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PSYCHIATRIC NEWS

The First and Last Word in Psychiatry

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rightdirectionforme.com

Depression can feel like you're lost in the woods, but help is available. That's the concept behind a new campaign from the Partnership for Workplace Mental Health and the Employers Health Coalition. See article at right.

Workers Pointed In 'Right Direction' for Depression Care

An innovative intervention enters the workplace wilderness to seek out hidden depression and bring into treatment those who live with the illness.

BY AARON LEVIN

Depression has suggested many metaphors over the years. Now comes the turn of a large brown bear with a rep tie.

A coalition of 300 major U.S. employers along with the American Psychiatric Foundation's (APF) Partnership for Workplace Mental Health has launched a new initiative—"Right Direction"—to increase employees' understanding of depression's debilitating effects and encourage those who need care to seek it. The concept behind the initiative is that having depression can make one feel lost and alone in the wilderness, hence the bear who finds himself in all types of workplace scenes.

Depression matters to employers because of the prevalence of the condition and its impact on productivity, with annual productivity losses estimated at about $44 billion.

"Our goals are to increase awareness of depression, reduce stigma, and encourage employees who might be depressed to seek help," said Marcas Miles, M.A., director of programs, communications, and community initiatives at Employers Health Coalition

see **Right Direction** on page 25

DSM-5 Sleep-Wake Disorders Section Targets Comorbidity

The *DSM-5* sleep-wake disorders section includes disorders that are not mental disorders because they often co-occur.

BY LYNNE LAMBERG

The classification of sleep-wake disorders in *DSM-5* aims to help psychiatrists, mental health clinicians, and general medical clinicians diagnose and treat sleep-wake complaints. It also offers guidance on when to refer a patient to a sleep specialist for further assessment and treatment planning, Charles Reynolds III, M.D., chair of the *DSM-5* Sleep-Wake Disorders Work Group, told *Psychiatric News*.

The sleep-wake disorders section encompasses 10 disorders or disorder groups that prompt patients to complain of unsatisfactory quality, timing, and amount of sleep, often accompanied by daytime distress and impairment.

Since sleep-wake disorders present in different ways at different ages, the section provides diagnostic criteria across the lifespan, said Reynolds, an endowed professor in geriatric psychiatry and director of the Aging Institute at the University of Pittsburgh Medical Center.

"Sleep is of the brain, by the brain, for the brain," Reynolds asserted. "It is a fundamental operating state of the central nervous system and central to overall health and well-being."

Brain circuits that regulate mood are close to those that regulate sleeping, waking, and arousal. Treating sleep-wake disorders, he said, may promote

see **Sleep-Wake Disorders** on page 26

PERIODICALS: TIME SENSITIVE MATERIALS

INSIDE

THERE ARE GOOD REASONS AMERICAN PROFESSIONAL AGENCY IS A LEADER IN PROVIDING MALPRACTICE INSURANCE FOR PSYCHIATRISTS

HERE ARE TWO OF THEM.

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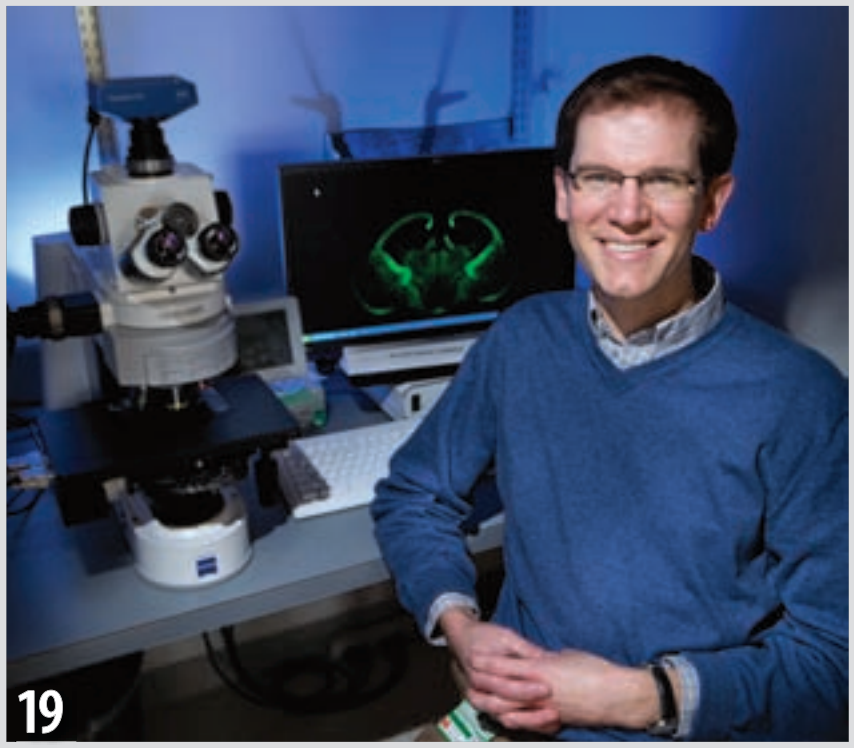

PROFESSIONAL NEWS

COMMUNITY NEWS

APA INSTITUTE

CLINICAL & RESEARCH NEWS

Register Now for Institute!

Rudy Balasko/Shutterstock

APA's next major meeting—the 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." Advance registration is now open at www.psychiatry.org/ips. Housing information and reservations can also be accessed at that site.

Departments

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.

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.

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*Based on a Phase 3, double-blind, randomized clinical trial in patients with schizophrenia; Abilify Maintena (n=269) vs placebo (n=134).

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.

Continued on next page.

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

400MG

Abilify Maintena™

(aripiprazole) for extended release injectable suspension

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

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.
- **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.

Otsuka Lundbeck

ABILIFY MAINTENA™ (aripiprazole) for extended-release injectable suspension, for intramuscular use

BRIEF SUMMARY OF PRESCRIBING INFORMATION (For complete details, please *see Full Prescribing Information and Medication Guide.)*

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

See full prescribing information for complete boxed warning.

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death
- ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis

INDICATIONS AND USAGE: ABILIFY MAINTENA (aripiprazole) is 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.

CONTRAINDICATIONS: ABILIFY MAINTENA is contraindicated in patients with a known hypersensitivity to aripiprazole. Hypersensitivity reactions ranging from pruritus/urticaria to anaphylaxis have been reported in patients receiving aripiprazole.

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.

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.

Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850
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 09US12L-1001B February 2013

Institute on Psychiatric Services

American Psychiatric Association

65TH IPS

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It is indeed my pleasure to welcome you to the 2013 Institute on Psychiatric Services (IPS), in Philadelphia, October 10-13. This year's meeting, whose theme is *Transforming Psychiatric Practice, Reforming Health Care Delivery*, will be innovative, diverse, comprehensive, and professionally fulfilling.

The APA's Institute on Psychiatric Services has become a "must attend" professional meeting, attracting an international audience yet still maintaining a community and public mental health focus. Attendees this year will be able to select from many high-quality scientific sessions related to the meeting's theme, including the expanding field of integrated care and its impact on the future of psychiatry and psychiatric practice, the movement of the Affordable Care Act towards full implementation, homelessness and veteran's issues, to name just a few. Additionally, the Institute is an excellent one-stop resource for those who need to satisfy professional CME or Maintenance of Certification (MOC) requirements and, as always, there will be ample opportunities for attendees to network with experts, colleagues, advocates, and peers.

Over 100 workshops, lectures, symposia, innovative programs and forums are planned, as well as half- and full-day seminars and courses. Some of the more popular courses, from previous meetings, will again be offered to assist attendees in mastering important new material in depth and will cover diverse issues including primary care skills for psychiatrists and psychopharmacology. And in keeping with the recent changes in our field, we are pleased to add to the program new courses in CPT coding and DSM-5.

This year's IPS will offer these other exciting features:

- A new format, invited seminars, will provide up-to-date information in areas of special interest to the meeting's diverse attendees – HIV management in psychiatric disorders; career paths for IMGs; clinical work with persons who are homeless; Buprenorphine training; integration of primary care and behavioral health; neuropsychosocial mechanisms underlying racist and sexist events in our daily practice and finding the ideal job in psychiatry.
- An 'Un-Debate' led by Pennsylvania consumer advocate Joseph Rogers.
- A special session commemorating a half-century of community mental health featuring, among others, pioneers John A. Talbott, M.D., and Paul Jay Fink, M.D.
- A behavioral health and primary care integration track, that includes multiple sessions in which psychiatrists, other behavioral health professionals, and primary care providers will discuss their different clinical perspectives and how we can more effectively collaborate in providing care to our mutual patients.
- Sessions on culturally-appropriate assessment, the impact of health care reform on the mental health of diverse and underserved populations, suicide screening and response in general hospitals, as well as racial stress, coping and socialization in black families will be offered as part of the ten year tradition of the APA Office of Minority and National Affair's OMNA on Tour series.
- The Opening Session Keynote Address will be delivered by Estelle Richman, a nationally recognized expert on issues of behavioral health and children's services, a pioneer in the creation of consumer driven and friendly mental health services, an advocate for the integration of funding for behavioral health systems and a recipient of the Harvard University, Kennedy School of Government's Innovation Award for the redesign of the Philadelphia behavioral health system.
- Lecturers will include:
  - SAMHSA Administrator, Pamela Hyde, J.D.;
  - Prominent community psychiatrists – Drs. Mark Ragins, David A. Pollack, and Lisa Dixon;
  - Ezra S. Susser, M.D., on global community mental health;
  - Howard H. Goldman, M.D., on health care reform and psychiatric sertvices;
  - Colleagues from the psychiatric administration and research arenas: Raquel E. Gur, M.D., Ph.D., on detection and intervention of psychosis-prone youth and Arthur Evans, M.D., on models of health reform and financing;
  - Fran Silvestri on leadership and knowledge exchange in transforming mental health services.

Come participate in what promises to be a very vibrant educational exchange at the APA's 2013 Institute on Psychiatric Services and enjoy the cultural and historical offerings of Philadelphia —the city considered by many to be the birthplace of American psychiatry!

Sincerely,

Altha J. Stewart, M.D.
Scientific Program Chair

Register by September 20 and Save with Advance Registration:
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Travel Information

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Call **1-877-212-5752** and identify yourself as an **APA IPS Attendee**.

ROOM TYPE	RATE
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Schedule At-A-Glance

***Members Only Registration*: 3:30 p.m. – 5:00 p.m. on Wednesday, October 9, 2013**

Thursday, October 10, 2013	
7:30 a.m. – 5:30 p.m.	On-Site Check-In and Registration
8:00 a.m. – 5:00 p.m.	Educational Sessions and Posters
12 noon – 1:30 p.m.	Opening Session and Awards Ceremony, featuring APA President, Jeffrey A. Lieberman, M.D., and Keynote Speaker, Estelle Richman
1:30 p.m. – 5:00 p.m.	CME Certificate of Attendance Booth Open
1:30 p.m. – 5:30 p.m.	Exhibit Hall Hours
Friday, October 11, 2013	
7:30 a.m. – 5:30 p.m.	On-Site Check-In and Registration
8:00 a.m. – 5:00 p.m.	Educational Sessions and Posters
8:00 a.m. – 5:00 p.m.	CME Certificate of Attendance Booth Open
10:00 a.m. – 12:30 p.m. 1:30 p.m. – 5:30 p.m.	Exhibit Hall Hours
7:30 p.m. – 9:00 p.m.	American Association of Community Psychiatrists Reception for all attendees
Saturday, October 12, 2013	
7:30 a.m. – 5:00 p.m.	On-Site Check-In and Registration
8:00 a.m. – 5:00 p.m.	Educational Sessions and Posters
8:00 a.m. – 5:00 p.m.	CME Certificate of Attendance Booth Open
10:00 a.m. – 12:30 p.m.	Exhibit Hall Hours
Sunday, October 13, 2013	
7:30 a.m. – 10:30 a.m.	On-Site Check-In and Registration
8:00 a.m. – 12 noon	Educational Sessions
8:00 a.m. – 12 noon	Certificate of Attendance Booth Open

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STANDARD REGISTRATION FEES	**Early Bird** 6/3-7/26	**Advance** 7/27-9/20	**Onsite** 9/21-10/13
Full-Time	$265	$320	$390
Member-in-Training	$75	$90	$105
Daily Registrant	$160	$190	$235
Daily Registrant-Sunday Only	$80	$95	$120
Program Presenter Full-Time	$200	$200	$270
Program Presenter Daily	$100	$100	$135
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1 Does not include APA Fellows, Distinguished Fellows, Distinguished Life Fellows, or Life Fellows.

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Includes Advocacy Group Members, Mental Health Chaplains, Social Workers, Nurses, Physician Assistants, Psychiatric Residents/Fellows and Public Agency Clinical Staff (Masters Level or less). These registrations will not be complete until credentials are provided. To qualify, a copy of your valid student ID, a letter from your institution or organization verifying employment or membership, or a copy of your certification letter must be submitted with your registration form or received within seven (7) days of your online registration. If your verification is not received in the time period, your registration will be cancelled.

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Begin the visa application process immediately. The visa process takes longer then you may anticipate. For further information, visit the State Department website at https://esta.cbp.dhs.gov.

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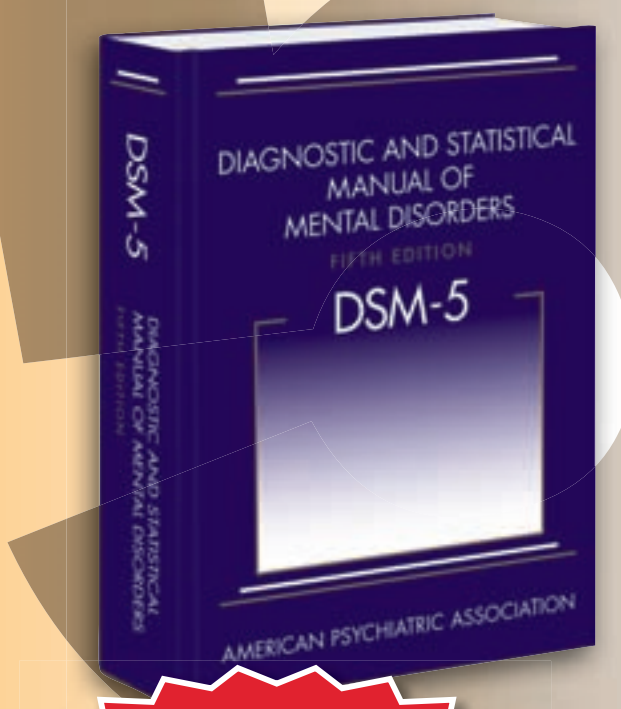

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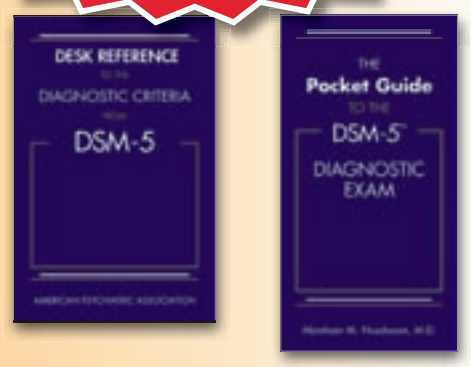

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FROM THE PRESIDENT

Early Detection of Schizophrenia: The Time Is Now

BY JEFFREY LIEBERMAN, M.D.

Medical research often takes a slow and unpredictable pace. The hours spent defining the question, setting up the experiment, and acquiring and then analyzing the data before getting to see the results makes for a long and arduous process. When you then add the time that it takes for new research findings to be translated into clinical practice, the rate of change in health care can be glacial. Psychiatry is certainly no exception to the seemingly snail's pace of progress in health care.

But despite this pervasive pattern, research does periodically gain sufficient momentum to make inroads into clinical practice and move the field forward, as was the case with the introduction of antipsychotic and antidepressant drugs, lithium, community mental health, the development of time-limited forms of psychotherapy (for example, cognitive-behavioral therapy, interpersonal therapy, and dialectical behavior treatment) and cognitive remediation.

I believe that we are at another game-changing moment in psychiatry with the rise of the early detection and intervention strategy (EDIS). This new therapeutic strategy and model of care could have a significant effect on our ability to treat and limit the morbidity of mental illness beginning with schizophrenia and related psychotic disorders.

While schizophrenia has been historically associated with a therapeutic nihilism due to its devastating and often irreversible consequences, research over the last two decades has changed attitudes and inspired optimism. Studies show that the earlier patients are diagnosed and treated, the better their responses to treatment. This leads to improved outcomes and higher chances of full recovery. The corollary to this is continued engagement of patients in treatment following their recovery and relapse prevention.

Among the reasons for this are findings from neuroimaging studies showing that the hallmark clinical deterioration of schizophrenia is associated with cortical gray matter atrophy, reflecting the loss of cell processes and synaptic connections. Unlike Alzheimer's disease though, for which there currently is no "disease-modifying" treatment, early intervention and relapse prevention methods for schizophrenia coupled with antipsychotic medication may prevent illness progression.

Moreover, additional research and first-person reports indicate that resilience, coping skills, and peer and family support can substantially contribute to favorable outcomes and recovery. Collectively, these findings have suggested the value of early detection, intervention, and sustained engagement with treatment to enhance recovery and prevent disability.

Unfortunately, these encouraging research findings have been slow to translate into clinical practice in the United States. It will not come as a surprise that an important reason for the slow implementation of the EDIS model of care is a lack of adequate financing. Many individuals in the earliest stages of psychosis do not have health insurance, and even if they do, their plans do not cover comprehensive psychosocial and rehabilitative services. And while the public mental health system is designed to serve individuals without health insurance and to provide services not covered by insurance, the system favors individuals who have already become disabled by mental illness, limiting the availability of services for patients in the early stages of psychotic disorders.

However, there are signs that state governments are beginning to grasp the implications of this new care model and implement it. New York, for example, has funded four demonstration programs providing EDIS services with plans to expand. In addition, based on the experience and anticipated results of the NIMH's ambitious Recovery After an Initial Schizophrenia Episode study, the Centers for Medicare and Medicaid Services and the Substance Abuse and Mental Health Services Administration are considering funding and supporting EDIS services and models of care.

This new therapeutic model involves a multi-element team-based approach focused on recovery and composed of four components of care: (1) reducing the duration of active symptoms through rapid diagnosis and treatment of patients with first-episode psychosis; (2) sustaining treatment engagement and preventing psychotic relapse; (3) integrating pharmacologic management with psychosocial therapies and recovery-oriented approaches including shared decision making; and (4) offering social and vocational services, substance abuse treatment, and family education and support. This model of care requires financing schemes that will support sustained patient engagement and community functioning and that extend across adolescence to adulthood.

More than a century after Kraepelin initially defined schizophrenia as a progressive illness leading to clinical deterioration and 60 years since the introduction of antipsychotic drugs, psychiatry has within its grasp the potential to limit the morbidity and disability associated with this disorder. EDIS could be the next great advance in psychiatric medicine and mental health care. PN

APA Announces New Time-Saving Benefit

Another free service has been added to the list of benefits available to APA members. This newest benefit is Psychiatry Resources Online (PsychPRO), an innovative, time-saving tool that APA members can access at the point-of-care from their iPad, mobile phone, or laptop computer. Unlike other health care sites, PsychPRO is an on-demand, noncommercial, and neutral marketplace, focused on point-of-service resources for patient care. PsychPRO provides members with a single place to find a full array of product resources, easy to search and easy to order, all at no cost to APA members.

Resources include the following:

- Patient education materials
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PsychPRO is HIPAA compliant and meets the highest standard of Internet security, SSL (Secure Sockets Layer).

To access this new members-only benefit, visit the APA Web site at www.psychiatry.org and log in using your APA user name and password. Then look for "Member Benefits" under "Join and Participate."

Please note that this service is not available to members outside of the United States.

PROFESSIONAL NEWS

Psychiatrist Involved in Collaborative Care Before Concept Existed

Collaborative care can be "a part of what you do, or it can be all of what you do," says one expert. "For most of us, it is part of what we do." This is the third in a series on integrated care.

BY MARK MORAN

While on a Navajo Indian reservation in Kayenta, Ariz., working as a staff psychiatrist for the Indian Health Service (IHS), Lori Raney, M.D., discovered a love for the American West and a knack for working as a team member with primary care physicians.

"The Indian Health Service is a self-contained system with mental health, primary care, dental care, and vision care working together," Raney said. "I was the only psychiatrist, and every morning I was expected to meet with the rest of the physicians—we all showed up regardless of discipline."

That was in the mid-1990s. Raney had completed a residency program known for traditional psychodynamic training at Sheppard Pratt Hospital in Baltimore when a fellow trainee who had taken a position with the IHS called his colleagues in the East with word that there were jobs available in a ruggedly beautiful landscape.

"Several of us went out there together, and I fell in love with the West," she recalled. After two years as director of the Counseling Services Department at Kayenta, Raney took a position as clinical director for the entire ambulatory care clinic, also on the Navajo reservation—the first psychiatrist to hold that position. "For five years I supervised all the primary care doctors and got a lot of practice in running a primary care clinic," she said. "It's the foundation of my interest in merging mental health and primary care."

Today, Raney is one of the leaders within psychiatry of the movement toward collaborative care and is chair of the APA Work Group on Integrated Care. The names—integrated care, collaborative care—are used interchangeably, but in fact denote different models of care.

A true collaborative-care model is different from simply co-locating a psychiatrist in a primary care clinic, which is what is usually meant by integration. "What makes collaborative care unique is that a team of clinicians from different disciplines, including psychiatry, work together, screening patients, tracking their progress, and making sure they improve over time," Raney explained. "The psychiatrist works closely with a care manager on a consultative basis for a caseload of patients and is readily and immediately available to primary care physicians in a way psychiatry has never traditionally been."

Following her experience in the IHS, Raney moved to Durango, Colo., where she started a family and began working for the next 13 years as medical director of a community mental health center for Axis Health System.

Lori Raney, M.D.

Lori Raney, M.D., urges psychiatrists to look to their own community health centers and hospitals for ways in which they can contribute their expertise to the care of patients in primary care and those with chronic medical conditions.

It was in 2006, she said, that the leadership of Axis became very interested in the then-nascent integrated-care movement. The catalyst was a widely disseminated finding that individuals with severe mental illness were dying on average 25 years earlier than the general population.

"That was a wake-up call that got the attention of a lot of mental health centers," Raney said. It demonstrates the shared and mutually reinforcing interests—of both the primary care and mental health sectors—that is driving the integration of the two. Just as psychiatrists have an opportunity to assist in the management of depressive and anxiety disorders among patients in primary care settings (and among those with multiple, chronic medical conditions), so the mental health sector needs to incorporate the skills and expertise of primary care to monitor, manage, and treat metabolic disease and other chronic medical conditions among the population with severe and persistent mental illness.

INTEGRATED CARE
Putting Together the Puzzle

Going 'Full Bore' Into Collaborative Care

In 2007, Raney said Axis went "full bore" into collaborative care, and she became the consultant psychiatrist for a Federally Qualified Health Center and a School Based Health Center. In 2011, she helped design and open the new Cortez Integrated Health Care Clinic, bringing primary and mental health care under one roof.

"My office is literally in the primary care suite, so I am right there with the primary care doctors seeing my patients with severe mental illness but also providing consultation to primary care and behavioral health providers as questions come up," she said. "I can walk out of my office and into an exam room with a primary care clinician and help that clinician with a patient if needed. And I do that quite frequently."

Today, Raney continues an eclectic practice doing plenty of what looks like traditional psychiatry along with varieties of consultative, integrated, and collaborative care. "My current practice is a mix of things," she said. "I see my patients in the community mental health center, but I also go to a federally qualified primary health care center where I work as a consultant psychiatrist on a collaborative care team. I do a lot of consultation with the behavioral health care and primary care providers, and I do educational meetings on a monthly basis. And I do some consultative work to school-based health clinics."

Raney also has a small private practice in the community.

She emphasized that the opportunity to fashion a collaborative practice according to a clinician's own setting, circumstances, and personal interests should be one of the attractions of the integrated-care movement—and a source of comfort to clinicians who may think that traditional one-on-one psychiatry is going to disappear.

It won't. "This is one of the important things—that collaborative care can be a part of what you do, or all of what you do," Raney told *Psychiatric News*. "For most of us, it is part of what we do."

She urges psychiatrists to make use of a growing number of resources for learning how to do collaborative care; at this year's APA Institute on Psychiatric Services in Philadelphia in October, there will be some 20 workshops and symposia on the subject. Also, she recommended that psychiatrists look to their own community health centers and hospitals for how they can contribute their expertise. "A hospital psychiatrist can be thinking, 'there's a handful of patients with congestive heart disease and other chronic medical conditions and comorbid psychiatric illness that are high utilizers of health care resources—how can I help with these patients?' "

Psychiatrists Urged to Consider Retraining

She also urged psychiatrists to think about retraining in general medical skills. At APA's annual meeting in San Francisco in May, Raney organized a symposium titled "Primary Care Skills for Psychiatrists."

"It was in the afternoon on the last day of the meeting, and we thought no one would show up," she said. "But it was an overflow crowd of around 250 psychiatrists, and we couldn't get everyone in a room that accommodated 77."

For the profession in general, Raney said that the collaborative-care movement is an opportunity to address the perennial problems of training a sufficient workforce. "We will never have enough psychiatrists and will never talk enough young people into entering our field," Raney said. "So we need to think in new ways about how to use our workforce to meet the needs of the population. I personally find this work to be incredibly rewarding because I am able to utilize and extend my expertise in a way that I never have before." PN

APA has posted a number of resources on integrated care for members on its Web site at http://www.psychiatry.org/practice/professional-interests/integrated-care.

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.

PROFESSIONAL NEWS

Is It Time to Retire Paper Drug Labeling?

FDA-approved information about drugs for health professionals and patients is already available electronically on the Internet. Do we still need the paper pamphlets stuffed in drug packages?

BY JUN YAN

Ten years ago, the Food and Drug Administration (FDA) issued a set of regulations, known as the "electronic labeling rule," to require manufacturers to submit drug labeling information electronically to the agency, so that FDA-approved drug information can be accessible on the Internet and through electronic medical record systems.

Today, this electronic labeling system exists in parallel with the old paper-based system, creating potential redundancy and inconsistency. Whether paper labeling for medications should be eliminated is a topic of debate, with no consensus among industry, regulators, pharmacists, physicians, and patient advocates, according to a report by the Government Accountability Office (GAO) released July 8.

In the regulatory context, drug labeling refers to FDA-approved prescribing information (also known as the package insert), whose target readers are health care professionals who prescribe and dispense medications; the patient package insert, which is given to patients when they receive the drug; and the Medication Guide, which is also intended for patients and specifically required for certain drugs deemed to pose high safety risks.

Drug labeling in this context does not refer to the information printed on the cartons and containers of drug products.

The content of each drug labeling, which includes the drug's indications, dosage, efficacy, pharmacology, and warnings and precautions, must be approved by the FDA. Manufacturers are required to update the approved labeling content to the FDA's electronic labeling depository within 30 days of approval of a new drug or a revision to the previously approved labeling. The approved labeling is then posted on the FDA's dedicated Web site at http://labels.fda.gov and the National Library of Medicine's DailyMed Web site at http://dailymed.nlm.nih.gov/dailymed.

Drug manufacturers and others have advocated eliminating paper labeling, leaving electronic labeling as the sole source of this information. This would ensure that only the most current FDA-approved labeling information is publically available soon after a labeling change is made. Paper labeling cannot be updated, printed, and distributed promptly, resulting in potential inconsistency between the electronic labeling and still-circulating paper labeling.

Revisions to drug labeling occur often and may include new indications, newly recognized side effects, and added safety warnings. As more drugs are getting approved by the FDA under the condition of postmarketing safety studies or surveillance, labeling changes have increased in the past few years. FDA officials told the GAO that there were 747 labeling changes in 2010, 975 in 2011, and 1,357 in 2012.

Electronic labeling information is easier to read, as it is subject to a minimum font-size requirement and can be easily enlarged on a computer screen. The font size on a paper package insert is limited by space and tends to be very small.

Other advantages of electronic labeling cited in the report include convenience of searching for specific information and ease of translation into other languages.

Nevertheless, the GAO report outlined objections to substituting paper labeling with an electronic format. FDA officials told the GAO that eliminating paper labeling will require certain federal regulations, which currently require prescribing information to be "in or with" the drug packaging, to be rewritten. Pharmacies are concerned that the potential cost and liability of printing and providing labeling information to patients will be shifted from the drug manufacturers to pharmacists. Patient advocates say that not all patients have access to the Internet or are able to find the right information easily.

The GAO examination of the impact of completely switching to electronic labeling was mandated by the Food and Drug Administration Safety and Innovation Act of 2012. PN

"Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of Its Exclusive Use" is posted at http://www.gao.gov/assets/660/655760.pdf. The FDA's electronic labeling rule and guidance to industry is posted at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072331.pdf.

RESIDENTS' FORUM

Residents Will Be Ambassadors of Medical Technology

BY DANIEL KARLIN, M.D.

My training in medical informatics leads me to be almost infinitely optimistic about the idea of electronic medical records (EMRs), while my experience in an array of training environments continuously reminds me how far we are from the ideal.

Even as our technological systems move toward meaningful use and the financial compensation that accompanies adopting those systems, we as physicians often find ourselves frustrated with the usability of existing systems and with the sometimes intrusive tasks that accompany them. Checking a box labeled "no heart failure" for each patient discharged from an inpatient psychiatric unit because the entire hospital tracks heart-failure compliance metrics can feel both inane and burdensome.

We have the technological capacity to radically improve health care, yet if misused, it can dramatically disrupt workflow, breach privacy, slow care, and annoy users; is it any wonder that satisfaction with EMRs is a topic of constant debate? Yet in that discussion, it seems we lose sight of the basic promises and pitfalls of the inevitable insinuation of technology into our practices; the potential value that can come from (albeit forced) reexamination of workflows.

In my experience, trainees and early career psychiatrists can play a critical role in realizing the value of technology in clinical settings.

Where is the value of technology added? A primary advantage is increased fidelity. A properly stored electronic record is not as susceptible to modification, loss, or accidental destruction as the equivalent paper record, and it does not suffer from the curse of unreadable handwriting. Younger physicians are more accustomed to accessing information via computer and have a strong sense of how best to present and organize data. We found resident input invaluable in the creation of our new electronic consult/liaison note at Tufts Medical Center. Design suggestions and process leadership from residents created a note that is more usable and readable and forms the basis for a hospitalwide model.

Ease of access is another benefit. Electronic storage and retrieval means that information can be viewed and entered from whatever location is desired. Young physicians have pioneered mobile access to the medical record, driven by their familiarity with mobile technology and their desire to use it to improve their practice.

Perhaps most importantly, EMRs allow "reusability" of data. This refers to the ability to ask questions of the stored information that are different from the purposes that prompted its original recording. These data can be repurposed for any number of secondary tasks: clinical decision support, patient registries, quality improvement, safety monitoring, and research.

This has dramatically shrunk the time of traditional chart reviews from weeks to seconds and expanded the number of patients from hundreds to thousands or more. Learning psychiatry with these techniques has a transformative effect that is tangible: with the push of a button, clinicians can examine their prescribing habits and access information on intervention patterns not easily evident in paper charts. Young psychiatrists are learning to move this information to the forefront of their quality improvement efforts.

Psychiatrists in training are particularly able to evaluate the match between problems and technological solutions.

see ***Residents' Forum*** *on page 14*

Daniel Karlin, M.D., recently completed his chief residency at Tufts Medical Center, where he will remain as an assistant professor of psychiatry, associate residency training director, and director of psychiatry informatics.

PROFESSIONAL NEWS

High Rates of Mental Illness Associated With Gang Membership

A study of gang members raises the question of whether targeted efforts to address mental disorders in this group would reduce their involvement in antisocial behaviors, including violence.

BY MARK MORAN

Gang membership and involvement in gang violence should be routinely assessed in young men presenting to health care services with psychiatric morbidity in urban areas with high levels of gang activity.

That's the take-home message from a study appearing online in *AJP in Advance* July 12 that showed extraordinarily high rates of mental illness among young male gang members in Great Britain.

The study found rates of psychosis, antisocial personality disorder, alcohol dependence, and anxiety, among other disorders, far in excess of the expected prevalence in the general population.

"No research has previously investigated whether gang violence is related to psychiatric illness, other than substance misuse, or if it places a burden on mental health services," said lead author Jeremy Coid, M.D., of the Forensic Psychiatry Research Unit, Queen Mary University of London, in a statement. "Here we have shown unprecedented levels among this group, identifying a complex public-health problem at the intersection of violence, substance misuse, and mental health problems among young men."

Coid and colleagues conducted a cross-sectional survey of 4,664 men aged 18 to 34 in Great Britain using random location sampling, oversampling men from areas with high levels of violence and gang activity.

Respondents completed a questionnaire that incorporated questions from several tested instruments for measuring psychopathology—the Psychosis Screening Questionnaire, the Structured Clinical Interview for *DSM-IV* Personality Disorders Screening Questionnaire, the Hospital Anxiety and Depression Scale, the Alcohol Use Disorders Identification Test, and the Drug Use Disorders Identification Test.

Participants were asked if they had ever deliberately attempted to kill themselves. They were also asked if they were currently taking any prescribed psychotropic medications, had consulted a medical practitioner over the prior 12 months for mental health problems, had ever seen a psychiatrist or psychologist, or had ever been admitted to a psychiatric hospital.

Finally, they were asked about gang membership and involvement in violence, including whether they had been "in a physical fight [or] assaulted or deliberately hit anyone in the past five years."

They were paid 5 pounds British for their participation (about $7.55 U.S.).

Of the total sample, 3,284 (70.4 percent) reported that they had not been violent in the past five years, 1,272 (27.3 percent) said they had assaulted another person or been involved in a fight, and 108 (2.1 percent) said they were currently a member of a gang.

> "Replication of these findings in the U.S., with more direct methods for assessing psychopathology, is important. . . ."

Nejron Photo/Shutterstock

For the purposes of analysis, participants were divided into three mutually exclusive groups according to their answers: (1) nonviolent men—participants reporting no violent behavior over the past five years and no gang membership; (2) violent men—those reporting violence over the past five years but no gang membership or involvement in gang fights; and (3) gang members.

Results show a marked gradient with psychiatric morbidity and service use infrequent among nonviolent men but increasing progressively from violent nonmembers to gang members. Of the 108 gang members surveyed, 85.8 percent had an antisocial personality disorder, 67 percent were alcohol dependent, and 25.1 percent screened positive for psychosis.

In addition, about 57 percent were drug dependent, 34 percent had attempted suicide, and nearly 59 percent had an anxiety disorder.

Regarding psychiatric service use, 27.1 percent said they had consulted a medical professional about symptoms, and 20.7 percent acknowledged a psychiatric admission. Twelve percent said they had consulted a psychiatrist, and 15.9 percent had received a psychiatric medication.

As a result of their findings, "it is important that physicians and other health professionals assess gang membership in young urban men," the researchers said. "Risk of relapse and failed intervention are elevated among those who return to gang activities, and gang members should be helped to understand the risks to their mental health."

Commenting on the study to *Psychiatric News*, past APA President Paul Appelbaum, M.D., chair of the APA Committee on Judicial Action, called the report a pioneering study of psychopathology among gang members. Appelbaum is the Dollard Professor of Psychiatry, Medicine, and Law and director of the Division of Law, Ethics, and Psychiatry at Columbia University.

"Their study raises, but cannot answer, the question of whether targeted efforts to address mental disorders in members of gangs might reduce their involvement in antisocial behaviors, including violence," he said. "However, replication of these findings in the U.S., with more direct methods for assessing psychopathology, is important for at least two reasons: (1) the self-reported rates of psychopathology are so high that one must wonder about the accuracy of gang members' responses—screening instruments based on self-report often identify cases that would not qualify for a formal diagnosis; and (2) whether British gangs differ in some systematic way from their American counterparts that would result in elevated rates of mental disorders is unclear." PN

"Gang Membership, Violence, and Psychiatric Morbidity" is posted at http://ajp.psychiatryonline.org/article.aspx?articleID=1712526.

Key Points

A survey of British men showed very high rates of mental illness and psychiatric service utilization in young male gang members.

- 85.8 percent of gang members indicated symptoms of an antisocial personality disorder.
- Two-thirds were alcohol dependent.
- One-fourth of gang members screened positive for psychosis.
- Only a small percentage had received psychiatric care or a psychiatric medication.

Bottom Line: Gang membership and involvement in gang violence should be routinely assessed in young men presenting to health care services with psychiatric morbidity in urban areas with extensive gang activity.

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 .

COMMUNITY NEWS

Treatment-Law Evaluation Shows That Investment Pays Off

An exhaustive research project shows that mandated outpatient mental health treatment is effective and can cut costs to the state providing it.

BY AARON LEVIN

A program of court-mandated assisted outpatient treatment (AOT) in New York appears to reduce the costs allocated for mental health services, according to a study posted online in *AJP in Advance* July 30.

The reduction in costs reflected fewer repeated episodes of expensive inpatient psychiatric treatment as patients instead received outpatient care and appropriate medications, said Jeffery Swanson, Ph.D., a professor of psychiatry and behavioral sciences at Duke University, and colleagues.

Jeffery Swanson, Ph.D.

"Cost is important," said Swanson in an interview with *Psychiatric News*. "Even if people conclude that there is some benefit to outpatient treatment, it doesn't seal the deal if it's too costly."

Cost was just one issue that led to the current research by Swanson's group. The first version of New York's AOT law (often referred to as "Kendra's Law") was passed in 1999 and included a provision for evaluation by the state's Office of Mental Health. That assessment of the law's impact was positive but "fiercely contested," in Swanson's words, by those concerned either with its possible expense to the state or by civil libertarians who argued that the mandated treatment was overly coercive to patients.

That controversy led to a legislative requirement for an independent evaluation when the law was reauthorized in 2005. The task was assigned to a consortium of researchers led by Swanson and colleagues from Duke, the Policy Research Associates in Delmar, N.Y., Harvard Medical School, and the University of Virginia. Additional funding was provided by the MacArthur Foundation.

The study compared a sample of 520 AOT participants in New York City and 114 from Albany, Erie, Monroe, Nassau, and Rensselaer counties with 255 voluntary users of intensive community-based treatment in the same areas. The AOT patients had to be at least 18 years old, unable to live safely in the community, and with a history of violence and at least two recent hospitalizations or incarcerations.

"The vast majority of AOT patients receive their order when in involuntary treatment, and it gets them into [outpatient] treatment," added Swanson's colleague Marvin Swartz, M.D., also a professor of psychiatry and behavioral sciences at Duke.

After patients started AOT, hospitalizations decreased, while use of case management, assertive community treatment, other outpatient services, and psychotro-

see ***Evaluation*** *on page 14*

New York's AOT Experience

In day-to-day practice, New York's system of assisted outpatient treatment (AOT) is a multifaceted affair.

The AOT infrastructure does not directly provide mental health services, explained psychiatrist Ryan Bell, M.D., J.D., medical director of the Steve Schwarzkopf Community Mental Health Center in Rochester.

Ellen Dallager

Bell works closely with Monroe County AOT coordinator Kim Butler, M.S.W., whose staff arranges for court-mandated evaluations and sends patients designated for AOT to outpatient clinics like Bell's.

"The success of the system depends on the coordinators," he said. "If they're good, the patient does not see the process as punitive."

Once AOT is indicated, Butler explains to the patient, "We think you need extra help, and I'm here to help coordinate your care." She and Bell discuss with the patient how that help will be provided, which may mean housing assistance or work in the courts, as well as medication and therapy.

Butler puts in the extra hours needed to follow patients wherever they are in the community, Bell said. "We want to create a relationship. They have to believe that you want the best for them, to be healthy but not to punish them."

Earlier in his career, Bell worked in other states with forms of AOT but where resources were limited. "You can have court-ordered treatment, but you have to have treatment to send people to," he said. The added clinical and social-service resources provided by the legislature are critical, said Bell.

New York recently amended the law to permit AOT for up to 12 months rather than the original six months. That may reflect findings from a study led by Jeffrey Swanson, Ph.D., that patients who remained in the program for at least seven months had better outcomes (see story above left).

The effort pays off for many patients, said Bell, recalling the words of one who told him: "Assisted outpatient treatment made me get the help I needed until I wanted the help I needed."

Physician Payment Sunshine Act Now Makes Company Gifts Public

The first stage of the Physician Payment Sunshine Act (PPSA) is now in effect. Medication and device manufacturers are required to collect and track transfers of payment and ownership information to physicians.

In general, you will be publicly reported if you accept any of the following paid for directly or indirectly by a pharmaceutical or medical-device manufacturer:

- A meal
- A book or publication
- Other items of value

While these transactions are not illegal, the PPSA requires the pharmaceutical or medical-device manufacturer to report any physician who receives these or other items of value after July 31 to the Centers for Medicare and Medicaid Services (CMS) so that CMS can make the physicians' names and their acceptance of a gift public on a CMS Web site. Regulations implementing the PPSA are complex, and APA encourages members to take the following steps:

- If you have not already done so, register immediately at CMS's Open Payments Web site at http://go.cms.gov/openpayments, so you can receive timely notifications of reports in which you may have been mentioned, following manufacturers' submission of reports to CMS. Being registered with Open Payments will also allow you to quickly dispute any erroneous information contained in manufacturers' submitted PPSA reports.

- Participate in APA's webinar on Thursday, September 12, at noon Eastern or Pacific time. APA's general counsel and deputy director of regulatory affairs will explain the PPSA, including the law's exceptions and consequences. There will be an opportunity for Q & A as well. Look for registration details in the *Psychiatric News Update* e-mail newsletter. (If you do not receive this newsletter, send an e-mail to cbrown@psych.org.)

- Ask before taking a meal, book, gift, or other item of value whether this is a "reportable" transaction until you further understand the rules.

The next stage of the PPSA goes into effect next year. On March 31, 2014, manufacturers and group purchasing organizations (GPOs) must report the data to CMS for 2013. Beginning in August 2014, CMS must provide physicians with consolidated reports of all manufacturers' and GPOs' reports for the prior calendar year in which they are named. Physicians may access these reports through a Web site portal maintained by CMS and will have 45 days to review the report and, if necessary, initiate disputes with the applicable manufacturer or GPO.

The law, passed by Congress as part of the Affordable Care Act, is landmark legislation that seeks to enhance transparency of financial interactions between certain manufacturers and physicians and teaching hospitals. PN

APA has posted a number of resources to help members become familiar with the new law. They can be accessed at psychiatry.org/sunshineact. Among them is a downloadable brochure on the PPSA and frequently asked questions.

COMMUNITY NEWS

Several Issues Differentiate MH Care in Rural, Urban Youth

Rural children tend to receive the same attention as urban children for serious mental illness, but disparities remain regarding treatment in their less seriously ill peers.

BY AARON LEVIN

Maria Dryfhout/Shutterstock

Children with high psychiatric impairment who live in rural areas are just as likely as their urban counterparts to be diagnosed and treated for mental health conditions, but rural children with less-acute impairment are less likely to be diagnosed with a psychiatric disorder than are children in urban areas (the exception is attention-deficit/hyperactivity disorder [ADHD]).

Once diagnosed, though, rural children tend to receive prescriptions significantly more often and counseling less often than their urban peers, said Jennifer Lenardson, M.H.S., David Hartley, Ph.D., and colleagues in a new report from the Maine Rural Health Research Center at the University of Southern Maine in Portland. The center has produced a number of reports on mental health in recent years.

"This is an important study that replicates findings from the same source that found that rural adults with depression are less likely to receive any or adequate counseling compared with their urban counterparts," said John Fortney, Ph.D., a professor in the Department of Psychiatry at the University of Arkansas for Medical Sciences and an investigator at the Central Arkansas Veterans Healthcare System, in an interview with *Psychiatric News*.

The Maine researchers drew on data from the Medical Expenditure Panel Survey (MEPS) conducted from 2002 through 2008, covering 41,359 urban and 8,432 rural children aged 5 to 17. Respondents' interview information was verified by additional contacts with providers. The Columbia Impairment Scale was used to identify mental health problems.

The observed variation in mental health impairment—29.8 percent in rural areas vs. 24.8 percent in urban ones—might seem small but translates to almost 450,000 children with mental health impairment in the rural population, a significant difference epidemiologically and clinically, said Fortney, an expert on rural mental health who was not involved with the Maine study.

Higher rates of poverty, public-insurance coverage, and mental health impairment may account for these differences, suggested the authors.

Overall rates of psychiatric diagnoses were similar in both settings. The exception was ADHD rates, which were higher in rural areas (6.2 percent vs. 5.1 percent). About 8 percent of rural children received a prescription for a psychiatric medication, compared with 6.4 percent of urban children.

Whether lower rates of diagnosis among children with subacute mental health problems indicate a need for treatment is not clear, the researchers noted. "[T]he lack of mental health specialty providers in rural areas means there is, in many cases, no provider available to determine whether treatment is indicated."

Developing tools to help primary care clinicians or school counselors assess children's needs and suggest referral options might be one way to overcome some of these differences, suggested the authors.

Shortages of mental health specialists in rural areas have left treatment in the hands of primary care providers, who are more likely to prescribe medications than to provide counseling or psychotherapy.

Rural children with "likely" psychiatric impairment received counseling as often as urban youngsters, suggesting that the few available mental health providers in rural areas are focusing on delivering services to those most in need, said Fortney. "This suggests that rural providers are doing a good job of reaching those with the most need."

Families with a preference for pharmacological treatment may not experience disparities in care because the study found no rural-urban differences in receipt of psychotropic medications, he said.

"The bad news is that most kids with likely mental health impairment were not diagnosed or were not receiving any mental health treatment," said Fortney. "This suggests that access to services needs to be improved in both urban and rural areas."

Strategies used in rural areas are likely to be very different than those in urban areas, however.

"In urban areas where there are [many] mental health specialists, a public-awareness campaign might be used to encourage treatment seeking," Fortney suggested. "In rural areas, the strategies should focus on supporting primary care providers in their treatment of mental health disorders."

The study was funded by the Office of Rural Health Policy, Health Resources and Services Administration of the U.S. Department of Health and Human Services. PN

"Patterns of Care for Rural and Urban Children With Mental Health Problems" is posted at http://muskie.usm.maine.edu/Publications/MRHRC/WP49-Rural-Children-Mental-Health.pdf.

Residents' Forum

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They are intimately familiar with the work of psychiatry and its many guises, yet free to see beyond entrenched workflows and patterns. They are aware of the increasing role of technology in their lives, often embracing it, yet wary of it too. They are aware that a new app or EMR is just a tool that, when applied appropriately, may help them with fundamental aspects of their lives and work. The cautious acceptance that they have struck with the technology in their personal lives matches the ideal relationship with the increasingly technology-driven psychiatric workplace.

I don't believe it is possible to overstate residents' role in embracing the potential benefits of technology, proactively defining its use and scope, and carefully interweaving it to balance risks and rewards.

Engagement in these processes does not require extraordinary technical knowledge or training; rather it is born of interest, cautious optimism, open-mindedness, and a willingness to engage in metaclinical thinking—to consider the recording, collection, and use of the information that emerges from our clinical encounters as another area where we should work for continual improvement. It has been my role in pushing toward this ideal that fuels my optimism. PN

Evaluation

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pic prescription fills increased, they noted.

On average, annual costs per patient in the New York City sample declined from $104,753 to $52,386 in the second year after discharge to AOT. Average annual costs in the other counties fell from $104,284 to $39,142.

"The costs of AOT are an investment," Swanson told *Psychiatric News*. "The state spends less, and the savings can be reallocated across systems."

Concerns that services for voluntary patients would be crowded out when resources were shifted to AOT participants proved true only in the short run, he said. Thanks to the state's allocation of an additional $35 million to expand capacity, service access for both groups eventually equalized.

Those added resources are critical if an AOT system is to work properly, said Swartz. New York will have to maintain that financial commitment to continue the same level of services. Other states contemplating a similar approach to mandated outpatient treatment will have to commit to similar levels of support to make AOT effective. PN

"The Cost of Assisted Outpatient Treatment: Can It Save Money?" is posted at http://ajp.psychiatryonline.org/article.aspx?doi=10.1176/appi.ajp.2013.12091152.

COMMUNITY NEWS

Ruth Peterkin/Shutterstock

Abundant Sunshine Isn't Only Reason To Practice Psychiatry in Puerto Rico

Puerto Rico is a paradise in many ways, and its residents appreciate psychiatric care. But several factors make it a challenging setting in which to practice.

BY JOAN AREHART-TREICHEL

Anyone who has vacationed on the island of Puerto Rico was undoubtedly enthralled by Flamenco Beach; Mosquito Bay, where the water glows aquamarine by moonlight; the lush El Yunque rainforest; and the Spanish colonial buildings in Old San Juan.

But what would it be like to live in Puerto Rico and practice psychiatry there? Splendid in many ways, psychiatrists who are natives of Puerto Rico attest. Yet it is not without serious challenges, they add.

"It is spring all year; the beaches are only 30 minutes away!" Juan Fumero, M.D., reported during a recent interview with *Psychiatric News*. In addition to being an adult psychiatrist in private practice in Puerto Rico, Fumero is on the medical faculty of one of the two major psychiatric hospitals in Puerto Rico.

Juan Fumero, M.D.

Juan Fumero, M.D.: The diversity of patients adds to the enjoyment of practice.

"Our island is composed of different cultures—native, and a lot of influence from Europe and the United States," said Fumero. "So we are very diverse. And this diversity adds to our enjoyment in working with patients."

"We Puerto Ricans tend to be social, to spend a lot of time with our extended families, and to receive a lot of support from them," Lelis Nazario, M.D., chair of psychiatry at the University of Puerto Rico, commented. "I also like our warm climate and the beaches. I loved living in Boston during my psychiatry residency, but I couldn't take the weather!"

When you treat patients in Puerto Rico, you also get to know their families and sometimes even their neighbors when family members or neighbors accompany them to doctor visits, observed William Julio, M.D. Julio is a geriatric psychiatrist and treasurer of the Puerto Rico Psychiatric Society. "Around Christmas, they will bring you fresh fruits or vegetables from their gardens. It is one of the pleasant things about treating patients here."

Fumero also noted that there are "many academic activities for psychiatrists and other health professionals. Also, we have several research centers that create an opportunity to obtain Hispanic data about mental disorders. Such data are particularly valuable in light of the growing Hispanic population in the United States."

William Julio, M.D.

William Julio, M.D., with his wife, Karen Pujals, who is completing her doctorate in psychology, and their son, William Daniel.

Resources Can Be Lacking

Puerto Rican psychiatrists could, however, benefit from more resources, Julio indicated. "When I was doing my residency in New York City, there were many resources for patients and so many professionals working in an interdisciplinary way." That is not always the case in Puerto Rico.

Fumero concurred: "We lack specialized care for conditions such as dual diagnoses and eating disorders. We only have a couple of psychiatry training programs, so we don't have enough psychiatrists. There are probably around 450 of us on an island with some 4 million people."

Because of a paucity of funds, "it is difficult to hire psychiatrists in an academic environment," Nazario noted.

Managed care constraints are also a big headache for psychiatrists in Puerto Rico, Anisssa Hernandez, M.D., asserted. "I don't feel that I can practice freely, because a third person is telling me how to do it." Hernandez completed her psychiatry training eight years ago. Today she is in private practice and affiliated with psychiatric hospitals in Puerto Rico.

Julio has the same complaint about dealings with managed care. Most of his patients are enrolled in the Medicare Part C Program, which is essentially managed care Medicare. Consequently, he noted, he often has difficulty obtaining authorization to give patients medications or to hospitalize them.

Moreover, reimbursement by Medicare, Medicaid, and health insurance companies is lower in Puerto Rico, a U.S. territory, than in the rest of the United States for the same type of treatment, Julio pointed out. "As a result, many of our psychiatrist colleagues have moved to the mainland to practice." And it is not just psychiatrists, but other types of physicians in Puerto Rico who are frustrated by the difficulties of practicing on the island, Fumero added.

Discrimination a Long-Time Problem

Indeed, discrimination has been a problem in Puerto Rico for 500 years, ever since it was a colony of Spain, then of France, then of Holland, and finally of the United States, Hernandez observed.

see ***Puerto Rico*** *on page 23*

APA INSTITUTE

Why Should Residents Go to APA's Institute On Psychiatric Services?


Samuel Borges Photography/Shutterstock

BY WIL BERRY, M.D.

Psychiatry residents offer testimonials about why attendance at APA's fall institute is important for both career and collegiality reasons.

When I attended my first Institute on Psychiatric Services (IPS) last year, which was held in New York City, I was struck by the contrast to the larger, bustling APA annual meeting I had attended. The IPS was smaller, intimate, easy to navigate, and, to me, more interesting. If the annual meeting was stadium rock, this was like a great group performing in a smaller venue; I felt as though I could get close to the stage, maybe even get to know the band.

From a trainee perspective, this accessibility may be the most exciting part of the IPS, which is being held this year in Philadelphia October 10 to 13. While like the annual meeting, the schedule is filled with interesting sessions, workshops, and lectures, and more, you don't have to shoulder crowds, and each event tends to be more personal. The speakers—who are internationally recognized leaders in psychiatry—are available to answer questions and get to know trainees personally, contributing to the institute's general tone of mentorship.

Beyond easy access to speakers, the IPS encourages psychiatry residents to get directly involved in the action by chairing sessions or being presenters. Ultimately though, this accessibility is worth only as much as what is being accessed, and this is the other area in which the IPS shines. It is a conference with a long tradition (this coming one is the 65th!) and an emphasis on public, community, and clinical psychiatry. It is thus suffused with a spirit of spontaneity and intellectual energy—often driven by the many events sponsored by the American Association of Community Psychiatrists—that make being a young psychiatrist in attendance such a rewarding experience.

As for Obianuju "Uju" Obi, M.D., M.P.H., a psychiatry resident at Columbia Univeristy, this will be her first IPS, and this is what she told me: "I am very excited about the opportunity to partake in a 'must be there' event. The program appears to be jam-packed with innovative ideas and debates that will stimulate the mind and stimulate the field of psychiatry. This year's theme of 'Transforming Psychiatric Practice, Reforming Health Care Delivery' is timely and includes sessions that will help APA members gain a better understanding of how health care reform will impact them. Often in medical school and in residency, didactics are focused on epistemological theory and accumulation of evidence-based medicine, but the IPS, although a part of this strain of teaching is included, is also focused on moving the field into the community and finding ways of doing so through experimentation via a mix of lectures, workshops, symposia,

*see **Institute** on page 25*

Wil Berry, M.D., is chief resident in the New York University Department of Psychiatry.

FDA Approves Antipsychotic to Treat Bipolar Depression

The Food and Drug Administration opens an additional door for treating depression in patients with bipolar I disorder.

BY AARON LEVIN

The Food and Drug Administration (FDA) has approved new indications for the atypical antipsychotic medication lurasidone (Latuda; manufactured by Sunovion) in the treatment of patients with depressive episodes associated with bipolar I disorder. The approval covers use of the medication alone and in conjunction with lithium or valproate.

"Its utility as monotherapy and adjunctive therapy places the drug in a select position in an area with few other medication choices," said Roger McIntyre, M.D., a professor of psychiatry and pharmacology at the University of Toronto, in an interview with *Psychiatric News*. Lurasidone is already approved for use in patients with schizophrenia.

Clinical trials indicated that the drug appeared to cause fewer metabolic problems or weight gain than other drugs in its class, said McIntyre, who formerly consulted with Sunovion's Canadian affiliate but does not do so now. "It's as close to weight-neutral as possible."

The existing alternatives, quetiapine (Seroquel) and an olanzapine/fluoxetine combination (Symbyax), both induce weight gain, and the latter is also difficult to titrate, said McIntyre.

At APA's 2013 annual meeting in San Francisco in May, McIntyre called weight gain a "brain hazard," because obesity in bipolar patients lessens chances for recovery from manic episodes and increases their risk for depression.

In two six-week clinical trials submitted to the FDA, lurasidone was tested over its complete daily dosing range of 20 mg to 120 mg, and average weight gain was 0.3 kg with monotherapy and 0.1 kg with adjunctive use, said psychiatrist Antony Loebel, M.D., chief medical officer at Sunovion. Trial results were presented in poster sessions at APA's 2012 annual meeting and have been submitted for publication.

The new indication should help fill an unmet need for more treatment options that clinicians can use in patients with bipolar depression, Loebel told *Psychiatric News*. There currently is a mismatch between symptoms and treatment choices, he said. "Most medications approved by the FDA for bipolar disorder address the manic stage. However, patients spend most of their time in the depressive phase and find it more distressing but have fewer options for treatment."

The clinical trials recorded effects on body mass index, lipids, glucose, and insulin. The trials included patients with bipolar I disorder who had a history of depression and at least one manic episode, said Loebel.

As with other drugs in its class, the new indications come with black-box warnings noting that lurasidone is not approved for treating elderly patients with dementia-related psychosis. And as is the case with antidepressants, it also includes warnings that clinicians need to monitor patients closely for suicidality as treatment begins. Lurasidone is not approved for use in patients under age 18. PN

More about treating depression in bipolar I patients is posted at http://psychnews.psychiatryonline.org/newsarticle.aspx?articleid=1702075.

CLINICAL & RESEARCH NEWS

Study Finds Less or No Medication After Psychosis Fosters Recovery

A long-term study adds to evidence that recovery from psychosis is possible, and the key may lie in using less antipsychotic medication after a psychotic episode ends.

BY JOAN AREHART-TREICHEL

If remitted first-episode psychosis patients reduce their antipsychotic medication dosage or discontinue it, they will experience a higher relapse rate than remitted first-episode patients who continue on a maintenance antipsychotic medication dosage, studies have found. However, all of these studies were limited to two years or less.

Now a new study that lasted seven years has confirmed that result—a higher relapse rate during the first two years in the lower-dosage/discontinuation group than in the maintenance group. But this new study has also found something surprising: whereas the former group had the same rate of symptom remission at seven years as the latter group, it had significantly greater functional improvement and recovery at seven years.

The study was published online July 3 in *JAMA Psychiatry.* The lead researcher was Lex Wunderink, M.D., Ph.D., a psychiatrist at the University Medical Center Groningen in the Netherlands and part of the Early Intervention in Psychosis team at Friesland Mental Health Services.

The focus of this study was a total of 103 patients with antipsychotic-medication-induced remission from a first-episode psychosis. After six months of sustained remission, they were randomly assigned for 18 months to an antipsychotic medication dose reduction or discontinuation strategy or to an antipsychotic medication maintenance strategy.

After that, treatment was at the discretion of the individuals' clinicians. Then five years later, or seven years from the start of the study, the researchers conducted an interview with each subject to determine outcome.

The subjects were evaluated on the number of relapses they had experienced during the previous five years. Relapses were retrospectively assessed by interviewing the patients and checking their information with that of their attending clinicians, their medical records, and their admission and prescription data. Relapse was defined as a symptom exacerbation during at least one week.

The Positive and Negative Syndrome Scale (PANSS) was used to measure subjects' symptoms during the previous six months. The Groningen Social Disability Schedule (GSDS) was used to measure disability in various domains—self-care; housekeeping; family, partner, and peer relationships; community integration; and work function. In addition, subjects were evaluated for recovery-related factors such as experiencing both

see ***Recovery*** *on page 26*

Reducing, Stopping Medication Associated With Better Outcome

At seven-year follow-up, symptom remission was comparable in the antipsychotic dose reduction/discontinuation group and the antipsychotic maintenance group. But functional improvement was significantly better in the former. And the rate of recovery (which included both symptomatic remission and functional improvement in a subject for at least six months) was significantly greater in the former.

	Dose reduction/ discontinuation (n=52)	Maintenance treatment (n=51)	Total sample (n=103)
Recovery	21 (40.4%)	9 (17.6%)	30 (29.1%)
Remission			
Symptomatic	36 (69.2%)	34 (66.7%)	70 (68.0%)
Functional	24 (46.2%)	10 (19.6%)	34 (33.0%)

Source: Lex Wunderink, M.D., Ph.D., et al., *JAMA Psychiatry,* July 3, 2013

Combining Insomnia, Depression Treatment May Improve Outcome

In people with both depression and insomnia, determining which disorder surfaced first may be key to improving clinical care.

BY LYNNE LAMBERG

Studying the timing of emergence of symptoms in people with both depression and insomnia may help identify differences in patients' clinical presentation and aid treatment decisions, according to experts at the joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society in Baltimore in June.

Insomnia is both a risk factor for depression and a symptom of depression, noted Rachel Manber, Ph.D., a professor of psychiatry and behavioral sciences at Stanford University School of Medicine.

Manber reported preliminary findings from the multisite Treatment of Insomnia and Depression (TRIAD) clinical trial, for which she is the principal investigator.

TRIAD, funded by the National Institute of Mental Health, seeks to determine whether combined treatment of major depressive disorder and insomnia improves depression outcome.

Started in 2008, TRIAD has enrolled about 150 participants, Manber told *Psychiatric News*. Recruitment recently concluded. Treatment will continue through the end of this year at Stanford, Duke University, and the University of Pittsburgh.

Participants receive 16 weeks of treatment with the antidepressants citalopram, sertraline, or desvenlafaxine. Choice of medication is based on the individual's previous medication use, response, and tolerance. Participants also receive either cognitive-behavioral therapy for insomnia (CBTI) or desensitization psychotherapy for insomnia.

A pilot study, published by Manber and colleagues in the journal *Sleep* in April 2008, found that augmenting an antidepressant medication with brief, symptom-focused CBTI helped alleviate both depression and insomnia in individuals with both disorders.

Sergey Ivanov

About half the TRIAD participants reported at baseline that their insomnia started before their current depressive episode, Manber said. The remainder said their insomnia started at the same time as their depression or afterward. Members of both groups reported comparable severity of insomnia and depression.

In the first group, Manber said, insomnia may be independent of depression and require separate treatment.

If insomnia has emerged as a symptom of depression, she added, one might expect that treating the depression adequately will prompt the insomnia to resolve. While that often occurs, insomnia persists in some patients even after the depression remits. People who toss and turn often come to view the bed as a cue for poor sleep, she noted, and develop an insomnia disorder that needs additional sleep-focused treatment.

TRIAD participants who reported having insomnia before they experienced depression had higher scores on the Childhood Trauma Questionnaire,

see ***Insomnia*** *on facing page*

Pieces of Autism Puzzle Slowly Coming Together

Research into autism is advancing slowly but steadily on several fronts, even as patients and their families await signs of progress on treating the illness.

BY AARON LEVIN

Autism was first described and named by Leo Kanner, M.D., in a classic 1943 paper, but most research into the condition has occurred only since 1980.

Yet three decades of investigation have only just begun to reveal an understanding of the disorder's origins and possible treatments, said Jeremy Veenstra-VanderWeele, M.D., an assistant professor of psychiatry, pediatrics, and pharmacology at Vanderbilt University.

Several obstacles have frustrated progress in research, said Veenstra-VanderWeele in a recent interview with *Psychiatric News* on the Vanderbilt campus.

Too often, intervention studies have used small sample sizes or failed to include control groups, he said. Outcome measures are hindered by difficulties in self-reporting from patients, so parent or teacher reports must serve as substitutes.

Medications used to treat autism are not specific to the disorder, he said. "In schizophrenia, you have antipsychotics, but for autism, there's no 'anti-autistic.' " In contrast, some behavioral treatments, especially early intensive behavioral intervention, based on the work of B.F. Skinner and others, do show promise.

"This nonspecific treatment has the best evidence for working and the biggest potential benefit for treating autism—at the moment," he said. The caveat comes because information is accumulating steadily on risk factors for autism spectrum disorder, any of which might someday open channels for treatment. For example, an increasing number of genes have been shown to influence autistic phenotypes, although so far any single gene contributes barely 1 percent to 2 percent of the risk.

"The good news is that we can take these risk factors into mice, rats, and zebra fish and see what they do in the brain," he said.

Signaling Pathways Provide Clue

Studies of Fragile X by Veenstra-VanderWeele and others point to particular signaling pathways (metabotropic glutamate-5 receptors) that appear to change in individuals with autism. They are now testing medications that "tune down" responsivity in the pathway.

Other pathways like GABA-B agonists have been tested as well, but conclusions have been hampered by outcome measures that show positive effects on the global impression of severity but not on individual measures of symptoms.

In another line of attack, a National Institutes of Health study of intranasal oxytocin found better emotional communication and attention to social cues in autism subjects. Those effects will now be tested by researchers at the University of North Carolina, Harvard, Vanderbilt, and Mount Sinai School of Medicine to see if improvements in social functioning can be replicated in real-world settings, he said.

Internet Touts Unproven Treatments

Complicating matters for both researchers and clinicians is the availability of multiple unproven "treatments" promoted over the Internet.

"With autism, it's particularly striking that there are many proposed treatments in use, but there's so little data," he said. "Thousands of children are taking intranasal oxytocin or SSRIs or were given hyperbaric oxygen or chelation therapy without any data on how well they worked."

A further check on initially positive interventions comes by tapering patients off medications to see whether the benefit is specific, he explained. "That's rarely done with freelance treatments."

The changes to the definition of autism in *DSM-5* will require adjustments for researchers, Veenstra-VanderWeele noted. Diagnoses formerly joined are now separated, changing how populations are defined. "*DSM-5* eliminates language that was confounding, instead of lumping groups that were different," he said.

Ongoing studies can still use *DSM-IV* criteria to study the now-eliminated Asperger's syndrome, he said, although new studies will use *DSM-5,* especially as they relate to verbal impairment and cognitive function.

In the clinic, though, *DSM-5* won't make a lot of difference in how the disorder is diagnosed, he pointed out. Adjustments in diagnostic terminology can help patients retain access to care. A former Asperger's patient can now be described as having autism with a high IQ and good verbal ability and thus be able to access services that he or she might not have previously.

As for the future, a better understanding of the social brain may lead to better medications that work in conjunction with other therapies, said Veenstra-VanderWeele. Drugs—such as atypical antipsychotics, SSRIs, or oxytocin—that tackle individual symptoms may each help some subset of patients, but are not transformative.

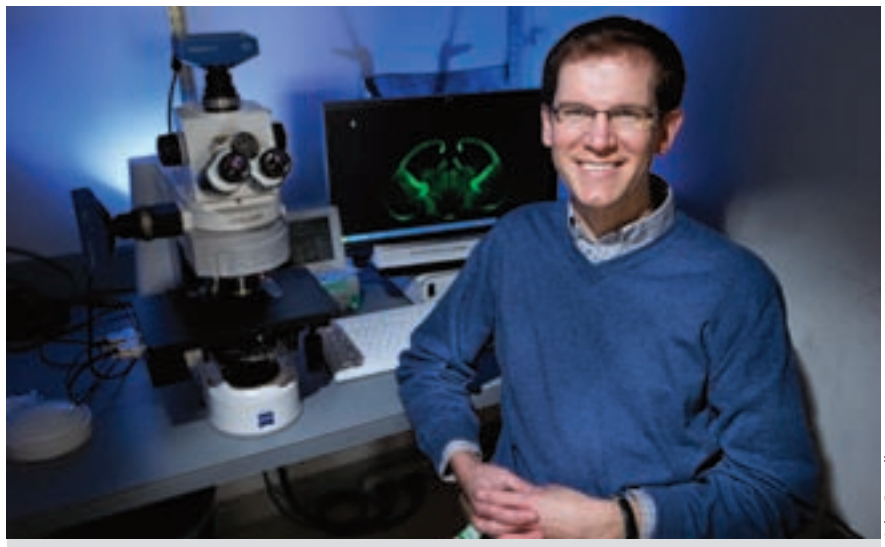
"Every time I go to the clinic, I struggle when I have to tell families that we may not have anything that will actually help their children, but we can still support them as we try what we know," he said.

Treating autism will mean integrating many disciplines, said Veenstra-VanderWeele. "As we gain a better understanding of the biology of autism, we shouldn't discard teaching and psychology," he said. "Medications may emerge that put the brain in a better place to learn, but we still need treatments that work together."

Finally, researchers, clinicians, and families can learn something from children with autism.

"There are some children with autism who society says are extremely impaired, but who are reasonably happy," he said. "Maybe we can help them construct a good, reasonable life within the context of their capacities, so they can have a meaningful job and experiences in life that are joyful, and we should be pleased by that success." PN

Information about the Vanderbilt Kennedy Center's Treatment and Research Institute for Autism Spectrum Disorders is posted at http://kc.vanderbilt.edu/triad/.



John Russell

Medications may someday be available that improve autistic children's ability to learn, but until then clinicians need to integrate interventions from several disciplines, according to autism specialist Jeremy Veenstra-VanderWeele, M.D.

Insomnia

continued from facing page

indicating childhood adversity such as sexual or other physical abuse. This surprising finding, Manber said, raises the possibility that events that disrupt sleep in childhood may foster both insomnia and depression later on.

In another report on TRIAD findings at the sleep meetings, Andrew Krystal, M.D., a professor of psychiatry and behavioral sciences at Duke University School of Medicine, analyzed participants' responses to the Ford Insomnia in Response to Stress Test (FIRST).

The FIRST asks respondents about their likelihood of sleeping poorly after a bad day at work or an argument, before leaving on vacation, and in other situations. It assesses trait-like vulnerability to developing insomnia under stress.

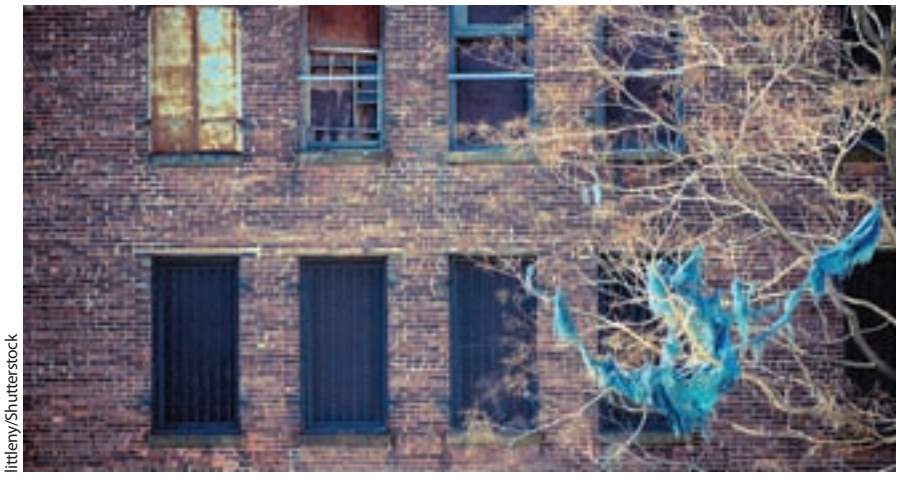
"We were attempting to test a bias in the field that is not empirically based," Krystal said, "that insomnia occurring in people with depression is driven by the depression and that there is a diminished etiologic role of factors that precipitate and/or perpetuate insomnia where depression or other conditions are not present.

"Our analysis appears to speak against that bias," he said. It suggests that the same factors that seem to precipitate and/or perpetuate primary insomnia—which include dysfunctional beliefs and attitudes about sleep, worrying about sleep, stress, and anxiety—play a comparable role in insomnia that develops in people with depression.

The findings, he said, provide the first evidence that there is a trait vulnerability to developing insomnia under stress among at least some patients with major depression, similar to that in people with primary insomnia. PN

Information about the TRIAD study is posted at http://clinicaltrials.gov/ct2/show/NCT00767624 and http://www.triadproject.org/. An abstract of "Cognitive Behavioral Therapy for Insomnia Enhances Depression Outcome in Patients With Comorbid Major Depressive Disorder and Insomnia" is posted at http://www.journalsleep.org/ViewAbstract.aspx?pid=27114.

CLINICAL & RESEARCH NEWS



littleny/Shutterstock

Mentally Ill People Often Live In Disadvantaged Areas

Structural inadequacy—a measure of the number of vacant or demolished buildings and gas-service shutoffs—was the variable accounting for the greatest disparity in neighborhoods.

BY MARK MORAN

The neighborhood environment in which people with severe mental illness live may be a factor in whether they are able to integrate into the community successfully.

But a study analyzing neighborhood geography in Philadelphia published in the August *Psychiatric Services* showed that neighborhoods with a large concentration of adults with serious mental illness had higher levels of physical and structural inadequacy, drug-related activity, and crime than comparison neighborhoods.

Likewise, higher levels of physical and structural inadequacy, crime, drug-related activity, social instability, and social isolation were associated with a higher concentration of people with serious mental illness in the neighborhood's adult population.

Among the factors assessed, the biggest disparity was in the physical and structural characteristics of neighborhoods, with those where seriously mentally ill people lived having a larger number of vacant buildings and properties, gas-service shutoffs, and demolished buildings.

"These findings establish the importance of further exploration of the degree to which environmental factors may act as either barriers or facilitators to the functioning and participation of persons with serious mental illness," said principal author Mark Salzer, Ph.D., of the Department of Rehabilitation Sciences at Temple University and colleagues in their study report. "This is especially true of physical characteristics, for which the largest effects were observed. Studying these factors. . .could do much to help identify new areas of intervention intended to promote the functioning and integration of persons with serious mental illness."

Data for people who used mental health services for treatment of a serious mental illness were obtained under a business-associate agreement with Community Behavioral Health (CBH), a publicly run managed care organization that manages behavioral health services for Medicaid recipients in Philadelphia. The dataset consisted of 15,246 individuals aged 18 to 64 who were eligible for Medicaid throughout 2000 and who had a claim for at least one inpatient or two outpatient Medicaid-reimbursed services from 1997 to 2000 that were related to diagnoses of an affective disorder or schizophrenia.

The addresses of individuals with serious mental illness in the CBH dataset were matched to the U.S. census block group in which their residence was located. Then a comparison group of 15,246 randomly generated address points representative of the general Philadelphia population was created and matched with the corresponding census block group.

A wide range of variables and characteristics for each census block group was assessed. A set of 22 variables measuring several broad areas—crime, physical and structural inadequacy, economic and housing market values (home values, rent levels, median income, and lien sales for delinquent property taxes), and social isolation (proportion of industrial properties, commercial properties, one-person households, households recently moved within one year, and renter-occupied properties indicating less opportunity for social interaction)—was selected from these data sources to compare across the different census block groups.

The analysis showed that individuals with serious mental illness lived in neighborhoods with more serious crime, higher amounts of delinquent crime, and far more drug-related activity than the neighborhoods of the comparison group. But the biggest disparity distinguishing the neighborhoods where people with severe mental illness lived was in the areas' physical and structural characteristics.

Neighborhoods where those with mental illness tended to live were also likely to have higher social instability and a higher probability for social isolation, but the difference was not statistically significant.

Salzer and colleagues said their findings are important because they provide a foundation for future research on neighborhood and environment and functioning of people with severe men-

see ***Disadvantaged*** *on page 25*

FROM THE EXPERTS

Solution-Based Therapy Assuming More Prominent Role

BY ANNE BODMER LUTZ, M.D., B.S.N.

As physicians shift care from a disease-centered to a patient-centered clinical method, there is a need for a compatible counseling paradigm. Solution-focused therapy is a competency-based model that minimizes emphasis on past problems and failings and instead focuses on patient strengths and resources. The solution-focused approach often results in briefer lengths of treatment and thus is an essential skill for physicians, and in particular for psychiatrists, whose services are in short supply and high demand.

A solution-focused conversation begins with problem-free talk inviting patients to discuss parts of their life that are going well, the strengths and talents that contributed to this, the people they most appreciate in their life, and what they most appreciate about them. These people are critical relationship resources through which patients develop their solutions.

Compliments are used frequently and function to support what is working well in the patient's life, thereby setting up the expectation for future success. Direct compliments such as "Wow!" candidly praise patients on something they have said or done. Indirect compliments such as "How did you do that?" are in the form of a question and allow patients to describe their own successes.

Diagnosing and amplifying positive differences, also known as exceptions, are other tools used in the solution-focused approach. Paying attention to times that patients are doing things differently, in a positive way when the problem did not occur or was less severe, are called positive differences or exceptions. These positive differences require the closest attention and signify solutions already occurring within the patient's experience. For example, pausing the conversation when a patient identifies a time when he or she was sober, felt happier, or got along better with a spouse by asking "Was this different?" "How was it different?" "Was it helpful?" "How was it helpful? " and "How did they do it?" will amplify the patient's success.

Solution-focused scaling questions ask patients to rate their goals, satisfaction, coping strategies, successes, motivation for change, and confidence on a numerical scale from 1 to 10. They help to formulate goals and measure myriad patient issues from a multitude of perspectives. They are constructed in such a way that the number 10 highlights a positive aspect such as satisfaction that their problem is solved. The use of scales can further amplify a patient's success by asking what makes the number not

see ***From the Experts*** *on page 24*

Anne Bodmer Lutz, M.D., B.S.N., is the director of training at the Institute of Solution-Focused Training and an assistant professor at the University of Massachusetts. She is the author of *Learning Solution-Focused Therapy: An Illustrated Guide,* which may be preordered from American Psychiatric Publishing at http://www.appi.org/SearchCenter/Pages/SearchDetail.aspx?ItemId=62452. Members are eligible for a discount.

SSRI May Prevent Depression In Patients With Certain Cancers

Since antidepressants have been demonstrated to prevent depression in individuals with head and neck cancer, could they also prevent depression in individuals with other kinds of cancer?

BY JOAN AREHART-TREICHEL

For what appears to be the first time, researchers have shown that a medication can prevent depression in patients being treated for a particular type of cancer.

The trial was headed by William Lydiatt, M.D., of the Department of Otolaryngology–Head and Neck Surgery at the University of Nebraska, and findings were published online June 20 in *JAMA Otolaryngology-Head and Neck Surgery.*

Up to half of patients undergoing treatment for head and neck cancer are known to develop major depressive disorder. Thus, Lydiatt and his colleagues decided to conduct a large double-blind, placebo-controlled clinical trial to see if antidepressant treatment could prevent depression in such patients.

One hundred and forty-eight nondepressed patients starting treatment for head and neck cancer were randomized to receive either the SSRI antidepressant escitalopram or a placebo for 16 weeks. They were evaluated for depression during a three-month follow-up period.

Twenty-five percent of the subjects in the placebo group developed depression, while only 10 percent in the escitalopram group did—a significant difference. Also, subjects who had received the antidepressant reported a better quality of life than those getting a placebo at each time point throughout the study.

The findings have important clinical implications, the researchers pointed out.

For example, antidepressant treatment might especially benefit head and neck cancer patients who receive radiation treatment, since subjects in the study who received radiation had a higher rate of depression than did the subjects who received surgical treatment. "The observed relationship between radiation dose and development of depression in this study suggests a direct link between radiation and depression," the researchers said. "Even though this study was not powered to detect differences in depression rates for placebo compared with escitalopram within the surgery or radiation groups, we observed that fewer patients taking escitalopram developed depression in both groups, and the difference was larger in the radiation group. The mechanism behind these differences in rate will require further investigation."

In addition, antidepressant treatment might prevent not only depression, but also suicide in patients with head and neck cancers, since previous research has shown that such patients have a risk of suicide three times greater than the general population and two times greater than cancer patients in general.

Finally, antidepressant treatment might be able to prevent depression in patients with cancers other than head and neck cancer. "Determining which cancer patients will become depressed is nebulous," the researchers noted. "Social support, sex, and history of depression are all potential predictors of a major depressive disorder. However, they are not consistent and are not exclusive. Because of the lack of a clear method to predict who will become depressed, the use of a prevention paradigm seems to offer considerable benefit at an acceptable risk."

"This study is important in many ways," Michelle Riba, M.D., a professor of psychiatry and a psycho-oncologist at the University of Michigan and a former APA president, told *Psychiatric News*. "It looked at a population of patients, those with head and neck cancer, where depression is a very prominent and serious condition. It studied a way to help patients in a preventive paradigm, using escitalopram. Furthermore, even though the study wasn't designed to study quality of life, patients in the escitalopram arm had an overall improved quality of life during the study and three months consecutively after the cessation of the drug therapy."

The study was funded by the National Institute of Mental Health and the University of Nebraska Medical Center. PN

An abstract of "Prevention of Depression With Escitalopram in Patients Undergoing Treatment for Head and Neck Cancer" is posted at http://archotol.jamanetwork.com/article.aspx?articleid=1699734.

When Parents Focus on Weight, Kids' Eating Disorder Risk Rises

Parents need to be careful in discussing weight issues with their children in light of findings suggesting that such discussions can increase the risk of developing an eating disorder.

BY JOAN AREHART-TREICHEL

Jaimie Duplass/Shutterstock

At a workshop concerned with binge eating last year, Chevese Turner, the founder and chief executive officer of the Binge Eating Disorder Association, said that when she was little, her mother had anorexia nervosa and talked a lot about dieting. Both factors encouraged Turner to start binge eating, she believes (*Psychiatric News,* June 1, 2012).

Now a new study reinforces Turner's assumption. It has found a link between parents' discussion of weight with their adolescents and the adolescents engaging in unhealthy eating behaviors such as dieting, laxative use, and binge eating.

The study, headed by Jerica Berge, Ph.D., an assistant professor of family medicine and community health at the University of Minnesota, was published online June 24 in *JAMA Pediatrics.*

Berge and her colleagues first surveyed approximately 2,400 adolescents from 20 public middle schools and high schools in the Minneapolis/St. Paul area to determine whether they were overweight and whether they engaged in unhealthy eating behaviors. The adolescents came from diverse racial and ethnic backgrounds and were mostly from low, low-middle, and middle socioeconomic backgrounds.

The researchers then surveyed about 3,500 parents of the adolescents—50 percent of the adolescents had both parents surveyed—to learn whether the parents discussed weight or healthful eating with their youngsters and to see if there were any associations between parental conversations on these topics and adolescents engaging in unhealthy eating behaviors.

They found that such a relationship did exist.

For example, adolescents who were not overweight and whose mothers talked about healthful eating were significantly less likely to diet than were nonoverweight adolescents whose mothers talked about weight (27 percent versus 35 percent).

Similarly, overweight adolescents whose mothers talked about healthful eating were significantly less likely to diet than were overweight youngsters whose mothers talked about weight (40 percent versus 53 percent).

When their fathers talked about weight, nonoverweight adolescents were significantly more likely to diet than when their fathers did not discuss weight (33 percent versus 22 percent).

The findings were comparable for overweight youngsters. When their fathers talked about weight, 64 percent dieted, whereas when fathers talked about healthy eating, only 49 percent did.

As for the prevalence of binge eating, it was significantly lower among nonoverweight adolescents whose mothers didn't discuss weight than among nonoverweight adolescents whose mothers did discuss it (4 percent

see ***Weight*** *on page 25*

DSM-5 SELF-EXAM

Trauma and Stress-Related Disorders

In *DSM-5*, the stressor criterion (Criterion A) is now explicit for acute stress disorder and posttraumatic stress disorder regarding whether the trauma was experienced directly, witnessed, or experienced indirectly. Also, the *DSM-IV* A2 Criterion regarding the subjective reaction to the traumatic event (for example, experiencing "fear, helplessness, or horror") is eliminated. Adjustment disorder served as a residual diagnostic category in *DSM-IV* for individuals who exhibit clinically significant distress but do not meet diagnostic criteria for a more discrete disorder. In *DSM-5,* it is reconceptualized as a heterogeneous array of stress-response syndromes that occur after exposure to a distressing (traumatic or nontraumatic) event. Whereas for posttraumatic stress disorder there were three major symptom clusters in *DSM-IV* (for example, reexperiencing, avoidance/numbing, and arousal), in *DSM-5* there are now four symptom clusters because the avoidance/numbing cluster is divided into two clusters: avoidance and persistent negative alterations in cognition and mood. The *DSM-IV* childhood diagnosis of reactive attachment disorder had two subtypes: the emotionally withdrawn/inhibited subtype and the indiscriminately social/disinhibited subtype. In *DSM-5*, these subtypes are defined as distinct disorders: reactive attachment disorder and disinhibited social engagement disorder.

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_10.pdf. The book, available in October, 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. Posttraumatic stress disorder in *DSM-5* is placed within which of the following diagnostic categories?
a) anxiety disorders
b) depressive disorders
c) trauma and stress related disorders
d) other disorders
e) Section III

2. *DSM-IV* required which type of reaction to the trauma as a criterion for the diagnosis that has been eliminated in *DSM-5*?
a) fear, helplessness, or horror
b) insomnia or hypersomnia
c) avoidance
d) foreshortened sense of the future
e) flashbacks

3. Two years after the death of her husband, a 70-year-old woman is seen for complaints of sadness, anger regarding her husband's unexpected death after a heart attack, a yearning for him to come back, and unsuccessful attempts to move out of her large home because of her inability to remove his belongings. Which diagnosis would best fit this patient?
a) major depressive disorder
b) posttraumatic stress disorder
c) adjustment disorder
d) personality disorder
e) normative stress reaction PN

CLINICAL & RESEARCH NEWS

Aaron Levin

What the rest of the world considers recreation, Vanderbilt University's Blythe Corbett, Ph.D., sees as a laboratory and a new place to test therapy for children with autism.

Children With Autism Learn From Peers in Novel Program

"All the world's a stage," said Shakespeare, and sometimes the stage is a good place for kids with autism to prepare for the world.

BY AARON LEVIN

A theater and a leafy playground are unlikely venues for research or therapy, yet those are laboratories for Blythe Corbett, Ph.D., an assistant professor of psychiatry at Vanderbilt University.

"Those places can inspire psychologists and psychiatrists to think beyond our traditional therapies and utilize novel treatments and experiences that are out there but that we are not thinking about," said Corbett in a recent interview in her campus office.

The large, tree-shaded playground nearby contains a maze of elevated purple-painted steel walkways. Corbett sends 8- to-12-year-old children out to play in groups of three. One child has been diagnosed with autism. The second, matched for age and gender, is a typically developing young person ("peer" in Corbett's terms) who acts as a control subject. The third is a "confederate," a sort of junior research assistant, recruited by Corbett for his or her "natural social abilities," she said. All the children carry small radio units with microphones in belt pouches so researchers can listen to and record their conversations. The confederates also wear earphones to listen for instructions from the researchers.

Sometimes the kids just play, but at key moments, Corbett or one of her graduate students radios the confederates to engage the others in play or to have them break off and play again on their own.

The interactions are recorded by four video cameras, and the research team codes the children's behavior for later analysis.

"During free play, the children with autism act much like the typically developing kids," said Corbett. "But when a confederate solicits play, they are less cooperative, show less verbal initiation, and are more likely to say 'no thanks' when invited to play."

Corbett's team has used the system for several years, initially to observe behavior for its own sake. Now they also use play as a means to measure changes first seen in treatment in a real-world setting.

For instance, following a two-week intervention, children with autism demonstrate a level of play similar to their pretreatment levels, she said. She has found that to improve their play, those children often need someone familiar—a child with whom they've played before—to serve as a "bridge" to a new play situation.

"They need a little bit of scaffolding to transfer a newly learned social skill to another environment," she said.

With adolescents, Corbett uses the electronic game Wii rather than the playground as a play setting. She also runs the adolescents through a social-stress test—giving a speech before an audience of impassive adult authority figures in white lab coats.

"The teens with autism do not find it stressful, as measured by a rise in cortisol, but the typically developing ones do, which is appropriate," she said. "Perhaps the adults are not perceived as stressors by those with autism."

A second avenue of research leads Corbett back to an earlier career as a professional actor and writer.

She created the SENSE Theatre, a two-week, half-day summer camp, when she was at the University of California, Davis. (SENSE stands for Social Emotional NeuroScience Endocrinology.) Children and adolescents with autism learn acting techniques such as role-playing, improvisation, and performance from trained, typically developing youth actors. The youth actors and camp counselors also blend in classical behavioral strategies such as positive reinforcement or extinction to improve the social skills of the children with autism.

Corbett writes the scripts herself. She can modify a character or expand or shorten a child's role, depending on the young actor's capabilities.

"We usually think of theater as a recreational activity, but actors learn to master social communication and think flexibly, the very skills that people with autism need to learn," she said.

Pre- and post-tests of young people in the theater program show an improvement in identification of and memory for faces, ordinarily a problem for children with autism, she noted. There is also an initial rise in stress levels (as measured by cortisol) followed by a reduction as they habituate and adapt to the new environment.

Corbett sees wider lessons in her work for studying and treating children with autism or other disorders.

"When you have a condition in which interaction with peers is impaired, then there is a need for peers to be a part of the treatment," she said. "Children with autism learn from those who matter to them, but also can learn to generalize from those experiences." PN

↗ Information about the SENSE lab at Vanderbilt University is posted at http://kc.vanderbilt.edu/senselab.

Steve Heap/Shutterstock

Puerto Rico

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"And when you are subjugated and don't feel free century after century, that leads to underlying anger, aggression, and depression," she continued, adding that that is evidenced in her patients. "I have observed in my patients how frustrated and disappointed they are by how things are working" on the island, she said.

Another stressor for the people of Puerto Rico is a rising crime rate, Fumero reported. "Many people are afraid, and that just adds to the economic and domestic stressors they are already facing." There are several reasons for this rising crime rate, Julio explained. One is that efforts to secure the U.S. border with Mexico to prevent the illegal entry of drugs have led to drugs being trafficked through Puerto Rico instead. Another reason is that the unemployment rate in Puerto Rico is high—14 percent or 15 percent, about twice that on the U.S. mainland.

The health care reform law could also have an effect on psychiatric care on the island, Nazario said, since "if it affects people in the United States, it will affect us." For instance, if it leads to lower reimbursement rates for psychiatrists, it would be especially hard on Puerto Rican psychiatrists since their reimbursement rates are already low.

"I think the act will impact Puerto Rican psychiatrists who are not board certified, and many are not," said Julio. "The reason why is that after 2015, if you are not board certified, you will not be able to bill Medicare or Medicaid."

Regardless of the impact of the Affordable Care Act on Puerto Rico, the Puerto Rican health care system should be revised, Hernandez maintained. If she could change only one thing about practicing psychiatry in Puerto Rico, it would be to "change the system," she said. "We need a system that allows psychiatrists and health care professionals to practice without having insurance plans interfering."

But even with these hurdles, Puerto Rican psychiatrists love their island, their people, and especially helping their patients. As Hernandez stated, "I try to give them hope, to show them that they have the power within themselves to construct a better world." PN

LETTERS TO THE EDITOR

Telepsychiatry Obstacles Need to Be Removed

This is in response to APA President Jeffrey Lieberman's column titled "Will The Government Do The Right Thing?," which appeared in the July 5 issue.

One quick and easy change that the federal government could make immediately to improve access to psychiatric care is to remove obstacles to telepsychiatry. Psychiatric providers are in short supply in many locations. As a geriatric psychiatrist with experience in providing care by telepsychiatry, I know that it works well and have first-hand experience with these obstacles, and I see no good reason for them to be in place.

One serious obstacle is that the Centers for Medicare and Medicaid Services (CMS) will reimburse providers only for services provided via telepsychiatry if the patient is in a location designated as a rural health professional shortage area (HPSA). Even if the patient is in a mental HPSA that is not also designated a rural one, CMS will not reimburse. This seems very unreasonable; the patients still have very limited access to mental health providers even if not "rural."

The second main obstacle is the unreasonable CMS reimbursement frequency of the subsequent hospital care E/M codes (99231-3), which are limited to one visit every three days; this is inappropriate for inpatients. A new lesser HCPCS code (G0459) was created that can be reimbursed for the days in between, but the 9923X codes should not be limited just because the service was provided via telemedicine. Also, be aware that Medicare HMOs often have even more limitations on telemedicine reimbursements than regular Medicare.

The Telemedicine Promotion Act of 2012 (HR 6719, 112th Congress) introduced by Rep. Mike Thompson (D-Calif.) would likely have remedied most of these unreasonable limitations, but to my knowledge has not yet been introduced in the 113th Congress.

Thank you for your concern in this matter. I would very much like to hear of any progress made in this area.

ANDREW POWELL, M.D.
Cabot, Ariz.

Response from Janice Brannon, M.A., deputy director for state affairs in APA's Department of Government Relations:

Thank you very much for responding to Dr. Lieberman's column. In your response, you indicate that unfettered telepsychiatry could help solve psychiatric workforce shortages and improve access to care—we couldn't agree more. There are still far too many annoying barriers to the daily use of telemedicine. State licensure laws and Medicare reimbursement requirements are two of the largest.

The good news is that private payers and Medicaid in many states are aware of the cost, service, and quality benefits provided by the use of telemedicine and have changed their policies to cover services provided through telecommunication. In fact, approximately 19 states have passed mandates that private insurance must cover and reimburse health care services provided via telemedicine to the same extent as those provided in person. Under Medicaid, approximately 44 states have some form of reimbursement in their programs.

Again, this is the good news on the reimbursement front. The tougher area for change has been Medicare. Despite this program being an early adopter of telemedicine years ago, it has been slow to keep up with the technological and societal changes that make this service delivery method such an accepted norm today.

This is not to say that APA hasn't been an active advocate for telemedicine. Just last year, APA cowrote a letter with the American Telemedicine Association to CMS on a CPT coding issue regarding the elimination of code 90862 for pharmacologic management. CMS's new code did not work for providing telemedicine oversight of patients with mental health diagnoses in rural hospitals who needed to be seen on rounds more than every three days. This collaboration resulted in getting CMS to clarify the code definition and to assign a value to it—a small step forward but a step forward nonetheless.

Now, to your point about CMS's requirement for services to be reimbursed only when provided in areas designated "rural": your timing is impeccable. CMS has recently proposed alterations to its urban/rural definitions for telemedicine. The proposed definitions should extend reimbursable telemedicine services to 1 million more beneficiaries living in large metropolitan areas. The proposed rule was published in the *Federal Register* July 19. We encourage all telepsychiatry advocates to comment on the proposal. As the public and providers' acceptance and use of technology continues to evolve, we must all work together to assure that the government looks beyond the metaphorical walls it has built and "does the right thing."

The proposed rule is posted at http://www.regulations.gov/#!documentDetail;D=CMS-2013-0155-0010; comments may be submitted at the top right side of the page under "Comment Now." PN

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.

From the Experts

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lower. Asking patients what it would take to raise the number by one point helps formulate realistic small next steps toward achieving their goals.

The miracle question is a unique solution-focused question that helps patients construct a vision of their future. The following is a description of the miracle question. "Suppose that tonight after you have done your usual things and have fallen asleep, a miracle happens. The miracle is that the problems that brought you here are solved, but because you were sleeping, you didn't know that it happened. When you wake up in the morning, what do you suppose would be the first thing you would notice that would tell you a miracle has happened and the problems that brought you here are solved?"

This question transforms the patient's attention from the presenting problem to a problem that is solved. It enables patients the freedom to think beyond the problems that seem insurmountable and allows them to identify resources that they may not remember or recognize when their minds are clouded by the problem.

Consider the following case and what solution-focused questions you might ask:

Maria is a 65-year-old Hispanic woman diagnosed with diabetes mellitus, cardiovascular disease, hypertension, and depression. She is on a "boatload" of medications including insulin, multiple heart medications, and sertraline for depression. She is morbidly obese and interested in weight-reduction surgery but cannot get her diabetes under enough control to be a surgical candidate. The surgeons told her that her hemoglobin A1C would have to be at 7 for her to be a surgical candidate. She brought it from 14.9 to 8.5, but was told that this was not good enough. She likes to take drug holidays from all her medications.

Here are some possible questions: Managing all these medications must be very challenging; how have you been able to do this? How else have you managed? There must be a "good reason" for you to take drug holidays? Is it different for you to be interested in weight reduction? How did you come to this decision? What have you tried so far to reduce your weight that has worked for you? You managed to get your HgBA1C down from 14.9 to 8.5; how did you do this? Supposing 10 reflects that you are confident that you will be able to get the surgery, and 1 the opposite, where would you say things are now? What makes it not lower? What would it take to raise it by one point?

Solution-focused therapy is a brief therapy model that is uniquely adapted and easily integrated into patient-centered clinical care. Its language is both hopeful and optimistic. Solution-focused therapy puts ownership of patients' health back into their hands, reminding them of the control, authority, and responsibility they have over their lives. This feels good to patients and physicians alike. PN

References are posted at http://www.psychnews.org/update/experts_3_13.html.

EXCLUSIVE ONLINE CONTENT

APA Announces 2013 Award Winners

Psychiatrists and other individuals who have gone to exceptional lengths to help people with mental illness, conducted groundbreaking research in the field of psychiatry, or provided extraordinary service to APA were honored at the Convocation of Distinguished Fellows and Fellows at APA's 2013 annual meeting in San Francisco in May. The list of honorees and the awards they received are posted at http://psychnews.psychiatryonline.org/newsArticle.aspx?doi=10.1176/appi.pn.2013.8b26.

Right Direction

continued from page 1

in Canton, Ohio. The national coalition oversees corporate group purchases of pharmacy benefits and other services.

The campaign includes an evaluation component, which will be led by Debra Lerner, Ph.D., M.S., a professor at Tufts University School of Medicine.

"Our goal will be to figure out if the program is being used, who uses it, how they use it, and if it has an impact," said Lerner, who is also director of the Program on Health, Work, and Productivity at the Tufts Institute for Clinical Research and Health Policy Studies. Lerner has conducted research on other workplace intervention programs targeting depression.

"Right Direction is an organizational-level effort to raise awareness and educate employees," noted Lerner. "We will look at variables like the numbers screened and treated, but also try to get harder-to-find data on work performance."

Right Direction deploys the tools of modern business, mainly delivered over the Web, to inform human resources personnel and then all employees about depression. These include a Web site, posters, e-mails, and PowerPoint slides. The PHQ-9 serves as a self-administered screening instrument.

The material informs employees about the symptoms of depression and how they are manifested in the workplace, said Clare Miller, director of APF's Partnership for Workplace Mental Health. One message that employees will receive, for example, explains how "reduced interest, low motivation, slowed thoughts, and difficulty making decisions can result in poorer-quality work." Employees are urged to seek help for themselves or their families through medical professionals and their employee-assistance program.

The human resources managers at the corporations that make up Employers Health Coalition and the partnership are now reviewing Right Direction material and planning ways to communicate the information to workers and to integrate the campaign with existing employee-assistance programs and programs of insurers, Miller told *Psychiatric News*.

Several companies will spend the next few months laying this groundwork, then roll out the full campaign during Mental Health Awareness Week in October, said Miles.

If they do, they might make clear to their employees that the burden of depression needn't be, well, unbearable.

Right Direction, a program of APF's Partnership for Workplace Mental Health and the Employers Health Coalition, is supported by Takeda Pharmaceuticals U.S.A. Inc. and Lundbeck U.S. PN

Information about the Right Direction campaign is posted at http://www.rightdirectionforme.com.

Institute

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and innovative programs. Nothing is shied away from as long as there is room for learning!

"The pros and cons for me are that my curiosity will almost certainly be exploited as I attempt to stretch myself thin in attending the varied sessions whose topics include racial stress, addiction and marijuana use, 'bending' diagnostic criteria, prison culture, and even a documentary film by Bud Cleary, a filmmaker with a mental illness. Add to that the gratification of meeting new and established colleagues, and what Wil remarked on—the ability as a trainee to be in the trenches and enjoy an enlightening experience with one another. And to be in Philadelphia, one of the country's oldest cities, is an added bonus. I can't wait!"

The Opening Session keynote address will be delivered by Estelle Richman, a nationally recognized expert on behavioral health services and the recipient of the Harvard University Kennedy School of Government's Innovation Award for her work in the Philadelphia behavioral health system. Invited seminars will provide information on HIV management in psychiatric disorders, career paths for international medical graduates, clinical work with homeless people, among other topics.

A number of special sessions have been planned by APA's Office of Minority and National Affairs on topics such as culturally appropriate psychiatric assessment; suicide screening in general hospitals; and racial stress, coping, and socialization in black families. Also, more than 100 workshops, lectures, and seminars are scheduled, to be presented by a diverse and energetic collection of speakers. All of it is happening in Philly, a city that is, arguably, where community psychiatry began in America.

Whether you're a veteran of academic conferences or have never been to one before, you won't regret a trip to the IPS, and we hope to see you there. PN

More information about the IPS, including online registration, can be accessed at http://www.psychiatry.org/learn/institute-on-psychiatric-services. Save on fees by registering now; advance registration ends September 20.

Disadvantaged

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tal illness. "[T]he still nascent body of research in this area has yet to ascertain the extent to which a worse physical or crime environment may serve as an impediment to community integration of persons with serious mental illness," they noted. "Thus, although it is not possible to draw direct implications from the current study about the impact of neighborhood factors on community integration, the findings . . . provide a broader foundation for future research to identify barriers and facilitators to community participation of persons with serious mental illness. The need for research on the relationship between neighborhood characteristics and community integration is especially important, given that housing interventions for persons with serious mental illness continue their shift away from congregate housing and toward scattered-site independent housing units in the community. . . . Additional research in this area could help refine housing approaches to promote better community integration of persons with serious mental illness." PN

"Comparing Neighborhoods of Adults With Severe Mental Illness and the General Population: Research Implications" is posted at http://ps.psychiatryonline.org/journal.aspx?journalid=18.

Weight

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versus 8 percent).

Similar findings emerged for overweight adolescents. The prevalence of binge eating was 9 percent in youngsters whose mothers didn't discuss weight, but 13 percent in youngsters whose mothers did.

"These findings suggest that parents should avoid conversations that focus on weight or losing weight and instead engage in conversations that focus on healthful eating, without reference to weight issues," Berge and her team concluded. "This approach may be particularly important for parents of overweight or obese adolescents."

Psychiatrists can also "use the results of this study to guide their conversations with parents and adolescents about eating behaviors," Berge suggested in an interview with *Psychiatric News.*

"I think these are important findings," Michael Devlin, M.D., codirector of eating disorders research at the New York State Psychiatric Institute, told *Psychiatric News*. "They support the idea that despite our concerns about obesity and its comorbidities, the most useful health-promotion messages relate to lifestyle and not weight and that weight-related messaging—particularly messages that evoke shame or contribute to stigma—can be counterproductive. The next step would be to examine this cohort, or some similar cohort, over time to examine the longer-term 'hard outcomes' of medical risk factors, such as blood pressure, insulin sensitivity, blood lipids, and others, and the quality of life in groups exposed to weight versus lifestyle-related messages."

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

An abstract of "Parent Conversations About Healthful Eating and Weight" is posted at http://archpedi.jamanetwork.com/article.aspx?articleid=1700514.

Recovery

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symptomatic remission and functional improvement as measured by the PANSS and GSDS for at least six months preceding the seven-year interview.

The initial relapse rates were twice as high in the dose reduction/discontinuation group as in the maintenance-therapy group. But the curves then approached each other and came on par at about three years of follow-up. From then on, the relapse rates did not differ significantly between the two groups.

Moreover, by the seven-year follow-up interview, the dose reduction/discontinuation group had experienced significantly more functional improvement than the maintenance group had. And also by the seven-year interview, 40 percent of the dose reduction/discontinuation group had recovered from their illness, whereas only 18 percent of the maintenance group had—a significant difference.

Results Unexpected

"These findings were quite surprising to all of us," Wunderink told *Psychiatric News*. "We did not expect to find any significant effect of the original treatment strategies after seven years of follow-up, because from the original trial's endpoint to follow-up five years later, the patients' treatment had been completely at the discretion of the attending clinicians, and functional outcome after two years follow-up was not significantly different."

"Of course the results will have to be replicated to change guidelines," Wunderink continued. "But the results show that it might be the best strategy in first-episode patients who are sufficiently free of symptoms during six months (that is, meet remission criteria) to follow a dose-reduction strategy. This strategy will require close monitoring, and if symptoms recur, then the dose will have to be adequately adjusted."

So if after remission is achieved, an antipsychotic dose reduction/discontinuation does promote recovery, how might it do so? One possibility, Wunderink and his colleagues suggested, is that antipsychotics not only counter psychosis, but also compromise important mental activities such as alertness, curiosity, drive, and executive function. Another possibility, they said, is that being in the antipsychotic-reduction/discontinuation group motivated subjects to actively participate in their own recovery.

Maintenance Might Not Be Best Course

"This important study suggests that an antipsychotic dosage reduction/discontinuation (DR) strategy in remitted first-episode psychosis patients might have advantages at seven-year follow-up on recovery and functional remission, but not in symptom remission," Matcheri Keshavan, M.D., a professor of psychiatry at Harvard Medical School and a schizophrenia recovery expert, said during an interview. "These findings raise questions about the benefits of maintenance antipsychotics. [However,] these findings should be considered with caution because of three caveats."

The first, he said, is that the "study defined first-episode psychosis broadly (as schizophrenia or other psychoses). We already know that some patients, such as those with brief psychotic disorders and psychoses not otherwise specified, may do well without long-term antipsychotics. Thus, the findings cannot be generalized to schizophrenias defined narrowly."

The second, he said, is that "some patients in the DR strategy continued to be on medications, albeit at a smaller dose. Thus, it may be best for the clinician to consider a minimum effective dose strategy rather than total discontinuation in many patients."

And finally, he said, "less than half of patients in either strategy had achieved recovery at follow-up, highlighting, as the authors themselves point out, the need for alternative pharmacological, or perhaps psychosocial, interventions."

The research was funded by unconditional grants from Janssen-Cilag Netherlands and Friesland Mental Health Services. PN

An abstract of "Recovery in Remitted First-Episode Psychosis at Seven Years of Follow-up of an Early Dose Reduction/Discontinuation or Maintenance Treatment Strategy" is posted at http://archpsyc.jamanetwork.com/article.aspx?articleid=1707650.

Key Points

- Remitted first-episode psychosis subjects were assigned to either maintenance antipsychotic medication or a dose-reduction/discontinuation of antipsychotic medication. During the next five years, treatment was at the discretion of their physicians. At the end of that time, the dose-reduction/discontinuation group showed a higher rate of recovery than did the maintenance group.
- A schizophrenia expert not affiliated with the study says that "these findings raise questions about the benefits of maintenance antipsychotics" but notes that some of the subjects who received a dose reduction/discontinuation strategy continued on medication, although at a smaller dose. "Thus, it may be best for the clinician to consider a minimum effective dose strategy rather than total discontinuation."
- The lead researcher shares that opinion: "The results show that it might be the best strategy in first-episode patients who are sufficiently free of symptoms during six months (meet remission criteria) to follow a dose-reduction strategy. This strategy will require close monitoring, and if symptoms recur, then the dose will have to be adequately adjusted."

Sleep-Wake Disorders

continued from page 1

brain health and cognitive fitness and prevent cognitive disorders.

The sleep-wake disorders section includes disorders that are not mental disorders, such as narcolepsy, sleep-related breathing disorders, and restless legs syndrome. That's because depression, anxiety, and cognitive impairment often accompany such disorders, Reynolds said. *DSM-5* distinguishes narcolepsy, known to be associated with hypocretin deficiency, from other forms of hypersomnolence.

Sleep-wake disturbances may be a tipoff to underlying medical and neurological disorders, Reynolds noted, including congestive heart failure, Parkinson's disease, and Alzheimer's disease, and may exacerbate these disorders.

As *DSM-5* states, "coexisting clinical conditions are the rule, not the exception." Sleep-wake disturbances at a physiological as well as a behavioral level, Reynolds noted, may be a marker for developing mental disorders. They also may contribute to alcohol and other substance use and abuse and may be associated with use of medications for various illnesses.

Charles Reynolds, M.D.

Sleep-wake disorders may be a sign of a developing mental disorder, says Charles Reynolds, M.D.

The Sleep-Wake Disorders Work Group aimed to boost recognition of the bidirectional relationship between mental disorders and sleep-wake disorders and the need for comprehensive treatment, Reynolds said.

"When I treat a depressed patient who gets better but still complains of insomnia, I know my job is not done," he said. "If I don't treat the insomnia, my patient is at risk for relapse."

This understanding led to a fundamental shift away from the previous classification of insomnia as primary or secondary, he said. The new insomnia disorder section includes comorbid mental disorders and physical conditions that should be addressed in treatment.

The sleep-wake disorders section also includes circadian rhythm sleep-wake disorders, such as delayed and advanced sleep-phase disorders associated with irregular schedules and shift work. Unlike *DSM-IV-TR*, *DSM-5* does not include jet lag. *DSM-5* also covers parasomnias—abnormal events occurring in sleep or sleep-wake transitions—and nightmare disorder.

Work group members sought to incorporate polysomnographic and other validated laboratory-based measures into diagnostic criteria. The use of biological markers, Reynolds said, may help clinch the diagnosis in ambiguous clinical cases.

"Our neuroscience needs to go further," Reynolds stated. PN

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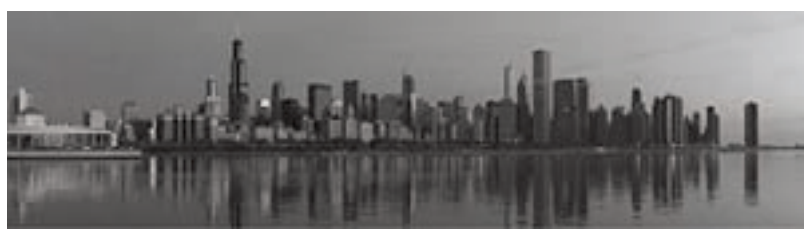

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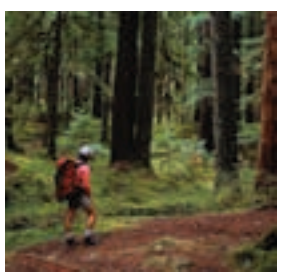

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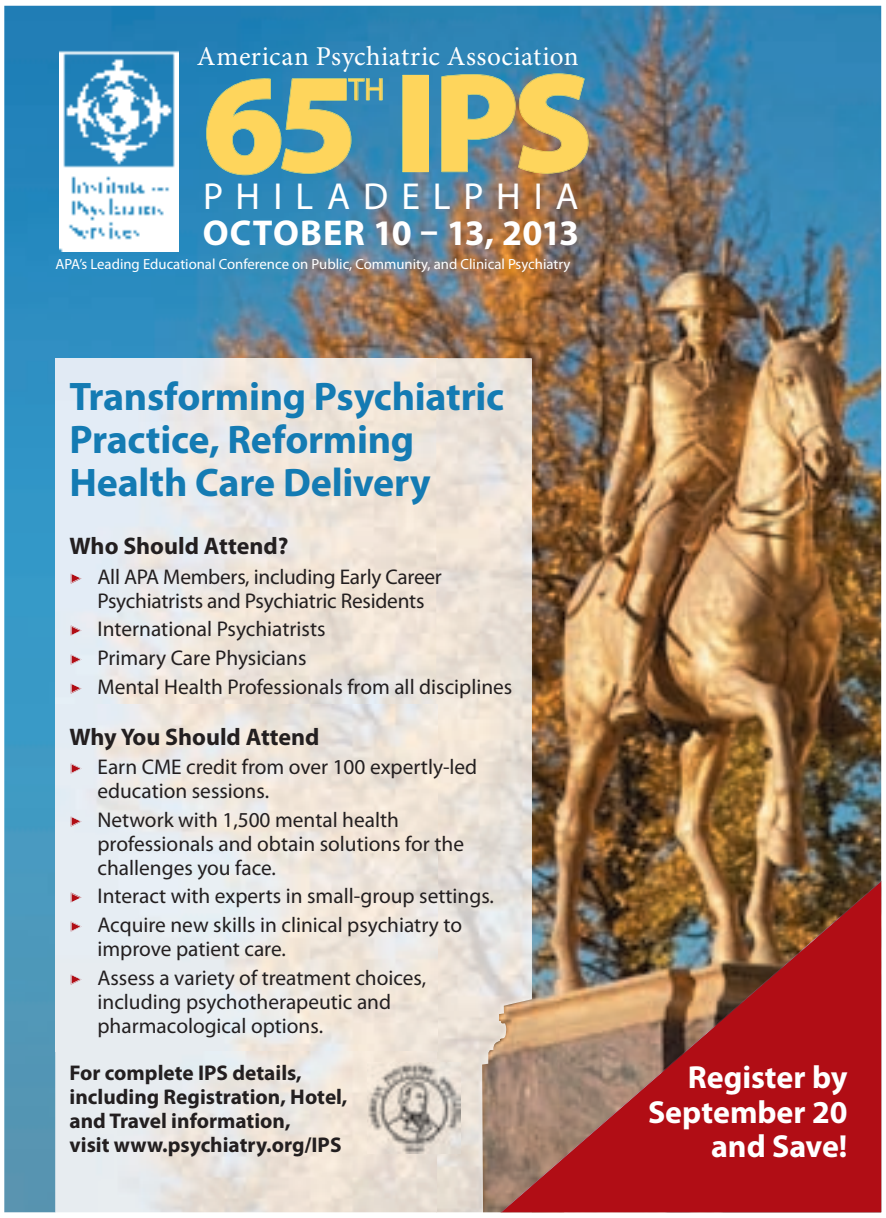

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Adult or child psychiatrist, for FT private outpt. practice in Orange Co., n ear ocean! Paperless EMR, FT staff & mentoring. Must type well! Flexible hrs, high pay, no holidays. New grad, BE or BC ok. Ph: 949-768-2988. Email CV to tms@drkinback.com

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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.

BEAUTIFUL NORTHERN CALIFORNIA POSITION
THERAPEUTIC SOLUTIONS, P.C.
Adult and Adolescent Psychiatrist Needed

- Full-time position, Monday - Friday, 8 a.m.-5 p.m.
- Comprehensive practice with outpatient services, IOP and PHP services, as well as outpatient ECT and TMS.
- Limited office call.
- Very competitive salary with bonus structure included.
- Excellent benefits package.
- Our location offers quality housing prices, little traffic, regional airport, 1½ hour drive to Sacramento, 2 hour drive to Napa Valley, 3 hour drive to San Francisco and the coast.

For further info contact
Pamela Mayhew
Practice Administrator, at:
pmayhew@therapeuticsolutionspc.com.

Adult and youth out-patient psychiatric positions available with Butte County Behavioral Health Department. $150/hour for contracted out-patient positions. Regular help positions also available. We are a HPSA/NHSC-designated County. Please contact Dr. Carolyn Kimura, Medical Director, at 530/891-2850.

COLORADO

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

VIEW THE CLASSIFIEDS ONLINE AT WWW.PN.PSYCHIATRYONLINE.ORG

CONNECTICUT

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.

Full time psychiatrist; 75% work on a 20 bed psychiatric unit, 25% in an adult outpatient service. Stable, collaborative multidisciplinary team in an award winning community hospital. Competitive salary and benefits, reasonable on call; ABPN certified/eligible. Contact robert.grillo@midhosp.org, 860-358-6760.

FLORIDA

Lakeside Behavioral Healthcare
Treatment. Recovery. Hope

Immediate opening in Orlando, Florida. Are you looking for a rewarding and flexible career opportunity in beautiful Central Florida? LOOK NO FURTHER! We are a large comprehensive Behavioral Health Agency and Specialty Hospital committed to providing the highest quality of care to our patients. We are expanding both inpatient and outpatient services and looking for a enthusiastic, dedicated Psychiatric Certified A.R.N.P or Psych Certified Physician Assistant to join our staff. Our benefits and salary are highly competitive and include malpractice insurance, paid leave, additional voluntary compensation for on-call or added weekend and holiday duty if you desire. Florida's beautiful beaches are only 45 minutes away and weather is ideal year around in family friendly Orlando. Visit our website to learn more about our agency @ www.Lakesidecares.org or contact bradd@lakesidecares.org or phone Brad Deaton @ 407.875.3700 Ext. 6469 to set up an interview in person or to receive additional information.

Coastal Behavioral Healthcare, Inc., is seeking a Psychiatrist for a 30 bed adult crisis stabilization unit hospital setting. Requires current licensure by the state of Florida. This is a fulltime forty hour per week position with full benefits and the potential for additional income by participation in the on-call rotation. A competitive salary and excellent benefit package is offered. We are located on the Gulf of Mexico, with beautiful white beaches, in Sarasota, FL e-mail resume to: Judy Brewer, HR Director at jbrewer@coastalbh.org Phone: (941) 927-8900 x 3309 Drug-Free Workplace / EOE

UNLIMITED INCOME. Clearwater, Destin, Jacksonville, Kissimmee, Melbourne, Sarasota, or Winter Park. Consultation practice, full or part-time. NO CALL. Great salary and benefits package based on production. We are a reputable, ethics-based practice with a team approach to nursing home patient care. Call Linda at 866-936-5250.

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.

FORT LAUDERDALE - PLANTATION, FL; PEMBROKE PINES, FL
PRIVATE PRACTICE OPPORTUNITY

AN ESTABLISHED AND VERY BUSY PRIVATE PRACTICE SEEKS BC/BE PSYCHIATRIST TO SEE ADULT, ADOLESCENT, AND CHILD OUTPATIENTS. WE ARE CURRENTLY EXPANDING INTO A MAJOR HOSPITAL SYSTEM, SO THE TIME IS RIGHT! INCOME POTENTIAL IN THE TOP 5%, WITH A STARTING BASE NEGOTIABLE. THE MAJORITY OF PATIENTS ARE SELF-PAY OR PPO. PART TIME OR FULL TIME. PLEASE EMAIL CV TO: PSYCHJOB88@AOL.COM.

Henderson Behavioral Health seeks a Florida licensed psychiatrist to provide psychiatric services at our facility in Ft. Lauderdale, Florida. For more information, please contact Medical Director, Dr. Sahasranaman: 954-731-5100 ext 3058, bsahas@hendersonbehavioralhealth.org, or Recruiter, Jessica Hickman: 954-777-1630, jhickman@hendersonbehavioralhealth.org

GEORGIA

The State of Georgia Department of Behavioral Health and Developmental Disabilities is currently recruiting for board-certified and board eligible psychiatrist to work at one of our six hospitals located throughout the following cities in Georgia: Atlanta, Savannah, Milledgeville, Thomasville, Columbus, Augusta. We have current openings for full-time, part-time and hourly Psychiatrists. Positions are available on both acute and chronic forensic and adult mental health units. All psychiatrists will lead a multi-disciplinary team of professionals providing quality care to both voluntary and involuntary patients. Our state facilities provide academic affiliations and promote academic collaborations, along with an excellent benefits package and competitive salary. Please forward your CV to ncnathaniel@dhr.state.ga.us

Come join our incredible behavioral health team. Come to the Peach State!!!

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)

KENTUCKY

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.

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.

MAINE

Adult Psychiatrist

MaineGeneral Medical Center in Augusta/Waterville, Maine is seeking a BC/BE adult psychiatrist with interest in substance abuse. You will be joining a staff of five employed physicians and four psychiatric mental health nurse practitioners who provide multidisciplinary inpatient, outpatient and consultative services. Work schedule is five eight-hour days. We will have a 30-bed Inpatient program at our new Augusta Campus in November, five Intensive Outpatient Programs, an ACT Team and an outpatient clinic. We also provide consultative support for our inpatient medical and surgical services. We offer excellent benefits including relocation assistance and competitive salary. MaineGeneral is located in scenic central Maine and is a short drive away from ski resorts, lakes and rivers, award-winning golf courses, abundant hiking trails, and the beautiful Maine coast. We are just an hour north of Portland, Maine's largest city, and three hours from Boston.

Send your CV to Lisa Nutter, Physician Recruiter at lisa.nutter@mainegeneral.org or call 1-800-344-6662. Please visit us at www.mainegeneral.org to learn more about our new 2013 Regional Hospital and expansion plans.

CLASSIFIEDS

MARYLAND

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.

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

MASSACHUSETTS

CAMBRIDGE: Outpatient Psychiatrists

Positions available at Cambridge Health Alliance Department of Psychiatry, Harvard Medical School. Full and part time opportunities in adult outpatient services. Outpatient programs consist of multidisciplinary practice teams located at outpatient psychiatry program settings and at local neighborhood medical clinics throughout the Alliance, including specialized services for Latino, Portuguese, Asian, and Haitian patients.

The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School with excellent residencies in adult and child psychiatry. We are committed to improving the health of our communities and seek candidates with particular interest and experience in working with ethnic and minority populations, interest in academic/teaching endeavors, and sensitivity working with under-served multi-cultural populations in a public setting.

Qualifications: BE/BC, demonstrated commitment to public sector populations, strong clinical skills, strong leadership and management skills, team oriented, problem solver. Bilingual and/or bicultural abilities are desirable. Interest and experience with dual diagnosis and/or substance use disorders preferred. Competitive compensation, excellent benefit package. Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. CV & letter to Susan Lewis, Department of Psychiatry, 1493 Cambridge Street, Cambridge, MA; Fax: 617-665-1204.**Email preferred: SLewis@challiance.org.**

Medical Director–Boston/Cape Cod

Pembroke Hospital is seeking a full time Medical Director to join our 115-bed psychiatric facility's Leadership Team. The ideal candidate will be Board Certified with Medical Director level experience & 5 plus years experience in an inpatient behavioral health setting. The Medical Director will oversee the PI/Quality program, Utilization Review committee, and work with the CEO in new program development. The successful candidate will have strong interpersonal, written & verbal communication skills & a passion for providing excellent care in a cost effective, changing healthcare environment. The Medical Director will supervise Physician staff and have both administrative/clinical duties. Because we have physicians on site 24/7, **there is no routine weeknight or weekend call requirement.** The Medical Director position comes with a very competitive compensation package of salary & benefits including paid time off, CME, malpractice reimbursement & opportunities to earn additional income. Pembroke Hospital is part of the Arbour Health System & a subsidiary of Universal Health Services, Inc (UHS). We are located in Pembroke, MA only 8 miles from the coast in a beautiful suburban community within easy reach of Boston & Cape Cod. **Contact Will DeCuyper, In-house Recruiter @ 866-227-5415 OR email will.decuyper@uhsinc.com**

CAMBRIDGE: Outpatient Consultation-Liaison Psychiatry Position

PSYCHIATRIST: Cambridge Health Alliance is seeking a half- to full-time psychiatrist to join our Consultation-Liaison Psychiatry Service. We serve a multi-ethnic and diverse patient population. The position will be focused on clinical work and program development in our general hospitals and our outpatient service integrated in primary care. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment coupled with a strong academic tradition and existing collaboration with medicine, make this an ideal opportunity for candidates interested in integrated medical and psychiatric care with underserved populations. We have strong training programs in Primary Care, Adult and Child Psychiatry, 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.**

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.

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

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

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

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CLASSIFIEDS

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.

Psychiatrist needed by Community Counseling Center of Cape Girardeau, MO at locations in Perryville, MO and Ste. Genevieve, MO. Requires M.D. or foreign equivalent; completion of residency in Psychiatry; and eligibility for medical licensure in the state of Missouri. Fax CV to Sondra Elfrink at 573-651-4345.

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

Medical Director & Associate Positions – Northern NJ - Seeking psychiatrists in private practice who want to follow inpatients on adult psych unit in Jersey City. Administrative stipends available for PT admin work. Can round in the a.m. or p.m. and go to practice the rest of the time. Great opportunity to grow one's practice, increase revenue. Additional income to the psychiatrist such as being paid for weekend call plus additional revenue that I would be happy to discuss with you. Please contact **Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

CHILD & ADOLESCENT PSYCHIATRIST
Millburn, Montclair and Bridgewater, NJ

Child/Adolescent Psychiatrist positions are available in our Millburn, Montclair and Bridgewater, New Jersey locations, to join our private upscale fee-for-service comprehensive child, adolescent and adult therapy Center. Candidate will be part of a multi-disciplinary team and will provide psychiatric evaluation, medication management and, if desired, psychotherapy, in a supportive collegial atmosphere. Salary and benefit package are generous, and include excellent medical and dental insurance benefits, generous vacation and CME time, retirement plan and more. Opportunities for growth also exist. Candidate must be board certified or board eligible in child/adolescent psychiatry. E-mail cv to abbazn@aol.com.

NEW MEXICO

LAS CRUCES: Child, General or Geriatric Psychiatrists. 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

NEW YORK CITY & AREA

PSYCHIATRIST
Ambulatory Clinic * Part Time

The Mount Sinai Medical Center, founded in 1852, is a 1,171-bed, tertiary-care teaching facility acclaimed internationally for excellence in clinical care. Located on Manhattan's Upper East Side, the center encompasses The Mount Sinai Hospital and Mount Sinai School of Medicine.

Currently, the Department of Psychiatry has an immediate Part Time opening for a Psychiatrist to work in our HIV ambulatory care clinic and provide outpatient evaluations, as well as assist with the psychopharmacologic and psychotherapeutic management of patients. Qualified candidates will possess a valid license to practice psychiatry in the State of New York. Spanish speaking applicants and those with psychosomatic medicine fellowship training are preferred.

Along with competitive compensation, this position will include an academic appointment commensurate with experience in the Department of Psychiatry at the Mount Sinai School of Medicine. **Interested applicants should contact: Dr. Kim Klipstein, Director of Behavioral Medicine and Consultation Psychiatry at 212-659-8712 or email your CV to:**

kim.klipstein@mssm.edu

Mount Sinai Medical Center is an equal opportunity/affirmative action employer. We recognize the power and importance of a diverse employee population and strongly encourage applicants with various experiences and backgrounds.

Mount Sinai Medical Center
An EEO/AA-D/V Employer

Moonlighting Positions

The St. Vincent's Westchester division of Saint Joseph's Medical Center has per diem shifts available for psychiatrists in our evaluation and admissions service. Choice of evening, night-time or weekend hours in an excellent work environment. Send CV to: Dean Harlam, M.D., Chief Medical Officer; St. Vincent's Hospital Westchester; 275 North Street, Harrison, NY 10528. E-mail: dharlam@svwsjmc.org. Phone: 914-925-5310. EOE.

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.

Mount Vernon Hospital, Mount Vernon, NY, is seeking the following BE/BC Psychiatrists: one part-time for its ACT Team and one full time for its consultation program.

Competitive salary, excellent benefits.

The hospital is also seeking per diem Psychiatrists for its night and weekend call schedule.

Email contact information to Claus von Schorn, cvonschorn@sshsw.org OR mtarantino1@sshsw.org.

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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Addiction Psychiatrist/ Unit Chief

Full-time position available for an Addiction Psychiatrist/ Unit Chief on the Chemical Dependency Unit at Flushing Hospital Medical Center. Supervise residents, fellows, medical students, and other trainees. Fully-staffed by Internists and PA's. Full compliment of CASACs and Social Workers. Research opportunities available. Work within the larger MediSys Health Network with extensive Psychiatric services and resources. Competitive salary, paid malpractice insurance, and full benefits. Please send your CV to Seeth Vivek, MD fax: 718-206-7169 or Email svivek@jhmc.org

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Director - Child and Adolescent Inpatient Research

The Department of Psychiatry Research at Zucker Hillside Hospital seeks a F/T Director of Child and Adolescent Inpatient Research to assume a leading role in federally funded translational research projects in the area of Adolescent Psychiatry. Research will focus on treatment and prevention of psychotic illness among adolescents. Candidate must possess medical degree, NYS medical license, 10+ years experience in research and/or clinical research and a record of prior publications. Send CV to NSLIJ at Jmann4@nshs.edu. EOE.

NEW YORK STATE

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.**

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.

CLASSIFIEDS

Rockland Psychiatric Center, Orangeburg, NY
Inpatient and Outpatient Psychiatrists

Rockland Psychiatric Center is the largest NY State psychiatric hospital, affiliated with New York University and located 18 miles north of Manhattan in the scenic lower Hudson Valley.

We are looking for a staff psychiatrist for one of our admissions units, and psychiatrists for our Middletown and Monticello outpatient clinics, located 60 miles north of Manhattan in Orange and Sullivan counties. Supervisory position possible for qualified candidate.

Regular hours, optional on-call for extra pay, excellent benefits including state retirement system. Weekly grand rounds, large medical staff, collegial atmosphere. With 400 inpatient beds and an extensive regional outpatient network, there are many opportunities for movement and advancement once on staff.

Send CV to Mary Barber, MD, Clinical Director, mary.barber@omh.ny.gov.

NORTH CAROLINA

Horizon Health seeks a **Medical Director** for a 13-bed Geriatric Inpatient Psychiatric Program near **Raleigh, NC**. $100K Medical Director stipend, plus billings. Easy drive from Raleigh. New program expanding rapidly with great potential for growth. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

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

OKLAHOMA

Horizon Health seeks a **Medical Director** for our 10-bed Geriatric inpatient Behavioral Health programs our client hospital **Eastar Health Systems, in Muskogee, OK.** Experience with geriatric population preferred. Excellent income and practice opportunity. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com. EOE

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

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.

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

MEDICAL DIRECTOR & ASSOCIATE POSITIONS – Employment or Contractor Positions in Lancaster, PA – VERY attractive compensation packages available; PT work is also available. Involves inpatient work on adult & geropsych units. Plans to expand services and open outpatient in the works. A beautiful area in eastern PA; strong medical community; an easy drive to several metro areas. Please **call Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com

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.

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

TEXAS

PSYCHIATRISTS

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.

We will have needs in our
Crisis Services and Outpatient Clinics
seeking both Child/Adolescent and Adult

Positions are full time and
may offer flex hours
Some positions have no on-call and
are M-F

Texas licensure is required for all positions

Interviewing now for current open positions and near future start dates

MHMRA offers competitive salary plus an excellent benefits package including generous retirement plans which match up to 10%. Houston offers excellent quality of life; lower than average cost of living, no state income tax and exciting cultural, entertainment, sporting and tourists venues.

Contact Charlotte Simmons at (713) 970-7397, or submit your C.V. to charlotte.simmons@mhmraharris.org, fax 713-970-3386 or apply online at www.mhmraharris.org.

DALLAS: Arlington, DeSoto and Rockwall areas. General and Child Psychiatrists. Independent contractor compensation. Stipend options for leadership roles in inpatient services. Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com

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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

CLASSIFIEDS

VERMONT

Central Vermont Medical Center
Central to Your Well Being

Central Vermont Medical Center Adult Inpatient and Geriatric/Adult Outpatient Opportunities

Seeking a BC/BE Psychiatrist to join the staff on our 14 bed Inpatient Unit. You will be joining two other attending Psychiatrists to take care of patients on the inpatient unit as well as provide consultation to the emergency room and medical floor. Extremely reasonable call obligation. Work with a highly trained, seasoned, friendly team of professionals including nurses, social workers and nurse practitioners in the context of a biopsychosocial model of care. We have excellent support from in-hospital IV teams, blood drawing teams, hospitalists and our own NP's who perform all histories and physicals. You will also have the opportunity to perform ECT in a state-of-the-art setup with our anesthesiology group. Third year medical students from University of Vermont rotate through our service and thus provide teaching opportunities.

Our Family Psychiatry practice is growing their staff to add a specialty in Geriatric Psychiatry. You would join 2 other well established and respected psychiatrists (adult & child) as well as a Nurse Practitioner and MSW. A strong referral base will come from CVMC's large primary care service as well as our 153 bed Rehabilitation and Nursing center. BC/BE in Adult/Geriatric Psychiatry.

Salary and benefits are excellent. Tuition loan repayment is available.

Please contact Sarah Child, Manager of Physician Services for more information. Sarah.Child@cvmc.org. 802-225-1739. www.CVMC.org

VIRGINIA

PSYCHIATRY OPPORTUNITY WILLIAMSBURG, VIRGINIA

Premier provider of Psychiatry services seeks a BC/BE Psychiatrist for its 57-bed Psychiatric Pavilion. In this position, you will serve Adult and Geriatric patients as well as impaired professionals with acute psychiatric illnesses, including those with dual diagnosis. The Pavilion will meet a community need for inpatient psychiatric care, while also addressing a national need for psychiatric services for physicians, dentists, nurses and other professionals in need of care.

Williamsburg is located on the Virginia Peninsula in the Hampton Roads metropolitan area of Virginia. It is well-known for Colonial Williamsburg.

To learn more, contact Beth Briggs at 800-678-7858 x64454 or ebriggs@cejkasearch.com. ID#151022PY

Faculty Position Child & Adolescent Psychiatry

Virginia Tech Carilion School of Medicine and Carilion Clinic a physician-led multispeciality academic healthcare organization with over 600 physicians, has a fulltime position for a Child and Adolescent Psychiatrist. The position is associated with the new allopathic medical school and Carilion Roanoke Memorial Hospital, a 700-bed academic tertiary referral center with 12 acute child and adolescent psychiatric beds and community outpatient services. Responsibilities include direct clinical services, teaching medical students, and supervising psychiatry residents and fellows. Child and Adolescent call coverage shared with 5 psychiatrists.

Submit CV and cover letter to Amy Silcox Physician Recruiter, amsilcox@carilionclinic.org or call 540-224-5187.

WEST VIRGINIA

Excellent private practice opportunity for a adult/ or child-trained psychiatrist in Southern West Virginia to join a well-established practice. In-patient, out-patient, and consultation services. Exceptional salary and benefits. Good place to raise children. Easy drive to several big cities, heaven for outdoor lovers. Can help with visa conversion and sponsorship. Fax cv to (304) 252-1703 or email nafa2 @aol.com.

Comprehensive community mental health center is seeking a Psychiatrist to provide general psychiatric services in southern West Virginia. Monday-Friday with NO call rotation. Competitive Salary and Fringe Benefits. May be eligible for Federal Loan repayments. J-1 eligible applicants encouraged to apply. Submit resume to Southern Highlands Community Mental Health Center, 200 12th Street Extension, Princeton, WV 24740 or judymassaro@shcmhc.com.

? Did you know

that APA provides support for managing a practice? We provide members a wide variety of practical assistance on day-to-day issues that arise in managing a practice, such as reimbursement, relationships with managed care companies, coding, documentation, Medicare, Medicaid, establishing or closing a practice, and mental health/addiction parity. APA Members may access practice management assistance by calling the HelpLine at 800.343.4671, sending email to hsf@psych.org or through our website at www.psychiatry.org/practice

Fellowships

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.

Practice for Sale

Well-established outpatient psychiatric private practice of 30 years in Orlando, FL, looking for a psychiatrist to take over the practice of adults only. For details, call 321-438-3158.

Pristiq® *desvenlafaxine* Extended-Release Tablets

BRIEF SUMMARY. See package insert for full Prescribing Information. For further product information and current package insert, please visit www.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.

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

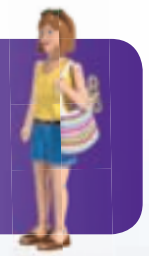
PRISTIQ Extended-Release Tablets are indicated for the treatment of major depressive disorder in adults.

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.

Pfizer