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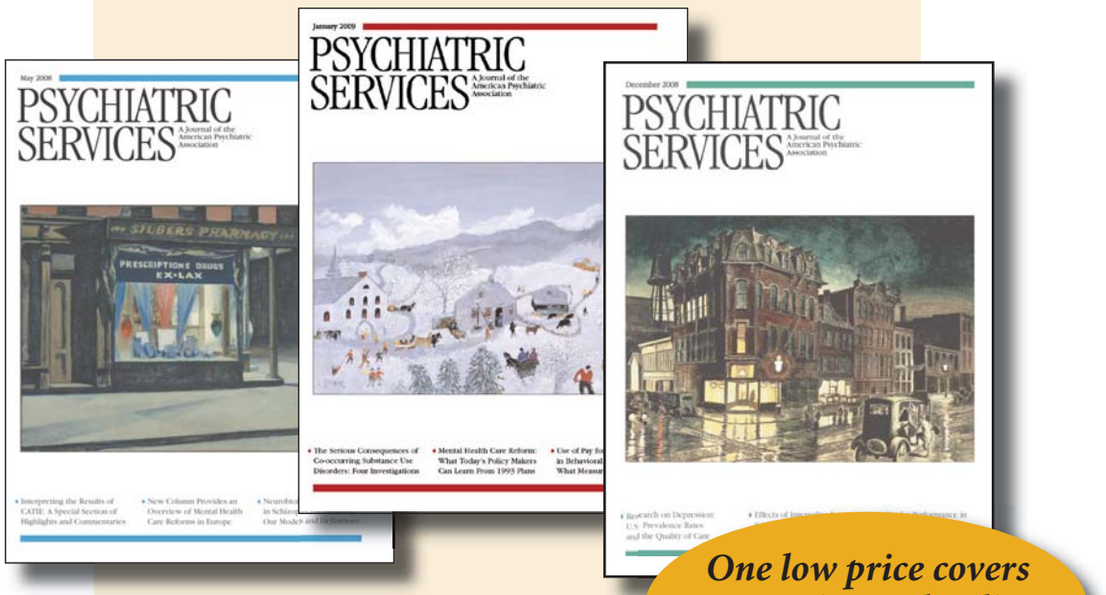

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This program will be conducted on May 18, 2009, during the APA 2009 Annual Meeting

AUGMENTATION STRATEGIES FOR MAJOR DEPRESSIVE DISORDER:

THE EVIDENCE FOR EFFECTIVE CLINICAL DECISION-MAKING IN IMPROVING PATIENT CARE

MONDAY, MAY 18, 2009 | Breakfast: 6:30–7:00 AM | Symposium: 7:00–9:00 AM
Hilton San Francisco Hotel | Grand Ballroom, Salon B | **SAN FRANCISCO, CALIFORNIA**

AGENDA

6:30–7:00 AM Breakfast

7:00–7:05 AM Introduction & Overview
MADHUKAR H. TRIVEDI, MD (Chairperson)
University of Texas Southwestern Medical Center

7:05–7:30 AM Inadequate Treatment Response in Major Depressive Disorder: Predictors and Strategies for Selecting Next-Step Treatments
ROY H. PERLIS, MD, MSC
Harvard Medical School

7:30–7:55 AM Effective Management of Treatment-Resistant Depression: Evidence-Based Approaches Beyond First-Line Antidepressant Monotherapy
MADHUKAR H. TRIVEDI, MD

7:55–8:20 AM Atypical Antipsychotics as Augmentation Agents for Major Depressive Disorder: Efficacy and Tolerability
GEORGE I. PAPAKOSTAS, MD
Harvard Medical School

8:20–9:00 AM Panel Discussion/Question and Answer Session
ALL FACULTY

Sponsored by the American Psychiatric Association

Supported by an educational grant from AstraZeneca

EDUCATIONAL ACTIVITY LEARNING OBJECTIVES

At the conclusion of this symposium, the participant should be able to:

- Discuss and interpret the clinical implications of factors underlying inadequate response to antidepressant therapy in patients with MDD
- Compare and contrast the rationale for using different second-line strategies in patients who do not respond adequately to antidepressants
- Evaluate the clinical trial evidence for the use of atypical antipsychotics in the management of MDD

CME STATEMENT

This symposium will be conducted on May 18, 2009, during the APA 2009 Annual Meeting. The American Psychiatric Association (APA) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The APA designates this educational activity for a maximum of 2 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity. Attendees must be registered for the APA Annual Meeting to attend this symposium. Seating is limited and will be based on first-come, first-served. For more information about the meeting, please visit the APA Web site at www.psych.org or contact the APA toll free at 1-888-357-7924 (within the US or Canada) or 703-907-7300.

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GEODON is indicated for the treatment of schizophrenia.

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As with all antipsychotic medications, a rare and potentially fatal condition known as neuroleptic malignant syndrome (NMS) has been reported with GEODON. NMS can cause hyperpyrexia, muscle rigidity, diaphoresis, tachycardia, irregular pulse or blood pressure, cardiac dysrhythmia, and altered mental status. If signs and symptoms appear, immediate discontinuation, treatment, and monitoring are recommended.

Prescribing should be consistent with the need to minimize tardive dyskinesia (TD), a potentially irreversible dose- and duration-dependent syndrome. If signs and symptoms appear, discontinuation should be considered since TD may remit partially or completely.

Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON, and it is not known if GEODON is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia.

Precautions include the risk of rash, orthostatic hypotension, and seizures.

In short-term schizophrenia trials, the most commonly observed adverse events associated with GEODON at an incidence of ≥5% and at least twice the rate of placebo were somnolence and respiratory tract infection.

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BRIEF SUMMARY. See package insert for full prescribing information.

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

INDICATIONS—GEODON Capsules is indicated for the treatment of schizophrenia and acute manic or mixed episodes associated with bipolar disorder with or without psychotic features. GEODON® (ziprasidone mesylate) for Injection is indicated for acute agitation in schizophrenic patients.

CONTRAINDICATIONS — *QT Prolongation:* Because of GEODON's dose-related prolongation of the QT interval and the known association of fatal arrhythmias with QT prolongation by some other drugs, GEODON is contraindicated in patients with a known history of QT prolongation (including congenital long QT syndrome), with recent acute myocardial infarction, or with uncompensated heart failure (see **WARNINGS**). Pharmacokinetic/pharmacodynamic studies between GEODON and other drugs that prolong the QT interval have not been performed. An additive effect of GEODON and other drugs that prolong the QT interval cannot be excluded. Therefore, GEODON should not be given with dofetilide, sotalol, quinidine, other Class Ia and III anti-arrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol, or tacrolimus. GEODON is also contraindicated with drugs that have demonstrated QT prolongation as one of their pharmacodynamic effects and have this effect described in the full prescribing information as a contraindication or a boxed or bolded warning (see **WARNINGS**). GEODON is contraindicated in individuals with a known hypersensitivity to the product. **WARNINGS — *Increased Mortality in Elderly Patients with Dementia-Related Psychosis:* Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. GEODON (ziprasidone) is not approved for the treatment of patients with dementia-related psychosis (see BOXED WARNING). *QT Prolongation and Risk of Sudden Death:* GEODON use should be avoided in combination with other drugs that are known to prolong the QT_c interval. Additionally, clinicians should be alert to the identification of other drugs that have been consistently observed to prolong the QT_c interval. Such drugs should not be prescribed with GEODON. A study directly comparing the QT/QT_c-prolonging effect of GEODON with several other drugs effective in the treatment of schizophrenia was conducted in patient volunteers. The mean increase in QT_c from baseline for GEODON ranged from approximately 9 to 14 msec greater than for four of the comparator drugs (risperidone, olanzapine, quetiapine, and haloperidol), but was approximately 14 msec less than the prolongation observed for thioridazine. In this study, the effect of GEODON on QT_c length was not augmented by the presence of a metabolic inhibitor (ketoconazole 200 mg bid). In placebo-controlled trials, GEODON increased the QT_c interval compared to placebo by approximately 10 msec at the highest recommended daily dose of 160 mg. In clinical trials the electrocardiograms of 2/2988 (0.06%) GEODON patients and 1/440 (0.23%) placebo patients revealed QT_c intervals exceeding the potentially clinically relevant threshold of 500 msec. In the GEODON patients, neither case suggested a role of GEODON. Some drugs that prolong the QT/QT_c interval have been associated with the occurrence of torsade de pointes and with sudden unexplained death. The relationship of QT prolongation to torsade de pointes is clearest for larger increases (20 msec and greater) but it is possible that smaller QT/QT_c prolongations may also increase risk, or increase it in susceptible individuals, such as those with hypokalemia, hypomagnesemia, or genetic predisposition. Although torsade de pointes has not been observed in association with the use of GEODON at recommended doses in premarketing studies, experience is too limited to rule out an increased risk. A study evaluating the QT/QT_c prolonging effect of intramuscular GEODON, with intramuscular haloperidol as a control, was conducted in patient volunteers. In the trial, ECGs were obtained at the time of maximum plasma concentration following two injections of GEODON (20 mg then 30 mg) or haloperidol (7.5 mg then 10 mg) given four hours apart. Note that a 30 mg dose of intramuscular GEODON is 50% higher than the recommended therapeutic dose. The mean change in QT_c from baseline was calculated for each drug using a sample-based correction that removes the effect of heart rate on the QT interval. The mean increase in QT_c from baseline for GEODON was 4.6 msec following the first injection and 12.8 msec following the second injection. The mean increase in QT_c from baseline for haloperidol was 6.0 msec following the first injection and 14.7 msec following the second injection. In this study, no patient had a QT_c interval exceeding 500 msec. As with other antipsychotic drugs and placebo, sudden unexplained deaths have been reported in patients taking GEODON at recommended doses. The premarketing experience for GEODON did not reveal an excess of mortality for GEODON compared to other antipsychotic drugs or placebo, but the extent of exposure was limited, especially for the drugs used as active controls and placebo. Nevertheless, GEODON's larger prolongation of QT_c length compared to several other antipsychotic drugs raises the possibility that the risk of sudden death may be greater for GEODON than for other available drugs for treating schizophrenia. This possibility needs to be considered in deciding among alternative drug products. Certain circumstances may increase the risk of the occurrence of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QT_c interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QT_c interval; and (4) presence of congenital prolongation of the QT interval. GEODON should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias (see CONTRAINDICATIONS, and see *Drug Interactions* under PRECAUTIONS). It is recommended that patients being considered for GEODON treatment who are at risk for significant electrolyte disturbances, hypokalemia in particular, have baseline serum potassium and magnesium measurements. Hypokalemia (and/or hypomagnesemia) may increase the risk of QT prolongation and arrhythmia. Hypokalemia may result from diuretic therapy, diarrhea, and other causes. Patients with low serum potassium and/or magnesium should be repleted with those electrolytes before proceeding with treatment. It is essential to periodically monitor serum electrolytes in patients for whom diuretic therapy is introduced during GEODON treatment. Persistently prolonged QT_c intervals may also increase the risk of further prolongation and arrhythmia, but it is not clear that routine screening ECG measures are effective in detecting such patients. Rather, GEODON should be avoided in patients with histories of significant cardiovascular illness, eg, QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. GEODON should be discontinued in patients who are found to have persistent QT_c measurements >500 msec. *Neuroleptic Malignant Syndrome (NMS):*** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported. ***Tardive Dyskinesia (TD):*** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients undergoing treatment with antipsychotic drugs. Although the prevalence of TD appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop TD. If signs and symptoms of TD appear in a patient on GEODON, drug discontinuation should be considered. ***Hyperglycemia and Diabetes Mellitus:*** Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical antipsychotics. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON, and it is not known if GEODON is associated with these events. Patients treated with an atypical antipsychotic should be monitored for symptoms of hyperglycemia. **PRECAUTIONS — *General:*** Rash: In premarketing trials, about 5% of GEODON patients developed rash and/or urticaria, with discontinuation of treatment in about one-sixth of these cases. The occurrence of rash was dose related, although the finding might also be explained by longer exposure in higher-dose patients. Several patients with rash had signs and symptoms of associated systemic illness, e.g., elevated WBCs. Most patients improved promptly upon treatment with antihistamines or steroids and/or upon discontinuation of GEODON, and all patients were reported to recover completely. Upon appearance of rash for which an alternative etiology cannot be identified, GEODON should be discontinued. Orthostatic Hypotension: GEODON may induce orthostatic hypotension associated with dizziness, tachycardia, and, in some patients, syncope, especially during the initial dose-titration period, probably reflecting its α_1-adrenergic antagonist properties. Syncope was reported in 0.6% of GEODON patients. GEODON should be used with particular caution in patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Seizures: In clinical trials, seizures occurred in 0.4% of GEODON patients. There were confounding factors that may have contributed to seizures in many of these cases. As with other antipsychotic drugs, GEODON should be used cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in a population of 65 years or older. Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia, and GEODON and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia. **(See also Boxed WARNING, WARNINGS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis).** Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, GEODON elevates prolactin levels in humans. Tissue culture experiments indicate that approximately one third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time. Potential for Cognitive and Motor Impairment: Somnolence was a commonly reported adverse event in GEODON patients. In the 4- and 6-week placebo-controlled trials, somnolence was reported in 14% of GEODON patients vs 7% of placebo patients. Somnolence led to discontinuation in 0.3% of patients in short-term clinical trials. Since GEODON has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about performing activities requiring mental alertness, such as operating a motor vehicle (including automobiles) or operating hazardous machinery until they are reasonably certain that GEODON therapy does not affect them adversely. Priapism: One case of priapism was reported in the premarketing database. Body Temperature Regulation: Although not reported with GEODON in premarketing trials, disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Suicide: The possibility of a suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. GEODON prescriptions should be written for the smallest quantity of capsules consistent with good patient management to reduce overdose risk. Use in Patients with Concomitant Illness: Clinical experience with GEODON in patients with certain concomitant systemic illnesses is limited. GEODON has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies. Because of the risk of QT_c prolongation and orthostatic hypotension with GEODON, caution should be observed in cardiac patients (see ***QT Prolongation and Risk of Sudden Death*** in **WARNINGS** and Orthostatic Hypotension in **PRECAUTIONS**). ***Information for Patients:*** To ensure safe and effective use of GEODON, the information and instructions in the *Patient Information Section* should be discussed with patients. ***Laboratory Tests:*** Patients being considered for GEODON treatment who are at risk of significant electrolyte disturbances should have baseline serum potassium and magnesium measurements. Low serum potassium and magnesium should be repleted before treatment. Patients who are started on diuretics during GEODON therapy need periodic monitoring of serum potassium and magnesium. Discontinue GEODON in patients who are found to have persistent QT_c measurements >500 msec (see **WARNINGS**). ***Drug Interactions:*** (1) GEODON should not be used with any drug that prolongs the QT interval. (2) Given the primary CNS effects of GEODON, caution should be used when it is taken in combination with other centrally acting drugs. (3) Because of its potential for inducing hypotension, GEODON may enhance the effects of certain antihypertensive agents. (4) GEODON may antagonize the effects of levodopa and dopamine agonists. Effect of Other Drugs on GEODON: *Carbamazepine*, 200 mg bid for 21 days, resulted in a decrease of approximately 35% in the AUC of GEODON. *Ketoconazole*, a potent inhibitor of CYP3A4, 400 mg qd for 5 days, increased the AUC and C_{max} of GEODON by about 35%-40%. *Cimetidine*, 800 mg qd for 2 days, did not affect GEODON pharmacokinetics. Coadministration of 30 mL of *Maalox* did not affect GEODON pharmacokinetics. Population pharmacokinetic analysis of schizophrenic patients in controlled clinical trials has not revealed any clinically significant pharmacokinetic interactions with benztropine, propranolol, or lorazepam. Effect of GEODON on Other Drugs: In vitro studies revealed little potential for GEODON to interfere with the metabolism of drugs cleared primarily by CYP1A2, CYP2C9, CYP2C19, CYP2D6, and CYP3A4, and little potential for drug interactions with GEODON due to displacement. GEODON 40 mg bid administered concomitantly with *lithium* 450 mg bid for 7 days did not affect the steady-state level or renal clearance of lithium. GEODON 20 mg bid did not affect the pharmacokinetics of concomitantly administered *oral contraceptives*, ethinyl estradiol (0.03 mg) and levonorgestrel (0.15 mg). Consistent with in vitro results, a study in normal healthy volunteers showed that GEODON did not alter the metabolism of *dextromethorphan*, a CYP2D6 model substrate, to its major metabolite, dextrorphan. There was no statistically significant change in the urinary dextromethorphan/dextrorphan ratio. ***Carcinogenesis, Mutagenesis, Impairment of Fertility:*** Lifetime carcinogenicity studies were conducted with GEODON in Long Evans rats and CD-1 mice. In male mice, there was no increase in incidence of tumors relative to controls. In female mice there were dose-related increases in the incidences of pituitary gland adenoma and carcinoma, and mammary gland adenocarcinoma at all doses tested. Increases in serum prolactin were observed in a 1-month dietary study in female, but not male, mice. GEODON had no effect on serum prolactin in rats in a 5-week dietary study at the doses that were used in the carcinogenicity study. The relevance for human risk of the findings of prolactin-mediated endocrine tumors in rodents is unknown (see Hyperprolactinemia). Mutagenesis: There was a reproducible mutagenic response in the Ames assay in one strain of *S. typhimurium* in the absence of metabolic activation. Positive results were obtained in both the in vitro mammalian cell gene mutation assay and the in vitro chromosomal aberration assay in human lymphocytes. Impairment of Fertility: GEODON increased time to copulation in Sprague-Dawley rats in two fertility and early embryonic development studies at doses of 10 to 160 mg/kg/day (0.5 to 8 times the MRHD of 200 mg/day on a mg/m^2 basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m^2 basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m^2 basis). The fertility of female rats was reduced. ***Pregnancy—Pregnancy Category C:*** There are no adequate and well-controlled studies in pregnant women. GEODON should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. ***Labor and Delivery:*** The effect of GEODON on labor and delivery in humans is unknown. ***Nursing Mothers:*** It is not known whether, and if so in what amount, GEODON or its metabolites are excreted in human milk. It is recommended that women receiving GEODON should not breast feed. ***Pediatric Use:*** The safety and effectiveness of GEODON in pediatric patients have not been established. ***Geriatric Use:*** Of the approximately 4500 patients treated with GEODON in clinical studies, 2.4% (109) were 65 years of age or over. In general, there was no indication of any different tolerability for GEODON or of reduced clearance of GEODON in the elderly compared to younger adults. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to GEODON, or cause poorer tolerance or orthostasis, should lead to consideration of a lower starting dose, slower titration, and careful monitoring during the initial dosing period for some elderly patients. **ADVERSE REACTIONS — *Adverse Findings Observed in Short-term, Placebo-Controlled Trials:*** The following findings are based on the short-term placebo-controlled premarketing trials for schizophrenia (a pool of two 6-week, and two 4-week fixed-dose trials) and bipolar mania (a pool of two 3-week flexible-dose trials) in which GEODON was administered in doses ranging from 10 to 200 mg/day. ***Adverse Events Associated with Discontinuation:*** Schizophrenia: Approximately 4.1% (29/702) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 2.2% (6/273) on placebo. The most common event associated with dropout was rash, including 7 dropouts for rash among GEODON patients (1%) compared to no placebo patients (see **PRECAUTIONS**). Bipolar Mania: Approximately 6.5% (18/279) of GEODON-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse event, compared with about 3.7% (5/136) on placebo. The most common events associated with dropout in the GEODON-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash, and vomiting, with 2 dropouts for each of these events among GEODON patients (1%) compared to one placebo patient each for dystonia and rash (1%) and no placebo patients for the remaining adverse events. ***Adverse Events at an Incidence ≥5% and at Least Twice the Rate of Placebo:*** The most commonly observed adverse events associated with GEODON in schizophrenia trials were somnolence (14%) and respiratory tract infection (8%). The most commonly observed adverse events associated with the use of GEODON in bipolar mania trials were somnolence (31%), extrapyramidal symptoms (31%), dizziness (16%), akathisia (10%), abnormal vision (6%), asthenia (6%), and vomiting (5%). The following list enumerates the treatment-emergent adverse events that occurred during acute therapy, including only those events that occurred in 2% of GEODON patients and at a greater incidence than in placebo. Schizophrenia: Body as a Whole—asthenia, accidental injury, chest pain. Cardiovascular—tachycardia. Digestive—nausea, constipation, dyspepsia, diarrhea, dry mouth, anorexia. Nervous—extrapyramidal symptoms, somnolence, akathisia, dizziness. Respiratory—respiratory tract infection, rhinitis, cough increased. Skin and Appendages—rash, fungal dermatitis. Special Senses—abnormal vision. Bipolar Mania: Body as a Whole—headache, asthenia, accidental injury. Cardiovascular—hypertension. Digestive—nausea, diarrhea, dry mouth, vomiting, increased salivation, tongue edema, dysphagia. Musculoskeletal—myalgia. Nervous—somnolence, extrapyramidal symptoms, dizziness, akathisia, anxiety, hypesthesia, speech disorder. Respiratory—pharyngitis, dyspnea. Skin and Appendages—fungal dermatitis. Special Senses—abnormal vision. ***Dose Dependency:*** An analysis for dose response in the schizophrenia trials revealed an apparent relation of adverse event to dose for the following: asthenia, postural hypotension, anorexia, dry mouth, increased salivation, arthralgia, anxiety, dizziness, dystonia, hypertonia, somnolence, tremor, rhinitis, rash, and abnormal vision. ***Extrapyramidal Symptoms (EPS):*** The incidence of reported EPS for GEODON patients in the short-term, placebo-controlled schizophrenia trials was 14% vs 8% for placebo. Objectively collected data from those trials on the Simpson-Angus Rating Scale and the Barnes Akathisia Scale did not generally show a difference between GEODON and placebo. ***Dystonia:*** Prolonged abnormal contractions of muscle groups may occur in susceptible individuals during first few days of treatment. Dystonia may occur at any dose level but with greater frequency and severity with high potency and at higher doses of first generation antipsychotic drugs. Elevated risk is observed in males and younger age groups. ***Vital Sign Changes:*** GEODON is associated with orthostatic hypotension (see **PRECAUTIONS**). ***Weight Gain:*** In short-term schizophrenia trials, the proportions of patients meeting a weight gain criterion of ≥7% of body weight were compared, revealing a statistically significantly greater incidence of weight gain for GEODON patients (10%) vs placebo patients (4%). A median weight gain of 0.5 kg was observed in GEODON patients vs 0.0 kg in placebo patients. Weight gain was reported as an adverse event in 0.4% of both GEODON and placebo patients. During long-term therapy with GEODON, a categorization of patients at baseline on the basis of body mass index (BMI) showed the greatest mean weight gain and the highest incidence of clinically significant weight gain (>7% of body weight) in patients with a low BMI (<23) compared to normal (23-27) or overweight (>27) patients. There was a mean weight gain of 1.4 kg for patients with a "low" baseline BMI, 0.0 kg for patients with a "normal" BMI, and a 1.3 kg mean weight loss for patients with a "high" BMI. ***ECG Changes:*** GEODON is associated with an increase in the QT_c interval (see **WARNINGS**). In schizophrenia trials, GEODON was associated with a mean increase in heart rate of 1.4 beats per minute compared to a 0.2 beats per minute decrease among placebo patients. ***Other Adverse Events Observed During the Premarketing Evaluation of GEODON:*** Frequent adverse events are those occurring in at least 1/100 patients; infrequent adverse events are those occurring in 1/100 to 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. Schizophrenia: Body as a Whole — *Frequent:* abdominal pain, flu syndrome, fever, accidental fall, face edema, chills, photosensitivity reaction, flank pain, hypothermia, motor vehicle accident. Cardiovascular System — *Frequent:* tachycardia, hypertension, postural hypotension; *Infrequent:* bradycardia, angina pectoris, atrial fibrillation; *Rare:* first-degree AV block, bundle branch block, phlebitis, pulmonary embolus, cardiomegaly, cerebral infarct, cerebrovascular accident, deep thrombophlebitis, myocarditis, thrombophlebitis. Digestive System — *Frequent:* anorexia, vomiting; *Infrequent:* rectal hemorrhage, dysphagia, tongue edema; *Rare:* gum hemorrhage, jaundice, fecal impaction, gamma glutamyl transpeptidase increased, hematemesis, cholestatic jaundice, hepatitis, hepatomegaly, leukoplakia of mouth, fatty liver deposit, melena. Endocrine — *Rare:* hypothyroidism, hyperthyroidism, thyroiditis. Hemic and Lymphatic System — *Infrequent:* anemia, ecchymosis, leukocytosis, leukopenia, eosinophilia, lymphadenopathy; *Rare:* thrombocytopenia, hypochromic anemia, lymphocytosis, monocytosis, basophilia, lymphedema, polycythemia, thrombocythemia. Metabolic and Nutritional Disorders — *Infrequent:* thirst, transaminase increased, peripheral edema, hyperglycemia, creatine phosphokinase increased, alkaline phosphatase increased, hypercholesteremia, dehydration, lactic dehydrogenase increased, albuminuria, hypokalemia; *Rare:* BUN increased, creatinine increased, hyperlipemia, hypocholesteremia, hyperkalemia, hypochloremia, hypoglycemia, hyponatremia, hypoproteinemia, glucose tolerance decreased, gout, hyperchloremia, hyperuricemia, hypocalcemia, hypoglycemic reaction, hypomagnesemia, ketosis, respiratory alkalosis. Musculoskeletal System — *Frequent:* myalgia; *Infrequent:* tenosynovitis; *Rare:* myopathy. Nervous System — *Frequent:* agitation, extrapyramidal syndrome, tremor, dystonia, hypertonia, dyskinesia, hostility, twitching, paresthesia, confusion, vertigo, hypokinesia, hyperkinesia, abnormal gait, oculogyric crisis, hypesthesia, ataxia, amnesia, cogwheel rigidity, delirium, hypotonia, akinesia, dysarthria, withdrawal syndrome, buccoglossal syndrome, choreoathetosis, diplopia, incoordination, neuropathy; *Infrequent:* paralysis; *Rare:* myoclonus, nystagmus, torticollis, circumoral paresthesia, opisthotonos, reflexes increased, trismus. Respiratory System — *Frequent:* dyspnea; *Infrequent:* pneumonia, epistaxis; *Rare:* hemoptysis, laryngismus. Skin and Appendages — *Infrequent:* maculopapular rash, urticaria, alopecia, eczema, exfoliative dermatitis, contact dermatitis, vesiculobullous rash. Special Senses — *Frequent:* fungal dermatitis; *Infrequent:* conjunctivitis, dry eyes, tinnitus, blepharitis, cataract, photophobia; *Rare:* eye hemorrhage, visual field defect, keratitis, keratoconjunctivitis. Urogenital System — *Infrequent:* impotence, abnormal ejaculation, amenorrhea, hematuria, menorrhagia, female lactation, polyuria, urinary retention, metrorrhagia, male sexual dysfunction, anorgasmia, glycosuria; *Rare:* gynecomastia, vaginal hemorrhage, nocturia, oliguria, female sexual dysfunction, uterine hemorrhage. **Adverse Finding Observed in Trials of Intramuscular GEODON:** In these studies, the most commonly observed adverse events associated with the use of intramuscular GEODON (≥5%) and observed at a rate on intramuscular GEODON (in the higher dose groups) at least twice that of the lowest intramuscular GEODON group were headache (13%), nausea (12%), and somnolence (20%). **Adverse Events at an Incidence >1% in Short-Term Fixed-Dose Intramuscular Trials:** The following list enumerates the treatment-emergent adverse events that occurred in ≥1% of GEODON patients (in the higher dose groups) and at least twice that of the lowest intramuscular GEODON group. Body as a Whole — headache, injection site pain, asthenia, abdominal pain, flu syndrome, back pain. Cardiovascular — postural hypotension, hypertension, bradycardia, vasodilation. Digestive — nausea, rectal hemorrhage, diarrhea, vomiting, dyspepsia, anorexia, constipation, tooth disorder, dry mouth. Nervous — dizziness, anxiety, insomnia, somnolence, akathisia, agitation, extrapyramidal syndrome, hypertonia, cogwheel rigidity, paresthesia, personality disorder, psychosis, speech disorder. Respiratory — rhinitis. Skin and Appendages — furunculosis, sweating. Urogenital — dysmenorrhea, priapism. **DRUG ABUSE AND DEPENDENCE — *Controlled Substance Class:*** GEODON is not a controlled substance. **OVERDOSAGE** — In premarketing trials in over 5400 patients, accidental or intentional overdosage of GEODON was documented in 10 patients. All patients survived without sequelae. In the patient taking the largest confirmed amount (3240 mg), the only symptoms reported were minimal sedation, slurring of speech, and transitory hypertension (BP 200/95).

Revised August 2008

This program will be conducted on May 17, 2009, during the APA 2009 Annual Meeting

DELIVERING OPTIMAL CARE FOR COMPLEX BIPOLAR PATIENTS:

AN AUDIENCE-GUIDED SYMPOSIUM

SUNDAY, MAY 17, 2009 | Lunch: Noon–12:30 PM | Symposium: 12:30–2:30 PM
Westin St. Francis Hotel | Grand Ballroom (Mezzanine Level) | **SAN FRANCISCO, CALIFORNIA**

AGENDA

Noon–12:30 PM	Lunch	
12:30–12:35 PM	Welcome and Introductions **GARY SACHS, MD (Chairperson)** Harvard Medical School	
12:35–12:55 PM	What Defines Quality of Care in Bipolar Disorder? **RICHARD C. HERMANN, MD, MS** Tufts University School of Medicine	
12:55–1:15 PM	What Does the Payor's Data on Quality of Care Tell Us? **PHYLLIS GREENWALD, MD** Aetna Behavioral Health King of Prussia	
1:15–1:35 PM	How Do We Know if Medications Are Working? **MICHAEL J. OSTACHER, MD, MPH** Harvard Medical School	
1:35–1:55 PM	How Do We Care for Complex Bipolar Patients? **GARY SACHS, MD** Harvard Medical School	
1:55–2:30 PM	Question and Answer Session **ALL FACULTY**	

Sponsored by the American Psychiatric Association

Supported by an educational grant from AstraZeneca

EDUCATIONAL ACTIVITY LEARNING OBJECTIVES

At the conclusion of this symposium, the participant should be able to:

- Describe the role of quality measures of care for bipolar disorder in quality improvement activities
- Review the payor's role in measuring and encouraging quality care for patients with bipolar disorder
- Describe a strategy for maximizing the use of effective treatment while minimizing the continued use of ineffective treatments
- Discuss how a multimodal approach can be used to deliver improved quality of care for this disease

CME STATEMENT

This symposium will be conducted on May 17, 2009, during the APA 2009 Annual Meeting. The American Psychiatric Association (APA) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The APA designates this educational activity for a maximum of 2 *AMA PRA Category 1 Credits*™. Physicians should only claim credit commensurate with the extent of their participation in the activity. Attendees must be registered for the APA Annual Meeting to attend this symposium. Seating is limited and will be based on first-come, first-served. For more information about the meeting, please visit the APA Web site at www.psych.org or contact the APA toll free at 1-888-357-7924 (within the US or Canada) or 703-907-7300.

If any participant of this activity given by The France Foundation is in need of accommodation, please fax written requests to 1-860-434-5390.

Isaac Ray Award

Isaac Ray Award

The American Psychiatric Association and the American Academy of Psychiatry and the Law invites nominations for the Isaac Ray Award for 2010. This Award honors Dr. Isaac Ray, one of the original founders and the fourth President of the American Psychiatric Association, and is presented to a person who has made outstanding contributions to forensic psychiatry or to the psychiatric aspects of jurisprudence. The Award, which will be presented at the Convocation of Fellows at the Annual Meeting of the American Psychiatric Association in New Orleans, LA, in May 2010, includes an honorarium of $l,500. The recipient obligates him or herself to deliver a lecture or series of lectures on these subjects and to present the manuscript for publication.

Nominations are requested as follows:

- a primary nominating letter (sent with the consent of the candidate), which includes a curriculum vitae and specific details regarding the candidate's qualifications for the Award; and
- a supplemental letter from a second nominator in support of the candidate.

Additional letters related to any particular candidate will not be accepted or reviewed by the Award Committee. Nominators should not submit letters on behalf of more than one candidate. Nominations will be kept in the pool of applicants for two years.

The deadline for receipt of nominations is July 1, 2009.

Nominations, as outlined above, should be submitted to:

J. Richard Ciccone, M.D.
Chairperson
Isaac Ray Award Committee
American Psychiatric Association
1000 Wilson Boulevard, Suite 1825
Arlington, VA 22209

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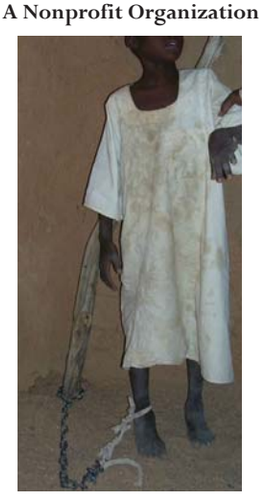

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Professor of Psychiatry

Department of Psychiatry
Judge Baker Children's Center and Harvard Medical School

The Department of Psychiatry at the Judge Baker Children's Center and Harvard Medical School are seeking a researcher at the professorial level to investigate specifically the effects of malnutrition on development and mental health. The researcher should hold an MD or PhD degree with a preference for an MD. He/she should have a proven track record in studying malnutrition and other related adversities that affect the long-term development of children. Candidates must have a national or international reputation and scholarly achievements appropriate for appointment at the level of Professor at Harvard Medical School. The applicant will be expected to pursue his/her own program of extramurally-funded research and to develop collaborative projects within the Judge Baker Children's Center and the larger Harvard community. A focus both on high quality research and on malnutrition are consistent with the Judge Baker Children's Center mission to conduct research on factors associated with children's mental health and to generate knowledge that can inform interventions and services for children, particularly the most disadvantaged. Academic appointment will be through the Department of Psychiatry at Children's Hospital Boston.

Please submit CV and letter of interest to:

Dr. William R. Beardslee
Chairman, Search Committee, Department of Psychiatry
Children's Hospital Boston
21 Autumn Street
Boston, Massachusetts 02215

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ALEXANDRIA Strong Clinical Skills. Prefer experience in General Outpatient, Inpatient Psychiatry, and Substance Abuse. CV/Application to heather.ball@va.gov or mail to Heather Ball/Psychiatry Service (116), P.O. Box 69004, Alexandria, LA 71306-9004. For additional questions, please call (318) 466-2958.

SHREVEPORT Prefer experience in general psychiatry, including inpatient, outpatient, consultative, or telemedicine psychiatry. Interested candidates should submit a CV to Sherri Collier, Human Resources (05), Overton Brooks VA Medical Center, 510 E. Stoner Ave, Shreveport, LA 71101 or via email: sherri.collier@va.gov phone: (318) 990-5147.

FAYETTEVILLE, FORT SMITH, ARKANSAS; BRANSON, MISSOURI Contact Betty Gray (479)443-4301 ext 5188 or email: betty.gray@va.gov.

MUSKOGEE, OK Contact Jason Cleveland, HRMS at 918-577-3800.

JACKSON, MISSISSIPPI Duties may involve several aspects of general psychiatry, including inpatient, outpatient, consultative, or telemedicine psychiatry. Interested candidates should submit a CV to Felicia Owens, Human Resources (05P), VA Medical Center, 1500 E. Woodrow Wilson Dr., Jackson, MS 39216 or Felicia.owens@va.gov phone: 601-364-1575. Equal Opportunity Employer.

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Specialist Psychiatrist

Infant, Child and Adolescent Mental Health Service

Position No. 50901-44006

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For more information, please contact:
Julie A. Oliver,
Physician Recruiter
St. John's Clinic
Phone: 800-218-5079
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APEX MEDICAL CENTER

Academic Leadership Opportunities in the Department of Psychiatry

The Department of Psychiatry and its UBC Institute of Mental Health (IMH) in the Faculty of Medicine at the University of British Columbia (UBC) is recruiting to fill a number of positions in Vancouver, British Columbia, Canada. Vancouver is situated on the west coast of Canada and has been named one of the most desirable places to live in the world.

There are a number of outstanding opportunities for individuals including:

- UBC Endowed IMH Chair – Geriatric Psychiatry - full-time, tenure/tenure track
- UBC Endowed IMH Chair - Child and Adolescent Psychiatry - full-time, tenure/tenure track
- UBC Endowed IMH Chair – Psychotherapy - full-time, tenure/tenure track
- Two (2) full-time tenure track faculty positions in the UBC Department of Psychiatry

UBC Endowed Chairs

The UBC Department of Psychiatry and its UBC Institute of Mental Health

The UBC Institute of Mental Health, in the Department of Psychiatry has the mandate to create new knowledge relevant to mental illnesses and to translate this into improved preventative, diagnostic and therapeutic clinical strategies. An immediate objective of the Institute is to recruit three outstanding faculty members as clinician scientists to UBC and the Province of British Columbia in the areas of: **(1) Child and Adolescent Psychiatry, (2) Geriatric Psychiatry and (3) Psychotherapy**. These new chairs will join a team of clinical and basic science colleagues and clinicians already in place at UBC and the Provincial Health Services Authority including 3 Canada Research Chairs in Neuroscience, BC Leading Edge Endowment Fund Chairs in Depression Research and Addictions, and additional endowed Chairs/Professorships and a numerous clinicians in all areas of Psychiatric care.

The successful candidates will establish collaborative and innovative research programs to meet the mandate of the Institute as well as participate in the undergraduate and post graduate teaching activities of the Department of Psychiatry. The Chairs will become founding members of the UBC Institute of Mental Health and will play a key leadership role within the UBC Department of Psychiatry Programs in which they will be members.

The successful candidates must have the appropriate qualifications and an outstanding record of accomplishments in research, education and clinical care and an international reputation for excellence and leadership. We expect to fill these positions at the rank of full Professor; however, candidates with a promising record of achievement will also be considered for a position at the rank of Associate Professor. The Chairs will be appointed to tenure/tenure track positions with an anticipated start date of July 1, 2009 with an application deadline of May 31, 2009. Salary and rank will be commensurate with qualifications and experience and are subject to final University and budgetary approval.

Opportunities within the Provincial Health Services Authority or Vancouver Coastal Health Authority in clinical care activities are possible.

Full-time Tenure/Tenure Track Positions – UBC Department of Psychiatry

The UBC Department of Psychiatry is recruiting for up to two (2) full-time faculty positions at the rank of Assistant or Associate Professor. These clinician or basic scientist positions will be aligned with the Department's strategic priorities to increase our commitment to clinical and basic research; enhance clinical care through translation of science into practice; enhance our educational programs and build capacity to develop exceptional teachers; build and grow our commitment to our community and our partners. We expect that one position will be appointed in the Basic Neuroscience Division and one position will be appointed in the Clinical and Behavioural Neuroscience Division in one of the clinical programs.

The successful candidates will have a record of accomplishments in research, education and clinical care and will establish collaborative and innovative research programs focused on clinical and translational research, as well as participating in the undergraduate and post graduate teaching activities of the Department of Psychiatry.

The successful candidates must have the appropriate qualifications (MD and/or PhD) and clinician scientist applicants must be certified by the Royal College of Physicians and Surgeons of Canada as a Psychiatrist or be eligible for RCPSC Academic Certification in Psychiatry upon appointment.

Candidates will be appointed to a tenure or tenure track position with an anticipated start date of July 1, 2009 with an applications deadline of May 31, 2009. Salary and rank will be commensurate with qualifications and experience and are subject to final University and budgetary approval.

Opportunities within the Provincial Health Services Authority or Vancouver Coastal Health Authority to participate in clinical care activities are possible and encouraged.

*

UBC hires on the basis of merit and is committed to employment equity. We encourage all qualified persons to apply. However, Canadians and permanent residents of Canada will be given priority.

Applications should include curriculum vitae, a letter identifying the position of interest that includes a description of research interests and plans, evidence of teaching effectiveness and three letters of reference. Application materials should be sent to:

Dr. L. Trevor Young, Professor and Head
c/o Janie McCallum
Department of Psychiatry
Detwiller Pavilion, Room 2C1
2255 Wesbrook Mall
Vancouver, B.C. V6T 2A1

Phone: 604-822-7310
E-mail: janie.mccallum@ubc.ca

UBC DEPARTMENT of Psychiatry

Vancouver CoastalHealth
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Provincial Health Services Authority
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BC Mental Health & Addiction Services

Atascadero State Hospital

BE/BC Psychiatrist

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For a prompt and confidential review, send CV to:

Jeanne Garcia, M.D.
P. O. Box 7001
Atascadero, CA 93423-7001
(805) 468-2005 or fax (805) 468-2138
or e-mail us: jeanne.garcia@ash.dmh.ca.gov

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Rush Medical College/Rush University Medical Center

Chair, Department of Psychiatry

Rush Medical College at Rush University Medical Center is seeking outstanding candidates for the position of Endowed Professor and Chair of the Department of Psychiatry. The Department is founded on a long tradition of excellence in clinical care, research and teaching. Currently, there are five endowed chairs in the department. The Department Chair has oversight over the Sections of Adult and Child Psychiatry. **Rush** is committed to providing outpatient and inpatient psychiatry services, with separate inpatient units for geriatric psychiatry; adult affective disorders, general psychiatry, and child psychiatry. The Chair also has responsibility for fully accredited training programs in Adult Psychiatry and Child Psychiatry.

Candidates must have an outstanding record of commitment to clinical service and research, and substantial administrative experience with an established national reputation as an academic leader. A commitment to advancement of the Department's research mission is also important. In addition, candidates must possess a commitment to innovation in the field and the leadership skills necessary for faculty development and advancement of clinical and academic missions.

Rush Medical College is one of the oldest medical colleges, established in 1837, and one of the largest private academic medical centers in Illinois. The Rush System for Health encompasses an 824 bed hospital serving adults and children, the 110 bed Johnston R. Bowman Center, Rush University, and four affiliate hospitals. **Rush** is a thriving center for basic and clinical research, with a newly built state-of-the-art research facility and over 1,600 active investigations.

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We encourage women and minorities to apply. Nominations or letters of interest that include curriculum vitae should be sent to:

Julie Karstrand
Staff Support for Search/Office of the Dean
Rush University Medical Center
600 South Paulina · Chicago, Illinois 60612

Or preferably electronically to: Julie_Karstrand@rush.edu

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April 2009

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AMERICAN PSYCHIATRIC ASSOCIATION

2009 ANNUAL MEETING ONLINE

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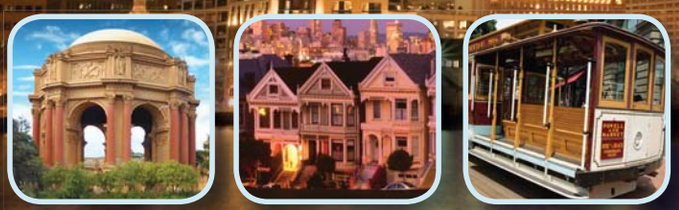

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*The American Psychiatric Association is accredited by the ACCME to provide Continuing Medical Education for physicians. The APA designates (each of the presentations) in this educational activity for a maximum of *1-3 AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

THE APA ANNUAL MEETING ONLINE WWW.PSYCH.ORG/AMLIBRARY

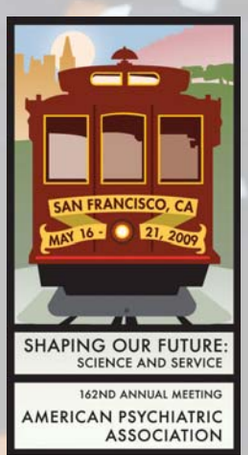
Employers and Candidates Connect through the APA Job Bank

Employers

- Post your psychiatric position with the APA Job Bank at **psych.org/jobbank** and reach qualified professionals.
- Use the many resources of the APA Job Bank to make a smart recruitment decision.
- Advertise in the *Psychiatric Services* or *Psychiatric News* classifieds and the APA Job Bank and receive a 10% discount on each.
- Post your psychiatric position with the APA Job Bank before the APA Annual Meeting in San Francisco, May 16-21, and use the Conference Connection to set up interviews with candidates at the meeting.

Candidates

- Search the most comprehensive online listing of psychiatric positions at **psych.org/jobbank**.
- Register to post your resume, receive instant job alerts, use the career tools and more.
- Visit the APA Job Bank and find the ideal position.
- Use the APA Job Bank's Conference Connection to contact prospective employers and set up interviews at the APA Annual Meeting in San Francisco, May 16-21.



Call 703-907-7330 to post your psychiatric position