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PSYCHIATRIC NEWS

The First and Last Word in Psychiatry

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AP Photo/Jessica Hill

Six months after the tragic shootings in Newtown, Conn., a ceremony was held at Edmond Town Hall last month honoring the 20 children and six adults killed at Sandy Hook Elementary School. Above are two of the families who attended. Newtown held a moment of silence for the victims of the massacre. See story below.

AMA Declares Obesity Disease Requiring Treatment

Interventions for obesity can include medical treatments, including medication or surgery, but also psychosocial and behavioral therapies.

BY MARK MORAN

Obesity is a disease requiring a range of medical interventions to advance obesity treatment and prevention.

That's what the AMA's House of Delegates declared last month during its annual policymaking meeting in Chicago.

"Recognizing obesity as a disease will help change the way the medical community tackles this complex issue that affects approximately 1 in 3 Americans," AMA board member Patrice Harris, M.D., said in a statement. "The AMA is committed to improving health outcomes and is working to reduce the incidence of cardiovascular disease and type 2 diabetes, which are often linked to obesity."

Patrice Harris, M.D.

In an interview with *Psychiatric News*, Harris—a former member of the APA Board of Trustees—said she believes the policy adopted by the House will "elevate the way physicians communicate with patients" about obesity. She said the new policy is in keeping with

see ***Obesity*** *on page 26*

Psychiatrists Deeply Involved In Newtown's Recovery

Recovering from last December's killing of 26 students and educators at Sandy Hook Elementary School is a long slow process, but one with more than a glimmer of hope.

BY AARON LEVIN

The horrific mass shooting that took the lives of 20 young students and six educators at Sandy Hook Elementary School in Newtown, Conn., December 14, 2012, has produced an extended response from the state's mental health community.

In the days following the tragedy, several mental health and social service organizations collaborated on offering drop-in help at a town middle school, a service that continued until April 10 (*Psychiatric News*, February 1).

The Connecticut Psychiatric Society (CPS) arranged for 150 volunteers to counsel Newtown residents during that time, said CPS President Carolyn Drazinic, M.D.

Eventually, the Newtown Health District established a coordinating council for mental health that included several area medical and mental health personnel.

Over the last six months, psychiatrists and others have worked to help Newtown recover and prevent future incidents by advocating for mental health concerns at the state and federal levels, providing direct mental health services, or helping the townspeople cope with their losses.

One unexpected consequence arose well beyond Newtown after the tragedy, said Harold Schwartz, M.D., psychia-

see ***Newtown*** *on page 25*

PERIODICALS: TIME SENSITIVE MATERIALS

INSIDE

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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.

NEW

400MG ONCE-MONTHLY

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
Marketed by Lundbeck, Deerfield, IL 60015 USA

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 09US12L-1001B February 2013

Institute on Psychiatric Services

American Psychiatric Association

65TH IPS

PHILADELPHIA

OCTOBER 10 – 13, 2013

APA's Leading Educational Conference on Public, Community, and Clinical Psychiatry

Transforming Psychiatric Practice, Reforming Health Care Delivery

Who Should Attend?

- All APA Members, including Early Career Psychiatrists and Psychiatric Residents
- International Psychiatrists
- Primary Care Physicians
- Mental Health Professionals from all disciplines

Why You Should Attend

- Earn CME credit from over 100 expertly-led education sessions.
- Network with 1,500 mental health professionals and obtain solutions for the challenges you face.
- Interact with experts in small-group settings.
- Acquire new skills in clinical psychiatry to improve patient care.
- Assess a variety of treatment choices, including psychotherapeutic and pharmacological options.

For complete IPS details, including Registration, Hotel, and Travel information, visit www.psychiatry.org/IPS

Transforming Psychiatric Practice, Reforming Health Care Delivery

65TH IPS

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:
www.psychitatry.org/IPS

Transforming Psychiatric Practice, Reforming Health Care Delivery

65TH IPS

TRAVEL INFORMATION & SCHEDULE AT-A-GLANCE

Travel Information

Conference Location:

Philadelphia Marriott Downtown
1201 Market Street
Philadelphia, PA 19107

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

ROOM TYPE	RATE
Single Rate (1 person in one room)	$219.00
Double Rate (2 people in one room)	$239.00

Amtrak

Receive a 10% discount off the lowest available rail fare to Philadelphia as an APA IPS attendee. Use Convention Fare Code: X95M-964. Cannot be booked online. Please call 1-800-872-7245.

MacNair Travel

Call MacNair Travel Management to assist with your IPS travel arrangements at 1-877-650-4266 or email apa@macnairtravel.com. Be sure to identify yourself as an IPS attendee.

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

Register by September 20 and Save with Advance Registration:
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REGISTRATION INFORMATION

Register Online Today!

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Register by September 20th to save with Advance Registration Fees!

Complete program details and non-member fees can be found online.

APA Member Registration Fees

Standard Registration: include admission to over 100 scientific program sessions (excluding Courses) and the exhibit hall. Courses require an additional fee.

Gold Registration: includes the APA Psych Services on Demand with a standard registration. APA Psych Services on Demand is a digital library of over 150 hours of educational content presented at the 2013 IPS.

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
Program Presenter-Sunday Only	$50	$50	$70
Medical Student	Fee Exempt	Fee Exempt	Fee Exempt
APA Honorary Fellow [1]	Fee Exempt	Fee Exempt	Fee Exempt
Course on Psychopharmacology	$325	$350	$380
Course on CPT Coding	$325	$350	$380
Course on Primary Care Skills for Psychiatrists	$165	$175	$190
Course on DSM-5	$325	$350	$380
Full-Day Course on Treating the Homeless Mentally Ill	Fee Exempt	Fee Exempt	Fee Exempt
Full-Day Course on Buprenorphine Training	Fee Exempt	Fee Exempt	Fee Exempt

GOLD REGISTRATION FEES	**Early Bird** 6/3-7/26	**Advance** 7/27-9/20	**Onsite** 9/21-10/13
Full-Time	$565	$620	$690
Member-in-Training	$225	$240	$255
Daily Registrant	$460	$495	$535
Daily Registrant-Sunday Only	$380	$395	$420
Program Presenter Full-Time	$500	$500	$570
Program Presenter Daily	$400	$400	$435
Program Presenter-Sunday Only	$350	$350	$370
Medical Student	$150	$150	$150
APA Honorary Fellow [1]	$150	$150	$150

1 Does not include APA Fellows, Distinguished Fellows, Distinguished Life Fellows, or Life Fellows.

Confirmation

If you do not receive registration and/or course enrollment confirmation within two weeks of registering, contact the APA Meeting Registration office.

Payment

The APA only accepts VISA, Mastercard, American Express, money order, or a check (in U.S. funds only), payable to the American Psychiatric Association. APA does not accept bank or wire transfers. Registrations will not be processed without proper payment. American Psychiatric Association, Institute on Psychiatric Services Meeting Registration, 1000 Wilson Boulevard, Suite 1825, Arlington, VA 22209. Mailed and faxed forms will not be accepted after September 20, 2013.

Non-Physician Provisional Registration

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.

Travel Visa

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.

On-Site Check-In and Registration

Attendees may pick up their registration badge and materials in Franklin Hall B, Level 4, Philadelphia Downtown Marriott during these times:

Wednesday, October 9	3:30 p.m. – 5:00 p.m. (Members Only)
Thursday, October 10	7:30 a.m. – 5:30 p.m.
Friday, October 11	7:30 a.m. – 5:30 p.m.
Saturday, October 12	7:30 a.m. – 5:00 p.m.
Sunday, October 13	7:30 a.m. – 10:30 a.m.

NOTE: *The APA shares, with exhibitors, some personally-identifying information about the IPS registrants. This includes your name, title, mailing address, and email address.*

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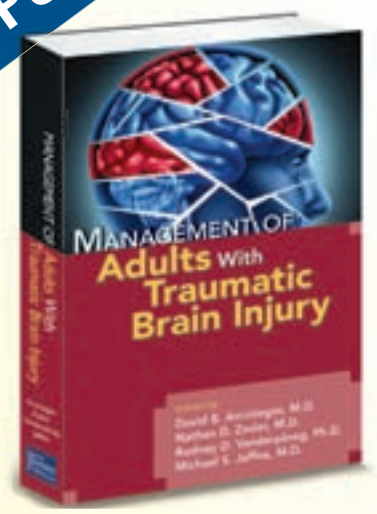

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Management of Adults with Traumatic Brain Injury is an up-to-the-minute, comprehensive, and useful text designed to support busy physicians, nurses, and mental health professionals working with persons with traumatic brain injury (TBI) and their families.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

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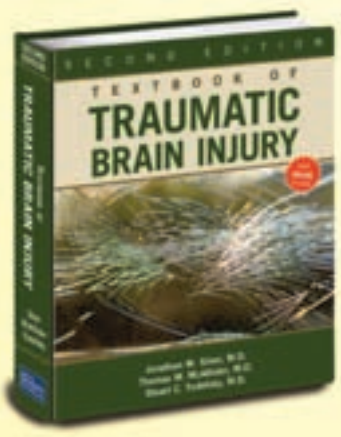

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Thomas W. McAllister, M.D.,
and Stuart C. Yudofsky, M.D.

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

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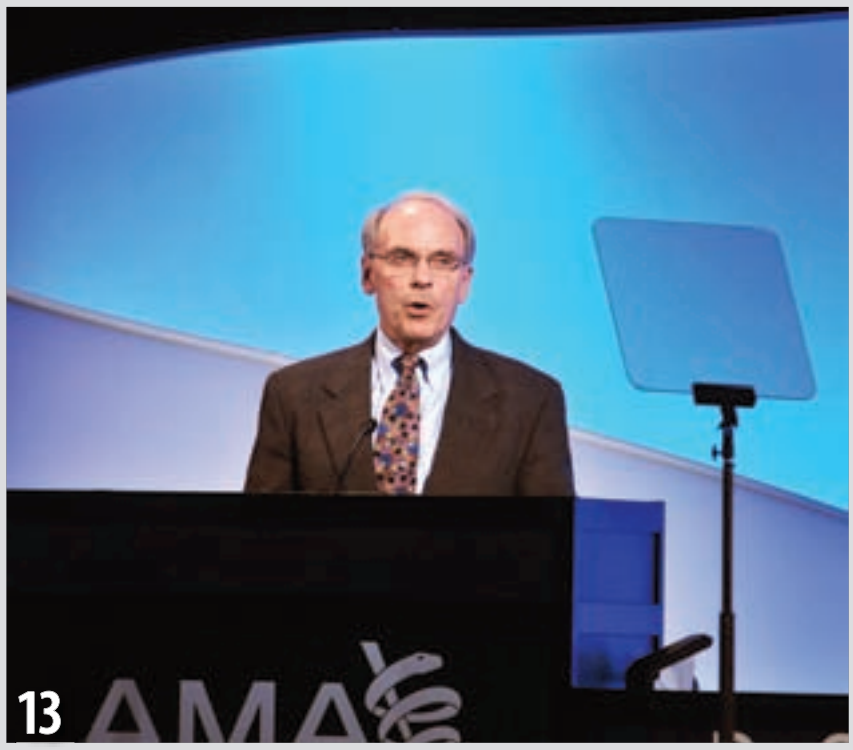

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Register Now for Institute!

G. Widman for GPTMC

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.

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FROM THE PRESIDENT

Psychiatry: Nothing to Be Defensive About

BY JEFFREY LIEBERMAN, M.D.

The integrity of our profession and the science of psychiatry are being questioned—again by articles in the media. Two recent missives, which I found particularly disturbing, are by the noted columnist David Brooks ("Heroes of Uncertainty," *New York Times*, May 28) who calls psychiatry a "semi-science," and by Leonard Sax, a British psychologist (*Wall Street Journal*, June 26), who accused *DSM-5* of having "broadened the definition of mental illness to absurdity." Although the most recent media criticisms have been focused on the process and finished product of *DSM-5*, such invective is really nothing new. But it may be time to respond in a new way.

I recently wrote an article for the *Scientific American* blog (http://blogs.scientificamerican.com/mind-guest-blog/2013/05/20/dsm-5-caught-between-mental-illness-stigma-and-anti-psychiatry-prejudice/) that explores how stigma and antipsychiatry sentiments fuel prejudice against our field and our patients. But I think it's also important to note how the unwillingness of the public and pundits to accept psychiatry as a scientific discipline and full-fledged medical specialty perpetuates the false dualism of the mind and the brain—attempting to transport psychiatry back to the Cartesian philosophy of the 17th century. It also undermines the progress that has been made to deconstruct the almost unfathomable complexity of the brain into its constituent neurobiological mechanisms that mediate emotion, perception, and cognition.

The intellectual thrust of psychiatry, throughout its entire history, has been to understand the maladies of the mind in terms of the brain. Prior to the 18th century, mental illness was considered a spiritual or moral affliction. When enlightenment thinking inspired the view of mental illnesses as medical conditions, psychiatrists proceeded to examine the brain but found no visible pathology. Even Freud, a neurologist, appreciated the need to invoke the brain to understand behavior and psychopathology. His "Project for a Scientific Psychology" anticipated a neurobiological explanation for mental processes and unconscious psychic phenomena. However, the science of his day was inadequate for the audacity of his vision, and he was required to resort to clinical and metaphysical conceptions of mental mechanisms. It has only been in the last half century that we have been able to even envision the possibility of achieving Freud's dream.

Many critics take issue with the fact that our disorders do not manifest in lesions or biologic abnormalities. But numerous nonpsychiatric conditions are clinically diagnosed without observable pathology or laboratory tests (such as migraine headaches, irritable bowel syndrome, etc.). Interestingly, our critics do not cast aspersions on PTSD, which also has no physical diagnostic stigmata—because that would be politically incorrect.

The maturation of psychiatry has been limited largely by technology. Just as Galileo could not confirm heliocentrism until the telescope was developed, and Pasteur required the light microscope to identify microorganisms, psychiatry could not begin to gain traction on the functions of the brain until the emergence of psychopharmacology, modern neuroimaging methods, and molecular genetics. These technologies, combined with rigorous scientific methodology, have enabled psychiatrists, psychologists, and neuroscientists to begin to integrate the mind and the brain.

The dependence of medical progress on enabling technologies was made very clear recently with the announcement of President Obama's Brain Activity Map Project. The sheer magnitude and complexity of the brain, with its 100 billion cells, 30 trillion synaptic connections, myriad interwoven neural circuits, and vast mosaic of gene expression, requires a great leap forward in technology and instrumentation to help us further elucidate its relationship to mental functions and behavior. This big science project, along with the Human Connectome Project, is intended to address this need, just as the Human Genome Project did previously.

Our understanding of the relationship between the brain and mental disorders may have been slow to develop, but recent advances in research have shown us that they are biological in nature and caused by genetics and environmental factors. Patients are not responsible for their mental illness, and psychiatrists are doing their best to recognize and treat mental disorders and help patients as best we can within the limits of our knowledge. For this noble mission, we have nothing to be defensive about. PN

Collaborative Care Well Suited To New Medicaid Health Home Option

Implementation of collaborative care for the 20 percent of Medicaid beneficiaries with depression could save the program approximately $15 billion a year. This is the first in a series of articles on integrated care.

BY MARK MORAN

A model of collaborative care is well suited to the new Medicaid "health home" state option, authorized by the Affordable Care Act (ACA).

So say five national leaders in integrated care in a policy brief developed for the Centers for Medicare and Medicaid Services by the Center for Health Care Strategies and by Mathematica Policy Research.

The policy brief, published in May, is one more sign that integrated care has surpassed the "tipping point" and is quickly becoming a dominant feature of health system reform. ("Collaborative Care" and "integrated care" are often used interchangeably, but collaborative care is a specific model backed by evidence that includes a psychiatric consultant as a core member of the care team; integrated care is a more general concept that simply means the integration of mental health care and primary care and may or may not include the involvement of a psychiatrist.)

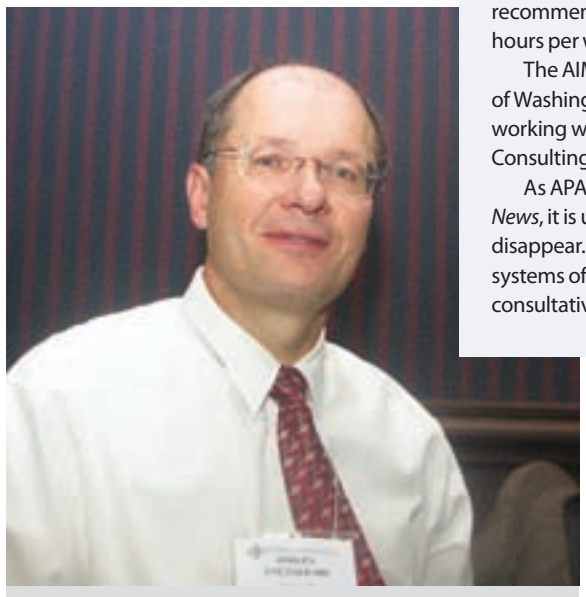
Integrated-care models have evolved from the traditional consultative role that consultation-liaison psychiatrists have practiced, to a "co-located" model in which psychiatrists see individual patients in a primary care clinic, to a fully collaborative care model in which a psychiatrist takes responsibility for a caseload of primary care patients and works closely with primary care clinicians and other primary care–based mental health care providers.

In their policy brief, Jürgen Unützer, M.D., and colleagues described in detail how a psychiatrist would operate within a collaborative care system (see sidebar).

Though models may differ, the core principles of collaborative care are constant: patient-centered care teams providing evidence-based treatments to a defined population of patients using a measurement based "treat-to-target" approach. (The latter refers to the use of tested instruments so that symptoms can be measured with numerical targets established for clinical treatment goals.) The concept is a feature of the delivery-system reforms in the new health care reform law, and policymakers and many clinicians have converged on the idea that the full range of medical services should be brought together in one patient-centered location.

APA's Council on Healthcare Systems and Financing has established the Work Group on Integrated Care, and a growing and dedicated cadre of psychiatrists is advancing the cause of integrated care and the participation of psychiatrists in integrated-care models. In coming editions, *Psychiatric News* will profile some of these psychiatrists and focus on the opportunities and challenges associated with this emerging model of care.

Among those will be Wayne Katon, M.D., who was the subject of a "Q and A" column about psychiatry, mental health, and integrated care in the June 19 *JAMA*. In that issue Katon said health reform has provided a tremendous stimulus for positive change in terms of integrating of mental health care into primary care.



Mark Moran

Jürgen Unützer, M.D., says psychiatric consultants in a collaboartive care network provide mental health specialty support for the primary care treatment team, particularly regarding patients who are not improving as expected.

"We've seen more interest in the last five years than the last 20," he said. "There are a number of dissemination centers around the country that are helping to train clinicians in this model. There is also an overrepresentation of people with mental illness among the currently uninsured individuals who may gain access to insurance through health reform. That's another incentive to adopt collaborative-care models to help provide mental health care more efficiently."

But if integrated or collaborative care really is the wave of the future, it is one that may take different shapes as it rolls in depending on regional variations, state laws, payment systems, and other factors. The policy brief by Unützer and colleagues focused on collaborative care as it may fit into the Medicaid Health Home State Plan Option.

Under that option as delineated by the ACA, states can link Medicaid beneficiaries who have at least two chronic conditions, have one chronic condition and are at risk for another, or have a serious mental illness to a health home to coordinate that person's health care. Regardless of the conditions targeted by the health home, the associated providers must meet all federal and state qualifications to serve as health homes and must deliver a defined set of services. Across these services, a key desired outcome of the health home model is improved integration of primary and behavioral health care delivery.

In their brief, Unützer and colleagues outlined the clinical and cost-savings benefits of collaborative care. More than 70 randomized, controlled trials have shown collaborative-care models for common mental disorders such as depression to be more effective and cost-effective than usual care, across diverse practice settings and patient populations, they noted.

One of the largest randomized, controlled trials of this model is the IMPACT study conducted by Unützer and colleagues at the University of Washington from 1998 to 2003. That study randomized 1,801 depressed adults in 18 primary care clinics to usual care—defined as primary care or referral to specialty mental health as available—or a 12-month collaborative-care intervention. The study involved 450 primary care providers in eight health care organizations operating in five states; in the original IMPACT study and numerous replications, patients receiving collaborative care were found to have less depression, less physical pain, better functioning, and a higher quality of life. There was also greater patient and provider satisfaction.

"Importantly, from a public-policy standpoint, IMPACT has been found to lower overall costs substantially for patients receiving the intervention through more efficient mental health treatment and

see ***Collaborative Care*** *on page 25*

Psychiatrists' Role in Integrated Care

So what exactly would a psychiatrist do in an integrated care system?

Jürgen Unützer and colleagues, in a policy brief for the Centers for Medicare and Medicaid Services, noted that psychiatric consultants provide mental health specialty support for the primary care treatment team, particularly regarding patients who are not improving as expected. Consultant responsibilities include regular (usually weekly) reviews of a caseload of patients treated for common mental disorders such as depression in a primary care practice by a consulting psychiatrist, with a focus on patients who are not improving as expected and treatment recommendations for those patients to the treating primary care physician.

"In most cases, recommendations are summarized in brief, focused written or electronic notes to the primary care physician [PCP]," they wrote.

Review and recommendations are typically provided through a care manager supporting the PCP in primary care, but in some cases the communication is directly between the PCP and the consulting psychiatrist. "The consulting psychiatrist is also available to the PCP during the week by pager to answer questions about recommendations made," they wrote. "The level of effort for consultants is typically three hours per week for each care manager's primary care caseload (typically 50-100 patients)."

The AIMS (Advancing Integrated Mental Health Solutions) Center at the University of Washington has posted a sample job description for a consultant psychiatrist working within an integrated care system at http://uwaims.org/files/team-building/ConsultingPsychiatristJobDescription.pdf.

As APA President-elect Paul Summergrad, M.D., noted in an interview with *Psychiatric News*, it is unlikely that traditional forms of psychiatric practice will all change, let alone disappear. But in the meantime, psychiatrists should educate themselves about evolving systems of integrated care in their area and may want to begin experimenting with a consultative role to existing collaborative care networks.

PROFESSIONAL NEWS

Scientific Advances Changing Forensic Psychiatry

In the 19 years since it became an official subspecialty, forensic psychiatry has become increasingly science based. And it will likely be even more so during the next decade.

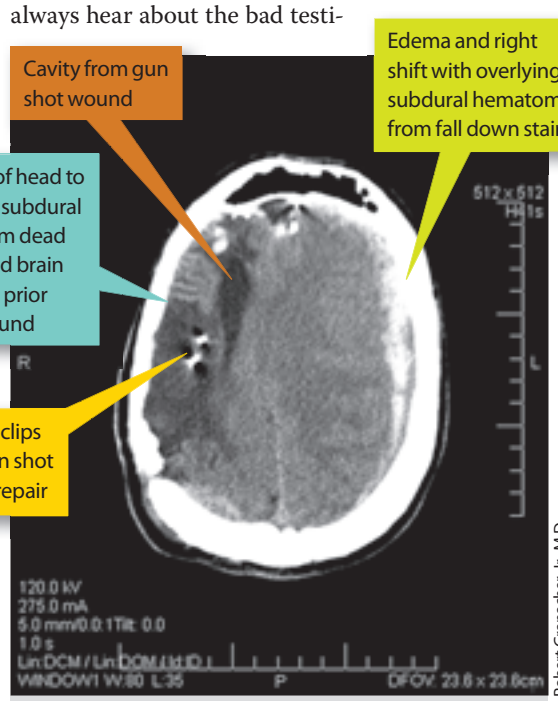
BY JOAN AREHART-TREICHEL

In the years both before and after it became an official subspecialty in 1994, forensic psychiatry has changed in dramatic ways, forensic psychiatrists agree.

For one, "the field has expanded to include correctional psychiatry," reports Paul Appelbaum, M.D., the Dollard Professor of Psychiatry, Medicine, and Law and director of the Division of Law, Ethics, and Psychiatry at Columbia University and chair of the APA Committee on Judicial Action.

A second change, he told *Psychiatric News*, "has been the steady introduction of a more systematic means of assessment in the forensic realm. For many years, forensic psychiatrists had to rely on clinical evaluations to gain information about people's mental states, perhaps supplemented by collateral information such as records or interviews with family members. And that is still the case. However, those clinical evaluations have in many settings been supplemented by more systematic data-gathering tools, such as scales for the assessment of symptoms and mental states."

"I think the field has been evolving over the past 20 to 30 years, with a gradual development of ethical guidelines and the development of practice guidelines for the profession," Howard Zonana, M.D., a professor of psychiatry at Yale Medical School and a clinical adjunct professor at Yale Law School, said in an interview. "Training programs have increased around the country in terms of offering subspecialty training. The boards have developed, and hopefully the quality of testimony has risen as a result of that. You always hear about the bad testimony, but I think that the general run of testimony has improved."



Robert Granacher, Jr., M.D.

Brain images such as this one are being used more and more often in forensic cases.

"The field has [also] greatly expanded in many civil areas beyond the traditional criminal-activity evaluations that we have done," Patricia Recupero, M.D., J.D., a clinical professor of psychiatry at Brown University, told *Psychiatric News*. "So forensic psychiatry has become much more important in child custody, disability evaluations, and perhaps more significantly for the public, in sickness-for-duty evaluations—the ability of people to return to work after a psychiatric illness."

"And a very new trend that we are in the initial stages of," she said, "is the reaction to the Newtown, Conn., shootings and the state of gun violence in the United States.... Forensic psychiatrists can be advocates and provide governments and other agencies with testimony about the effectiveness of various forms of mental health treatment in avoiding or decreasing violence."

But perhaps the greatest change in forensic psychiatry in recent years has been the increasing use of science in the field, several forensic psychiatrists indicated.

"We are seeing a growing introduction of both structural and functional neuroimages, electrophysiological studies, and genetic information in court in connection with a variety of claims, ranging from the use of such information to support diagnostic claims to the use of this information to establish impairment of function or the presence of injuries," Appelbaum said.

Forensic psychiatrist William Bernet, M.D., a professor emeritus at Vanderbilt University, concurred: "The brain-imaging movement in forensic psychiatry in recent years is a reflection of the push in all of psychiatry, and with the completion of the human genome project, there is a lot of interest in genetic testing in forensic situations."

For example, there is evidence that if a male of European background has the low-activity version of the MAO-A gene and was seriously abused as a child, he is four or five times more likely to be a violent adult than if he didn't have the two factors. Bernet has used this information in court seven or eight times, he said.

During the next decade, still more scientific advances will assume a vital role in forensic psychiatry, Bernet predicted. For instance, to determine whether a person who has served a sentence may be dangerous if released from prison, a forensic psychiatrist might use psychological testing and actuarial evaluation, in which he or she looks "statistically at things he has done and estimate from that what his future is going to be. But I think that 10 years from now, brain scans and genetic testing will be used as well."

"Structural magnetic resonance imaging [MRI], which I use all the time, is exceedingly good at telling us about traumatic brain injury and other conditions," Robert Granacher Jr., M.D., a clinical professor of psychiatry at the

see ***Forensic*** *on page 12*

Forensic Psychiatry's Challenges and Rewards

"The greatest challenge of practicing forensic psychiatry is reducing the complexity of the mind to something that can be measured and then explained," forensic psychiatrist Robert Granacher Jr., M.D., a clinical professor of psychiatry at the University of Kentucky, told *Psychiatric News*. "Due to the complexity of the brain, psychiatry lags behind almost all other medical specialties in its ability to measure things.... But we can measure the brain much better today than a decade ago. And 10 years from now, it will be even better than that."

Another challenge, Granacher observed, is that it "requires tremendous ability to analyze and store large amounts of data. It's not unusual in a complex forensic case to have to go through 20,000 pages of information."

"A lot of what forensic psychiatrists do is review most, if not all, of the treatment records of the person they are evaluating," Patricia Recupero, M.D., J.D., a clinical professor of psychiatry at Brown University, pointed out. "Getting those records is sometimes difficult. Getting collateral information, information about how the person is actually functioning in their usual environment, contacting family members or people who know them is a challenge, because maybe they were estranged from their family, maybe they don't want their family to know they are undergoing evaluation . . . ," she said.

"One of the rewards of practicing forensic psychiatry is that it's fascinating to try to get to the bottom of a case, to try to figure out what actually happened," William Bernet, M.D., a professor emeritus of psychiatry at Vanderbilt University, said during an interview. "And it's fun to be an educator; juries and judges are really interested in what we have to say. I think it's fun to put complex scientific information into language that the everyday citizen can understand."

"As forensic psychiatrists on an individual case, we're not supposed to be rooting for one side or the other," Recupero explained. "So even if a defense lawyer were to retain me to do an evaluation, I would not be rooting for the defendant. I would be rooting for justice and trying to provide the best information I could for the best outcome for the whole judicial process without slanting things. So personal gratification comes from doing a good job at that, as opposed to the outcome of the case."

The Law and Neuroscience Project

Since 2007, the MacArthur Foundation has funded a multimillion-dollar endeavor called the Law and Neuroscience Project, one of the first systematic efforts in the United States to bring neuroscientists and legal scholars together in an effort to determine where neuroscience informs the legal process and where it may have little to say.

In the opinion of William Bernet, M.D., a professor emeritus of psychiatry at Vanderbilt University and a forensic psychiatrist, neuroscientists and legal scholars participating in the project "seem to be mainly interested in brain scans—what they mean in terms of forensic issues such as evaluating the defendant. But they are also interested in what is happening in the brains of jury members and judges and why some people are more sympathetic toward defendants, while others are more punitive toward them."

Neuroscientists and legal scholars involved with the project have also published papers that address questions such as these: Does neuroscience give us new insights into criminal responsibility? Does neuroscience give us new insights into drug addiction? Can neuroscience identify psychopaths? Can neuroscience identify pain?

More information about the project is posted at www.lawneuro.org.

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PROFESSIONAL NEWS

AMA Calls for Special Attention to Care for Dual-Eligible Patients

Individuals dually eligible for Medicare and Medicaid include many with psychiatric illness, and they account for a significant share of Medicare-Medicaid spending.

BY MARK MORAN

Health insurance benefits for patients who are dually eligible for both Medicare and Medicaid should be customized to the unique individual needs of a patient population that includes many individuals with psychiatric illness.

Moreover, the choice of "opting out" of managed care plans should be preserved for this population, and states should ensure that processes for opting out are made available to patients not less than 120 days prior to the implementation of a managed care program.

Those policies—and at least seven others affecting financing and delivery of care for a patient population of special importance to psychiatry—were approved by the AMA House of Delegates during last month's annual policymaking meeting in Chicago. The policies, approved unanimously and with little debate, were contained in a report by the AMA's Council on Medical Services titled "Delivery of Care and Financing Reform for Medicare and Medicaid Dually Eligible Beneficiaries."

Psychiatrist John McIntyre, M.D., a member of the council that wrote the report, told *Psychiatric News* that the population of individuals who qualify for both Medicare and Medicaid (dual eligibles) is small numerically—constituting about 15 percent of all those on Medicaid—but accounts for nearly 40 percent of all Medicare-Medicaid spending, or approximately $300 billion.

"A lot of these individuals are our patients," he said. "The report recognizes that many have mental illness, and the council felt strongly that benefits need to be customized to the unique needs of the individual patient."

(At the meeting last month, McIntyre was voted chair-elect of the council and will become chair at the end of next year's annual meeting.)

A number of states are adopting demonstration projects aimed at providing more integrated, cost-effective care for high-cost Medicare-Medicaid–eligible patients, and the new AMA policy emphasizes that a wide variety of "approaches to integrated delivery of care should be promoted under demonstrations such as patient-centered medical homes, with adequate payment to physicians, provision of care management and mental health resources." The council report further emphasizes that "delivery and payment reform for dually eligible beneficiaries should involve actively practicing physicians and take into consideration the diverse patient population and local area resource."

McIntyre noted that many integrated care demonstration projects involve a "care coordinator" who helps patients navigate their way through an integrated care network. The council report includes policy recommendations stressing that "care coordination demonstrations should not interfere with the established patient-physician relationships in this vulnerable population."

Another crucial reform highlighted in the council report is the need for alignment and coordination of services—including rules affecting physician care of patients—between the two programs. McIntyre noted that the disproportionate payment policies between Medicare and Medicaid create incentives for cost-shifting; for instance, nursing homes benefit from the hospitalization of patients (regardless of the necessity of hospitalization), because when patients return to the nursing home, Medicare will pay 100 percent of the care (whereas Medicaid rates are a fraction of the cost of care).

Finally, the report recognizes that many dually eligible individuals will require significant amounts of counseling and education regarding options for care under new integrated care demonstration projects.

"This is a patient group that is important to psychiatrists," McIntyre said. "This is a key report to come out of the council and has a lot of good information for clinicians. The policies AMA supports in this report are designed to protect the doctor-patient relationship, advocate for adequate resources, including funding for mental health care, and ensure that patients receive adequate counseling and education concerning their insurance options." PN

The AMA report on reform of financing and delivery of care for dual eligibles is posted at http://www.ama-assn.org/assets/meeting/2013a/a13-addendum-refcomm-a.pdf.

Key Points

AMA policy approved at last month's annual meeting of the House of Delegates includes the following recommendations for reform of the financing and delivery of care for "dual eligible" patients:

- Various approaches to integrated delivery of care should be promoted under demonstrations such as primary care physician-led patient-centered medical homes, with adequate payment to physicians, provision of care management, and mental health resources.
- Customized benefits and services from health plans are necessary according to each beneficiary's specific medical needs.
- Care coordination demonstrations should not interfere with the established patient-physician relationships in this vulnerable population.
- Delivery and payment reform for dually eligible beneficiaries should involve actively practicing physicians and take into consideration the diverse patient population and local area resources.
- States should provide education and counseling to beneficiaries on options for receiving Medicare and Medicaid benefits.
- Conflicting payment rules between the Medicare and Medicaid programs should be eliminated.
- Medicare and Medicaid benefit plans and the delivery of benefits should be coordinated.
- Care plans for beneficiaries should be streamlined among all clinical providers and social service agencies.
- The Centers for Medicare and Medicaid Services should require all states to develop processes to facilitate "opting out" of managed care programs by dually eligible individuals no less than 120 days before the implementation date of a state's dually eligible managed care program.

Forensic

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University of Kentucky and a forensic psychiatrist, said during an interview. But functional MRIs can tell forensic psychiatrists something that structural MRIs cannot, he explained, and that is brain activity. For instance, research has shown that telling a lie takes about three times more brain activity than telling the truth. As a result, it may eventually be possible to use fMRI scans to determine whether people on trial or testifying at trial are telling the truth, he noted.

But even if brain scans and genetic tests become increasingly accurate, it is not clear how useful such information will be in legal proceedings, Appelbaum emphasized. For example, "A question that remains to be answered concerns the validity of inferences that can be drawn from genetic information. To the extent that it establishes anything about a person, it will tend to establish proclivities for certain kinds of behaviors. . . , but will not in general be able to speak to why the particular act occurred."

Or as Bernet put it more bluntly: "Your genetic makeup doesn't make you do anything. It is only a risk factor."

Moreover, "Hard data from brain imaging and genetic studies aren't sufficiently mature for the courtroom yet and serve mostly to mislead jurors into adopting overly deterministic concepts of criminal behavior," Park Dietz, M.D., Ph.D., a forensic psychiatric in Newport Beach, Calif., asserted. "If a risk factor makes it 10 times more likely that carriers will commit a homicide, all that really means is that the defendant's biology raised his odds of killing from 5 in 100,000 to 5 in 10,000. Does that mean that he had no choice?"

Added Fred Berlin, M.D., Ph.D., a Johns Hopkins psychiatrist who, like Dietz, has testified in several high-profile criminal cases, "As science and technology continue to evolve, providing ever more informative contributions to the forensic field, it will still be critical that practitioners remain knowledgeable about mental experience and about the uniquely human and moral issues that must often be addressed in a court of law. There are some questions that science and technology alone simply cannot answer."

Meanwhile, it appears that courts are moving toward an evolving consensus that brain scans and genetic tests are appropriate for the penalty phase of

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PROFESSIONAL NEWS

Ted Grudzinski/AMA

Jeremy Lazarus, M.D., concluded his year as only the third psychiatrist president of the AMA at the June meeting of the House of Delegates.

Lazarus Recounts Year As AMA President

The AMA's voice helped secure an important victory in *Sutter v. Oxford Health Plans,* allowing individual physicians to come together as a group to fight the unfair business practices of large health insurance companies.

BY MARK MORAN

It was a year of tumult, challenges, and successes that outgoing AMA President Jeremy Lazarus, M.D., recalled in his presidential address last month at the AMA's House of Delegates meeting in Chicago.

Lazarus recounted legislative and legal victories by the AMA regarding physician payment, scope of practice, insurance coverage, and access-to-care issues, as well as the organization's continued pursuit of the goals of its strategic initiative: enhancing physician professional satisfaction and practice sustainability, changing and improving medical education for the 21st century, and improving health outcomes.

Lazarus noted that in February, he participated in a Senate hearing on the Physician Payment Sunshine Act, the new transparency regulations regarding interaction between physicians and representatives of the pharmaceutical, medical device, and other related industries.

"This provision will require those companies to report any payments or other 'transfers of value' they make to physicians on an annual basis and to publish that information via a public database," he said. "The AMA has long supported greater transparency between physicians and industry, but as I declared to the Senate directly—we want the law implemented appropriately and physician rights to challenge false or misleading reports protected."

The Centers for Medicare and Medicaid Services starts tracking this information on August 1, and not everyone is aware of it. "So we've launched a Sunshine Act resource page on our Web site to educate physicians on the requirements, and we're offering online modules and webinars to explain it in detail," he said.

(APA is also undertaking initiatives to educate members about the new law. See article on page 15.)

In another practice issue, the AMA has launched the Integrated Physician Practice Section (IPSS) to help physicians shape policy that enhances physician satisfaction and improves practice sustainability. "It's now crystal-clear to me that the future of medical care depends much on how well physician-led integrated practices work to keep patients healthy and how well they function for their physician members," Lazarus said. "In my practice, I've seen thousands of patients one at a time. Now we can leverage what we can do for so many more patients by working more effectively together. That's what the IPPS is all about. It will address the issues and needs facing physicians in group and integrated practices and provide a forum for those who have moved into the many new nontraditional types of practice."

State-Level Victories Achieved

He noted that the AMA earned more than 125 legislative victories at the state level—from insurer transparency to preserving medical liability reforms—by working with state medical societies. Among these was a major decision handed down by the U.S. Supreme Court in *Sutter v. Oxford Health Plans* that ruled that individual physicians can come together as a group to fight the unfair business practices of large health insurance companies. That decision concluded a dispute that alleged the company systematically bundled, down-coded, and delayed payments for 20,000 physicians in its network.

"The AMA-led brief with the Medical Society of New Jersey noted that health insurers know that arbitrating disputes with individual physicians works to their advantage," Lazarus said. "They allow contract violations and underpayments to persist and leave physicians helpless to fight them. But thanks to this ruling, thousands of physicians will be allowed to use class arbitration against a health insurer that has underpaid them for more than a decade. This finally gives physicians a weapon to challenge unfair payment practices."

Mental Health Put in Spotlight

A past speaker of the APA Assembly, and just the third psychiatrist to be president of the AMA, Lazarus brought a new focus on mental illness and the importance of psychiatry to the larger medical community. In his address to the House of Delegates, Lazarus noted that only a month after his inauguration as AMA president last year, the Aurora, Colo., shooting occurred in which 12 people were killed and some 58 wounded. It was followed by the tragic shooting in Newtown, Conn., in December.

"It brought to the forefront problems with our mental health system and our capacity to prevent at least some of these tragic events," he said. "And as a psychiatrist, I was at the same time all too aware of the potential backlash against mental health patients. . . . [W]e know that the vast amount of violence has no relation to mental illness. So we went to work on initiatives to remove the stigma still present against those with mental illness and to offer better treatment options for those affected. Shortly after Sandy Hook, we met with [Obama] administration officials in Washington to discuss a strategy to address gun regulation, mental illness, and public education. We also believe strongly that physicians must be able to have a frank discussion with their patients and families about firearm safety issues and risks. . . . And we are pleased also that the CDC will again be able to begin epidemiological research on gun violence to better inform the ongoing debate." PN

The AMA's Sunshine Act resource page is at http://www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports.page. To view a video interview with Lazarus at APA's 2013 annual meeting, go to http://www.psychiatry.org/advocacy--newsroom/newsroom/video-news. To view a video of Lazarus's address at the AMA meeting, go to http://www.ama-assn.org/ama/pub/news/speeches/2013-06-15-lazarus-annual-address.page.

Forensic

continued from facing page

criminal trials, even if they aren't suitable for determining guilt, Appelbaum pointed out.

Bernet thinks this trend will continue. "In fact, it is my hunch that over the years, brain scans and genetic information will undermine the use of the death penalty, because I think that more and more people will appreciate that many people commit crimes who don't have total control over what they do."

Regardless of the direction in which forensic psychiatry science is headed, courts will probably use it in some form if the past is any indication. Specifically, Deborah Denno, Ph.D., J.D., a professor of law at Fordham University, studied 81 criminal cases from 1994, when forensic psychiatry became an official subspecialty, up to 2011, to see how often judges admitted psychiatric genetic evidence into court proceedings. The evidence could have been, for example, that mental illness was prevalent in a defendant's family or that a defendant had a genetic propensity toward alcoholism or substance abuse.

During this 17-year period, Denno found, judges became increasingly accepting of such evidence. As an example in a well-publicized case, experts said that Susan Smith escaped the death penalty in 1995 for drowning her two children because depression and suicide attempts ran in her family.

Denno reported these findings February 22 at a meeting of the National Association of Criminal Defense Lawyers in Washington, D.C. PN

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- Successful Psychosocial Aging: Implications for Our Patients and Ourselves **DILIP JESTE, MD**
- Posttraumatic Stress Disorder: Recent Advances from Neurobiology to the Clinic **KERRY RESSLER, MD, PHD**
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- The Dementia Dilemma: Diagnosis and Treatment of Agitation and Psychosis **MARC AGRONIN, MD**
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- Bringing Accountability to Office-Based Treatment of Depression **MARK ZIMMERMAN, MD**
- Taming the Beast: Practical and Effective Non-Pharmacological Treatment Options for Bipolar Depression **SAUNDRA JAIN, MA, PSYD, LPC**
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- Neurostimulation for Mood Disorders **SCOTT AARONSON, MD**
- The Perils and Promise of Psychoactive Drugs: A Focus on Harm Reduction Psychiatry **ANDREW PENN, RN, MS, NP, CNS, APRN-BC**
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GOVERNMENT NEWS

Manufacturers to Begin Tracking Payments To Physicians for Sunshine Law

Physicians will have 45 days to review manufacturer reports and an additional 15 days to dispute reports that they believe are erroneous.

BY MARK MORAN

Important dates and deadlines are fast approaching for implementation of the Physician Payment Sunshine Act (PPSA).

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.

The law requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid, or the Children's Health Insurance Programs (CHIP)—as well as applicable group purchasing organizations (GPOs)—to report annually to the secretary of the Department of Health and Human Services certain payments or other transfers of value made to physicians and teaching hospitals.

Applicable manufacturers and GPOs are subject to civil monetary penalties ranging from $1,000 to $1 million if they fail to comply with the reporting requirements of the statute.

Beginning August 1 and continuing for the rest of the year, manufacturers will be required to collect and track transfers of payment and ownership information. On March 31, 2014, manufacturers and GPOs must report the data to the Centers for Medicare and Medicaid Services (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.

If a challenged payment is not resolved within 15 days of initiating a dispute, CMS will publish the payment, flagging it as "disputed." Failure to challenge an alleged mistaken payment within this time frame will result in CMS's acceptance of the payment as accurate.

Beginning September 30, 2014, CMS will publish the reported data on its public Open Payments Web site at go.cms.gov/openpayments.

wwwebmeister/Shutterstock

Q and A on the Sunshine Act

Here are some answers to important questions about the PPSA:

Who must submit reports?

Manufacturers of drugs, devices, biologicals, and other medical supplies covered under Medicare, Medicaid, or CHIP that operate in the United States. Manufacturers and GPOs must report ownership interests held by physicians and their close family members.

Who gets reported on?

"Covered recipients," which CMS defines as physicians and teaching hospitals.

What payments or transfers of value trigger reporting?

- Any direct payments or transfers of value to physicians and/or teaching hospitals of $10 or more.

- Indirect payments or transfers of value that a third party indicates are intended to be passed through to a physician.

- Indirect payments or transfers of value when manufacturers make a payment to a third party, such as a physician organization, and then require, instruct, or direct the payment or transfer of value to be a provided to a specific physician or intended generally for physicians (in the latter case without regard as to whether specific physicians are identified in advance).

What information must be reported?

- For each payment or transfer of value, applicable manufacturers and/or applicable GPOs must report the covered recipient's name and address; the covered recipient's specialty, NPI, and state license and number; amount of payment; date of payment; form of payment; nature of payment; name of the drug, device, biological, or medical supply associated with payment; national drug code, if possible; as well as the context of each transaction.

- For each ownership and investment interest, applicable manufacturers and/or applicable GPOs must report the covered recipient's name, address, specialty, NPI, and state license and number; dollar amount, value, and terms of ownership or investment interest; whether payment is held by an immediate family member of the physician; any payments or other transfers of value made to the physician owner or investor.

- For each payment related to research, applicable manufacturers and/or applicable GPOs must report the name of the institution receiving the payments and the principal investigators.

What is excluded from reporting?

- Certified and accredited CME.

- Buffet meals, snacks, soft drinks, or coffee generally available to all participants of large-scale events.

- Product samples that are not intended for sale and are intended for patient use.

- Educational materials that directly benefit patients or are intended for patient use (excludes textbooks).

- In-kind items used for the provision of charity care.

- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund.

*see **Sunshine** on page 27*

Enrollment in Health Insurance Exchanges to Open October 1

BY MARK MORAN

Beginning October 1, patients can enroll in the new Health Insurance Exchanges established by the Affordable Care Act.

Clinicians are urged to alert their patients to this important approaching date, to make them aware of this new option for health insurance coverage, and to discuss with them the possible benefits associated with this new way of accessing insurance coverage for medical care. Health insurance exchange plans offer the full range of benefits—including for psychiatric care—with no exclusions for preexisting conditions and no lifetime limits on benefit amounts.

Clinicians should note that some patients may require help in creating an account, applying for a plan, and maximizing their benefits and their cost savings.

Importantly, many low-income patients may qualify for cost savings and subsidies.

The health insurance exchanges, also known as the "marketplace," simplify the search for health coverage by gathering together in one place all the options available within a geographic area. With one application, patients can compare plans based on price, benefits, quality, and other features important to their medical needs. Patients, families, and clinicians can also get help online, by phone, by chat, or in person.

Information about prices and benefits is written in simple language, and individuals will get a clear picture of the premiums as well as the benefits and protections to which they are entitled before enrolling.

However, health exchanges vary from state to state in how well developed they are, and some states are choosing not to participate. Some states are well into the process with established Web sites, while many others have nothing posted yet. Patients and clinicians can sign up for updates so they can be alerted for changes as state exchanges evolve. PN

The Centers for Medicare and Medicaid Services has established an online resource that provides individuals all the information they will need to get started at https://www.healthcare.gov/marketplace/individual. Psychiatrists and patients can find information on the plans and assistance available in their state at https://www.healthcare.gov/what-is-the-marketplace-in-my-state.

INTERNATIONAL NEWS

WHO Plan Guides Nations on Improving Mental Health Care

The World Health Organization corrects an earlier oversight by approving a mental health action plan for its member countries.

BY AARON LEVIN

The World Health Organization (WHO) has adopted a draft comprehensive mental health action plan to be phased in by 2020. Paradoxically, the proposal is an outgrowth of a WHO plan on the prevention and control of noncommunicable diseases enacted in 2011—a plan that did *not* cover mental illnesses.

In response, several U.S. physicians, including Jeffrey Lieberman, M.D., now president of APA, organized a letter-writing campaign early in 2012 to the WHO Executive Board asking that mental health and mental illness issues be included in all health systems, said Eliot Sorel, M.D., a professor of global health and of psychiatry and behavioral sciences at George Washington University School of Medicine and School of Public Health, who was a cosigner of one letter (*Psychiatric News,* May 18, 2012).

At last year's World Health Assembly, WHO set in motion the mechanism to produce the action plan that was approved in May.

The new plan will "provide guidance for national action plans" and complements WHO's existing mental health gap action program, the goal of which is to expand mental health services in "low-resource settings."

The document noted that about 4 out of 5 people who need mental health care in low- or middle-income countries and nearly half of those in high-income countries do not receive such care.

APA's role should extend beyond gaining passage of the action plan, given the plan's seven-year horizon, said Sorel.

"It's important that the U.S. and APA be involved in the plan's implementation," he said. "WHO has only technical and advisory authority, so each WHO member country will track implementation and monitor the allocation of human and financial resources."

The new plan's goals include preventing mental disorders, providing care, enhancing recovery, and reducing mortality, morbidity, and disability for people with mental disorders. Accomplishing that will require improving countries' mental health care infrastructure while providing "comprehensive, integrated, and responsive mental health and social care services in community-based settings," according to the plan.

Implementation calls for the following six approaches to better mental health care:

- Universal health insurance
- Human rights
- Evidence-based practice
- A life-course approach
- Coordination with the general health, education, employment, housing, and other social sectors
- Empowering people with mental disorders in policy planning, service provision, research, and evaluation.

On a related front, in May 2012, the APA Assembly unanimously passed a resolution calling for creation of a new APA Council on Global Psychiatry that would "focus systematically on international membership, education, and advocacy." The resolution has been forwarded to an APA work group that is reviewing issues related to international psychiatrists, with a report from the work group to the Board of Trustees scheduled for 2014.

In other international action, the Assembly also asked APA to apply for consultative status as a nongovernmental organization to the United Nations. That request is under review by the United Nations, said Ricardo Juarez, senior program manager for international affairs in APA's Office of Minority and National Affairs. PN

The World Health Organization's "Draft Comprehensive Mental Health Action Plan 2013–2020" is posted at http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_10Rev1-en.pdf.

RESIDENTS' FORUM

The Soul of Psychiatry: Reflections at the End of Residency

BY DAVID HSU, M.D.

"Happiness lies in the absorption in some vocation which satisfies the soul."
—Sir William Osler

We never talk of souls any more. When Osler started the first residency program, he had the lives of clergy in mind. Physicians were to train like priests, and we still have priests in residency today. Osler believed that living in the hospital and seeing patients were good for the souls of residents. Now, at the end of my residency, I am humbled to have come this far in this honorable profession.

In residency, trainees learn to acquire the "soul" of psychiatry, the qualities that both sustain and define us. Like an Emersonian soul, it is imbued with a "wise silence" and a "common heart." Training in psychiatry provides insights about human nature that go beyond treating mental disorders to treating individuals who have those disorders. "Psyche" is Greek for "soul," a reminder for all psychiatrists, not just residents.

The Roman mythological story of Psyche and Cupid is quite inspirational. I've read it every year during residency as a reminder of the heights and depths to which human beings can aspire. Briefly, the god Cupid falls in love with a human, Psyche, and steals her away to his palace but does not reveal his identity or his appearance. Both fall madly in love, but he tells her that his identity must remain secret; otherwise, they cannot be together any more. Out of curiosity one night, she brings a lamp and sheds light onto her husband, revealing his true identity. Frightened, Cupid flees and leaves Psyche alone. She goes into a severe depression and attempts suicide three times by jumping into a river, each time saved by a spirit of the natural world. Psyche searches everywhere for her lover, even the Underworld, where she succumbs to a deep sleep. Cupid hears of this and flies to save her. With the help of Jupiter, Psyche becomes immortal and both marry in divine bliss.

The story of Psyche and Cupid teaches us that curiosity, for better or for worse, is a core feature of humanity. Psyche is also the only god who attempted suicide, and we learn from the story the importance of having relationships or staying connected. Over the years, I've learned to focus treatment plans on these two areas—that people are inherently curious and fundamentally social.

Finally, I'm struck by how creative mythological stories can be in resonating truths about the human spirit. Training to be a psychiatrist is truly a creative process. Few people really get that, and I think it is often overlooked. Residents are learning to create identities as psychiatrists and to help patients create narratives for themselves. Psychotherapy helps create meaning in lives where none was found or some was lost, essentially creating a personal mythology. The best paper I ever read was Otto Kernberg's "Thirty Ways to Destroy the Creativity of Psychoanalytic Candidates." It is full of sarcasm, but entirely humanistic. I think residency programs ought to make sure that trainees have plenty of opportunities for creative expression.

A patient recently asked me to pray for her soul. It was a 90-year-old woman with dementia who had fallen and broken her hip. After her operation, she thought she was in church and grasped my hands, saying in exuberant prosody, "Lord, bless our souls that we may exalt thee." Then, to my surprise, she closed her eyes, puckered up her lips, and whispered to me, "Now, give me some sugar." In my disbelief, I replied, "I'm sorry, ma'am, but I cannot kiss my patients." I bet even Osler didn't see that one coming.

My soul is content with ending residency, but my heart is excited when looking upon the future. A new era of psychiatry is just beginning. I am confident that the profession will continue to evolve for the better as we continue to help those in need. To my mentors and colleagues, thank you for imparting me with your wisdom and guidance all these years. To my patients, may you be filled with serenity in times to come. I also wish you the best, dear reader, and hope that you too are absorbed in a vocation that satisfies your soul. PN

David Hsu, M.D. is the graduating chief resident at the University of California, Davis, combined psychiatry and internal medicine program. He is starting a geriatric psychiatry fellowship in July at Harvard Medical School.

FROM THE EXPERTS

Pharmacological Treatments for Heavy Drinking

BY HENRY KRANZLER, M.D.

Drinking patterns vary considerably among individuals. However, medical and psychosocial problems increase as average drinking exceeds low levels and the frequency of intoxication increases. Although individuals with an alcohol use disorder (AUD) are often the focus of treatment efforts, heavy drinkers (who may not meet criteria for an AUD) are more numerous and a growing public-health concern. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) has identified low-risk drinking as weekly consumption of fewer than eight drinks for women and 15 drinks for men, with no heavy drinking (that is, for women, no more than three drinks in a day and, for men, no more than four drinks in a day). The clinically important adverse effects of heavy drinking suggest that interventions, including pharmacotherapy, are warranted for individuals who regularly exceed the NIAAA guidelines.

The major pharmacological approaches to treating heavy drinking are deterrent medications (for example, disulfiram), which produce adverse effects when alcohol is consumed, and medications that modify the activity of one or more of the neurotransmitter systems mediating alcohol reinforcement (for example, opioid antagonists). Disulfiram was the first medication approved by the Food and Drug Administration (FDA) to treat alcoholism, which occurred prior to the implementation of the rigorous requirements for efficacy that now exist. When combined with alcohol, disulfiram produces a characteristic set of unpleasant signs and symptoms, which are thought to deter drinking. However, in the largest controlled study of disulfiram, its beneficial effects were modest, though it may be more useful among alcoholics with whom special efforts are made to ensure compliance.

The opioid antagonists naltrexone and nalmefene have been approved to treat alcohol dependence in the United States and the European Union, respectively. In 1994, the FDA approved oral naltrexone, based on the results of two single-site studies, which showed it to be efficacious in the prevention of relapse to heavy drinking. The most recent meta-analysis of naltrexone showed that it

reduced the risk of any heavy drinking by about 17 percent relative to placebo and significantly reduced the number of heavy drinking days. Two alternatives to daily naltrexone treatment include a long-acting injectable formulation of naltrexone, which the FDA approved in 2006, and the "targeted" use of the oral medication to high-risk drinking situations. This as-needed approach was the basis for the recent approval of nalmefene by the European Medicines Agency to reduce heavy drinking in alcohol-dependent individuals.

Acamprosate is an amino acid derivative, the safety and efficacy of which have

*see **From the Experts** on page 26*

Henry Kranzler, M.D., is a professor of psychiatry at the Perelman School of Medicine of the University of Pennsylvania. He is the co-editor of *Clinical Manual of Addiction Psychopharmacology*, published by American Psychiatric Publishing. APA members may purchase the book at a discount at http://www.appi.org/SearchCenter/Pages/SearchDetail.aspx?ItemId=62132.

EDUCATION & TRAINING

Students' Perception of Clerkship Key to Psychiatry's Recruitment Success

Educational and curricular variables, such as the quality of a clerkship, and cultural variables such as the level of stigma about psychiatry among nonpsychiatric faculty may not be independent.

BY MARK MORAN

The quality of psychiatry clerkships, as rated by medical students, appears to affect recruitment rates into psychiatry.

Additionally, the reputation of the psychiatry department, the quality of resident teaching as perceived by medical students, and the regard in which psychiatry is held by nonpsychiatric faculty and other students at a medical school are also related to how well a program does in recruiting students into psychiatry.

Those were among the findings of two separate surveys—one of psychiatry medical school education leaders and another of medical students—to determine variables associated with recruitment success. Findings from the survey of psychiatry faculty were presented at the February meeting of the American Association of Directors of Psychiatric Residency Training, and the analysis of the survey of medical students was presented at APA's 2013 annual meeting in San Francisco in May.

Principal investigator John Spollen, M.D., an associate professor and vice chair for education at the University of Arkansas for Medical Sciences, said the quality of the psychiatry clerkship—when students get hands-on experience treating patients—appears to be a significant factor.

"There is a consistent finding that highly rated clerkships are associated with higher recruitment," he told *Psychiatric News*. "That's important to me because that is something I and other psychiatric educators have direct control over. Some of the other variables, such as stigma among nonpsychiatric faculty, are cultural factors that are harder to control.

"The clerkship is where students get the experience of hands-on patient care and seeing what it is that psychiatrists do," Spollen said. "It's a chance for students to see the strong interpersonal nature of the profession, when a lot of the rest of medicine doesn't have the same quality of relationship with patients. So students who are inclined to value the relationship with patients can become excited about psychiatry."

He noted that the relationship worked both ways—programs that had highly rated clerkships had better recruitment success, and those with poorly rated clerkships had poor recruitment.

Also noteworthy was the correlation between student perception of the quality of resident teaching and recruitment. "This was a measure of students' perception that residents and fellows provided effective teaching," Spollen said. "It may reflect something broader, like whether residents and fellows are good role models or provided a learning environment that makes psychiatry interesting."

Spollen, along with Deborah Hales, M.D., and Nancy Delanoche, M.S., from APA's Division of Education, gathered data from APA on recruitment rates from 124 U.S. allopathic medical schools from 2003-2011. Then they and colleagues from the Association of Directors of Medical Student Education in Psychiatry developed a 21-item survey of potentially relevant factors including information on curriculum (hours/length, settings, evaluations), educational leadership (course directors and deans), departmental and resident reputation, respect for psychiatry/antipsychiatry stigma among nonpsychiatric faculty, and availability of student interest groups.

Medical student education leaders in psychiatry from the top 25 and bottom 25 recruiting schools from 2003 to 2011 were subsequently surveyed by e-mail, and 76 percent completed the survey.

The second survey findings presented at the APA meeting used data from the American Association of Medical Colleges (AAMC) on NIH funding, tuition costs and student debt, as well as a subset of items from the Matriculation and Graduation Questionnaire (GQ) filled out by medical students across the country.

No significant correlations were found between recruitment rates for 2003 to 2011 and NIH funding, tuition, or various levels of debt. (However, in a subset analysis, 2009-2011 recruitment rates were negatively correlated with schools with an average student debt over $200,000.)

The survey of psychiatry faculty found that departmental/resident reputation and attitudes toward psychiatry as a profession by nonpsychiatric faculty and other students were related to recruitment success, while the AAMC and GQ results emphasized clerkship and resident teaching evaluations.

"These 'educational/curricular' and

see ***Clerkship*** *on page 24*

Cooper Medical School Wins Regional MindGames

Psychiatry residents at the Cooper Medical School of Rowan University/Cooper University Hospital in Camden, N.J., were the winners of the Philadelphia Psychiatric Society's (PPS) Third Annual MindGames Competition. They were led by faculty member Basant Pradhan, M.D. The competition, held at the Schuylkill River Park in March, was sponsored by the PPS Annual Colloquium of Scholars. It was composed of questions posed in a "Jeopardy"-style setting. The competition featured residents from area residency programs, including Drexel University, Temple University, Thomas Jefferson University, Einstein Healthcare Network, and the University of Pennsylvania.

On hand to participate in the fun was Deborah Hales, M.D., director of APA's Division of Education. The regional competition is similar to a competition sponsored each year by APA and the American College of Psychiatrists. That competition had its final round at APA's 2013 annual meeting.

From left: Deborah Hales, M.D. competition judge; team members Laura Hesselink, D.O., Mason Chang, M.D., and Amanda Gorecki, D.O.; Kenneth Weiss, M.D., competition judge; and Rajnish Mago, M.D., chair of the Philadelphia Psychiatric Society Annual Colloquium of Scholars.

Rowan University Cooper Medical School

Caution Urged for Clinicians Who Prescribe Opioids

Chronic pain is a complex psychosocial condition, and physicians who prescribe opiate painkillers should have a strategy for weaning patients off the medications and are urged to use a psychosocial approach.

BY MARK MORAN

Clinicians considering prescribing opioids for chronic-pain management need to carefully weigh the risks and benefits in the wake of rising rates of opioid addiction and overdose.

John Renner, M.D., associate chief of psychiatry at the VA Boston Healthcare System, and Roger Chou, M.D., an assistant professor of medicine at Oregon Health and Sciences University, urged caution in the use of opioids to treat chronic pain at a workshop on pain treatment and addiction risk at APA's 2013 annual meeting in San Francisco in May.

Both clinicians emphasized that while opioids can be extremely effective for severe chronic pain, their diversion and misuse are significant public-health problems. Renner presented data showing the recent rapid increases in deaths related to opioid overuse and in treatment rates for opioid addiction, while Chou outlined guidelines for prescribing opioids developed by the American Pain Society and the American Academy of Pain Medicine.

Renner also discussed efforts by the Food and Drug Administration (FDA) and Substance Abuse and Mental Health Services Administration (SAMHSA) to respond to what is considered a public-health rather than a criminal-justice problem. He also discussed emerging trends in the treatment of opiate addiction—especially the use of buprenorphine, naltrexone, and naloxone.

Renner also remarked on the emergence of a new and especially troubling phenomenon—combat veterans with a combination of chronic pain, substance abuse, posttraumatic stress disorder, and traumatic brain injury. "That's the constellation of really problematic patients we are going to be seeing in the VA," he said.

The trends in addiction and overdose related to prescription opioids are ominous. Renner showed data indicating that in 2010 more than 1.9 million people reported dependence on or abuse of opiate pharmaceuticals. Moreover, he said that by 2011 there were more than 400,000 emergency department visits related to abuse of opiate pharmaceuticals, surpassing the number related to heroin.

More individuals are now dying "because of the use of illegal and legal drugs than [from] motor-vehicle accidents," he said. "This is being primarily driven by opiate painkillers."

A number of initiatives are addressing the problem. In 2010 the FDA approved a version of OxyContin that when crushed becomes too slurry to inject; earlier this year the FDA said that all generic versions of the drug also had to be the same abuse-resistant formulation.

However, Renner noted a troubling undercurrent showing the stubborn nature of addiction—data from SAMHSA for 2012 showed a bump in heroin use that he said could be related to the introduction of these abuse-resistant formulations. "As people are no longer easily using some of the opiate pharmaceuticals, the problem hasn't simply gone away," Renner said. "They may be switching back to heroin as their drug of choice."

In addition, he noted that an FDA advisory panel this year recommended changing hydrocodone (Vicodin) from Schedule 3 to Schedule 2—a change that if implemented would restrict refills and prohibit fax or telephone scripts and prescribing by nurse practitioners or physician assistants. Only written prescriptions from a doctor would be allowed, and distributors would be required to store the drugs in special vaults.

(At the recent AMA House of Delegates meeting, physicians debated whether to lend AMA support for the rescheduling; see box above).

Key Points

- Abuse and diversion of prescription opiate painkillers has become an enormous public-health problem.
- Several initiatives by the FDA and SAMHSA are addressing this problem.
- There are guidelines to assist physicians in the best use of opioids for pain, emphasizing risk assessment for abuse and addiction before they are prescribed.

Bottom Line: Clinicians should carefully weigh risks and benefits of opioid use, assess patients for history of addiction, consider use of nonopioid and other adjunctive therapies first, and, if needed, use opioids as part of a multimodal psychosocial treatment strategy.

Federal Efforts Include Physician Education

Other federal initiatives include the FDA's Risk Evaluation Mitigation Strategy (REMS) Program in which pharmaceutical manufacturers of opiates contribute to a fund for continuing education of physicians on prescribing opiates and managing patients with chronic pain and/or addiction.

SAMHSA has instituted the Physician Clinical Support System–Buprenorphine and the Physician Clinical Support System for Opioid Therapy, both of which are Web-based training modules to guide clinicians in use of these drugs.

Finally, Renner said, State Prescription Drug Monitoring Programs, which are electronic databases designed to identify abuse and diversion of prescription drugs and facilitate treatment for those addicted to prescription drugs, show only variable and qualified success. Requirements for participation vary from state to state, and physician participation has been low; moreover, there are concerns about privacy and confidentiality, he said.

He urged clinicians to participate in such programs. "A goal would be for this program to be tied into an electronic medical record system, so that when prescribing, you would be able to check in real time the data on the prescription monitoring system," he said.

Use a Multimodal Strategy

Chou presented guidelines developed by the American Pain Society and the American Academy of Pain Medicine for prescribing opioids for noncancer chronic pain. He emphasized the need for clinicians to do a careful risk assessment of addiction history and drug-seeking behavior.

The guidelines' 22 recommendations include the following:

- Before initiating chronic opioid therapy (COT), clinicians should conduct a history, physical examination, and testing, including assessment of risk of substance abuse, misuse, or addiction.

- Clinicians may consider a trial of COT as an option if chronic noncancer pain is moderate or severe, is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harm.

- A benefit-to-harm evaluation, including a history, physical examination, and diagnostic testing, should be performed and documented before and on an ongoing basis during COT.

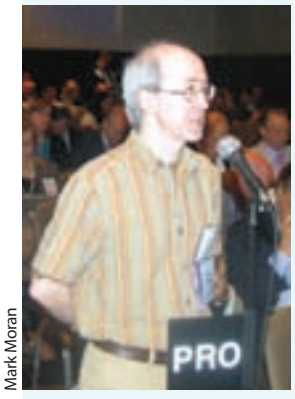
Chou also cautioned against continually upping the dosages of opioids when patients complain that pain is not ameliorated and urged clinicians to have a strategy for weaning patients off opioids. "Patients should have an exit strategy when starting an opioid," he said. "We want people to go in [to treatment] with a plan" to get off opioids.

Chou noted that use of opioids for pain may lower pain scores by a point or two, without necessarily improving real-world functioning. "This raises the question of what the goal of therapy is," he said.

He said treatment of patients with chronic pain should be a multidisciplinary endeavor and urged incorporation of nonopioid and nonpharmacologic therapies, including graded exercise and cognitive-behavioral therapy. "The data show that long-term benefits of opioid therapy are sparse, and we are not sure if they are improving functional outcome

*see **Opioids** on page 26*

AMA Delegates Debate Opioid Rescheduling



Mark Moran

Addiction psychiatrist Stuart Gitlow, M.D., argued at last month's meeting of the AMA House of Delegates that hydrocodone combination products (Vicodin) should be rescheduled as recommended by an FDA panel.

"We are in the middle of what the CDC describes as a prescribed opioid abuse epidemic, and Vicodin leads the way," Gitlow, a member of the Section Council on Psychiatry and the AMA's Council on Science and Public Health, said at the meeting. "The reason is because it is easier to prescribe than other narcotics in Schedule 2. The way to correct that is to make it so refills and telephone scripts are not allowed, because that is how this epidemic is caused."

But the resolution to have the AMA support the rescheduling was opposed by physicians in nursing homes and hospice care who argued it would interfere with care of patients with chronic pain. Karen Riley, deputy director for strategy at the FDA Office of External Affairs, testified at the meeting that the agency had received hundreds of public comments about the issue and was still assessing the recommendation. She noted that a decision would be made later this year.

CLINICAL & RESEARCH NEWS

Familial OCD: Environment, Genes Both Play Role

Psychiatrists are familiar with shared psychotic disorder, in which a couple experiences the same delusions. But can couples share obsessive-compulsive disorder? It may be possible.

BY JOAN AREHART-TREICHEL

Sergey Ivanov

Back in the 1920s, a youngster named "Martin" was plagued by thoughts that he feared would damn him to hell. During the 1950s, his daughter "Lynn" was as well. Although neither Martin nor Lynn was officially diagnosed with obsessive-compulsive disorder (OCD), it is likely that both suffered from it, not just on the basis of their symptoms, but because there is now ample evidence that OCD runs in families.

Yet when the illness clusters in families, how much is actually due to genes? A substantial amount, a study reported May 22 in *JAMA Psychiatry* suggests. The study was headed by David Mataix-Cols, Ph.D., a professor of clinical psychobiology at the Institute of Psychiatry at King's College, London.

The first arm of the study, which was conducted in Sweden, included some 25,000 Swedes diagnosed with OCD from 1969 to 2009, as well as all their first- , second- , and third-degree relatives available for study. This arm also included 10 control subjects for each OCD subject, matched by age, gender, migration status, and county of residence, as well as all their first- , second- , and third-degree relatives. The researchers then determined the odds of relatives of the OCD subjects having OCD, as compared with the relatives of the control subjects.

First-degree relatives of the OCD subjects were five times more likely to have OCD than first-degree relatives of the control subjects. Second-degree relatives of the OCD subjects were two times more likely to have OCD than second-degree relatives of the control subjects. And third-degree relatives of the OCD subjects were almost one-and-a-half times more likely to have OCD than third-degree relatives of the control subjects.

Thus, the more closely related one was to an OCD subject, the greater his or her chances of also having the disorder. Therefore, "OCD clusters in families primarily due to genetic factors," the researchers concluded.

In a second arm of the study, the researchers examined data from a population-based sample of more than 16,000 Swedish twins who had completed a questionnaire about various illnesses they had had, including OCD symptoms. The analysis showed that 47 percent of the familial risk for OCD in that cohort was due to genes, not to a shared environment. Thus, this "analysis confirmed that familial risk for OCD was largely attributable to . . . genetic factors, with no significant effect of shared environment," the researchers said.

Yet if about half the familial risk for OCD can be attributed to genes, not to a shared environment, that means that the remaining portion can be attributed to nonshared environmental factors, the researchers pointed out. And this finding has clinical implications, they asserted: "In the future, identification of environmental risk factors for OCD will be at least as important as, if not more important than, finding candidate genes for the disorder, because these risk factors may potentially be amenable to prevention or intervention strategies."

However, when *Psychiatric News* asked Mataix-Cols whether any environmental risk factors for OCD are known at this time, he said, "Unfortunately, nothing consistent. There is a lack of high-quality longitudinal research. Some cases may have an infectious/autoimmune origin (PANDAS), but this is controversial."

Finally, the researchers conducted a third arm of the study in which they examined rates of OCD in spouses or partners of the OCD subjects and of the control subjects.

They found that spouses or partners of the former were three times more likely to have OCD than spouses or partners of the latter, a finding they called "intriguing." They speculated, for example, that "[i]ndividuals preoccupied with contamination and cleanliness may be more likely to seek partners sharing this characteristic with them" or that "spouses could become more similar the longer they are married."

The study was funded by the Swedish Council for Working Life and Social Research, the Swedish Research Council, and the Swedish Ministry for Higher Education. PN

An abstract of "Population-Based, Multigenerational Family Clustering Study of Obsessive-Compulsive Disorder" is posted at http://archpsyc.jamanetwork.com/article.aspx?articleid=1689532.

Member-Get-A-Member Campaign Winners Announced

Next year it could be you!

The annual prize drawing for APA's International Member-Get-A-Member Campaign was held during APA's 2013 annual meeting in San Francisco. This campaign invites APA members to refer international colleagues for membership in the Association. The names of referrers and the names of referred colleagues are entered into a prize drawing the year the colleague joins APA. Here are the winners:

Grand-Prize Winners

The grand prize was free registration for APA's 2014 annual meeting, which is being held in New York from May 3 to 7. The winners were Ved Pal Mahla, M.B.B.S. (referrer) and Parshotam Dass Gargi, M.B.B.S. (new member from India).

Second Prize

The second prize was waived 2014 APA membership dues. The winners were Elzein Abbas Omara, M.D. (referrer) and Anne Omara, M.D. (new member from United Arab Emirates).

Third Prize

The third prize was a $100 American Psychiatric Publishing gift certificate. The winners were Alan Scott Wylie, M.D. (referrer) and Audrey Robertson Hillman, M.B.Ch.B. (new member from the United Kingdom). PN

More information on the International Member-Get-A-Member Campaign is posted at http://www.psychiatry.org/join-participate/international-member-get-a-member-recruitment-campaign.

Applicants Invited

The American Board of Psychiatry and Neurology is seeking applicants for its new Faculty Fellowship Award. The award is intended to support the development of innovative education and/or evaluation projects that promote effective residency/fellowship training or lifelong learning of practicing psychiatrists and neurologists. Preference will be given to projects that have the potential for use at more than one site and to applicants who are at a junior or mid-faculty level.

Up to two psychiatry and two neurology faculty fellows will be selected. The duration of the fellowship is two years with a maximum amount of funding of $50,000 a year or $100,000 total. Fellows will be required to dedicate at least 25 percent of their professional time to the project.

The deadline for applications is August 19. The fellowship will begin on January 1, 2014. More information can be obtained at http://abpn.com/forms.html#faculty-fellowship or from Dorthea Juul, Ph.D., at djuul@abpn.com.

Amygdala Size May Give Clue to Violence Risk

Could it be that the size of the amygdala plays a role in influencing an individual's actions?

BY JOAN AREHART-TREICHEL

The amygdala—that almond-shaped structure that sits in front of the hippocampus—is considered the brain's fear center. But when it is unduly small, it may contribute not to fear, but to aggressive, even violent, behaviors, a new prospective study suggests.

The findings were published May 6 in *Biological Psychiatry.* The lead researcher was Dustin Pardini, Ph.D., an assistant professor of psychiatry and psychology at the University of Pittsburgh. The senior researcher was Adrian Raine, Ph.D., a professor of criminology, psychiatry, and psychology at the University of Pennsylvania. Raine has been exploring the brains of antisocial individuals for several years (*Psychiatric News,* October 16, 2009).

In 1987, two University of Pittsburgh researchers—Rolf Loeber, Ph.D., and Magda Stouthamer-Loeber, Ph.D.—launched the Pittsburgh Youth Study, a longitudinal study of some 500 inner-city boys. Its goal was to document the development of antisocial and delinquent behavior from childhood to early adulthood. Pardini joined the research team nine years ago and is now codirector of the study with Loeber.

Pardini, Raine, Loeber, and Kirk Erickson, Ph.D., decided to use the Pittsburgh Youth Study for a new investigation. They recruited 56 men who had participated in the Pittsburgh Youth Study up to age 26 and whose levels of aggression and psychopathic features during childhood, adolescence, and early adulthood had been measured. According to self-assessment and criminal records, 20 had a history of chronic serious violence, 16 had a history of transient serious violence, and 20 had a history of no serious violence.

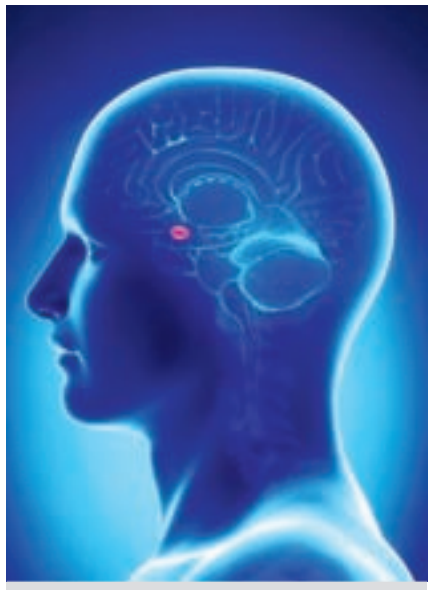
The researchers used structural MRI imaging to measure the amygdalae of the 56 subjects. They then assessed whether there was any correlation between amygdala size and levels of aggression and psychopathic features subjects had shown in childhood and adolescence, taking potential confounds such as race, age, handedness, IQ, concussion, and childhood maltreatment into consideration.

They found that subjects with smaller amygdalae exhibited significantly more aggression and psychopathic features in childhood and adolescence than did subjects with larger amygdalae.

Pardini, Raine, and their team then followed the subjects for three more years and during this time evaluated them for aggression, violence, and psychopathic traits. The researchers then evaluated whether there was an association between the size of the subjects' amygdalae three years earlier and their subsequent aggression, violence, and psychopathic traits, even after controlling for earlier levels of these features and other potential confounds.

Those with smaller amygdalae were three times more likely than those with larger amygdalae to exhibit aggression, violence, and psychopathic features three years later, they found.

"This is the first study to demonstrate that lower amygdalae volume is associated with features of aggression and psychopathy spanning from childhood to young adulthood," the researchers concluded. "It is also the first investigation to demonstrate that lower amygdala volume is a significant risk factor for future violent behavior."



CLIP Area/Custom media/Shutterstock

The amygdala is highlighted in this illustration. Researchers found that lower amygdala volume is a significant risk factor for future violent behavior.

Pardini told *Psychiatric News* that he and his colleagues do not think there are immediate clinical implications for their findings. "Research examining the neurobiological factors that may influence the development and persistence of violence and psychopathic features is still in its infancy. . . . This study suffered from several limitations such as the use of a relatively small sample. . . . Replication of the findings by other investigators using different samples is necessary. . . . And we also need to better understand how structural differences in the amygdala impact not only violent behavior, but other of the amygdala's functions such as fear conditioning and moral decision making."

The study was funded by the National Institute on Drug Abuse, National Institute of Mental Health, Pew Charitable Trusts, and the Office of Juvenile Justice and Delinquency Prevention. PN

An abstract of "Lower Amygdala Volume in Men Is Associated With Childhood Aggression, Early Psychopathic Traits, and Future Violence" is posted at www.biologicalpsychiatryjournal.com/article/S0006-3223(13)00312-0/abstract.

DSM-5 SELF-EXAM

Bipolar and Related Disorders

Based on new data available since *DSM-IV,* some changes have been made to the criteria and the text for bipolar disorder; however, the essential elements of the clinical symptoms associated with the depressive and manic-hypomanic components are relatively unchanged.

Given the long delay from first symptoms to correct diagnosis of bipolar disorder in the community, criteria now include an emphasis on changes in activity and energy as well as mood in the context of mania and hypomania in the hope that emphasis on this more objective component of mania will lead to earlier detection. The diagnosis of bipolar I disorder, mixed type, requiring that the individual simultaneously meet full criteria for mania and for major depressive episode, is removed. Instead, a new specifier "with mixed features" has been added that can be applied to episodes of mania or hypomania when depressive features are present and to episodes of depression in the context of lifetime diagnoses or either major depressive disorder or bipolar disorder when features of hypomania are present.

The questions below are from *DSM-5 Self-Exam Questions: Test Questions for the Diagnostic Criteria*, which may be preordered at http://www.appi.org/SearchCenter/Pages/SearchDetail.aspx?ItemId=62467 from American Psychiatric Publishing. The answers and rationales are posted at http://www.psychnews.org/pdfs/DSM-5_Self_Examination_QandA_8.pdf. The book, available in August, 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. Which of the following is a change made by *DSM-5* from the *DSM-IV* criteria for bipolar disorders?

a) "increased activity" has been added to the A criterion for manic and hypomanic episodes
b) bipolar disorder, mixed type, now requires a patient to simultaneously meet full criteria for mania and major depression
c) the removal of subsyndromal hypomania from the subtypes for bipolar not elsewhere classified (NEC)/NOS
d) the stipulation that manic or hypomanic episodes cannot be associated with recent administration of a drug known to cause similar symptoms
e) the clinical symptoms associated with hypomanic episode have been substantively changed from *DSM-IV.*

2. Which of the following statements correctly describes the primary diagnostic difference between manic and hypomanic episodes?

a) manic episodes have a greater variety of symptoms than do hypomanic episodes
b) manic episodes last for longer periods than do hypomanic episodes
c) manic episodes do not include any psychotic symptoms
d) hypomanic episodes do not cause clinically significant distress or impairment
e) hypomanic patients generally have less insight into their illness

see **DSM-5 *Self-Exam*** *on page 24*

CLINICAL & RESEARCH NEWS

Serdar Dursun, M.D., Ph.D.

Serdar Dursan, M.D., Ph.D.: While researchers hypothesized that sodium nitroprusside would ameliorate schizophrenia symptoms, they did not predict that "the improvement would be as fast as observed and so dramatic."

Surprising Drug Improves Schizophrenia Symptoms

A drug on the market for almost a century to treat severe high blood pressure produces rapid and long-lasting improvement of schizophrenia's positive and negative symptoms.

BY JOAN AREHART-TREICHEL

Once in a while, research findings published in medical journals seem too good to be true.

This is the case for results from a small proof-of-concept study published May 8 in *JAMA Psychiatry.* Scientists reported that a single infusion of the drug sodium nitroprusside into schizophrenia subjects led to a rapid and dramatic decline in both positive and negative symptoms—and the effects lasted for four weeks.

In an accompanying editorial, Joseph Coyle, M.D., a professor of psychiatry at Harvard Medical School and editor in chief of *JAMA Psychiatry,* described the results as "remarkable." Nonetheless, "the field is littered with small trials with robust outcomes that ultimately are not replicated," he cautioned.

The research was conducted by Canadian and Brazilian scientists with an interest in the same areas of research. The scientist leading the Canadian team was Serdar Dursun, M.D., Ph.D., a professor of psychiatry and neuroscience at the University of Alberta; the scientist leading the Brazilian team was Jaime Hallak, M.D., Ph.D., of the University of Sao Paulo.

Sodium nitroprusside has been in clinical use since 1929 for severe high blood pressure and is commercially available for intravenous administration. Dursun, Hallak, and their colleagues found in animal experiments that blocking NMDA glutamate receptors induced psychosis-like behavior, but that giving the animals sodium nitroprusside abolished the behavior. These findings prompted them to believe that sodium nitroprusside might improve symptoms in people with schizophrenia, and they decided to conduct a small study to test the hypothesis.

They conducted the study in a university teaching hospital in Sao Paulo. It included 20 inpatients aged 19 to 40 with a diagnosis of schizophrenia who were in the first five years of the illness and being treated with antipsychotics. Half of the subjects received an infusion of sodium nitroprusside, and half received an infusion of a placebo (a glucose solution). They were evaluated with the 18-item Brief Psychiatric Rating Scale and the negative subscale of the Positive and Negative Syndrome Scale before, during, and after treatment.

Dramatic Improvement Seen Within Hours

Most of the subjects who had received the sodium nitroprusside experienced a rapid—within hours—and dramatic improvement in both their positive and negative symptoms—an improvement that lasted for four weeks. Subjects who had received a placebo experienced no improvement.

"The results clearly show a therapeutic effect of sodium nitroprusside," the scientists concluded.

Furthermore, the sodium nitroprusside infusion was found to be safe in those who received it. As the researchers explained, "The dose used in this study was the minimum dose required for sodium nitroprusside to lower blood pressure in hypertensive patients, and it is well established that in normotensive individuals, much higher doses of sodium nitroprusside are needed to lower blood pressure than for hypertensive patients."

Dursun told *Psychiatric News* that he was surprised by these findings. "Based on the very impressive preclinical data. . . , we did hypothesize that sodium nitroprusside would improve schizophrenia symptoms. . . . However, we did not predict that the improvement would be as fast as observed and so dramatic."

As for the clinical implications of the findings, he said, "There is a need for a rapid-onset antipsychotic medication with minimal side effects to use in acute care and emergency settings. Therefore we can only hope that sodium nitroprusside may prove to address this gap in helping patients with schizophrenia." Moreover, "We are very keen to develop different easy-to-use formulations of sodium nitroprusside, such as transdermal patches or nasal sprays. . . and to investigate the effectiveness of these formulations in schizophrenia."

Key Points

- In a small proof-of-concept study, an infusion of sodium nitroprusside led to a rapid, dramatic decline in positive and negative symptoms in schizophrenia subjects, and the effects lasted four weeks.
- Such a dramatic effect after a single-dose treatment is not unprecedented. When a single dose of the drug ketamine was given to subjects with drug-resistant depression, a rapid improvement in mood occurred that persisted for a week or more.
- Experts suggest that sodium nitroprusside's effects in schizophrenia and ketamine's effects in depression may be related. Ketamine is known to counter NMDA glutamate receptors in the brain, and sodium nitroprusside may do the same.
- Sodium nitroprusside might find a use as a rapid-acting antipsychotic in acute care and emergency settings.

Comparison to Ketamine Made

Actually "such a persistent effect after a single-dose treatment is not unprecedented," Coyle noted in his editorial. "Recent research has demonstrated that a single dose of the NMDA receptor antagonist ketamine when given to patients with drug-resistant depression can provide a rapid improvement in mood that persists for a week or more" (*Psychiatric News,* September 17, 2010).

When Dursun was asked whether he sees a parallel between sodium nitroprusside's rapid and dramatic action against schizophrenia and ketamine's rapid and dramatic action against depression, he noted that "there may be some overlapping similarities. . . . The precise mechanism of action of sodium nitroprusside in schizophrenia remains unclear, but it seems likely that at least one mechanism is through the involvement of nitric oxide in modulating NMDA glutamate receptors."

Furthermore, there is "an increasingly compelling body of evidence from drug challenges, postmortem analyses, and gene-association studies that hypofunction of the NMDA receptor, a glutamate receptor subtype that mediates neural plasticity, is a core feature of schizophrenia," Coyle pointed out. "NMDA receptor hypofunction appears to be particularly relevant to negative symptoms and cognitive impairment in schizophrenia."

The research was funded by Brazil's Fundacao de Amparo a Pesquisa do Estado de Sao Paulo. PN

An abstract of "Rapid Improvement of Acute Schizophrenia Symptoms After Intravenous Sodium Nitroprusside: A Randomized, Double-Blind, Placebo-Controlled Trial" is posted at http://archpsyc.jamanetwork.com/article.aspx?articleid=1686035. An abstract of "Nitric Oxide and Symptom Reduction in Schizophrenia" is posted at http://archpsyc.jamanetwork.com/article.aspx?articleid=1686036.

Dependence May Result When Alcohol Used to Self-Medicate

Individuals who use alcohol to self-medicate mood symptoms have three times the risk that their drinking may lead to alcohol dependence than do nondrinkers with mood symptoms.

BY JOAN AREHART-TREICHEL

Christin Slavkov/Shutterstock

Using alcohol to self-medicate mood symptoms can be risky, a new study reported May 1 in *JAMA Psychiatry* suggests. The study was headed by Rosa Crum, M.D., a professor of epidemiology, psychiatry, and mental health at the Johns Hopkins Medical Institutions.

Data were derived from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), which was conducted by the National Institute on Alcohol Abuse and Alcoholism. It consisted of face-to-face interviews with a nationally representative sample of about 43,000 Americans to learn whether they had *DSM-IV* psychiatric or substance use disorders. The initial surveying took place in 2001 and 2002. The survey was again conducted in 2004 and 2005 with as many of the original subjects as possible—some 35,000 people. Crum and her colleagues used data from both the initial and follow-up surveys for their study.

First Crum and colleagues focused on the approximately 4,200 subjects who had been found in the first NESARC survey to have mood symptoms but not alcohol dependence and who had been asked whether they used alcohol to self-medicate their mood symptoms. Then, from the second survey, they evaluated whether subjects who had used alcohol to self-medicate their mood symptoms were more likely to develop alcohol dependence than were subjects who had not used alcohol to self-medicate mood symptoms.

The researchers found that subjects who had used alcohol to self-medicate their symptoms were three times more likely to develop alcohol dependence than were subjects who had not used alcohol to self-medicate. Moreover, 12 percent of the individuals who developed alcohol dependence could possibly attribute their dependence to self-medicating their mood symptoms with alcohol.

In addition, Crum and colleagues focused on about 1,500 subjects who had been found during the first NESARC survey to have both mood symptoms and alcohol dependence and who had been asked whether they used alcohol to self-medicate their mood symptoms.

Using data from the second survey, the researchers assessed whether subjects in this second group who had used alcohol to self-medicate mood symptoms were more likely to remain alcohol dependent than subjects who had not used alcohol to self-medicate their symptoms.

This turned out to be the case. Those who had used alcohol to self-medicate were three times more likely to remain alcohol dependent as were subjects who had not used alcohol to self-medicate. Furthermore, 31 percent of subjects who had been alcohol dependent and were still dependent at the time of the second NESARC survey could possibly attribute their persistent dependence to self-medicating their mood symptoms with alcohol.

Finally, the researchers assessed whether this link between self-medication and alcohol dependence or the link between self-medication and persistent alcohol dependence differed for various subgroups within the two cohorts—men and women, young and old, individuals of various ethnic or racial backgrounds, those with few mood symptoms or a lot of symptoms, and those who had received treatment for their mood symptoms and those who had not.

They found that similar links existed for all of these subgroups.

The two results that surprised them, Crum told *Psychiatric News,* were that the link held even among individuals who had received treatment for their mood symptoms and was found as well among individuals who did not meet full criteria for a mood disorder.

The findings have clinical implications, Crum suggested. "Individuals who report mood symptoms should have an evaluation to assess whether clinical treatment is needed, but should not drink alcohol to help themselves feel better. Patients with mood symptoms in psychiatric treatment may need to be educated regarding the potential risks of using alcohol for self-medication, as well as assessed for the presence of alcohol disorders."

The study was funded by the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, the Canadian Institutes of Health Research, the Manitoba Health Research Council, and the Johns Hopkins School of Medicine. PN

An abstract of "A Prospective Assessment of Reports of Drinking to Self-Medicate Mood Symptoms With the Incidence and Persistence of Alcohol Dependence" is posted at http://archpsyc.jamanetwork.com/article.aspx?articleid=1684867.

Varenicline Shows Promise As Alcohol Abuse Treatment

It appears that the smoking-cessation medication varenicline can also reduce alcohol use by people who are alcohol dependent.

BY JOAN AREHART-TREICHEL

A medication used to aid smoking cessation—varenicline (Chantix)—can also reduce alcohol dependence, according to a study published June 3 in the *Journal of Addiction Medicine.*

The study was conducted by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) Clinical Investigations Group—a multicenter team of researchers.

Two hundred men and women meeting criteria for alcohol dependence were recruited across five clinical sites. The subjects received varenicline or a placebo for 13 weeks.

Data showed that the varenicline group consumed significantly less alcohol and experienced significantly less alcohol craving than did the placebo group. Moreover, the average treatment effect of varenicline on alcohol use was similar for smokers and nonsmokers. Varenicline was also well tolerated. The most common side effects were nausea, abnormal dreams, and constipation, and those effects were generally mild, the researchers noted.

Thus, varenicline is "a potentially viable option for the treatment of alcohol dependence," the researchers concluded in their paper.

"This is an encouraging development in our effort to expand and improve treatment options for people with alcohol dependence," Kenneth Warren, Ph.D., acting director of NIAAA, said in an accompanying press statement. "Current medications for alcohol dependence are effective for some, but not all, patients. New medications are needed to provide effective therapy to a broader spectrum of alcohol-dependent individuals."

"Drinking and smoking often co-occur, and given their genetic and neurochemical similarities, it is perhaps not surprising that a smoking cessation treatment might serve to treat alcohol problems," Raye Litten, Ph.D., noted in the same statement. Litten, associate director of the NIAAA Division of Treatment and Recovery Research, was the lead investigator in the study.

Varenicline is a partial nicotinic acetylcholine agonist approved by the Food and Drug Administration for smoking cessation in 2006. PN

An abstract of "A Double-Blind, Placebo-Controlled Trial Assessing the Efficacy of Varenicline Tartrate for Alcohol Dependence" is posted at http://journals.lww.com/journaladdictionmedicine.

MED CHECK

BY LESLIE SINCLAIR

Lilly Halts Study on Beta Secretase Inhibitor

Eli Lilly and Co. announced June 13 that it has discontinued its phase 2 study (BACC) for ***LY2886721, a beta secretase (BACE) inhibitor,*** being investigated as a treatment for its potential to slow the progression of Alzheimer's disease. The termination was due to the appearance of abnormal liver biochemical tests, which were identified as part of routine monitoring. Lilly said it believes the abnormal liver biochemical tests are not related to the BACE mechanism, and the company continues to be interested in developing BACE inhibitors for patients with Alzheimer's disease. Lilly will conduct additional data evaluations before determining next steps for the entire LY2886721 clinical development program and will continue to monitor participants with abnormal liver values.

MedWatch Program Celebrates 20 Years With New Consumer Form

The Food and Drug Administration (FDA) is celebrating the 20th anniversary of its MedWatch program, which provides important safety information associated with FDA-regulated products, with a new form intended to encourage more consumer participation.

Under MedWatch, health care professionals and consumers submit reports to the FDA when they find a problem with a drug, medical device, biologic, or other FDA-regulated product. Over the years, most of the voluntary MedWatch forms have been submitted by health care professionals, but recently consumers have been increasingly interested in participating in the program. The new, consumer-friendly MedWatch reporting form is a response to consumer concerns that the form is too technical. FDA officials worked with groups such as AARP, Consumers Union, and the National Women's Health Network in developing the new form. Also being introduced is a new Web-based learning tool, called MedWatchLearn, which is designed to educate students, health care professionals, and consumers on how to complete a report properly. MedWatchLearn also provides examples of quality reports that include critical information to help FDA evaluate the event or product-quality complaint.

Canada Approves Aripiprazole As MDD Add-On

Bristol-Myers Squibb Canada announced June 6 that ***Abilify (aripiprazole)*** has received an additional approval from Health Canada as an adjunct treatment for major depressive disorder (MDD) in adults who had an inadequate response to prior antidepressant treatments during the current episode. When used with an antidepressant, Abilify has been shown to improve symptoms in adults with MDD who had an inadequate response to at least two trials with antidepressants during the current episode. It is the first add-on treatment for MDD to be approved in Canada. The Health Canada approval is based on results from three six-week, double-blind, randomized, placebo-controlled, multicenter studies (n=1,088). The results from all three studies indicated significant improvement in depressive symptoms in adult patients with a primary diagnosis of MDD who had experienced an inadequate response to monotherapy with two or more antidepressants. Significant improvements in depression symptoms were seen in the second week of add-on treatment with Abilify, when compared with the control subjects.

Abilify is also the first Health Canada–approved antipsychotic for adolescents (schizophrenia patients aged 15 to 17 and for acute treatment of manic or mixed episodes in bipolar I disorder as monotherapy in adolescent patients aged 13 to 17). It was first approved in July 2009 by Health Canada for treatment of schizophrenia and related psychotic disorders in adults and for treatment of manic or mixed episodes in bipolar I disorder in adults as acute monotherapy or co-therapy with lithium or divalproex sodium when there is an insufficient acute response to these agents alone.

Lynn Watson/Shutterstock

Walgreens Reaches Settlement For $80 Million

On June 11, Illinois-based pharmacy chain Walgreens said it had reached an agreement with the Drug Enforcement Administration (DEA) and the Department of Justice, which settles and resolves all administrative and civil matters arising out of DEA's concerns relating to the distribution and dispensing of controlled substances out of a Jupiter, Fla., Walgreens distribution center. The Walgreens Jupiter is one of 12 distribution centers owned and operated by the Walgreens Corporation, which is also the parent company of more than 7,800 Walgreens retail pharmacies in the United States. Walgreens Jupiter distributes controlled substances exclusively to Walgreens pharmacies located on the East Coast. On April 4, 2012, the DEA Miami Field Division served an Administrative Inspection Warrant on Walgreens Jupiter and its top six retail pharmacies in Florida after it became aware of "an unprecedented number" of record-keeping and dispensing violations, most related to dispensing of oxycodone.

Under the terms of the agreement, Walgreens will pay $80 million. The agreement resolves all pending litigation and requires Walgreens to surrender its DEA registrations at only six of its more than 800 Florida pharmacies until May 2014 and at its Jupiter distribution center until September 2014. "As part of the agreement with DEA and our continuing desire to work with DEA to combat prescription drug abuse, we have identified specific compliance measures—many of which Walgreens has already taken—to enhance our ordering processes and inventory systems; to provide our team members with the tools, training, and support they need to ensure the appropriate dispensing of controlled substances; and to improve collaboration across the industry," said Kermit Crawford, Walgreens' president of pharmacy, health, and wellness. PN

Clerkship

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'environmental/cultural' factors are probably not independent," Spollen said. "Further study of this subject should include qualitative analysis of high- versus low-recruiting schools and evaluations of culture, climate, and stigma involving medical students directly in high- versus low-recruiting schools. Potential interventions to improve recruitment rates might include curricular and teaching improvements, mentoring programs and student interest groups that might help buffer against antipsychiatry stigma, and possibly 'appreciative inquiry-led' culture-change initiatives." PN

DSM-5 Self-Exam

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3. A 25-year-old graduate student presents to a psychiatrist complaining of feeling down and "not enjoying anything." Her symptoms began about a month ago along with insomnia and poor appetite. She has little interest in activities and is having difficulty attending to her schoolwork. In taking a history, she recalls a similar episode one year prior that lasted about two months before improving without treatment. She also reports several episodes of increased energy in the past two years. These episodes usually last one to two weeks, during which time she is very productive and sees herself as more social and outgoing. She tends to sleep less during those times, but feels energetic during the day. Friends tell her that she speaks more rapidly during those times, but they do not see it as off-putting and in fact tell her she is more outgoing and clever during those periods. She has no medical problems, does not take any medications, or abuse drugs or alcohol. Which of the following is her most likely diagnosis?

a) bipolar I disorder, current episode depressed
b) bipolar II disorder, current episode depressed
c) bipolar I disorder, mixed
d) cyclothymic disorder
e) major depressive disorder PN

Newtown

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trist-in-chief at the Institute of Living and vice president of behavioral health at Hartford Hospital.

"After the shooting, we had a crush of children and adolescents brought into the emergency department by families who feared they could become seriously dangerous," he told *Psychiatric News*.

On the legislative front, new mental health legislation enacted so far in Connecticut is a mixed bag, said Schwartz, who is also legislative chair of the CPS. On the positive side, steps were taken to increase access to early treatment for young people, expand training in mental health first aid, and develop school-based mental health programs.

"But I'm disappointed in proposals requiring that all voluntarily hospitalized psychiatric patients be reported to the state and are thus prevented from obtaining gun permits," said Schwartz. Under existing law, patients involuntarily committed by the courts are added to the registry and the federal gun-purchase database, but those hospitalized under a physician's emergency certificate are not.

"That is ironic," said Schwartz. "Putting patients on a registry would have little value for public safety but would discourage patients from coming in for treatment."

The CPS was also instrumental in passage of a draft statement in the APA Assembly in May calling for improved firearms safety, restriction of access to guns by people considered dangerous (whether mentally ill or not), research on violence, and improved mental health services and access to care. The APA Board of Trustees is scheduled to discuss the Assembly's proposal at its meeting this month.

Trauma-Care Training Added

Meanwhile, numerous mental health agencies, hospitals, and university psychiatry departments are caring for Newtown residents or training those who help them.

"We're working on building capacity in the community by increasing the skills in trauma care among local mental health providers so they can offer their expertise to the primary care community," Charles Herrick, M.D., chief of psychiatry at Danbury Hospital, told *Psychiatric News*.

After the acute phase, it was important to help local clinicians learn how to screen for reactions to trauma, psychologist Stephen Marans, Ph.D., of the Yale Child Study Center, said in an interview.

Marans and Yale colleague Steven Southwick, M.D., a posttraumatic stress disorder specialist at the West Haven Veterans Affairs Medical Center, started a program that has trained about 40 mental health care providers in trauma-focused cognitive-behavioral therapy.

The Yale team has also been directly involved at Sandy Hook Elementary School, said Marans. "We've offered in-classroom assistance and consulted with families, teachers, and administrators about how to reestablish order and predictability in children's lives."

"There can be a disruption of baseline capacity for regulation of feelings, thought, and behavior," Marans noted. For instance, some first graders may show increased anxiety and greater startle response.

"We've suggested techniques to calm the class if there is a loud noise," he said. They conduct screenings of children with traumatic symptoms, discuss those findings with parents, and refer some children for trauma-focused treatments.

"We also see children helping each other to better understand what's going on in their own bodies," he said. "But returning to routine is easier said than done. There are a lot of evidence-based mental health treatments for people who have experienced trauma, but there is also a gap in the number of clinicians with training in those treatments."

In a separate program, psychiatrist John Woodall, M.D., a resident of Newtown, works with older children. Woodall developed the Unity Project 13 years ago, based on his work for the U.S. Department of State training mental health personnel for work in postconflict Bosnia and Uganda.

Focus Moves to Resilience Response

"We need to switch from the traditional mental health model to a resilience response, a model that mobilizes communities and increases capacity," Woodall said. "So we work on mental health goals, not mental illness symptoms."

The Unity Project was working with high-school students in Newtown even before the tragedy. At the request of local educators after the shooting, Woodall spun off an organization called Peacebuilders for youth aged 11 to 14.

"Rather than succumbing to despair, fear, or blame, adolescents in the program have responded to the tragedy with compassion and a desire to improve the world now," said Woodall.

The broader Newtown community is trying to heal as well. The town has hired child and adolescent psychiatrist Jill Barron, M.D., of Yale School of Medicine to prepare a mental health needs assessment, which will soon be completed.

"The vast majority in the area are normal people who have experienced an overwhelming tragedy," said Herrick. "They are not mentally ill but still need some help."

There is nothing good about the deaths of children and their teachers, but perhaps something positive can grow in Newtown, said Woodall. "The town has responded really well. People are finding some higher meaning. The best thing for the children is that in 20 years they'll be involved some way in public service and won't see themselves as survivors or psychological casualties." PN

Connecticut's Web site "Resources to Help Cope With the Tragedy in Sandy Hook/Newtown" can be accessed at http://www.ct.gov/dmhas/cwp/view.asp?a=2911&q=515568.

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. Members who live in Area 2 and 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.

Collaborative Care

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lower use of inpatient care, pharmacy, and other outpatient services associated with comorbid medical conditions," Unützer and colleagues wrote. "Long-term (four-year) cost analyses from the IMPACT study found that patients receiving the collaborative care intervention had substantially lower overall health care costs than those receiving usual care. An initial investment in collaborative care of $522 during Year 1 resulted in net cost savings of $3,363 over Years 1-4. This corresponds to a return on investment of $6.50 per dollar spent, with average annual savings of $841. The collaborative care intervention yielded net savings in every category of health care costs examined, including pharmacy, inpatient and outpatient medical, and mental health specialty care."

Using those data, they estimated that implementation of collaborative care for the 20 percent of Medicaid members with diagnosed depression could save the Medicaid program approximately $15 billion a year.

"The research evidence for collaborative care for common mental disorders such as depression and anxiety disorders, along with robust experiencing such programs in diverse health care systems around the country, suggest that states should consider using this model as a building block for health homes and other initiatives that aim to better integrate care for Medicaid beneficiaries with chronic physical and behavioral health needs," they wrote. PN

The policy brief, "The Collaborative Care Model: An Approach for Integrating Physical and Mental Health Care in Medicaid Health Homes," is posted at http://www.medicaid.gov/State-Resource-Center/Medicaid-State-Technical-Assistance/Health-Homes-Technical-Assistance/Guide-to-Health-Homes-Design-and-Implementation.html.

The interview with Wayne Katon, M.D., in *JAMA* is available to subscribers at https://jama.jamanetwork.com/article.aspx?articleid=1697958.

Join APA's 100% Club

Are you a psychiatry resident or training director? If so, you may be interested in having your training program become a member of an exclusive organization within APA—the 100% Club. This club was established to encourage residents throughout the United States and Canada to join APA and to do so with all of the other trainees in their programs.

Beginning this year, eligibility for the 100% Club has been expanded to four levels of membership (Platinum, Gold, Silver, and Bronze). Programs that have been 100% Club members for five consecutive years receive special recognition at the Platinum level, and programs in all levels receive recognition in *Psychiatric News* and a recognition certificate.

The deadline to qualify for the 100% Club for the 2013-2014 academic year is October 31. To verify your program's current membership and coordinate new enrollments, send an e-mail to Neila Ariasaif in the APA Membership Department at nariasaif@psych.org. More information is posted at http://www.psychiatry.org/join-participate/becoming-a-member/100-club-for-residency-training-programs.

Obesity

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AMA's commitment to improve health outcomes, which is one of the organization's long-term strategic objectives.

Harris added that treatment of obesity should encompass a variety of interventions depending on the needs of the individual patient—medical treatments, including surgery or medication, but also psychosocial and behavioral interventions. She added also that obesity has been viewed by some as a lack of willpower with regard to eating, a stigma that should be dispelled by the understanding of obesity as a disease.

> "Recognizing obesity as a disease will help change the way the medical community tackles this complex issue that affects approximately 1 in 3 Americans."

But opinion in the House of Delegates was far from unanimous. A report from the AMA's Council on Science and Public Health (CSPH) examined in depth the public health implications of obesity and explored the potential benefits—but also the scientific challenges—of defining obesity as a disease.

"Without a single, clear, authoritative, and widely accepted definition of disease, it is difficult to determine conclusively whether or not obesity is a medical disease state," the CSPH report states. "Similarly, a sensitive and clinically practical diagnostic indicator of obesity remains elusive. Obesity, measured by BMI, is clearly associated with a number of adverse health outcomes, with greater consistency across populations at the highest BMI levels. However, given the existing limitations of BMI to diagnose obesity in clinical practice, it is unclear that recognizing obesity as a disease, as opposed to a "condition" or "disorder," will result in improved health outcomes. The disease label is likely to improve health outcomes for some individuals, but may worsen outcomes for others."

Robert Gilchick, M.D., a public health physician and member of the CSPH who spoke for the council, argued against the definition. "We recognize obesity as a serious health condition with increased risk for disease, but the difficulty in screening and measurement and the lack of a precise definition [of disease] are all problematic," he said. "We feel further that medicalizing obesity with a focus on pharmacologic and surgical interventions may reduce the focus on primary prevention efforts addressing underlying and upstream social determinants of obesity."

The CSPH report called only for reaffirmation of existing AMA policy regarding management of obesity. However, a separate resolution introduced by the American Association of Clinical Endocrinologists and six other physician groups urged that the AMA "recognize obesity as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention."

The resolution was supported by a wide range of physician groups and was approved by the House of Delegates.

"Obesity has unfortunately been considered a consequence of lifestyle choices, but we now have an abundance of evidence identifying obesity as a multi-metabolic and hormonal disease," said John Seibel, M.D., of the American Association of Clinical Endocrinologists. "Obesity is a pathophysiologic process involving characteristic signs and symptoms and morbidity. Hormonal and metabolic abnormalities are heterogenous in nature and are likely to require multiple risk-stratified interventions including but not limited to lifestyle interventions." PN

The policies and resolutions adopted by the AMA House of Delegates are posted at http://www.ama-assn.org/ams/pub/meeting/reports-resolutions-listing.shtml.

New AMA Policies of Interest to Psychiatrists

- **Gun safety and mental health:** A new resolution adopted by the House of Delegates supports federal and state research on firearm-related injuries and deaths and the rights of physicians to have "free and open communication with their patients regarding firearm safety and the use of gun locks in their homes." The same resolution also supports "initiatives to enhance access to mental and cognitive health care, with greater focus on the diagnosis and management of mental illness and concurrent substance abuse disorders, and work with state and specialty medical societies and other interested stakeholders to identify and develop standardized approaches to mental health assessment for potential violent behavior."
- **Welcoming gay and lesbian physicians:** The Gay and Lesbian Medical Association (GLMA) was admitted to the House of Delegates. "Gay, lesbian, bisexual, and transgender (GLBT) physicians and medical students will now have an important voice within the house of medicine that will enhance AMA policy and programs, especially those that affect GLBT physicians, students, and patients," said incoming AMA President Ardis Dee Hoven, M.D.
- **Student debt:** Delegates adopted a policy to work with other health profession organizations to advocate for a reduction of the fixed interest rate of the Stafford student loan program. "To help students, residents, and physicians manage their medical student loan debt, the AMA has advocated for numerous policies, including the creation of additional tuition-assistance and loan-forgiveness programs," said AMA Board member Stephen Permut, M.D. "A reduction in the fixed interest rate of Stafford loans, combined with other advocacy efforts, will help physicians and physicians-in-training better manage their debt burden."
- **Opposition to genetic discrimination:** Delegates adopted a policy strongly opposing discrimination based on an individual's genetic information and supporting legislation that would provide robust and comprehensive protections against genetic discrimination and misuse of genetic information.
- **Public access to genetic data:** Delegates approved policy that encourages companies, laboratories, researchers, and providers to share data publicly on genetic variants and the clinical significance of those variants through a system that assures patient and provider privacy.
- **Pharmacy compounding safety:** Delegates adopted new policy recommending that traditional compounding pharmacies be subject to state board of pharmacy oversight. It also supports FDA oversight and regulation of facilities that compound sterile drug products without receiving a prescription order prior to compounding and introducing these drugs into interstate commerce.
- **Opposition to lifetime ban on blood donations from gay men:** Delegates adopted policy opposing the FDA's current lifetime ban on blood donations from men who have sex with men. The policy also expresses support for the use of rational, scientifically based deferral periods that are fairly and consistently applied to blood donors.

From the Experts

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been well demonstrated in Europe. In 2004, the FDA approved acamprosate for clinical use in the United States. A subsequent meta-analysis showed that acamprosate significantly reduced the risk of any drinking and increased the cumulative duration of abstinence. However, placebo-controlled, multicenter trials in the United States, Europe, and Australia failed to detect beneficial effects of acamprosate in the treatment of alcohol dependence.

The anticonvulsant topiramate, although not approved to treat alcohol dependence, shows considerable promise in single-site and multicenter trials to reduce heavy drinking. The active medication resulted in significant reductions in drinks/day, drinks/drinking day, drinking days, and heavy drinking days. Although apparently more efficacious than other treatments for heavy drinking, topiramate treatment is associated with a variety of adverse events, which can limit its clinical utility.

In summary, a growing number of medications have been approved to treat alcohol dependence. It appears that these medications also can be used to reduce heavy drinking in individuals whose goal is not to stop drinking completely. This creates a new opportunity for primary care practitioners and psychiatrists to intervene pharmacologically with heavy drinkers. Further research that considers how best to assist heavy drinkers in reducing their drinking is needed to diminish the substantial medical and psychosocial risks associated with this behavior. PN

References are posted at http://www.psychnews.org/update/experts_3_6.html.

Opioids

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and may actually make it worse in some patients," he noted. "We don't have lots of evidence on how effective or safe they are in higher-risk patients, which includes a lot of patients with chronic pain."

"We want people to start on a low dose," he explained. "No opioid is safe, and we need to be cautious about how we use these drugs. The benefits of opioids for pain are finely balanced with the harms, and I am hoping the trend is [away from] jumping to use of opioids so quickly and toward use of nonopioid and other adjunctive therapies first." PN

"Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain" is posted at http://www.jpain.org/article/S1526-5900(08)00831-6/fulltext#sec3.1.1.

Sunshine

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- Discounts (including rebates).

- A transfer of anything of value to a physician when the physician is a patient and not acting in his/her professional capacity as a physician.

- The loan of a medical device for a short-term trial period, which does not exceed 90 days, to permit the evaluation of the covered device by the covered recipient.

- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

- In the case of a physician who is a licensed nonmedical professional, a transfer of anything of value to the physician if the transfer is payment solely for the nonmedical professional services of such licensed nonmedical professional (for instance, payments to a physician who is licensed to practice law and is retained by the manufacturer to provide legal advice).

- In the case of a covered recipient who is a physician, the transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the physician with respect to a civil or criminal action or an administrative proceeding.

- A transfer of anything for which the value is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the manufacturer during the calendar year exceeds $100 (subject to increase each year using the consumer price index). PN

More information about the PPSA's reporting requirements is posted on APA's Web site at www.psychiatry.org/sunshine act. APA will continue to update this site as more information about complying with the PPSA becomes available. Also, APA will hold a webinar on this subject in the fall, with an opportunity to get your PPSA questions answered by APA's deputy director for regulatory affairs and its general counsel. The date and time will be sent to APA members in the *Psychiatric News Update*. If you are not a subscriber, please send your name and e-mail address to cbrown@psych.org.

Avoid the Sunshine Act's 'Reportable Traps'

Physicians need to be alert to scenarios that could trigger being mentioned in a manufacturer's report when the Physician Payment Sunshine Act (PPSA) requires pharmaceutical and medical device manufacturers to report transfers of value or payments to physicians beginning August 1. Those reports will be submitted to the federal Centers for Medicare and Medicaid Services (CMS) and published on a public Web site. Here are some scenarios that may involve "reportable traps" for which physicians should be on the lookout.

- **Manufacturer advertising at state psychiatric or medical society meetings.** Physicians should be wary of having their name on contracts with pharmaceutical or medical device manufacturers that advertise at their state psychiatric society or medical society. By signing such a contract after August 1, the physician risks having the transfer of value or payment made from the pharmaceutical company to the state society attributed to him or her.
- **Medical conferences outside U.S. territory.** Physicians should not think they can evade being captured in pharmaceutical or medical device manufacturers' reports by attending medical conferences held outside of U.S. territory. The PPSA requires reporting by manufacturers who are in "common ownership" with manufacturers who sell or distribute drugs or medical devices within the United States and its territories. So a subsidiary drug company operating in France and giving physicians transfers of value or payments at an international medical conference held in France could find their transfers to be "reportable" under the PPSA.
- **Nonaccredited or noncertified CME events.** Physicians should be circumspect about attending nonaccredited or noncertified continuing medical education events. Any transfers of value or payments made by a pharmaceutical or medical device manufacturer to physicians at these events (including in the form of food or beverage) which exceeds $10 in value must be reported. (CMS did create an exemption for accredited and certified CME events, but it is not a blanket exemption. Even at such accredited and certified CME events, transfers of value or payments may be reportable if the CME fails to satisfy a three-prong "independence" test certifying that the manufacturer did not directly select or pay the accredited or certified CME speaker.)
- **"Readily identifiable" physicians.** The PPSA includes a reporting exception for manufacturers that will allow them to provide conference recipients with buffet meals, coffee, or snacks at "large-scale events," which are defined as events in which the attendees are not "readily identifiable" to the manufacturers. However, if a physician at a small conference in which he or she is identifiable accepts a drug manufacturer's $25 buffet meal, the physician can expect to find his name listed in a report submitted to CMS detailing taking part in the manufacturer's buffet meal. Moreover, CMS has not provided a threshold for determining whether an event is large or small. A rule of thumb is that if a physician is being asked to swipe a card at a conference to have access to a manufacturer's meals, snacks, or trinkets, the manufacturer has probably decided it will be reporting this transfer of value to CMS.
- **Watch out for textbooks.** Physicians should think twice before accepting a textbook from a manufacturer of pharmaceuticals or devices. While the PPSA allows manufacturers to share educational materials with physicians if such materials are provided for the benefit of the patient, the rule specifically excludes textbooks. In other words, any transfers of textbooks to physicians who are acting in their capacity as physicians, even if on behalf of the physician's patients, must be reported by the drug or device manufacturer to CMS.
- **Grants or awards to psychiatric societies.** If APA members or state district branch executives run a psychiatric society and receive grants or awards from pharmaceutical or device manufacturers, such grants will trigger reporting if the payments or transfers, whether direct or indirect to the physician recipients, are made at the direction, instruction, or requirement of the manufacturer.
- **Disclosure documents and identification numbers.** As physicians prepare for the launch of PPSA reporting on August 1, they are cautioned to check any conflict-of-interest documents or disclosure documents they have signed. The content of these documents needs to be continuously monitored and kept consistent with what appears in manufacturers' reports upon their initial submission to CMS in March 2014. Additionally, physicians should ensure CMS has a correct identification number on file, including their NPI and any numbers indicating their specialty. Manufacturers required to report under PPSA will be making use of these numbers as a means of identifying physicians who have received transfers of value or payments from them.

Help Build a Gateway for Better Health

At Northwest Permanente, P.C., we want every patient we see to receive the medical care they need to live long and thrive. We also offer NWP physicians the opportunity to pursue their personal and professional goals with equal passion through cross-specialty collaboration and work-life balance. We invite you to consider these opportunities with our physician-managed, multi-specialty group of 1,000 physicians who care for 479,000 members throughout Oregon and Southwest Washington.

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To apply, please visit our Web site at: **http://physiciancareers.kp.org/nw/** and click on Career Opportunities. You may also email your CV to **Laura Russell, Sr. Recruiter: Laura.A.Russell@kp.org**. For more information please call **(800) 813-3762.**

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Diversity

The word describes the populations we serve, our professional colleagues and our own workplace opportunities. It's an exciting and rewarding environment made more so by a stable organization already working towards successful healthcare integration. Join us for professional growth and career options that make a difference in the lives of those who need our help.

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For consideration, email your CV to: omd@dmh.lacounty.gov
Roderick Shaner, M.D., Medical Director
Los Angeles County Department of Mental Health
550 South Vermont Avenue
Los Angeles, California 90020
(213) 738-4603

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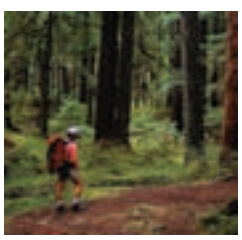

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Saint Francis Behavioral Health Group is seeking a **BC Psychiatrist** to lead its dedicated **psychiatric team** at Johnson Memorial Hospital, a 92-bed Community-based acute care hospital located in Stafford Springs, Connecticut. In this role, you'll lead and oversee the delivery of behavioral health care in the inpatient unit, outpatient service and emergency department. Additionally, the Medical Director will provide clinical care to patients, lead the development of a multidisciplinary team, ensure compliance with policies and regulatory requirements, and work with other clinical and support services to ensure behavioral health objectives are met system wide. This position involves a mix of clinical and administrative duties. Join us, and use your collaborative and business development skills to lead the program's growth while establishing and maintaining best practices in patient care.

The Stafford Springs area is a welcoming blend of rural and suburban living, rich in New England history, culture and recreation. Hartford, Manchester and Enfield are close by and Boston and New York are within easy driving distance.

Bring your vision and desire to excel in a behavioralal health leadership role to JMMC. Contact Christine Bourbeau, Director of Physician Recruitment, today at 855-894-5590, or email your CV and letter of interest to CBourbea@stfranciscare.org for immediate consideration.

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Universal Health Services, Inc. (UHS) www.uhsinc.com is the largest facilities based behavioral health provider in the country. Our nearly 200 facilities operate independently and develop programs that satisfy the needs of each community. Our services touch more than 350,000 lives each year – from youth and adult programs to dedicated services for the military.

We are currently recruiting **General, Geriatric, Addiction and Child Psychiatrists.** We offer diverse practice settings and career opportunities with work/life balance. Competitive compensation packages will be offered including bonus opportunity and student loan assistance depending on location. **Some locations H1/J1 eligible.**

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- **PENNSYLVANIA**–Philadelphia-Clarion
- **SOUTH CAROLINA** – Aiken - Columbia
- **TENNESSEE** – Nashville-Ashland City - Memphis
- **TEXAS** – Dallas and San Antonio
- **UTAH** – Salt Lake City and Provo/Orem
- **VIRGINIA**–Portsmouth and VA Beach - Leesburg
- **WASHINGTON** – Seattle area
- **WEST VIRGINIA** – Huntington

For more information about these and other locations and positions contact: **Joy Lankswert, UHS In-house Physician Recruitment @ 866-227-5415 ext: 222 or email joy.lankswert@uhsinc.com.** See all UHS positions and facilities at www.physician-practiceopportunities.com

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FOCUS Health is searching for board certified psychiatrists to join our Utilization Review Panel today!
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ARKANSAS

Horizon Health seeks a **Medical Director** for our 15-bed Geriatric inpatient psychiatric program our client hospital **National Park Medical Center in Hot Springs, AR**. 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.

LITTLE ROCK: Child, General & Geriatric Psychiatrists. Inpatient & Partial Services. Fulltime positions offering salary, benefits & bonus opportunity. Contact Tiffany Crawford, In-house recruiter @ 866-227-5415; OR email tiffany.crawford@uhsinc.com.

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

- Full-time position, Monday-Friday, 8 a.m.-5 p.m.
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- 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.

Chief of Psychiatry

The Greater Los Angeles Health Care System (GLA) is seeking a full-time Chief of Psychiatry/ACOS for Mental Health (MH), to oversee inpatient and outpatient MH care provided to Veterans living in the Greater Los Angeles Area and to direct all of psychiatric care. GLA is the largest healthcare system in the VA with outstanding clinical, education, research and residency programs. This physician will serve as the Associate Chief of Staff for Mental Health and Psychiatry. The individual will participate in patient care, teaching, research and administrative activities of the Department, as assigned.

Candidate must be board certified Psychiatrist with qualification to provide leadership as Chief of Psychiatry and ACOS of MH at the Greater Los Angeles Health Care System (GLA). Candidates must also: (1)be a U.S. citizen or must have proper authorization to work in the United States (2) possess a current, full and unrestricted license to practice in a state, territory or commonwealth of the United States or District of Columbia; (3) be proficient in spoken and written English, and (4) pass a pre-employment physical. Direct Deposit is required. The position is subject to random drug testing. A recruitment incentive may be offered to secure a highly-qualified candidate.

Interested candidates must apply online at www.USAJobs.gov using announcement number 13-852956-TCM. You must submit a application VAF 10-2850 (Application for Physician and Dentist) http://www.va.gov/vaforms/medical/pdf/vha-10-2850-fill.pdf, Curriculum Vitae, and answer the questionnaire.

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Private Outpatient Psychiatric Clinic in expansion seeks a BC/BE Adult or Child/Adolescent Psychiatrist full-time, to join our growing multidisciplinary private practice. You will be working with another psychiatrist, two Nurse Practitioners, one Psychologist and one LMFT. We also have a very well trained and supportive staff. We offer an excellent salary from 205K to 235K, without benefits. Regular schedule is Mondays to Fridays from 9 to 5 (we can consider some flexibility on the scheduling), no calls. Our patients are Adolescent and Adults mostly with primary mood and anxiety disorders, some with dual diagnoses. Most off our patients are from major insurers, we are not accepting Medicare or Medical. Please send letter of interest and CV to Pedro Guimaraes, M.D. at pedroguimaraes.md@gmail.com.

CLASSIFIEDS

PSYCHIATRIST
Oakland, CA
(San Francisco Bay Area)

La Clínica de La Raza seeks a lead psychiatrist in a community based mental health clinic serving adults and children. Spanish speaking preferred but not required. Competitive salary and benefits. Federally Qualified Health Center- site eligible for **NHSC loan repayment opportunity.** Regular schedule, no nights/weekends. Position provides clinical leadership and direct services for adults with serious mental illness as well as short term outpatient stabilization. Fast paced environment, looking for innovative collaborative team leader committed to wellness and recovery. Please send letter of interest and CV to Leslie Preston at Lpreston@laclinica.org.

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

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

COLORADO

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

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.

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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.

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Florida Licensed BE/BC psychiatrist and advanced registered nurse practitioner needed for a Joint Commission Accredited community mental health center and psychiatric hospital. Excellent benefits and location. **Contact:** Suresh P. Rajpara, M.D., Chief Medical Officer, Jerome Golden Center for Behavioral Health, 1041 45th Street, West Palm Beach, Fl 33407. Phone: (561) 383-5917; Fax: (561) 514-1239; Email: aabad@jeromegoldencenter.org.

GEORGIA

Faculty Position
Atlanta, Georgia

Emory University School of Medicine, Department of Psychiatry and Behavioral Sciences is seeking qualified candidates at open academic rank to hold the position of Chief of Adult Outpatient Services at The Emory Clinic, Inc. The physician will provide the administrative oversight for the adult outpatient practice which includes the coordination of clinicians' activities, performance of quality activities (including participation with the monthly departmental quality meeting), supervising educational activities and coordinating the outpatient research with investigators in the adult clinic. The physician will provide adult psychiatric outpatient care. Demonstrated research and administrative acumen is a prerequisite for this position. Emory University offers nationally competitive salary commensurate with experience. Send letter of interest and CV to Frank Brown, MD sdpfwb@emory.edu. Emory University is an AA/EO employer.

ATLANTA: Geriatric, General & Child Psychiatrists for Staff Positions – Inpatient and Partial O/P settings.
SAVANNAH: General or Geriatric Psychiatrist – Inpatient & Partial services. Leadership opportunity.
SAINT SIMONS: General Psychiatrist – Inpatient & Partial services.
All positions offer salary, benefits, bonus opportunities. Full time & Part-time position options.

Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

PSYCHIATRIST

Lookout Mountain Community Services in NW GA is seeking a Psychiatrist for its Outpatient program. Applicants must possess or be eligible for a valid physician's license from the state of Georgia, and be board eligible or board certified. Interested parties should send their curriculum vita to:

Susan Hamby
jobs@lmcs.org
(706)638-5445 fax

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.

MAINE

Liberty Healthcare anticipates an opening for a full-time attending Psychiatrist at the Riverview Psychiatric Center in Augusta, Maine. This position offers a small case load, competitive compensation package, regular 40-hour workweeks, minimal on-call, 7+ weeks off annually, liability insurance, onsite CME, relocation assistance and a collegial work environment. Psychiatrists who have an interest in providing inpatient services to adults who have serious and persistent mental illness and/or forensic patients are encouraged to apply. Details online at www.libertyhealthcare.com/upload/303.pdf. Contact Ian Castronuovo at (610) 389-7430 or ianc@libertyhealth.com.

MARYLAND

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

Incredible Sunsets - Endless Waterviews - Psychiatrist needed on 24-bed adult inpatient psychiatric unit on the beautiful Eastern Shore. There is also IOP and Outpatient Addiction Program. Cambridge is located on the Choptank River in Dorchester County - a county of 1,700 miles of shoreline and is only an hour to Annapolis and Ocean City, and an hour and 45 minutes to Baltimore. Live and work in a place where many want to retire - a great quality of life. Also, seeking a Psychiatrist for one weekend per month of coverage for 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 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

Joshi & Merchant, M.D., P.A., Outpatient Psychiatry Services, in Columbia, MD, is looking for a Board-Certified Psychiatrist to work full-time with adult outpatients. Please forward resume to Milan Joshi, M.D. by email (milanjoshi11@gmail.com) or call 410-299-8147.

CLASSIFIEDS

MASSACHUSETTS

OUTPATIENT/ ADULT or CHILD CITY COMPENSATION/COUNTRY LIVING!

Harrington Hospital seeks a Full-Time Outpatient Adult and/or Child Psychiatrist to join our psychiatric team of physicians, licensed therapists and an advanced clinical nurse specialist. We offer excellent working conditions and a supportive staff with nursing staff available for med calls and other psychiatrists available for vacation coverage. We are opening new sites and expanding our services in Southern Worcester County.

Harrington Hospital is a 114 bed acute care independent, community hospital located in South Central Massachusetts with clinics located in Charlton, Southbridge and Webster. We are a teaching affiliate for the University of Massachusetts and St. Elizabeth's. Our community is small, friendly, and safe with great schools, low cost of living, and beautiful countryside.

Requirements:MA license or license eligible; Board Certified or Eligible

Benefits include: signing bonus, flexible schedule, free parking, collegial medical staff, EMR, CME Program, part-time positions also available.

Tom Trask
Executive Director Physician Services
508-764-2424
ttrask@harringtonhospital.org

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.**

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.

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.**

The Department of Psychiatry at Mount Auburn Hospital, affiliated with Harvard Medical School, is recruiting for a position in our Outpatient Psychiatry Service. Responsibilities include evaluation and treatment of adult patients with a variety of psychiatric disorders, including dual diagnosis patients, and coordination of care with other psychiatric clinicians and with primary care and specialty physicians. The department continues to develop programs integrating psychiatry with primary care. Position includes participation in the teaching activities of the Department. Academic appointment to the clinical faculty at Harvard Medical School is anticipated. Please send letter of interest and cv to: Joseph P. D'Afflitti, M.D., Chair, Department of Psychiatry, Mount Auburn Hospital, 330 Mount Auburn Street, Cambridge, MA 02138; tel: 617 499-5665, ext 4212; email: jdafflit@mah.harvard.edu.

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

Psychiatrist: Psychiatric Associates of West Michigan, PLC is looking for both an adult and child and adolescent psychiatrist to join a busy, well established physician owned practice in Kentwood, MI. Great work environment, exceptional staff, excellent income and benefits with the potential for partnership. Please send CV to amandam@pawm.net or fax 616-719-4480

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

MERIDIAN: Child and/or General Psychiatrist. OLIVE BRANCH: Child Psychiatrist. Inpatient, Partial & O/P Services. Fulltime positions offering salary, benefits & bonus opportunity. Contact Tiffany Crawford, In-house recruiter @ 866-227-5415; OR email tiffany.crawford@uhsinc.com.

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

Make An Income that Matches All the Work You Do - 20 Minutes From St. Louis - 30 Minutes To Work - Seeking a Psychiatrist for a very lucrative position with a very successful group practice in Festus. Work would be primarily inpatient work on adult & geropsych units in Farmington. 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 H1 and J1 Visa is needed. Please **call Terry B. Good, Horizon Health, at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

MONTANA

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

NEW JERSEY

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 multidisciplinary 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.

CLASSIFIEDS

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. Also hourly contract pos. available for 24 hrs per week for outpatient work. Please contact **Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

NEW MEXICO

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

NEW YORK CITY & AREA

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.

VA NY Harbor is initiating a search for 2 full time psychiatrists to work in the outpatient clinic at the Brooklyn Campus on 800 Poly Place. The clinic is staffed by a multi-disciplinary team and provides treatment for a wide range of psychiatric illnesses. Treatment focuses on evidence based practices and the Recovery model. Salary is commensurate with experience and is highly competitive. US citizenship required. Interested applicants should provide CV's to Dr. Adam Wolkin (Adam.Wolkin@VA.Gov).

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.

NEW YORK STATE

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.

GREATER BINGHAMTON HEALTH CENTER (GBHC)
Binghamton, NY
Adult and Child/Adolescent Psychiatrists
Board Eligible/Board Certified
(Limited Permit eligible applicants will also be considered)

GBHC, a JCAHO Accredited NYS Office of Mental Health Facility, nestled in scenic Upstate NY, is seeking full-time, Adult and Child and Adolescent Psychiatrists for its inpatient and outpatient facilities.

- Must be NYS licensed/license eligible
- All positions are M-F, 8-4:30. Voluntary, low stress, on call is available
- Generous and comprehensive benefits package, including medical/dental/vision insurance, paid vacation, holiday, personal and sick time, excellent retirement plan, and educational/professional leaves.
- Abundant on-site CME
- National Health Svcs Corp (NHSC) and Doctors Across New York (DANY) loan repayment may be available to qualified candidates
- Quality, affordable housing, regional airport, 3 hour drive to NYC, high quality public and private schools, Binghamton University, beautiful parks, recreation, cultural centers, and home to the Binghamton Mets baseball, Binghamton Senators Hockey, Zoo, Tri-Cities Opera, Forum Theatre, Anderson Center, 1 hour from the gorgeous Finger Lakes wine country

For further info contact: Renee O'Brien, Dir. of Human Resources, Greater Binghamton Health Center, 425 Robinson St., Binghamton, NY 13901. Fax: 607-773-4117 E-Mail: renee.obrien@omh.ny.gov or phone at (607) 773-4013, An EO/AAE).

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

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

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

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

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

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

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

UNIVERSITY of ROCHESTER MEDICAL CENTER

The University of Rochester Department of Psychiatry seeks full-time, board eligible or certified psychiatrists committed to developing careers as members of a dynamic and growing faculty. Positions are available in ambulatory settings that emphasize integrated, team-based care and the implementation and study of evidence-based practice in close collaboration with primary care. We also seek faculty members interested in developing their skills as hospitalists, with ECT, and in our Comprehensive Psychiatric Emergency Program. A license to practice in New York State is required.

We excel in helping early and mid-career psychiatrists realize their career development goals in medical education, clinical care and research. Located between Lake Ontario and New York's scenic Finger Lakes region, Rochester provides a rich variety of social, recreational, cultural and educational opportunities. Additional information about the department is available at http://www.urmc.rochester.edu/smd/Psych.

The University of Rochester has a strong commitment to principles of diversity and, in that spirit, actively encourages applications from groups underrepresented in higher education and medicine. Women, minorities, individuals with disabilities and veterans are encouraged to apply. We offer competitive compensation and benefits.

Interested applicants should e-mail inquires and a C.V. to:http://www.rochester.edu/working/hr/jobs/

Linda H. Chaudron, MD, MS
Professor of Psychiatry
Associate Chair, Clinical Services
Department of Psychiatry
University of Rochester Medical Center
300 Crittenden Boulevard
Rochester, NY 14642-8409
Linda_Chaudron@urmc.rochester.edu
Phone: (585)273-2113;
Fax: (585)273-1066

Mid-Hudson Valley

Ulster County Dept. of Mental Health seeks a full-time Psychiatrist to work in its outpatient mental health clinics. We are looking for a recovery oriented board certified or board eligible community psychiatrist to treat adult patients. Kingston is located in the beautiful Hudson Valley, two hours north of NYC. Based on qualifications, salary ranges btw $152,600 - $184,325. Good benefits, NYS retirement system, onsite psychopharmacology supervision and collegial atmosphere. No on-call or weekends. All Civil Service Laws, Rules and Regulations Apply. Ulster County is an Equal Opportunity Employer. Send CV to JuLita Adamczak, MD, Medical Director, FAX#845-340-4094 or email: jada@co.ulster.ny.us. Telephone #845-340-4173. Ulster County Dept. of Mental Health, 239 Golden Hill Lane, Kingston, NY 12401.

CLASSIFIEDS

Medical Director Inpatient Psychiatry

Unity Health System in Rochester, NY seeks Medical Director for our Inpatient Mental Health Services. Responsibilities include providing clinical oversight on two 20-bed acute psychiatric inpatient units; assuring compliance with system and departmental policies; individual clinical and administrative supervision of psychiatrists; administrating the on-call system for Behavioral Health; providing direct clinical care to patients in the units; being actively involved in QI initiatives and risk management issues.

Position is approximately 50% clinical and 50% administrative. Requires: MD/DO; board certification in psychiatry; current NYS medical license; 2-3 years administrative experience in behavioral health at level of clinical or medical director; minimum one year clinical experience in inpatient behavioral health setting.

Interested candidates may email CV and cover letter to: Becky Jones, Physician Recruiter, bjones@unityhealth.org.

Moonlighting Positions

St. Vincent's Westchester, a 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 available. 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

NORTH CAROLINA

Now recruiting for Board Certified or Board Eligible Psychiatrists Coastal Carolina Neuropsychiatric Center, PA has multiple locations in NC. In-patient, out-patient, and a combination of both may be available. Competitive salary and benefits package.

H1 & J1 visa applicants may apply
Submit CV's to:
info@coastalcarolinapsych.com

Great Opportunity in Private Practice

Carolina Partners in Mental HealthCare, PLLC is seeking psychiatrists and physician extenders for our practices in Cary, NC and Chapel Hill, NC. **Carolina Partners** is a private multi-disciplinary mental health group practice with fourteen treatment sites in North Carolina. You get full partnership from day one with no buy-in. Good income, great flexibility. Full time preferred but will consider part time as well. Visit us on the web at carolinapartners.com. Send CV and letter of interest to Stan Monroe at: carolinapartners@bellsouth.net ; fax 919-908-8167; mail to 1502 W. Hwy 54, Suite 103, Durham, NC 27707, Attn: Executive Director.

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

OHIO

PSYCHIATRIST POSITION OPEN IN COLLEGE COUNSELING CENTER

The Ohio State University Counseling and Consultation Service is searching to fill a full-time Psychiatrist position. This position provides outpatient mental health treatment; consultation with faculty, staff and students on mental health concerns; and supervision to clinical staff in training. An M.D./D.O. degree is required; a current Ohio medical license or interim Ohio medical license with ability to obtain an unrestricted license within 6 months of hire; completed psychiatric residency training; a current DEA Certificate; and board eligible/certified by the American Board of Psychiatry & Neurology. To apply for this position go to https://www.jobsatosu.com/ and search job posting #376755. The application deadline is July 28, 2013.Candidates will need to include with their application, a cover letter, curriculum vitae, and three letters of recommendation. The letters should be sent/e-mailed to the attention of Marusela Anders at anders.40@osu.edu. Visit us at www.ccs.osu.edu.

Southern OH - 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. Great place to raise a family. 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.

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

The Penn State Department of Psychiatry is recruiting in-patient and consultation-liaison psychiatrists for its growing faculty. With our clinical partner, Pennsylvania Psychiatric Institute, the Department staffs three clinics, with outpatient and partial hospital programs for children and adults, 58 adult and 16 child/adolescent beds, ECT and other neuromodulation services, specialty sleep and eating-disorders programs, and expanding psychiatric consultation for Penn State Hershey Medical Center. Our current psychiatry faculty numbers 52, with planned increases, plus 24 residents and fellows, also likely to expand. We are about to start a new Psychology Internship. We have a growing research portfolio and new research groups about to join us, with basic and clinical science and close collaboration with allied neuroscience disciplines at several Penn State campuses.

Successful candidates should have strong clinical and teaching skills and, optimally, potential for scientific and scholarly achievement. We offer a very attractive compensation package commensurate with qualifications.

Central Pennsylvania fosters a delightful quality of life, with ready access to major metropolitan areas like D.C., Baltimore, Philadelphia, and NYC, while placing you in a picturesque and historic environment, with superb schools and varied recreation.

Candidates with interest and skills in these areas should send a curriculum vitae and cover letter to:

Alan J. Gelenberg, M.D.
Shivley/Tan Professor and Chair
Penn State Hershey Medical Center
Department of Psychiatry, H073
500 University Drive, P.O. Box 850
Hershey, PA 17033
Phone: 717.531.8516
Fax: 717.531.6491
agelenberg@hmc.psu.edu

Penn State Hershey Medical Center is committed to affirmative action, equal opportunity and the diversity of its workforce.

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 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

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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.

SOUTH CAROLINA

Medical Director Position - Make A Difference in This Community/Hospital - Head up an 8-bed inpatient Geropsychiatric Unit; salaried with benefits or practice opportunity for those who prefer independent contract. Weekend call is 1 in 3 or 4. Rounding on weekends is not necessary unless there is an admission on Friday or Saturday. Great group of people to work with; huge amount of support. Located in northeast SC, easy drive to Florence, SC. Please **call Terry B. Good at 1-804-684-5661,** Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

TENNESSEE

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

CLASSIFIEDS

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

Three full-time positions available for Adult Psychiatrist, Child Psychiatrist and Geriatric Psychiatrist. The department seeks Adult Psychiatrist who is BE/BC (at time of hire), Child Psychiatrist who is BE/BC (at the time of hire) in the subspecialty of Child and Adolescent Psychiatry, and Geriatric Psychiatrist who is BE/BC (at the time of hire) in the subspecialty of geriatric psychiatry and will become involved in the development of a Geriatric Psychiatry Fellowship. Positions may include inpatient and/or outpatient. Program activities include clinical care of patients combined with teaching and supervision of residents and medical students. Adult or Child position may be considered for Director of Outpatient Clinic Programs. Research is encouraged but not essential. Salary and academic rank are commensurate with experience and qualifications. Salary is competitive with funding available through the Medical School, faculty private practice and extramural contracts.

ETSU is located in Johnson City which is the perfect blend of four mild and beautiful seasons, gentle mountains and a symphony orchestra. Come explore this ideal family location of college/urban sophistication surrounded by national forests and serene pastures. No state income tax, low cost-of-living, low crime rate, lots of parks, golf courses, and lakes. Apply to this position at https://jobs.etsu.edu. Telephone inquiries should be made at (423) 439-2235 or e-mail at lovedayc@etsu.edu. AA/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.

VERMONT

Central Vermont Medical Center

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

VIRGINIA BEACH: Addiction Psychiatrist – Inpatient Services. **LEESBURG, PORTSMOUTH:** Child Psychiatrists for Residential Treatment and/or Inpatient Services. All positions are fulltime offering salary, benefits and bonus opportunity. **Contact Will DeCuyper, In-house Recruiter @ 866-227-5415 OR email will.decuyper@uhsinc.com.**

WASHINGTON

Immediate need for a B/C Adult Psychiatrist to join 2 B/C Psychiatrists in Yakima, WA. Employed position comes with excellent comprehensive benefits package. No outpatient responsibilities during call week. Family friendly community, 4 beautiful seasons with 300+ days of sunshine, easy access to an array of outdoor activities, low cost of living and no state income tax. Send you inquires to physicianrecruitment@yvmh.org or visit us at www.yakimavalleyliving.org to learn more!

WEST VIRGINIA

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

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.

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

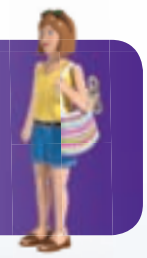
PRISTIQ Extended-Release Tablets are indicated for the treatment of major depressive disorder in adults.

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