamentary rules, ensuring that procedure was followed. None of that was terribly surprising, either. What was surprising is just how much work APA does not only for its members, but for our patients—as well as those who may someday need our care.

For example, I had not been fully cognizant of the work that APA is doing to ensure that parity laws are implemented in a way that is truly fair and equitable for our patients. I learned that APA is aggressively pursuing an arduous fight to improve access to care in a strategic and sophisticated manner. APA staff described to the BOT how hundreds of members have voiced complaints regarding implementation of the new CPT codes in ways that potentially violate parity.

In response, APA has been addressing each complaint with the insurers and other payers, some of who immediately changed their ways. As might be expected where money is involved, not all payers have agreed to make the changes that will increase coverage for mental conditions to the same level as other medical illnesses. Indeed, some payers remain defiantly out of line with the intent of the Mental Health Parity and Addiction Equity Act. I was pleased—no, relieved—that APA is in the fray to safeguard our patients' right to be treated fairly. It is the humane thing to do.

Another issue that the APA BOT addressed is the terrible problem that firearms present for our country. During the meeting, we discussed how the dominant rhetoric in the media relates to understandable concerns that arise when mass tragedies occur. What most of the public does not know is that most gun deaths are due to suicide and murder. Indeed, the suicide rate is up, and in 2010, there were 38,364 suicides in the United States, on

*see **Viewpoints** on page 22*

Maria Oquendo, M.D., is APA's secretary and a member of the Board of Trustees.

K. Ciappa for GPTMC

Philadelphia's Restaurant Scene Is Sizzling

While you are in Philadelphia for APA's Institute on Psychiatric Services October 10 to 13, you'll find a menu of restaurants that make most cities envious.

BY JAMES GILFOIL, M.D.

No, you didn't read that headline incorrectly. There is not only a restaurant "scene" in Philadelphia, but it is, as they say, "smoking.' " Over the last few years, there's been a tremendous upswing in the number of young, creative chefs flocking to our city. Here are a few options to nourish your body after the scientific sessions nourish your mind.

My current favorite is Greg Vernick's **Vernick Food and Drink**, selected by the *Philadelphia Inquirer* restaurant critic, Craig LaBan, as the "Best New Restaurant of 2013." You can customize your meal by choosing an array of small plates, ordering the standard three-course dinner, or mixing and matching. Almost everything is terrific, but especially the toasts with all sorts of toppings.

Another mouth-watering option is **The Farm and Fisherman,** a wonderful, unpretentious BYOB spot, with award-winning Josh Lawler at the helm. The menu is small, but terrifically focused, and anything with beets is a winner. The sweetbreads, the duck confit, the pork, and whatever fish Josh is doing are definitely worth ordering. Perhaps the most winsome thing about Farm is the ambience created by the welcoming staff.

Another top spot on your "must try" list is **Talula's Garden**. It's certainly one of the most beautiful spaces in town, the menu and service are first rate, and its patio is the most romantic in the city.

Fond, in South Philly, is very similar to Farm, and it used to be a BYOB too, but now it has a full bar and cocktail "program." Outstanding selections include foie gras and sweetbreads, among many others.

Two other top picks are **Sbraga** and **Fork**. Sbraga, with another award winner at the stove, has an extremely reasonable prix-fixe menu at $49 for four courses, with $35 for the beverage pairing. For entrees, you can sample roast pork with provolone bread pudding and long hots—a take on the Philly roast pork sandwich—or Tennessee hot chicken—a take on Nashville's hot chicken—among others. The venerable Fork has made quite a comeback. The room has always been one of the best dining spaces in town, and now new chef Eli Kulp has returned excitement to a dining destination that had begun to fade. I was in the restaurant shortly after Kulp arrived—the vibe was electric and the food outstanding. The waiters have always been consummate professionals with outstanding advice, and they don't introduce themselves by name—a plus in my book!

I haven't mentioned the currently most lauded BYOB—Bibou. It has gotten a rave review by the *Inquirer*, and it's hard to find anyone saying anything negative about it. Go, if you can get in, and see what all the fuss is about.

Among other top picks are **Barbuzzo** and **Jamonera**—the twin jewels of the Marcie Turney and Valerie Safran empire at the corner of 13th and Sansom. The former does a fabulous job with its Italian-focused menu, and the latter deserves kudos for its interpretation of Spanish cuisine. Speaking of Italian and Spanish, Mark Vetri's **Osteria** is still superb, and his **Amis** is certainly good, but it's not as good or creative as Barbuzzo.

For Israeli cuisine, try **Zahav,** with its fabulous hummus selection—it'll make you rethink all the mediocre hummus you've had in the past—and the over-the-top grilled duck hearts that'll make you look at those creatures in a new light.

Rob Halpern is probably our top practitioner of molecular gastronomy at his underrated BYO restaurant **Marigold Kitchen** in West Philly. It's well worth a try, and it's crazy reasonable.

J. Fusco for GPTMC

Diners and bar-goers enjoy the casually elegant atmosphere at Ellen Yin's Fork. The restaurant credited with Old City's restaurant revival in the 1990s serves delicious New American dishes created with local ingredients.

More casual choices include **Brauhaus Schmitz**—a, what else, German brewhouse—and **Percy Street Barbecue** with pretty good Texas barbecue. If you go to the Reading Terminal, you must eat at **DiNic's,** whose roast pork was christened the "Best Sandwich in America." I know people who have come here for conventions and eaten at DiNic's every day while in town. Order it with provolone and broccoli rabe, and let the juices soak into the bread before you take your first bite.

These ideas ought to keep you happily wined and dined during your stay here. I hope they will whet your appetite for a return visit. PN

See the box on page 3 for registration information.

James Gilfoil, M.D., is a psychiatrist in private practice in Bryn Mawr, Pa. He loves to eat.

Genome Analysis Quantifies Risk Across Psychiatric Disorders

A new genomic study puts numbers on the role genes play in various psychiatric disorders and the overlapping pathology between certain disorders.

BY JUN YAN

By scanning the genomes of tens of thousands of patients and control subjects, researchers have quantified how much common single nucleotide polymorphism (SNP) variants contribute to the overall risk of five psychiatric disorders as well as the amount of overlap between the disorders.

The five disorders studied were schizophrenia, bipolar disorder, major depression, autism spectrum disorder (ASD), and attention-deficit/hyperactivity disorder (ADHD).

Heritable common SNP variants contribute about 17 percent to 28 percent of the risks of these disorders (see table), the study showed.

Schizophrenia and bipolar disorder had the largest genetic overlap in paired analysis between disorders, followed by correlations between bipolar and depression, between schizophrenia and depression, and between ADHD and depression. The correlation was low between schizophrenia and ASD and nonsignificant for all other pairings.

The numbers from this study represent low-end estimates because other types of mutations, such as rare variants and copy number variations, were not included, the researchers noted. For example, twin and family studies previously estimated that heredity overall contributes about 81 percent of the risk of schizophrenia, but this study estimated that SNP-based heritability contributes 23 percent of that risk.

This study is the second major publication from the Cross-Disorder Group of the Psychiatric Genomics Consortium. The first study, published February 28 in the *Lancet*, identified four chromosomal regions with mutations linked to all five psychiatric disorders (*Psychiatric News*, April 5). The group has been conducting genome-wide association studies (GWAS) on data pooled from multiple countries. It receives funding from the National Institute of Mental Health (NIMH) and other governments, including those of Australia and the Netherlands.

Taken together, these cross-disorder genomic analyses add weight to the theory that each psychiatric disorder is not a single construct with an etiology and pathway distinct from other disorders. Rather, a disorder can be deconstructed into a combination of dysfunctions in various "dimensions" or "domains," and some patients across different disorders may share the same pathology and genetic risks in a particular dimension, such as executive function or working memory. This is an area the NIMH has been intensively pursuing for the past few years through its Research Domain Criteria (RDoC) project.

"The best way to think about this is to imagine a house with many beams. When this group of beams or that group of beams break, the house would collapse in ways that look different from the outside, but inside it may be that some of the same beams have broken," Bruce Cuthbert, Ph.D., who is heading the RDoC project, explained in an interview with *Psychiatric News*. He is also the director of the NIMH Division of Adult Translational Research and Treatment Development.

"The GWAS data are consistent with the RDoC framework," Cuthbert said. For example, the study shows that the magnitude of variability between schizophrenia and bipolar disorder is about the same as the variability within bipolar data, which supports the notion that schizophrenia and bipolar share

see **Genome Analysis** on page 22

More Than Nature Is at Work

Common SNP variants can account only partially for how much heredity contributes to the risk of psychiatric disorders.

	Heritability of common SNP variants	Heritability estimated from twin/family studies
Schizophrenia	0.23	0.81
Bipolar disorder	0.25	0.75
Major depression	0.21	0.37
Autism	0.17	0.80
ADHD	0.28	0.75

Source: Cross-Disorder Group of the Psychiatric Genomics Consortium, *Nature Genetics*, August 11, 2013

DSM-5 SELF-EXAM

Somatic Symptom and Related Disorders

In *DSM-5*, the term "somatoform disorders" is replaced by somatic symptom and related disorders. In *DSM-IV-TR* there was significant overlap across the somatoform disorders and a lack of clarity about their boundaries. These disorders are primarily seen in medical settings, and nonpsychiatric physicians found the *DSM-IV-TR* somatoform diagnoses problematic to use. The *DSM-5* classification reduces the number of disorders and subcategories to avoid problematic overlap. Diagnoses of somatization disorder, hypochondriasis, pain disorder, and undifferentiated somatoform disorder are removed. *DSM-5* now allows for the complexity of the interface between psychiatry and medicine. Individuals with somatic symptoms plus abnormal thoughts, feelings, and behaviors may or may not have a diagnosed medical condition. It is clear from a large body of research that the relationship between somatic symptoms and psychopathology exists along a spectrum, and the arbitrary high symptom count required for *DSM-IV-TR* somatization disorder did not accommodate this spectrum. Psychological factors affecting other medical conditions and factitious disorder are moved into the somatic symptom disorders chapter because somatic symptoms are predominant in both, and both are most often encountered in medical settings. Criteria for conversion disorder (functional neurologic symptom disorder) are modified to emphasize the essential importance of the neurological examination, and in recognition that relevant psychological factors may not be demonstrable at the time of diagnosis.

The questions below are from *DSM-5 Self-Exam Questions: Test Questions for the Diagnostic Criteria*, which may be preordered from American Psychiatric Publishing at http://www.appi.org/SearchCenter/Pages/SearchDetail.aspx?ItemId=62467. The answers and rationales are posted at http://www.psychnews.org/pdfs/DSM-5_Self_Examination_QandA_12.pdf. The book, available in January 2014, contains 500 questions for all the categories of psychiatric disorders and includes Section III. The questions were developed under the leadership of Philip Muskin, M.D., a professor of clinical psychiatry at Columbia University College of Physicians and Surgeons.

1. In *DSM-IV-TR* a patient with a high level of anxiety about having a disease and many associated somatic symptoms would be given the diagnosis of hypochondriasis. What *DSM-5* diagnosis would apply to this patient?

a) hypochondriasis
b) illness anxiety disorder
c) somatic symptom disorder
d) generalized anxiety disorder
e) somatoform disorder NOS

2. A young woman is hospitalized for evaluation of fits of movement in which she appears to lose consciousness, rock her head from side to side, and move her arms and legs in a nonsynchronous, bicycling pattern. The episodes occur a few times a day and last for 2 to 5 minutes. EEG during the episodes does not reveal any ictal activity. After a fit, her sensorium appears clear. What is the most likely *DSM-5* diagnosis?

a) epilepsy
b) malingering
c) somatic symptom disorder
d) conversion (functional neurological symptom disorder), attack-seizure subtype
e) factitious disorder

3. Which of the following is the key feature of factitious disorder in *DSM-5*?

a) somatic symptoms
b) conscious misrepresentation and deception
c) external gain associated with illness
d) absence of another medical disorder that may cause the symptoms
e) normal physical exam and laboratory tests PN

Dementia-Risk Rises in Patients With Depression and Diabetes

Now that comorbid depression and diabetes has been found to be a dementia risk factor, researchers need to learn whether depression treatment in people with both illnesses can avert dementia.

BY JOAN AREHART-TREICHEL

Several studies have shown that depression is a risk factor for dementia. The same holds for diabetes. And when people who have diabetes are also depressed, their danger of developing dementia appears to be even greater than if they only have diabetes (*Psychiatric News*, July 6, 2012).

Now a new prospective study headed by Mark Sullivan, M.D., Ph.D., a professor of psychiatry and behavioral sciences at the University of Washington, confirms the earlier findings in a study published online August 14 in *JAMA Psychiatry*.

Sullivan studied approximately 3,000 middle-aged and older individuals with type 2 diabetes who were being treated at 52 clinics throughout the United States and Canada. All of the subjects were evaluated for depression at the start of the study, as well as 20 months and 40 months later, with the nine-item Patient Health Questionnaire (PHQ-9), a well-validated diagnostic instrument for use in primary care settings. A score of 10 or more on the PHQ-9 has been shown to have a 77 percent sensitivity and 94 percent specificity to the diagnosis of major depression by a structured psychiatric interview.

Five percent of the subjects had a score of 10 or greater at all three time assessments. Five percent had a score of 10 or more at baseline, but less than 10 at the 20-month and 40-month assessments. Sixty-two percent never had a score of 10 or more, and 28 percent had other patterns or missing data. At baseline, as well as at 20 months and 40 months, the subjects were also evaluated with multiple tests that measure cognition.

Subsequently the researchers compared the 20-month cognitive test results of subjects who had scored 10 or more on the PHQ-9 at baseline with the test results of subjects who scored 9 or lower at baseline, taking possible confounders into consideration—for example, age and other demographic factors; a history of cardiovascular disease; body mass index; smoking or alcohol use; or whether they had been given glucose-lowering treatment, insulin treatment, blood pressure treatment, or lipid treatment for their diabetes.

The researchers also compared the 40-month cognitive test results of subjects who had scored 10 or more on the PHQ-9 at 20 months with the 40-month test results of subjects who had not scored 10 or more at 20 months.

At both of the follow-up assessments, subjects with a prior depression status were found to perform significantly more poorly on cognitive tests than subjects without such a status. And subjects who had scored 10 or more on the PHQ-9 both at baseline and at 20 months showed the greatest cognitive decline.

Sullivan told *Psychiatric News* that he was surprised by "how rapidly the cognitive decline developed, that it developed in all patient subgroups, and that it affected all cognitive domains."

The findings have clinical implications for psychiatrists, Sullivan added. "In patients with diabetes, depression detection and treatment might be important for dementia prevention."

A key factor that still needs to be studied is whether depression treatment might reduce the risk of dementia among individuals with comorbid depression and diabetes.

Although the means by which depression might contribute to cognitive decline and dementia in individuals with diabetes are unclear, Sullivan and his colleagues suggested possible explanations in their report. For example, both depression and diabetes are associated with systemic inflammation, decreased insulin sensitivity, and autonomic dysfunction, which might mediate the effects of depression on dementia risk. Alternatively, dysregulation of the hypothalamic-pituitary axis by depression might damage brain areas involved in cognition or decrease neurogenesis in areas essential for memory, such as the hippocampus.

The study was funded by the National Institutes of Health. PN

An abstract of "Association of Depression With Accelerated Cognitive Decline Among Patients With Type 2 Diabetes in the ACCORD-MIND Trial" is posted at http://archpsyc.jamanetwork.com/article.aspx?articleid=1727436.

Mental Illness Linked to Premature Death in Epilepsy Patients

Individuals with epilepsy and depression, as well as those with epilepsy and substance abuse, are at increased risk of dying by suicide, perhaps because their mental illness is going untreated.

BY JOAN AREHART-TREICHEL

Having epilepsy may predispose someone to premature death, especially if there is comorbid depression or substance abuse, according to a study conducted in Sweden and reported online in the *Lancet* July 22. This finding highlights the need for clinicians to screen for psychiatric illness in patients with epilepsy.

Since everyone living in Sweden has a personal identification number that can be linked to numerous types of national registries, psychiatric epidemiologists often use data from Sweden for their studies, as did the researchers for this study, which was led by Seena Fazel, M.D., a senior clinical research fellow in the Department of Psychiatry at the University of Oxford in England.

The researchers had two goals. First, they wanted to learn how prevalent premature mortality is among epilepsy patients compared with the general population and also compared with the siblings of epilepsy patients (to account for possible familial confounding). Second, they wanted to determine the causes of premature mortality among epilepsy patients and especially the role that comorbid psychiatric illness might play.

Their subjects were all individuals born in Sweden from 1954 to 2009 who had been diagnosed with epilepsy—some 70,000 individuals. They matched each subject with up to 10 individuals from the general population who were of the same age and gender, but did not have epilepsy. They also included about 81,000 individuals who were siblings of the epilepsy subjects, but did not have epilepsy.

The researchers then determined the premature death rates for each of these three groups—that is, how many died by age 56—and then compared the premature mortality findings for the epilepsy cohort with those for the general population and the epilepsy patients' siblings.

Approximately 6,200 of the individuals with epilepsy (9 percent) died prematurely, and their average age at death was 35. Moreover, their chances of dying so early were 11 times greater than those of the general population and of their unaffected siblings, after adjusting for sociodemographic factors. "The overall high rates of premature mortality were surprising," Fazel told *Psychiatric News*.

The major causes of premature death in individuals with epilepsy were natural ones, and particularly brain tumors and diseases of the nervous system related to epilepsy.

However, 972 (16 percent) of the premature deaths were from external causes, notably nonvehicular accidents such as falls, drowning, drug poisoning, or suicide.

Key Points

- People with epilepsy are more likely to die prematurely than the general population, due in large part to psychiatric comorbidity.
- Individuals with epilepsy and depression, as well as those with epilepsy and substance abuse, are at increased risk of dying from suicide.
- Clinicians caring for epilepsy patients need to screen for and treat patients' depression, substance abuse, or other comorbid psychiatric illnesses—not just to improve the patients' quality of life, but to save their lives.

Depression, Substance Abuse Especially Prevalent

The researchers found as well that 75 percent of the epilepsy patients who died prematurely had comorbid psychiatric disorders, particularly depression or substance abuse, and that incidence of suicide deaths was particularly high in this group.

see **Premature Death** on page 22

Childhood Stomach Pains May Foretell Adult Anxiety Disorders

A study linking abdominal pain in childhood with anxiety disorders in adolescence and early adulthood suggests that such pain and anxiety have common origins.

BY JOAN AREHART-TREICHEL

Who would have thought that childhood functional abdominal pain—that is, periodic abdominal pain that cannot be attributed to organic disease— might presage anxiety and depression later in life?

Yet that is what data from a new study indicate.

The study was headed by Lynn Walker, Ph.D., a professor of pediatrics and director of the Division of Adolescent Health at Vanderbilt University. The findings were published online August 12 in *Pediatrics*.

Walker and colleagues studied 332 children who had received extensive medical evaluations and were found to have functional abdominal pain, as well as 147 age-matched children from the same area who did not experience such pain.

The subjects were reassessed during adolescence and early adulthood to determine whether they experienced anxiety disorders or depressive disorders.

The researchers found that 51 percent of the subjects who had experienced chronic abdominal pain as youngsters met criteria for an anxiety disorder at some point during the follow-up period, and 30 percent currently met criteria for an anxiety disorder.

In contrast, only 20 percent of controls met criteria for an anxiety disorder at some point, and just 12 percent met criteria for a current anxiety disorder.

Regarding depressive disorders, the lifetime risk among the subjects was significantly higher in the abdominal-pain group than in controls—40 percent versus 16 percent—but current depressive disorders were rare at follow-up and did not differ significantly between the two groups. The reason for this latter finding, the researchers suggested, may be that depression follows a more episodic course than anxiety disorders, and therefore they "did not detect increased risk at the single snapshot evaluation conducted in adolescence or early adulthood."

Thus it appears that functional abdominal pain in childhood predicts a long-term increased risk for developing anxiety disorders and possibly depressive disorders as well.

The findings have implications for psychiatrists, Walker told *Psychiatric News*, highlighting that "a biopsychosocial approach is most effective in the treatment of chronic or recurrent pain. Psychiatrists are important members of the multidisciplinary team as they can identify and treat psychosocial issues that may be missed in a medical evaluation that focuses primarily on ruling out disease. Psychiatrists can be particularly helpful," he added, "in explaining to patients that the relationship between anxiety and pain is not necessarily cause-effect, but rather that anxiety and pain interact with each other in a vicious cycle. By reducing anxiety, we can begin to break that cycle."

"This is an important study conducted by an outstanding group of researchers," John Campo, M.D., chair of psychiatry at Ohio State University, said during an interview. Campo published seminal research on the subject in the July 2001 *Pediatrics*.

"A cross-sectional relationship between functional abdominal pain and anxiety has been noted in multiple studies in children, adolescents, and adults, but the nature of this observed 'comorbidity' is unclear. Though unidirectional causal models (i.e., functional abdominal pain causes the associated anxiety or vice versa) have been entertained, this study's findings that functional abdominal pain and anxiety are associated longitudinally into adulthood offers some support for the notion that functional abdominal pain and anxiety may share common risk factors or perhaps even be manifestations of a common disorder."

Yet another reason to believe that functional abdominal pain is closely related to anxiety, and perhaps to depression, was the discovery that anxiety and depression are implicated in irritable bowel syndrome and that antidepressants can help some irritable bowel syndrome patients (*Psychiatric News*, September 21, 2007).

The study was funded by the National Institutes of Health, the Vanderbilt Kennedy Center, and the Vanderbilt Digestive Disease Research Center. PN

Sergiy Bykhunenko

An abstract of "Functional Abdominal Pain in Childhood and Long-Term Vulnerability to Anxiety Disorders" is posted at http://pediatrics.aappublications.org/content/early/2013/08/07/peds.2012-2191.abstract.

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Early-Onset Dementia Linked To Alcohol Abuse, Other Factors

In this nationwide cohort study, researchers identify nine risk factors for dementia that could be traced to adolescence, suggesting strong opportunities for early intervention.

BY JOAN AREHART-TREICHEL

The next time college students are tempted to drink to excess, they might want to worry not only about ending up in the hospital, but also about developing early-onset dementia.

This possibility may sound outlandish to them, but alcohol abuse has been found to be a prime risk factor for early-onset dementia—dementia beginning before age 65— in a large study published online August 12 in *JAMA Internal Medicine*.

The lead researcher, Peter Nordstrom, Ph.D., a professor in geriatric medicine at Umea University in Sweden, told *Psychiatric News* that he was surprised by this finding. "It seems that alcohol intoxication is a much stronger risk factor for early-onset dementia than anyone could have expected," he said.

The focus of the study that Nordstrom and his colleagues conducted was some 500,000 men with an average age of 18 who had been conscripted for military service in Sweden between 1969 and 1979. They had all undergone extensive cognitive and medical examinations, the results of which were available to Nordstrom and his colleagues.

The researchers also obtained information about the subjects' educational level and income 15 years after they had been conscripted. The researchers tracked the subjects' biological parents through the Statistics Sweden database, which also gave information on which of the parents had developed dementia.

Medical information about the subjects in the years following conscription, including information on whether any developed early-onset dementia, was

see **Dementia** on page 24

Study Finds Psychiatric Factors Not Linked To Multiple Homicide Victims

Though more than a third of the defendants had prior psychiatric treatment, few received treatment in the three months preceding the crime of which they were accused.

BY MARK MORAN

Psychiatric factors do not appear to predict whether a homicide defendant used a firearm, killed multiple victims, or is convicted of the crime, a finding that would seem to counter the popular notion—prevalent in the wake of recent mass killings that have made the news—that perpetrators of mass gun violence are invariably mentally ill.

The finding is from a study appearing in the September *American Journal of Psychiatry* that assessed the association between homicide and a wide range of demographic and clinical variables.

"It is notable that clinical variables, such as Axis I diagnoses, were not associated with offense characteristics or case outcomes when demographic and historical characteristics of the cases were included in the models," wrote lead author Edward Mulvey, Ph.D., of the University of Pittsburgh Medical Center, and colleagues. "In particular, while age and race were significantly related to the use of a firearm, the addition of clinical variables to demographic and historical variables did not improve model fit. Furthermore, a model including demographic/historical and clinical variables did not significantly predict a guilty verdict, suggesting that case-specific factors were more salient in these determinations."

Ken Hoge

Steven Hoge, M.D., says that study findings showing low rates of treatment in the period prior to a crime suggest that crime-prevention strategies relying on psychiatrists' reports regarding treatment encounters will not be effective.

In the study, defendants charged with homicide in a U.S. urban county between 2001 and 2005 received a psychiatric evaluation after arrest. Demographic, historical, and psychiatric variables as well as offense characteristics and legal outcomes were described. The researchers examined differences by age group and by race; they also looked at predictors of having multiple victims, firearm use, guilty plea, and guilty verdict.

Fifty-eight percent of the sample had at least one Axis I or II diagnosis using *DSM-IV* criteria, most often a substance use disorder (47 percent). Axis I or II diagnoses were more common (78 percent) among defendants over age 40. Although 37 percent of the sample had prior psychiatric treatment, only 8 percent of the defendants with diagnosed Axis I disorders had outpatient treatment during the three months preceding the homicide.

That suggests limited opportunities for prevention by mental health providers, Mulvey and colleagues said. "The rate of previous treatment observed in this sample raises issues relevant to mental health policy," they wrote. "Although 53 percent of the sample were diagnosed with an Axis I diagnosis (including substance use disorders), less than half of these individuals had ever been hospitalized. Also, among those with an Axis I diagnosis, only 8 percent had received any treatment in the three months preceding the homicide offense. Moreover, this low frequency of recent psychiatric treatment differed markedly by race. . . . Widespread disparities in access to care and cultural differences regarding help seeking are likely explanations for this difference. The low rate of treatment in the months preceding the offense, however, highlights the need for enhanced engagement of high-risk individuals (especially during times of emotional crisis) if mental health care providers expect to have an impact on serious violence."

Steven Hoge, M.D., chair of APA's Council on Psychiatry and Law, reviewed the report. "Individuals with an Axis I disorder were overrepresented among homicide defendants," he told *Psychiatric News*, "but this was due to the high rate of substance use disorders found. The relationship between substance use and serious criminal behavior is well established. The study identified only 15 individuals—just 5 percent of the sample—who had a mental disorder and no co-occurring substance use disorder. Identification and treatment of substance use disorders are important not only to alleviate individual suffering, but also to improve public safety.

"The study findings address current concerns regarding gun use and mass killings by those with mental illnesses," he continued. "There is widespread belief that mental illness is an important cause of firearm violence and mass murder. In fact, the researchers found no relationship between the presence of psychiatric disorders and the use of firearms. Nor did the presence of a psychiatric disorder relate to offenses involving multiple victims. These findings suggest that policies designed to keep firearms out of the hands of individuals with a history of mental illness will not prove to be effective as a targeted strategy."

Hoge also said the study underscores the need for better access to psychiatric treatment, particularly substance use treatment. However, crime-prevention strategies that rely on psychiatrists' reports are likely to be ineffective because most of this population is not in treatment or getting timely treatment. PN

"Psychiatric Characteristics of Homicide Defendants" is posted at http://ajp.psychiatryonline.org/data/Journals/AJP/927544/994.pdf.

Key Points

- Researchers found no relationship between the presence of psychiatric disorders and the use of firearms. Also, the presence of a psychiatric disorder was not related to offenses involving multiple victims.
- Although 37 percent of the sample had prior psychiatric treatment, only 8 percent of the defendants with diagnosed Axis I disorders had outpatient treatment during the three months preceding the homicide.
- Individuals with an Axis I disorder were overrepresented in homicide defendants, but this was due to the high rate of substance use disorders found in this population.

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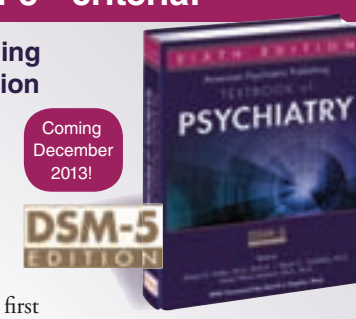

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Deep Dive Into Science Holds Hope For Drug Discoveries

Vanderbilt University brings a "Big Pharma" research model into the friendlier and less risk-averse confines of academia.

BY AARON LEVIN

Medicinal chemist Craig Lindsley, Ph.D., worked at several pharmaceutical companies before leaving for academia in 2006, the better to pursue discovery of new psychiatric drugs.

In academia, following the science is less risky, said Lindsley, who now holds the William K. Warren Jr. Chair in Medicine and is a professor of pharmacology and chemistry and director of medicinal chemistry and codirector (with Jeffery Conn, Ph.D.) of the Vanderbilt Center for Neuroscience Drug Discovery.

"At Vanderbilt, we can go very, very deep into the basic science, which helps you be more successful in drug discovery, because you have so much more knowledge about the target, the ligands, and so on," he said in a recent interview in his office in Nashville.

The path through the warren of potential compounds starts with high-throughput screening, using robotics and sophisticated software to rapidly test hundreds or thousands of compounds against likely targets. Promising "hits" pass though cell-based functional assays, and then a select few molecules are tested in animals.

In fact, the Vanderbilt center functions as a small, industry-style biotech group within the university and runs on two related tracks, said Lindsley. This model is springing up on a number of U.S. medical campuses. Johns Hopkins, the University of North Carolina, the Broad Institute, Harvard, University of California San Francisco, University of California Davis, the Scripps Research Institute, and many others now have drug discovery programs, he said.

"We have a basic science group staffed by grad students and post-docs and funded by NIH to develop the biology and chemistry around novel targets or to look at novel ways of modulating known targets," he said. That part of the enterprise produces the bulk of the center's journal publications.

"We publish more primary papers than we patent compounds, because we find a lot of molecules that fall short of being potential drugs," said Lindsley, who is also editor in chief of the journal *ACS Chemical Neuroscience*. "They can't be patented or they have some fatal flaw as a drug, but they can still be wonderful, in vivo, proof-of-concept tools."

Busy in those labs are 30 medicinal chemists, a drug metabolism and pharmacokinetics group, a molecular pharmacology group, and a behavioral group working with rodents. Each program has a primary pharmacodynamics assay.

"Anything in mice and rats, we do here," he said.

The staff scientists, in contrast, handle the first rounds of drug development. Eventually, they hope, the big pharmaceutical companies will license the most-promising compounds. "We de-risk things for Big Pharma. It's a win-win for everyone."

In January, for example, the center licensed to AstraZeneca rights to compounds that act on the M4 muscarinic acetylcholine receptor.

Aaron Levin

Basic science into drug discovery at Vanderbilt may lead to compounds that stimulate other labs to develop new medications, "a huge win" for all concerned, says Craig Lindsley, Ph.D., of the Vanderbilt Center for Neuroscience Drug Discovery.

Lindsley's own work now focuses on the metabotropic glutamate receptor 5 (mGluR5), a G protein-coupled muscarinic acetylcholine receptor for schizophrenia and other psychiatric and neurological disorders.

Early evidence suggests that in Fragile X syndrome, allosteric modulators such as mGluR5 antagonists may block the overproduction of proteins that influence attention-deficit, hyperactivity, or impulse-control symptoms.

Allosteric modulators dial receptor activity up or down, affecting symptoms downstream. They're proving to be attractive new pathways for drug development because they offer a way of fine-tuning receptor activity, he explained.

For example, ketamine is well-known as an NMDA open-channel antagonist and has shown promise in the treatment of depression.

"mGluR5 is a close signaling partner for the NMDA receptor, but it modulates NMDA receptor currents indirectly," said Lindsley, who has a grant from the National Institute of Mental Health to develop antagonist compounds that ratchet down those currents, working "like a dimmer switch."

Alternatively, positive allosteric modulators functioning as mGluR5 potentiators could be developed to turn up those receptor currents, which might ease the

see **Drug Discoveries** on page 24

FROM THE EXPERTS

Major Depressive Disorder: Long-Term Course, Treatment, and Complications

BY MARTIN KELLER, M.D.

Major depressive disorder (MDD) is a lifelong illness for a significant proportion of patients, with high rates of chronicity and recurrence. The median duration of an episode is six months. The likelihood of remaining depressed for many years is high (30 percent are still depressed after one year, 20 percent after two years, 12 percent after five years, 8 percent after 10 years, 6 percent after 15 years, and 4 percent after 30 years). The risk of recurrence after recovery is extremely high (36 percent after one year following recovery, 40 percent after two years, 60 percent after five years, 65 percent after 10 years, 85 percent after 15 years, and greater than 90 percent after 30 years).

Numerous continuation and maintenance studies found that a meaningful proportion of patients with MDD benefit substantially from long-term/maintenance treatment. The high rates of chronicity and recurrence led to consistent recommendations that the majority of patients with MDD should receive long-term treatment with medication and/or psychotherapy that have demonstrated efficacy.

The rest of this article will focus on clinical variables that often complicate the course in patients with MDD and must be actively monitored and treated.

Subsyndromal symptoms are present in the vast majority of individuals who recover from an episode of MDD, with or without treatment. The presence of these symptoms suggests that the MDD is still clinically active and unremitted. This leads to a significant increase in risk for early relapse into full criteria MDD and should not be interpreted as an apparent state of wellness by either the clinician or patient. The clinician must continue to treat these symptoms in an effort to bring the patient to an asymptomatic state.

see **From the Experts** on page 23

Martin Keller, M.D., is professor emeritus of psychiatry and human behavior at Brown University's Alpert Medical School and strategic academic planning director of the Mood and Anxiety Disorders Research Program at Butler Hospital. He is also coauthor of *Clinical Guide to Depression and Bipolar Disorder: Findings From the Collaborative Depression Study,* which APA members may preorder at a discount from American Psychiatric Publishing Inc. at http://www.appi.org/SearchCenter/Pages/SearchDetail.aspx?ItemId=62433.

Fluid Excess in Brain May Help Predict Autism

Seeing a child younger than 12 months of age with an abnormally rapidly growing head suggests that the child might have autism and that a brain scan might be in order.

BY JOAN AREHART-TREICHEL

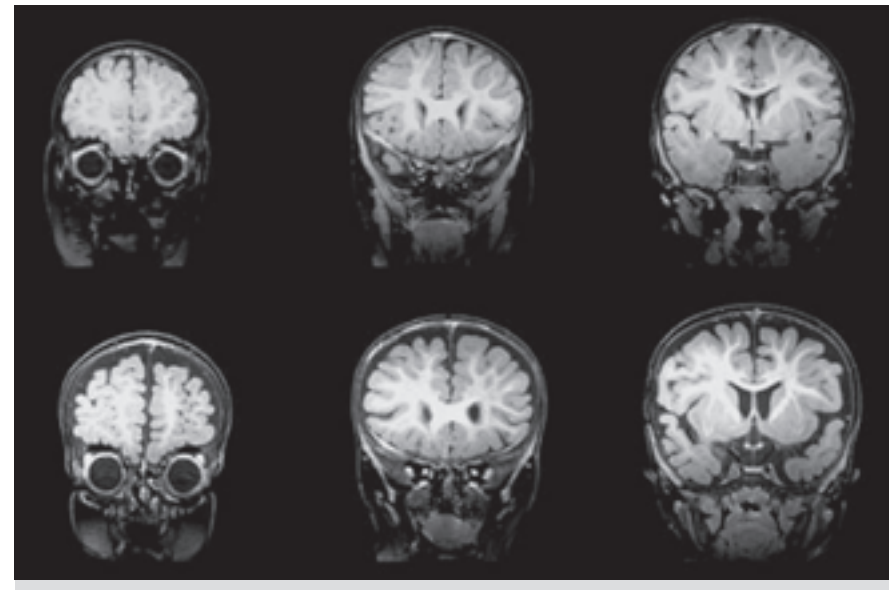
It is known that individuals with autism are born with a normal head size, but that head growth accelerates compared with typically developing children, sometime during the first year of life.

Thus, it is possible that if excessive head growth during the first year of life characterizes autism, then excessive cerebral volume growth during the first year might do so as well. And indeed a prospective study published online July 9 in *Brain* suggests that this is the case.

The senior scientist was David Amaral, Ph.D., chair and research director of the MIND Institute at the University of California, Davis. The study included 55 infants—33 at high genetic risk for autism because they had an older sibling with autism and 22 not at high genetic risk. Amaral and his colleagues used MRI imaging to visualize the brains of all of these infants between ages 6 months and 9 months.

The brains of 43 of the 55 infants (27 at high risk and 16 at low risk) were also imaged between ages 12 months and 15 months, and the brains of 42 of the infants (26 high risk and 16 low risk) were imaged between ages 18 months and 24 months.

All of the infants were also evaluated for factors related to cognition, socialization, communication, and motor functioning. By age 24 months or later—on average at 33 months—10 of the infants (all high risk) met *DSM-IV* criteria for autism. Amaral and his colleagues then assessed whether there had been, between ages 6 months and 24 months, brain anomalies in infants later diagnosed with autism.



David Amaral, Ph.D., et al.

The top panel shows MRIs of a 9-month-old infant with normal brain development who was later confirmed as having typical development. The bottom panel shows MRIs of a 9-month-old infant with excessive extra-axial cerebrospinal fluid and enlarged brain volume who was diagnosed with autism spectrum disorder.

They found that such anomalies did appear. Compared with the other infants, those who were later diagnosed with autism had significantly more cerebrospinal fluid in the subarachnoid space, particularly over the frontal lobes between ages 6 months and 9 months, which persisted and remained elevated at 12 months to 15 months and still at 18 months to 24 months.

In addition, infants who developed autism had significantly larger total cerebral volumes at both the 12- to 15-month evaluation and at the 18- to 24-month evaluation. And perhaps most strikingly, there was a high correlation between the amount of cerebrospinal fluid in the

see **Autism** on page 24

Health Mentors Prove Valuable for Those With Serious Mental Illness

A health mentoring program may be the key to fighting cardiovascular disease among individuals with psychiatric disorders.

BY VABREN WATTS

Though it is the leading cause of death among the general population, cardiovascular disease poses a greater risk to people with severe mental illness (SMI)—reducing life expectancy by at least 25 years, according to the Centers for Disease Control and Prevention (CDC). Fortunately, researchers at the Geisel School of Medicine at Dartmouth may have found an approach that they believe will help prolong life in those at highest risk for vascular mortality.

The approach, described in the August *Psychiatric Services*, is the In SHAPE program, a fitness- and health-mentoring program designed to improve cardiorespiratory fitness, physical fitness, and weight loss among overweight and obese adults with SMI.

"Changing health behaviors including exercise and nutrition are important steps in addressing this health disparity," lead author and director of Dartmouth Centers for Health and Aging, Stephen Bartels M.D., told *Psychiatric News*.

According to Bartels, previous studies have yielded disappointing results by focusing primarily on weight loss through dietary restrictions to achieve clinically significant cardiovascular risk reduction among SMI patients. He explained that numerous factors can contribute to this lack of success—including metabolic burdens of antipsychotics, lack of motivation due to the mental illness, difficulty affording healthy foods, and inadequate access to fitness centers.

The In SHAPE program addressed these issues by allowing free access to a fitness club with health mentors who met with the patients once a week to provide personalized fitness plans and reinforce physical activity. In addition, participants partook in cooking classes, grocery-store tours, and weekly sessions with a registered dietician.

The sample size included 133 adults with SMI and a body mass index (BMI) over 25. The patients were randomly divided into two groups—In SHAPE or active control. The control group received a one-year free fitness club membership and health education materials but lacked one-on-one mentoring.

Peter Bernik/Shutterstock

Both groups were evaluated on changes in cardiorespiratory fitness—as accessed by the six-minute walk test—and weight loss. Positive changes in physical activity and dietary behaviors were also analyzed. All participants were assigned to the same gym and were required to be stable on psychiatric medication at least two months prior to the study. Psychiatric disorders of the study subjects included major depression, bipolar disorder, schizoaffective disorder, and schizophrenia. Diagnoses were based on the Structured Clinical Interview for *DSM-IV*.

After 12 months, In SHAPE participants overwhelmingly increased cardiorespiratory fitness to a greater extent than their control counterparts—as indicated by the In SHAPE group's ability to cover five times as much distance during a six-minute walk test as controls. Forty percent of the In SHAPE subjects achieved clinically significant improvement in cardiorespiratory fitness, com-

see **Mentors** on page 22

JOURNAL DIGEST

BY VABREN WATTS

No Genetic Link Found For Alzheimer's Disease And Parkinson's Disease

For years, scientists have speculated that there may be a genetic association between Alzheimer's disease (AD) and Parkinson's disease (PD). According to a study in *JAMA Neurology*, evidence does not seem to back this theory.

Researchers at Cardiff University School of Medicine in the United Kingdom examined the genetic overlap of the neurodegenerative diseases by performing a combined genomewide association analysis in more than 3,000 patients with AD and 5,000 patients with PD. The study showed no evidence of gene overlap on any chromosome that would increase the risk of both PD and AD.

The study authors concluded that "our findings therefore imply that loci that increase the risk of both Parkinson's and Alzheimer's are not widespread and that the pathological overlap could instead be 'downstream' of the primary susceptibility genes that increase the risk of each disease."

Moskvina V, Harold D, Russo G, et al. "Analysis of Genome-Wide Association Studies of Alzheimer Disease and of Parkinson Disease to Determine if These 2 Diseases Share a Common Genetic Risk." 2013. JAMA Neurol. Aug 5 [Epub ahead of print] http://archneur.jamanetwork.com/article.aspx?articleid=1723187

Oprah and Einstein May Help Detect Dementia

A report in *Neurology* suggests that faces such as those of Albert Einstein, John Kennedy, and Oprah Winfrey may help identify early dementia in individuals aged 40 to 65.

The study, led by researchers at the Cognitive Neurology and Alzheimer's Disease Center at Northwestern University, consisted of a face-recognition test of 20 famous people that was administered to individuals with early-onset dementia and to people without dementia. The participants were awarded points for faces they could name or identify through a description. The participants also underwent MRI brain scans to evaluate tissue damage.

The results showed that those with early-onset dementia scored significantly worse—with an average of 79 percent in face recognition and 49 percent in naming the faces—than did those who were free of dementia. The latter group scored 97 percent on face recognition and 93 percent on naming. Among those with early-onset dementia, the MRI scan showed that people who score low on naming were more likely to have loss of tissue in the left temporal lobe, while those who lacked the ability to recognize faces had tissue loss in both lobes. The study concluded that the distinction between one's ability to recognize a face and actually naming it can help identify an individual's specific cognitive impairment.

Gefen T, Wieneke C, Martersteck A, et al. "Naming vs Knowing Faces in Primary Progressive Aphasia: A Tale of 2 Hemispheres." 2013 Neurology.81(7):658-64. http://www.neurology.org/content/81/7/658.long

Employment Gaps Can Predict Late-Life Cognitive Function

Researchers from the University of Luxembourg reported in the *Annals of Epidemiology* that certain activities performed during extended periods away from work are associated with later cognitive function and change.

More than 18,000 retired Europeans who experienced employment gaps of six months or more during their work life were evaluated for cognitive dysfunction as assessed by immediate recall, verbal fluency, and orientation tests.

The results showed that those with employment gaps due to unemployment and sickness were at highest risk for late-life cognitive impairment, whereas those with employment gaps for maternity leave or time tending to family were at lowest risk for cognitive decline.

"There may be different mechanisms at work, for instance maternity spells may reduce the stress of balancing family and work tasks," said lead author Anja Leist, Ph.D. "The [current] findings are in line with other studies that suggest that cognitively stimulating activities can indeed increase cognitive reserve and delay cognitive decline in older age."

Leist A, Glymour M, Mackenbach J, et al. "Time Away From Work Predicts Later Cognitive Function: Differences by Activity During Leave." 2013. Ann Epidemiol.23(8):455-62. http://www.annalsofepidemiology.org/article/S1047-2797(13)00142-7/abstract

Raising Grandchildren Can Raise Grandparents' Depression Risk

Keeping grandchildren 24 hours every day can increase risk for depression in grandmothers, according to a study published in *Nursing Outlook*.

Carol Musil, Ph.D, R.N., a professor of nursing at Case Western Reserve University, led a seven-year study comparing depressive symptoms in grandmothers who served as full-time caregivers of their grandchildren with grandmothers who weren't full-time caregivers for their grandchildren. The participants, who were from rural, urban, and suburban backgrounds, were also evaluated on factors of intrafamily strain and resourcefulness.

Ingrid Balabanova/Shutterstock

Serving as full-time caregivers of their grandchildren may increase grandparents' risk for depression.

The data showed that grandmothers who served as full-time caregivers had a significantly higher incidence of depressive symptoms and intrafamily strain than their counterparts who did not raise their grandchildren. Grandmothers who raised their grandchildren indicated that they were not opposed to receiving various forms of help.

The researchers noted that women who raise their grandchildren might be open to resourcefulness training, which could help reduce depressive symptoms. "They need support from others," said Musil, "but the most important thing is to maintain and perhaps develop new cognitive and behavioral skills and approaches for handling some very challenging family issues."

Musil C, Jeanblanc A, Burant C, et al. "Longitudinal Analysis of Resourcefulness, Family Strain, and Depressive Symptoms in Grandmother Caregivers." 2013. Nurs Outlook. 61(4):225-34. http://www.nursingoutlook.org/article/S0029-6554(13)00098-5/abstract

Allergy and Asthma May Contribute to ADHD Onset

Researchers in the Department of Pharmacy at the University of Groningen in the Netherlands evaluated 4,420 young boys with and without attention-deficit/hyperactivity disorder (ADHD) to determine whether there was an association between ADHD diagnosis and a history of asthma and allergic disorders.

Published in the *Annals of Allergy, Asthma, and Immunology (AAAI)*, the results showed that among children with ADHD, 34 percent had asthma and 35 percent had an allergic disorder.

"Our study provides additional evidence to support the hypothesis that atopic disorders, such as asthma and food allergies, increase the risk of developing ADHD," the authors wrote.

Gailen Marshall, M.D, editor in chief of *AAAI* said that "further research is needed to understand why there appears to be an increased risk of developing ADHD in children with allergy and asthma."

Hak , de Vries T, Hoekstra P, et al. "Association of Childhood Attention-Deficit/Hyperactivity Disorder With Atopic Diseases and Skin Infections? A Matched Case-Control Study Using the General Practice Research Database." 2013. Ann Allergy Asthma Immunol. 111(2):102-6. http://www.annallergy.org/article/S1081-1206(13)00357-8/abstract

Night Shifts Associated With Anxiety and Depression

Does working overnight increase a person's risk of developing an anxiety or depressive disorder? A study in *PloS One* investigated the association between night work and mental illness onset by evaluating psychiatric, insomnia, and fatigue symptoms of more than 2,000 Norwegian nurses who had worked night shifts or did not do so during the prior 12 months.

The data showed that nurses with current or previous overnight schedules reported more insomnia and fatigue than those who never worked overnight. Anxiety and depression, which were assessed by the Hospital Anxiety and Depression Scale, were not associated with night work.

The researchers did note limitations that point to the need for further research. For example, "All participants of the present study were nurses, restricting the range of both socioeconomic status and work content. Thus, generalization to the general [overnight] shift work population might be limited. . . ." PN

Oyane NM, Pallesen S, Moen BE, et al. "Associations Between Night Work and Anxiety, Depression, Insomnia, Sleepiness and Fatigue in a Sample of Norwegian Nurses." 2013. PLoS One.8(8). http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0070228

LETTERS TO THE EDITOR

Asylum Should Be Available To All Who Need It

As I turned the pages of the June 21 issue of *Psychiatric News* and reached page 13, my eyes jumped to the headline, "Psychiatrists Have Role in Assessing Candidates for Asylum." My heart raced, my spirits soared, and my admiration for our Association and its newspaper ascended. Asylum was a longstanding interest of mine (Geller JL, Morrissey JP: Asylum within and without asylums. *Psychiatric Services* 55:1128-1130, 2004) and here was APA suggesting psychiatrists play significant roles in determining who in America needs asylum.

As I read the article, my mood dropped as if I was in rapid-cycling bipolarity. This was not an article about asylum for those in the United States with serious mental illness uncared for, untreated, perhaps untreatable, and dangerous, such as persons with serious mental illness and fire-setting, traumatic brain injuries, pedophilia, major neurocognitive impairments from chronic alcohol misuse, and others. No, this was about political asylum.

Despite kicking myself for my naivete and abject misplaced optimism, I read on. I found that the cohort of persons with severe mental illness mentioned above might well qualify for "political asylum." According to the article, "Under the Convention Against Torture, an individual must establish that it is 'more likely than not' that he or she would be tortured if forced to return to the proposed country of removal. Torture is defined as intentional acts that cause severe mental or physical pain." Seems to me that all we have to do is replace "country" with "county" and that perfectly fits the population of concern.

If we can evaluate persons from other countries who need "asylum," isn't it time we return to evaluating Americans with serious mental illness and comorbid conditions rendering them persistently dangerous to others, or even themselves, who need "asylum"?

And of course, once identified, then we need to actually provide "asylum." For some this would be in an asylum; for others this could be done through wrap-around asylums, well known as WAA's.

JEFFREY GELLER, M.D.
Worcester, Mass.
Dr. Geller is APA's Area 1 trustee.

Response from Howard Zonana, M.D., a member of APA's Committee on Judicial Action and a corresponding member of APA's Council on Psychiatry and Law. Dr. Zonana was quoted in the article to which Dr. Geller refers.

Yes, there are major problems with the U.S. system of mental health care—inadequate numbers of hospital beds, lack of access to care for many uninsured, and much more, although we no longer use the term "mental asylum." But I would contend that these problems should not make us withdraw from treating and evaluating those in need, whether or not they are U.S. citizens. The community mental health center where I work evaluates and treats individuals without demanding proof of citizenship, as I believe it should. I also think that working with attorneys who are providing services pro bono in aiding deserving asylum applicants is the kind of activity we should be encouraging in our residency programs.

There are many conceivable responses to working with individuals who are seeking asylum in the United States because of well-founded fears of persecution on account of race, religion, nationality, political opinion, or membership in a particular social group as recognized by U.S. law and policy. It is our mission as psychiatrists to work toward creating a world where all those who need psychiatric care have access to it.

Another Win for Patients

The Illinois State Medical Society (ISMS) was pleased to team with the Illinois Psychiatric Society (IPS) and APA to oppose proposed legislation in Illinois that would have dangerously expanded psychologists' scope of practice to include prescribing rights (*Psychiatric News*, June 13). We are also grateful to the AMA's Scope of Practice Partnership for critical grant support used in stopping this flawed legislation.

While the Illinois legislature adjourned its spring session without enacting the prescribing bill, we stand ready with our psychiatrist members and colleague organizations if the prescribing proposal resurfaces here.

ISMS will oppose any proposed law that could threaten patient safety. Sponsors of the prescribing legislation claimed that there were adequate "safeguards" in the proposal, but ISMS believes there is no better safeguard than the detailed and extensive biomedical education physicians receive.

On behalf of ISMS's 11,000 members, we thank IPS, APA, and the AMA for their diligence in standing with us to protect Illinois patients.

ELDON A. TRAME, M.D.
President
Illinois State Medical Society

Letters Invited

Readers are invited to submit letters up to 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 cbrown@psych.org. Clinical opinions in letters are not peer reviewed and thus should be independently verified.

Industry

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cians, trainees, and medical students is the best way to minimize any biases in marketing messages.

"We need to look to our leadership to help us learn this approach and help doctors make decisions based on the best evidence," said Robinowitz.

However, like it or not, the reality is that corporations exist to produce profits as well as products, she added. "Drug companies perform a useful function, and they must make money or they won't invest in our field."

Somewhere out there between the bathwater and the babies lies a place where industry can make medicines and equipment while health professionals can find unbiased information about them.

"Educational interventions have been able to move the needle on whether other physicians are affected by industry influence," said Fugh-Berman.

If enough physicians can learn to avoid the social obligations that industry cultivates and if academic medicine maintains its distance from industry, she said, "a new social norm may emerge that rejects transactions fraught with conflicts of interest." PN

An abstract of "Physicians Under the Influence: Social Psychology and Industry Marketing Strategies" is posted at http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1748-720X. Adriane Fugh-Berman's PharmedOut site can be found at http://www.pharmedout.org/.

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Medical professional liability policies can vary widely from one company to the next. It is important for psychiatrists to know the full – and accurate – story on a policy. Whether it is reviewing the difference between occurrence and claims-made policies or explaining how another policy might leave the doctor with an uninsured risk, I have done my job when I help psychiatrists evaluate their options to make the right choice.

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Viewpoints

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average about 105 each day (http://www.cdc.gov/violenceprevention/pdf/suicide-datasheet-a.PDF). APA is working hard to engage in the public debate on guns to underscore the frequency of suicide as a heartbreaking consequence of having them easily available.

I am pleased that not only does APA concern itself with helping its members and our patients, but also many other constituencies as well—including juveniles in the penitentiary system, many of whom would benefit from mental health care. Amazingly enough, several states have statutes on the books that permit juveniles to be tried and sentenced by adult courts without judicial review of the individual case or assessment of mental or neurodevelopmental issues that may be essential to a full understanding of the situation. Recognizing that neurodevelopmental disorders and mental illness may play a significant role in criminal behavior in children and adolescents, the BOT addressed the fact that many youngsters incarcerated in this country lack access to appropriate and desperately needed mental health care and approved a position statement advocating for these youth. They certainly need all the help and support they can get to ensure the system gives them a fair shake.

I encourage you to get involved with APA, whether at the district branch level or at the national level. There is a lot of work to be done, and we could most definitely use your help and energy. After all, APA is active in addressing issues of critical importance to us! PN

A summary of the actions taken by the Board of Trustees at its July meeting is posted at http://www.psychiatry.org/network/board-of-trustees/governance-meeting-archives.

Genome Analysis

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much of the same genetic etiology. Also, "there is tremendous variability within a disorder," which is consistent with the multidimensional nature of each disorder, Cuthbert pointed out.

Genomewide analyses have not been able to pinpoint the genetic causes of major psychiatric disorders, the researchers said, not because the culpable risk mutations do not exist, but because there are many risk mutations scattered throughout the genome, each contributing a small effect to the overall risk. Therefore, a huge number of samples are needed to achieve adequate statistical power.

The five psychiatric disorders have been included in the cross-disorder group's analyses to date because "these are the disorders for which large-scale collaborative efforts have been able to collect the needed genomic data," Kenneth Kendler, M.D., one of the lead authors of the study and a professor of psychiatry at Virginia Commonwealth University, told *Psychiatric News*.

As more samples in other disorders are added to the datasets, "we have new disorders joining [the future studies], including drug abuse, obsessive-compulsive disorder, and possibly eating disorders," Kendler said.

As incomplete as the current GWAS discovery is, heritable risks are only a part of the pathophysiology of psychiatric disorders. Disease-triggering environmental factors and gene-environmental interactions remain mostly unknown. Other research methods are needed to clarify the sources of environmental risks, Kendler noted. PN

An abstract of "Genetic Relationship Between Five Psychiatric Disorders Estimated From Genome-Wide SNPs" is posted at www.nature.com/ng/journal/vaop/ncurrent/full/ng.2711.html.

Premature Death

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Specifically, individuals with epilepsy and comorbid depression were 23 times more likely to die by suicide than general population controls who had neither epilepsy nor depression. In contrast, general population controls who were depressed but without epilepsy were only 10 times more likely to die by suicide those who had neither epilepsy nor depression.

Substance abuse comorbid with epilepsy also was associated with likelihood of death by suicide, as people with both conditions were 22 times more likely to die from suicide than general population controls who had neither epilepsy nor substance abuse.

In contrast, control subjects who abused substances but did not have epilepsy were nine times more likely to die by suicide than controls who had neither epilepsy nor substance abuse.

Are Depression, Substance Abuse Being Missed?

Thus, "substance misuse in suicide mortality was at least as important as depression," the researchers said in their report, emphasizing the substantial contribution of psychiatric morbidity to the premature deaths. Fazel suggested that "One possibility that needs further investigation is that individuals with epilepsy are not being treated effectively for their comorbid depression or substance abuse."

Their findings have implications for psychiatrists and other physicians who treat epilepsy patients, the researchers believe.

For example, "Patients with psychiatric comorbidity in the period immediately after the first diagnosis of epilepsy represent a high-risk population that might benefit from closer monitoring, consultation with liaison psychiatry, and more intensive treatments," they noted. Since "around a third of epilepsy subjects had a comorbid psychiatric diagnosis, and around a 10th had comorbid substance misuse," clinicians caring for epilepsy patients should step up their liaison with psychiatric and addiction services, they suggested.

"The results from this rigorously performed well-controlled study cry out to rectify the severe underfunding of epilepsy research," Deborah Weisbrot, M.D., an associate professor of psychiatry at Stony Brook University Medical Center and an epilepsy expert, told *Psychiatric News*. "This study presents another compelling argument for the need for clinicians to screen for psychiatric comorbidities in epilepsy, not only to improve patients' quality of life, but more importantly to potentially save lives."

The study was funded by the Wellcome Trust, Swedish Research Council, and Swedish Prison and Probation Service. PN

"Premature Mortality in Epilepsy and the Role of Psychiatric Comorbidity: A Total Population Study" is posted at www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)60899-5/abstract.

Mentors

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pared with 20 percent in the control group.

Though there was no mean difference in weight loss among the two groups, In SHAPE participants were more than twice as likely to achieve both weight loss and cardiovascular health. In addition, In SHAPE participants were more likely to be consistent in physical activities and showed more awareness of steps needed to improve their dietary behavior than did the comparison group.

"Our results demonstrate that a health-mentor intervention may help to overcome the motivational challenges and low self-efficacy often experienced by persons with SMI," the researchers said.

Though study outcomes were promising, Bartels did acknowledge limitations, such as subjects' homogeneity in gender, race, and location. "We are currently writing up the results of a second randomized controlled trial of In SHAPE in a more ethnically diverse population, which has an 18-month follow-up. This replication study will be helpful in confirming In SHAPE as an evidence-based practice and its effectiveness in a different and highly representative population," said Bartels.

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

"Clinically Significant Improved Fitness and Weight Loss Among Overweight Persons With Serious Mental Illness" is posted at http://ps.psychiatryonline.org/article.aspx?articleID=1687831.

APA Members Invited to Conference

Integrated care—a practice model that is now burgeoning in the wake of the Affordable Care Act—will be just one of the major topics covered in this year's annual conference of the Association of Medicine and Psychiatry (AMP). The conference will be held at the Blackstone Renaissance Hotel in Chicago on October 4 and 5. APA members are invited to attend.

The conference will feature nationally known experts on the interface between psychiatry and medicine, including Keynote Speaker Edward Post, M.D. He will discuss "Lessons From the VA on the Integration of Medicine and Psychiatry." Also, the conference will again include the Resident Clinical Vignette Presentations and dedicated time for the poster session and AMP reception on October 4. PN

More information is posted at www.assocmedpsych.org. Wayne Katon, M.D., an expert in integrated care, is president of AMP. A recent *Psychiatric News* interview with him is posted at http://psychnews.psychiatryonline.org/newsArticle.aspx?doi=10.1176/appi.pn.2013.8a15 .

Ketamine

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and abnormalities in glutamatergic signaling have been implicated in major depressive disorder.

Previous studies demonstrated rapid effects for ketamine in patients with treatment-resistant depression; however, the studies lacked adequate sample sizes and appropriate pharmacological controls.

"Our study was the first controlled trial to compare ketamine with another drug that causes psychoactive side effects . . . and the first trial of ketamine to be conducted at more than one site. . . . The findings were replicated across both sites," Mathew told *Psychiatric News*.

The study enrolled 73 patients with a primary diagnosis of major depressive disorder as assessed with the Structured Clinical Interview for *DSM-IV*. All participants had a history of multiple antidepressant therapy failure.

Patients were randomly assigned to receive either a single intravenous infusion of ketamine at a concentration of 0.5 mg/kg or a transient infusion of the active placebo, midazolam. Changes in depression symptoms were evaluated by the Montgomery-Asberg Rating Scale (MADRS) and Quick Inventory of Depressive Symptomatology—Self-Report (QIDS-SR), and adverse physiological events were assessed with the Patient-Rated Inventory of Side Effects and the Clinician-Administered Dissociative State Scale.

Dramatic Drop in Depression Symptoms

Within 24 hours, patients who were given ketamine demonstrated an 18-point drop in the MADRS score, compared with a 12-point drop in the midazolam group. QIDS-SR scores had also significantly improved in the ketamine group. The ketamine cohort's drug response rate was 64 percent, while the response was 28 percent in the midazolam group.

Though mean MADRS and QIDS-SR scores and drug response rates did not differ between both groups at an evaluation seven days post treatment, 44 percent of those in the ketamine group still had a positive response at that evaluation.

bionichepharmausa.com

A study in this month's *AJP* suggests that ketamine, an FDA-approved anesthetic drug, may be the next advancement in treating major depressive disorder.

> "Our study was the first controlled trial to compare ketamine to another drug that causes psychoactive side effects."

The most serious side effects—reported up to four hours after ketamine infusion—were dizziness, headache, nausea, dry mouth, decreased energy, and poor coordination. Ketamine also increased mean blood pressure from 122/72 mm Hg to 141/81 mm Hg within one hour of infusion, whereas midazolam did not cause a blood pressure spike. Mean blood pressure was normalized after four hours in the ketamine subjects.

The researchers concluded that "the large and rapid antidepressant effect of ketamine we observed in these patients is especially significant given the poor prognosis for improvement with currently available antidepressant treatments in treatment-resistant major depression . . . . This further supports NMDA receptor modulation as a novel mechanism for accelerated improvement in severe and chronic forms of depression."

Too Soon to Consider Clinical Use

Psychiatrist John Rush, M.D., the vice-dean of clinical sciences at Duke-National University of Singapore, told *Psychiatric News* that "the effects of ketamine [in this study] on treatment-resistant depression appear to be both quick and quite substantial." He added, however, that "it would be premature and potentially dangerous to turn this into practice." Rush explained that according to the study's results, ketamine comes with a range of side effects, and it is unknown how ketamine will be tolerated in a larger and "more realistic" population.

"Patients in this trial were highly selected to [have] treatment-resistant depression without other commonly encountered issues like substance abuse and history of psychotic symptoms," said Rush.

Mathew agreed. "Yes, caution is urged, and we recommend that ketamine be administered by clinicians who are experienced in the administration of anesthetic agents and who have expertise in cardiorespiratory monitoring," he cautioned.

Mathew said that other clinical studies, including a trial in phase 2 development by Janssen Research & Development LLC, are under way and are investigating the more-detailed molecular mechanism of ketamine associated rapid antidepressant effects.

Mathew noted that he and his colleagues are conducting larger studies that are seeking to optimize ketamine dosage in treatment-resistant depression.

The study was funded by the National Institute of Mental Health, the Brain & Behavior Research Foundation, the Brown Foundation Inc., and the National Center for Advancing Translational Sciences. PN

"Antidepressant Efficacy of Ketamine in Treatment-Resistant Major Depression: A Two-Site Randomized Controlled Trial" is posted at http://ajp.psychiatryonline.org/Article.aspx?ArticleID=1733362.

From the Experts

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Impairment in psychosocial functioning can be overlooked whether treating episodes of MDD or subsyndromal symptoms. It is essential that clinicians remain mindful of the evidence that depression, including minimal symptoms, has negative effects on psychosocial functioning. These impairments in functioning are known to increase and decrease with fluctuations in the severity of depression. Of critical importance is that these functioning impairments are associated with decreased likelihood of recovery and increased probability of recurrence of the MDD in those who do recover. Although successful treatment of depression is also likely to improve functioning, using modalities that specifically target impairment in functioning is indicated.

Conversion to bipolar disorder is another complicating variable in long-term treatment of MDD. Nearly 20 percent of adults first diagnosed with MDD will develop bipolar disorder during the course of three decades of follow-up. Higher rates of conversion have been found in children and adolescents, with reports of approximately 2.5 percent to 6.5 percent each year. Individuals with a history of psychosis, a family history of bipolar disorder, an earlier age at onset, and subthreshold hypomanic symptoms are at higher risk for developing bipolar disorder. However, the positive predictive value of these risk factors for individuals is limited. Consequently, close monitoring for the onset of hypomanic/manic symptoms is critical for all patients with MDD. If these symptoms are present, vigorous treatment of the symptoms should begin rapidly.

Severe anxiety symptoms develop in patients with MDD with a probability of at least 50 percent. These anxiety (psychic and somatic) symptoms are correlated with worse clinical course and worse treatment outcomes for MDD. Importantly, there is an increased risk of suicidality and suicide in the presence of anxiety symptoms (comorbid psychic anxiety, panic attacks, severe anxiety, and panic disorder) in those with MDD starting within a year. This has led to a unique addition of anxiety severity dimensions to the diagnosis of mood disorders in *DSM-5*. Consequently, clinicians must continually assess for the development and severity of comorbid anxiety and rigorously treat the anxiety as well as the depression and monitor both on a regular basis.

In summary, there has been an enormous amount of recent research on the long-term clinical course of MDD and on specific features that have a high probability of occurring over time. Those covered in this column are critical to understanding, anticipating, and treating common complications. The inclusion of measurement of anxiety severity in *DSM-5* represents a major advance in the nomenclature for psychiatry and should have a meaningful positive impact on the assessment and treatment of MDD.

Patients, their families, and others in their support system should be given detailed information concerning the pernicious course of MDD and potential complicating risk factors. The need for adherence to the recommended treatment must be stressed as there are strong data that MDD has a very high rate of discontinuation of treatment and under treatment. PN

References for this article are posted at http://www.psychnews.org/update/experts_3_14.html.

Dementia

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obtained through the Swedish National Hospital Discharge Patient Register or the Swedish National Drug Register.

It turned out that 487 subjects had developed early-onset dementia, at an average age of 54. The early-onset dementias included vascular dementia, frontal lobe dementia, Alzheimer's disease, and dementia of an unspecified type.

Finally the researchers compared characteristics of the 487 subjects who had developed early-onset dementia with characteristics of the rest of the cohort and found that nine factors appeared to predict significantly increased risk of developing early-onset dementia.

> "It seems that alcohol intoxication is a much stronger risk factor for early-onset dementia than anyone could have expected."

Three of the risk factors—low level of cognitive function, short height, and high blood pressure—had been noted at the time of conscription-related evaluation. The remaining six—alcohol abuse, stroke, antipsychotic medication use, abuse of drugs other than alcohol, father's dementia, and depression—had been identified during the years of follow-up.

The most potent risk factor was alcohol abuse. Those who had abused alcohol to the extent that they needed to be hospitalized were five times more likely to later develop early-onset dementia than subjects who were not known to be alcohol abusers and had never been hospitalized for this reason. The next most potent predictors were stroke and antipsychotic medication use.

In addition, the odds of developing early-onset dementia were twice as high for those who had been treated in the hospital for depression as for those who had not, and twice as high for those whose father had been diagnosed with dementia as for those whose father had not.

Further, men in the lowest third of cognitive function and with at least two other risk factors had a 20 times greater risk of developing early-onset dementia than had men in the highest third of cognitive function and with no risk factors.

Thus, while reducing excessive alcohol consumption in late adolescence might help prevent early-onset dementia, targeting high blood pressure in late adolescence might be another way to prevent the disorder, Deborah Levine, M.D., an assistant professor of medicine at the University of Michigan, suggested in an accompanying editorial. In fact, it might be a way to prevent late-onset dementia as well, since research has shown that high blood pressure in midlife is associated with late-onset dementia.

"Much of psychiatric research is moving toward prevention, and this article is another important step toward understanding prevention strategies for dementia," Molly McVoy, M.D., training director of the Child and Adolescent Psychiatry Fellowship at University Hospitals/Case Western Reserve, told *Psychiatric News*. "The study's strengths include the fact that initial assessments were conducted in person, by physicians, and the dementia diagnoses were confirmed by independent evaluators. Further studies will need to verify the risk factors presented in this article in a way other than by *ICD* coding—that is, by independent analysis—to avoid the confounding factors of using claims-made data without independent validation."

The study was funded by the Swedish Research Council and the Swedish Dementia Foundation. PN

An abstract of "Risk Factors in Late Adolescence for Young-Onset Dementia in Men" is posted at http://archinte.jamanetwork.com/article.aspx?articleid=1726998.

Ethics

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Not long ago, Milone said, a psychiatrist agreed to discount his fee for a patient who he believed didn't have much money. Subsequently the psychiatrist Googled the patient to learn more about him and found out that he lived in a mansion. The psychiatrist was furious and confronted him about it. It turned out that he did live in the mansion, but in the basement, and worked for the owners to help pay his way through college.

"This is an example of how patient-targeted Googling can go awry and put you in a bad place," Milone noted. "It is also an example of why members of the APA Ethics Committee generally discourage Googling patients."

Yet if current technology presents ethical conundrums, future technological developments will probably present even more.

"One of the ethical concerns about the initial evaluation of a patient is that it takes place in a face-to-face situation," said Stephen Scheiber, M.D., an adjunct professor of psychiatry at Northwestern University and an APA Ethics Committee member. "Well, that was great 20 years ago. But does face-to-face include Skyping a patient while you're sitting in your office? These are things that are coming at us at a rapid pace, and I think it is going to accelerate. And we'll need to make sure that ethical considerations are taken into account early rather than after the fact."

In Malone's opinion, psychiatrists will be increasingly pressured to conduct therapy via the Internet, and "they'll need to resist it," he said. PN

APA's ethics procedures, *Principles of Medical Ethics With Annotations Especially Applicable to Psychiatry*, is posted at http://psychiatry.org/File%20Library/Practice/Ethics%20Documents/principles2013--final.pdf.

Autism

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subarachnoid space at ages 6 to 9 months and the severity of autism symptoms at 24 months—the more fluid, the more severe the symptoms.

Thus, an abnormally large head, as well as an abnormally large brain volume, and particularly a surplus of cerebrospinal fluid in the subarachnoid space over the frontal lobes, may be defining characteristics of autism during the first year of life.

If that is the case, then these anomalies might be used to help diagnose autism as early as age 6 months, the researchers believe. Diagnosis currently takes place on average at age 4, according to 2012 data from the Centers for Disease Control and Prevention.

"Seeing a child younger than 12 months of age with an abnormally rapidly growing head (particularly a sibling of a child with autism spectrum disorder) is a reasonable signal for an early MRI evaluation," Amaral said in an interview with *Psychiatric News*. "The presence of increased [cerebrospinal] fluid would [then] be a warning sign that the child should be closely monitored for behavioral signs of autism spectrum disorder," and if the child showed such signs, then intensive behavioral therapy could be implemented earlier than is often the case.

"We are following up this study in a variety of ways," Amaral said. "Perhaps most fortuitous is that we are collaborating with Dr. Joe Piven at the University of North Carolina, who is the principal investigator of a multisite study called the Infant Brain Imaging Study. This is also an infant-sibling study, but the population of children studied is much larger than in our study. We hope to determine whether our finding is replicable within the next year."

The research was funded by the National Institutes of Health. PN

"Early Brain Enlargement and Elevated Extra-Axial Fluid in Infants Who Develop Autism Spectrum Disorder" is posted at http://brain.oxfordjournals.org/content/early/2013/08/09/brain.awt166.abstract.

Drug Discoveries

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positive, negative, and cognitive symptoms of schizophrenia, he said. Work on this drug candidate included a successful preclinical collaboration with Janssen Pharmaceutica.

The mGluR5 antagonists are in the late stage of development in the Vanderbilt labs as Lindsley and his colleagues refine their chemistry to identify which ones might be ready—in perhaps a year—to be tested in humans.

They will continue work on compounds even after licensing, he noted. "We develop back-up molecules with different chemotypes or different pharmacological profiles."

But the rewards go beyond patents and profits, he said. "If something we do becomes a therapeutic, that's a big win for us, but if the basic science we've done encourages others to start programs, and they develop a drug that traces back to our basic science, that's a huge win as well." PN

Information about the Vanderbilt Center for Neuroscience Drug Discovery is posted at http://www.vcndd.com.

Erratum

The article "Abundant Sunshine Isn't Only Reason to Practice Psychiatry in Puerto Rico," which appeared in the August 16 issue, incorrectly reported that physicians who are not board certified will no longer be able to bill Medicare or Medicaid beginning in 2015. PN

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University of California, San Francisco at S.F. General Hospital

The UCSF Department of Psychiatry seeks 2 faculty psychiatrists. The position offers opportunities in resident and student teaching, patient care & clinical leadership for a multidisciplinary staff; developmentof scholarship; & clinical research. Candidates must be Board certified/eligible; possess a current California medicallicense & DEA certification at the time of appointment; graduated from an APA-approved psychiatry residency program; have inpatient or psychiatric ER experience; established record of clinical, educational, & leadership skills; commitment to an academic career & demonstratedcultural competence working with underserved & culturally diversepopulations. Email cover letter, CV & 3 recommendation letters to Mark Leary MD, Deputy Chief, SFGH Psychiatry, c/o stephany.medina@ucsf.edu. USCF is an Equal Opportunity/Affirmative Action Employer. All qualified applicants are encouraged to apply. Further information about the University of California, San Francisco, is available at diversity.ucsf.edu. UCSF seeks candidates whose skills, and personal and professional experience, have prepared them to contribute to our commitment to diversity and excellence, and the communities we serve.

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

Fax CV to Uday Mukherjee, MD at
(209) 525-6291 or
Email: umukherjee@stanbhrs.org.

COLORADO

Denver Health (DH) is seeking a full-time BC/BE psychiatrist for the Psychiatric Emergency Services at DH. Duties include: acute treatment of psychiatric emergencies, consultation with mobile crisis, jails, and Denver CARES.

A 525 licensed bed hospital, DH is the Rocky Mountain Region's Level I academic trauma center and the safety net hospital for the Denver area. The DH system, which integrates acute and emergency care with public and community health, includes the Rocky Mountain Regional Trauma Center, Denver's 911 emergency medical response system, Paramedic Division, eight family health centers, 15 school-based health centers, the Rocky Mountain Poison and Drug Center, NurseLine, Denver CARES, and Denver Public Health.

Interested candidates should send CV to Jeanette.moore@dhha.org

Denver Health is an equal opportunity employer.

CLASSIFIEDS

Horizon Health seeks an **Attending Psychiatrist** for a new 22-bed Senior Behavioral Health program at our client hospital **Exempla Lutheran Medical Center** in **Wheat Ridge, CO.** Excellent practice opportunity and income. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com. EOE

Chief Medical Officer (CMO)

Behavioral Healthcare, Inc., a local nonprofit behavioral health organization located in the Denver metro area, provides Medicaid members with mental health services. BHI is seeking a part-time CMO. For more info or to apply visit BHICares.org.

CONNECTICUT

2 psychiatrists needed: 1st working 1/2 time in general adult outpatient clinic and 1/2 time in peri-natal & post natal mood disorders clinic. 2nd working 3/4 time on 20 bed inpatient unit and 1/4 time in general adult clinic. Award winning community hospital, collegial multidisciplinary staff, reasonable on-call, competitive salary/benefits. Apply in confidence to robert.grillo@midhosp.org or call 860-358-6761.

Adult/ Child Psychiatrist
Fairfield, CT

Group Psychiatry practice is seeking a full-time Psychiatrist. Excellent salary and benefits. Email CV to: doctorbeach52@gmail.com or fax to Attn: Evelyn A. 203-255-3126.

FLORIDA

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

GEORGIA

PSYCHIATRIST

New Horizons Community Service Board in Columbus, Georgia is seeking an Adult Psychiatrist for its Outpatient/Court Services 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, have completed a three-year residency in an accredited facility and be board eligible or board certified. Excellent salary with a comprehensive benefits package. Interested parties should send their curriculum vitae to:

Shannon Robertson
srobertson@newhorizonscsb.org
706/317-5001
706/317-5004 (Fax)

ILLINOIS

Adult Psychiatrist – Northwest Suburbs of Chicago Outstanding career opportunity for BC/BE psychiatrist to join well established private practice in our Schaumburg and Crystal Lake offices. Flexible hours, outpatient only, no hospital work. On call rotation for practice every 12 weeks. For more information contact Paula Comm, Practice Administrator at 847 240-2211 x224 or Fax resume to: 847-240-2418 or email at pmc@prapsych.com.

Geriatric Psychiatry Director

The University of Illinois College of Medicine at Peoria Department of Psychiatry invites applications for Director of Geriatric Psychiatry.

This new, full-time Assistant or Associate Professor appointment is a perfect opportunity to lead our expanding geriatric services and to build a teaching model for our fully-accredited residency training program. Responsibilities include development of an inpatient Geriatric Teaching Unit, resident and medical student education and supervision, administration, and scholarship. The Director will support development of specialized outpatient clinics, oversee a growing ECT practice, and assist in the creation of a TMS service. The position will also receive support for the development of a geriatric fellowship, if interested. Our state-of-the-art behavioral health facilities provide a wonderful working and educational environment for faculty, residents, and medical students.

Applicants should be BE/BC in general psychiatry (BE/BC in geriatric psychiatry preferred), have interest and aptitude in academia, and be eligible for an unrestricted Illinois medical license. We offer excellent salary and benefits. We are an AA/EO employer. To learn more, please contact Ryan Finkenbine MD, Chair, at (309) 495-1645 or ryanf@uic.edu. Visit this job posting at: http://jobs.uic.edu/job-board/job-details?jobID=30623

KENTUCKY

HOPKINSVILLE (North of Nashville): Staff Psychiatrist for inpatient and partial programs – General Adult services with opportunity to work with military program. **Contact Will DeCuyper, In-house Recruiter @ 866-227-5415 OR email will.decuyper@uhsinc.com.**

NEAR ASHLAND, KY - Hospital Named 10th in the Top 100 Best Places to Work - Outpatient Position with some on-call duties for the geropsych unit. Enjoy small town living; laid-back, wonderful quality of life. An easy drive to Huntington, WV and Cincinnati, OH. Salaried position with attractive bonus plans; medical school loan repayment plan up to $200k. Join our top notch team at this truly impressive hospital and enjoy where you live & work every day. Please **call Terry B. Good, Horizon Health, at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

Horizon Health seeks a Psychiatrist for our 10-bed Senior Adult, and 10-bed Adult, inpatient Behavioral Health programs our client hospital **St. Claire Regional Medical Center in Morehead, KY.** Experience with geriatric population preferred. Excellent salary, benefits and practice opportunity. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com. EOE.

MARYLAND

Springfield Hospital Center in Sykesville, MD is accepting applications for a **Forensic Psychiatrist**. Eligible candidates must have board certification including added qualifications in forensic psychiatry (or equivalent). Duties include pretrial evaluations of competency to stand trial and criminal responsibility, competency restoration, and training of residents and students. Please forward a CV and inquiry to Erik Roskes, MD, Director, Forensic Services, Springfield Hospital Center, by fax (410.970.7105) or email (erik.roskes@maryland.gov).

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 **Paramjit Agrawal, M.D., Clinical Director, SHC, 6655 Sykesville Road, Sykesville, MD 21784. For questions, call (410)970-7006 or e-mail paramjit.agrawal@dhmh.state.md.us.** EOE

PSYCHIATRIST

BE/BC Psychiatrist needed 10-20 hours a week (additional hours are possible if necessary) for outpatient community mental health facility on Maryland's scenic Eastern Shore, one hour, 15 minutes from Baltimore-Washington area. The clinic is located in a Professional Shortage Area, is a National Health Service Corps site and is eligible for loan repayment. Send resume/vitae with cover letter to Michael Campbell. LCSW-C, Director, Caroline Co. Mental Health Clinic, P.O. Box 10 Denton, Md. 21629, phone 410-479-3800, ext. 117, fax 410-479-0052 or e-mail mike.campbell@maryland.gov - EOE

www.psychiatry.org

Incredible Sunsets – Endless Waterviews – Psychiatrist needed on 24-bed adult inpatient psychiatric unit on the beautiful Eastern Shore. Dorchester County—a county of 1,700 miles of shoreline and is an easy drive to Annapolis, Ocean City, and Baltimore. A wonderful laid back quality of life. Also, seeking a Psychiatrist within commuting distance to help with 1 or 2 weekends per month on the unit. Please **call Terry B. Good, Horizon Health, at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

MASSACHUSETTS

Berkshire Health Systems

Psychiatrist Opportunity in the Beautiful Berkshires. Top notch colleagues.

Berkshire Medical Center's Department of Psychiatry and Behavioral Science provides you the opportunity to become part of a stable, highly integrated clinical collaboration among Psychiatry, Primary Care, and Medical Specialty Services. Our Health System has an excellent opportunity for an Adult Psychiatrist to work in a highly integrated clinical collaborative at the interface of Primary Care and Behavioral Health. A clinical background in geriatric psychiatry is preferred. Our psychiatry residency program allows you to contribute to the education of the next generation of mental health specialists. Berkshire Medical Center is nationally recognized by HealthGrades and many other independent organizations for outstanding care.

Please contact Antoinette Lentine in the Physician Recruitment Department at 413-395-7866 or e-mail at mdrecruitment@bhs1.org.

Wellesley, MA, Child or Adult Psychiatrist, Outpatient. Unique opportunity to become part of a thriving, multidisciplinary private group practice in the western suburbs of Boston. Comprehensive Psychiatric Associates currently has eight psychiatrists, a clinical nurse specialist, and twenty-three psychotherapists. Excellent support services allow you to provide great psychiatric care while our experienced staff does the rest. Beautiful office space in a great location. Half-time to full-time, minimum 18 hours per week. Board-certified and at least two years post-training strongly preferred. Learn more about us at www.WellPsych.com. CV and letter to Bruce Black, MD, drblack@wellpsych.com or fax 781-239-3272.

UMass Memorial Medical Center/University of Massachusetts Medical School Department of Psychiatry in Worcester, MA seeks a BC/BE Psychiatrist for its University Hospital Outpatient Clinic. Candidates should have strong academic credentials and sound clinical skills, and interest in pursuing academic opportunities in either training or research. An academic appointment, commensurate with experience, is available. Interested applicants are encouraged to submit CVs and letters of interest to: psychiatryrecruitment@umassmemorial. org

CLASSIFIEDS

CAMBRIDGE
Consultation-Liaison Psychiatry and Woman's Health Position

PSYCHIATRISTS: Cambridge Health Alliance is seeking two providers for half- to full-time positions in our Consultation-Liaison Psychiatry and Woman's Mental Health Service. The positions will focus on clinical work and program development in our general hospitals, primary care, specialty medical clinics, and our new, innovative telemedicine program. Clinicians will be co-located and integrated into the medical sites. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment coupled with a strong academic tradition and existing collaboration with our medical colleagues, make this an ideal opportunity for candidates interested in integrated medical and psychiatric care with underserved and multi-ethnic patient populations. We have strong training programs in Primary Care, Adult and Child Psychiatry, Geriatric, and Psychosomatic Medicine and innovative educational programs for medical students. There are many opportunities for teaching and research. Academic appointment is anticipated, as determined by the criteria of Harvard Medical School.

Qualifications: BC, strong clinical skills, commitment to public sector populations, team oriented, problem solver, interested in working closely with primary care and medical specialists. Fellowship training in Psychosomatic Medicine, as well as bilingual and/or bicultural abilities, is desirable. Interest and experience with substance use disorders preferred. We offer competitive compensation and excellent benefits package. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. CV & letter to Susan Lewis, Department of Psychiatry, 1493 Cambridge Street, Cambridge, MA; Fax: 617-665-1204. **Email preferred: SLewis@challiance.org.**

INPATIENT PSYCHIATRIST NORTH OF BOSTON

Full-time, salaried psychiatry position available on the 22-bed, general adult inpatient psychiatry unit at Melrose-Wakefield Hospital, a full-service community hospital 8 miles north of Boston. On-call coverage is optional. The adult unit is part of Hallmark Health's comprehensive behavioral health service that includes geriatric inpatient units at Lawrence Memorial Hospital in Medford, ECT, and outpatient services at Community Counseling in Malden and Medford. Voted One of Boston Magazine's Best places to work in Boston, we offer a competitive compensation and benefits package and flexible schedule. Tufts faculty appointment available. Current MA professional license is preferred.

If interested, please forward your CV to Gina Mariona via email: gmariona@hallmarkhealth.org or call 781-338-7517.

Link to Annual Meeting Microsite:
http://annualmeeting.psychiatry.org/

Outpatient Psychiatrist
BRIGHAM AND WOMEN'S HOSPITAL

Our vibrant Department of Psychiatry is seeking an academic psychiatrist to be the Clinical and Educational Director of the Women's Mental Health Division. The position involves both a leadership role within the Division and responsibilities as an outpatient psychiatrist. The Division provides care to a diverse population with a range of psychiatric conditions that present during reproductive life transitions and in varied obstetric and gynecologic contexts including the neonatal ICU, and is a major teaching site for the Harvard Longwood Residency Training Program and Harvard Medical School. The successful candidate will be a women's mental health clinician with particular interest and expertise in perinatal psychiatry and leadership experience or potential. We are seeking applicants who are skilled at complex diagnostic assessment, psychopharmacologic management and focused psychotherapy, and are also collaborative with a multidisciplinary team, inspiring to trainees, and interested in engaging with care innovation and clinical research. Academic rank at Harvard Medical School will be commensurate with experience, training and achievements.

If interested, please send CV by 12/1/13 to: Hadine Joffe, MD MSc, Director of Women's Mental Health Division, Department of Psychiatry, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115; mplatner@partners.org

Harvard Medical School and Brigham and Women's Hospital are Affirmative Action/Equal Opportunity Employers. We strongly encourage applications from women and minorities.

UMass Memorial Medical Center/ University of Massachusetts Medical School Clinical/Academic Adult, Child and Geriatric Psychiatry Positions Currently Available in the Department Of Psychiatry

The Department of Psychiatry at UMass Memorial Health Care in Worcester, MA is currently accepting inquiries from physicians/psychologists interested in exploring affiliated clinical/academic job opportunities. The Department has a faculty of more than 300 physicians/psychologists engaged in a variety of clinical and academic pursuits. It is the largest and most highly regarded provider of psychiatric services in Central Massachusetts. Clinical, teaching and research opportunities are currently available at a wide variety of affiliated sites and programs. Below are brief descriptions of some of these attractive opportunities:

- Full and Part time Adult and Child positions available with our outpatient services at our University campus and affiliated Community Mental Health Centers.
- Part-time psychiatrist position to support our Adult Consult Liaison service.
- Geriatric Psychiatry position, part of a joint venture between UMass and Fallon Community Health Plan, designed to improve the quality and delivery of geriatric mental health care in Central Massachusetts. The position involves direct patient care, as well as consultation with PCPs, mental health clinicians and other professionals involved in providing geriatric care.

Interested candidates are encouraged to submit CVs and Letters of Introduction to:

psychiatryrecruitment@umassmemorial.org, Attention: David DeLuca, Physician/Faculty Recruiter. Candidates are also encouraged to visit the Psychiatry Department's Website at: www.umassmed.edu/psychiatry.

UMass Memorial Medical Center and The University of Massachusetts Medical School are equal opportunity employers.

MICHIGAN

Horizon Health, together with client hospital seeks a Child/Adolescent Psychiatrist to join a behavioral health team of psychiatrists, psychologists, social workers and medical consultants. The program offers 61 licensed inpatient psychiatric beds (47 adult and 14 adolescent) and 7 licensed inpatient chemical dependency beds. Located in Saginaw, a city of Michigan and the seat of Saginaw County, located in the Flint/Tri-Cities region of Michigan. Child/Adolescent Psychiatrist will be employed by hospital. Hospital package will include competitive salary, full benefits, and insurance coverage. Interested candidates please submit CV to Mark Blakeney: mark.blakeney@horizonhealth.com ; Voice: 972-420-7473; Fax 972-420-8233. EOE

MINNESOTA

Psychiatric Opportunities!

Join an organization on the cutting edge of psychiatric care that presents many new and exciting challenges and experiences! BE/BC psychiatrists needed in: Addiction, Adult, and Forensics, We also have a Forensic Medical Director opportunity available.

Contact Lena today for additional information: 651-431-3672 or lena.garcia@state.mn.us

Did you know that APA offers educational, policy, and clinical resources to help **geriatric psychiatry** providers focus on prevention, evaluation, diagnosis and treatment of mental and emotional disorders in the elderly? You can also find links to related organizations. www.psychiatry.org/practice/professional-interests/geriatric-psychiatry

MISSISSIPPI

Horizon Health seeks a **Medical Director** for a 19-bed Adult Inpatient Psychiatric Program in **Northern MS.** Well established, busy program with full complement of support staff and administration. $200K+ Salary, Full Benefits, CME, Relocation and more. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com. EOE

MISSOURI

KANSAS CITY – Child Psychiatrist: Inpatient and Partial programs. **NEVADA – Child Psychiatrist:** Residential and I/P services. **J1 eligible in Nevada and H1 both locations. Top compensation, benefits and bonus opportunity!** Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

Close to St. Louis - Make an Income that Matches All the Work You Do - Seeking a Psychiatrist for a very lucrative position with a successful group practice in Festus. Work would be primarily inpatient work on adult & geropsych units in a general hospital. Ideal opportunity for someone who wants the ability to make a very large income based on all your hard work. All billing and scheduling is done for you. Can also employ if in need of H1 or J1 Visa. Please **call Terry B. Good, Horizon Health, at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

MONTANA

Horizon Health seeks a Psychiatrist for a 24-bed (12 adult, 12 geriatric) behavioral health inpatient hospitalization program for short-term behavioral health treatment in beautiful **Helena, MT**. Offering a competitive salary and benefits. Contact: Mark Blakeney, Horizon Health, mark.blakeney@horizonhealth.com or FAX: 972-420-8233. EOE

NEW JERSEY

Northern NJ – Attractive Compensation Packages with base salary and benefits and RVU based bonus plans that will allow psychiatrists to make well over their base. Inpatient adult and geriatric work; units are all voluntary patients. Please contact **Terry B. Good at 1-804-684-5661,** Fax#: 804-684-5663; Email: terry.good@horizonhealth.com.

Stress Care of New Jersey, LLC a Community Mental Health Center in Matawan, NJ is seeking FT or PT Psychiatrists. Benefits available. Fax CV to (732) 679-4549 or email to Stressmg@optonline.net. To learn more about Stress Care, please visit our website, www.stresscareclinic.com.

NEW MEXICO

LAS CRUCES: Child, General or Geriatric Psychiatrist. Inpatient & Partial Services. Fulltime position offering top salary, benefits & bonus opportunity. **J1 and H1 eligible.** Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com

CLASSIFIEDS

NEW YORK CITY & AREA

PSYCHIATRISTS

Full time position available at Kirby Forensic Psychiatric Center, a New York State Office of Mental Health facility specializing in the treatment of a wide range of patients with forensic concerns. The psychiatrist leads a multi disciplinary team with, opportunities to utilize clinical, administrative and teaching skills. Prior forensic training is not required, but opportunities exist to develop forensic skills. Kirby is affiliated with several major residency and forensic fellowship programs and there is an opportunity to teach. In addition to a competitive salary, NY State provides a generous and comprehensive benefits package including an outstanding Pension plan. Physician can earn additional income through voluntary on-call program.

We are conveniently located near the Triboro (Robert F. Kennedy) Bridge in New York City.

Please fax, e-mail or mail resume to:
Kirby Forensic Psychiatric Center
Wards Island Complex
Wards Island, NY 10035
Michal Kunz, M.D., Clinical Director
Fax 646 672 6893
e-mail:Michal.kunz@omh.ny.gov
Kirby Forensic Psychiatric Center is an equal opportunity employer

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

Bellevue Hospital Center
South Manhattan Healthcare Network

Bellevue Hospital Center, part of the New York University Langone Medical Center, is seeking board certified/eligible psychiatrists for psychiatry positions on inpatient psychiatry, consultation liaison, and in the general outpatient clinic. The positions include teaching opportunities. Qualified candidates are eligible for faculty appointment at a suitable rank. Our services provide compassionate, culturally sensitive care to patients with a range of diagnoses and psychosocial complexities. Access is available to a complete range of medical and specialty consult services. Chinese and/or Spanish speaking psychiatrists and those with addictions expertise are especially sought.

CV and inquiries should be sent to:
Mary Anne Badaracco, M.D.
Chief of Psychiatry
Bellevue Medical Center
Department of Psychiatry
Mary.Badaracco@nyumc.org

For information on all advertising products that the American Psychiatric Association has to offer, please visit: www.appi.org/Journals/Pages/AdvertisingInfo.aspx

NEW YORK STATE

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

St. Lawrence Psychiatric Center
Psychiatrists
NYS Licensed or Limited Permit
(Limited Permit option – see below)**
Salary based on experience
Earn up to an additional $74,000/year through a voluntary on-call program
Fringe Benefits equal to 50.16% of your salary
Monday – Friday, 8:00A – 4:30P

St. Lawrence Psychiatric Center is seeking Licensed Psychiatrists for Adult, Children/Youth, and Sex Offender Treatment Inpatient Services and for Adult and Children/Youth Outpatient Services.

- National Health Services Corps (NHSC) student loan repayment may be available (Up to $60,000 for a 2-year FT commitment; up to $170,000 with a 5-year FT commitment, and possible total debt alleviation with 6 or more years of service)
- Doctors Across New York (DANY) loan repayment or sign-on bonuses may be available (applications are time limited and considered in the order in which they are received).
- Excellent NYS Benefits to include medical/dental/vision insurance, paid vacation, holiday and sick time, an excellent retirement plan, and educational and professional leaves.
- Our location offers quality housing prices, mild traffic, a regional airport, Clarkson University, St. Lawrence University, and 2 SUNY colleges; 1 hr drive to Ottawa; 2 hr drive to Montreal, Lake Placid, and Syracuse.

**Limited Permit Option: If you have finished your residency, but not the USLME, you may be appointed on limited permit, initially for 2 years, renewable for further 2 years.

Applications are available by calling
(315) 541-2179
or send resume to:
Personnel Office
St. Lawrence Psychiatric Center
1 Chimney Point Drive
Ogdensburg, NY 13669-2291
or to Angela Grant at
Angela.Grant@omh.ny.gov.

SLPC is a fully accredited Joint Commission program/AA/EEOE/Self-indemnified.**Affiliated with SUNY Upstate Medical University.**

ELMIRA PSYCHIATRIC CENTER
Adult and Adolescent Psychiatrists
Board Eligible/Board Certified
$168,421 - $256,700*
Limited Permit eligible applicants will also be considered

- All positions **M-F 8-4:30**
- Student loan repayment available
- Excellent NYS benefits package
- Inpatient, Outpatient and Day Treatment services
- Our location offers: quality housing prices; little traffic; regional airport; Cornell University; 4hr drive to NYC, Toronto & Philadelphia; 5-1/2 hr drive to Boston & DC; less than 1hr to Finger Lakes Wine Country; Watkins Glen International Racetrack.

*Includes voluntary low stress on-call at regular pay rate.

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

NORTH CAROLINA

HERE WE GROW AGAIN!

Monarch, a non-profit CABHA certified Behavioral Health agency is currently hiring Psychiatrist and PMHNPs in several locations in NC. We provide services through our Open Access Model and always put the people we support first. We currently have full time openings in Raleigh, Greensboro, and Rocky Mount. We also have a few part time positions open as well. Come to a growing organization and help us Make Dreams take Flight!

If interested please contact:
Brandon Springs
704-816-7524
Brandon.Springs@MonarchNC.org

Now recruiting for Board Certified or Board Eligible Psychiatrists. Coastal Carolina Neuropsychiatric Center, PA has multiple locations in NC. In-patient, outpatient, and a combination of both may be available. Competitive salary and benefits package. H1 & J1 visa applicants may apply. Qualified applicants, please send CV to info@coastalcarolinapsych.com.

NORTH DAKOTA

Sanford Clinic North – Fargo, ND has full-time positions available for Adult Psychiatrists in its Behavioral Health Sciences Service. The department is staffed by more than 30 psychiatrists, clinical nurse specialists, doctorate-level psychologists and master's-level psychologists offering a continuum of care, from inpatient hospitalization and partial hospitalization programs, to outpatient individual and group therapy including eating disorders at Sanford's highly regarded Eating Disorders Institute. Responsibilities include teaching psychiatry resident and medical students through the University of North Dakota School of Medicine. Live and work in the progressive communities of Fargo-Moorhead-West Fargo, home to nearly 200,000. This metropolitan community offers excellent schools, a wonderful blend of cultural and sports events, big name entertainment, year-round outdoor recreation and much more. To learn more contact: Jill Gilleshammer, Physician Recruiter, Phone: (701) 417-4852; Email: Jill.Gilleshammer@sanfordhealth.org; Website: careers.sanfordhealth.org

OREGON

Horizon Health seeks a Medical Director for a NEW 10 bed IP general Older Adult / Geriatric Psych program. At the center of healthcare in the **Yamhill Valley** and surrounding areas located in **McMinnville, OR.** The award-winning, modern facility houses state-of-the-art services. Client hospital provides all the latest technology to provide the best healthcare available. Responsibilities include attending Medical Director duties for inpatient program and routine MD administrative duties. Offering an attractive income package and located in the heart of Willamette Valley's wine country, midway between the coast and Portland and 30 miles from the capital city of Salem. McMinnville is a wonderful place to live! Contact: Mark Blakeney, email: mark.blakeney@horizonhealth.com or fax: 972-420-8233. EOE

PENNSYLVANIA

Crisis Center Medical Director. Full time position. Either FT Crisis Center @ Mercy Fitzgerald Hospital or half time Crisis and flexible half time practice @ hospital (inpatient/consults) and office. 1:4 weekend rounds on 21 bed adult unit. Paid medical and occurrence malpractice. Compensation is either a competitive salary or a higher salary/ practice draw. Mercy Psychiatry Associates has been practicing for 22 years and provides all psychiatric services to Mercy Fitzgerald Hospital. PA license. Board certified or eligible, if less than five years post residency. Flexibility, productivity, and availability are rewarded. To apply please contact: Jeffrey J. Dekret, M.D.Director of Psychiatry, MFH, 610-237-4123, Fax 610-237-4695.

Psychiatry Openings - Wellspan Health - York, PA is seeking BC/BE Adult, Geriatric and/or Child Psychiatrists. Join a large, well-respected medical group with low MD turnover. We are a top rated health system with a focus on a high-quality patient care. Excellent schedule with great benefits. Outpatient focus with inpatient available. Great location near Balt/DC and Phila. Call Cris Williams at 717-812-4487 or email cwilliams9@wellspan.org.

LANGHORNE, PA – ATTENDING ON GEROPSYCHIATRIC UNIT – Seeking Board Certified Psychiatrist in practice in the area who wishes to incorporate some inpatient work into their daily schedule to increase revenue and grow their practice. This is a fantastic way to quickly grow one's business, or for a group practice to expand their market to another area. Please contact **Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

CLASSIFIEDS

We have exciting full and part-time positions in our five-hospital system close to Philadelphia and Wilmington. There are immediate openings in our outpatient psychotherapy practice which includes the **Women's Behavioral Health Program, Child/Adolescent, and General Adult.** Psychiatrists provide both psychotherapy and medication management. We also seek psychiatric leadership of our Pain Management Program.

Excellent salaries and benefit package. Send CV to Kevin Caputo, MD, Chairman Department of Psychiatry, Crozer-Keystone Health System, One Medical Center Blvd., Upland, PA 19013 or call 610-874-5257.

C/A Psychiatrist - 50 Minutes from Pittsburgh – Forbes' Top Ten "Best Places to Live Cheaply" because of the low cost of living, highly rated schools, low unemployment and low crime rate. Impressive general hospital with new Child/Adol. Pavilion; this is an inpatient and outpatient position; salaried with benefits and attractive bonus plan. Top-notch staff; great quality of life—truly a "must see" position when considering a new job in a new place. Contact **Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; terry.good@horizonhealth.com. EOE

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SOUTH CAROLINA

Telepsychiatry Position in Northeastern SC – Close to Florence – Seeking Psychiatrist to be Medical Director on 8-bed inpatient geropsychiatric unit; telepsychiatry can be done every other weekday. No rounding required on weekends. Please **call Terry B. Good, Horizon Health, at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

TENNESSEE

Horizon Health, in partnership with **Livingston Regional Hospital** in **Livingston, TN**, near beautiful **Dale Hollow Lake,** has an exciting opportunity for a **Medical Director** at our 10-bed Geriatric Inpatient Psychiatric Program. Excellent income with great quality of life! 2 hours from Nashville and Knoxville and one of the lowest costs of living in the U.S. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com. EOE

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The Mental Health Mental Retardation Authority of Harris County (MHMRA) in Houston, Texas is one of the largest mental health centers in the United States. In anticipation of expected growth in 2013 we are now recruiting for additional BE/BC psychiatrists throughout the Agency.

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The Department of Psychiatry and Behavioral Sciences of the University of Texas Medical School at Houston has an extraordinary opportunity for psychiatrists seeking to develop and implement new outpatient clinical and research initiatives in community based outpatient clinics within the Houston area with our partner Harris Health. We are also adding faculty to our 250 bed inpatient hospital, the Harris County Psychiatric Center. Our inpatient and outpatient services include unique and robust clinical and research initiatives. The Department is looking to expand clinical and research areas and is seeking general psychiatrists, child and adolescent psychiatrists and geriatric psychiatrists to join a growing academic department dedicated to excellence in training and education, and primacy in research and investigation. The Medical School is part of the University of Texas Health Science Center Houston, located in the Texas Medical Center – the largest medical center in the world. Individuals applying for these positions must be Board Certified in general psychiatry, child & adolescent psychiatry and geriatric psychiatry or have completed an accredited training in these specialty and subspecialty areas in the United States. Additionally, they must be licensed or be eligible for licensing in the State of Texas. Depending upon the applicant's qualification and credentials, faculty appointments at the level of Assistant Professor, Associate Professor or Professor will be offered. Salary levels are very competitive and also carry excellent fringe benefit packages. To find out more information about these unique academically driven positions or to apply for them, please write to Jair C. Soares, M.D., Professor and Chair, and include a copy of your curriculum vitae and a letter of interest to 1941 East Road, Houston, Texas 77054, e-mail: Jair.C.Soares@uth.tmc.edu; phone 713-486-2507; fax 713-486-2553. The University of Texas Health Science Center at Houston is an EO/AA employer. M/F/D/V

VIRGINIA

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Fellowships

Offering its 37th year of fellowship training in Psychosomatic Medicine, this ACGME-accredited fellowship is currently accepting applications for three PGY-5 positions to start July 1, 2014. Under the guidance of Drs. Thomas Wise and Catherine Crone, the program provides comprehensive training and mentorship in the care and understanding of psychiatric issues in the medically ill. Both inpatient and outpatient consultation-liaison experiences are provided in areas that include collaborative care with internal medicine, oncology, organ transplantation, ob-gyn, and HIV services. Didactic seminars in liaison approaches, administrative issues, neurology, hypnosis, and primary psychosomatic medicine topics help to round out the fellowship training experience. Opportunities in teaching, academic writing, research, and outpatient psychotherapy are encouraged and readily available. The fellowship is based at Inova Fairfax Hospital, an 876-bed tertiary care teaching hospital located in the heart of the DC Metro area.

Interested individuals should contact:

Catherine Crone, M.D., F.A.P.M.
PM Fellowship Program Director
George Washington University
Medical Center c/o Inova Fairfax Hospital
3300 Gallows Road, Falls Church, VA
22042
Phone: 703-776-3626
E-mail: cathy.crone@inova.org

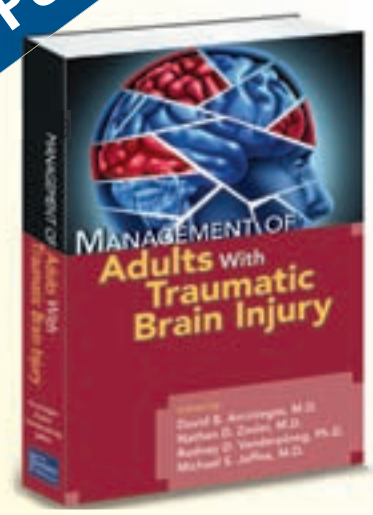
Geriatric Psychiatry Fellowship Program: The University of Texas Health Science Center at **San Antonio** is currently accepting applications for 2014-2015. This one-year program offers training in a wide variety of outpatient, inpatient and consultative settings, as well as opportunities for research and teaching. Interested individuals should contact (210)567-5432.

FELLOWSHIP
PUBLIC PSYCHIATRY at YALE

Yale School of Medicine is accepting applications for a one-year Fellowship in Public Psychiatry for July 2014, at the level of Instructor in the Yale Department of Psychiatry, for individuals interested in developing leadership skills in public mental health and administration. The fellows will spend 50% time engaged in seminars and other academic activities at the CT Mental Health Center (CMHC), a state funded community mental health center at Yale University in New Haven. One fellow will spend 50% time in clinical activities at CMHC and 2 fellows will spend their 50% clinical time at CT Valley Hospital in Middletown. Salary will be at the level of a junior faculty member. All candidates must be eligible for board certification and CT licensure. Minority applicants are encouraged to apply. For further information contact Jeanne Steiner, D.O. Medical Director, CMHC – Yale Univ., 34 Park St New Haven, CT 06519 or Jeanne.Steiner@yale.edu.

JUST PUBLISHED!

Management of Adults With Traumatic Brain Injury



Edited by
David B. Arciniegas, M.D.,
than D. Zasler, M.D.,
Rodney D. Vanderploeg, Ph.D.,
and Michael S. Jaffee, M.D.

Management of Adults with Traumatic Brain Injury is an up-to-the-minute, comprehensive, and useful text designed to support busy physicians, nurses, and mental health professionals working with persons with traumatic brain injury (TBI) and their families. Understanding and improving outcomes after TBI requires consideration of the effects of biomechanical forces on the brain and the interactions between the injury, the person experiencing it, and the psychosocial context in which TBI and its consequences occur.

A multidisciplinary approach to the management of persons with TBI therefore is essential. Accordingly, this book presents and synthesizes the work of internationally recognized brain injury clinicians, scientists, and educators who were selected by a team of editors with backgrounds in psychiatry, neurology, psychology, and physiatry. This broad range of perspectives enhances understanding and provides nuanced yet practical information on the neuropsychiatric management of persons with TBI.

Evidence-informed, concise, and clinically rich, this book will be of enormous value to health care providers grappling with the neurological and mental health consequences of this widespread public health problem.

The volume offers many useful features to its readers, including:

- Chapters written by an internationally known group of editors and contributors offering cutting-edge, multidisciplinary perspectives in brain injury medicine.
- Guidance on the identification and management of early and late postinjury neuropsychiatric disturbances as well as their psychological and psychosocial consequences.
- Identification of special issues relevant to the evaluation and treatment of TBI and postconcussive symptoms among military service members and Veterans.
- Discussion of the ethics and methods of forensic assessment of persons with TBI.
- Key Clinical Points that highlight concepts, assessment issues, and clinical management strategies in each chapter.
- A wealth of tables and figures to enhance the accessibility and clinical utility of the book, as well as appendices of additional readings and relevant websites for persons and families affected by TBI and the clinicians providing their care.

Impressive breadth and depth of coverage, logical structure, clinically rich detail, and concise presentation make *Management of Adults with Traumatic Brain Injury* a must-read for every physician, nurse, and mental health practitioner working to improve the lives of persons with TBI.

2013 • 587 pages • ISBN 978-1-58562-404-1 • Paperback
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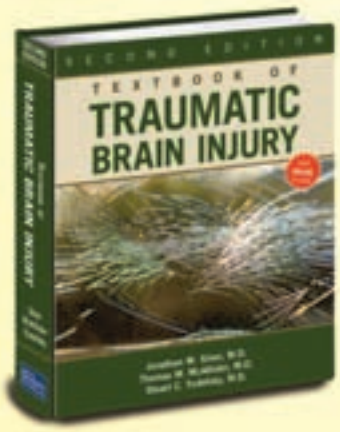

Textbook of Traumatic Brain Injury, Second Edition

Edited by Jonathan M. Silver, M.D.,
Thomas W. McAllister, M.D.,
and Stuart C. Yudofsky, M.D.

This edition of *Textbook of Traumatic Brain Injury* has been thoroughly revised and updated from the 2005 first edition to reflect the exponential expansion of research and clinical data amassed in the intervening years. Each chapter was written and reviewed by the foremost authorities in neuropsychiatry, neurology, rehabilitation medicine, and the other specialties who assess, diagnose, and treat these patients.

The book has been closely edited to achieve a level of writing that is consistent and engaging and that addresses the needs of all medical professionals.

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BRIEF SUMMARY. See package insert for full Prescribing Information. For further product information and current package insert, please visit www.pristiqhcp.com or call Pfizer US Medical Information toll-free at (800) 438-1985.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction in risk with antidepressant use in patients aged 65 and older *[see Warnings and Precautions (5.1) in the full prescribing information]*.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber *[see Warnings and Precautions (5.1) in the full prescribing information]*.

PRISTIQ is not approved for use in pediatric patients *[see Use in Specific Populations (8.4) in the full prescribing information]*.

INDICATIONS AND USAGE: PRISTIQ, a serotonin and norepinephrine reuptake inhibitor (SNRI), is indicated for the treatment of major depressive disorder (MDD) *[see Clinical Studies (14) and Dosage and Administration (2.1) in the full prescribing information].* The efficacy of PRISTIQ has been established in four short-term (8-week, placebo-controlled studies) and two maintenance studies in adult outpatients who met DSM-IV criteria for major depressive disorder.

CONTRAINDICATIONS: Hypersensitivity—Hypersensitivity to desvenlafaxine succinate, venlafaxine hydrochloride or to any excipients in the PRISTIQ formulation. Angioedema has been reported in patients treated with PRISTIQ *[see Adverse Reactions (6.1) in the full prescribing information]*. **Monoamine Oxidase Inhibitors**—The use of monoamine oxidase inhibitors (MAOIs) intended to treat psychiatric disorders with PRISTIQ or within 7 days of stopping treatment with PRISTIQ is contraindicated because of an increased risk of serotonin syndrome. The use of PRISTIQ within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated *[see Dosage and Administration (2.6) and Warnings and Precautions (5.2) in the full prescribing information].* Starting PRISTIQ in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome *[see Dosage and Administration (2.6) and Warnings and Precautions (5.2) in the full prescribing information].*

WARNINGS AND PRECAUTIONS: Suicidal Thoughts and Behaviors in Adolescents and Young Adults—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 to 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 1,000 patients treated) included 14 additional cases of increases among those aged <18, 5 additional cases of increases among those aged 18 to 24, 1 fewer case of decrease among those aged 25 to 64, and 6 fewer cases of decrease among those aged ≥65.

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 Dosage and Administration (2.4) and Warnings and Precautions (5.7) 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 healthcare 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 has been reported with SNRIs and SSRIs, including PRISTIQ, alone but particularly with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort), and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Patients should be monitored for the emergence of serotonin syndrome. The concomitant use of PRISTIQ with MAOIs intended to treat psychiatric disorders is contraindicated. PRISTIQ should also not be started in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue. All reports with methylene blue that provided information on the route of administration involved intravenous administration in the dose range of 1 mg/kg to 8 mg/kg. No reports involved the administration of methylene blue by other routes (such as oral tablets or local tissue injection) or at lower doses. There may be circumstances when it is necessary to initiate treatment with a MAOI such as linezolid or intravenous methylene blue in a patient taking PRISTIQ. PRISTIQ should be discontinued before initiating treatment with the MAOI *[see Contraindications (4.2) and Dosage and Administration (2.6) in the full prescribing information]*. If concomitant use of PRISTIQ with other serotonergic drugs, including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, tryptophan, and St. John's Wort is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases. Treatment with PRISTIQ and any concomitant serotonergic agents should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated. **Elevated Blood Pressure:** Patients receiving PRISTIQ should have regular monitoring of blood pressure since increases in blood pressure were observed in clinical studies *[see Adverse Reactions (6.1) in the full prescribing information]*. Pre-existing hypertension should be controlled before initiating treatment with PRISTIQ. Caution should be exercised in treating patients with pre-existing hypertension, cardiovascular, or cerebrovascular conditions that might be compromised by increases in blood pressure. Cases of elevated blood pressure requiring immediate treatment have been reported with PRISTIQ. 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) in the full prescribing information].* **Abnormal Bleeding:** SSRIs and SNRIs, including PRISTIQ, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs, warfarin, and other anticoagulants may add to this risk. Case reports and epidemiological studies (case-control and cohort design) have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding. Bleeding events related to SSRIs and SNRIs 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 phase 2 and phase 3 studies, mania was reported for approximately 0.02% 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. **Discontinuation Syndrome:** 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 the full prescribing information].* **Seizure:** Cases of seizure have been reported in pre-marketing clinical studies with PRISTIQ. PRISTIQ has not been systematically evaluated in patients with a seizure disorder. Patients with a history of seizures were excluded from pre-marketing clinical studies. PRISTIQ should be prescribed with caution in patients with a seizure disorder. **Hyponatremia:** Hyponatremia may 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). Cases with serum sodium lower than 110 mmol/L have been reported. Elderly patients may be at greater risk of developing hyponatremia with SSRIs and SNRIs. Also, patients taking diuretics or who are otherwise volume depleted can be at greater risk *[see Use in Specific Populations (8.5) and Clinical Pharmacology (12.6) in the full prescribing information].* Discontinuation of PRISTIQ 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 can lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. **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: The following adverse reactions are discussed in greater detail in other sections of the label: Hypersensitivity *[see Contraindications (4)],* Suicidal Thoughts and Behaviors in Adolescents and Young Adults *[see Warnings and Precautions (5.1)],* Serotonin Syndrome *[see Warnings and Precautions (5.2)],* Elevated Blood Pressure *[see Warnings and Precautions (5.3)],* Abnormal Bleeding *[see Warnings and Precautions (5.4)],* Narrow-Angle Glaucoma *[see Warnings and Precautions (5.5)],* Activation of Mania/Hypomania *[see Warnings and Precautions (5.6)],* Discontinuation Syndrome *[see Warnings and Precautions (5.7)],* Seizure *[see Warnings and Precautions (5.8)],* Hyponatremia *[see Warnings and Precautions (5.9)],* Interstitial Lung Disease and Eosinophilic Pneumonia *[see Warnings and Precautions (5.10)]*. **Clinical Studies Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in clinical practice. Patient exposure—PRISTIQ was evaluated for safety in 4,158 patients diagnosed with major depressive disorder who participated in multiple-dose pre-marketing studies, representing 1,677 patient-years of exposure. Among these 4,158 PRISTIQ treated patients; 1,834 patients were exposed to PRISTIQ in 8-week, placebo-controlled studies at doses ranging from 50 to 400 mg/day. Out of the 1,834 patients, 687 PRISTIQ treated patients continued into a 10-month open-label study. Of the total 4,158 patients exposed to at least one dose of PRISTIQ; 1,320 were exposed to PRISTIQ for 6 months, representing 1,058 patient-years of exposure, and 274 were exposed for one year, representing 241 patient-years of exposure. Adverse reactions reported as reasons for discontinuation of treatment—In the pooled 8-week placebo-controlled studies in patients with MDD, 12% of the 1,834 patients who received PRISTIQ (50 to 400 mg) discontinued treatment due to an adverse reaction, compared with 3% of the 1,116 placebo-treated patients. At the recommended dose of 50 mg, the discontinuation rate due to an adverse reaction for PRISTIQ (4.1%) was similar to the rate for placebo (3.8%). For the 100 mg dose of PRISTIQ the discontinuation rate due to an adverse reaction was 8.7%. The most common adverse reactions leading to discontinuation in at least 2% and at a rate greater than placebo 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 longer-term studies, up to 11 months, the most common was vomiting (2%). Common adverse reactions in placebo-controlled MDD studies—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. The incidence of common adverse reactions that occurred in ≥2% of PRISTIQ-treated MDD patients and twice the rate of placebo at any dose in the pooled 8-week, placebo-controlled, fixed-dose clinical studies (placebo, n=636; PRISTIQ 50 mg, n=317; PRISTIQ 100 mg, n=424; PRISTIQ 200 mg, n=307; PRISTIQ 400 mg, n=317) included Cardiac disorders: Blood pressure increased (1% placebo, 1% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 2% PRISTIQ 400 mg); Gastrointestinal disorders: Nausea (10% placebo, 22% PRISTIQ 50 mg, 26% PRISTIQ 100 mg, 36% PRISTIQ 200 mg, 41% PRISTIQ 400 mg), Dry mouth (9% placebo, 11% PRISTIQ 50 mg, 17% PRISTIQ 100 mg, 21% PRISTIQ 200 mg, 25% PRISTIQ 400 mg), Constipation (4% placebo, 9% PRISTIQ 50 mg, 9% PRISTIQ 100 mg, 10% PRISTIQ 200 mg, 14% PRISTIQ 400 mg), Vomiting (3% placebo, 3% PRISTIQ 50 mg, 4% PRISTIQ 100 mg, 6% PRISTIQ 200 mg, 9% PRISTIQ 400 mg); General disorders and administration site conditions: Fatigue (4% placebo, 7% PRISTIQ 50 mg, 7% PRISTIQ 100 mg, 10% PRISTIQ 200 mg, 11% PRISTIQ 400 mg), Chills (1% placebo, 1% PRISTIQ 50 mg, <1% PRISTIQ 100 mg, 3% PRISTIQ 200 mg, 4% PRISTIQ 400 mg), Feeling jittery (1% placebo, 1% PRISTIQ 50 mg, 2% PRISTIQ 100 mg, 3% PRISTIQ 200 mg, 3% PRISTIQ 400 mg); Metabolism and nutrition disorders: Decreased appetite (2% placebo, 5% PRISTIQ 50 mg, 8% PRISTIQ 100 mg, 10% PRISTIQ 200 mg, 10% PRISTIQ 400 mg); Nervous system disorders: Dizziness (5% placebo, 13% PRISTIQ 50 mg, 10% PRISTIQ 100 mg, 15% PRISTIQ 200 mg, 16% PRISTIQ 400 mg), Somnolence (4% placebo, 4% PRISTIQ 50 mg, 9% PRISTIQ 100 mg, 12% PRISTIQ 200 mg, 12% PRISTIQ 400 mg), Tremor (2% placebo, 2% PRISTIQ 50 mg, 3% PRISTIQ 100 mg, 9% PRISTIQ 200 mg, 9% PRISTIQ 400 mg), Disturbance in attention (<1% placebo, <1% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 1% PRISTIQ 400 mg); Psychiatric disorders: Insomnia (6% placebo, 9% PRISTIQ 50 mg, 12% PRISTIQ 100 mg, 14% PRISTIQ 200 mg, 15% PRISTIQ 400 mg), Anxiety (2% placebo, 3% PRISTIQ 50 mg, 5% PRISTIQ 100 mg, 4% PRISTIQ 200 mg, 4% PRISTIQ 400 mg), Nervousness (1% placebo, <1% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 2% PRISTIQ 400 mg), Abnormal dreams (1% placebo, 2% PRISTIQ 50 mg, 3% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 4% PRISTIQ 400 mg); Renal and urinary disorders: Urinary hesitation (0% placebo, <1% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 2% PRISTIQ 400 mg); Respiratory, thoracic and mediastinal disorders: Yawning (<1% placebo, 1% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 4% PRISTIQ 200 mg, 3% PRISTIQ 400 mg); Skin and subcutaneous tissue disorders: Hyperhidrosis (4% placebo, 10% PRISTIQ 50 mg, 11% PRISTIQ 100 mg, 18% PRISTIQ 200 mg, 21% PRISTIQ 400 mg); Special Senses: Vision blurred (1% placebo, 3% PRISTIQ 50 mg, 4% PRISTIQ 100 mg, 4% PRISTIQ 200 mg, 4% PRISTIQ 400 mg), Mydriasis (<1% placebo, 2% PRISTIQ 50 mg, 2% PRISTIQ 100 mg, 6% PRISTIQ 200 mg, 6% PRISTIQ 400 mg), Vertigo (1% placebo, 2% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 5% PRISTIQ 200 mg, 3% PRISTIQ 400 mg), Tinnitus (1% placebo, 2% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 1% PRISTIQ 200 mg, 2% PRISTIQ 400 mg), Dysgeusia (1% placebo, 1% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 1% PRISTIQ 200 mg, 2% PRISTIQ 400 mg); Vascular disorders: Hot flush (<1% placebo, 1% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 2% PRISTIQ 400 mg).

Sexual function adverse reactions—The incidence of sexual function adverse reactions that occurred in ≥ 2% of PRISTIQ treated MDD patients in any fixed-dose group (pooled 8-week, placebo-controlled, fixed and flexible-dose, clinical studies) included Men only (placebo, n=239; PRISTIQ 50 mg, n=108; PRISTIQ 100 mg, n=157; PRISTIQ 200 mg, n=131; PRISTIQ 400 mg, n=154): Anorgasmia (0% placebo, 0% PRISTIQ 50 mg, 3% PRISTIQ 100 mg, 5% PRISTIQ 200 mg, 8% PRISTIQ 400 mg), Libido decreased (1% placebo, 4% PRISTIQ 50 mg, 5% PRISTIQ 100 mg, 6% PRISTIQ 200 mg, 3% PRISTIQ 400 mg), Orgasm abnormal (0% placebo, 0% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 3% PRISTIQ 400 mg), Ejaculation delayed (<1% placebo, 1% PRISTIQ 50 mg, 5% PRISTIQ 100 mg, 7% PRISTIQ 200 mg, 6% PRISTIQ 400 mg), Erectile dysfunction (1% placebo, 3% PRISTIQ 50 mg, 6% PRISTIQ 100 mg, 8% PRISTIQ 200 mg, 11% PRISTIQ 400 mg), Ejaculation disorder (0% placebo, 0% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 5% PRISTIQ 400 mg), Ejaculation failure (0% placebo, 1% PRISTIQ 50 mg, 0% PRISTIQ 100 mg, 2% PRISTIQ 200 mg, 2% PRISTIQ 400 mg), Sexual dysfunction (0% placebo, 1% PRISTIQ 50 mg, 0% PRISTIQ 100 mg, 0% PRISTIQ 200 mg, 2% PRISTIQ 400 mg); Women only (placebo, n=397; PRISTIQ 50 mg, n=209; PRISTIQ 100 mg, n=267; PRISTIQ 200 mg, n=176; PRISTIQ 400 mg, n=163): Anorgasmia (0% placebo, 1% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 0% PRISTIQ 200 mg, 3% PRISTIQ 400 mg).

Other adverse reactions observed in clinical studies: Other infrequent adverse reactions, not described elsewhere in the label, occurring at an incidence of <2% in MDD patients treated with PRISTIQ were: *Cardiac disorders*—Tachycardia; *General disorders and administration site conditions*—Asthenia; *Investigations*—Weight increased, liver function test abnormal, blood prolactin increased; *Musculoskeletal and connective tissue disorders*—Musculoskeletal stiffness; *Nervous system disorders*—Syncope, convulsion, dystonia; *Psychiatric disorders*—Depersonalization, bruxism; *Renal and urinary disorders*—Urinary retention; *Skin and subcutaneous tissue disorders*—Rash, alopecia, photosensitivity reaction, angioedema. In clinical studies, there were uncommon reports of ischemic cardiac adverse reactions, 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.

Laboratory, ECG and vital sign changes observed in MDD clinical studies—The following changes were observed in placebo-controlled, short-term 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. The percentage of patients who exceeded a predetermined threshold value included: Total Cholesterol increase of ≥50 mg/dl and an absolute value of ≥261 mg/dl (2% placebo, 3% PRISTIQ 50 mg, 4% PRISTIQ 100 mg, 4% PRISTIQ 200 mg, 10% PRISTIQ 400 mg), LDL Cholesterol increase ≥50 mg/dl and an absolute value of ≥190 mg/dl (0% placebo, 1% PRISTIQ 50 mg, 0% PRISTIQ 100 mg, 1% PRISTIQ 200 mg, 2% PRISTIQ 400 mg), Triglycerides, fasting, ≥327 mg/dl (3% placebo, 2% PRISTIQ 50 mg, 1% PRISTIQ 100 mg, 4% PRISTIQ 200 mg, 6% PRISTIQ 400 mg).

Proteinuria—Proteinuria, greater than or equal to trace, was observed in the fixed-dose controlled studies. This proteinuria was not associated with increases in BUN or creatinine and was generally transient. The percentage of patients with proteinuria in the fixed-dose clinical studies were 4% placebo, 6% PRISTIQ 50 mg, 8% PRISTIQ 100 mg, 5% PRISTIQ 200 mg, 7% PRISTIQ 400 mg.

Vital sign changes—Mean changes observed in placebo-controlled, short-term, fixed-dose, pre-marketing, controlled studies with PRISTIQ in patients with MDD included Blood pressure: Supine systolic bp (-1.4 mm Hg placebo, 1.2 mm Hg PRISTIQ 50 mg, 2.0 mm Hg PRISTIQ 100 mg, 2.5 mm Hg PRISTIQ 200 mg, 2.1 mm Hg PRISTIQ 400 mg); Supine diastolic bp (-0.6 mm Hg placebo, 0.7 mm Hg PRISTIQ 50 mg, 0.8 mm Hg PRISTIQ 100 mg, 1.8 mm Hg PRISTIQ 200 mg, 2.3 mm Hg PRISTIQ 400 mg); Pulse rate: Supine pulse (-0.3 bpm placebo, 1.3 bpm PRISTIQ 50 mg, 1.3 bpm PRISTIQ 100 mg, 0.9 bpm PRISTIQ 200 mg, 4.1 bpm PRISTIQ 400 mg); Weight: (0.0 kg placebo, -0.4 kg PRISTIQ 50 mg, -0.6 kg PRISTIQ 100 mg, -0.9 kg PRISTIQ 200 mg, -1.1 kg PRISTIQ 400 mg).

Treatment with PRISTIQ at all doses from 50 mg/day to 400 mg/day 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. The proportion of patients with sustained elevation of supine diastolic blood pressure included 0.5% placebo, 1.3% PRISTIQ 50 mg, 0.7% PRISTIQ 100 mg, 1.1% PRISTIQ 200 mg, 2.3% PRISTIQ 400 mg. Analyses of patients in PRISTIQ short-term controlled studies who met criteria for sustained hypertension revealed a consistent increase in the proportion of patients who developed sustained hypertension. This was seen at all doses with a suggestion of a higher rate at 400 mg/day.

Orthostatic hypotension—In the short-term, placebo-controlled clinical studies with doses of 50 to 400 mg, systolic orthostatic hypotension (decrease ≥30 mm Hg from supine to standing position) occurred more frequently in patients ≥65 years of age receiving PRISTIQ (8%, 7/87) versus placebo (2.5%, 1/40), compared to patients <65 years of age receiving PRISTIQ (0.9%, 18/1,937) versus placebo (0.7%, 8/1,218). **Postmarketing Experience**—The following adverse reaction has been identified during post-approval use of PRISTIQ. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: *Skin and subcutaneous tissue disorders*—Stevens-Johnson syndrome. **DRUG INTERACTIONS: Monoamine Oxidase Inhibitors (MAOI)**—*[see Dosage and Administration (2.6), Contraindications (4) and Warnings and Precautions (5.2) in the full prescribing information]*. **Serotonergic Drugs**—*[see Dosage and Administration (2.6), Contraindications (4) and Warnings and Precautions (5.2) in the full prescribing information].* **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 that 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 co-administered with warfarin. Patients receiving warfarin therapy should be carefully monitored when PRISTIQ is initiated or discontinued *[see Warnings and Precautions (5.4) in the full prescribing information]*. **Potential for Desvenlafaxine to Affect Other Drugs**—Clinical studies have shown that desvenlafaxine does not have a clinically relevant effect on CYP2D6 metabolism at the dose of 100 mg daily. Substrates primarily metabolized by CYP2D6 (e.g., desipramine, atomoxetine, dextromethorphan, metoprolol, nebivolol, perphenazine, tolterodine) should be dosed at the original level when co-administered with PRISTIQ 100 mg or lower. Reduce the dose of these substrates by one-half if co-administered with 400 mg of PRISTIQ. The substrate dose should be increased to the original level when 400 mg of PRISTIQ is discontinued. **Other Drugs Containing Desvenlafaxine or Venlafaxine**—Avoid use of PRISTIQ with other desvenlafaxine-containing products or venlafaxine products. The concomitant use of PRISTIQ with other desvenlafaxine-containing products or venlafaxine will increase desvenlafaxine blood levels and increase dose-related adverse reactions *[see Adverse Reactions (6) in the full prescribing information]*. **Ethanol**—A clinical study has shown that PRISTIQ 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.

USE IN SPECIFIC POPULATIONS: Pregnancy—Pregnancy Category C: *Risk summary*—There are no adequate and well-controlled studies of PRISTIQ in pregnant women. In reproductive developmental studies in rats and rabbits with desvenlafaxine succinate, evidence of teratogenicity was not observed at doses up to 30 times a human dose of 100 mg/day (on a mg/m^2 basis) in rats, and up to 15 times a human dose of 100 mg/day (on a mg/m^2 basis) in rabbits. An increase in rat pup deaths was seen during the first 4 days of lactation when dosing occurred during gestation and lactation, at doses greater than 10 times a human dose of 100 mg/day (on a mg/m^2 basis). PRISTIQ should be used during pregnancy only if the potential benefits justify the potential risks to the fetus. *Clinical considerations*—A prospective longitudinal study of 201 women with history of major depression who were euthymic at the beginning of pregnancy, showed women who discontinued antidepressant medication during pregnancy were more likely to experience a relapse of major depression than women who continued antidepressant medication. *Human data*—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) in the full prescribing information]*. *Animal data*—When desvenlafaxine succinate was administered orally to pregnant rats and rabbits during the period of organogenesis at doses up to 300 mg/kg/day and 75 mg/kg/day, respectively, no teratogenic effects were observed. These doses are 30 times a human dose of 100 mg/day (on a mg/m^2 basis) in rats and 15 times a human dose of 100 mg/day (on a mg/m^2 basis) in rabbits. However, fetal weights were decreased and skeletal ossification was delayed in rats in association with maternal toxicity at the highest dose, with a no-effect dose 10 times a human dose of 100 mg/day (on a mg/m^2 basis). **When desvenlafaxine succinate was administered orally to pregnant rats throughout gestation and lactation, there was a decrease in pup weights and an increase in pup deaths during the first four days of lactation at the highest dose of 300 mg/kg/day. The cause of these deaths is not known. The no-effect dose for rat pup mortality was 10 times a human dose of 100 mg/day (on a mg/m^2 basis). Post-weaning growth and reproductive performance of the progeny were not affected by maternal treatment with desvenlafaxine succinate at a dose 30 times a human dose of 100 mg/day (on a mg/m^2 basis). 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 to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use**—Safety and effectiveness in pediatric patients have not been established *[see Boxed Warning and Warnings and Precautions (5.1) in the full prescribing information]*. Anyone considering the use of PRISTIQ in a child or adolescent must balance the potential risks with the clinical need. **Geriatric Use**—Of the 4,158 patients in clinical studies with PRISTIQ, 6% were 65 years of age or older. No overall differences in safety or efficacy were observed between these patients and younger patients; however, in the short-term placebo-controlled studies, there was a higher incidence of systolic orthostatic hypotension in patients ≥65 years of age compared to patients <65 years of age treated with PRISTIQ *[see Adverse Reactions (6) in the full prescribing information]*. For elderly patients, possible reduced renal clearance of PRISTIQ should be considered when determining dose *[see Dosage and Administration (2.2) and Clinical Pharmacology (12.3) in the full prescribing information]*. SSRIs and SNRIs, including PRISTIQ, have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event *[see Warnings and Precautions (5.9) 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, Cockcroft-Gault) 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 (12.3) in the full prescribing information]*. **Hepatic Impairment**—The mean terminal half life ($t_{1/2}$) 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. The recommended dose in patients with moderate to severe hepatic impairment is 50 mg/day. Dose escalation above 100 mg/day is not recommended *[see Clinical Pharmacology (12.3) in the full prescribing information]*.

DRUG ABUSE AND DEPENDENCE: Controlled Substance—PRISTIQ is not a controlled substance.

OVERDOSAGE: Human Experience with Overdosage—There is limited clinical trial experience with desvenlafaxine succinate overdosage in humans. However, 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. **Management of Overdosage**—No specific antidotes for PRISTIQ are known. In managing over dosage, consider the possibility of multiple drug involvement. In case of overdose, call Poison Control Center at 1-800-222-1222 for latest recommendations.

This brief summary is based on PRISTIQ Prescribing Information LAB-0452-8.0, revised February 2013.

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Major Depressive Disorder (MDD) can make it all feel overwhelming.

Consider PRISTIQ® (desvenlafaxine) 50 mg for your adult MDD patients

An SNRI with a starting dose that is the proven effective dose* and a low discontinuation rate due to adverse reactions[1]

- Discontinuation rate due to adverse reactions comparable to placebo (4.1% vs 3.8%)[2]
- Most commonly observed adverse reactions vs placebo include nausea (22% vs 10%), dizziness (13% vs 5%), hyperhidrosis (10% vs 4%), constipation (9% vs 4%), and decreased appetite (5% vs 2%)

*50 mg per day is the recommended dose for most patients. The maximum recommended dose in patients with severe renal impairment (24-hr CrCl less than 30 mL/min, C-G) or end-stage renal disease (ESRD) is 50 mg every other day. Supplemental doses should not be given to patients after dialysis.

Important Safety Information for PRISTIQ

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction in risk with antidepressant use in patients aged 65 and older.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers 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. Angioedema has been reported in patients treated with PRISTIQ.
- **Serotonin syndrome and MAOIs:** Do not use MAOIs intended to treat psychiatric disorders with PRISTIQ or within 7 days of stopping treatment with PRISTIQ. Do not use PRISTIQ within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start PRISTIQ in a patient who is being treated with an MAOI such as linezolid or intravenous methylene blue.

Selected 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.**
- The development of a potentially life-threatening serotonin syndrome has been reported with SSRIs and SNRIs, including with PRISTIQ, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort) and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). If such events occur, immediately discontinue PRISTIQ and any concomitant serotonergic agents, and initiate supportive treatment. If concomitant use of PRISTIQ with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increase.
- Patients receiving PRISTIQ should have regular monitoring of blood pressure, since 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, cardiovascular or cerebrovascular 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.
- 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.
- PRISTIQ should be used cautiously in patients with a history or family history of mania or hypomania or with a history of seizure disorder.
- 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 rather than abrupt cessation is recommended whenever possible.
- 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 at least 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%).

Indication

PRISTIQ Extended-Release Tablets are indicated for the treatment of major depressive disorder in adults.

References: 1. Thase ME, Kornstein SG, Germain JM, Jiang Q, Guico-Pabia C, Ninan PT. An integrated analysis of the efficacy of desvenlafaxine compared with placebo in patients with major depressive disorder. *CNS Spectr.* 2009;14(3):144-154. **2.** Clayton AH, Kornstein SG, Rosas G, Guico-Pabia C, Tourian KA. An integrated analysis of the safety and tolerability of desvenlafaxine compared with placebo in the treatment of major depressive disorder. *CNS Spectr.* 2009;14(4):183-195. **3.** Data on file. Pfizer Inc, New York, NY.

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

Pristiq® desvenlafaxine 50 mg
EXTENDED-RELEASE TABLETS

MORE THAN 14 MILLION PRESCRIPTIONS FILLED[3†]

To learn more about PRISTIQ, go to **www.pristiqhcp.com**

†IMS Health data, February 2013; total prescriptions filled year-to-date 2013. Includes data for 50-mg and 100-mg tablets.

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