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Why Patient Input Will Be Key Element Of *DSM-5* Field Trials

Treatment Refusal Often Exposes Needs of Patient, Physician

> Historic Visit Led To Reform of Abusive Psychiatric System



FDA Approves New Medication To Treat Schizophrenia



Films, TV Shows Honored For Depictions of Those With Mental Illness

### **54** Several Developments Poised to Change Substance Abuse Tx

PERIODICALS: TIME-SENSITIVE MATERIALS



Colleen Reilly, director of the Typical or Troubled program, and Richard Harding, M.D., president of the American Psychiatric Foundation, urge attendees at an October conference on the program to suggest ways to improve its education of teachers and school staff about the warning signs of psychiatric conditions in youth.

### Foundation's School MH Program Seeks Ways to Build on Success

Educators and mental health professionals who have participated in the American Psychiatric Foundation's eight-year-old "Typical or Troubled" program want to build on its success in improving the mental health of the nation's students.

### BY RICH DALY

he signature program of the American Psychiatric Foundation (APF), called "Typical or Troubled," has achieved notable successes in helping to improve student mental health in locations across the country, and plans are under way to expand the program and make it even more effective.

The program was launched eight years ago in response to the Columbine High School shootings. It provides written information and presentations that local school and mental health staff use to educate teachers about the signs of mental illness in students and school and community referrals that provide "scientifically correct interventions" to children who need them, said Richard Harding, M.D., APF president, at an October conference at APA headquarters in Arlington, Va.

> The purpose of the conference was to review the effectiveness of the program with mental health and education professionals who have presented it in their school systems.

Since its launch, the Typical or Troubled program has grown quickly as local mental health professionals have presented it in 310 urban, suburban, and rural high schools and middle schools throughout the country. So far, more than 25,000 educators have participated in the program, affecting an estimated 320,000 students.

"We travel the country and see a need for it everywhere," said APF Executive Director Paul Burke, at the conference.

The Typical or Troubled curriculum instructs teachers and school staff to recognize when mental illness rather than typical youth angst may be present among their students. For example, educators are told to watch for students who have intense fears of becoming obese, with no relationship to their body weight, as a possible sign of an eating disorder. After the presentation about psychiatric disorders, teachers are told about local resources that offer mental health screening and treatment for troubled teens.

After eight years, organizers view the results as encouraging, with nearly 90 percent of educators who participated in a Typical or Troubled program able to displease see APF Program on page 38

# Psychiatrists Notch Victory In Fight Against CPT Coding Bias

The move to reimburse psychiatrists for generic E/M codes reflects a recognition of the greater diversity of services psychiatrists now provide to medically complicated patients.

BY MARK MORAN

nsurers in New York state and at least one large insurer in Massachusetts will now be reimbursing psychiatrists for evaluation and management (E/M) codes that many insurers have restricted psychiatrists from using.

Psychiatrists along with staff in APA's Office of Healthcare Systems and Financing (OHSF) said that the move marks an important change recognizing that psychiatrists today offer services that are more varied and complex than those reflected in the psychotherapy with E/M codes (the 908 codes)—the only E/M codes that most insurers reimburse psychiatrists for using.

In an October 26 letter to all insurers in New York, State Superintendent of the Office of Insurance James Wrynn told insurers they must accept and process all health care claims with E/M codes submitted by psychiatrists and "may not limit the types of CPT codes that [they accept] from psychiatrists to the codes specifically designated as 'psychiatric' in the AMA's CPT codes reporting guidelines and conventions."

please see Coding Bias on page 38



This issue of *Psychiatric News* contains a special section beginning on **page 15** that provides information on the candidates running in APA's 2011 election to help you choose APA's next leaders. Also, see page 6 for a special message from APA President Carol Bernstein, M.D., on why you should learn about the candidates and have your voice heard in your Association. Voting begins on **December 22.** 

FDA-APPROVED FOR THE TREATMENT **OF PATIENTS WITH SCHIZOPHRENIA** 

# **COMING SOON**

AVAILABLE IN PHARMACIES **BEGINNING FEBRUARY 2011** 



### Indication and usage

LATUDA is an atypical antipsychotic agent indicated for the treatment of patients with schizophrenia. Efficacy was established in four 6-week controlled studies of adult patients with schizophrenia.

Important Safety Information about LATUDA

### WARNING: 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. LATUDA is not approved for the treatment of dementia-related psychosis. The effectiveness of LATUDA for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Please see brief summary of prescribing information on adjacent pages, including Boxed Warning.

FOR MORE INFORMATION, PLEASE CALL 1-888-394-7377 OR VISIT WWW.LATUDA.COM LATUDA® and 쓧숙 are registered trademarks of Dainippon Sumitomo Pharma Co. Ltd. Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Dainippon Sumitomo Pharma Co. Ltd.

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劣<sub>SUNOVION</sub>

LATUDA® (lurasidone HCl) Tablets

Brief Summary (for full prescribing information, see package insert)

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

Elderly patients with dementia-related psychosis treated with antipsychotic are at an increased risk of death. Analyses of 17 placebo-controlled druas 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.

LATUDA is not approved for the treatment of patients with dementia-related psychosis. [see Warnings and Precautions (5.1)]

#### 1. INDICATIONS AND USAGE

LATUDA is indicated for the treatment of patients with schizophrenia The efficacy of LATUDA in schizophrenia was established in four 6-week controlled

Studies of adult patients with schizophrenia [see Clinical Studies]. The effectiveness of LATUDA for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient [see Dosage and Administration].

### 4. CONTRAINDICATIONS

LATUDA is contraindicated in any patient with a known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone [see Adverse Reactions (6.6)].

LATUDA is contrainfacted with strong CYP3A4 inhibitors (e.g., ketoconazole) and strong CYP3A4 inducers (e.g., rifampin) [see Drug Interactions (7.1)].

### 5. WARNINGS AND PRECAUTIONS

5.1 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. LATUDA is not approved for the treatment of dementia-related psychosis [see Boxed Warning].

### 5.2 Cerebrovascular Adverse Reactions, Including Stroke

subjects with dementia, there was a higher incidence of cerebrovascular adverse reactions (cerebrovascular accidents and transient ischemic attacks), including fatalities, compared to placebo-treated subjects. LATUDA is not approved for the treatment of patients with dementia-related psychosis [see also Boxed Warning and Warnings and Precautions (5.1)].

### 5.3 Neuroleptic Malignant Syndrome

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic

drugs, including LATUDA. 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 creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. 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 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 NMS.

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

### 5.4 Tardive Dyskinesia

Tardive Dyskinesia is a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements that can 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 cases of 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 that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, LATUDA 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 on LATUDA, drug discontinuation should be considered. However, some patients may require treatment with LATUDA despite the presence of the syndrome.

### 5.5 Metabolic Changes

Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

### Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. 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 atvoical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Because LATUDA was not marketed at the time these studies were performed, it is not known if LATUDA is associated with this increased risk

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

suspect drug. Pooled data from short-term, placebo-controlled studies are presented in Table 1.

### Table 1: Change in Fasting Glucose

Serum Glucose

	Placebo	LATUDA 20 mg/day	LATUDA 40 mg/day	LATUDA 80 mg/day	LATUDA 120 mg/day			
	Mean Change from Baseline (mg/dL)							
	n=438 n=71 n=352 n=270 n=283							
Serum Glucose	-0.7	-0.6	2.5	-0.9	2.5			
Proportion of Patients with Shifts to $\geq$ 126 mg/dL								

14.3%

10.0%

10.0%

(≥ 126 mg/dL) (34/397) (7/60) (47/328) (24/241)(26/260) In the uncontrolled, longer-term studies (primarily open-label extension studies), LATUDA was associated with a mean change in glucose of +1.6 mg/dL at week 24 (n=186), +0.3 mg/dL at week 36 (n=236) and +1.2 mg/dL at week 52 (n=244).

11.7%

Dyslipidemia Undesirable atterations in lipids have been observed in patients treated with atypical antipsychotics. Pooled data from short-term, placebo-controlled studies are presented in Table 2

### Table 2: Change in Fasting Lipids

8.6%

	Placebo	LATUDA 20 mg/day	LATUDA 40 mg/day	LATUDA 80 mg/day	LATUDA 120 mg/day		
Mean Change from Baseline (mg/dL)							
n=418 n=71 n=341 n=263 n=268							
Total cholesterol	-8.5	-12.3	-9.4	-9.8	-3.8		
Triglycerides	-15.7	-29.1	-6.2	-14.2	-3.1		
Proportion of Patients with Shifts							

Froportion of Fauents with Shifts						
	Total Cholesterol	6.6%	13.8%	7.3%	6.9%	3.8%
	(≥ 240 mg/dL)	(23/350)	(8/58)	(21/287)	(15/216)	(9/238)
	Triglycerides	12.5%	14.3%	14.0%	8.7%	10.5%
	(≥ 200 mg/dL)	(39/312)	(7/49)	(37/264)	(17/196)	(22/209)

In the uncontrolled, longer-term studies (primarily open-label extension studies), LATUDA was associated with a mean change in total cholesterol and triglycerides of -4.2 (n=186) and -13.6 (n=187) mg/dL at week 24, -1.9 (n=238) and -3.5 (n=238) mg/dL at week 36 and -3.6 (n=243) and -6.5 (n=243) mg/dL at week 52, respectively

Weight Gain Weight gain has been observed with atvoical antipsychotic use. Clinical monitoring of veight is recommended.

Pooled data from short-term, placebo-controlled studies are presented in Table 3. The mean weight gain was 0.75 kg for LATUDA-treated patients compared to 0.26 kg for placebo-treated patients. In study 3 [see Clinical Studies (14.1)] change in weight from baseline for danzapine was 4.15 kg. The proportion of patients with a 2% increase in body weight (at Endpoint) was 5.6% for LATUDA-treated patients versus 4.0% for placebo-treated patients

### Table 3: Mean Change in Weight (kg) from Baseline

		Ũ	0 ( 0,			
		Placebo (n=450)	LATUDA 20 mg/day (n=71)	LATUDA 40 mg/day (n=358)	LATUDA 80 mg/day (n=279)	LATUDA 120 mg/day (n=291)
[	All Patients	0.26	-0.15	0.67	1.14	0.68

In the uncontrolled, longer-term studies (primarily open-label extension studies), LATUDA at week 36 (n=303) and -0.71 kg at week 52 (n=244).

5.6 Hyperprolactinemia As with other drugs that antagonize dopamine D<sub>2</sub> receptors, LATUDA elevates prolactin levels.

Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotrophin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male patients [see Adverse Reactions (6)].

In short-term placebo-controlled studies, the median change from baseline to ndpoint in prolactin levels for LATUDA-treated patients was 1.1 ng/mL and was -0.6 ng/mL in the placebo-treated patients. The increase in prolactin was greater in female patients; the median change from baseline to endpoint for females was 1.5 ng/mL and was 1.1 ng/mL in males. The increase in prolactin concentrations was dose-dependent (Table 4).

### Table 4: Median Change in Prolactin (ng/mL) from Baseline

<b>o</b> ( <b>o</b> <i>j</i> )						
	Placebo	LATUDA 20 mg/day	LATUDA 40 mg/day	LATUDA 80 mg/day	LATUDA 120 mg/day	
All Patients	-0.6	-1.1	0.3	1.1	3.3	
	(n=430)	(n=70)	(n=351)	(n=259)	(n=284)	
Females	-1.5	-0.7	-0.9	2.0	6.7	
	(n=102)	(n=19)	(n=99)	(n=78)	(n=70)	
Males	-0.5	-1.2	0.5	0.9	3.1	
	(n=328)	(n=51)	(n=252)	(n=181)	(n=214)	

The proportion of patients with prolactin elevations  $\ge$  5x ULN was 3.6% for LATUDAtreated patients versus 0.7% for placebo-treated patients. The proportion of female patients with prolactin elevations  $\ge 5x$  ULN was 8.3% for LATUDA-treated patients versus 1% for placebo-treated female patients. The proportion of male patients with prolactin elevations ≥ 5x ULN was 1.9% versus 0.6% for placebo-treated male patients.

In the uncontrolled longer-term studies (primarily open-label extension studies) LATUDA was associated with a median change in prolactin of -1.9 ng/mL at week 24 (n=188), -5.4 ng/mL at week 36 (n=189) and -3.3 ng/mL at week 52 (n=243). 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 considered in a patient with previously detected breast cancer. As is common with compounds which increase prolatin release, an increase in mammary gland neoplasia was observed in a LATUDA carcinogenicity study conducted in rats and mice [see Nonclinical Toxicology]. 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, but the available evidence is too limited to be conclusive.

### 5.7 Leukopenia, Neutropenia and Agranulocytosis

Leukopenia/neutropenia has been reported during treatment with antipsychotic agents. Agranulocytosis (including fatal cases) has been reported with other agents in the class Possible risk factors for leukopenia/neutropenia include pre-existing low white blood cell count (WBC) and history of drug induced leukopenia/neutropenia. Patients with a

pre-existing low WBC or a history of drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and LATUDA should be discontinued at the first sign of decline in WBC, in the absence of other causative factors

Patients with neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count < 1000/mm<sup>3</sup>) should discontinue LATUDA and have their WBC followed until recovery.

### 5.8 Orthostatic Hypotension and Syncope

LATUDA may cause orthostatic hypotension, perhaps due to its  $\alpha 1\text{-adrenergic}$  receptor antagonism. The incidence of orthostatic hypotension and syncope events from short-term, placebo-controlled studies was (LATUDA incidence, placebo incidence): orthostatic hypotension [0.4% (4/1004), 0.2% (1/455)] and syncope [<0.1% (1/1004), 0%]. Assessment of orthostatic hypotension defined by vital sign changes (> 20 mm Hg decrease in systolic blood pressure and  $\geq$  10 bpm increase in pulse from sitting to standing or supine to standing positions). In short-term clinical trials orthostatic hypotension occurred with a frequency of 0.8% with LATUDA 40 mg, 1.4% with LATUDA 80 mg and 1.7% with LATUDA 120 mg compared to 0.9% with placebo.

LATUDA should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of myocardial infarction, ischemia, or conduction abnormalities), cerebrovascular disease, or conditions that predispose the patient to hypotension (e.g., dehydration, hypovolemia, and treatment with antihypertensive medications) Monitoring of orthostatic vital signs should be considered in patients who are vulnerable to hypotension.

### 5.9 Seizures

As with other antipsychotic drugs, LATUDA should be used cautiously in patients with a history of seizures or with conditions that lower the seizure threshold, e.g., Alzheimer's dementia. Conditions that lower the seizure threshold may be more prevalent in patients 65 years or older.

In short-term placebo-controlled trials, seizures/convulsions occurred in < 0.1% (1/1004) of patients treated with LATUDA compared to 0.2% (1/455) placebo-treated patients.

### 5.10 Potential for Cognitive and Motor Impairment LATUDA, like other antipsychotics, has the potential to impair judgment, thinking or

motor skills. In short-term, placebo-controlled trials, somnolence was reported in 22.3% (224/1004) of patients treated with LATUDA compared to 9.9% (45/455) of placebo patients, respectively. The frequency of somnolence increases with dose; somnolence was reported in 26.5% (77/291) of patients receiving LATUDA 120 mg/day. In

these short-term trials, somnolence included: hypersomnia, hypersomnolence, sedation and somnolence. Patients should be cautioned about operating hazardous machinery, including motor

vehicles, until they are reasonably certain that therapy with LATUDA does not affect them adversely.

### 5.11 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 LATUDA for patients who will be experiencing conditions that 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 [see Patient Counseling Information (17.9)].

### 5.12 Suicide

The possibility of a suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. Prescriptions for LATUDA should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

In short-term, placebo-controlled studies in patients with schizophrenia, the incidence of treatment-emergent suicidal ideation was 0.6% (6/1004) for LATUDA treated patients compared to 0.4% (2/455) on placebo. No suicide attempts or completed suicides were reported in these studies

### 5.13 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. LATUDA is not indicated for the treatment of dementia-related psychosis, and should not be used in patients at risk for aspiration pneumonia

### 5.14 Use in Patients with Concomitant Illness

Clinical experience with LATUDA in patients with certain concomitant systemic illnesses is limited [see Use in Specific Populations (8.7, 8.8)]. LATUDA 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 [see Warnings and Precautions (5.1, 5.8)].

### **6 ADVERSE REACTIONS**

6.1 Overall Adverse Reaction Profile

The following adverse reactions are discussed in more detail in other sections of the labeling:

- Use in Elderly Patients with Dementia-Related Psychosis [see Boxed Warning and Warnings and Precautions (5.1)]
- Cerebrovascular Adverse Reactions, Including Stroke [see Warnings and Precautions (5.2)1
- Neuroleptic Malignant Syndrome [see Warnings and Precautions (5.3)]
- Tardive Dyskinesia [see Warnings and Precautions (5.4)]
   Hyperglycemia and Diabetes Mellitus [see Warnings and Precautions (5.5)]
- Hyperprolactinemia [see Warnings and Precautions (5.6)]
- Leukopenia, Neutropenia, and Agranulocytosis [see Warnings and Precautions (5.7)]
   Orthostatic Hypotension and Syncope [see Warnings and Precautions (5.8)]
- Seizures [see Warnings and Precautions (5.9)]
   Potential for Cognitive and Motor Impairment [see Warnings and Precautions (5.10)]
- Body Temperature Regulation [see Warnings and Precautions (5.11)]
- Suicide [see Warnings and Precautions (5.12)]
- Dysphagia Isee Warnings and Precautions (5.13)]
- Use in Patients with Concomitant Illness [see Warnings and Precautions (5.14)]

The information below is derived from a clinical study database for LATUDA consisting of over 2096 patients with schizophrenia exposed to one or more doses with a total experience of 624 patient-years. Of these patients, 1004 participated in short-term placebo-controlled schizophrenia studies with doses of 20 mg, 40 mg, 80 mg or 120 mg once daily. A total of 533 LATUDA-treated patients had at least 24 weeks and 238 LATUDA-treated patients had at least 52 weeks of exposure.

Adverse events during exposure to study treatment were obtained by general inquiry and voluntarily reported adverse experiences, as well as results from physical examinations, vital signs, ECGs, weights and laboratory investigations. Adverse experiences were recorded by clinical investigators using their own terminology. In order to provide a meaningful estimate of the proportion of individuals experiencing adverse events, events were grouped in standardized categories using MedDRA terminology.

The stated frequencies of adverse reactions represent the proportion of individuals who experienced at least once, a treatment-emergent adverse event of the type listed Treatment-emergent adverse events were defined as adverse experiences, which started or worsened on or after the date of the first dose through seven days after study medication discontinuation. There was no attempt to use investigator causality assessments: i.e., all events meeting the defined criteria, regardless of investigator causality are included. It is important to emphasize that, although the reactions occurred during treatment with LATUDA, they were not necessarily caused by it. The label should be read in its entirety to gain an understanding of the safety profile of LATUDA.

The figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical studies. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatment, uses and investigators. The cited figures, however, do provide the prescriber with some basis for estimating the relative contribution of drug and nondrug factors to the adverse reaction incidence in the population studied

### 6.2 Clinical Studies Experience

The following findings are based on the short-term placebo-controlled premarketing studies for schizophrenia in which LATUDA was administered at daily doses ranging from 20 to 120 mg (n=1004).

Commonly Observed Adverse Reactions: The most common adverse reactions (incidence  $\geq$  5% and at least twice the rate of placebo) in patients treated with LATUDA were somnolence, akathisia, nausea, parkinsonism and agitation.

Adverse Reactions Associated with Discontinuation of Treatment: A total of 9.4% (94/1004) LATUDA-treated patients and 5.9% (27/455) of placebo-treated patients discontinued due to adverse reactions. There were no adverse reactions associated with discontinuation in subjects treated with LATUDA that were at least 2% and at least twice the placebo rate

Adverse Reactions Occurring at an Incidence of 2% or More in LATUDA-Treated Patients: Adverse reactions associated with the use of LATUDA (incidence of 2% or greater, rounded to the nearest percent and LATUDA incidence greater than placebo) that cocurred during acute therapy (up to 6-weeks in patients with schizophrenia) are shown in Table 5.

Table 5: Adverse Reaction in 2% or More of LATUDA-Treated Patients and That Occurred at Greater Incidence than in the Placebo-Treated Patients in Shortterm Schizophrenia Studies

	Percentage of Patients Reporting Reaction			
Body System or Organ Class Dictionary-derived Term	Placebo (N=455)	AII LATUDA (N=1004)		
Gastrointestinal Disorders				
Nausea	6	12		
Vomiting	6	8		
Dyspepsia	6	8		
Salivary hypersecretion	<1	2		
General Disorders and Adminis	stration Site Conditions			
Fatigue	3	4		
Musculoskeletal and Connecti	ve Tissue Disorders			
Back Pain	3	4		
Nervous System Disorders				
Somnolence*	10	22		
Akathisia	3	15		
Parkinsonism**	5	11		
Dystonia***	1	5		
Dizziness	3	5		
Psychiatric Disorders				
Insomnia	7	8		
Agitation	3	6		
Anxiety	3	6		
Restlessness	2	3		

Note: Figures rounded to the nearest integer

Somnolence includes adverse event terms: hypersomnia, hypersomnolence, sedation and somnolence

\*Parkinsonism includes adverse event terms: bradykinesia, cogwheel rigidity, drooling extrapyramidal disorder, hypokinesia, muscle rigidity, parkinsonism, psychomotor

retardation, and tremor \*Dystonia includes adverse event terms: dystonia, oculogyric crisis, oromandibular dystonia, tongue spasm, torticollis, and trismus

### 6.3 Dose-Related Adverse Reactions

Based on the pooled data from the placebo-controlled, short-term, fixed-dose studies, among the adverse reactions that occurred with a greater than 5% incidence in the patients treated with LATUDA, the apparent dose-related adverse reactions were akathisia and somnolence (Table 6).

### **Table 6: Dose-Related Adverse Events**

	Percentage of Subjects Reporting Reaction					
Adverse Event Term	Placebo (N=455) (%)	LATUDA 20 mg/day (N=71) (%)	LATUDA 40 mg/day (N=360) (%)	LATUDA 80 mg/day (N=282) (%)	LATUDA 120 mg/day (N=291) (%)	
Akathisia	3	6	11	15	22	
Somnolence*	10	15	19	23	26	

Note: Figures rounded to the nearest integer Somnolence includes adverse event terms: hypersomnia, hypersomnolence, sedation and somnolence

### 6.4 Extrapyramidal Symptoms

In the short-term, placebo-controlled schizophrenia studies, for LATUDA-treated patients the incidence of reported EPS-related events, excluding akathisia and restles 14.7% versus 5.1% for placebo-treated patients: and the incidence of akathisia for LATUDA treated patients was 15.0% versus 3.3% for placebo-treated patients. Akathisia appeared to be dose-related and the greatest frequency of parkinsonism and dystonia occurred with the highest dose of LATUDA, 120 mg/day (Table 7) Table 7: Percentage of EPS Compared to Placebo

LATUDA LATUDA LATUDA LATUDA Placebo 0 mg/day 40 mg/day 80 mg/day 120 mg/day (N=455) (N=71) (N=360) (N=282) (N=291) Adverse Event Term (%) (%) (%) (%) (%) All EPS events 10 24 26 39 All EPS events, excluding Akathisia 22 5 6 13 11 Restlessness Akathisia 3 6 11 15 22 0 Dystonia' 1 4 5 7 10 Parkinsonism 5 6 17 Restlessness 2 4

Note: Figures rounded to the nearest integer

4 PSYCHIATRIC NEWS / December 3, 2010

Dystonia includes adverse event terms: dystonia, oculogyric crisis, oromandibular dystonia, tongue spasm, torticollis, and trismus

Parkinsonism includes adverse event terms: bradykinesia, cogwheel rigidity, drooling, extrapyramidal disorder, hypokinesia, muscle rigidity, parkinsonism, psychomotor and tremo

In the short-term, placebo-controlled schizophrenia studies, data was objectively collected on the Simpson Angus Rating Scale for extrapyramidal symptoms (EPS), the Barnes Akathisia Scale (for akathisia) and the Abnormal Involuntary Movement Scale (for dyskinesias). The mean change from baseline for LATUDA-treated patients was comparable to placebo-treated patients, with the exception of the Barnes Akathisia Scale global score (LATUDA, 0.2; placebo, 0.0). The percentage of patients who shifted from normal to abnormal was greater in LATUDA-treated patients versus placebo for the BAS (LATUDA, 16.0%; placebo, 7.6%) and the SAS (LATUDA, 5.3%; placebo, 2.5%). 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 reater 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.

In the short-term, placebo-controlled clinical trials, dystonia occurred in 4.7% of LATUDA-treated subjects (0.0% LATUDA 20 mg, 4.2% LATUDA 40 mg, 4.6% LATUDA 80 mg and 6.5% LATUDA 120 mg) compared to 0.7% of subjects receiving placebo. Seven subjects (0.7%, 7/1004) discontinued clinical trials due to dystonic events – 4 were receiving LATUDA 80 mg/day and 3 were receiving LATUDA 120 mg/day.

6.5 Laboratory Test Abnormalities and ECG Changes in Clinical Studies Laboratory Test Abnormalities

In a between-group comparison of the pooled data from short-term, placebo-controlled studies, there were no clinically important changes in total cholesterol measurements; triglycerides or glucose from Baseline to Endpoint [see Warnings and Precations(5,5)]. There were also no clinically important differences between LATUDA and placebo in mean change from baseline to endpoint in routine hematology, urinallysis, or serum chemistry. LATUDA was associated with a dose-related increase in prolactin Concentration [see Warnings and Precautions (5.6)] Creatinine: In short-term, placebo-controlled trials, the mean change from Baseline in

creatinine was 0.06 mg/dL for LATUDA-treated patients compared to 0.03 mg/dL for placebo-treated patients. A creatinine shift from normal to high occurred in 3.1% (30/977) of LATUDA-treated patients and 1.4% (6/439) on placebo. The threshold for high creatinine alue varied from  $\geq$  1.1 to  $\geq$  1.3 mg/dL based on the centralized laboratory definition for each study [see Dosage in Special Population: Use in Specific Populations].

Study (see Dosage in Special roputation), use in Specific roputations]. Transaminases: The mean changes in AST and ALT for LATUDA- and placebo-treated patients were similar. The proportion of patients with transaminases (AST and ALT) elevations  $\geq$  3 times ULN was similar for all LATUDA-treated patients (0.8% and 0.8%, respectively) to placebo-treated patients (0.9% and 1.1%, respectively).

### ECG Changes

Electrocardiogram (ECG) measurements were taken at various time points during the LATUDA clinical trial program. No post-baseline QT prolongations exceeding 500 msec were reported in patients treated with LATUDA. Within a subset of patients defined as having an increased cardiac risk, no potentially important changes in ECG parameters. were observed. No cases of torsade de pointes or other severe cardiac arrhythmias were observed in the pre-marketing clinical program. The effects of LATUDA on the QT/QTc interval were evaluated in a dedicated QT study

involving 97 clinically stable patients with schizophrenia or schizoaffective disorder, who were treated with LATUDA doses of 120 mg daily, 600 mg daily, or ziprasidone 160 mg daily. Holter monitor-derived electrocardiographic assessments were obtained over an eight hour period at baseline and steady state. No patients treated with LATUDA experienced QTc increases > 60 msec from baseline, nor did any patient experience a QTc of > 500 msec.

6.6 Other Adverse Reactions Observed During the Premarketing Evaluation of LATUDA

Following is a list of MedDRA terms that reflect adverse reactions reported by patients treated with LATUDA at multiple doses of  $\geq$  20 mg once daily during any phase of a study within the database of 2096 patients. The reactions listed are those that could be of clinical importance, as well as reactions that are plausibly drug-related on pharmacologic or other grounds. Reactions listed in Table 5 are not included. Although the reactions reported occurred during treatment with LATUDA, they were not necessarily caused by it.

Reactions 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 (frequent) (only those not already listed in the tabulated results from placebocontrolled studies appear in this listing); those occurring in 1/100 to 1/1000 patients (infrequent); and those occurring in fewer than 1/1000 patients (rare). Blood and Lymphatic System Disorders: Infrequent: anemia: Rare: leukopenia.

Cardiac Disorders: Frequent: tachycardia; Infrequent: AV block 1st degree, angina

pectoris, bradycardia Ear and Labyrinth Disorders: Infrequent: vertigo

<u>Le disorders: Frequent:</u> hured vision <u>Gastrointestinal Disorders:</u> Frequent: abdominal pain, diarrhea; Infrequent: gastritis, dysphagia

General Disorders and Administrative Site Conditions; Rare: Sudden death Investigations: Frequent: CPK increased Metabolic and Nutritional System Disorders: Frequent: decreased appetite

Musculoskeletal and Connective Tissue Disorders: Rare: rhabdomvolvsis Nervous System Disorders: Infrequent: tardive dyskinesia, cerebrovascular accident, dysarthria, syncope; Rare: neuroleptic malignant syndrome, seizure Psychiatric Disorders: Infrequent: abnormal dreams, panic attack, sleep disorder; Rare:

suicidal behavior

Renal and Urinary Disorders: Infrequent: dysuria; Rare: renal failure Reproductive System and Breast Disorders: Infrequent: amenorrhea, dysmenorrhea;

Rare: breast enlargement, breast pain, galactorrhea, erectile dysfunction Skin and Subcutaneous Tissue Disorders: Frequent: rash, pruritus; Rare: angioedema Vascular Disorders: Infrequent: hypertension, orthostatic hypotension

7 DRUG INTERACTIONS

Given the primary CNS effects of LATUDA, caution should be used when it is taken in combination with other centrally acting drugs and alcohol. 7.1 Potential for Other Drugs to Affect LATUDA

LATUDA is not a substrate of CYP1A1, CYP1A2, CYP2A6, CYP4A11, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6 or CYP2E1 enzymes. This suggests that an interaction of

LATUDA with drugs that are inhibitors or inducers of these enzymes is unlikely. LATUDA is predominantly metabolized by CYP3A4; interaction of LATUDA with strong

and moderate inhibitors or inducers of this enzyme has been observed (Table 8). LATUDA should not be used in combination with strong inhibitors or inducers of this enzyme *[see* Contraindications (4)].

### Table 8: Summary of Effect of Coadministered Drugs on Exposure to LATUDA in Healthy Subjects or Patients with Schizophrenia

Coadministered drug	Dose schedule		Effect on LATUDA pharmacokinetics		Recommendation
	Coadministered drug	LATUDA	C <sub>max</sub>	AUC	
Ketoconazole (strong CYP3A4 inhibitor)	400 mg/day for 5 days	10 mg single dose	6.9-times LATUDA alone	9-times LATUDA alone	Should not be coadministered with LATUDA
Diltiazem (moderate CYP3A4 inhibitor)	240 mg/day for 5 days	20 mg single dose	2.1-times LATUDA alone	2.2-times LATUDA alone	LATUDA dose should not exceed 40 mg/day if coadministered
Rifampin (strong CYP3A4 inducer)	600 mg/day for 8 days	40 mg single dose	1/7 <sup>th</sup> of LATUDA alone	1/5 <sup>th</sup> of LATUDA alone	Should not be coadministered with LATUDA
Lithium	600 mg BID for 8 days	120 mg/day for 8 days	0.9-times LATUDA alone	1.1- times LATUDA alone	No LATUDA dose adjustment required.

### 7.2 Potential for LATUDA to Affect Other Drugs Digoxin (P-gp substrate): Coadministration of LATUDA (120 mg/day) at steady state

with a single dose of digoxin (0.25 mg) increased  $C_{max}$  and AUC<sub>(0.29</sub> for digoxin by approximately 9% and 13%, respectively relative to digoxin alone. Digoxin dose adjustment is not required when coadministered with LATUDA. Midazolam (CYP3A4 substrate): Coadministration of LATUDA (120 mg/day)

at steady state with a single dose of 5 mg midazolam increased midazolam  $C_{\rm max}$  and AUC\_{(0.24)} by approximately 21% and 44%, respectively relative to midazolam alone. Midazolam dose adjustment is not required when coadministered with LATUDA.

Oral Contraceptive (estrogen/progesterone): Coadministration of LATUDA (40 mg/ day) at steady state with an oral contraceptive (OC) containing ethinyl estradiol and norelgestimate resulted in equivalent  $AUC_{(0,24)}$  and  $C_{max}$  of ethinyl estradiol and norelgestromin relative to OC administration alone. Also, sex hormone binding globulin levels were not meaningfully affected by coadministration of LATUDA and OC. Dose adjustment of OC dose is not required when coadministered with LATUDA 8. USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

### **Teratogenic Effects** Pregnancy Category B

Lurasidone was not teratogenic in rats and rabbits. There are no adequate and well-controlled studies of LATUDA in pregnant women. No teratogenic effects were seen in studies in which pregnant rats and rabbits were given lurasidone during the period of organogenesis at doses up to 25 and 50 mg/kg/day, respectively. These doses are 3 and 12 times, in rats and rabbits respectively. The maximum recommended human dose (MRHD) of 80 mg/day based on body surface area.

No adverse developmental effects were seen in a study in which pregnant rats were given lurasidone during the period of organogenesis and continuing through weaning at doses up to 10 mg/kg/day; this dose is approximately equal to the MRHD based on body surface area.

### Non-teratogenic Effects

Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates. These complications have varied in severity, while in some cases symptoms have been self-limited, in other cases neonates have required ensive care unit support and prolonged hospitalization.

LATUDA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

. 8.3 Labor and Delivery The effect of LATUDA on labor and delivery in humans is unknown. 8.4 Nursing Mothers

LATUDA was excreted in milk of rats during lactation. It is not known whether LATUDA or its metabolites are excreted in human milk. Breast feeding in women receiving LATUDA should be considered only if the potential benefit justifies the potential risk to the child. 8.5 Pediatric Use

### afety and effectiveness in pediatric patients have not been established.

8.6 Geriatric Use Clinical studies of LATUDA in the treatment of schizophrenia did not include sufficient numbers of patients aged 65 and older to determine whether or not they respond differently from younger patients. In elderly patients with psychosis (65 to 85), lurasidone concentrations (20 mg/day) were similar to those in young subjects [see Clinical

Pharmacology. No dose adjustment is necessary in elderly patients. Elderly patients with dementia-related psychosis treated with LATUDA are at an increased risk of death compared to placebo. LATUDA is not approved for the treatment of patients with dementia-related psychosis [see Boxed Warning].

### 8.7 Renal Impairment

It is recommended that LATUDA dose should not exceed 40 mg/day in patients with in or boots and severe renal impairment ( $C_{trz} \ge 10$  mL/min to < 50 mL/min). After administration of a single dose of 40 mg LATUDA to patients with mild, moderate

and severe renal impairment, mean  $C_{max}$  increased by 40%, 92% and 54%, respectively and mean AUC\_{0----} increased by 53%, 91% and 2- times, respectively compared to healthy matched subjects.

### 8.8 Hepatic Impairment

It is recommended that LATUDA dose should not exceed 40 mg/day in patients with noderate and severe hepatic impairment (Child-Pugh Class B and C). In a single-dose study of LATUDA 20 mg, lurasidone mean AUC (-) stig was 1.5-times higher in subjects with mild hepatic impairment (Child-Pugh Class A), 1.7-times higher in subjects with moderate hepatic impairment (Child-Pugh Class B) and 3-times higher in subjects with severe hepatic impairment (Child-Pugh Class C) compared to the values for healthy matched subjects. Mean  $C_{max}$  was 1.3, 1.2 and 1.3-times higher for mild, moderate and severe hepatically impaired patients respectively, compared to the values for healthy matched subjects

### 8.9 Gender

Population pharmacokinetic evaluation indicated that the mean AUC of LATUDA was 18% higher in women than in men, and correspondingly, the apparent oral clearance of LATUDA was lower in women. Mean  $C_{max}$  of LATUDA was similar between women and men. No dosage adjustment of LATUDA is recommended based on gender.

### 8.10 Race

Although no specific pharmacokinetic study was conducted to investigate the effects of race on the disposition of LATUDA, population pharmacokinetic evaluation ervealed no evidence of clinically significant race-related differences in the pharmacokinetics of LATUDA. No dosage adjustment of LATUDA is recommended based on race

8.11 Smoking Status

Based on in vitro studies utilizing human liver enzymes, LATUDA is not a substrate for CYP1A2; smoking is therefore not expected to have an effect on the pharmacokinetics of LATUDA.

### 10. OVERDOSAGE

10.1 Human Experience In premarketing clinical studies involving more than 2096 patients and/or healthy subjects, accidental or intentional overdosage of LATUDA was identified in one patient who ingested an estimated 560 mg of LATUDA. This patient recovered without sequelae. This patient resumed LATUDA treatment for an additional two months.

### 10.2 Management of Overdosage

Consult a Certified Poison Control Center for up-to-date guidance and advice. There is no specific antidote to LATUDA, therefore, appropriate supportive measures should be instituted and close medical supervision and monitoring should continue until the patient recovers

Cardiovascular monitoring should commence immediately, including continuous electrocardiographic monitoring for possible arrhythmias. If antiarrhythmic therapy is administered, disopyramide, procainamide, and quinidine carry a theoretical hazard of additive QT-prolonging effects when administered in patients with an acute overdose of LATUDA. Similarly the alpha-blocking properties of bretylium might be additive to those

CILATUDA, resulting in problematic hypotension. Hypotension and circulatory collapse should be treated with appropriate measures. pinephrine and dopanies should not be used, or other sympathomimetics with beta-agonist activity, since beta stimulation may worsen hypotension in the setting of LATUDAinduced alpha blockade. In case of severe extrapyramidal symptoms, anticholinergic medication should be administered.

Gastric lavage (after intubation if patient is unconscious) and administration of activated charcoal together with a laxative should be considered.

The possibility of obtundation, seizures, or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis.

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# Features

Volume 45 Number 23 December 3, 2010

### **PROFESSIONAL NEWS** Addressing Tx Refusal Requires Delicate Balance

All patients who refuse treatment have a reason, and a psychiatrist consulted on their care must understand the ethical issues involved in each situation.

**Soviets Reformed System** After Visit Documents Abuse In the last of our series, Psychiatric News looks at a landmark 1989 visit of U.S. psychiatrists to the Soviet Union to investigate claims about abuse of psychiatry. Major changes soon followed.

### **Stereotypes Color Views Of Doctors, Patients**

Interactions between patients and mental health clinicians of diverse ethnicity, often impeded by preconceived ideas, can improve with better training and a little insight.

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**Rediscovering the Soul: Next Medical Advance?** A psychotherapist and best-selling author says that the souls of modern patients-and of doctors who care for them-are in urgent need of attention.

### GOVERNMENT NEWS Volunteer M.D.s Would **2** Get Liability Coverage 🤳

Physicians who offer free medical care to low-income people at community health centers would gain malpractice lawsuit protection under new federal legislation.

### LEGAL NEWS **APA Supports Suit** On Same-Sex Marriage **JU** APA joins other mental health groups in an amicus brief citing psychological and emotional benefits that same-sex couples and their children would gain if the couples were allowed to marry.

**CLINICAL & RESEARCH NEWS** Persistant ADHD Linked to 🤈 **Poor Adult Functioning** A long-term follow-up study of young patients with ADHD connects childhood and adult presentations of the disorder.

Many Obstacles Thwart Addiction Care Outcomes 3 Getting effective substance abuse treatment to Americans who need it is a huge challenge for a host of reasons, and some of these challenges are being met head on.

# Why Patients' Input Crucial **To Success of Field Trials**

This article is the third in a series of commentaries by the chair of the DSM-5 Task Force on the manual's development. The series will continue until the release of DSM-5 in May 2013.

here is a clear relationship

between greater patient

satisfaction and bet-

ter outcomes, including

adherence to treatment.

In many studies, patients have repeatedly

said that they desire empathy, compassion,

understanding, and active listening skills

that may improve patient satisfaction is

fully soliciting a patient's symptoms and

concerns. A study in the January 20, 1999,

Journal of the American Medical Association

by M. Kim Marvel and colleagues found

that physicians often neglect to give ade-

quate time and attention to uncovering a

patient's entire range of complaints. Their

survey of more than 250 family physicians

found that less than one-third (28 percent)

of the doctors fully inquired about their

patients' symptoms. The JAMA article

David J. Kupfer, M.D., is chair of the DSM-5

Task Force and a professor of psychiatry at

the University of Pittsburgh Medical Center

and Western Psychiatric Institute and Clinic.

One specific feature of the clinical visit

from their health care providers.

### BY DAVID J. KUPFER, M.D.

also reported that once a clinician honed in on a primary complaint, the likelihood that he or she would go back and question the patient about all additional complaints was low (8 percent).

In psychiatric populations, a significant number of patients experience comorbid symptoms that may be impairing and distressing and require treatment. As such, the design and implementation strategy of the DSM-5 field trials (as discussed in the October 1 and October 15 issues) actively involves patients in the study assessments to acquire a broader collection of information. This is done by using a set of questionnaires that cover a wide range of psychiatric symptoms, prompting clinicians to engage in a "review of mental health systems" for all patients.

Patients who endorse an item on an initial form will be asked to complete an additional short measure that assesses symptoms in greater detail. The use of patient-outcome measures for these added assessments is especially valuable, as they are designed to help clinicians gain insight please see DSM-5 on page 36

Important Annual Meeting Announcements Early-Bird Registration Ends January 3!

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APA members can now register, enroll in courses, and make hotel reservations for APA's 2011 annual meeting in Hawaii at advanced registration fees. Registration and hotel information, including hotel rates and descriptions, can be accessed on APA's Web site at <www.psych.org/ annualmeeting>. This year's Convocation lecturer is human-rights activist and Nobel Peace Prize recipient Archbishop Desmond Tutu.

 Look for Annual Meeting Information Online Visit <www.psych.org/annualmeeting> to view the entire Annual Meeting Advance Registration Packet. This contains information on airline

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reservations, registration, housing, courses, local information about Hawaii, and other topics. The site will be updated as specific details on the scientific program are finalized.

### • New This Year!

Pre- and post-meeting tours will be offered to the outer Hawaiian islands. While in Honolulu, be sure to take advantage of the many tours and fun activities available for the whole family. Don't be left out-sign up now! Information on tour packages is posted on APA's Web site.

More information is available by calling the APA Meetings and Conventions Department at (703) 907-7822 or by e-mailing apa@psych.org.

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# **from the president** You've Heard It Before: Your Vote *Does* Matter

### BY CAROL A. BERNSTEIN, M.D.

Please vote! As the special election section that begins on page 15 of this issue tells you, it's time once again for APA members to select their next leaders. All APA members with a valid e-mail address on file will receive a link to their personalized electronic ballot on December 22; other members will receive a paper ballot. Votes must be received by 5 p.m.

Eastern time on February 7, 2011.

The election cycle is an important time of year for APA. I know that many of you are "election saturated" and that it is difficult to feel that your one vote matters. But as our recent national elections demonstrate, one vote absolutely matters, and I urge you not to allow frustrations from November 2 to translate into apathy about APA.

Organized medicine is at an important crossroads as we enter an era in which health care reform and parity are being implemented. For the first time in our nation's history, most Americans will have access to affordable, effective health care through the Patient Protection and Affordable Care Act, and those suffering from mental illness, including substance abuse disorders, have the same right to treatment as those suffering from other diseases. Despite the naysayers, while funding for some provisions of the new law may be delayed, the principles are finally in place.

This is a critically important time for medicine in general and psychiatry in particular. As we enter into the process of electing our officers and trustees, I urge you to think seriously about voting for those who you feel will best represent our Association in the years ahead. I feel privileged to have the opportunity to be in a leadership position and look forward to continuing to collaborate with those who will guide APA through these challenging times in the future.

We have a diverse slate of talented and experienced candidates. Ask yourself what type of person in each contest would best represent psychiatry at this point. Will this candidate put aside personal issues or views to consider the good of the Association and to carry out its policies? Will this candidate be open and available to the membership? Will this candidate devote the time and energy needed to be an effective leader? Will this candidate represent us well in work with policymakers as well as with other physicians? Will this candidate be an effective worker as well as appropriately inspirational?

There are numerous ways for you to learn about our candidates. As always, this issue of *Psychiatric News* provides candidates' biographical information and positions on issues important to psychiatry. However, in this age of electronic communication, it is easy to learn even more by visiting the Web sites of candidates who have them and contacting them directly by e-mail. (The URLs of candidates' Web sites and contact information can be accessed at <www.psych.org/Resources/Governance/



Elections/Candidate-Contact-Information.aspx>). I also encourage you to share your ideas, concerns, and vision with them, since it is useful for candidates to have multiple perspectives from our membership. You can also contact colleagues who may know the candidates and who have had an opportunity to work with them in other venues. Taking the time to read about

and reach out to candidates will ensure that you are doing your part to help APA steer a sound course for the future.

APA is one of a few major medical organizations that allow members to vote directly for their national leaders. Yes, less than one-third of our eligible voting members cast a ballot in APA's election. Why is that the case? Is this lack of participation a reflection of pessimism or a statement that there aren't real differences between candidates? Are members too busy caring for patients to research candidates or issues? Or are these members willing to delegate the election process to those most involved and active in APA?

I am looking for ways to engage more of our members in participating in the electoral process and taking on leadership roles in the Association. I hope some of you will consider running for national office in the next cycle, and I would welcome the opportunity to speak with any of you who are interested. In particular, I would like to encourage our younger members to become involved in this way.

I am hopeful that the simplicity of voting electronically will encourage more of you to vote this year. If you have additional ideas about how to improve voter turnout, please contact me at carol.bernstein@ nyumc.org. And to those of you who do take the time to learn about the candidates and vote, you have my thanks. We all benefit from your involvement. ■

### **Nominations Invited**

**P** sychiatry residency training directors are invited to nominate one resident for the American Psychiatric Leadership Fellowship. The two-year program is designed to develop future leaders in psychiatry. During this time, fellows will participate in a component of the APA governance structure, attend APA annual meetings, and receive leadership training.

Psychiatry residents who are in PGY-2 at the time of nomination (or PGY-3 of a five-year program), are APA members or have applied for membership, and have passed all national or state board exams needed for full state licensure are eligible.

The deadline for nominations is January 15, 2011. More information and nomination requirements are posted at <www. psycb.org/sbare/OMNA/psychiatricleadership-fellowship.aspx>.

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# **professional** <u>news</u> Border Often Murky Between Autonomy, Medical Necessity

A psychiatrist called in to assess a patient who has refused treatment must tread carefully in weighing patients' rights against the duty to help a person in serious need of medical care.

BY AARON LEVIN

ne case still haunts psychiatrist Ramaswamy Viswanathan, M.D., D.Sc., a clinical associate professor of psychiatry and division chief of consultation-liaison services at SUNY Downstate Medical Center in Brooklyn, N.Y., years after the encounter with his patient.

A 30-year-old Jehovah's Witness on renal dialysis and with gastrointestinal bleeding refused a blood transfusion because her religion forbade it. After some discussion, Viswanathan persuaded her to accept the transfusion. Once the patient was stabilized, however, the violation of her religious norms distressed her severely. She became depressed enough to require hospitalization. Worse, her decision alienated her family and separated her from her church and the social support it might have provided.

In time, Viswanathan learned a lesson from the experience.

"If I were seeing this patient today, I would accept that religious beliefs are more important than life for some people," he told listeners at a forum on ethical issues raised when patients refuse treatment. The session was part of the APA Institute on Psychiatric Services in Boston in October.

That case reflected a number of ethical dimensions that physicians frequently face in practice. Culture and decisional capacity as well as religion can play a role in addressing these issues when a patient does not want to be treated.

The bases of ethical care in American medicine are values that sometimes find themselves in conflict: autonomy, beneficence, nonmaleficence, and justice, said another panelist, Ramotse Saunders, M.D., a clinical assistant professor at Downstate Medical Center.

Differences in the strength of those values may vary, especially among non-Western populations, said Saunders.

"There is a lively debate in the biomedical literature arguing that bioethical concerns are universal but that bioethics are a 'Western' idea and largely for one group within that tradition," he said.

Furthermore, even if both doctor and patient nominally come from the same culture, they may have different socioeconomic backgrounds or life experiences and thus may have different views on treatment decisions.

Other nations may legally require doctors to act "in the best interests of the patient," in effect, mandating beneficence over autonomy. Physicians anywhere may rate beneficence higher than other values because it is their job to diagnose and treat patients, Viswanathan noted.

Sometimes, patients' treatment refusal may reflect not only deeply held religious or cultural beliefs but also uncertainty, fear of the unknown, or unacknowledged anxiety, said Viswanathan. Psychiatrists' therapeutic skills can help open a patient to the need for certain treatments when others have failed in such an effort.

"Other doctors use rational, 'engineering' models to try to persuade a patient to accept treatment," he said. When that doesn't work, a psychiatrist may be called in to see the patient.

"I recommend letting patients talk over their anxieties," said Viswanathan. "The psychiatrist begins by validating what the patient feels. That can begin a self-caring process that may relieve many anxieties, resulting in more rational behavior by the patient and more openness to treatment."

He recounted a case in which a young woman refused a recommended Caesarean section without saying why. After a discussion with a psychiatrist, she revealed that an aunt had undergone this procedure, which resulted in considerable pain, and the patient was afraid the same thing might happen to her. After this discussion, she was able to analyze her own situation more objectively and eventually agreed to the procedure.

In psychiatry, the balance between autonomy and beneficence often arises around involuntary treatment, said panelist Sharath Puttichanda, M.D., a third-year



From left: Ramotse Saunders, M.D., Sharath Puttichanda, M.D., and Ramaswamy Viswanathan, M.D., D.Sc., all of Downstate Medical Center in New York, discuss the often convoluted causes of a patient's refusal of treatment and the ethically appropriate responses.

resident at Downstate Medical Center.

At one pole lies the view that the patient (at least when fully competent) is in control of his or her destiny. At the other is the question of deciding when a serious mental disorder deprives the patient of the capacity for treatment decision making or is likely to result in harm to the patient or to others. Somewhere between the two poles lies the border of paternalism.

"The principle of utilitarianism asks whether it is ultimately beneficial to the mentally ill person and to society to deprive a person of autonomy temporarily," said Puttichanda. Treatment, not mere confinement, is essential, however. APA's model law on involuntary treatment has five criteria: evidence of serious mental illness, a reasonable prospect that it is treatable, refusal of treatment, decisional incapacity, and the likelihood that harm to self or others could occur.

Yet questions remain about the value of involuntary commitment, aside from the matter of safety, he noted. For example, "How therapeutic is the entire process of forcing treatment on patients?" and "How do any legal repercussions compromise ethical obligations?"

The only certainty is uncertainty, Puttichanda stated. "You do the best you can and document everything."

### **Activist Honored for Gay-Marriage Advocacy**

Evan Wolfson, J.D. (right), receives the John Fryer Award last month at APA's Institute on Psychiatric Services in Boston. At left is Ubaldo Leli, M.D., president of the Association of Gay and Lesbian Psychiatrists (AGLP).

The award is jointly sponsored by APA and the AGLP.

Wolfson, a long-time gay-rights activist, is founder and executive director of Freedom to Marry. He has been director of the Marriage Project at the Lambda Legal Defense and Education Fund and was co-counsel in the landmark Hawaii marriage case *Baehr v. Miike*. (In that case, the Hawaii Supreme Court ruled that the state's prohibition on same-sex marriages amounted to discrimination. The ruling resulted in a backlash by opponents of same-sex marriage and contributed to a nationwide debate on the issue.)

In an address at the institute titled "2020 Vision: Winning the Freedom to Marry This Decade," Wolfson praised the legacy of psychiatrist John Fryer, M.D., and hailed APA for its advocacy of same-sex marriage and for the path it has traveled since 1973 when homosexuality was removed from *DSM*. "APA was once a part of the problem and now has spent several important decades being part of the solution," he said.

Noting that five states and the District of Columbia now legally recog-

nize same-sex marriage, Wolfson said 2010 has been a "historic year of accomplishment for the freedom to marry." Wolfson said state law and public opinion are the two crucial areas of contention in pursuit of same-sex marriage.

He cited, by way of comparison, legal battles for the right of mixed-race couples to marry. At the time of the landmark 1967 Supreme Court case *Loving v. Virginia*, which struck down Virginia's prohibition on mixed-race marriage, Wolfson said all but 16 states had already legalized

mixed-race marriage. By that measure, the movement for same-sex marriage has work to do.

But in the court of public opinion, the movement is winning hearts and minds: two polls—one by CNN and one by the Associated Press—showed that a majority of Americans now favor same-sex marriage, Wolfson said.

"We have crossed an important threshold," he said.

(By contrast, at the time of the Loving decision, 70 percent of Americans said they opposed mixed-race marriage, he said.)

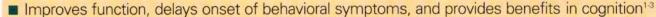
Fryer was a gay psychiatrist who appeared at APA's 1972 annual meeting in Dallas wearing a wig and a mask to shield his identity. The public appearance of a gay psychiatrist explaining at an APA meeting why he could not be open within his profession helped to galvanize a group of largely closeted gay psychiatrists within APA at a time when homosexuality was still widely viewed as pathological by psychiatrists and others. The following year homosexuality was removed from *DSM*.

The Web site of Freedom to Marry is <www.freedomtomarry.org>.



8

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Namenda

NAMENDA is contraindicated in patients with known hypersensitivity to memantine HCI or any excipients used in the formulation. The most common adverse events reported with NAMENDA vs placebo (≥5% and higher than placebo) were dizziness, confusion, headache, and constipation. In patients with severe renal impairment, the dosage should be reduced.

 References: 1. Reisberg B, Doody R, Stöffler A, Schmitt F, Ferris S, Möbius HJ, for the Memantine Study Group. Memantine in moderate-to-severe Alzheimer's disease. N Engl J Med. 2003;348:1333-1341. 2. Tariot PN, Farlow MR, Grossberg GT, Graham SM, McDonald S, Gergel I, for the Memantine Study Group. Memantine treatment in patients with moderate to severe Alzheimer disease already receiving donepezil: a randomized controlled trial. JAMA. 2004;291:317-324. 3. Cummings JL, Schneider E, Tariot PN, Graham SM, for the Memantine MEM-MD-02 Study Group. Behavioral effects of memantine in Alzheimer disease patients receiving donepezil treatment. *Neurology*. 2006;67:57-63. 4. Data on file. Forest Laboratories, Inc. 5. NAMENDA\* (memantine HCI) Prescribing Information. Forest Pharmaceuticals, Inc., St Louis, Mo. 6. Wimo A, Winblad B, Stöffler A, Wirth Y, Möbius HJ. Resource utilisation and cost analysis of memantine in patients with moderate to severe Alzheimer's disease. *Pharmacoeconomics*. 2003;21:327-340. 7. Winblad B, Poritis N. Memantine in severe dementia: results of the "M-BEST Study (Benefit and efficacy in severely demented patients during treatment with memantine). *Int J Geriatr Psychiatry*. 1999;14:135-146.

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#### Tablets/Oral Solution Br Only

### Briel Summary of Prescribing Information.

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

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

### CONTRAINDICATIONS

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

### PRECAIMONS

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

### Neurological Conditions

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

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

#### Special Populations Hepatic Impairment

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

#### **Renal Imnaliment**

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

### Drun-Drun Interactions

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

Effects of Namenda on substrates of microsomal enzymes: In vitro studies conducted with marker substrates of CYP450 enzymes (CYP1A2, -2A5, -2C9, -2D6, -2E1, -3A4) showed minimal inhibition of these enzymes by memanine in addition, in vitro studies indicate that at concentrations exceeding those associated with efficacy, memantine does not induce the cytochrome P45C scienzymes CYP142, CYP2C9, CYP2E1, and CYP3A4/5. No pharmacokinetic interactions with drugs metabolized by these enzymes are expected

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

Acetylcholinesterase (AChE) inhibitors: Coadministration of Namenda with the AChE inhibitor denepszil HCI did not affect the pharmacoknetics of either compound. In a 24-week controlled clinical study in patients with moderate to severe Alzhermen's disease, the adverse event profile observed with a combination of memoritine and conepezil was similar to that of donenezil alone.

Drugs eliminated via renal mechanisms' Because memantine is eliminated in Drugs eleminated varienal mechanisms: Because memorithe is alliminated in part by tubular secretion, coadministration of drugs that use the same renal cationic system including hydrochrotothiazide (HCTZ), triamterene ("A), metformin cimetidine, ranitidine, quinidine, and nicotine, could potentially result in altered plasma levels of both agents. However, coadministration of Namenda and HCTZ/TA did not affect the bioavailability of either memanine or TA, and the bicevalability of HCT2 decreased by 20%. In addition, coadministration of memanher with the similypergytenic drug Glucevance's (glyburite and metformin HCII, did not affect the pharmacowine cs of emprinting metforming albebride cubatence. memantine, mettormin and glybunide. Furthermore, memantine did not modify the serum glucose lowering effect of Glucovance<sup>3</sup>. Drugs that make the urine alkaline: The clearance of memantine was

reduced by about 80% under alkaline urine conditions at pH 8. Therefore, alterations of urine pH towards the alkaline condition may lead to an accumulation of the drug with a possible increase in adverse effects. Unne pH is artered by diet, drugs (s.g. carbonic arhydrase inh bloss, socium b carbonata) and clinical state of the patient (s.g. renal tubular addoss ur severe infections of the unitinary track. Hence, memantum should be used with caution under these conditions

**Carcinogenesis, Mutagenesis and Impairment of Fertility** There was no evidence of carcinogenicity in a 113-week oral study  $\pi$  mide at deses up to "opkgoday (10 times time at 10-week or a study time at deses up to 40 "opkgoday (10 times time maximum recommended human dose (MRHO) on a morim basis). There was also no evidence of caronogencidty in rats orally dosed at up to 40 mg/kg/day for 71 weeks tollowed by 20 mg/kg/day (20 and 10 times time MRHD on a mg/m basis, respectively) through 128 weeks.

Memantine produced no avidence of genotoxic potential when evaluated in the in vitro S. typhimurium or E. coli reverse mulation assay, an in vitro chromosomal aberration test in human lymphocytes, an in vivo cytogenetics assay for chromosome damage in rats, and the in vivo mouse micronucleus assay. The results were equivocal in an in vitro gene mutation assay using Chinese hamster V79 ce Is.

No impairment of fertility or reproductive performance was seen in rats administered up to 18 mg/kg/day (9 times the MRHD on a mg/m basis) praily from 14 days prior to mating through gestation and lactation in ternales, or for 60 days prior to mating in males

#### Pregnancy

Pregnancy Outgoory 8: Memantine given onally to pregnant rats and pregnant rabbits during the period of organogenesis was not teratogenic up to the highest doces tested (18 mg/kg/dg) in rats and 30 mg/kg/da) in rabbits, which are 9 and 30 times, respectively, the maximum recommended human dose [MRHD] on a mg/mf basist.

Slight maternal toxicity, decreased pup weights and an increased incidence of con-ossified cervical vertebrae were seen at an oral cose of 18 mo/kn/day in a study in which rats were given oral memantine beginning pre-mating and continuing through the postpartur period. Slight material toxicity and decreased pub weights were also seen at this dose in a study in which rats were treated from day 15 of gastation through the post-partum period. The no-effect dose for these effects was 6 mg/kg, which is 3 times the MRHD on a mo/mr basis.

There are no adequate and well-controlled studies of memantine in pregnant women. Memantine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

### Nursing Mothers

It is not known whether memantine is excreted in rouman breast milk, Because many drugs are excreted in human milk, caution should be exercised when memantine is administered to a nursing mother. Pediatric Use

There are no adequate and well-controlled trials documenting the safety and efficacy of memanting in any illness occurring in children

#### ADVERSE REACTIONS

The experience described in this section derives from studies in patients with Alzheimer's disease and vascular dementia.

Adverse Events Leading to Discontinuation: In placebo-controlled trials in which dementia patients received doses of Namenca up to 20 mg/day, the likelihood of discontinuation because of an adverse event was the same in the Namenda group as in the placebo group. No individual accerse event was associated with the discontinuation of treatment in 1% or more of Namenda-treated patients and at a rate greater than placebo

Adverse Events Reported in Controlled Trials: The reported adverse events in Namenda (memantine hydrochloride) trials reflect experience gained under closely monitored conditions in a highly selected patient population. In actual practice or in other clinical trials, these frequency estimates may not apply, as the conditions of use reporting behavior and the types of patients freated may differ. Table 1, isls treatment-errergent signs and symptoms that were reported in at least 2% of patients in placebo-controlled dementia trials and for which the rate of occurrence was greater for patients treated with a frequency of all least 5% and twice the placebo. No adverse event occurred at a frequency of all least 5% and twice the placebo rate.

Table 1: Adverse Events Reported in Controlled Clinical Trials in at Least 2% of Patients Receiving Namenda and at a Higher Frequency than Placebotreated Patients

Body System Adverse Event	Placebo (N = 922) %	Namenda (N = 940) <sub>Na</sub>
Body as a Whole	-	
Fatigue		2
Pain	• • •	3
Cardiovascular System		
Hypertension	2	4
Central and Peripheral Nervous System		
Dizziness	5	7
Headache	3	6
Gastroinfestinal System		
Const pation	3	5
Vomiting	2	3
Musculoskeleta: System		
Back pair	2	3
Psychiatric Disorders		
Confusion	5	6
Somno ence	2	3
Hal ucination	2	3
Respiratory System		
Caughing	3	4
Dyspinea	1	2

Other adverse events occurring with an incidence of at least 2% in Namenda freated patients but at a greater or equal rate on placebo were agita: on, fal. inflicted injury, urmary incontinence, diarrhea, bronch tis, insomnia, ur nary tract infection, influenza like symptoms, abnormal gait, depression, .pper resp.ratory tract infection anxiety, periphera; edama, nausea, anorexia, and arthralgia.

The overall profile of adverse events and the incidence rates for individual adverse events in the subpopulation of patients with moderate to severe Alzheimer's clisease were not different from the profile and incidence rates described above for the overall dementia population.

Vital Sign Changes: Namenda and placebo groups were compared with respect to (1) mean change from baseline in vita signs (pulse, systolic blood pressure, diastolic blooc pressure and weight) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. There were no clinically important changes in vital signs in patients treated with Namenda. A comparison of suprime and standing vital sign measures for Namenda and placebo in e derly normal subjects indicated that Namenda treatment is not associated with orthostatic changes.

Laboratory Changes: Namenda and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and uninalysis variables and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Namerida treatment.

ECG Changes: Namenda and placebo proups were compared with "RSDec" to (1) mean change from baseline in various ECE parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in ECG parameters associated with Namenda

### Other Adverse Events Observed During Clinical Trials

Namenda has been administered to approximately 1350 patients with dementia, of whom more than 1200 received the maximum recommended dose of 20 mg/day. Patients received Namenda treatment for periods of up to 884 days, with 862 patients receiving at least 24 weeks of treatment and 387 patients receiving 48 weeks or more of treatment

Treatment emergent signs and symptoms that accurred during 8 controlled clinical trials and 4 open-label trials were recorded as adverse events by the clinical investigators using terminology of their own choosing. To provide an overall estimate of the proportion of individuals having similar types of events, the events were grouped into a smaller number of standardized

categories using WHC term hology, and event frequencies were calculated actoss all studies.

All adverse events occurring in at least two patients are included, except for nose already listed in Table 1. WHO terms too general to be informative, minor symptoms or events unlikely to be crug-caused le.g., because they are common in the study population. Events are classified by body system and listed using the following definitions: frequent adverse events - those cocurring in 1/100 to 1/1000 patients: intrequent adverse events those cocurring in 1/100 to 1/1000 patients. These adverse events are not necessarily related to Alamenda treatment and in most cases were observed. at a subilar frequency in placebo-treated natients in the controlled studies. Body as a Whole: Frequent: syncone. Infrequent: hypothermia, alleroid reaction

Cardiovascular System: Frequent: cardiac failure. infrequent: angina pectoris, bradycardia. myocardial infarction, thrombophisbilis, at a fibrillation, hypotension, cardiac arrest, postural hypotension, pumonary embolism, pulmonary edema.

Central and Peripheral Nervous System: Frequent: transient schemic attack, cerebrovascular accident iver; go, ataxia, hypokinesia, intrequent parestoesia, convulsions, extrapyramidal disorder, hypertonia, tremor aphasia, hypoesthesia, abriormal coordination, hem plegia, hyperkinesia, involuntary muscle contractions, stupor, cerebral hemorrhape, neuralcia, ptosis, neuropathy

GastroIntestinal System: intrequent: gastroenteritis, civerticulitis, gastrointestinal hemor/hage, melena, esophageal ulceration

Hamic and Lymphatic Disorders: Frequent: anemia, Intrequent: leukopenia, Metabolic and Nutritional Disorders; Frequent; increased alkaline phosphatase, decreased weight, infrequent: dehydration, hyponatremia, and availed diabetes mellitus.

Psychiatro Disorders: Frequent: aggressive reaction Intrequent, delusion, personality d sorder, emotional lability, nervousness, sleep disorder. Ilbido increased, psychosis, amnesia, apathy, paranoic reaction, thinking abnormal, crying abnormal, appetite increased, paron ria, delirium, depersonalization. neurosis, suicide attempt

Respiratory System: Frequent: pneumonia. Infrequent: aonea. asthma. hemotitysis

Skin and Appendages: Frequent: rash. Infrequent, skin ulceration, pruritus cellulitis, eczema, cermatitis, erythematous rash, alopecia, unicaria. Special Senses: Frequent: cataract: conjunctivitis. Infrequent: macula

lutea degeneration, decreased visual acuity, decreased hearing, tinnitus, blephants, blurred vision, correat opacity, glaccoma, conjunctival hemorrhage eye pain, retinal hemorrhage, xerochthalmia, diplopia, abnormal lacrimation, myopia, retina detachment.

Urinary System: Frequent: frequent micturition, infrequent: dysuria. hemaluria, urinary retention.

#### Events Reported Subsequent to the Marketing of Namenda, both US and Ex-US

Although no causal relationship to memantine treatment has been found the following adverse events have been reported to be temporally associated with memantine treatment and are not described elsewhere in labeling; aspiration pneumonia, asthenia, atrioventricular block, bons fracture, carpal tunnel syndrome, cerebral infarction, chest pain. cholelithiasis, claudication, colitis, deep venous thrombosis, decreased evel of consciousness (including loss of consciousness and rare reports of coma), dyskinesia, dysphagia, encephalopathy, gastritis, gastroesophageal reflux, grand maliconvulsions, intracrania, hemorrhage, hepatitis (including increased ALT and AST and hepatic failure), hyperglycemia, hyperlipidemia, hypoglycemia, ileus, increased NR, impotence, lethargy, malaise, myoclonus, neuroleptic malignant syndrome, acute pancreatits. Parkinsonism, acute renal faiture (including increased creatinine and renal insufficiency), prolonged QT interval restlessness, sepsis, Stevens-Johnson syndrome, suicidal ideation, sudden death, supraventricular tachycarcia, tachycardia, tardive dyskinesia, thrombocytopenia, and hallucinations (both visual and auditory)

#### ANIMAL TOXICOLOGY

Memoritine induced neuronal lesions (vacualation and necrosis) in the multipolar and pyramidal cells in cortical layers III and IV of the posterior cingulate and retrosplanial neocortices in rats similar to those which are known to occur in rodents administered other NMDA receptor artagonists. Les ons were seen after a sincle dose of memantine, in a study in which rats were given daily oral doses of memantine for 14 days, the no-effect dose for heuronal necrosis was 6 times the maximum recommended human dose on a morni basis. The potential for induction of central neuronal vacuolation and recrosis by NMDA receptor antagonists in humans is unknown

### DRUG ABUSE AND DEPENDENCE

Controlled Substance Class: Memantine HCI is not a controlled substance Physical and Psychological Dependence: Memantine HCI is a low to moderate affinity uncompetitive NMDA antagonist that did not produce any evidence of drug-seeking behavior anegoties had too produce any evidence of drug-seeking behavior or withdrawal symptoms upon discontinuation in 2.504 patients who participated in clinica trials at therapeutic doese. Post marketing data, culside the U.S., retrospectively cellected, has provided no evidence of drug abuse or dependence.

### OVERDOSAGE

Signs and symptoms associated with memantine overdosage in clinical trials and from worldwide marketing experience include agitation, confusion, ECG changes, loss of consciousness, psychosis, restlessness, s owed movement som notence, stupps unsteady gait, visual hallucinations, vertigo, vomiting, and weakness. The largest known ngestion of memaning worldwide was 2.0 grams in a patient who took memant he in conjunction with unspecified antid abetic medications. The patient experienced coma, diplopia, and agitation, but subsequently recovered.

Because strategies for the management of overdose are continually evolving, it is advisable to contact a poison control center to determine the latest recommendations for the management of an overdose of any drug. As in any cases of overdose, general supportive measures should be utilized, and treatment should be symptomatic. Elimination of memantine can be enhanced by acidification of urine.

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# Historic Visit Documented Abuses, Led to Psychiatric System Reform

The visit to the Soviet Union was a measure of change under way in the U.S.S.R. and the desire of the Soviet government to reunite its economy with the West. This is the conclusion of a three-part series on the abuse of psychiatry during the Cold War.

BY MARK MORAN

wenty-five years after Soviet war hero General Pytor Grigorenko was incarcerated in a psychiatric hospital following his protest of human-rights abuses, and 18 years after Vladimir Bukovsky released to the Western press copies of forensic reports on Grigorenko and five other Soviet human-rights activists who had been similarly detained, the Soviet Union was in turmoil.

Grigorenko's incarceration and the release of the "Bukovsky papers" were sentinel events in the growing awareness among

### Resources

The abuse of psychiatry in the Soviet Union, and the protest of that abuse by APA and other psychiatric organizations and individuals, was an epic chapter in the Cold War. The following resources were valuable in creating this three-part series for *Psychiatric News* and provide a fuller account of this turbulent period in psychiatry's history:

### Books

• Cold War in Psychiatry: Secret Factors, Human Actors, by Robert van Voren (Rodopi Publishers, 2010)

• Psychiatric Terror: How Soviet

*Psychiatry Is Used to Suppress Dissent,* Peter Reddaway and Sidney Bloch, M.D. (Basic Books, 1977)

• *Soviet Psychiatric Abuse: The Shadow Over World Psychiatry*, by Peter Reddaway and Sidney Bloch, M.D. (Westview Press, 1985)

• Changing American Psychiatry: A Personal Perspective, by Melvin Sabshin, M.D. (American Psychiatric Publishing Inc., 2008)

### **Journal Articles**

"Assessment of Recent Changes in Soviet Psychiatry: Report of the U.S. Delegation," *Schizophrenia Bulletin,* supplement to volume 15, number 4, 1989
"Political Abuse of Psychiatry in the Soviet Union and in China: Complexities and Controversies," R.J. Bonnie, *Journal* of the American Academy of Psychiatry and the Law, vol. 30, no. 1, 2002

• "Psychiatry on the Side of Angels: The Falun Gong and Soviet Jewry," Alan Stone, M.D., *Journal of the American Academy of Psychiatry and the Law,* vol. 30, no. 1, 2002

"Semyon Gluzman and the Unraveling of Soviet Psychiatry," R.J. Bonnie, *Journal of the American Academy of Psychiatry and the Law*, vol. 29, no. 3, 2001
"Unwilling Patients," Anatoly Koryagin, M.D., *The Lancet*, vol. 317, no. 8224, 1981

Western psychiatrists of the Soviet practice of using psychiatric hospitalization—sometimes augmented by use of drugs—to punish and contain political dissent.

The subject had dominated the 1977 meeting of the World Psychiatric Association (WPA) in Honolulu, resulting in a resolution censuring the Soviet All-Union Society of Psychiatrists and Neuropathologists. Prior to the follow-up meeting in 1983 in Athens, Greece, the All-Union Society withdrew from the world body, under threat of expulsion. Throughout the 1980s, APA's Committee on International Abuse of Psychiatry sought contact with incarcerated individuals believed to be held for nonmedical reasons (*Psychiatric News*, November 5 and November 19).

But change was brewing in the U.S.S.R., and by 1989 Mikhail Gorbachev was in power promising *perestroika*—a comprehensive restructuring of Soviet politics and economy—and *glasnost*, a policy of openness and transparency.

Hoping to revitalize a stagnant economy, Gorbachev and his ministry of foreign affairs, under the leadership of Eduard Shevardnadze, sought better ties with Europe and the United States, including a readmission of the All-Union Society to the WPA. But for that they needed to demonstrate adherence to the human-rights stipulations of the 1975 Helsinki Accords, which they had long ignored, including an end to the use of psychiatric hospitalization to detain political dissidents.

What would evolve from negotia-

### 'Hyperdiagnosis' Found Pervasive

William Carpenter, M.D., director of the Maryland Psychiatric Research Center, was a member of a four-person team that in 1989 interviewed individuals who had recently been released from Soviet hospitals after being diagnosed with schizophrenia or other major mental illnesses.

"We didn't think any of them had schizophrenia or a psychotic illness, though there were some we thought did have more minor symptoms," he recalled. "The one I remember best was an impressive man in his 50s, very robust, who talked freely and assertively. My impression was that he had had a lot of trouble with the government related to political activities. He had suffered from incarceration and was tortured with neuroleptic drugs, which can cause severe dysphoria in nonpsychotic individuals. And he may have been one of the individuals who had been given sulfazine injections.

"It was possible to think he might have a bit of hypomania or grandiosity," Carpenter said. "On the other hand, he might have been someone who could have had a career as a charismatic political leader."

Carpenter's recollections underscore the issue of "hyperdiagnosis"—the stretching of diagnostic categories to include a range of normal behaviors—that was highlighted by the American delegation as a pervasive problem in the Soviet psychiatric system.

The comprehensive report published in the wake of the 1989 visit noted that hyperdiagnosis was most evident in the large number of detainees diagnosed with schizophrenia or "sluggish schizophrenia," but was also apparent in other diagnostic areas. According to the report, "Specific examples of psychopathy identified in the interviews included 'unitary activity,' which related to a high level of commitment to a single cause such as political reform, and 'failure to adapt to society,' used in describing a patient with 'inability to live in society without being subjected to arrest for his behavior.' "

Carpenter recalled dissident Ukrainian psychiatrist Semyon Gluzman, M.D., who explained that the relatively poor training received by Soviet psychiatrists meant that diagnoses rendered by the psychiatric establishment in Moscow would stand little chance of being challenged by psychiatrists outside of Moscow. "If a patient came to a hospital having been diagnosed with sluggish schizophrenia, there was no one with the capacity to question it," Carpenter said.

Consequently, many psychiatrists may have known that they were "treating" political dissidents, but the authoritarian system allowed no challenge to the establishment.

Carpenter added that in a repressive culture, even a more rigorously scientific diagnostic system was vulnerable to manipulation. "I for one would argue that [the Soviets] didn't need [the diagnosis of sluggish schizophrenia] to label dissidents as mentally ill," he told *Psychiatric News.* "They could have used any diagnostic manual, including *DSM*. No diagnostic system will stand in the way of a willful application of a diagnosis for political purposes."

tions between the U.S. State Department and the Soviet Ministry of Foreign Affairs—with the crucial participation of the National Institute of Mental Health (NIMH) and APA—was a remarkable diplomatic endeavor to systematically investigate claims by humanrights activists who said dissidents were still being detained in psychiatric facilities and to assess more generally the state of Soviet psychiatric practice.

In late February 1989, a delegation of 26 psychiatrists, forensic experts, Sovietoloplease see Visit on page 37



A delegation of 26 psychiatrists, forensic experts, and Sovietologists visited the Soviet Union in February 1989 to conduct videotaped interviews with hospitalized and released psychiatric patients and to investigate conditions at Soviet psychiatric hospitals.

# **Professional news** How Cultural Views Filter Doctor-Patient Encounter

Clinicians can avoid unconscious racial or ethnic bias when collecting patient data by understanding the sources of possible misinterpretation.

### BY AARON LEVIN

ow could well-meaning, highly educated mental health clinicians create a pattern of care that appears to be discriminatory?

For the last five years, Margarita Alegria, Ph.D., and colleagues have recorded and deconstructed doctor-patient encounters seeking answers to that question.

"Treatment depends on patients' description of their own symptoms and on nonverbal cues they present, and both are socially constructed," said Alegria at the APA Institute on Psychiatric Services in Boston in October.

At the same time, the clinician's ability to comprehend patients' language, symptoms, and emotions is also filtered through his or her own cultural perspective.

"The interaction is a translation of a translation," said Alegria, a professor of psychology in the Department of Psychiatry at Harvard Medical School and director of the Center for Multicultural Mental Health Research at Cambridge Health Alliance. "It's no wonder people get lost in that translation."

Those cultural fault lines can interfere with diagnosis and treatment and determine whether a patient feels willing to return for follow-up care.

n October, the U.S. Food and Drug

Administration (FDA) approved

another second-generation antipsy-

chotic (SGA), Latuda (lurasidone), for the

treatment of schizophrenia in adults. The

newly approved medication by Sunovion

Pharmaceuticals Inc. is the manufacturer's

first to gain FDA approval. The company,

which is the U.S. subsidiary of Dainippon

Sumitomo Pharma Co. Ltd., was formed by

Council on Research and Quality Care and

professor and chair of the Department of

Psychiatry at Columbia University's College

of Physicians and Surgeons, commented on

it and other atypical agents of the same

class," he said, "is its high affinity for the

5-HT7 receptor and its preclinical evi-

dence for cognitive enhancement, but

this has to be confirmed by future stud-

ies." (The drug's binding affinity for the

serotonin type 7 [5-HT7] receptor in the

"The most notable distinction between

Jeffrey Lieberman, M.D., chair of APA's

a merger with Sepracor Inc. in April.

the new drug to Psychiatric News.

The disconnection can occur when a clinician, pressed for time, resorts to shortcuts. Looking at a particular patient, the clinician recalls previously encountered patients identified with the same group—blacks, whites, Asians, or Latinos, for example. Conscious or not, that practice leads to systematic bias in data collection and interpretation, said Alegria.

Her study was based on 129 videos of first office visits to 47 health care clinicians. The visits were followed by separate postdiagnostic interviews with patients and clinicians and with chart reviews. The patients were mostly lowincome African Americans, whites, and Latinos, while 66 percent of the clinicians were white.

The researchers concluded that five mechanisms seemed to explain how the patient-clinician pairs interacted.

First, cultural dissimilarities between patient and clinician appeared to limit diagnostic assessment, said Alegria. Overall, the clinicians asked only one-third of these dissimilar patients about the most basic *DSM-IV* criteria.

"Many patients mentioned symptoms, but the providers didn't follow through and ask probing questions." They also



Margarita Alegria, Ph.D.: "Use the initial interview primarily for building engagement with patients, but also to prepare them for gathering data and building a relationship based on their needs."

asked different questions depending on a patient's race or ethnicity.

For instance, Latinos were asked fewer questions about substance use than whites were, but received more questions about depression than were asked of either whites or blacks.

Second, 82 percent of the clinicians mentioned using intuition in diagnosing or treating a patient. They used words such as "gut," "experience," or "just knowing" to describe how they arrived at conclusions about a patient's condition.

The third mechanism at work in these encounters involved communications, which varied with the ethnicity pairing. When both patient and clinician were Latinos, for example, questions were more likely to include "partnership and activating statements," such as "What do you think?"

When both were white, there was more joking, which was not seen in the Latino pairs. Relatively more biomedically oriented questions came up in the white dyads than in the Latino ones. When ethnicity of the clinician and patient was mixed, small talk about weather or sports was more frequent.

The fourth mechanism was stereotyping, which occurred in both directions, Alegria noted. In followup interviews, the patients overestimated the age, income, and educational standing of the clinicians and misjudged their marital status, while clinicians often underestimated the socioeconomic status of their patients. Each transferred stereotypes about the other's group to the individual.

A lack of cultural awareness also prevents understanding of differences, said Alegria. Patients want doctors who listen, spend time with them, pay attention to their needs, and manage the cultural differences.

"Listening," though, is not the same for all. Blacks in her study indicated that listening meant respecting the patient as an expert on himself or herself. For whites, it meant feeling comfortable enough to express their feelings to the clinician.

For Latinos, it meant following the patient's story, not asking the same question repeatedly, and paying attention to the individual by maintaining eye contact and providing other nonverbal cues confirming a focus on the patient.

please see Cultural Views on page 37

# New Medication Approved To Treat Schizophrenia

The newly approved second-generation antipsychotic Latuda may be a prescription for fewer troublesome extrapyramidal side effects.

BY JENNIFER KELLY

brain is one way that this new medication is thought to elicit effects in treating symptoms of schizophrenia.)

This same evidence, he continued, "may also contribute to fewer extrapyramidal symptoms [EPS] based on the drug's potent in vitro binding affinity for D2 receptors."

With regard to EPS, lurasidone's profile is "similar to that of risperidone, olanzapine, and ziprasidone but is worse than clozapine and quetiapine," said Lieberman.

Lieberman pointed out that lurasidone was "reviewed by the FDA in record time. This may be due to either the efficiency in the development process by the drug company or improved efficiency of reviews of new drugs by the FDA under the leadership of Hamburg." Margaret Hamburg, M.D., was appointed FDA commissioner in 2009.

According to the manufacturer, lurasidone is expected to be available in pharmacies beginning in February 2011.

Lurasidone's exact mechanism of action is unknown. According to the manufac-

turer, the effects of lurasidone are thought to be mediated in part by antagonism at central dopamine type 2 (D2) and serotonin type 2A (5-HT2A) receptors. Lurasidone also has the ability to antagonize  $\alpha$ 1 receptors, which may result in orthostatic hypotension and/or syncope.

Like other SGAs, the medication's prescribing information carries a blackbox warning. The warning describes the increased risk of death associated with the off-label prescribing of SGAs, especially when these agents are used to treat behavioral problems in the elderly suffering from dementia-related psychosis.

The FDA approval of lurasidone is based on data collected from 40 clinical trials, including four six-week controlled clinical trials that examined the safety and efficacy of lurasidone in adults with schizophrenia. Treatment with lurasidone was associated with improvements in both positive and negative symptoms, including delusions, hallucinations, flat affect, memory, and attention.

Researchers reported that patients treated with lurasidone showed not only improvements in symptoms, but also decreases in the severity or worsening of EPS. These improvements were indicated by patients' Positive and Negative Syndrome Scale scores, as well as scores on the Brief Psychiatric Rating Scale.

The most commonly reported side effects in the clinical trials were agitation,

akathisia, nausea, Parkinsonian-like symptoms, and somnolence. Adverse effects such as akathisia and somnolence appeared to be dose related. Even at lower doses, side effects such as dizziness and postural hypotension were also reported. However, "the side-effect profile is favorable for a low risk of weight gain and metabolic side effects," Lieberman said.

According to the prescribing information, lurasidone is contraindicated in patients who are also taking medications that are strong CYP3A4 inhibitors or inducers such as ketoconazole or rifampin, respectively. Additionally, it is recommended that dosage adjustments be considered in patients who are also taking drugs that are moderate CYP3A4 inhibitors or have moderate to severe renal or hepatic impairment. In these instances, the dosage of the drug should not exceed 40 mg daily, according to the manufacturer.

Lurasidone is available in 40 mg and 80 mg tablets. The recommended starting dose is 40 mg, which may be increased to the recommended maximum daily dosage of 80 mg. Lurasidone should be taken by mouth, once daily, with food.

The FDA news release on Latuda's approval is posted at <www.fda.gov/News Events/Newsroom/PressAnnouncements/ ucm231512.htm>. Prescribing information is posted at <www.latuda.com/ LatudaPrescribingInformation.pdf>.



# When expressing emotions is a matter of chance, consider PBA

- Pseudobulbar affect (PBA) is a poorly understood neurologic condition characterized by episodes of crying or laughing that are sudden, frequent, and involuntary<sup>1</sup>
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- PBA can disrupt lives, causing significant functional impairment<sup>1</sup>
- Understanding PBA can be a relief to patients and their families

### Learn more at PBAinfo.org

pseudobulbar affect

**Reference: 1.** Dark FL, McGrath JJ, Ron MA. Pathological laughing and crying. *Aust N Z J Psychiatry*. 1996;30(4):472-479.



# **Professional News** Scientists Honored for MH Research Advances

NARSAD continues to move forward on the pathway from discovery to recovery for individuals and families living with mental illness.

BY TAMMIE LEE DEMLER

ecognized as the leading donor-supported organization dedicated to finding the causes, improved treatments, and potential cures for mental illness, NARSAD: The Brain and Behavior Research Fund highlighted key discoveries in mental health at its 22nd annual Mental Health Research Symposium in New York City in October.

NARSAD was launched in 1981 by two neighbors in Kentucky who had children with mental illness and garnered support from four mental health associations: the American Mental Health Foundation, National Alliance on Mental Illness, Mental Health America, and the Depression and Bipolar Support Alliance. Former APA President Herbert Pardes, M.D., has been president of NARSAD's Scientific Council since its inception in 1986.

This year's Mental Health Research Symposium featured 11 leading mental health researchers who shared new insights and breakthrough research with conference participants. Six of the research panelists received NARSAD Outstanding Achievement Awards at the NARSAD National Awards Dinner, held the same day as the symposium. The remaining five researchers were NARSAD young investigators conducting research with the help of NARSAD grants.

The award recipients were recognized for their outstanding achievement in their research area. Here are this year's winners and the awards they received:

• Ming Tsuang, M.D., Ph.D., D.Sc., of the University of California, San Diego: Lieber Prize for Outstanding Achievement in Schizophrenia Research

• Robert Malenka, M.D., Ph.D., of Stanford University: Goldman-Rakic Prize for Outstanding Achievement in Cognitive Neuroscience

• Stephen Glatt, Ph.D., of the State University of New York, Upstate Medical University: Sidney R. Baer Jr. Prize for Innovative Schizophrenia Research

• Lars Vedel Kessing, M.D., D.M.Sc., of the University of Copenhagen: Bipolar Mood Disorders Research Prize for Outstanding Achievement in Mood Disorder Research

• Avshalom Caspi, Ph.D., of the Duke



Herbert Pardes, M.D. (fourth from left), president of the NARSAD Scientific Council, poses with the six winners of NARSAD's lifetime achievement awards. They also received awards to recognize their work within specific areas of psychiatry. The winners are (from left) Stephen Glatt, Ph.D., Ming Tsuang, M.D., Ph.D., D.Sc., Robert Malenka, M.D., Ph.D., Terrie Moffitt, Ph.D., Lars Vedel Kessing, M.D., D.M.Sc., and Avshalom Caspi, Ph.D.

Institute for Genome Sciences and Policy and the Institute of Psychiatry/King's College and Terrie Moffitt, Ph.D., of Duke University and the Institute of Psychiatry/ King's College London: Ruane Prize for Outstanding Achievement in Childhood and Adolescent Psychiatric Research.

Here are the five NARSAD young investigators who participated in the symposium and the presentations they gave:

• Tatiana Melnikova, M.D., Ph.D., Johns Hopkins School of Medicine, "Changes in the Neuregulin Pathway May Play a Role in Schizophrenia"

- Rakesh Karmacharya, M.D., Ph.D., McLean Hospital, "Disease-Specific Cellular Signatures in Schizophrenia and Bipolar Disorder"
- Stefan Rowny, M.D., Columbia University, "Functional Neuroanatomy Changes With ECT vs. MST in Geriatric Depression"
- Andreas Keller, Ph.D., Rockefeller University, "Identifying Cognitive Processes Affected in Schizophrenia"

please see NARSAD on page 39

### Accurate Portrayals of Mental Illness Win Awards for Films, TV Shows

Mental health problems facing military personnel and their families are given special attention at this year's Voice Awards ceremony.

Popular TV series such as "Army Wives" and "Grey's Anatomy" earned plaudits for raising awareness about mental health problems, including substance abuse, in responsible and accurate portrayals, at the fifth annual Voice Awards ceremony held at Paramount Studios in Los Angeles in October.

This year's event marked the fifth anniversary of the awards, whose sponsor is the federal Substance Abuse and Mental Health Services Administration (SAMHSA). This year, as in past years, the American Psychiatric Foundation (APF) served as a program partner for the awards, and APF staff served on the panel of judges.

"The Voice Awards have grown in range and impact over the past five years and will continue to grow in the future," APF Executive Director Paul Burke told *Psychiatric News.* "We are proud to be a program partner."

Burke attended the ceremony, as did Jeffery Borenstein, M.D., chair of APA's Council on Communications and host of the PBS television series "Healthy Minds." BY EVE BENDER

Borenstein presented a vignette from the series and also one of the Consumer Leadership Awards.

"Healthy Minds" first aired in 2006 on a public television station in New York; it is produced by WLIW-21 in association with WNET.org. With funding from APF, the series premiered nationally in October 2009 (*Psychiatric News*, May 15, 2009). Each half-hour episode focuses on a different psychiatric disorder and features interviews with people who are in recovery from mental illness, Borenstein explained.

In an interview with *Psychiatric News*, Borenstein characterized the Voice Awards as "essential to the campaign to reduce the stigma surrounding mental illness" and said he hopes that the awards will continue to encourage people in the entertainment industry to present storylines in a way that educate the public."

Emmy Award-winning actor Hector Elizondo and Academy Award-winning actor Lou Gossett Jr. co-hosted the ceremony, in which special recognition was given to shows that dealt with posttraumatic stress disorder (PTSD) among



American Psychiatric Foundation (APF) Executive Director Paul Burke (right), shown with psychiatrist and "Healthy Minds" host Jeffrey Borenstein, M.D., said that SAMHSA's Voice Awards have grown considerably in scope and influence since they were established five years ago. The APF is a program partner in the annual awards ceremony.

returning U.S. veterans and its impact on military families.

The 2010 Voice Award Winners are as follows:

• "Army Wives" (Lifetime) for a series of episodes addressing how PTSD and traumatic brain injuries can affect military personnel and their families.

• "Desperate Housewives" (ABC) for the

episode "How About a Friendly Shrink?" addressing inpatient psychiatric care.

• "Grey's Anatomy" (ABC) for the episodes "Good Mourning" and "Goodbye" addressing the effects of PTSD on military families.

• "Mental" (Fox) for the episode "Lines in the Sand" addressing the effects of PTSD on military families.

please see Voice Awards on page 39

# **Spotlight Shined on Hollywood's Unrealistic Portrayal of Women**

A Hollywood mental health advocacy group partners with the Girl Scouts to work toward elimination of media images that may contribute to the development of eating disorders and other psychiatric problems in women and girls.

### BY RICH DALY

he specific mental health consequences of extended exposure to portrayals of unrealistic and unhealthy behaviors of girls and women may not be clear, but some advocates see enough data to cause concern and to take action. A mental health advocacy group that already has helped change Hollywood portrayals of people with psychiatric illness informed *Psychiatric News* that it will team up with the Girl Scouts to try to reduce the amount of potentially harmful pop-culture messages to which girls and young women are exposed.

A formal announcement of the campaign, including its launch date, will come after finalization of its details.

The nonprofit advocacy group, the Entertainment Industry Council (EIC), was founded by actors and other Hollywood professionals, to work within the film industry to change stereotypical and inaccurate entertainment images of people with mental illness as unusually violent or irreversibly ill. The EIC's efforts-which include presenting its annual PRISM Awards to recognize accurate depictions of mental illness in entertainment industries and providing expert consultants to movie and television studios-have resulted in a growing body of accurate depictions of people who suffer from mental illness, including substance use disorders.

Hollywood studios "found that the more accurate the portrayals were, the more positive the audience reaction was to the production," Marie Gallo Dyak, vice president of programming and government relations at the EIC, told *Psychiatric News*.



Actress Geena Davis tells congressional staff about her efforts to fund research on the extent and impact of unhealthy media images to which girls are routinely exposed.

Specifically, the EIC and the Girl Scouts will work to reduce the pervasive "unhealthy" media images of young women and girls as "hypersexualized," physically perfect, and superficial. They also



will encourage portrayals of girls in ageappropriate attire and as positive characters, along with male characters who value the female characters for more than their appearance.

Current media content includes few strong, healthy role models for girls, said Laurie Westley, senior vice president of public policy at Girl Scouts of the U.S.A., in an interview with *Psychiatric News*.

That assessment echoes research on inaccurate media portrayals of women and girls, including some studies funded by Geena Davis, the Academy Award–winning actress. One of her studies found that only 10 percent of the people writing and producing movies are women. A national survey by the Girl Scout Research Insti-



tute (GSRI) found that 88 percent of girls believe that popular media place "a lot of pressure on girls to be thin."

The abundance of unhealthy media portrayals could have clinical consequences. Research has linked higher exposure to media portrayals of "hypersexualized" and unhealthy body images of college-aged women to the development of psychiatric disorders, such as eating disorders and depression, according to a 2007 report by the American Psychological Association. The report's authors noted that little research has been done on the impact of exposure to such images on the still-developing minds of younger girls.

please see **Hollywood** on page 30

You care for your patients with schizophrenia and want to offer treatment choices that are right for them.

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November 2010

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# **COMMUNITY NEWS** Patients' Souls Called Medicine's Missing Link

Small changes, beginning with the attitude clinicians bring to a patient encounter, can transform psychiatric and other medical care.

he notion that your patients have a "soul" and that your treatments can touch or transform something less (or more) substantial than a neurotransmitter may sound, in the context of modern biomedical science,

quaint today. But author and psychotherapist

Thomas Moore, Ph.D., believes the souls of patients in the care of modern medicine are in need of urgent attention. And so too, he says, are the souls of their doctors.

Moore is the bestselling author of *The Care of the Soul: A Guide for Cultivating Depth and Sacredness in Everyday Life*, the 1992 book that asserted that the greatest poverty in today's technologically triumphant culture is a lack of attention to the soul.

In a new work, *Care of the Soul in Medicine*, published this year by Hay House Publishers, Moore asserts that this soulpoverty extends to modern medicine.

In an interview with *Psychiatric News*, Moore said modern medical care has come to be dominated by a highly mechanistic philosophy deriving from the relatively recent 18th century while jettisoning a far more ancient wisdom about care of the soul that dates to the time of classical philosophers.

Much of his new book is focused on care of the soul in general-medical settings, especially in hospitals and in the care of the dying. But Moore said the message of his book should resonate with psychiatrists.

"I understand the field has become more biological," he said. "My sense is that people entering medicine today get this very intelligent, up-to-date training in biomedical science. And when I talk to psychiatrists about a spiritual approach to healing, it doesn't seem to them to have that intelligence behind it.

"But I would want psychiatrists to know there is a whole world of knowledge and wisdom outside the biological tradition that goes back several thousand years," Moore said. "They should give a philosophical and spiritual approach to the patients in their care another look, and they may find that it can be very substantive and would complement their biological work."

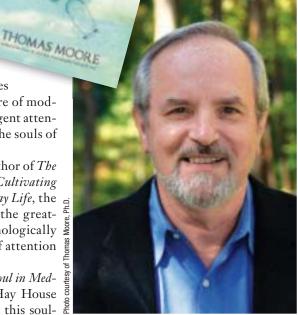
### **Transforming the Medical Setting**

But what is the "soul," and how does one care for it?

The question itself invites speculation that has kept philosophers busy for centuries. But for the purpose of his book

### BY MARK MORAN

and his message to physicians, Moore speaks of the soul as where one cradles the meaning of one's relationships and memories, the sense of mystery about one's



Thomas Moore, Ph.D.: "I would want psychiatrists to know there is a whole world of knowledge and wisdom outside the biological tradition that goes back several thousand years."

own life, and one's understanding of the meaning of illness and death.

To care for the soul in medicine then would be to adopt practices that seek not just the "cure" of disorders, but care for and attention to patients' significant relationships, poignant memories, spiritual quests and interests, as well as their understanding of their illness. Such an approach, he believes, calls for changes in the way doctors are trained and in the way they approach their patients, but it also entails a transformation of the settings in which care is provided to include incorporation of nature, art, and music into the architecture of hospitals and doctors' offices.

His remedies for what ails modern medicine may seem to some either quixotic or "unscientific" (or even "antiscientific"), but his thoughts echo those of such respected thinkers as biomedical ethicist Daniel Callahan, Ph.D., who has written extensively of the need to return to "caring over curing."

"You don't have to talk too long to patients and their families, as well as doctors and nurses, before they express a common feeling that contemporary medicine, for all its technological virtuosity, lacks something," he said. "Patients and families will talk about how the medical establishment is just so huge and they feel like a piece of machinery. When I tell them about how images and architecture can transform a healing environment—about how the way a hospital room looks and feels can be a part of healing—they are a little surprised, but they know what I am saying. So I seem to be giving people a language for talking about things they know intuitively."

Moore is careful not to be critical of physicians—"they get enough criticism," he said—and noted that after the success of his 1992 book, it was the medical establishment that came to him. As part of his research for the book, he was invited to spend two days each month over a two-year period at St. Francis Hospital in Hartford, Conn.

### "If you see the brain as a collection of neurochemicals, you are going to use chemicals to treat people."

"When I first wrote *Care of the Soul*, I didn't have medicine in mind at all," Moore said. "But I began getting invitations to talk at medical schools, and right up to the present time I have been visiting medical schools, hospitals, and cancer wards all over the country and in Ireland."

### Reclaiming an Ancient Wisdom of the Soul

What does Moore, an admirer of Carl Jung (but he is not, he said, a Jungian), think of the widespread use of pharmacologic agents to treat psychiatric disorders? "It's a complicated issue, and I have nothing against the use of pharmacologic treatments in conjunction with other approaches," he said. "But I think it goes hand in hand with the prevailing philosophy of our time that is based on treating people as mechanical systems. If you see the brain as a collection of neurochemicals, you are going to use chemicals to treat people.

"That's the underlying mythology of our time. It is useful as far as it goes, but I think it leaves much to be desired and ignores a vast trove of wisdom about the soul that predates the 20th century."

His recommendations for reform seem to require changes in a medical system that is itself vast and unwieldy. But Moore believes that even small changes—beginning with the attitude clinicians bring to a patient encounter can be transformative, even of a 15-minute med check.

"I think psychiatrists would find their work so much more pleasurable and fulfilling if they could reach past the prevalent biological view of a human being and enjoy the complexity of human life," Moore said. "They could allow themselves to be instructed by the arts, by fiction and drama, painting and music and allow those to inform their practice. It would humanize their work so that they would have a warmer and more fulfilling experience in a context that would be incredibly rich, even if they only had 15 minutes."

It's not the amount of time spent with a patient that's key, he said. "I can spend 50 minutes with a patient and it seems like nothing. It's where you are coming from that makes the difference."

### **APA Minority Fellowships Invites Applicants**

P sychiatry residents are invited to apply for APA's Minority Fellowships Program (MFP). The MFP provides educational opportunities not only to minority residents, but to all residents interested in providing quality and effective service to minorities and the underserved.

The fellowships provide funding for psychiatry residents to experience a specialized educational program specifically geared toward building leaders who will be able to improve the quality of mental health care for the following federally recognized ethnic minority groups: American Indians, Native Alaskans, Asian Americans, Native Hawaiians, Native Pacific Islanders, African Americans, and Hispanics/Latinos. The fellowships are also designed to involve residents in the work of the Association and to give APA the perspective of young psychiatrists.

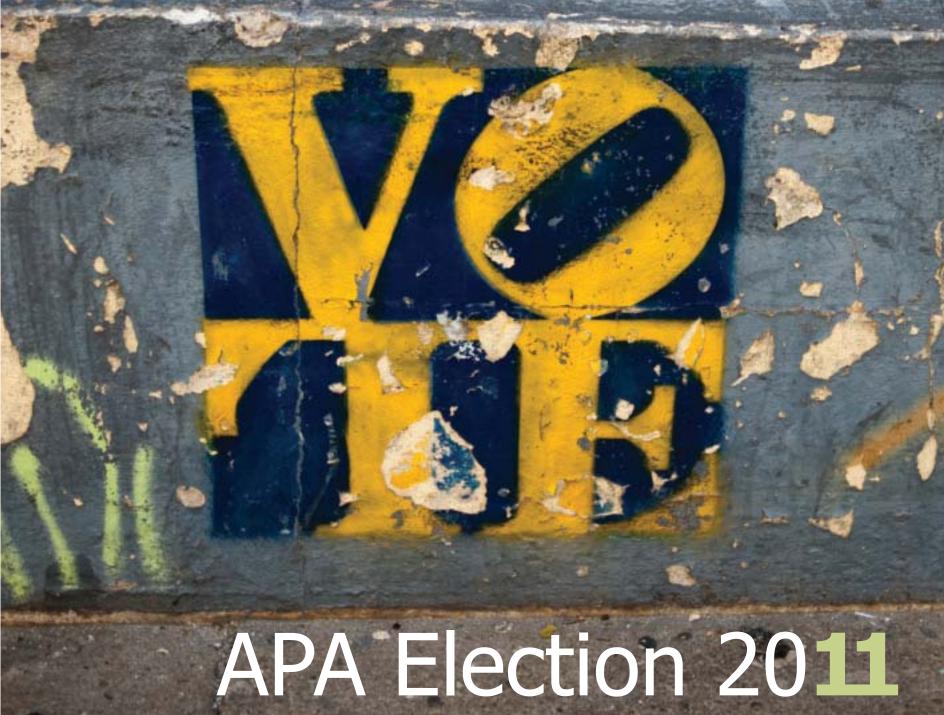
There are three groups of MFP fellows: APA/SAMHSA Fellows (funded by the Substance Abuse and Mental Health Services Administration), APA/ SAMHSA Substance Abuse Fellows (funded by the Centers for Substance Abuse Treatment and Substance Abuse Prevention), and APA/Diversity Leadership Fellows (funded by AstraZeneca). Fellows serve for one year, except for the Diversity Leadership Fellows, who serve for two years. The SAMHSA and Substance Abuse Fellows receive a stipend based on their postgraduate year and availability of federal funds. Diversity Leadership Fellows do not receive stipends; however, travel funds are available for specific APA meetings and special projects. Psychiatry residents must be at least a PGY-2 in July 2011 and remain in training during the entire academic year.

All applicants must be APA members. SAMHSA applicants must be U.S. citizens or permanent residents at the time of application. SAMHSA substance abuse applicants must be in their PGY-5 of training in July 2011 and in a substance abuse training program approved by the affiliated medical school or agency where a significant number of substance abuse patients are from minority and underserved groups. Federal employees are ineligible.

Diversity Leadership applicants do not have to be U.S. citizens, permanent residents, or graduates of a U.S. medical school.

All applicants are welcome to apply regardless of race, ethnicity, gender, national origin, religion, sexual orientation, or disability.

The deadline for applications is January 31, 2011. More information is available from Marilyn King at (703) 907-8653 or mking@psych.org or online at <www.psych.org/Resources/OMNA/ MFP.aspx>. This special **ELECTION SECTION** provides information on the **11 CANDIDATES** running for office in the **ASSOCIATION'S 2011 ELECTION**.



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# INSIDE

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For this section, the candidates in APA's 2011 election were asked to supply a biographical sketch and a statement in which they could discuss their views on any issues in psychiatry. This information is intended to help voters cast their ballots for the candidates they believe are best qualified for office. Also, candidates were asked to list by approximate percentages their primary professional activities and sources of professional income. The deadline for candidates' information for this section was October 15. Here are a few more notes about this year's election:

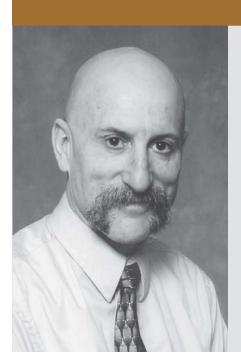
APA voting members are urged to cast their ballots online. It is hoped that the ease offered by Internet voting will encourage more members to participate in the election.

Online information about the candidates, links to their Web sites, APA's election guidelines, and other pertinent material can be accessed from APA's homepage at <www.psych.org>.

A referendum is being held this year. APA received a member petition requesting that a statement regarding maintenance of certification requirements of the American Board of Psychiatry and Neurology be put to a vote of the APA membership. See page 23 for more information.

On December 22, ballots will be mailed to all voting members, and instructions for voting online will be e-mailed to all members whose e-mail address is on file with APA. Mailed ballots must be received by Intelliscan Inc. no later than February 7, 2011. This is also the deadline for online voting.

# CANDIDATES



### **CANDIDATES FOR PRESIDENT-ELECT**

### Jeffrey L. Geller, M.D., M.P.H.

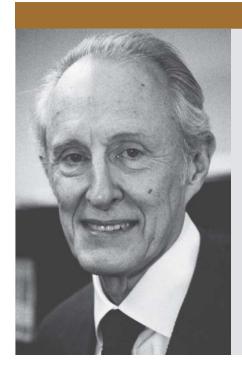
Academic Psychiatry: 30 years ◆ State Hospital Work: 30 years ◆ Community Mental Health Care: 27 years; Forensic Practice: 26 years ◆ Resident Supervision: 24 years ◆ University of Massachusetts Medical Outpatient: 23 years ◆ Public Sector Administration: 23 years ◆ APA Vice President: 2009-

◆ APA Board of Trustees: 2006 ◆ APA Assembly: 1993-2006;
 *Psychiatric Services:* 1992- ◆ APA
 Components: 1983- ◆ APA Ron Shellow
 Award: 2006 ◆ APA Van Ameringen
 Award: 2003

### Dilip V. Jeste, M.D.

Distinguished Professor of Psychiatry and Neurosciences, University of California, San Diego, 1986- APA Council on Aging, 1994-99 American Psychiatric Institute for Research and Education (APIRE) Board of Directors, 1998-2004 DSM-5 Task Force, 2006- APA Distinguished Life Fellow, 2008- APA Trustee-at-Large, 2008-APA Research Award, 2005 APA Distinguished Lecturer Award, 2000, 2009 Institute of Medicine, 2007





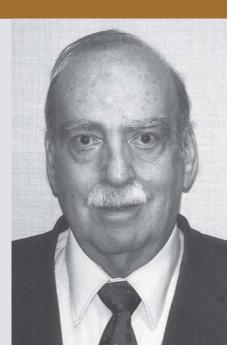
### **CANDIDATES FOR SECRETARY**

### Roger Peele, M.D.

Chief Psychiatrist, Montgomery County, Maryland APA Secretary, 2010-Clinical Professor, George Washington University Member, Board of Trustees, 1986-87, 1989-1992, 2001-Assembly, 1975- DSM-III work groups (1975-80), DSM-III-R Task Force (1983-87), DSM-IV Task Force (1989-1994), DSM-5 Task Force (2007-) Coauthor: Clinical Manual of Supportive Psychotherapy

### Sidney H. Weissman, M.D.

Private Practice of Psychiatry and Psychoanalysis ◆ Professor of Clinical Psychiatry, Northwestern University ◆ Past President, Illinois Psychiatric Society ◆ Former Trustee of APA ◆ Former Representative to APA Assembly ◆ Past President, American Association of Directors of Psychiatric Residency Training ◆ Past Chair, APA Scientific Program Committees



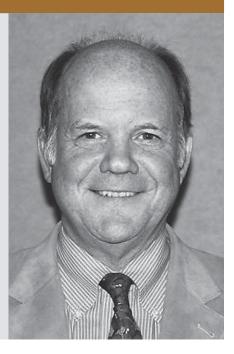
### Candidates for Area 2 Trustee

### Jack Drescher, M.D.

Private Practice, 1985- Clinical Associate Professor, New York Medical College, 2009- New York County District Branch: President, 2000-01, Newsletter Editor, 2001- APA Special Presidential Commendation, Distinguished Psychiatrist Lecturer, 2009 Chair, APA Committee on Gay, Lesbian, and Bisexual Issues, 2000-06 President-Elect, Group for the Advancement of Psychiatry, 2009-

### James E. Nininger, M.D.

Private Practice, 1977- Clinical Associate Professor of Psychiatry, Cornell University Medical College
Speaker, APA Assembly, 2004-05 President, New York State Psychiatric Association, 1998-2002 Member, APA Board of Trustees, 2003-05, 2008Vice Chair, Steering Committee on Practice Guidelines, 2009Member, American Psychiatric Foundation Board of Trustees, 2010-



# ABOUT THE CANDIDATES



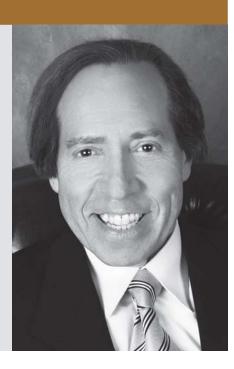
### **CANDIDATES FOR AREA 5 TRUSTEE**

### James A. Greene, M.D.

Practice of Adult and Geriatric Geriatric Medical Care, 1991-97 Chair of Psychiatry, University of Tennessee, 2005- + President, Tennessee Psychiatric Association, 1983-84, 2008-10 APA: Assembly Representative, 1993-, Committee on Access and Effectiveness of Psychiatric Services for the Elderly, Committee on Long-Term Care and Treatment for the Elderly, Committee on Psychiatric Administration and Management

### Gary S. Weinstein, M.D.

Private Practice of Adult Psychiatry, 1982- 
 Associate Clinical Professor, University of Louisville School of Medicine, 1985- + APA: Assembly Speaker, 2009-10, Board of Trustees, 2008-10 Joint Reference Committee, 2008- Committee on Advocacy and Litigation Funding, 2005-09, Finance and Budget Committee, 2008-09 Area 5: Representative, 2003-07, Deputy Representative, 1999-2003





### Kurt L. Cousins, M.D., M.B.A.

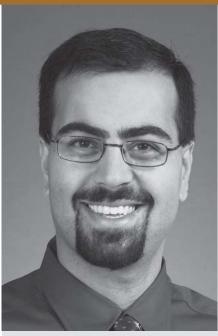
PGY-3, Psychiatry, University of Maryland/Sheppard Pratt 
 Co-Chair, Residents and Fellows Committee, Maryland Psychiatric Society, 2010- Member, Psychotherapy Committee, American Academy of Child and Adolescent Psychiatry, 2009- Member, Public Health Committee, American Medical Association Resident and Fellow Section, 2010-

### CANDIDATES FOR MEMBER-IN-TRAINING TRUSTEE-ELECT



### David I. Driver, M.D.

Psychiatry Resident, Georgetown University Hospital, 2008- 
 APA Area 3 Memberin-Training Deputy Representative, 2010- • Secretary, District of Columbia Psychiatric Society, 2009-10 Member, Ethics Committee, Washington Psychiatric Society, 2009- 
 Member-in-Training Representative, Washington Psychiatric Society, 2009-10 Member, Ethics Committee, Georgetown University Hospital, 2008-10



### Alik S. Widge, M.D., Ph.D.

Psychiatry Resident, University of Representative, APA Area Committee of Members-in-Training, 2010-11 Member, Psychiatry Residency Review Committee, Accreditation Council for Graduate Medical Education, 2011-13 • American Medical Association: Chair, Medical Student Section, 2005-06; Chair, Committee on Long-Range Planning, Resident and Fellow Section, 2010-11

# **CANDIDATES**

CANDIDATES FOR PRESIDENT-ELECT

### Jeffrey L. Geller, M.D., M.P.H.



"To reduce the gap in medical service, I shall propose vigorous steps to combat the misery and national loss involved in mental illness." —President Eisenhower, 1955

APA members not only face old quagmires that have lingered since Eisenhower's State of the Union message, but also new ones with potentially harmful outcomes for our members and our patients.

A sense of never-ending problems and challenges can be gleaned from former APA presidents' annual speeches:

The greatest therapeutic error is administering too much medication (Everts, 1886).

The populations of our hospitals could be reduced and better served in noninstitutional care (Barrett, 1922).

The complexities of modern hospitals contribute to a loss in dealing with patients as individuals (White, 1925).

There are a myriad of new problems: reimbursement at less than the cost of providing treatment; shifts to less expensive practitioners (APRN, PA, MSW, psychologist); devalued CPT codes; inadequate numbers of minority psychiatrists, e.g., Hispanics, African Americans; and a loss of trust in psychiatrists. Our patients fare worse: health care disparities, rising Medicare drug costs, meds contributing to obesity and diabetes, homelessness, substance abuse, and a greater likelihood of ending up in county jail than in a state hospital.

The current APA Vision Statement informs us: APA is an organization of psychiatrists working together to ensure humane care and effective treatment for all persons with mental illness, including substance use disorders. It is the voice and conscience of modern psychiatry. Its vision is a society that has available, accessible quality psychiatric diagnosis, treatment, and prevention.

APA leadership needs the resolve to turn this vision into reality. What APA members need now is APA ACTION.

Attack stigma and discrimination directed at psychiatric patients and psychiatrists. Provide tools and supports for treatment of co-occurring psychiatric and substance abuse disorders.

Attend to specific needs of each minority, underrepresented, and IMG group of psychiatrists.

Advocacy shall be zealous and directed by our members.

Child/Adolescent psychiatry shall move up APA's list of priorities.

Treatment provided by APA members shall be appropriately valued and reimbursed. Integrated systems of care shall be an APA focus.

Outpatient/inpatient psychiatrists shall have reasonable caseloads, safe working environments, and realistically be able to provide psychotherapy.

Nurturing residents, fellows, and early career psychiatrists shall be paramount.

Like any good treatment plan, each of these goals needs interventions. If elected, I would work to create these with the president, Board of Trustees, and membership within 60 days of taking office as president-elect, and I would report to you, the members, on a regular and ongoing basis. I would begin, at the same time, working on the release of DSM-5, scheduled to occur during the term of the president you choose in this election.

There should be no doubt that if we responsibly improve the practice of psychiatry, we will dramatically improve the care and treatment of psychiatric patients.

I welcome your feedback and support.

Je me félicite de vos commentaires et de la prise en charge.

Acojo con tus comentarios y apoyo.

### Primary Professional Activities and Sources of Income

As professor and director of public sector psychiatry, I am full time at the University of Massachusetts Medical School, where I do teaching, mentoring, and supervision; patient care; research and administration: 75% of income. On my own time, I do state and agency consultation and other forensic work: 25% of the time.

### 

### Dilip V. Jeste, M.D.



I am honored to be a candidate for APA president-elect. We are in the midst of exciting scientific and technological advances, evolving health care reform, and economic restructuring. APA needs a strong leader with passion to rejuvenate the organization. My personal and professional experiences have prepared me to take on such a role. I was born in a village in India and became the first Jeste to go to medical school. My wife and I immigrated to the U.S. with relatively few resources other than a desire to learn and grow. I studied at Cornell (psychiatry), George Washington University (neurology), and National Institutes of Health (research). Since

joining it as a resident, APA has been an integral part of my professional life. I am a psychiatrist specializing in psychotic disorders and geriatrics, and am privileged to be one of about 60 psychiatrists across the world elected to the Institute of Medicine. My wife is a child psychiatrist, and we have two daughters, both studying medicine.

I have broad-based experience as a clinician, researcher, teacher, advocate, and leader. I established a geriatric psychiatry division at UCSD that partners with a large public mental health system. My research has spanned from neuroscience to community psychiatry, and from schizophrenia to healthy aging. I have mentored over 200 young trainees, many of them women and members of underrepresented minority groups, who have developed successful professional careers. I have visited Capitol Hill to lobby for mental health parity. As their president, I have worked hard to shape several psychiatric organizations (including the American Association for Geriatric Psychiatry), in ways that enhanced their missions.

I have no financial relationship with industry.

My priorities as APA president would include:

**Ensuring that no psychiatric patient is left behind:** There is no health without mental health. I will forcefully advocate to ensure quality mental health care by qualified providers for all those who need it-including children, older adults, veterans, and underserved minorities.

Working to improve the environment in which psychiatry is practiced: I will work on issues facing practicing psychiatrists such as adequate reimbursement, scope of practice, electronic health records, maintenance of certification, and industry relationships.

Feeling the pulse and responding to the needs of grassroots membership: I will reach out to individual APA members and district branches via enhanced interactive electronic communication and networking.

**Promoting diversity:** I will form a think tank to bring together experts from within and outside APA and charge them with proposing creative and practical plans of action to make the APA leadership representative of the U.S. psychiatric community. I will work strenuously to implement these proposals with clearly defined timelines.

Helping develop future leaders: I will make a concerted effort to expand mentorship and early leadership opportunities for members-in-training and early career psychiatrists-the future of our profession.

Improving collaboration with psychiatric subspecialties: I will work with various subspecialty organizations in psychiatry to facilitate discounted dual membership, joint advocacy, and ongoing dialogue on issues of mutual concern.

I would welcome the privilege of serving as APA president and ask for your support. Working together, we can help APA fulfill its mission of "being the voice and conscience of psychiatry."

I request your input and feedback. Please visit my Web site at <www.dilipjeste.com>.

### **Primary Professional Activities and Sources of Income**

### **Professional Activities**

- 90%-Administration, clinical work, research, and teaching at the University of California, San Diego School of Medicine and Veterans Affairs San Diego Healthcare System
- 10%-Editorship of the American Journal of Geriatric Psychiatry, grand rounds, and other lectures at universities

### Income

70%—University of California, San Diego, School of Medicine

- 18%-Veterans Affairs San Diego Healthcare System
- 12%-Editorship of the American Journal of Geriatric Psychiatry, grand rounds, and other lectures at universities

# ABOUT THE CANDIDATES

### CANDIDATES FOR SECRETARY

### **Roger Peele, M.D.**



### Three key roles for the secretary are:

- The approval of the minutes,
- Reviewing potential conflicts of interest within APA, and
- Voting on all issues that come to the Board of Trustees.

### Minutes:

The superb official minutes developed by APA staff have been brought to the attention of less than 1 percent of the APA members months after they are developed. As secretary, I am in the process of increasing the breadth and speed

of their distribution.

### Conflicts of Interest:

How APA addresses conflict of interest impacts APA's credibility. The secretary reviews disclosures for potential conflicts of interest. Clearly the secretary's own potential conflicts should be known. My campaign statements in recent years have been quite specific as to income. All members have potential conflicts. (My special interests are adequate Medicaid and Medicare payments.) I believe that the best way to address potential conflicts is not by excluding members from participation, but through specific transparency.

### Key Issues for the Board:

A major issue the Board will address is **APA's governance.** My guiding principle will be to vote for proposals that increase members' opportunities to impact the direction of APA. APA members' interest may reflect the state they come from; the subspecialty they practice; or more personal interests, such as gender, race, ethnic background, or sexual orientation. It is essential that many MITs and ECPs have a role in APA's governance. I have worked to make the Assembly more representative: among my efforts, I supported minority representation to be in the Assembly, was speaker of the Assembly when it voted to add MITs, and my speaker's report (1987) advocated bringing subspecialty organizations into APA governance. This expansion of providing members with representation must continue.

Early in the coming decade, the Board must address three topics: *DSM-5*, **Parity**, and **Maintenance of Certification**.

As for *DSM-5*, my vote will be for a conservative book, as the science of the proven causes of psychiatric disorders has grown little since *DSM-IV*.

We must monitor parity closely to assure that the goal of absolute nondiscrimination is achieved. One opening for insurance companies to attempt to discriminate is for them to adopt their own limiting "clinical best practices." Just as APA sets the diagnostic standards, *DSM*, so it must set treatment standards. Some years ago, Ron Shellow and I initiated the motion that APA develop practice guidelines. They must be kept current. We must not allow anyone else to set the standards of treatment.

Current best-practice documents are also important in the new recertification process (maintenance of certification), where it appears that we will compare our clinical work with those practices. Again, APA needs to make this effort a priority so that no other agent can claim to be the source of best practices. (Hopefully, the concept of patient participation in MOC will soon die.)

My APA activities and brief CV can be found at <RogerPeele.com>.

### **Primary Professional Activities and Sources of Income**

### **Professional Activities**

95%—County government:

- 80%—Clinical and teaching 15%—Administrative
- 5%—Volunteer at a primary care clinic

### Income

100%—Montgomery County, Md. (about \$200,000/year, including benefits)

### 

### Sidney H. Weissman, M.D.



In the second decade of the 21st century, psychiatry will confront numerous challenges and opportunities. To ensure that quality **clinical practice** is maintained, **psychiatric education** is enhanced, **research** is maintained and expanded, and the public support of **psychiatric services** is maintained and enhanced, psychiatry needs a strong, focused APA. The strength of APA comes from its members and the ability of its leaders to develop policies and actions to address these challenges and work with the APA members and its district branches to accomplish its goals.

Each challenge has a number of specific goals to which APA must devote its resources:

### **Clinical Practice**

- Ensure that psychiatric parity is established to reach all citizens.
- Work to develop a patient care "Bill of Rights."
- Ensure patient confidentiality.
- Maintain vigilance and effective actions in scope-of-practice actions.

### **Psychiatric Education**

- Enhance and maintain clear standards for residency education.
- Enhance and maintain clear standards for the maintenance of board certification and licensure.
- Assist other psychiatric associations in ensuring that regulatory standards developed by others that affect psychiatric education and practice are relevant for psychiatry.

### **Psychiatric Research**

- Develop strategies to maintain and enhance funding at NIH for NIMH that enhance all areas of psychiatric research.
- Work with other associations to enhance federal funding for medical research.
- Provide support to academic departments to enhance research activities.

### **Psychiatric Services**

Ensure funding on the federal and state levels to provide adequate psychiatric services for individuals who cannot afford private care.

■ Work with other associations to ensure adequate mental health funding and facilities at the state and federal levels.

### Functions of APA Secretary

The secretary of APA has three critical functions. First, the secretary serves as a voting member of the Board of Trustees. Second, the secretary serves on the Board Executive Committee. In these roles, the secretary works with others to develop and implement APA policy. Having served on the Board of Trustees for six years, I have the qualifications to address and shape with our colleagues the responses to the critical issues that confront American psychiatry.

The APA secretary has an additional responsibility. The secretary serves as chair of the APA Conflict of Interest Committee. This committee was created by a Board action in 2010 which developed **policies and procedures to be developed and followed in all APA organizational relationships.** I had the honor and privilege to serve as chair of the Board committee that developed these policies and procedures, which are now referred to by many as the APA Code of Conduct.

Today I am a psychiatrist in private practice who worked for 40 years in academic psychiatry reaching the rank of professor at two medical schools. I have served as president of psychiatric associations and on the Board of Trustees of a teaching hospital. Voting for me will ensure that we continue to strongly address the issues that are vital to psychiatry.

### **Primary Professional Activities and Sources of Income**

### **Professional Activities**

60%—Private practice of psychiatry 20%—Consultations to varied mental health groups 20%—Academic activities

### Income

95%—Private practice 5%—Consultations

# CANDIDATES

### CANDIDATES FOR AREA 2 TRUSTEE

### Jack Drescher, M.D.



I am a psychiatrist in private practice and an independent scholar. Due to a confluence of interests, I have frequently been a psychiatric spokesperson on mental health and psychological issues of interest to the general public. I've been interviewed and quoted for print, television, radio, and Internet media outlets locally, nationally, and overseas. I believe psychiatrists should engage with the public, defining ourselves and what we do rather than having ourselves defined by others. While not always an easy task, as your Area 2 trustee, I will bring to APA's Board a high degree of

enthusiasm, much energy for creative work, and a continued focus on outreach to our members and the public.

I am a distinguished fellow of APA and have worked within APA governance at the district branch, Area 2, and national levels. In the New York County DB, I served on the Committee on Ethics, served as secretary for four years and then as DB president (2000-2001). Currently I serve as the DB's newsletter co-editor. Within Area 2, I was an associate editor of the NYSPA *Bulletin* and have served on NYSPA task forces.

At the national level, I was a member of APA's Committee on Abuse of Psychiatry and Psychiatrists. I was chair of APA's Committee on Gay, Lesbian, and Bisexual Issues and a member of the Council on Minority Mental Health and Mental Health Disparities from 2000-2006. From 2006-2008, I served as a consultant to APA's Committee on Public Affairs and continue to serve APA in the capacity of media spokesperson regarding APA policies. I have been a member of the *DSM-5* Work Group on Sexual and Gender Identity Disorders since 2008.

My scholarly work includes an authored textbook, 20 edited volumes, chapters in major psychiatric textbooks, and publications in peer-reviewed journals. For 10 years I was editor-in-chief of the peer-reviewed *Journal of Gay and Lesbian Mental Health* and currently serve as that journal's emeritus editor.

I am president-elect of the Group for the Advancement of Psychiatry, a psychiatric think tank. I am a member of the AMA, the Medical Society of the State of New York, and the N.Y. County Medical Society. I am also a member of the American College of Psychiatrists, the New York Academy of Medicine, the Society for the Scientific Study of Sexuality, and the International Academy of Sex Research. I am fellow and past trustee of the American Academy of Psychoanalysis and Dynamic Psychiatry and have served as a board member of the Accreditation Council for Psychoanalytic Education. I teach at two psychoanalytic institutes in New York City.

There are many issues we face as psychiatrists, and space limitations do not allow me to address them in this particular venue. Whatever the tasks we face in the near future, I have a capacity for hard work and getting the job done. As Area 2 trustee, I will bring those qualities to the APA Board, where I hope to represent the needs of our patients, our members, and our profession.

Primary Professional Activities and Sources of Income

### **Professional Activities**

95%—Private practice 5%—Teaching, writing, editing

Income

96%—Private practice

### 

### James E. Nininger, M.D.



We are faced with critical challenges, underfunding of services, bureaucratic restrictions, and increasingly liberal scopes of practice. All contribute to erosion of proper treatment for our patients and barriers in access to quality care.

In New York we must remain vigilant in sustaining the gains we have made in parity and scope of practice, and speak up on issues such as proper privacy of medical records, the need to fix the Medicare rate formula, and the need to help define the appropriate role of electronic health records. At the same time we expand and refine our electronic communication abilities, we need to pro-

vide greater personal outreach to members in the field and impart to training directors and early career psychiatrists the importance of psychiatrists' active involvement on behalf of our patients. This includes strengthening liaisons with the AMA, state medical societies, and advocacy groups. In New York, a strong alliance with the medical society has helped us to avoid intrusions into our scope of practice. To foster recruitment, we must continue to forge alliances with our allied psychiatric groups, consider shared-dues strategies, and be sensitive to the needs of international medical graduates and minority representatives, many of whom serve valiantly in the public sector.

APA has made progress in the prioritization of goals, removal of redundancy in committee and component functions, and the establishment of financial oversight mechanisms that include Assembly input to ensure fiscal responsibility. We must strive to improve communication with and between our Assembly reps and members at large and our executive directors, presidents, and presidents-elect of our district branches. I feel it is important to seek out input from our members and would plan to continue and expand the use of our Area 2 "e-surveys." I have lobbied in Albany for NYSPA and in Washington, D.C., for APA and serve on the Board of the APA PAC. At the New York County District Branch, I established the first Task Force on Psychiatry and Nursing Homes, chaired the Committee on Aging for 14 years, and was among the first group of psychiatrists to volunteer services to the homeless. I volunteered at Pier 94 and ground zero with Disaster Psychiatry Outreach following 9/11 and in Louisiana following Katrina, and I coordinate the Assembly liaison representatives to the APA Committee on Psychiatric Dimensions of Disasters. At APA nationally, I currently serve as vice chair of the Steering Committee on Practice Guidelines, am a board member of the newly appointed American Psychiatric Foundation, serve as Area trustee on the APA Board, and have been appointed to the Ad Hoc Work Group on Reserve Planning and to the Task Force to Review DSM-5 Disclosures and Interests.

I have worked with diverse groups to establish consensus; have represented NYSPA as treasurer, vice president, and two terms as president and Area representative; and served on the APA Board of Trustees as speaker-elect and speaker of the Assembly prior to becoming Area 2 Trustee. I would be honored to serve as your Area 2 trustee.

### **Primary Professional Activities and Sources of Income**

### **Professional Activities**

70%—Private practice

70%—New York, N.Y. 30%—Briarcliff Manor, N.Y.

- 30%—Psychiatrist to residential home for adolescents: Pleasantville Cottage School, Pleasantville, N.Y.

### Income

- 70%—Private Practice
- 30%—Pleasantville Cottage School

# ABOUT THE CANDIDATES

### CANDIDATES FOR AREA 5 TRUSTEE

### James A. Greene, M.D.



The role of Area Trustee presents an opportunity to listen, to educate, and to represent our members on the APA Board. APA has downsized or sunset many components and committees; thus, it is even more important that our district branches and membership are better represented on the Board of Trustees.

We are faced with major challenges including undervaluation and underfunding of our services, the stigma of mental illness, managed care restrictions, workforce reentry issues, scope-of-practice issues, and the new health care bill. We must remain vigilant in maintaining the gains we have achieved

while striving for more.

As a three-term president of the Tennessee Psychiatric Association, I am aware of the need to never rest in our efforts to defend against psychologists prescribing, as we have fought the challenge yearly for each of the past 12 years. As an educator, I work closely with UTHSC Department of Family Medicine to promote training and collaboration between family physicians and psychiatrists, understanding of what problems can be treated by the primary care physician, and when and how to consult a psychiatrist. We have developed telepsychiatry models within the faculty practice group to bring the expertise of our faculty to rural communities in Tennessee and northern Mississippi.

I have encouraged our faculty and MIT psychiatrists to become more involved in district branch and APA activities, and we have maintained 100 percent APA membership for the past four years. I have worked with the other three academic chairs of psychiatry in Tennessee to encourage the same at their institutions.

As a former CEO of a private psychiatry contract management company, I have a good understanding of the importance of leadership and teamwork in achieving progress. Having built a psychiatric management company from start-up to number 5 in the U.S. before merging with the number 1 company, I understand overcoming adversity and the importance of building carefully and maintaining financial stability while growing.

Having spent more than 35 years as a clinician in group, solo, and faculty privatepractice models, I fully understand the challenges facing psychiatrists today. We are constantly asked to provide more and better care with fewer resources and for less revenue.

I have worked throughout my career representing psychiatry in organized medicine at state and national levels and worked with the APA delegation to achieve a better understanding of the contributions and needs of psychiatry. I have served in a leadership capacity in several affiliate organizations including president of the Southern Psychiatric Association and the Board of Directors of both American Geriatrics Society (three years) and American Association for Geriatric Psychiatry (six years). As the only psychiatrist at the 1995 White House Conference on Aging, I worked with other mental health professionals and APA staff to obtain top priority for parity as an emphasis for both Congress and the White House.

If elected trustee for Area 5, I will use my hard-earned skills to work for you.

### **Primary Professional Activities and Sources of Income**

### **Professional Activities**

100%-Professor and chair of psychiatry, University of Tennessee College of Medi-

- cine, Memphis 30%—Faculty clinical practice
- 10%—Teaching
- 60%—Administration

### Income

90%—University of Tennessee College of Medicine 10%—University of Tennessee Medical Group (faculty practice group)

### Gary S. Weinstein, M.D.



The practice of psychiatry has been under outrageous assault from forces larger than any individual. Unfair payment practices, bureaucratic demands, and scope-of-practice issues are not getting easier to combat. APA has acted to help with these problems for many years but at this critical time needs to do even more.

I have worked hard in leadership positions within APA to help members and their patients and am honored to be nominated for Area 5 trustee. My focus has always been on achieving results in practical ways. Being inclusive and promoting diversity while persistently pursuing goals has

helped, along with the mutual efforts of many others, shape APA to be more responsive and effective.

My efforts have and will continue to include the following priorities:

### **General Member Needs**

- Work for equitable payment.
- Support for psychiatric practice business needs.
- Supply the best science for treatment decisions.
- Continuing medical education and lifelong-learning opportunities as part of APA member benefits.
- Expand a two-way communication process for information sharing and feedback.

### Women and Minority Needs

- Equality of appointments based on proportional representation.
- Firm policy against any unfair practice related to gender or minority status.

### Members-in-Training Needs

- Expand leadership opportunity and training within APA.
- Assist in the transition to early-career jobs and starting practice.
- Communicate using the latest innovative technologies.

### **Patient Needs**

- Reduce barriers to access and quality care, and ensure full parity occurs.
- Reduce stigma and discrimination.
- Demand privacy controls be included in electronic health records.

### Advocacy Needs

- Work closely with the AMA and allied organizations for common professional goals.
- Partner with primary care groups to enhance practice opportunities.
  - Partner with district branches to support grassroots work in state legislatures.
  - Lobby at all levels of government for the needs of psychiatry.
  - Keep psychologists and others from being "voted" psychiatric physician privileges.
  - Highlight the special needs of states in the Southeast region.

Even before starting private practice, I worked at the DB level, eventually serving in all executive positions including ethics chair, and have given continuous service to APA for over 30 years. In the APA Assembly, I was the Area 5 deputy representative (vice chair) for four years, then the Area 5 representative (chair) for four years. A main goal was helping each DB and component group in Area 5 become stronger and more capable of helping their members. As speaker of the Assembly, I facilitated this for all Areas. For two years, as speaker-elect and then as speaker, I served on the APA Board of Trustees, including 2009-2010, when I was also on the Board Executive Committee.

Close alliances at all levels of APA governance along with my significant leadership and committee work have prepared me to work effectively for Area 5 as trustee. I am excited about this opportunity and ask for your vote.

### **Primary Professional Activities and Sources of Income**

### **Professional Activities**

100%—Private practice

Income

100%—Private practice

# CANDIDATES

### CANDIDATES FOR MEMBER-IN-TRAINING TRUSTEE-ELECT

### 

### Kurt L. Cousins, M.D., M.B.A.



I have followed a nontraditional path to medicine. After a decade of applying myself to professional success in investment banking and management consulting, I became ready, through a series of volunteer experiences, to pursue a career in psychiatry. As a longtime volunteer leader of an American Red Cross disaster relief team, I spent September 11, 2001, at ground zero, where I set up a psychiatric emergency room. In that intense emotional environment, I recognized the unique opportunity to help trauma victims and people with extremely painful emotional experiences. I became

committed to psychiatry and have remained so ever since. Now I am a PGY-3 resident at University of Maryland/Sheppard Pratt and plan to begin child and adolescent fellowship training in July 2011. I received my M.D. from the University of North Carolina and my M.B.A. from the Wharton School of the University of Pennsylvania.

### This is what I believe:

**Our future depends on strong leadership and diversity.** Our leaders are aging (40 percent will retire by 2015), and I will propose more leadership development programs. Minorities are underrepresented, and I will advocate for increased recruitment of racial, ethnic, and sexual minorities. A shortage of psychiatrists exists; I will advocate for new, innovative recruitment strategies.

We can create more programming for ourselves. We can better understand how APA works and how it can support us now and during our transition to becoming early career psychiatrists (ECPs). The more that we become involved in APA as membersin-training (MITs), the more likely we will be involved as ECPs, and thereafter. Therefore I propose that APA brings us together in a network of committees that report to the APA councils and in a format that emulates the AMA Resident and Fellow Section. (I serve on its Public Health Committee.) Furthermore, I propose special-interest list serves and groups for MITs similar to AACAP's. (I serve on the AACAP Psychotherapy Committee.)

We can do better for our patients. I will use my business background to contribute to APA's lobbying efforts targeting health care reform and parity implementation. I will advocate for reducing health care disparities. I will propose increases in public-health and policy-related research initiatives.

The more of us there are, the louder our voice. I have worked to increase membership in Maryland and will work with the district branches and state associations to further increase MIT membership nationwide.

I will advocate for you. With the Maryland Psychiatric Society, I successfully advocated for more MIT programming. With AACAP, I advocated with child psychiatrists last May on Capitol Hill for resident and fellow loan repayment.

I have sought to represent my peers as president of my college class, as vice president and treasurer of my medical school student body, and as house staff representative during PGY-1. I currently serve as a board member on the Alumni Class Leaders Council at the University of Pennsylvania and as co-chair of the Resident and Fellow Committee at the Maryland Psychiatric Society.

I ask for your vote.

Primary Professional Activities and Sources of Income

**Professional Activities** 100%—University of Maryland

Income 100%—Residency training

### David I. Driver, M.D.



Over the past few years, APA has undergone major restructuring, redefining goals and policies. Additionally, our country's administration has begun pushing forward legislation that will have long-lasting repercussions on our health care system as a whole. During this time of change when policy is being drafted and implemented, to be your representative on a board that holds the authority to formulate and implement broad-reaching policies would be an honor and a privilege.

Diverse experiences have given me a sense of who I am and my desired role in life. When I was in the military, the

informal expectation was to leave any position held and any unit assigned better than you found it. These important tenets were instilled in me then, and I strive to uphold them today. I endeavor to not only leave my program better than I found it, but as a resident and future psychiatrist, I am compelled to work to improve the experiences of all residents as well as positively impact our profession.

I am a candidate who is in a position to "hit the ground running." From drafting organizational policy that affected thousands of trainees, to evaluating the feasibility of a tertiary care center's mass casualty plan, I have experience serving in a multitude of capacities. I have served in leadership positions in medical and nonmedical organizations, held numerous positions as an advocate for large groups of people on a broad variety of committees, and received extensive formal training in leadership and the fundamentals required to excel while working collaboratively on professional boards and committees. This experience and training will allow me to remain focused on representing your voice while contributing to our organization in a succinct, effective manner.

Should I be elected, I plan to focus on the following:

• Working collaboratively with our Assembly MIT representatives to establish effective communication channels between residents, fellows, early career psychiatrists, and the APA leadership to both ensure our concerns are brought to the table and keep members apprised of relevant board activities.

■ Increasing opportunities for and the involvement of residents, fellows, and early career psychiatrists in APA.

■ Facilitating a spirit of collegial collaboration between specialties, particularly medicine and psychiatry.

■ Working to ensure psychiatrists are informed and have clear guidance on implementing an electronic health records system while avoiding breaches of confidentiality and violations of laws and suffering related penalties.

Ensuring psychiatrists have clear guidance on how to ethically interact with industry.

**Primary Professional Activities and Sources of Income** 

### **Professional Activities**

80%—Resident in general psychiatry, Georgetown University Hospital 20%—Staff psychiatrist, MedOptions (moonlighting)

### Income

60%—Psychiatry resident 40%—Staff psychiatrist, MedOptions (moonlighting)

# ABOUT THE CANDIDATES

### Alik S. Widge, M.D., Ph.D.



I am running to be your next member-in-training (MIT) trustee because MITs are the most important voice in APA. We will be the most affected by every decision APA makes today, because we and our patients will face the consequences for our entire careers. APA will depend on our dues and advocacy in the future, which means that APA needs to invest in supporting us now. In conversations with trainees nationwide, you have asked APA for **better listening and communication**, **expanded mentoring/networking**, and **continued advocacy for trainees and patients**. I have worked on all three during

my past organized-medicine service, and would be honored to do so again as your representative on the Board.

As a student at the University of Pittsburgh and Carnegie Mellon, I worked in hightech labs, free clinics, community and academic hospitals, a stand-alone psychiatric hospital, and a public-health organization in rural India. I saw the challenges facing psychiatry, but I also saw the tremendous power of organized physicians to overcome those challenges. I had the privilege of serving as chair of the AMA's Medical Student Section, on the board of the AMA's Political Action Committee, and on numerous policy and planning committees. I learned the complexities of the legislative process and academic medicine, but more importantly, I learned to work collaboratively with my peers and with senior physicians. In all those groups, we built new channels to communicate with members and made our organizations more responsive, just as I hope to do within APA.

I currently represent MITs from Area 7 (the western U.S. and Canada) in the APA Assembly, which has introduced me to the challenge of communicating with many sparsely populated states. I also serve on the ACGME's Psychiatry Residency Review Committee, which lets me learn from residents and fellows in programs of every size and focus. As MIT trustee-elect, I would continue those conversations and work to direct APA resources to the three areas you have identified as priorities:

Improve communications to and from APA and our MITs.

- Electronically (social networking, e-mail, and a better APA Web site)
- In person (MIT leaders holding "town-hall" events locally and at meetings)

### Expand mentoring/networking for MITs with diverse needs.

- Developing state and local mentorship programs, for MITs interested in private and community psychiatry
- Networking and social events at national meetings, for researchers and those interested in psychiatric subspecialties

Both the above plus better connections to other national groups, for underrepresented minorities within psychiatry

### Strengthen advocacy for MITs and our patients.

• Work through the AMA to promote psychiatry's value to other specialties and establish us as a "medical home" for our patients

Advocate for MITs' access to employee benefits, child care, and duty-hour regulations that recognize our unique needs

• Actively promote access to psychiatric care and psychiatrists' unique role in the mental health care team

I am grateful for the chance to serve and represent you this past year, and I ask for your support once more in order to continue being a strong voice for you and your patients.

### **Primary Professional Activities and Sources of Income**

### **Professional Activities**

- 100%—Psychiatry resident (research track), University of Washington Medical Center/Harborview Medical Center/Seattle VA Medical Center 75%—Direct patient care
  - 25%—Research (neurostimulation for treatment of severe mental illness)

### Income

100%—Psychiatry resident, University of Washington

### MEMBER titioned by APA members og the American Board of REFERENDUM

The American Psychiatric Association was petitioned by APA members to hold a referendum on the issue of informing the American Board of Psychiatry and Neurology (ABPN) as follows regarding its proposed maintenance of certification requirements.

The patient feedback requirements for the purpose of reporting to the Board is unacceptable, as it creates ethical conflicts, and has the potential to damage treatment.
 The requirements other than a cognitive knowledge examination once in 10 years, regular participation in continuing medical education, and maintenance of licensure pose undue and unnecessary burden on psychiatrists.

You will be asked to vote in favor of or against this statement on the ballot for APA's 2011 election. The following are statements provided by APA's Board of Trustees and the petitioners to explain their respective positions. Passage of a measure in a member referendum requires (a) valid ballots from at least 40 percent of the voting members, (b) the affirmative vote of at least one-third of all the voting members of the Association, and (c) the affirmative vote of a majority of those members who return a valid ballot.

### **Board of Trustees Statement**

The proposed requirement of the ABPN for patient feedback is part of the American Board of Medical Specialties (ABMS) Maintenance of Certification Program affecting all medical specialties, not just psychiatry. The ABPN will ask physicians to complete a small number of feedback evaluations over a 10-year period. Only the physician will see the evaluations and attest that evaluations have been completed. The ABPN will *not* receive or review *any* patient information.

The Ethics Committee of APA reviewed the ABPN/ABMS requirement and determined it did not violate APA's *Principles of Medical Ethics With Annotations Especially Applicable to Psychiatry*. Requirements for patient satisfaction surveys, independent of certification, are part of the health care reform bill.

APA will continue to work closely with ABPN, ABMS, and other organizations to reduce unnecessary burdens that may be associated with MOC programs and to assure that such programs are consistent with high-quality patient care.

### **Petitioner Statement**

Our petition is not against soliciting patient feedback, but against the pernicious effect of an external mandate for it as a condition for maintaining certification. This will damage the time-honored doctor-patient relationship. Patients may now think that their doctors are treating them nicely not because of their intrinsic worth or the doctor's helpful nature, but because the doctor has to comply with an external agency requiring it. Distrustful patients might become even more distrustful. There is potential for ethical conflicts and damage to treatment by preferential treatment of a select few patients whose feedback the psychiatrist has decided to seek for his/her own benefit (maintenance of certification), distortion of transference, and adversely influencing prescriptions, limit settings, and discharge plans. Requiring 10 chart reviews, 10 peer reviews, and 10 patient reviews every three years is onerous. Any supposed benefits are questionable. Making too many demands on physicians' time can impair performance.

WWW.PSYCHNEWS.ORG 23

# government news

# **Psychiatrists Can Have Key Role in Care Model**

Psychiatrists interested in participating in integrated care programs which are expected to dominate in medicine's future—may find models emerging through large companies, insurers, or local governments.

### BY RICH DALY

new type of medical organization is expected to rise to prominence in the coming years and could impact many psychiatrists and other small- and solo-practice physicians.

Accountable care organizations (ACOs) aim to coordinate care among multiple clinicians treating the same patients for varying conditions, improve patients' clinical outcomes, and lower the cost of that care. The movement to shift physicians away from independently operating solo or small practices to large practices or physician-hospital partnerships is being driven by the new health care reform law, private insurers, and an expected decline in reimbursements.

John McIntyre, M.D., a member of the AMA's Council on Medical Service (CMS) and a former APA president, said the AMA is working to identify ways that coming ACO regulations could keep that payment model from "squeezing out" small and solo practitioners in favor of large practices and hospital-led groups.

But even with better protections under the ACO system, small- and solo-practice psychiatrists will need to better integrate their patient care with that provided by other physicians, because all public and private payment systems are moving to reward such integration, McIntyre told *Psychiatric News*.

Integration "is now the exception rather than the rule among psychiatrists," he said.

APA plans to advise psychiatrists during the transition to this new model, McIntyre noted. For instance, in September APA's Board of Trustees approved a position statement calling for increased coordination of care between psychiatrists and primary care physicians. The need for such integration was demonstrated by research estimating that 25 percent of the patients of primary care physicians have comorbid and diagnosable psychiatric disorders and would benefit from psychiatric and integrated care. The gap between the episodes of treatment provided by psychiatrists and the estimated patient need is more than 368,000 annual visits.

"These individual visits are rarely, if ever, identified and addressed in the current fragmented health system . . . ," said the APA position statement. "The integration of psychiatric care and primary care has consistently been demonstrated [in numerous randomized, controlled trials] to enhance access, improve quality, enhance individual outcomes, and diminish costs."

Better patient care coordination by psychiatrists and other physicians, according to research summarized in the position statement, would improve patient health and lower costs stemming from untreated mental illness. The position statement urges changes in state and federal laws and regulations to encourage greater collaboration and integration of psychiatry and primary care.

Karen Sanders, associate director for publically funded services in APA's Office of Healthcare Systems and Financing, said psychiatrists have recently begun asking her and organizations long focused on integrated care models about how they might fit into such programs.

"Up until now psychiatrists have been noticeably absent [from discussions about increasing integrated care], so psychologists have been filling the gap," she told *Psychiatric News*.

Those estimates are in line with other recent physician workforce projections, said APA Medical Director James H. Scully Jr., M.D., in an interview with *Psychiatric News*. Such expected physician shortfalls are a sharp departure from predictions of a physician surplus issued as recently as the mid-1990s.

### New Law Will Aggravate M.D. Shortage

The health care reform law's provisions that are expected to exacerbate the shortage include a requirement that all states offer Medicaid access by 2014 to any individual or family whose income is up to 133 percent of the federal poverty level (\$14,404 for an individual and \$29,327 for a family of four in 2010), as well as the 2014 requirement that insurers accept all applicants and that most Americans obtain health insurance. Although the projections were not broken down for all specialties, the shortage in the number of primary care physicians was expected to rise from 9,000 in 2010 to 45,400 in 2020.

AAMC officials attributed the widening gap to a rapidly aging U.S. population in addition to the increased access that will follow implementation of the new health care law.

"The United States already was struggling with a critical physician shortage, and the problem will only be exacerbated as 32 million Americans acquire health care coverage, and an additional 36 million people enter Medicare," according to an AAMC statement issued with the new projections in late October.

### Impact to Be Felt on Mental Health Care

The shortage of primary care physicians is expected especially to impact patients who need mental health care. *please see Shortage on page 39* 

### **APA Launches List Serve**

To support psychiatrists interested in integrated care programs, APA recently launched a list serve focused on distributing and exchanging related information among members. By early November, the list serve had attracted more than 20 psychiatrists.

Psychiatrists also have begun to attend meetings of national groups focused on integrated care, such as the Patient Centered Primary Care Collaborative (PCPCC), which is a coalition of employers, insurers, physicians, and patient advocates focused on improving quality and lowering costs. Such groups have long been dominated by primary care physicians, and as a result, many of the integrated care programs in private and public insurance will be designed around those clinicians.

Psychiatrists may qualify as the designated physician coordinating all of a patient's care in some of these health care systems. For example, through the new health care reform law's initiative to encourage integrated care groups, such as medical homes, individual psychiatrists can qualify as the central primary care providers to patients with serious and persistent mental illness. However, psychiatrists can attain that status only if they meet specific standards, which will be spelled out in future regulations.

Many psychiatrists, Sanders said, may better fit into ACOs created by the health care reform law to receive much higher reimbursements in exchange for improving care while lowering costs. These organizations, likely either physician networks or physician and hospital partnerships, will be more clearly detailed in future federal regulations.

### **ACO Examples Emerging**

Some private insurers and employers are already funding their own versions of ACOs. One example that includes psychiatrists is the Care Community of North Carolina. This organization has used aspects of a medicalhome model to assign patients to a primary care physician, who then coordinates any care needed from other specialists. The organization also includes extra support, such as nurses on call to handle patient inquiries or emergencies and to decide whether a patient's condition requires a physician's attention.

"So there are models where providers can be loosely affiliated but still be linked in so that they can improve care through health information technology [HIT] improvement [and] performance-measurement initiatives and still be able to change the payment model from one that is more feefor-service based to one that is value based," said Mark Zezza, Ph.D., a research director at the Engelberg Center for Health Reform at the Brookings Institution, in an interview.

Medicare's initial pilot ACO must launch by the beginning of 2012, likely followed by an expansion throughout Medicare several years later. Medicare will pay ACOs through a global budget. ACOs that are able to meet quality-of-care indicators while finding ways to hold down overall costs can divide the remaining funds among their members as profit. ACO-driven payment models are intended to replace the existing fee-for-service payment system by paying their physician members for all the health needs of a set number of patients *please see ACOs on page 39* 

### More Insured Patients to Worsen Critical Physician Shortage

The health care reform law will greatly expand access to health care, but steps have not been taken to increase the number of physicians in the future. People with mental illness could have a particularly difficult time getting the care they need.

he shortage of physicians in the United States today has become even more acute with enactment of the health care reform law. While millions more patients will receive insurance, medical school and residency slots have not been substantially increased, leaving too few doctors to meet the increased demand for medical care. One effect of this imminent development is an expected decrease in the amount of mental health care provided by primary care physicians, who will face ever-increasing demands for their time, say mental health advocates like John Bartlett, M.D., M.P.H., a psychiatrist and senior advisor for the Primary Care Initiative at the Carter Center in Atlanta.

Primary care physicians now provide the majority of screening and treatment for psychiatric illness, according to research findings from multiple studies. For example, the 2005 and 2006 National Survey on Drug Use and Health, a nationally representative sampling, found 62 percent of adults who sought mental health care received it from their primary care physicians; 11 percent received such care from another type of physician who also was not a psychiatrist.

The expected nationwide shortage of physicians in coming years grew by 50 percent following enactment of the health



John Bartlett, M.D., says that both public and private insurers are expected to make a large investment in retraining physicians to better coordinate patient care with other clinicians.

care reform law earlier this year, according to new workforce projections by the Association of American Medical Colleges (AAMC). The nation will face an estimated 62,900 physician shortfall in 2015 and a 91,500 shortfall by 2020.

# Treat your patients with the demonstrated efficacy of LEXAPRO<sup>1-5</sup>

In adults with MDD and Generalized Anxiety Disorder (GAD)<sup>1</sup>

In adolescents aged 12 to 17 with Major Depressive Disorder (MDD)<sup>1</sup>



### WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Lexapro or any other antidepressant in a child, adolescent or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients less than 12 years of age.

Please see additional Important Safety Information on following pages.

# See the effect of LEXAPRO

Proven efficacy in MDD in adolescents aged 12 to 17,\* and in MDD and GAD in adults<sup>1-5</sup>

There is no generic available for LEXAPRO

### Significantly improved MDD symptoms in adolescents<sup>2</sup>

Lexapro (escitalopram oxalate) is indicated for the acute and maintenance treatment of major depressive disorder (MDD) in adults and adolescents aged 12-17 years. Lexapro is also indicated for the acute treatment of generalized anxiety disorder (GAD) in adults.

\*LEXAPRO is indicated as an integral part of a total treatment program for MDD. Drug treatment may not be indicated for all adolescents with this syndrome.

### **IMPORTANT SAFETY INFORMATION (continued)**

### Contraindications

- Lexapro is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs). There have been reports of serious, sometimes fatal, reactions with some cases resembling neuroleptic malignant syndrome (NMS) and serotonin syndrome. Features may include hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Serotonin syndrome was reported for two patients who were concomitantly receiving linezolid, an antibiotic which has MAOI activity. Lexapro should not be used in combination with an MAOI or within 14 days of discontinuing an MAOI. MAOIs should not be initiated within 14 days of discontinuing Lexapro.
- Lexapro is contraindicated in patients taking pimozide or with hypersensitivity to escitalopram or citalopram.

### 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 within the first few months of treatment or when changing the dose. Consideration should be given to changing the therapeutic regimen, including discontinuing medication, in patients whose depression is persistently worse, 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. Families and caregivers of patients treated with antidepressants should be alerted about the need to monitor patients daily for the emergence of agitation, irritability, unusual changes in behavior, or the emergence of suicidality, and report such symptoms immediately. Prescriptions for Lexapro should be written for the smallest quantity of tablets, consistent with good patient management, in order to reduce the risk of overdose.



- Significantly higher rates of response and remission vs placebo in MDD and GAD in adults<sup>4,5</sup>
- A major depressive episode may be the initial presentation of bipolar disorder. In patients at risk for bipolar disorder, treating such an episode with an antidepressant alone may increase the likelihood of precipitating a mixed/ manic episode. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine if they are at risk for bipolar disorder. Lexapro should be used cautiously in patients with a history of mania or seizure disorder. Lexapro is not approved for use in treating bipolar depression.
- The concomitant use of Lexapro with other SSRIs, SNRIs, triptans, tryptophan, antipsychotics or other dopamine antagonists is not recommended due to potential development of life-threatening serotonin syndrome or neuroleptic malignant syndrome (NMS)-like reactions. Reactions have been reported with SNRIs and SSRIs alone, including Lexapro, but particularly with drugs that impair metabolism of serotonin (including MAOIs). Management of these events should include immediate discontinuation of Lexapro and the concomitant agent and continued monitoring.
- Patients should be monitored for adverse reactions when discontinuing treatment with Lexapro. During marketing of Lexapro and other SSRIs and SNRIs, there have been spontaneous reports of adverse events occurring upon discontinuation, including dysphoric mood, irritability, agitation, dizziness, sensory

disturbances (e.g., paresthesias), anxiety, confusion, headache, lethargy, emotional lability, insomnia and hypomania. A gradual dose reduction rather than abrupt cessation is recommended whenever possible.

• SSRIs and SNRIs have been associated with clinically significant hyponatremia. Elderly patients and patients taking diuretics or who are otherwise volume-depleted appear to be at a greater risk. Discontinuation of Lexapro should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted.

Please see Boxed Warning on first page and additional Important Safety Information on next page.



Visit the LEXAPRO website at www.lexapro.com

**LEXAPRO:** Proven efficacy in MDD in adolescents aged 12 to 17, and in MDD and GAD in adults<sup>1-5</sup>

### Warnings and Precautions (continued)

- SSRIs (including Lexapro) and SNRIs may increase the risk of bleeding. Patients should be cautioned that concomitant use of aspirin, NSAIDs, warfarin or other anticoagulants may add to the risk.
- Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Lexapro does not affect their ability to engage in such activities.
- Lexapro should be used with caution in patients with severe renal impairment or with diseases or conditions that alter metabolism or hemodynamic responses. In subjects with hepatic impairment, clearance of racemic citalopram was decreased and plasma concentrations were increased. The recommended dose of Lexapro in hepatically impaired patients is 10 mg/day.
- For pregnant or nursing mothers, Lexapro should be used only if the potential benefit justifies the potential risk to the fetus or child.

### Be Forest Pharmaceuticals, Inc.

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### Visit the LEXAPRO website at www.lexapro.com

### **Adverse Reactions**

- In clinical trials of MDD, the most common adverse reactions in adults treated with Lexapro (approximately 5% or greater and at least twice the incidence of placebo) were nausea (15% vs 7%), insomnia (9% vs 4%), ejaculation disorder (9% vs <1%), fatigue (5% vs 2%), somnolence (6% vs 2%), and increased sweating (5% vs 2%). In pediatric patients, the overall profile of adverse reactions was similar to that seen in adults; however, the following additional adverse reactions were reported at an incidence of at least 2% for Lexapro and greater than placebo: back pain, urinary tract infection, vomiting, and nasal congestion.</li>
- In clinical trials of GAD, the most common adverse reactions in adults treated with Lexapro (approximately 5% or greater and at least twice the incidence of placebo) were nausea (18% vs 8%), ejaculation disorder (14% vs 2%), insomnia (12% vs 6%), fatigue (8% vs 2%), decreased libido (7% vs 2%) and anorgasmia (6% vs <1%).</li>

Please see accompanying brief summary of Prescribing Information for LEXAPRO, including Boxed Warning.

**References: 1.** LEXAPRO [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2009. **2.** Emslie GJ, Ventura D, Korotzer A, Tourkodimitris S. Escitalopram in the treatment of adolescent depression: a randomized placebo-controlled multisite trial. *J Am Acad Child Adolesc Psychiatry*. 2009;48:721-729. **3.** Burke WJ, Gergel I, Bose A. Fixed-dose trial of the single isomer SSRI escitalopram in depressed outpatients. *J Clin Psychiatry*. 2002;43:331-336. **4.** Davidson JRT, Bose A, Korotzer A, Zheng H. Escitalopram in the treatment of generalized anxiety disorder: double-blind, placebo controlled, flexible dose study. *Depress Anxiety*. 2004;19:234-240. **5.** Wade A, Lemming OM, Hedegaard KB. Escitalopram 10 mg/day is effective and well tolerated in a placebo-controlled study in depression in primary care. *Int Clin Psychopharmacol*. 2002;17:95-102.



### LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION Brief Summary: For complete details, please see full Prescribing Information for Lexapro.

Bret summary: For comprete detains, prease see ton Prescribing information for Lexapro. WARNINGS: SUICIDALITY AND ANTIDEPRESSANT DRUGS Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Lexapro or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric discorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Lexapro is not approved for use in pediatric patients less than 12 years of age. [See Warnings and Precautions: Clinical Worsening and Suicide Risk, Patient Counseling Information: Information for Patients, and Used in Specific Populations: Pediatric Use].

INDICATIONS AND USAGE: Major Depressive Disorder-Lexapro (escitalopram) is indicated for the acute and maintenance treatment of major depressive disorder in adults and in adolescents 12 to 17 years of age [see Clinical Studies]. A major depressive opisode (DSM-V) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agilation or retardation, increased fatigue, feelings of guilt or worthelesness, slowed thinking or impaired concentration, a suicide attempt or suicidal ideation. Generalized Anxiety Disorder-Lexapro is indicated for the acute treatment of Generalized Anxiety Disorder (GAD) in adults [see Clinical Studies]. Generalized Anxiety Disorder (DSM-VI) is characterized by excessive anxiety and worry (apprehensive expectation) that is persistent for at least 6 months and which the person finds difficult to control. It must be associated with a least 3 of the following or mind going blank, irritability, muscle tension, and sleep disturbance. CONTRAINORCIATIONS: Monagamine avides in Movings (MADIN: Concomitant use in patients taking

concentrating or ming going blank, irritability, muscle tension, and sleep disturbance. **CONTRAINDICATIONS:** Monoamine oxidase inhibitors (MAOIs)-Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated [see Warnings and Precautions]. Pimozide-Concomitant use in patients taking pimozide is contraindicated [see Drug Interactions]. Hypersensitivity to escitalopram or citalopram—Lexapro is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients in Lexapro.

citalopram or any of the inactive ingredients in Lexapro. WARNINGS AND PRECAUTIONS: Clinical Worsening and Suicide Risk-Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressant may have a role in induring worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction with antidepressant compared to placebo in adults beyond age 24; there was a reduction with antidepresses of placebocontrolled trials in adults with MDD, obsessive compulsive disorder (MOD) patients. The pooled analyses of placebocontrolled trials in adults with MDD or other psychiatric disorders included a total of 24 short-term trials of 9 antidepressant drugs in over 4700 patients. The pooled analyses of placebocontrolled trials in adults with MDD or other psychiatric disorders included a total of 295 short-term trials (median duration of 2 months) of 11 antidepressant drugs in over 470.00 patients. There was considerable with the highest incidence in MDD. The risk differences (drug cacebo), however, were re

TABLE 1				
Age Range	Drug-Placebo Difference in Number of Cases			
	of Suicidality per 1000 Patients Treated			
	Increases Compared to Placebo			
<18	14 additional cases			
18-24	5 additional cases			
	Decreases Compared to Placebo			
25-64	1 fewer case			
≥65	6 fewer cases			
number was not sufficient to reach any conclusicidality risk extends to longer-term use, in lence from placebo-controlled maintenance t an delay the recurrence of depression. All	tric trials. There were suicides in the adult trials, but the lusion about drug effect on suicide. It is unknown whether the e. beyond several months. However, there is substantial evi- rials in adults with depression that the use of antidepressants patients being treated with antidepressants for any indication for a biotechic termination and the severation of the severation of the model block for a biotechic moreover existence in the severation of the severation of the severation of the severation of severation			

the term of 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 monitors of a course of drug therapy, or at times of dose changes, either increases or decreases. The following symptoms, anxiety, agitation, panic attacks, insomnia, 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 sucidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality. Consideration should be given to changing the thrapeeutic regime, 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 discontinuu treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be altered about the need to monitor patients for the general or all site mergence of suicidality, and to report such symptoms is mediately to health care providers. Such monitoring should include daily observation by tamilies and caregivers [*see also Patient Counseling Information]*. Prescriptions for Lexapro should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overloss. Streading

tonin precursors (such as tryptophan) is not recommended. Treatment with Lexapro and any concomitant serotonergic or antidopaminergic agents, including antipsychotics, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated. <b>Discontinuation of Treatment with Lexapro-</b> During marketing of Lexapro and other SSRIs and SNRIs (serotonin and norepineprine 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, agittion, diziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with Lexapro. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate [see <i>Dosage</i> and <i>Administration</i> ]. <b>Secure-X-</b> Although anticonvulsant effects of racemic citalopram have been observed in aninal studies, Lexapro has not been reported in association with Lexapro treatment. Lexibar or the set and the treatment of major depressive disorder. Lexapro should be introduced with care in patients with a history of seizure disorder. <b>Activation of Mania/Hypomania</b> -In placebo-controlled trials of Lexapro in any or the set patients treat with placebo. Done additional case of hypomania has been reported in association with Lexapro reat antidure to major depressive disorder. Activation of mania/hypomania was reported in ansolatoproma and she termory of the set patie
es. Lexapro has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were generally excluded from clinical studies dur-

fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Furthermore, limited animal data on the effects of combined use of SSRIs and MAOIs suggest that these drugs may act synergistically to elevate blood pressure and evoke behavioral excitation. Therefore, it is recommended that Lexapro should not be used in combination with an MAOI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days should be allowed after stopping Lexapro before starting an MAOI. Serotonin syndrome has been reported in two patients who were concomitantly receiving linezolid, an antibiotic which is a reversible non-selective MAOI.

Reterming integration and antibuotic winch is a reversible inon-selective MAOI. ADVERSE REACTIONS: Clinical Trials Experience-Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. **Clinical Trial Data Sources: Pediatrics (6 -17 years)-**Adverse events were collected in 576 pediatric patients (286 Lexapro, 290 placebo) with major depressive disorder in double-blind placebo-controlled studies. Safety and effectiveness of Lexapro in pediatric patients less than 12 years of age has not been established. Adults Adverse events information for Lexapro may collected from 715 patients with major depressive disorder who were exposed to escitalopram and from 529 patients who were exposed to placebo in double-blind, placebocontrolled trials. Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events linito a smaller number of standardized event categories. In the tables and tabulations that follow, standard World Health Organization (WHO) terminology has been used to classily reported adverse events. The stated frequencies of adverse reactions represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event to fit type isted. An event was considered 1% for Lexapro and f% of 290 patients receiving placebo. The most common adverse event (incidence at least 1% for Lexapro and greater than placebo) associated with discontinuation of adverse events in patients receiving placebo. The diverse events in adverse events in patients receiving 10 mg/day Lexapro was folginificantly different from t

TABLE	-	
Treatment-Emergent Adverse Reactions	Observed with a Frequen	cy of ≥ 2%
and Greater Than Placebo for N	lajor Depressive Disorde	r
Adverse Reaction	Lexapro (N=715)	Placebo (N=592)
	(N=/15)	(N=09Z)
Autonomic Nervous System Disorders		
Dry Mouth	6%	5%
Sweating Increased	5%	2%
Central & Peripheral Nervous System Disorders		
Dizziness	5%	3%
Gastrointestinal Disorders		
Nausea	15%	7%
Diarrhea	8%	5%
Constipation	3%	1%
Indigestion	3%	1%
Abdominal Pain	2%	1%
General		
Influenza-like Symptoms	5%	4%
Fatigue	5%	2%
Psychiatric Disorders		
Insomnia	9%	4%
Somnolence	6%	2%
Appetite Decreased	3%	1%
Libido Decreased	3%	1%
Respiratory System Disorders		
Rhinitis	5%	4%
Sinusitis	3%	2%
Urogenital		
Ejaculation Disorder <sup>1,2</sup>	9%	<1%
Impotence <sup>2</sup>	3%	<1%
Anorgasmia <sup>3</sup>	2%	<1%

<sup>1</sup>Primarily ejaculatory delay. <sup>2</sup>Denominator used was for males only (N=225 Lexapro; N=188 placebo). <sup>3</sup>Denominator used was for females only (N=490 Lexapro; N=404 placebo)

Generalized Anxiety Disorder: Adults-The most commonly observed adverse reactions in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorgasmia. Table 3 enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-created patients.

		IABLE 3		
Treatment	t-Emergent Adverse	<b>Reactions Observed</b>	with a Frequency of $\ge 2\%$	

Adverse Reactions	Lexapro (N=429)	<u>Placebo</u> (N=427)	
Autonomic Nervous System Disorders	( - <i>i</i>		
Dry Mouth	9%	5%	
Sweating Increased	4%	1%	
Central & Peripheral Nervous System Disorders			
Headache	24%	17%	
Paresthesia	2%	1%	
Gastrointestinal Disorders			
Nausea	18%	8%	
Diarrhea	8%	6%	
Constipation	5%	4%	
Indigestion	3%	2%	
Vomiting	3%	1%	
Abdominal Pain	2%	1%	
Flatulence	2%	1%	
Toothache	2%	0%	
General			
Fatigue	8%	2%	
Influenza-like Symptoms	5%	4%	
Musculoskeletal System Disorder			
Neck/Shoulder Pain	3%	1%	
Psychiatric Disorders			
Somnolence	13%	7%	
Insomnia	12%	6%	
Libido Decreased	7%	2%	
Dreaming Abnormal	3%	2%	
Appetite Decreased	3%	1%	
Lethargy	3%	1%	
Respiratory System Disorders			
Yawning	2%	1%	
Urogenital			
Ejaculation Disorder <sup>1,2</sup>	14%	2%	
Anorgasmia <sup>3</sup>	6%	<1%	
Menstrual Disorder	2%	1%	

<sup>2</sup>Denominator used was for males only (N=182 Lexapro; N=195 placebo). <sup>3</sup>Denominator used was for females only (N=247 Lexapro; N=232 placebo). Dose Dependency of Adverse Reactions-The potential dose dependency of common adverse reactions (defined as an incidence rate of ≥5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). Table 4 shows common adverse reactions that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo-treated patients **TABLE 4** 

Incidence of Common Adverse Reactions in Patients with Majo

Depressive Disorder				
Adverse Reaction	Placebo	10 mg/day	20 mg/day	
	(N=311)	Lexapro	Lexapro	
		(N=310)	(N=125)	
Insomnia	4%	7%	14%	
Diarrhea	5%	6%	14%	
Dry Mouth	3%	4%	9%	
Somnolence	1%	4%	9%	
Dizziness	2%	4%	7%	
Sweating Increased	<1%	3%	8%	
Constipation	1%	3%	6%	
Fatigue	2%	2%	6%	
Indigestion	1%	2%	6%	
Male and Female Sexual Dysfunction and sexual satisfaction often occur as quence of pharmacologic treatment. Ir ward sexual experiences. Reliable esti sexual desire, performance, and satis physicians may be reluctant to discus experience and performance cited in p	manifestations of a particular, some evide mates of the incidence a faction are difficult to ss them. Accordingly, e	sychiatric disorder, they nce suggests that SSRIs and severity of untoward obtain, however, in part estimates of the incidence	may also be a conse- can cause such unto- experiences involving because patients and ce of untoward sexual	

TABLE 5 Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials				
Adverse Event	Lexapro	Placebo		
	In Males Only			
	(N=407)	(N=383)		
Ejaculation Disorder				
(primarily ejaculatory delay)	12%	1%		
Libido Decreased	6%	2%		
Impotence	2%	<1%		
	In Fema	ales Only		
	(N=737)	(N=636)		

Libido Decrease

 Inorgasmia
 3%
 1%

 There are no adequately designed studies examining sexual dysfunction with excitalopram treatment. Priapism has been reported with all SSHis. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRis, physiclans should routhely inquire about such possible side effects. Wita it Sign Changes-Leagn and placebo groups were compared with respect to (1) mean change from baseline in these studies. These and years of the possible and standing vital sign measures in subjects receiving Leagnor indicated that Leagno treatment is not associated with othesitic changes. Whigh Changes-Prittens treated with the Leagno in controlled traits did not differ from placebo-treated patients were compared with respect to (1) mean change from baseline in these variables. These analyses revealed no clinically important changes in baboratory test parameters associated with theyaper Distribution (Ho-SST), and placebo (N-SZT) groups were compared with respect to (1) mean change from baseline in these variables. These analyses revealed (1) decrease in heart rate of 2.2 bpm for Leagnor and (2) the incidence of patients meant with respect to (1) mean change from baseline in various SEG anomes Discover Outrially clinically significant thanges from baseline in these variables. These analyses revealed (1) adcrease in heart rate of 2.2 bpm for Leagnor and (2) the incidence of patients meant with respect to (1) mean change from baseline in these variables. These analyses revealed Uning the Premarketing Evaluation of Lesapor-Policiwing is alist of treatment-mergen adverse events, as defined in the introduction to the ADVFRS FRAFITONS section, reported of 3.9 msec for Leagnor and 3.7 msec for racewing Leagnor treatment. CFS Changes Electrocardial in rerease of 0.3 bpm for placebas and (2) an increase of 0.3 bpm for placebas and (2) an increase of 0.3 bpm for placebas and (2) an increase of 0.3 bpm f

**DRUG INTERACTIONS:** Serotonergic Drugs-Based on the mechanism of action of SNRIs and SSRIs including Lexapro, and the potential for serotonin syndrome, caution is advised when Lexapro is condiministered with other drugs that may affect the serotonergic neurotransmitter systems, such as triptans, linezoild (an antibiotic which is a reversible non-selective MAOI), lithium, tramadol, or SL John's Wort [see Warnings and *Precautions*]. The concomitant use of Lexapro with other SSRIs, SNRIs to tryptophan is not recommended. **Triptans**-There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan. If concomitant treatment of Lexapro with other SSRIs, SNRIs to tryptophane with use of an SSRI and a triptan. If concomitant treatment of Lexapro with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases [see Warnings and *Precautions*]. **CNS Drugs**- Given the primary CNS effects of escitalopram, caution should be used when it is taken in combination with other centrally acting drugs. **Alcohol-Although Lexapro** did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by patients taking Lexapro is not recommended. **Monoamine Oxidase Inhibitors (MAOIs**)-(see Contraindications and Warnings and Precautions]. **Drugs That Interfere With Hemostasis**: Epidemiological studies of the case-control and cohort design that have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding have also shown that concurrent use of an NSAID or aspirin may potentiate the risk of bleeding. Altered anticoagulant effects, including increased bleeding, have been reported when SSRIs and candministered with warfarin. Takitens receiving warfarin therapy should be carefully monitored when Lexapro is initiated or discontinued. **Climetidine**-In subjec

theophylline. The effect of theophylline on the pharmacokinetics of citalopram was not evaluated. **Warfarin**-Administration of 40 mg/day racemic citalopram for 21 days did not affect the pharmacokinetics of warfarin, a CYP3A4 substrate. Prothrombin time was increased by 5%, the clinical significance of which is unknown. **Carhamazepine**-Combined administration of racemic citalopram (40 mg/day for 14 days) and carbamazepine (tirtrated to 400 mg/day for 35 days) did not significantly affect the pharmacokinetics of carhamazepine, a CYP3A4 substrate. Although trough citalopram plasma levels were unaffected, given the enzyme-inducing properties of carbamazepine, the possibility that carbamazepine might increase the clearance of escitalopram should be considered if the two drugs are coadministered. **Triazolam**-Combined administration of racemic citalopram (titrated to 40 mg/day for 28 days) and the CYP3A4 substrate (200 mg), a potent CYP3A4 inhibitor, decreased the C<sub>MPX</sub> and Aufor (20 ketoconazole by 21% and 10%, respectively, and did not significantly affect the pharmacokinetics of citalopram. **Ritonavir**-Combined administration of racemic citalopram. **Ritonavir**-Combined administration of a single dose of 0.25 mg) did not significantly affect the pharmacokinetics of escitalopram. **CYP3A4** and scitalopram (20 mg) did not affect the pharmacokinetics of either ritonavir or escitalopram. **CYP3A4** and scitalopram (20 mg) did not significantly affect the pharmacokinetics of escitalopram. **CYP3A4** and inhibitor of CYP3A4, did not significantly affect the pharmacokinetics of escitalopram were not significantly different in poor metabolizera by **Cytochrome P4502De**-*In vitro* studies did not reveal inhibitor of 21 days) with the trixyclic and decremic dislopram, reacemic citalopram were not significantly different in poor metabolizera by Cytochrome P4502De-*In vitro* studies did not reveal inhibitor of 21 days) with the trixyclic and decitalopram metabolizers after unitue din vivo data suggesting a modest CYP2D6. Metap

Contract studies of the Contract of the Contr of 56 mg/kg/day is approximately 28 times the MRHD on a mg/m<sup>2</sup> basis. No teratogenicity was observed at any of the doses tested (as high as 75 times the MRHD on a mg/m<sup>2</sup> basis). When female rats were treated with escitalopram (6, 12, 24, or 48 mg/kg/day) during pregnancy and through weaning, slightly increased offspring mortality and growth retardation were noted at 48 mg/kg/day which is approximately 24 times the MRHD on a mg/m<sup>2</sup> basis. Slight maternal toxicity (clinical signs and decreased body weight gain and food consumption) was seen at this dose. Slightly increased offspring mortality was also seen at 24 mg/kg/day. The no-effect dose was 12 mg/kg/day which is approximately 6 times the MRHD on a mg/m<sup>2</sup> basis. In animal reproduction studies, racemic citalopram has been shown to have adverse effects on embry/oftetal and postnatil development, including teratogenic effects, when administered at doses greater than human (32, 56, or 112 mg/kg/day) to pregnant animals during the period of organogenesis resulted in decreased embry/oftetal growth and survival and an increased incidence of fetal abnormalities (including cardiovascular and skeletal defects) at the high dose. This dose was also associated with maternal toxicity (clinical signs and dos subscience) and a sign as a cardiovascular signal set and skeletal growth and survival and an increased incidence of test abnormalities (including cardiovascular and skeletal growth and survival and an increased incidence of test abnormalities (including cardiovascular signal skeleta) signal set as a sociated with maternal toxicity (clinical signs, signal set as a sociated with maternal toxicity (clinical signs, signal set as a sociated with maternal toxicity (clinical signs, signal set as a sociated with maternal toxicity (clinical signs, signal set as a sociated with maternal toxicity (clinical signs, signal set as a sociated with maternal toxicity (clinical signs, signal set as a sociated with maternal toxicity (clinical signs, signal set as a sociated with mater embryo/fetal growth and sürvival and an increased incidence of fetal abnormalities (including cardiovascular and skeletal defects) at the high dose. This dose was also associated with maternal toxicity (clinical signs, decreased body weight gain). The developmental no-effect dose was 56 mg/kg/day. In a rabbit study, no adverse effects on embryo/fetal development were observed at doses of racemic citalgram of up to 16 mg/kg/day. Thus, teratogenic effects of racemic citalopram were observed at a maternally toxic dose in the rat and were not observed in the rabbit. When female rats were treated with racemic citalopram (42, 61, 22, 8, or 32 mg/kg/day) from late gestation through wearing, increased offspring mortality during the first 4 days after birth and persistent offspring growth retardation were observed at the highest dose. The no-effect dose was 12.8 mg/kg/day. Similar effects on offspring mortality and growth were seen when dams were treated throughout gestation and early lactation at doses ≥ 24 mg/kg/day. A no-effect dose was not determined in that study. There are no adequate and well-controlled studies in pregnant womer, therefore, escitalopram should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Fregnancy-Nonteratogenic Effects-Neonates exposed to Lexapro and other SSNIs of SNIs, late in the third timester, have developed complications requiring proloned hospitalization, respiratory support. rimester, have developed complications requiring prolonged hospitalization, respiratory support 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 SSNIs and SNRIs or, possibly, a drug discontinua-tion syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrom [see Warnings and Precautions]. Infants exposed to SSRIs in late pregnancy may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN), PPHN occurs in 1-2 per 1000 live births in the general population and is associated with substantial neonatal morbidity and mortality. In a retrospective, case-control study of 377 women whose infants were born with PPHN and 836 wemen whose The brins in the general population and is associated with substantial neonatal motifolity and introlatily. Inter retrospective, case-control study of 377 women whose infants were born with PPHN and 836 women whose infants were born healthy, the risk for developing PPHN was approximately six-fold higher for infants exposed to SSRIs after the 20th week of gestation compared to infants were had not been exposed to antidepressants during pregnancy. There is currently no corroborative evidence regarding the risk for PPHN following exposure to SSRIs in pregnancy; this is the first study that has investigated the potential risk. The study did not include enough cases with exposure to individual SSRIs to determine if all SSRIs possed similar levels of PPHN risk. When treating a pregnant woman with Lexapro during the third trimester, the physician should carefully consider both the potential risks and benefits of treatment [see Dosage and Administration]. Physicians should note that in a prospective longitudinal study of 201 women with a nistory of major depression who were eurlymic at the beginning of pregnancy, women who discontinued antidepressant medication during pregnancy were more likely to experience a relapse of major depression than women who continued antidepressant medication. Labor and Delivery-The effect of Lexapro on labor and delivery in humans is unknown. **Nursing Mothers**-Escitalopram is excreted in human breast milk. Limited data from women taking 10-20 mg escitalopram showed that exclusively breast-fed infants receive approximately 3.9% of the maternal weight-adjusted dose of escitalopram and 1.7% of the maternal weight-adjusted dose of desmethylcitalopram. There were two reports of infants experiencing excessive weight-adjusted dose of desmethylcitalopram. There were two reports of infants experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a racemic citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of racemic citalopram by its mother and, in the second case, no follow-up information was available. Caution should be exercised and breastfeeding infants should be observed for adverse reactions when Lexapro is administered to a nursing woman. **Pediatric Use**-Safety and effectiveness of Lexapro has not been established in pediatric patients (less than 12 years of age) with Major Depressive Disorder. Safety and effectiveness of Lexapro has been established in adolescents (12 to 17 years of age) for the treatment of major depressive Disorder has not been systematically evaluated, maintenance efficacy can be extrapolated from adult data along with comparisons of escitalopram pharmacokinetic parameters in adults and Adolescent patients. Safety and effectiveness of Lexapro has not been established in pediatric patients less than 18 years of age with Generalized Anxiety Disorder. **Gentric Use**-Approximately 6% of the 1144 patients receiving escitalopram in controlled trials of Lexapro in major depressive disorder and Adole were 60 years of age or of age with Generalized Anxiety Disorder. Gerlatir Use-Approximately 6% of the 1144 patients receiving escitatopram in controlled trials of Lexapro in major depressive disorder and GAD were 60 years of age or older; elderly patients in these trials vase insufficient to adequately assess for possible differential efficacy and safety measures on the basis of age. Nevertheless, greater sensitivity of some elderly individuals to effects of Lexapro cannot be ruled out. SSRIs and SNRIs, including Lexapro, have been associated with cases of clinically significant hyponartermia in elderly patients, who may be at greater risk for this adverse event [see *Hyponatremia*]. In two pharmacokinetic studies, escitatopram half-life was increased by approximately 50% in elderly subjects as compared to young subjects and C<sub>MM</sub> was unchanged [see *Clinical* hyginardet José in classing subjects as compared to young subjects and C<sub>MM</sub> was unchanged [see *Clinical* hyginardet José in classing subjects as compared to young subjects and C<sub>MM</sub> was unchanged [see *Clinical* hyginard h elderly and younger patients, but again, greater sensitivity of some elderly individuals cannot be ruled out. DRUG ABUSE AND DEPENDENCE: Abuse and Dependence; Physical and Psychological Dependence-Animal studies suggest that the abuse liability of racemic citalopram is low. Lexapro has not been systematically studies suggest that the abuse liability of racemic citalogram is low. Lexapro has not been systematically studied in humans for its potential for abuse, tolerance, or physical dependence. The premarking clinical experience with Lexapro did not reveal any drug-seeking behavior. However, these observations were not systematic and it is not possible to predict on the basis of this limited experience the extent to which a  $\dot{CNS}$ -active drug will be misused, diverted, and/or abused once marketed. Consequently, physicians should carefully evaluate Lexapro patients for history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse (e.g., development of tolerance, incrementations of dose, drug-seeking behavior). **OVERDOSAGE:** Human Experience-In clinical trials of escitalopram, there were reports of escitalopram overdose, including overdoses of up to 600 mg, with no associated fatalities. During the postmarketing evaluation of escitalopram, Lexapro overdoses involving overdoses of over 1000 mg have been reported. As evaluation of escitalopram, Lexapro overdoses involving overdoses of over 1000 mg have been reported. As with other SSRIs, a fatal outcome in a patient who has taken an overdose of escitalopram has been rarely reported. Symptoms most often accompanying escitalopram overdose, alone or in combination with other drugs and/or alcohol, included convulsions, coma, dizziness, hypotension, insomnia, nausea, vomiting, sinus tachycardia, somnolence, and EGC changes (including OT prolongation and very rare cases of torsade de pointes). Acute renal failure has been very rarely reported accompanying overdose. **Management of Overdose**-Establish and maintain an airway to ensure adequate ventilation and oxygenation. Gastric evacua-tion by lavage and use of activated charcoal should be considered. Careful observation and early care case sign monitoring are recommended, along with general symptomatic and supportive care. Due to the large volume of distribution of escitalopram, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. There are no specific antidotes for Lexapro. In managing overdosage, consider the possibility of multiple-drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of any overdose.

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# government news

# Bill Would Have Government Pay Malpractice Costs for Some M.D.s

Under proprosed legislation, psychiatrists and other clinicians could forego obtaining liability insurance for care they provide as volunteers at community health centers.

### BY RICH DALY

sychiatrists and other physicians volunteering their medical expertise at community health centers might not need to worry about obtaining malpractice insurance if a federal legislative proposal to provide liability protection for such care becomes law.

However, the path to enactment for the Family Health Care Accessibility Act (HR 1745), which was approved by a House of Representatives panel in July, could be complicated by new estimates that set its price tag at more than twice as high as originally thought.

The Congressional Budget Office released an estimate in September that concluded that the proposal would cost

# legal news

about \$18 million over five years, significantly higher than its sponsors' initial estimates of \$7.5 million over that time. The bill's cost is based on estimates of the federal government's paying for the defense of any clinician facing a lawsuit relating to care at a community health center and paying proven claims.

Even with the higher price tag, supporters maintain that the legislation would bolster the substantial taxpayer saving already derived from these health centers. The federal government saves nearly \$18 billion a year by providing care through the health centers, instead of having to fund much more costly emergency-room care for indigent patients.

Moreover, supporters said they are

still optimistic about its outlook for passage due to its bipartisan support unusual in the current Congress—and the increasingly important role of community health centers in providing care to indigent Americans.

Rep. Tim Murphy (R-Pa.), a psychologist, sponsored the legislation and teamed up with Rep. Gene Green (D-Texas) to support physicians, especially retired ones, who want to volunteer to provide medical care at those health centers and may face substantial malpractice costs to do so, depending on their specialty area. Such costs can deter clinicians from volunteer work.

"It is extremely important to the community health centers in my area and across the country to be able to bring on licensed medical practitioners willing to volunteer their time with the support of federal liability coverage," said Green in a written statement.

Additionally, the centers have taken on a large and growing role in the public health care safety net under the health care reform law enacted earlier this year. That measure increased funding for community health centers by \$11 billion and required them to provide care for up 40 million patients by 2015, which would double their current capacity.

The measure would amend the Federal Tort Claims Act, which provides liability protection to employees and contractors of federally funded health centers because they are considered federal employees. That protection would be extended under the bill to clinicians who volunteer at the health centers.

"Although the amount of patients at community health centers is rapidly growing, the number of physicians available to treat these patients is decreasing," Murphy said after a subcommittee approved the legislation in July.

He pointed out that some community health centers report they are unable to fill up to 20 percent of their staff physician positions. Additionally, in 2009 more than 3,400 positions for primary care physicians were unfilled, stressing a system that is already far short of the capacity needed to treat the low-income people who depend on these health centers—70 percent of whom have incomes below the federal poverty level.

The health center legislation can be accessed at <bttp://thomas.loc.gov> by searching on the bill number; HR 1745. ■

# APA Joins Case to Overturn Ban on Same-Sex Marriage

The amicus brief APA signed onto asserts that marriage confers emotional and psychological benefits denied to same-sex couples under Proposition 8 and that the right to marry would benefit the children of such couples.

There is no scientific basis for distinguishing between same-sex couples and heterosexual couples with respect to the legal rights, obligations, benefits, and burdens conferred by civil marriage, according to a brief signed by APA in support of plaintiffs seeking to overturn California's Proposition 8, which banned same-sex marriage.

The amicus curiae, or "friend of the court," brief was filed by attorneys for the American Psychological Association, with the support of APA, the California Psychological Association, and the American Association for Marriage and Family Therapy.

The case at issue is *Perry v. Schwarzenegger*, a federal lawsuit filed in the United States District Court for the Northern District of California challenging the constitutionality of Proposition 8, a 2008 ballot initiative that amended the California constitution to mandate that "only marriage between a man and a woman is valid or recognized in California."

This past August, Chief Judge Vaughn Walker ruled that Proposition 8 violated the due-process and equal-protection clauses of the 14th Amendment to the United States Constitution.

The case, awaiting appeal, has garnered nationwide attention, and a wide variety of organizations have filed briefs in support of or against the plaintiffs. The brief signed by APA asserts that marriage confers emotional, psychological, and material benefits that are denied under Proposition 8 to same-sex couples.

BY MARK MORAN

"[E]mpirical research demonstrates that marriage has distinct benefits that extend beyond the material necessities of life," according to the brief. "As a legal institution, marriage also gives legally wed spouses access to a host of economic and social benefits and obligations. Research [has established] that both tangible and intangible elements of the marital relationship have important implications for the psychological and physical health of married individuals and for the relationship itself. Because they are denied the opportunity to marry, California partners in same-sex couples are denied these benefits."

The brief also argues that homosexuality is a normal expression of human sexuality, that gay men and lesbians form stable relationships equivalent in essential aspects to heterosexual relationships, and that many same-sex couples are currently raising children who will benefit if their parents are allowed to marry.

"Allowing same-sex couples to legally marry will not have any detrimental effect on children raised in heterosexual households, but it will benefit children being raised by same-sex couples," the brief states. "First, those children will benefit from having a clearly defined legal relationship with both of their *de facto* parents, particularly for those families that lack the means or wherewithal to complete a second-parent adoption. Such legal clarity is especially important during times of crisis, ranging from school and medical emergencies involving the child to the incapacity or death of a parent.

"Second, children will benefit from the greater stability and security that is likely to characterize their parents' relationship when it is legally recognized through marriage. Children benefit when their parents

### professional news

Hollywood continued from page 13

Moreover, the media can contribute to both an unhealthy obsession with underweight media figures and a food-focused culture linked to the nation's growing numbers of children who are overweight, according to Judy Shoenberg, senior researcher at the GSRI, at a Capitol Hill event on girls' media images.

The issue also has surfaced in Congress. Rep. Tammy Baldwin (D-Wis.) introduced legislation (HR 4925) last summer to fund an expansion of research on children's portrayals in the media.

The EIC partnership with the Girl Scouts aims to complement the scouts' other recent efforts in this area. The Girl Scouts recently partnered with the National Association of Broadcasters and the National Cable and Television Association to air a series of public-service announcements that encourage girls and young women to "Watch What You Watch" and avoid unhealthy images and are financially secure, physically and psychologically healthy, and not subjected to high levels of stress. They also benefit when their parents' relationship is stable and likely to endure. Thus, the children of same-sex couples can be expected to benefit when their parents have the legal right to marry."

More information about the case, including the brief filed by APA and other organizations, is posted at <www. ca9.uscourts.gov/content/view.pbp?pk\_ id=0000000472>.

portrayals that reinforce negative stereotypes about them.

The continued pop-culture perpetuation of unhealthy images of girls and women requires the existence of viewers who are willing to watch such television, movie, and advertising images. To address the issue from the consumer side, the initiative also seeks to encourage women and girls to stop spending time and money on entertainment or products that feature images that are detrimental to their own health—whether those images are in the traditional entertainment media or in the unfiltered world of online content. Loss of audience will decrease their profitability.

"We saw that with mental illness, where in addition to an increase in the number of accurate depictions, there was an increase in the depth of those portrayals," Dyak said about the impact of her group's effort.

The report of the American Psychological Association Task Force on the Sexualization of Girls is posted at <www.apa. org/pi/women/programs/girls/reportfull.pdf>.

# clinical & research news

# Sequelae of Childhood ADHD Often Evident in Adult Life

Researchers find that ADHD symptom rates persist into young adulthood for about 78 percent of boys with the disorder.

### BY AARON LEVIN

10-year follow-up study of boys with attention-deficit/hyperactivity disorder (ADHD) finds that the disorder persisted into their early adult years in 3 out of 4 of the subjects, leaving them vulnerable to poor psychiatric outcomes and life prospects, said Joseph Biederman, M.D., a professor of psychiatry at Harvard Medical School and Massachusetts General Hospital.

Long-term outcome data in those with ADHD are hard to come by, he said at the APA Institute on Psychiatric Services in Boston in October.

Not only can ADHD research be quite expensive and difficult to carry out, he explained, but also selection criteria, duration of follow-up, and age at follow-up can vary from study to study, making it difficult to compare study populations.

Definitions of persistence and remission in ADHD studies can also be problematic, said Biederman. A patient who loses just one symptom and thus falls below full diagnostic status may be considered in "syndromic" remission. Some researchers may use "symptomatic" remission, the loss of 50 percent of symptoms. Others may use "functional" remission, a status that indicates no symptoms and no impairment.

"Depending on the definition used, 10 percent to 70 percent of your sample achieves remission," said Biederman.

Long-term studies would help clarify the course of the disorder and link the pediatric and the adult literature on illness and treatment, he noted.

At the institute, Biederman reported on long-term outcomes in 110 boys with ADHD and 105 without.

The boys were aged 6 to 17 when they were first diagnosed with ADHD. The results of the 10-year follow-up of these subjects thus overlapped with retrospective data from studies of adult cohorts.

Biederman and colleagues defined remission using full *DSM-IV* criteria. By that standard, 65 percent of the patients

could be said to be in remission at the 10-year follow-up because they did not meet the full diagnostic criteria.

However, from another perspective, only a minority of these youngsters achieved complete remission. About 78 percent had some form of persistent ADHD—about 35 percent had full persistence of the disorder, and 43 percent had partial persistence. Of that 43 percent, 22 percent had subsyndromal ADHD, 15 percent had impaired functioning, and 6 percent were in remission and still being treated. Persistence of the ADHD cor-

related with having more psychiatric comorbidities, including, in

particular, oppositional-defiant disorder, conduct disorder, anxiety, and use of psychoactive substances.

Those children with persistent ADHD also tended to do worse in school: repeating grades, needing special classes, getting suspended, and having lower high-school graduation rates than controls.

"The majority continued to struggle into their adult years," said Beiderman. "Poor educational outcomes lead to poor job prospects and worse overall long-term outcomes in life."

Thus it is crucial to address ADHD aggressively in childhood and monitor children with the disorder for residual

### Should Emotion Receive Prominence In ADHD Diagnostic Criteria?

A speaker at AACAP's annual meeting argues that emotion has unique predictive power in attention-deficit/hyperactivity disorder and should be restored to the *DSM-5* description of the disorder.

motional impulsiveness has great predictive value in attention-deficit/hyperactivity disorder (ADHD) and thus should be returned to the *DSM-5* definition of the disorder, said Russell Barkley, Ph.D., at the annual meeting of the American Academy of Child and Adolescent Psychiatry in New York in October.

The inability to regulate emotions was included in George Still's original 1902 description of what is now called ADHD, but the *DSM-II*, published in 1968, failed to include deficient emotional self-regulation, and it has remained only an "associated feature" of the definition since that time, said Barkley, a clinical professor of psychiatry at the Medical University of South Carolina.

"The current *DSM-IV* definition also misses a substantial minority of adults who by other definitions might be considered to have the disorder," said Barkley.

Proposed criteria under discussion for *DSM-5* include only one element reflecting emotional impulsiveness, according to Barkley.

"The only item is the new one, which is 'often impatient,' " he said. "Otherwise, emotion is unrepresented so far in the proposed changes."

### BY AARON LEVIN

The *DSM-IV* standard was never designed for adults or tested on them, he said. "If we apply *DSM-IV* criteria to adults, we find that only 25 percent of these children continued to meet these criteria. Or do we shift to appropriate developmental criteria, needing only four symptoms instead of six, and insisting that you be at the 98th percentile in the adult population in severity and impaired in one or more life activities."

In that case, he said, 66 percent of these children met that criterion by follow-up at age 27.

Emotional impulsiveness contributed "uniquely and independently" to a number of outcomes, from school and work histories to marital and driving problems, in a study of Milwaukee children followed from early adolescence to age 27, he said. That work is reinforced by other studies showing that such impulsiveness drives away friends, spouses, and coworkers, he said. A boss can forgive distractibility but not displays of anger in the workplace.

Much comorbid oppositional-defiant disorder (ODD) can be explained by emotional impulsiveness, he said. In fact, when ADHD is treated successfully, ODD symptoms usually decline as well. Any residual ODD should be considered



Russell Barkley, Ph.D.: "Emotion needs to be returned to our current conceptualization" of ADHD. "It has just as great a role to play as inattentive and hyperactive behavior."

learned behavior and treated with appropriate therapy, Barkley said.

There is some overlap with the inhibitory component of ADHD, but Barkley would like to see emotional symptoms added in place of some hyperactivity symptoms to represent the emotional element in ADHD.

"Emotion needs to be returned to our current conceptualization of this disorder. It has just as great a role to play as inattentive and hyperactive behavior and will contribute variants and unique explanatory power to understanding these impairments across the life course," he said.

### 11-Year ADHD Follow-up Study Shows Greater Comorbidity

A study of young women (mean age 22 years) indicates that despite a 92 percent lifetime treatment rate for ADHD, many have high rates of other comorbid psychiatric diagnoses.

Diagnosis	With lifetime ADHD prevalence N=96	Controls N=91
Mood disorders	48%	10%
Anxiety disorders	83%	54%
Antisocial disorder	64%	12%
Disruptive disorders	46%	18%
Substance use	44%	22%
Eating disorders	25%	9%

Source: Carter Petty, M.A., Massachusetts General Hospital

manifestations of the disorder and comorbid disorders, he said.

"Loss of a symptom should not be confused with recovery," he emphasized.

On the same program, Carter Petty, M.A., of the biostatistical unit at Massachusetts General Hospital, reported on 11-year outcomes of ADHD in girls.

Girls are an understudied population, said Petty. For every girl in clinical populations with ADHD, there are nine boys. Girls are referred to clinics at half the rate boys are, possibly because they display fewer comorbid disruptive behaviors, he suggested.

For this study, Petty compared 96 girls who had ADHD with 91 girls who did not. Their median age at follow-up was 22. About 92 percent of subjects had been treated with medications, and 42 percent took medications in the year prior to the start of the study.

"ADHD in girls is associated with higher lifetime and current comorbidity with a wide-ranging list of psychiatric disorders," he pointed out.

Lifetime and prior-year rates of mood, anxiety, antisocial, disruptive, and substance use disorders were higher in girls with ADHD than the controls (see table).

"This indicates risks similar to those for boys, suggesting that ADHD is expressed similarly in both genders," said Petty. "The rates are also similar to rates for adults with ADHD, giving further support for the continuity of ADHD from childhood to adulthood." ■



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# clinical & research news **'Complex PTSD' May Result** When Trauma Is Ongoing

Knowing that violence against women is epidemic and endemic is essential to understanding the condition of women and nature of their treatment, says psychiatrist Judith Herman, M.D.

### BY AARON LEVIN

en's and women's experience of violence differs in several ways, a fact that has guided Judith Herman, M.D.'s clinical psychiatry practice.

"A knowledge of violence against women whose lives were dominated by sexual and physical assault allowed me to listen to patients in a new way," she said in accepting the Alexandra Symonds Award at the Institute on Psychiatric Services in Boston in October. The award is cosponsored by APA and the Association of Women Psychiatrists.

Herman is a clinical professor of psychiatry at Harvard Medical School and director of training in the Victims of Violence Program at the Cambridge Hospital.

Violence against women is prevalent everywhere, the most common humanrights violation in the world, she said.

For male violence victims, the most common perpetrator is a stranger, followed by an acquaintance. For women it's the opposite. Intimate partners are the most likely attackers, followed by acquaintances, and then strangers-even though violence by strangers gets the most attention in the media.

Violence and the attendant helplessness of its victims is also a transient experience for most men, while violence against women is likely to be repeated and prolonged, she said.

This may be one reason why lifetime prevalence of posttraumatic stress disorder (PTSD) is 10 percent for women and 5 percent for men.

What social conditions produce this prolonged trauma?

"There is an array of coercive techniques, of which violence is only one, whose purpose is to establish dominance and break down autonomy and initiative," she said. "The victim is unable to escape the perpetrator, creating a contaminated identity, so the person no longer has the will to resist."

Herman has suggested the term "complex PTSD" to cover trauma experienced not in a single instance but over weeks, months, or years. Complex PTSD is characterized in particular by somatization, dissociation, and affect dysregulation.

"It leads to a shamed and damaged sense of self, disrupted interpersonal relationships, and shattered systems of meaning," she explained. "Shame is one's vicarious experience of the other's scorn."

Nevertheless, research conducted in the 1970s on victims of single episodes of rape showed that adaptive strategies for recovery do exist, she said. Women who recovered shared several characteristics.

First, they took problem-solving actions following the rape. They reported the crime to the police, changed the locks

on their doors, or took self-defense classes, for example.

They also had strong family and social support. Even when it was not immediately forthcoming, they kept trying for a caring response from the people around them. The worst outcomes were found among women who were isolated and lacked such supports.

Finally, women who emerged the best managed to create some social meaning out of their experience. They took action to help other survivors or to prevent similar crimes from happening to other women.

"The only way to make it positive is to make better for others," Herman reported one woman telling her.

As for therapeutic interventions for women who are victims of violence in general, group therapy is a "wonderful modality" for helping them, Herman pointed out.

"Group members have compassion for other members of the group, but not for themselves," she said. "But the group experience teaches them to share, to receive feedback, and to lessen their own shame."

News, October 10).

October 21 in the British Medical Journal,

seems to complement the earlier finding:

When people live among those who are of

the same ethnic background, it may help

Munshi, M.D., a Medical Research Coun-

cil fellow/lecturer at the Institute of Psy-

subjects who were members of England's

main ethnic groups-Irish, white English,

black Caribbean, Bangladeshi, Indian, and

Pakistani-and who lived in almost 900

different geographic areas of England. Sub-

jects were evaluated with the Clinical Inter-

view Schedule-Revised for current anxiety

and depressive disorders. They were also

questioned to determine whether they were

the victims of discrimination in their com-

munities and whether they had social net-

works and support in those communities.

The study was headed by Javati Das-

The study included more than 4,000

safeguard their mental health.

chiatry, King's College, London.



Judith Herman, M.D., says that "complex PTSD"—trauma that occurs over months or years-can lead to a "shamed and damaged sense of self." Looking on is Leah Dickstein, M.D., who presented the Alexandra Symonds Award to Herman at the session.

Herman noted that images of the history of modern psychiatry are telling in their depiction of women. Paintings of Phillippe Pinel liberating the insane after the French revolution or of Charcot at the Salpêtrière

### **Ethnic Integration May Not Always Benefit Mental Health**

Ethnically dense neighborhoods seem to provide some shelter from mental illness. Absence of discrimination and the existence of social supports may explain this finding, but other factors are probably at work as well.

### BY JOAN AREHART-TREICHEL

ecent research has found that being The prevalence of current anxiety and a member of an ethnic minority and depressive disorders was 16 percent in the living in an area in which that ethnic white English group, 19 percent in the group is the minority population appears Irish group, 17 percent in the black Caribto be a risk factor for psychosis (Psychiatric bean group, 13 percent in the Bangladeshi group, 18 percent in the Indian group, and Now a new finding, reported online 20 percent in the Pakistani group.

> After adjusting for age, gender, marital status, educational level, and social class, the researchers assessed whether there was a significant link between living in an area with many people who share one's ethnicity and a reduced chance of having a current anxiety or depressive disorder.

> They did find such a link for the sample as a whole, and as Das-Munshi told Psychiatric News, "The associations were strongest and most marked for Irish and Bangladeshi people within the survey," with the relationship to lower levels of anxiety or depressive disorder reaching statistical significance.

> There was also a trend in this direction for black Caribbean, Indian, and Pakistani subjects, although it did not reach statistical significance.

> The researchers likewise found that for some of the groups, living in areas of higher own-group density was associated

demonstrating the neurological basis of mental illness both symbolize the mentally ill as women with undraped bosoms-"helpless, passive, vacant," said Herman.

It would take another century and a half to eliminate the patriarchal figure at the center of the frame and admit women as equals into the ranks of the profession.

That progress has been relatively recent. About 5 percent of the psychiatrists certified by the American Board of Psychiatry and Neurology in 1950 were women, she noted. That proportion grew to 20 percent in 1980, 42 percent in 2000, and Herman expects it to reach parity this year.

"We were part of a generation writing about rape, domestic violence, and child sex-

ual abuse," she said. "The awareness of the magnitude of this problem came from outside, came from the [women's] movement into psychiatry, and the vector was people like me."

with a reduction in the reporting of discrimination and with improved social support and stronger social networks. However, none of these factors fully explained the protective effect on mental health for subjects living in areas of higher owngroup density.

This finding surprised her and her colleagues, Das-Munshi told Psychiatric News, since other studies have found a link between social support in ethnically dense neighborhoods and mental health. For example, social support was found to be a critical protective factor against depression for Irish-born immigrants to London.

Whether less discrimination and more social support explain the psychic-shelter function of ethnically dense neighborhoods, other factors are undoubtedly involved as well, Das-Munshi and her colleagues believe. One possibility, they speculated, could be cultural identity. For instance, although most of the Irish in their study had migrated to England a long time ago, and their level of ethnic density was not as high as for some other ethnic groups, they still experienced the protective mental health benefits of living among people of their ethnic group who shared much of the same cultural identity including religion, group history, and other factors.

The study was funded by the U.K. Medical Research Council.

"Understanding the Effect of Ethnic Density on Mental Health: Multi-Level Investigation of Survey Data From England" is posted at <www.bmj.com/ content/341/bmj.c5367.full>. ■



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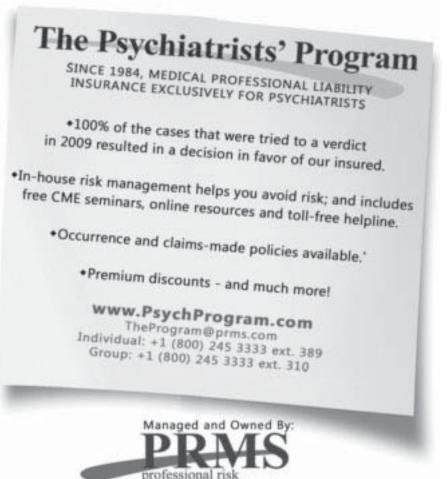


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# clinical & research news **Reform May Jolt Field** Plagued By Frustration

Although progress is being made toward getting effective treatment to Americans with substance abuse disorders, there are still daunting obstacles to overcome.

### BY JOAN AREHART-TREICHEL

n October 30, while thousands of Americans descended on Washington, D.C., to participate in a "sanity" rally, a small cadre of researchers sequestered themselves in a hotel nearby to tackle the challenge of getting effective treatment to Americans with "drinking and drugging problems," as one of the researchers put it.

Their presentations and informal discussions at the conference titled "The New Frontier in Addiction Treatment: Evidence-Based Policy and Practice" revealed how daunting the challenge of getting effective treatment to people with substance abuse problems actually is.

Only 25 percent of individuals with an alcohol use disorder seek help, John McKellar, Ph.D., a clinical assistant professor of psychiatry at Stanford University, reported, while Paul Roman, Ph.D., a distinguished research professor of sociology at the University of Georgia, noted that "Many people have a deep romance with their substances and fear that if they go for treatment, they'll have to give them up."

Even among those who pursue treatment, dropout rates are high, stated Laura Dietzen, M.A., director of data analysis at Polaris Health Directions in Fairless

Hills, Pa. In a 2004 study that she and her colleagues conducted of 315 patients in substance abuse treatment, the dropout rate was 66 percent. "The definition of dropout was a note in the clinical record that the patient had quit treatment at any time," Dietzen said. In a larger study of 1,500 such patients, which they conducted from 2003 to 2007, they found a dropout rate of 53 percent. "For this study, we looked at patients who dropped out within approximately 30 days of intake," Dietzen said.

And even when people do get substance abuse treatment, relapse is unfortunately still the norm, David Farabee, Ph.D., a professor-in-residence of psychiatry at the University of California at Los Angeles. lamented.

### Not Just an American Dilemma

And the dropout and relapse morass isn't just one that plagues the United States. It's occurring in other countries as well—for example, the Netherlands.

During the late 1990s, politicians in the Netherlands charged that substance abuse treatment services in their country were ineffective, and their outcry led to a nationwide treatment-reform program. One of the objectives was to offer evidence-based practices and a stepped-

### Medication Rare in Addiction Treatment

At the recent "New Frontier in Addiction Treatment" conference (see article above), Paul Roman, Ph.D., a distinguished research professor of sociology at the University of Georgia, argued that medications used to treat substance abuse, such as naltrexone, acamprosate, and buprenorphine, hold great promise but are "frozen."

'We have failed to educate the public about medication-assisted treatments, or MAT," he asserted. "The public doesn't know anything about this stuff. It needs to know something or we are not going to get anywhere with it." This is especially the case regarding youth with substance abuse problems, he believes.

Only about one-third of substance abuse programs in the United States are using MAT in one way or another, he continued. Usually they are larger programs located in a hospital setting or that have a physician on staff.

But even 41 percent of private substance abuse programs with a physician on staff do not use MAT, and 82 percent of public substance abuse programs with a physician on staff do not do so. Programs that place a strong emphasis on the 12-step model of treatment are significantly less likely to use MAT than other types of programs.

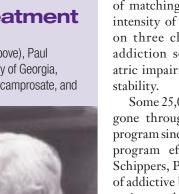
Another barrier to the use of MAT is lack of physician training in how to deploy the medication treatments, Roman pointed out. For example, psychiatrists may need guidance in using injectable naltrexone (Vivitrol)

"We would like to move MAT into primary care," said Roman, "but that is only a dream at this point. Peter Miller, Ph.D., a professor at the Medical University of South Carolina's Center for Drug and Alcohol Programs, agreed. The larger problem, Miller said, is that detecting or treating alcohol use disorders in primary care is far from routine.

"So is the fact that the glass is only one-third full in terms of using MAT a cause for alarm?" Roman asked. "I don't know," he said. "We have made progress, but this is a field that remains on the defensive."



Paul Roman, Ph.D.: "We have failed to educate the public about medication-assisted treatment" for substance abuse.



find out.

tive-behavioral therapy (BCBT) or standard CBT (SCBT). Drinking behavior was assessed at nine months followup. In ment, and in SCBT, only 41 percent did. Moreover, at follow-up, only 25 percent had achieved abstinence.

Furthermore, there is a high turnover rate of providers in the substance abuse treatment field, Patrick Flynn, Ph.D., director of the Institute of Behavioral Research at Texas Christian University, noted.

In the United States, there is no national strategy for delivering substance abuse

### **Research Findings Lost in Translation**

At the "New Frontier in Addiction Treatment" conference (see article at left), Harold Perl, Ph.D., discussed the challenge of disseminating not just new substance abuse treatments but other types of new medical treatments into clinical practice.

Perl is senior lead for behavioral research, dissemination, and training at the National Institute on Drug Abuse's Center for the Clinical Trials Network.

"Today, billions of dollars are spent on health research in the United States, but we still know little about how to get the results disseminated, because very little research is conducted on the subject," he stated. "More specifically, 99 percent of the National Institutes of Health research budget is spent on understanding disease and developing new treatments, but only 1.5 percent is spent on finding ways to effectively use those new treatments."

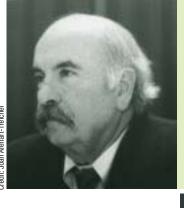
"Perhaps we are addicted to discovery and chasing that Nobel Prize without regard to the circumstances," he continued. "Few investigators focus on implementation science because the time spent on it is not valued. So we should reward those individuals who commit to this type of science."

"But it's not just implementation science that is needed to get new treatments out into the real world," he stressed. Human efforts are needed as well.

For example, one audience member said that she had tried to get addiction counselors to adapt a new evidence-based treatment, but had not succeeded because the counselors were so overwhelmed with other concerns, such as a lack of space, too few physicians, and inadequate funding levels. "Maybe you could help them with these concerns and thereby build an alliance with them," Perl suggested. "And after that, maybe they would be open to adopting the new treatment that you are promoting.'

"It is also important to have a team of individuals in an organization implement a new treatment," Perl noted. "One individual alone cannot do it. Moreover, it is a long-term process."

"We also know some of the things that don't work in the dissemination of new treatments," he pointed out, "for example, simply publishing research results or practice guidelines."



Patrick Flynn, Ph.D. : "We have a wealth of new knowledge out there waiting to be applied. We have to get it into the programs that are providing care."

care model, which consists of matching patients to the intensity of treatment based on three characteristicsaddiction severity, psychiatric impairment, and social

Some 25,000 patients have gone through this retooled program since 2002. But is the program effective? Gerard Schippers, Ph.D., a professor

of addictive behaviors and treatment evaluation at the University of Amsterdam, and colleagues conducted a study of some 600 alcoholic patients admitted for outpatient treatment in two addiction centers to

Patients were assigned on the basis of a stepped-care protocol to brief cogni-BCBT, only 59 percent completed treat-

> speakers indicated. It is the most transformative time that the substance abuse treatment field has ever seen due to the new health insurance reform law that is designed to provide 32 million uninsured Americans with health insurance, Deni Carise, Ph.D.,

please see Addiction on facing page

Deni Carise, Ph.D.:

"This is the most

our field has ever

seen."

treatment, Flynn asserted. Before 1992,

both substance abuse treatment research

and clinical care were under the same fed-

eral roof. Since then, they have been under

the aegis of two separate federal agen-

cies-the National Institutes of Health

for research and the Substance Abuse and

Mental Health Services Administration

(SAMSHA) for delivery of care. "So what

we have here in the U.S. is an orchestra

But the situation for substance abuse

care isn't all dour, several conference

Some Good News Reported as Well

without a conductor."

transformative time

# clinical & research news

# **Small Victories Are Big Milestones On Road to Recovery**

The often difficult-to-treat combination of substance use disorder and another mental illness requires a comprehensive, integrated, recoveryoriented approach to care.

# BY AARON LEVIN

o-occurring psychiatric and substance use conditions are a common combination, not an exception, and demand a simultaneous, multifront approach to treatment, said Kenneth Minkoff, M.D., at APA's Institute for Psychiatric Services in Boston in October.

"Which problem is primary?" Minkoff asked his audience. "All problems are primary, and the correct intervention is to deal with all the problems at the same time."

This comprehensive, continuous, integrated system of care (CCISC) rests on evidence-based principles of treatment articulated through clinical strategies applied by all members of the clinical team, he said.

The CCISC approach has been used in some way in 28 states and dozens of other jurisdictions, said Minkoff, manager of operations and senior advisor at ZiaPartners Inc., a behavioral-health consulting firm in San Rafael, Calif.

Minkoff said his goal is to develop an empathic, integrated, strength-based relationship with patients. Rather than starting with the patients' failures, he suggested, look at the times when they succeeded in not using substances. Discuss how they got to that point, how they stayed there, and when and why they went backward.

"Listen closely to patients on the first visit," he advised. "Get good at getting people's stories, not just their symptoms, then help them articulate their personal vision of treatment and outcomes."

Patients may have issues in many categories, not just addiction in combination with psychiatric disorder, but also general medical, housing, and employment problems.

The clinical team should identify each applicable issue then develop what Minkoff called a "parallel primary recovery process" to help patients move through stages of change and phases of recovery for each co-occurring condition.

Patients can be assessed in six dimensions, said David Mee-Lee, M.D., who spoke on the same panel: intoxication levels, biomedical conditions, emotional/behavioral issues, readiness to change, potential for relapse, and relapse prevention.

"Finally, there is the recovery environment in which the patient lives: the family, legal, work, and financial settings,"



David Mee-Lee, M.D., senior vice president of the Change Companies in Carson City, Nev., says that for patients with co-occurring disorders, psychiatrists should follow up a thorough biopsychosocial assessment with recovery planning that draws on patients' strengths, resources, and supports, as well as resolves their pathologies.

said Mee-Lee, who is senior vice president at the Change Companies in Carson City, Nev.

"The stages-of-change process is problem specific, not person specific," Minkoff said. "Help people make little bits of progress without struggling. Breaking down the process into small steps makes it easier to do."

In another example of technology in service to substance abuse treatment, there is a Web-based program from the Netherlands called "Drinking Less" that offers the public a chance to assess their drinking habits and, if they are overdoing it, attempt to quit or cut down with the help of CBT and self-control techniques, McKellar reported. A randomized, controlled study conducted in 2003-2004 showed that individuals who had participated in the program drank significantly less a year later than did those who had not participated, he said.

During an 11-month period, more than 18,000 people visited the "Drinking Less" Web site, and 24 percent of them took part in its program, according to information available on the site.

"Developing more accessible interventions such as this one could expand the reach of treatment," McKellar remarked.

# Where to Go From Here?

But where should the substance abuse treatment field go from here?

"I think we are starting to view addiction care as a broader health issue than we used to, and thus we are more interested in bringing it into the medical care system," Harold Perl, Ph.D., ventured. That's a positive shift, he believes. Perl is senior lead for behavioral research, dissemination, and training at the National Institute on Drug Abuse's Center for the Clinical Trials Network. For these patients, treatment is about learning first how to play an informed role in planning and managing their own treatment, and then in gaining self-management skills and a willingness to seek help from professionals, family, and peers when they hit rough spots.

And since hurdles do arise on the road to recovery, some kind of contingency planning is necessary, he said. "Don't create a learning process that moves faster than the person can handle."

If a patient was taking medications 75 percent of the time, try to get him or her to 80 percent, rather than 100 percent, for example.

Rewards are better than punishment, so applaud any small increment of success, he said.

Ultimately, the clinical team and the patient have to share an understanding of the patient's condition from his or her point of view, the diagnoses that the doctors have given the patient, and the treatment plan.

The patient's "job" means first coming to terms with the reality of having a substance abuse problem along with another psychiatric illness and then deciding that he or she wants neither and develops an identity than involves treatment for both, said Minkoff.

"It is our job to understand the patients" job, to join them in it, and help them do better," he said. ■

"If we're going to look at the larger picture, then let's also consider prevention," one discussant proposed. "Maybe we should focus more on changing people's environments than on changing people themselves to reduce substance abuse and addiction."

"That's a good point," Perl said. "We cannot change individual behavior in isolation."

Roman agreed, citing an example of how environment influences alcohol consumption at the University of Georgia. Back in the 1960s, Athens, the town where the university is located, was "dry" and had no bars. Today, there are 117 bars, and the University of Georgia was rated the fourth-biggest party school in the United States by the *Princeton Review* in 2009.

"I think the American way is to let the drinking or drugging environment blossom without any intervention, with a few exceptions, for example, stronger drinking and driving laws," Roman declared.

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# Addiction

continued from facing page

declared. Carise is senior vice-president and chief clinical officer of Phoenix House, which encompasses more than 100 substance abuse treatment programs in 10 states. The new health insurance law—the Patient Protection and Affordable Care Act—states that insurance companies must offer substance abuse treatment, so those programs need to gear up to treat more patients than they do now, she said.

Robert Morrison, executive director of the National Association of State Alcohol and Drug Abuse Directors, concurred: "We see federal health [insurance] reform having a huge impact on [substance abuse] services." The passage of universal health insurance in Maine, Massachusetts, and Vermont before the federal law was enacted increased demand for substance abuse treatment in those states, he said.

"We have a wealth of new substance abuse treatment knowledge out there waiting to be applied," Flynn observed.

For example, Katherine Watkins, M.D., a psychiatrist and researcher at the Rand Corp. in Santa Monica, Calif., and colleagues conducted a study to see whether addiction counselors could achieve competence in delivering group CBT for depression to substance abuse patients who were also depressed. The study showed that these counselors were effective in providing such therapy, Watkins reported. Furthermore, patients who received the counselors' help not only engaged in significantly less alcohol and drug use by the end of the study, but were significantly less depressed by then as well. "The study was for three years, and we conducted three- and six-month follow-ups," Watkins explained. "We finished data collection about a year ago."

# **Dissemination Is Under Way**

Efforts to disseminate evidencebased practices in the substance abuse treatment field are also under way. For instance, Randolph Muck, M.Ed., chief of the Targeted Populations Branch of SAMSHA's Center for Substance Abuse Treatment, and colleagues are training clinicians how to deliver evidence-based treatment to adolescents with substance abuse problems. After Muck and his colleagues have worked with clinicians intensively for three years, the clinicians should be able to replicate the treatment at their own site, Muck said.

Technology is likewise galvanizing substance abuse treatment.

For instance, Richard Rawson, Ph.D., associate director of the Semel Institute for Neuroscience and Human Behavior at the University of California at Los Angeles, and colleagues found, in a study in South Africa, that videoconferencing was an effective and economic way to train substance abuse treatment providers.

# residents' forum

# **Recession Imposes New Challenges On Psychiatric Care**

ew people in the United States have escaped the dramatic economic and social impact of the recession that has plagued the country for several years now. Many people with mental health problems, especially chronic disorders, have found themselves especially disadvantaged since they may possess lower skill sets and have fewer social supports than most of the U.S. populace.

Atlanta, where we are both residents, has turned out to be no exception to the economic downturn and its consequences, and since the recession began, we have encountered myriad difficulties in delivering the psychiatric care that our patients need.

With millions of jobs lost nationwide, many have found themselves not only losing their homes but also their health care coverage. This has led to more than 50 million Americans being uninsured, several million more than was the case just a few years ago. This rise has been coupled with an increased demand for psychiatric services, especially emergency and crisis services. Our outpatient clinics have historically served Georgia's uninsured indigent population, but staff are now seeing much greater diversity in the patient base. Our waiting rooms have teachers, business people, and academics sitting alongside our indigent patients, and in this economy some of those professionals may be indigent as well. Diversification in the patient population has presented new challenges for residents who now encounter different patient expectations, ideas, and concerns.

We have seen how disruption to patients' support networks can destabilize them in the community and negatively affect adherence to medications and attendance at psychiatric follow-up visits, which in turn increase the use of crisis intervention and inpatient treatment. For example, relatives and caregivers who are now dealing with more limited finances and time may struggle to provide their usual levels of support to our patients. A family's loss of its car can prevent a patient from being transported to an outpatient appointment or to get a prescription filled.

It has thus become routine that we need to inquire about patients' support networks and understand how recent financial changes may be related to our patients' current presentation. It is more crucial than ever that we work collaboratively with patients to produce plans that will safeguard their adherence to medications and psychiatric follow-up if circumstances have changed their support system. Our medications might not work for everyone, but left uncollected on a pharmacy shelf, they will certainly help no one. It is important to appreciate that our role can't end with the signing of a prescription

Arshya Vahabzadeh, M.D., and Justine Wittenauer, M.D., are PGY-1 residents in the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine. BY ARSHYA VAHABZADEH, M.D. JUSTINE WITTENAUER, M.D.



Arshya Vahabzadeh, M.D., and Justine Wittenauer, M.D.

but in collaborative efforts that enable our patients to receive the full care they need.

An important aspect of psychiatric treatment is continuity of care. Several media reports have indicated that many patients who need psychiatric crisis intervention have recently moved to Atlanta, either to find work or to move in with family members who can support them. Often patients have made few if any provisions for their mental health care needs in Atlanta prior to their move. As a result, patients frequently lose the continuity of their care, which is especially crucial for psychiatric patients. They experience decreased social support and find difficulty in obtaining medication refills in their new and unfamiliar environment. These factors, combined with the stress of moving and unemployment, create conditions that are ripe for causing a relapse or development of new mental health problems. It is important for us to recognize these stressors and be knowledgeable about local community services such as outpatient clinics and shelters. We should also remember to seek help from social workers experienced in connecting patients with appropriate resources.

Nationwide, our economic problems led to 32 state mental health agencies reporting budget cuts in 2009, despite a considerable rise in demand for services. This situation has forced both public and private hospitals to look closely at the services they provide, but even minor cutbacks affect accessibility of these services, often for people with few alternatives. An example of such a cutback was the loss of FOCUS, an intensive day program for uninsured adults with severe and persistent mental illness at Atlanta's largest public hospital, Grady Memorial. The program was widely acclaimed and provided a unique learning opportunity for residents, but it was not immune to the reorganization of services seen in many psychiatric hospitals in the last few years.

The loss of significant resources coupled with a rise in the need for psychiatric emergency services raises two points for residents. First, it illustrates how crucial it is that we take an active role in advocacy for our patients, our hospitals, and our profession. We must take the time to contact and meet with local and state policymakers to ensure that our voice is heard and our mental health resources are safeguarded. Second, we must remain up to date with local service availability and referral routes so we can minimize delays and obtain the care our patients need.

Thankfully, as residents we are fortunate to have the support and guidance of our experienced teachers to help us understand and navigate these new obstacles as well as traditional ones as we try to get the best care possible for our patients. At this especially difficult time, learning, resolve, and commitment will not only help our clinic practice but benefit our patients' lives.

# DSM-5

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into patient reports of their symptoms and functioning.

These brief measures are easy for patients to complete and evaluate numerous important domains of functioning, such as mood, anxiety level, change in cognition, sleep quality, substance use, and more. They also give patients an opportunity to discuss more concerns than if the clinician had concentrated primarily on the chief complaint.

Many of the questionnaires used in the field trials are drawn from the National Institutes of Health's aptly titled research initiative, Patient Reported Outcome Measure Information System (PROMIS). For instance, a patient who reports experiencing depressed mood or loss of interest would complete the eight-item PROMIS mood scale. This should alert the clinician to the level of depressed mood and the possible presence of a mood disorder or the presence of significant mood disturbance as part of any other disorder in the DSM.

The inclusion of these measures does add extra time to the field trial clinic visits, but the opportunity to gather potentially useful clinical data-and, in doing so, making patients active participants in their own care—outweighs the minor time cost. In fact, in the *7AMA* survey, visits in which patients completed their entire list of concerns lasted on average 15 minutes and 18 seconds-a mere 26 seconds longer than visits in which patients' concerns were not completely solicited (14 minutes and 52 seconds, on average). The forms completed by field trial clinicians include a reminder to ask whether the patient has any additional concerns not reflected in the measures. Of course, one of the goals of the field trials is to determine how feasible or realistic DSM-5 revisions are to realworld settings. If patient feedback suggests the questionnaires are burdensome, their role in DSM-5 may need to be reconsidered and reduced in importance.

Another aspect of the field trials designed with patients in mind is the structure of the study visits, which are staggered in a way to mimic routine clinic visits. All patients are asked to take part in a clinical interview during their first study appointment, and the interview is then repeated by a different clinician at a second visit. In the large-setting field trials, this second interview can occur as soon as four hours after the initial visit, enabling patients to complete both interviews in one day, or as late as two weeks later, allowing patients the flexibility to schedule the interviews concurrently with other appointments. The third study visit can occur anywhere from four to 12 weeks after the second. Since many patients see their psychiatrist for monthly or bimonthly medication checks, the third interview can take place at a time that coincides with a regularly scheduled appointment.

For the routine clinical-setting field trials, patients are asked to participate in only two interviews. The second study visit is scheduled four to 12 weeks after the first, again providing some flexibility to help reduce inconvenience to patients.

Asking patients to do anything beyond what they normally do at their appointments always carries some risk for creating burden. Then why are we asking patients to complete these forms? It is our hope that revisions to *DSM-5* will lead clinicians to perform more complete evaluations, and these questionnaires are designed to facilitate this. Patient measures are also informative to the clinician and provide a systematic method for collecting contemporaneous information. And based on findings from patient-satisfaction studies, we expect that many, perhaps even most, patients will appreciate and value the opportunity to have a fuller dialogue with their health care provider about their problems.

Whether this prediction is accurate and whether the forms help improve diagnosis and treatment planning remain to be seen. The routine clinical-practice field trials will be particularly helpful in answering these and other questions, and in the next column, I will discuss some important advantages these routine clinical-practice field trials offer over the larger, academic field trials.

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# Visit

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gists, and APA staff (including Ellen Mercer, director of APA's Office of International Affairs) traveled to the U.S.S.R. to conduct systematic videotaped interviews with hospitalized and released psychiatric patients and their relatives, and to investigate conditions at Soviet psychiatric hospitals.

"It was an extraordinary visit and a very well-coordinated work of diplomacy involving three major organizations—the State Department, APA, and the National Institute of Mental Health," recalled forensic psychiatrist Loren Roth, M.D., who was the psychiatric leader of the American delegation. "It took an enormous amount of planning and preparation to accomplish two fundamental purposes—a truly valid scientific assessment of Soviet psychiatry, including its diagnostic procedures, and assessment of the extent of abuse of psychiatry."

Most extraordinary was the unusual degree of access accorded the delegation: the Americans interviewed and videotaped patients—and where possible their relatives—without interference from authorities and in a neutral setting. Released patients were interviewed in a hotel room, while hospitalized patients were transferred and interviewed in a single Moscow hospital. The delegation was able to access records, collect urine samples, and assess the validity of Soviet diagnoses against American standards.

Moreover, they were allowed to enter Soviet psychiatric hospitals—including some of those most notorious for housing political dissidents—and interview patients at will.

"We were later told by the State Department and [then] Ambassador for Human Rights Richard Shifter that this was likely the most invasive human interchange one nation had ever conducted in another nation in the area of medical investigation," Roth told *Psychiatric News*.

It was a measure of the change under way in the U.S.S.R. and of the desperation on the part of the Soviet government to rejoin its economy with the Western world. As delegation member William Carpenter, M.D., remarked, "Sovereign nations just don't normally allow this kind of invasiveness."

# Snapshot of a System in Flux

The visit took place in an atmosphere of high drama and some tension. Memories of the trip, as related by delegation members to *Psychiatric News*, include some dramatic flourishes—among them a former patient, then on the run, who was briefly interviewed while in hiding; and more than one delegation member recalled eyebrow-raising approaches from prostitutes and merchants of black-market contraband, which were regarded as efforts to ensnare members of the delegation in compromising situations.

But the grave purpose was evident in the remarkable "snapshot" of a Soviet psychiatric system in flux that emerged and was recorded in a special book-length issue of *Schizophrenia Bulletin* titled "Assessment of Recent Changes in Soviet Psychiatry" published in English with side-by-side Russian translation. (The book appears as a supplement to *Schizophrenia Bulletin*, volume 15, number 4, 1989.)

APA Director of Research Darrel Regier, M.D., M.P.H., who was at the time director of the Division of Clinical Research at NIMH, designed and implemented along with Deputy Director Samuel Keith, M.D.—the standardized assessment methods used in the interviews.

Three teams—headed by a research psychiatrist and including a Russianspeaking psychiatrist, a forensic psychiatrist or psychologist, and two professional interpreters provided by the State Department—interviewed patients. The sample of patients for the interviews was derived from Amnesty International, a State Department list of possible dissidents, the National Academy of Sciences, and the International Association on the Political Use of Psychiatry.

That list included 33 then-hospitalized patients and 12 individuals who had been released from hospitals within the previous two years. Of the 33 hospitalized



# Ketamine and Memory Loss

n the article "Bipolar-Depression Improvement Follows Ketamine Infusion" in the September 17 issue, dissociation is described as a common side effect of ketamine. Actually, dissociation based on the loss of short-term memory has long been considered a major effect of ketamine. This function even led to the use of Sernyl, a ketamine, as an animal anesthetic. For a short time, there was also some experimentation with its use in pediatric surgery.

Instead of researchers' dismissing dissociation as an unrelated side effect of ketamine, it might be of interest to study the antidepressant effects of short-term memory loss. Such a study would be of special interest because of the possible link between the antidepressive effects of ECT Readers are invited to submit letters not more than 500 words long for possible publication. *Psychiatric News* reserves the right to edit letters and to publish them in all editions, print, electronic, or other media. Receipt of letters is not acknowledged. Letters should be sent by mail to *Psychiatric News*, APA, Suite 1825, 1000 Wilson Boulevard, Arlington, Va. 22209 or by e-mail to pnews@psych.org. Clinical opinions are not peer reviewed and thus should be independently verified.

and post-ECT memory loss.

In my book *Multiple Realities in Clinical Practice*, I have written about the effects of a ketamine, specifically Sernyl, on human subjects.

> JOHN S. KAFKA, M.D. Bethesda, Md.

patients, 17 were released prior to or concurrent with the delegation visit in what Regier called "the most miraculous recovery from mental illness ever visited upon a country."

Of the 16 remaining hospitalized patients, the U.S. team found evidence of severe psychotic disorder in nine patients, with diagnoses that broadly corresponded to those of the Soviet psychiatrists. Five of the hospitalized individuals, however, were found to have no mental illness at all, including one who had been diagnosed with schizophrenia following a period of active involvement in human-rights protests.

Additionally, the U.S. team found that neuroleptic medications had been used to treat patients for "delusions of reformism" and "anti-Soviet thoughts" in the absence of accepted indications of psychosis. Charges of the use of sulfazine injections, ostensibly to enhance neuroleptic treatment but typically producing pain, immobility, and muscle necrosis (suggesting punitive rather than therapeutic purposes), were also confirmed by the American delegation.

Among the 12 recently released patients, the U.S. team found no evidence of past or current mental disorder in nine, and the remaining three had mild symptoms that would not typically warrant involuntary hospitalization in Western countries (see box on page 9).

# Emergence of Independent Civil Society

The denouement of the remarkable confrontation between Western and Soviet psychiatry in the 1970s and 1980s—culminating in the 1989 delegation visit—was complex and not to everyone's liking.

At the meeting of the WPA that year in Athens, Greece, the All-Union Society was readmitted to the world body with conditions that some—such as Dutch human-rights activist Robert van Voren (author of a new book this year, *Cold War in Psychiatry: Human Factors, Secret Actors*)—considered weak and that were, in van Voren's view, largely ignored. Soviet psychiatry would remain well behind the West in standards of care, with some of those most culpable for past abuses still in power at the time of their readmittance to the WPA.

Others, like former APA medical director Melvin Sabshin, M.D., whose leadership was central throughout, said the most blatant state-sponsored abuses were ended and that the episode was a victory for ethics and for an empirical, evidence-based psychiatry over ideology.

Regier pointed to a follow-up visit of Soviet psychiatrists to the United States in 1990 in which they witnessed Western standards of care, and to renewed dialogue generally that included joint initiatives on mental health consequences of disaster and on treatment of depression in primary care.

He added that the 1989 visit and the publication of the *Schizophrenia Bulletin* report in Russian aided in the emergence over time of a new generation of psychiatrists determined to protect the profession from the arm of the state.

"One of the benefits of the report was to help them understand what had happened to their society and to their profession," Regier said. That viewpoint was echoed by delegation member Richard Bonnie, J.D., a professor of law and medicine at the University of Virginia School of Law. "One of the most important lessons from the period is the importance of a civil society, including independent professional organizations, separate and apart from the state," he told *Psychiatric News*. "The deformed nature of the Soviet psychiatric profession is one of the explanations for why it was so easily bent toward the repressive purposes of the state.

"So one of the things we wanted to support was the emergence of truly independent professional organizations that could develop and enforce codes of ethical conduct, advocate for the well-being of patients, and, when necessary, criticize regressive policies proposed by the state." ■

# Cultural Views

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Based on discussions with the patients and clinicians in her study, Alegria offered preliminary recommendations for training clinicians in diagnosing and treating patients of diverse backgrounds.

"First, make providers more uncertain about the use of intuition in patient encounters," she said. "Encourage them to be more self-reflective as well."

To those ends, she suggests using videotapes of doctor-patient encounters for later analysis, but not only by the clinicians. Ask patients to review the videos, too, and ask them when they felt connected to the therapist and when they did not, she said.

Ultimately, since the mental health workforce is so small relative to the need, and the patient population is becoming ever more diverse, perfectively matching provider and patient race or ethnicity is unlikely. If patients and clinicians can, however, make adjustments in their perceptions of groups different from their own, their encounter may prove to be a much more productive therapeutic experience than is now often the case, she said.

# Active in AMA? Let Us Know!

The AMA House of Delegates is composed primarily of physicians representing specialty organizations and physicians representing state medical societies. The AMA Section Council on Psychiatry continues to work well with the other medical specialty organizations involved in the AMA. It also wants to strengthen its relationship with the state medical societies, which comprise slightly more than half of the House of Delegates. To that end, APA would like to connect with psychiatrists who hold (or have held) leadership positions in their state or county medical society.

If you are a leader in your local or state medical society, or if you know of a psychiatrist colleague who has such involvement, please contact Becky Yowell at BYowell@psych.org or the section council chair, Carolyn Robinowitz, M.D., at carolynrobinowitz@usa.net.

# APF Program

cern the difference between typical teen behavior and the warning signs of mental illness, according to surveys that presenters conducted at the end of each session and that were compiled by APF. A similar percentage of educators were able to describe the warning signs of psychiatric illness among students. Approximately 75 percent were able to identify the professional services available to students in their school systems.

Of concern were the lower-thanhoped-for rates of program participants who identified students exhibiting the warning signs of a mental illness and took follow-up action, such as either talking to the students or their parents or referring them to a mental health professional in the school system. For example, in 2009 about 70 percent of the program's educator participants said they would talk to these students or their parents about a possible mental disor-



Bill Mecca, a crisis intervention specialist in Trumbull, Conn., says that a side benefit of the Typical or Troubled program is that it has helped schools overcome staff "territorialism" and better coordinate needed care for students.

der, and about 80 percent said that they would refer the students to a mental health professional.

The program evaluation did not ask educators why they preferred referring students to mental health workers instead of talking to the student or parents, but Linda Bueno, director of industry relations for APF, suggested that the preference stemmed from teachers' belief that mental health professionals are better trained to address psychiatric conditions with students and parents, and the teachers may be uncomfortable in conveying such information. Organizers of the program, which briefly addresses ways to discuss mental illness with students but provides no guidance on talking to parents, are considering adding information about communication with both students and parents.

APF is now conducting a follow-up survey to determine the extent to which participation in the program affected teacher responses to signs of mental illness in the months after the presentation.

# **Possible Improvements Identified**

The challenges of presenting unfamiliar information to educators during sessions that are usually wedged into packed teacher in-service and work days may require some tweaks to the program to grab their interest and improve its effectiveness, according to educators and others who have participated in the program and spoke at the October conference.

Michelle Timmons, a teacher-skills consultant and trainer of Typical or Troubled presenters in Ohio, suggested that teachers might absorb more of the



Jeannette Kaufman, a counselor for Charles County, Md., public schools, tells conference attendees about her efforts to inject more informal elements into her presentation of the program to increase its appeal to teachers.

information presented if the program was divided into mini-sessions scheduled over the course of a school year, instead of in the one- or two-hour sessions that the program now uses.

Jeanette Kaufmann, a counselor who has presented the Typical or Troubled program throughout Charles County,

In the letter, Wrynn stated that the

office has become aware that "certain

insurers refuse to accept and initiate the

processing of E/M CPT codes when psy-

chiatrists or other physicians submit those

codes for the treatment of a mental, ner-

vous, or emotional disorder or ailment."

He added that insurers who do so are in

an insurer must accept and initiate pro-

cessing of all health care claims submit-

ted by a psychiatrist pursuant to, and

consistent with, the current version of

the AMA's CPT codes, reporting guide-

lines, and conventions," Wrynn wrote.

"Accordingly, an insurer that refuses to

accept or initiate processing of an E/M

CPT code submitted by a psychiatrist

sion is a significant one that other states

should model. OHSF will be writing to

insurance commissioners in all of the

states informing them of the New York

directive and requesting them to send out

to the general medical CPT E/M codes (99201-99499) when these codes appro-

"As physicians, psychiatrists have access

Staff in APA's OHSF said that the deci-

"Because psychiatrists are physicians,

**Coding Bias** 

continued from page 1

violation of state law.

violates insurance law."

a similar letter if necessary.



Soundhari Balaguru, Ph.D., a psychology instructor at Harvard Medical School, offers suggestions on how to help educators identify the warning signs of serious mental illness among their students.

Md., public schools, said she and other program participants there noticed that teachers were much more engaged and responsive if they used a conversational approach instead of the scripted presentation provided by the program.

Implementing other suggestions would lead to a deeper revamping of the program. For example, Nadja Reilly, Ph.D., director of the Swensrud Depression Prevention Initiative at Children's Hospital Boston, suggested that program organizers add "peer leadership" elements to educate children to identify troubling signs among their fellow students. Additionally, elementary-school teachers might benefit from an amended version targeted to educators of younger children, according to Reilly.

Another major change that might benefit high-school seniors and garner more

priately describe the patient care they've provided," Ellen Jaffe, Medicare specialist with OHSF, told Psychiatric News. "The E/M codes are generic in the sense that they are intended to be used by all physicians, nurse practitioners, and physician assistants, and to be used in primary and specialty care alike. The decision to use one set of codes over another should be based on which code most accurately describes the services provided to the patient. The E/M codes give psychiatrists flexibility for reporting their services when the service provided is more medically oriented or when counseling and coordination of care are being provided more than psychotherapy."

The decision in New York was preceded by a similar one by Blue Cross/Blue Shield (BCBS) of Massachusetts in August. The new policy went into effect in September.

"We think this is momentous," Greg Harris, M.D., chair of the Committee on Managed Care of the Massachusetts Psychiatric Society (MPS), told Psychiatric News. "We have been working on this for a lot of years."

Harris, who is also a member of APA's Council on Healthcare Systems and Financing, said that psychiatric practice has evolved in such a way that the services clinicians provide today to medically complicated patients no longer fit neatly into

interest would be adding information to help college-bound students prepare for the psychological stresses and substance abuse issues they will likely face, said Bill Mecca, a crisis-intervention specialist in Trumbull, Conn.

"That could help them or other people they might interact with in college," Mecca added.

# **National Version Coming?**

Conference participants were excited that the Typical or Troubled program, which has drawn the attention of the Obama administration, could help inspire a national initiative.

Sen. Amy Klobuchar (D-Minn.) is expected to introduce legislation to train public-school teachers to identify the early warning signs of mental illness. The bill is based on an established program called Family-to-Family in Minnesota, which takes a slightly different approach than that of Typical or Troubled by training teachers to inform other educators and families about the warning signs of mental illness.

Although the fate of the expected federal legislation is uncertain, the need for this type of program is clear. Burke and other speakers highlighted the persistent, unmet mental health care needs of children in the United States, approximately 4 million of whom suffer from major mental health disorders, according to recent research. About 90 percent of these youngsters display warning signs of mental illness by age 15, but people around them need far more education to identify them.

"If this resulted in one less tragedy, then it would be worth everything," Burke said.

Information about the Typical or Troubled program is posted at <www. psychfoundation.org/OurPrograms/ TypicalorTroubled.aspx>.

either psychotherapy or medical management, the service categories traditionally used by psychiatrists.

Harris said use of the generic E/M codes allows for a more fluid approach to coding that better reflects the diverse services psychiatrists provide. "There are people for whom you are doing traditional psychotherapy, and there are patients for whom you are doing more medical-type evaluation and management services that are not strictly medication management," he said.

For example, a psychiatrist may be seeing a patient with bipolar disorder and advising the patient about all manner of issues related to general medical health without necessarily strictly managing psychiatric medications, he explained.

"We have argued that restricting us to the psychotherapy codes is discriminatory because it limits the scope of practice [to either psychotherapy or medication management]," he said. "And it is discriminatory because the restriction hasn't applied to other physicians. So we have argued for this as a matter of parity."

Harris added that MPS leaders hope to use the BCBS decision, as well as that by the New York State Office of Insurance, as a model for all insurers in Massachusetts to follow.

# ACOs

continued from page 24

based on their health conditions.

ACOs that fail to meet certain quality and cost-savings targets will face lower payments from Medicare. Likewise, individual clinicians who continue as unintegrated fee-for-service medical specialists are expected to face declining referrals, as ACOs look to partner with physicians who have shown they can lower costs and increase quality of care.

"The primary care doctors are going to have to work well with the specialists, and it is going to involve major cultural change in a lot of cases," Zezza said.

Although future private and publically funded ACOs will undoubtedly seek to include psychiatrists, the design of these ACOs will likely vary. Some ACOs are expected to use formally contracted specialists who will be committed solely to that ACO. But other ACOs will likely be open to nonexclusive agreements with specialists. That won't be an option for primary care physicians because each will be limited to treating patients in only one ACO, according to the health care law.

"Specialists can work with multiple ACOs, so maybe nothing has to change too much in terms of their business practices," Zezza said.

ety and their effects on military families.

A number of individuals were also hon-

First Lady Rosalynn Carter was hon-

ored for their work in raising awareness of

ored with the SAMHSA Special Career

Recognition Award for her work in advanc-

ing mental health awareness for 40 years.

veteran Moe Armstrong received a Life-

time Achievement Award for his contribu-

tions to the mental health recovery move-

ment and for establishing Vet-to-Vet, a

peer recovery program for veterans strug-

ers also received Consumer Leadership

Awards: Gavle Blueburd of Gainesville,

Fla; Fredrick Frese, Ph.D., of Akron,

Ohio; Clarence Jordan of Nashville,

Tenn.; LaVerne Miller of Delmar, N.Y.;

Lorrin Gehring of Provo, Utah, received

More information about the Voice

Awards is posted at <www.transitionyear.

org>. Episodes of "Healthy Minds" can

be accessed at <www.wliw.org/bealthy

and Janet Paleo of San Antonio, Tex.

the Young Adult Leadership Award.

minds>.

Five consumer advocates and lead-

gling with mental health problems.

Mental health advocate and Vietnam

mental health issues.

professional <mark>news</mark>

Physicians could benefit from ACO participation by taking advantage of HIT or cost-saving initiatives in those specific ACOs.

"So ideally it would help them become more efficient and work better with primary care physicians," Zezza said.

Fred Ralston Jr., M.D., president of the American College of Physicians, told *Psychiatric News* that psychiatrists considering the future of the practice of medicine should weigh "the hassles" and cost of joining an ACO against "the risk of being left out of an ACO that directs patients to

# Shortage

continued from page 24

"We feel that we will not have sufficient numbers of primary care doctors to support this [post health care reform] system," said Michael Barr, M.D., senior vice president of medical practice, professionalism, and quality at the American College of Physicians, during an October summit at the Carter Center Mental Health Program.

The summit convened medical experts

to analyze the potential of the looming physician shortage to impact patients' access to needed mental health care and to suggest ways to address that. Their recommendations are expected this winter.

The growing physician shortage also is expected to exacerbate the problem of most medical schools inadequately training their students to closely coordinate the treatment they provide to patients who are also receiving care from other physicians. The lack of care-coordination train-

ing in both residency and at many medical schools, said Bartlett, is most apt to affect patients with mental illness. That's because when a patient suffers from multiple chronic illnesses, psychiatric illness is usually one of them. And when mental illness is left untreated, it can undermine the ability of patients to follow the treatments for their other illnesses.

Scully noted that access to mental health care should improve as recent changes requiring public and private insurers to pay for such care are implemented under the 2008 federal insurance parity law and Medicare, which is now phasing in the same copayment for mental health care as it has for other types of health care.

"Changing the ways of paying for [mental health] care may affect more people than anything else," Scully said.

Additionally, he acknowledged that research has found shortcomings in the quality of mental health care provided by primary care physicians and urged primary care physician associations to enhance the mental health training they provide to their members.

Bartlett said both public and private insurers will spend "a lot of money" in the coming years to retrain physicians to better coordinate care with other clinicians.

Efforts to increase the overall number

other physicians in their specialty."

Psychiatrists interested in ACOs, Sanders said, should look for private insurers or employers in their area that are already launching such initiatives for information on whether psychiatrists would fit in that specific type of ACO. The PCPCC identifies emerging collaborative care pilot projects across the nation on its Web site.

More information on local collaborative care initiatives is posted at <www. pcpcc.net/pcpcc-pilot-projects>.

of medical school slots have had some success in recent years, Scully said. For instance, the increase in the number of new medical schools will help add 7,000 additional graduates every year over the next decade. Nearly two dozen medical schools either have opened recently or are expected to open in the next few years, which are the most new schools since the 1970s, Scully noted.

However, the estimated shortage of nonprimary care specialty physicians such as psychiatrists will remain,

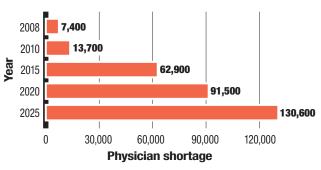
# Health Reform Could Worsen Physician Shortage

New physician workforce projections suggest that the health care reform

law will accelerate the severity of the physician-shortage problem in the

coming years as millions more Americans gain health insurance. The

situation raises the concerns of mental health advocates.



Source: AAMC Center for Workforce Studies, June 2010 Analysis

according to the AAMC, unless Congress increases Medicare-funded residency training slots by at least a 15 percent (that would add 4,000 physiciangraduates a year). Medicare funding for residency positions has been capped at 100,000 slots since 1997.

The Department of Health and Human Services (HHS) estimates that the overall physician supply will increase by just 7 percent in the next decade, which also is the expected growth rate for the number of psychiatrists. During the same period, one-third of all practicing physicians are expected to retire, and the number of Americans aged 65 and older is projected to grow by 36 percent, according to the AAMC figures.

Both APA and the AAMC are lobbying Congress for additional medical school and residency training funding. Specifically, new legislation is expected in the next Congress that would authorize a 15 percent increase in Medicare funding for residency slots, according to an AAMC official.

More AAMC projections are posted at <www.aamc.org/download/150584/data/ physician\_shortages\_to\_worsen\_witbout\_increases\_in\_residency\_tr.pdf>. The HHS physician-supply estimates are posted at <ftp://ftp.brsa.gov/bbpr/workforce/ physicianworkforce.pdf>.

# **Voice Awards**

continued from page 12

• "Mercy" (NBC) for the episode "Pulling the Goalie" addressing the effects of PTSD on military families.

• "Parenthood" (NBC) for the episodes "Pilot," "Man Versus Possum," and "The Deep End of the Pool" addressing Asperger's syndrome.

• "Temple Grandin" (HBO) for addressing autism.

# Film Category

"Adam" addressing Asperger's syndrome.
"The Dry Land" for addressing the effects of PTSD on military families.

• "Precious" for addressing depression.

# **Documentary Category**

• "Coming Home: Military Families Cope With Change" for addressing the effects of PTSD and traumatic brain injury on military families.

 "No Kidding, Me Too!" for addressing the effects of clinical depression, PTSD, bipolar disorder, and attention-deficit/ hyperactivity disorder on military families.
 "This Emotional Life" (PBS) for addressing PTSD, depression, and anxi-

# NARSAD

continued from page 12

• Carsten Nielsen, Ph.D., Ernest Gallo Clinic and Research Center, University of California, San Francisco, "Delta Opioid Receptors as Novel Targets for the Treatment of Schizophrenia."

Since 1987, NASARD has awarded a total of \$262 million in 3,832 research grants to scientists in the United States and 28 other countries. To date for 2010, NARSAD has awarded \$5 million in 57 new grants.

Benita Shobe, NARSAD president and CEO, emphasized that while nearly all charitable causes have seen a decline in donations due to the economic challenges of recent years, NARSAD strives to continue funding at the same rate.

"Economic uncertainty and instability have certainly impacted many of our donors and the support we've seen during the recession," Shobe said. "Throughout the economic recovery, NARSAD has been working tirelessly to maintain consistent support for its investigators and mental health research. In most cases, gift levels have stayed the same, signifying the importance of supporting NARSAD and its unique role in funding cutting-edge mental health research."

Exploring a better understanding of the "normal" function of the brain to better address the challenges of perceived "abnormality" is a key element to future research.

NARSAD's research funds are generated through personal philanthropic donations and are not permitted from pharmaceutical companies. All of NARSAD donations go directly to research, as all operational expenses are underwritten by two family foundations. NARSAD maintains a Web site with a community billboard featuring personal fundraisers sponsored by families who want to see donations go directly to research and events that highlight the scientific discoveries of NARSAD researchers.

*More information about NASARD is posted at <www.nasard.org>.* ■



# **Staff Clinician in Experimental Therapeutics & Pathophysiology Branch Division of Intramural Research Program** National Institute of Mental Health Bethesda, MD, USA



The National Institute of Mental Health (NIMH) Intramural Research Program, a major research component of the National Institutes of Health (NIH) and the Department of Health and Human Services (DHHS), housed at one of the premier research sites in the U.S., the 300 acre Bethesda campus of the NIH, near Washington D.C. with state-of-the-art clinical research unit and neuroimaging facilities (MRI, MRS, MEG, and polysomnography) dedicated to research, is recruiting a staff clinician to join the Experimental Therapeutics & Pathophysiology Branch of the Intramural Research Program of NIMH. Minimum qualifications are a doctoral degree, post-doctoral training, strong publication record, and demonstrated the ability to manage patients in research protocols and to effectively administrate resources when conducting clinical research (including recruitment, protocol development and implementation, and conducting single-site studies). The successful candidate will be primarily involved in patient research care and be part of a multidisciplinary team examining novel therapeutics and using neuroimaging and electrophysiological technologies to map brain activity associated with clinical response in patients with mood disorders. In addition to collaborative work within the team, there is opportunity for outstanding candidates to develop their own projects within the Branch.

Salaries are competitive and depend on level of experience. This is a full time position located in Bethesda, Maryland. Interested applicants should send a curriculum vitae, bibliography, statement of research interests, and three letters of recommendation to: Carlos Zarate, MD (zaratec@mail.nih.gov), Experimental Therapeutics & Pathophysiology Branch, NIMH, CRC, Bld. 10, Unit 7 Southeast, Room 7-3465, Bethesda, MD 20892-1282.



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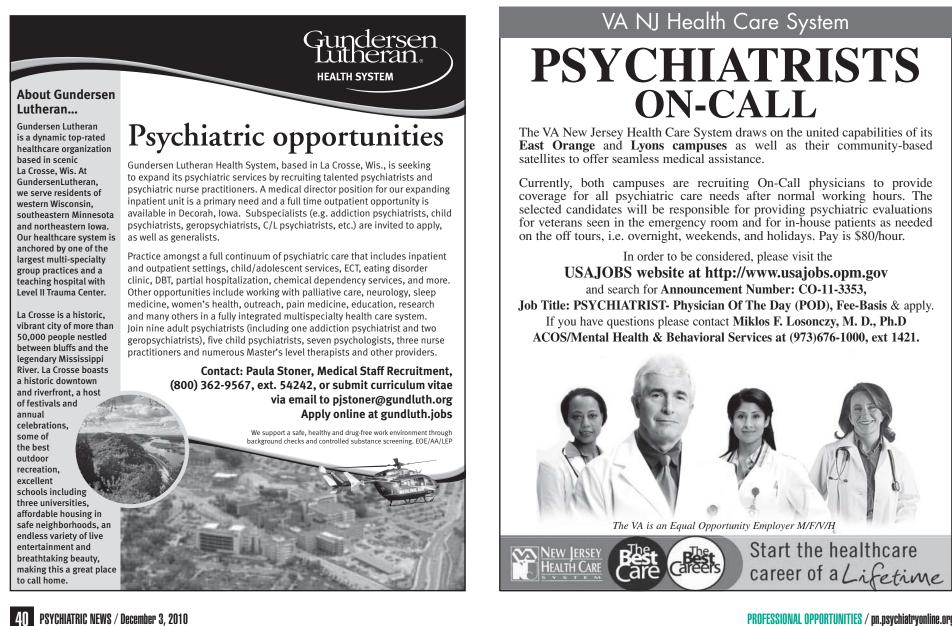
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Application deadline is December 31, 2010.

Interested applicants should send a letter of interest, a current Curriculum Vitae, and three letters of recommendation to Search Committee Chairperson:

> Michelle Jacobs-Elliott, M.D. Assistant Professor and Assistant Dean **Student Mental Health Care Center** University of Florida College of Medicine **Department of Psychiatry** P.O. Box 100256 Gainesville, Florida 32610-0256

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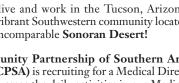
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- MISSOURI- Kansas City (General/Geriatric)
- NEVADA- Las Vegas
- NEW JERSEY- Westampton (just east of Philadelphia)
- PENNSYLVANIA- Philadelphia and State College, Shippensburg
- SOUTH CAROLINA- Columbia and Aiken • TENNESSEE- Nashville area - Medical Di-
- rector (Child)
- TEXAS- Austin, Dallas, San Angelo • WYOMING- Casper & Cheyenne

full list of facility locations.

Competitive compensation packages and benefits if employed, including bonus and student loan assistance opportunity depending on location. See the UHS website: www.uhsinc.com for

Locum Leaders is the psychiatry jobs leader. Locum tenens, perm, adult and child psych positions. Weekly pay, direct deposit, occurrence malpractice insurance, paid travel and housing, free CME and more. Visit www.locumleaders. com or call 877-562-8656.





Pharmacy Services Management.

The successful candidate will possess an unrestricted license to practice medicine (MD/DO) in the State of Arizona and be board certified or qualified in psychiatry by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry; and have at least two years experience working in a managed care setting with two years experience in medical administration and management. Knowledge of quality management and performance improvement and utilization management principles and practices is also required.

CPSA is the administrative organization responsible for coordination of publicly funded behavioral health treatment and prevention services in Southern Arizona (Pima County). We are a community-based, nonprofit organization dedicated to ensuring that individuals and families receive accessible, high-quality behavioral health services that are member and family driven, recovery oriented, respectful of cultural differences, and that foster hope and self-determination.

For more information about us, please access our website at www.cpsa-rbha.org. For more



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Over 400 permanent searches nationwide.

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ALASKA



# **Medical Director**

Come live and work in the Tucson, Arizona, area, a vibrant Southwestern community located in the incomparable Sonoran Desert!

**Community Partnership of Southern Ari**zona (CPSA) is recruiting for a Medical Director to oversee the daily activities in our Medical Management departments including Performance Improvement/Quality Management, Care Management/Utilization Management and

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Questions about the position may be directed to Marshall Lewis, MD, Behavioral Health Clinical Director, HHSA at Marshall.Lewis@sdcounty. ca.gov.

# **PSYCHIATRIC JOB FAIR!**

The Northern California Psychiatric Society's 26th Annual JOB FAIR for residents and all psychiatrists seeking full or part-time positions to be held Saturday, January 29, 2011 8:30 am in the Millberry Union Conference Center of UCSF in San Francisco. This established event connects more than 20 employers and 100 job seekers throughout the western US. For further information, call (415) 334-2418, ext. 105; FAX (415) 239-2533; or email rgeorgulas@ncps.org.

**Board Certified or Board Eligible Psychiatrist** for **Mental Health Rehabilitation Center** specializing in treatment resistant patients. Full or Part Time positions available. 98 bed locked facility including a 54 rehabilitation unit, a 12 bed personality disorder unit, and a 32 bed forensic diversion unit.

Seek experienced psychiatrist with interest in major psychiatric illnesses complicated by personality disorders and/or substance abuse. Strong medical skills and good supportive psychothreapy skills required. Familiarity with Clozaril therapy; dynamic supportive psychotherapy and Cognitive Behavioral Therapy encouraged.

Competitive salary. Negotiable based on experience. Congenial environment and well trained staff. Please contact Administrator Donna McGowan at (209) 667-9304 ext. 101, or email resume to dmcgowan@cptmhrc.com.

# COLORADO

Horizon Health seeks Medical Director and Attending Psychiatrist in Greeley, CO for a 22-bed Adult and Adolescent inpatient program and an outpatient psychotherapy and medication management clinic that sees all ages. Inpt srvcs operated on modified hospitalist model with core of three doctors covering inpt and outpt srvcs following either 6 adults or 4 adolescents based upon a 50% assign't to inpt and a 50% assign't in outpt. Call only every third week Monday through Thursday. Physicians hand off call responsibilities to our dedicated weekend doctors at 5:01 pm on Friday and enjoy weekends off with their families free of call responsibilities!

One hour from Denver, Boulder, and **Estes Park!** Great quality of life with outstanding salary and benefits. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth. com EOE.

**IMMEDIATE OPENING** for full-time psychiatrist in new High Security Forensic Institute at the Colorado Mental Health Institute @ Pueblo. Employed by the University of Colorado School of Medicine with full benefits, 4 1/2 weeks paid vacation, excellent CME program on campus, a strong, stable medical staff with little turnover, option for flexible schedule, including 4 ten-hour days, and a new salary schedule with optional paid call. We have no J1-Visa opportunities at this time.

## For further information, phone or e-mail A.O. Singleton, III, M.D. Chief of Medical Staff (719) 546-4637; al.singleton@state.co.us.

# CONNECTICUT

# Yale University - CMHC

The Yale University School of Medicine seeks psychiatrists for 2 full-time faculty positions at the Connecticut Mental Health Center [CMHC] for July 2011 that will carry academic appointments at the Assistant or Associate Professor level in the Department of Psychiatry. One is for the Medical Director of the Substance Abuse Treatment Unit [SATU], a program with strong clinical, research, and training components. Preference will be given to applicants with special training in Addictions who will be eligible for certification in Addiction Psychiatry at the time of appointment. The second position is within the Hispanic Clinic and preference will be given to candidates who are bilingual. Outstanding clinical and teaching skills are required

in both positions for roles in patient care as well as supervision of psychiatry residents and other trainees at CMHC, a core site for training and research within Yale's Department of Psychiatry. The positions include protected time for participation in a variety of Departmental research and educational activities. Applicants must be board certified or eligible in psychiatry, licensed to practice in CT and be legally employable.

Please send a CV and 3 references by **January 15, 2011** to Jeanne Steiner, D.O., Medical Director CMHC, 34 Park St., New Haven, CT, 06519. Direct inquiries to jeanne.steiner@yale. edu. Yale University is an affirmative action/ equal opportunity employer. Yale values diversity in its faculty, students, and staff, and especially encourages applications from women and underrepresented minority scholars.

VA Connecticut Healthcare System and Yale University School of Medicine, Department of Psychiatry is recruiting a Staff Psychiatrist in the field of posttraumatic stress disorder (PTSD). The candidate will be responsible for the development of a research program in the field of PTSD and as such will have protected research time. For clinical work, this person will function as a staff psychiatrist, providing psychiatric care to veterans within the psychiatry service and will work with a team of psychiatrists, psychologists and other members of a multidisciplinary team at the VA Connecticut Healthcare System and the National Center for Posttraumatic Stress Disorder. Applicants must have successfully completed psychiatric residency training in an accredited, U.S. program, be board certified (or eligible), licensed to practice in CT and legally employable. Preference will be given to applicants who have independent grant funding, show academic productivity and be in a position to grow a research program.

VACHS and Yale University are Equal Opportunity/Affirmative Action Employers. Women and members of underrepresented minority groups are encouraged to apply. All applicants tentatively selected for VA employment in a testing designated position are subject to urinalysis to screen for illegal drug use prior to appointment. Applicants who refuse to be tested will be denied employment with VA. This announcement is a solicitation for applications from current, former federal and the general public, U.S. CITIZENSHIP: All applicants for federal employment must be a U.S. Citizen. Actions to fill this position will not be based on discrimination which is prohibited by law. Academic rank will be dependant upon review of academic achievements and must meet qualifications to fulfill the Yale University School of Medicine criteria for faculty appointments.

Please mail, e-mail or fax CV/application (VA 10-2850), OF306 most recent SF-50 if, latest proficiency and training and award records no later than **December 15, 2010**, if applicable, to:

Department of Veterans Affairs VA Connecticut Healthcare System Human Resources Management Service/05 950 Campbell Avenue, West Haven, CT 06516 Attention: Emily I. Wayne-Lane Or email emily.wayne-lane@va.gov Fax (203) 937 4740 or 203-937-4718.

#### LEADERSHIP INPATIENT ADULT PSYCHIATRIST OPPORTUNITY CENTRAL CONNECTICUT

Opportunity for leadership role on 16-bed inpatient service within a community hospital. This position would provide clinical leadership and psychiatric care with a multidisciplinary team of mental health professionals. Crisis Center located in Emergency Department. Call is shared with colleagues from Department of Psychiatry and most is beeper call from home. Very competitive salary and benefits and adaptable hours for the right individual. We invite you to join an expanding team of psychiatrists who are part of Bristol Hospital's mission to serve its community and be recognized as one of the best community hospitals in Connecticut.

The practice is located in a family-oriented city located approximately two hours from NYC and Boston. Enjoy the charm of New England's four seasons with a choice of attractive communities with Connecticut's best rated schools, shopping, award-winning restaurants, and regional theatre and easy access to skiing and coastline.

For more information about this opportunity, please contact Carolyn Doughtie at

800.892.3846 or fax/email your CV to 860.714.8835. EOE.

## Email address:

cdoughti@bristolhospital.org Visit our website: www.bristolhospital.org

# FLORIDA

Attractive Practice Opportunity Near Cocoa Beach - Beautiful Area - Seeking Board Certified (or recent grad) Psychiatrist to join busy inpatient/outpatient practice in the area. Hospital-based adult/geropsych unit. Relocation package available. Please call Terry B. Good at 1-804-684-5661, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

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

# DAYTONA - MELBOURNE - ORLANDO - OCALA-

Psychiatrists needed for rapidly expanding Nursing Home Service. Great support. No call. Average Salary 210K + benefits. Part-time available. Some travel required. Must have FL Medicare & FL Medicaid individual provider #s. No Restrictions (H1B Candidates Considered). Call our Clinical Coordinator, Linda at 866-936-5250.

# **GEORGIA**

#### Medical College of Georgia Augusta, GA Growing Department Seeks New Faculty in Adult, Child and Adolescent, Neuroscience and Public Psychiatry Programs

The Medical College of Georgia (MCG) Department of Psychiatry and Health Behavior is recruiting MD and PhD faculty in adult, consultation/liaison, forensic, child and adolescent and public psychiatry. Both clinician-educator and research intensive positions are available, including a dedicated research neuroscientist position in psychotic disorders. The department, which is growing and financially stable, has strong training programs in general, child and adolescent, and forensic psychiatry, an internship program in health psychology, and competitively funded clinical and preclinical research. Our new public psychiatry partnership with the Georgia Department of Behavioral Health and Developmental Disabilities to manage and provide clinical care to the regional state hospital (located only five miles from the medical school campus), expands our faculty recruitment, educational and clinical research opportunities. MCG's strong research infrastructure includes core laboratories, statistical consultation and core genetics facilities. Extensive research training program for junior faculty includes a master's program in clinical translational, internal grant programs with generous career development awards.

Augusta, home of Masters Golf Tournament, is a charming Southern city with low cost of living (particularly housing), and is close to Georgia/ Carolina mountains and Georgia/Florida coast. The position has excellent salary and benefits. Academic appointment depends on qualifications. MCG is an equal employment, equal access and equal educational opportunity and affirmative action institution. It is the policy of the University to recruit, hire, train, promote and educate persons without regard to age, disability, gender, national origin, race, religion, sexual orientation or veteran status.

See http://www.mcg.edu/som/psychiatry/ for more information. Contact: Donald Manning, MD, Director of Public Psychiatry, dmanning@ mcg.edu or (706) 721-6719.

# Psychiatrist - Metro-Atlanta (contract)

**Cobb-Douglas Community Services Board**, a behavioral healthcare organization in metro Atlanta, seeks a part-time, BC/BE Psychiatrist for Community Outpatient Behavioral Health clinic. Please email CV to cholt@cobbcsb.com.

# **CONSULTATION-LIAISON PSYCHIATRIST -**

Emory University School of Medicine, Department of Psychiatry and Behavioral Sciences in Atlanta, Georgia is seeking a qualified candidate for consult liaison psychiatrist at the Assistant and/or Associate Professor (M.D.) rank. The successful candidate should be board eligible or board certified in Psychiatry. The institution offers nationally competitive salaries commensurate with experience. The position is located at Emory University Hospital Midtown, conveniently located in midtown Atlanta, Georgia. Emory University Hospital Midtown is easily accessible to the major interstates and is approximately one mile from CNN Center, Centennial Olympic Park, and The Georgia Aquarium. The position involves providing clinical consultative services to departments including medicine, surgery, and ob/gyn as well as on a long term acute care medical unit. The applicant will have the opportunity to supervise residents and students, as well as participate in relevant clinical research. Send CV and letter of intent to: Steven T. Levy, M.D., EUSOM, Department of Psychiatry and Behavioral Sciences, Tuft's House, 2004 Ridgewood Drive, Atlanta, GA 30322. AA/EOE.

#### PRIVATE PRACTICE OPPORTUNITY

Be the only psychiatrist accepting new patients in Hall County. GA. 50 miles north of Atlanta. Earning potential well over \$200,000. Email CV to mkingphd@gmail.com.

# ILLINOIS



Methodist Medical Center in Peoria, Illinois seeks two general adult Psychiatrists for its busy behavioral health service. Methodist, a 353-bed teaching facility affiliated with the University of Illinois College of Medicine, is the predominant behavioral health caregiver in the community and offers a full continuum of care in a modern state-of-the-art facility. The current physicians provide a mixture of inpatient/outpatient care and share a reasonable call coverage situation. An outstanding compensation and benefit package is offered.

**Peoria** is a great mid-size city centrally located 2 1/2 hours from Chicago and St. Louis. The community offers affordable housing, excellent schools, and a safe quality lifestyle notorious in the Midwest. **Please respond to:** Sheri Johns, Physician Recruiter, Methodist Medical Center of Illinois, 800-621-8543, email: sjohns@mmci. org. **Please visit our website: www.my-methodist.net.** 

# Chicago Area Psychiatrist Addiction & Pain Program

Advocate Christ Medical Center, Department of Psychiatry seeks a qualified and experienced Liaison Psychiatrist for our addiction and pain program. Candidates must be experienced in addiction psychiatry and psychosomatic medicine, hold a current Illinois license and be board certified or board eligible.

Advocate Christ Medical Center (ACMC) is a 695-bed, not-for-profit teaching, research and referral medical center located in the southwest suburbs of Chicago. ACMC is part of Advocate Health Care, Chicago's largest provider of care and one of the nation's leading integrated health systems. The selected candidate for this highly visible position will lead the addictions detox and medical psych unit which is joined with an active pain program and cooperate with a multidisciplinary consultation liaison service for hospital based medical and surgical services. There further exists the opportunity to teach and supervise medical students and residents. This exciting part time salaried position includes health and retirement benefits. The incumbent may also enjoy an opportunity to perform out patient work seeing substance abuse patients and general psychiatry as part of a progressive multi specialty psychiatric group practice located in Orland Park, Illinois. To apply directly, please submit a CV and cover letter to: donna.kutka@ advocatehealth.com or for more information contact Donna C. Kutka, RN, MS, Director, Physician Recruitment, at 708.684.5009.

**Chicago Suburb-Streamwood** Child Psychiatrists. Diverse position options - Inpatient, Residential, and Outpatient. Salary and Benefits for fulltime or hourly for part-time O/P only. Contact Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc. com.

Immediately seeking Child/Adolescent Psychiatrist for Summit Clinical Services, a wellestablished multidisciplinary mental health practice, composed of M.Ds, Licensed Psychologists, Licensed Clinical Social Workers, and Licensed Clinical Professional Counselors, in Chicago's western suburbs. The position offers an excellent opportunity to quickly build a practice among experienced professionals known for providing quality mental health services in a caring and respectful manner. Willingness to also be on staff at nearby hospital is desirable. Must be comfortable working with a conservative Christian patient population. Flexible hours, set by individual clinician, and generous compensation based on the number of hours worked. Benefits include health insurance and Flexible Spending Account; disability insurance, 401K; and opportunity for partnership and profit sharing.

For more information about our practice, see our Website at **www.summitclinical.com**. Contact Dan Wyma, M.D., at Summit Clinical Services, (630) 260-0606.

# IOWA

# CARVER COLLEGE OF MEDICINE

University of Iowa Health Care

The University of Iowa Roy J. and Lucille A. Carver College of Medicine, Department of Psychiatry is currently recruiting a Clinical Assistant Professor (non-tenure track) for the Medical Psychiatry (Med-Psych) unit and consultation service. This position may also have a joint appointment with the Department of Internal Medicine and Iowa City Veterans Affairs (VA) Medical Center. Our Med-Psych unit consists of 15 beds in a newly renovated (fall 2009), state-of-the-art inpatient unit.

Physicians must hold MD or DO degrees and have completed an internal medicine and psychiatry residency or combined internal medicine/psychiatry residency. At the time of the appointment, applicants must be dual board eligible or dual board certified in internal medicine and psychiatry and have experience in working at the interface of medicine and psychiatry preferably within a dual medical-psychiatric diagnosis unit. The candidate must also have a commitment to and experience in patient care and teaching in a combined medicine psychiatry residency program. Some research experience is highly desirable. The Department of Psychiatry at the University of Iowa Hospitals and Clinics has a wide range of clinical programs as well as residency and research programs. Iowa City provides the unique combination of a safe, small, and attractive college town with the opportunity to take advantage of abundant local and world-class cultural events. The school system is ranked among the best in the nation.

To apply for the positions, visit our website at **http://jobs.uiowa.edu**, requisition 57313. The University of Iowa is an Affirmative Action/ Equal Opportunity Employer. Women and minorities are strongly encouraged to apply.



The University of Iowa Roy J. and Lucille A. Carver College of Medicine, Department of Psychiatry is currently recruiting a Medical Director for its Neuromodulation Service. The Medical Director will be appointed to a position as Assistant Professor, Associate Professor or Professor for Clinical (Non-Tenure) and Tenure Track in adult psychiatry. This position will be responsible for managing and developing a neuromodulation service that includes electro-convulsive treatment, deep brain stimulation and rTMS. The successful candidate will have experience with one or more of these interventions and have interest in developing additional skills and knowledge about these treatment modalities. The Medical Director will be a provider of clinical care in these modalities as well as the clinical director.

Requirements: Physicians who hold MD or DO degrees and have completed a psychiatry residency. Applicants must be board eligible or board certified and have a commitment to patient care, teaching, and research. Applicants must also have experience with the delivery of the treatment modalities identified above and be interested in the development of new interventions as they become available. The Department of Psychiatry at the University of Iowa Hospitals and Clinics has a wide range of clinical programs as well as residency and research programs. Iowa City provides the unique combination of a safe, small, and attractive college town with the opportunity to take advantage of abundant local and world-class cultural events. The school system is ranked among the best in the nation.

To apply for the positions, visit our website at **http://jobs.uiowa.edu**, requisition **#**58651. The University of Iowa is an Affirmative Action/ Equal Opportunity Employer. Women and minorities are strongly encouraged to apply.

# **KANSAS**

# Civilian General/Adult Psychiatrist Opportunity at Fort Riley, KS.

Work as a civilian Psychiatrist at Irwin Army Community Hospital and help serve those who serve our country! Trustaff hires healthcare professionals to work as civilians at military and VA hospitals nationwide. We are seeking Psychiatrists for immediate long term full-time opportunities at Irwin Army Community Hospital, located at Fort Riley near Kansas State University in greater **Manhattan, KS**.

Working as a part of the hospital's Behavioral Health Team, you will have the rewarding opportunity to care for active duty military and their dependents. **As a company we are offering:** Exceptional Compensation Plan \$270-\$300k per year,Relocation, Continuing Education Assistance, 40 hour work week, 4 or 5 days per week M-F., limited on-call,Malpractice 100% Covered, Any state license is acceptable to work at this facility. **Contact:** Christine Fuka, 877-880-0346 x 1105, Fax: 866-546-3115, Email: cfuka@trustaff.com, www.trustaffgovernmenthealthcare.com.

# MAINE

Adult inpatient psychiatrist. Mid Coast Hospital is an independent, non-profit community hospital located in beautiful coastal Maine one of Maine's most desirable regions. We are searching for a second inpatient psychiatrist for our 12-bed unit. Our team uses a multi-disciplinary approach to treat both voluntary and involuntary patients. This is a full-time position for a BC/BE psychiatrist. Share on-call responsibilities with eight other physicians. 40-hour week. Generous benefits, excellent work environment. Please send letter of introduction with CV to: mmackellar@midcoasthealth.com.

# MARYLAND

# Faculty Opportunity Division of Child and Adolescent Psychiatry University of Maryland, Baltimore

The University of Maryland School of Medicine, Division of Child and Adolescent Psychiatry is seeking a full-time child and adolescent psychiatrist, psychologist, and social worker. The positions carry faculty appointments at the University and offer exciting opportunities for clinical care, teaching and research. Academic rank and salary are commensurate with experience.

Send a letter of introduction and CV to: David B. Pruitt, M.D, Professor of Psychiatry and Pediatrics, Director, Division of Child and Adolescent Psychiatry, 701 W. Pratt Street, #429, Baltimore, Maryland 21201.

The University of Maryland is an AA, EOE, and ADA Employer. Minorities and women are encouraged to apply. Springfield Hospital Center is seeking Boardcertified or Board-eligible general psychiatrists for our 350-bed MHA adult inpatient facility. Salary is negotiable, within MHA guidelines. Our rural, tobacco-free campus is 22 miles west of Baltimore, convenient to the Chesapeake Bay, Washington, and a variety of cultural, historic, sports, and recreational venues. Benefits include 27 paid days off in the first year, subsidized health insurance, free parking, a generous retirement program, and a truly pleasant workplace. A Medical Services physician is always on campus to attend to patients' somatic needs. Staff psychiatrists are not expected to work after hours, but some choose to supplement their salary by providing evening and weekend/holiday coverage under contract. In addition, we offer after-hours coverage contracts to psychiatrists who are not full-time staff members. Please send CV to Jonathan Book, M.D., Clinical Director, SHC, 6655 Sykesville Road, Sykesville, MD 21784. For questions, call (410)970-7006 or e-mail JBook@dhmh.state.md.us. EOE

The VA Maryland Health Care System (VAMHCS,), Mental Health Clinical Center (MHCC) is actively recruiting for a full time psychiatrist to work at the Perry Point Medical Center as clinical manager of inpatient mental health. This position is 50% administrative and 50% clinical; providing clinical care on the two inpatient units. Perry Point is a small town on the Chesapeake Bay about 35 miles north of Baltimore City. The MHCC is the largest clinical center within the VAMHCS and is organized into four Sub-Product lines: Inpatient Mental Health; Residential Treatment; Community (outpatient) Mental Health; and Special Programs (Addictions and Trauma). Mental health activities are conducted at all divisions and sites. Mental Health Professionals assigned across the various Sub-Product Lines consist of nurse practitioners, addiction therapists, vocational rehabilitation specialist, physician assistants, etc. The hospital has inpatient, outpatient, and residential programs for substance abuse, PTSD, and the chronically mentally ill. It also has a program in schizophrenia affiliated with the University of Maryland. The VAMHCS offers competitive salary rates, health, and life insurance, retirement planning including Thrift Savings Plan, generous paid leave and educational opportunities plus the satisfaction of serving those who served. Please mail your CV and Letter of Interest to Human Resources Management Service, Attn: Kenneth Reil, Jr., HR Specialist, P.O. Box 1045, Perry Point, MD 21902 or send by e-mail to Kenneth.ReilJr@va.gov. The VAMHCS is an Equal Opportunity Employer.

# MASSACHUSETTS

**Exceptional Professional Opportunity** for psychiatrist to provide high quality care as part of a well respected multidisciplinary private group practice loacted 2 hours north of NYC in Columbia County/Hudson Valley, NY and **neighboring Berkshire County, MA**. Inpt/ outpt. Flexible hours.

Excellent salary packages \$200,000 + (with opportunity for additional income). **Call Dennis Marcus, M.D.** at (413)528-1845, fax CV to (413)528-3667 or email to scppcmd@yahoo. com.

Child and/or Adult Psychiatrist to join, busy, large, established private psychiatric group practice. Work consists of outpatient psychiatric treatment, both psychotherapy and psychopharmacology, and some hospital consultations. A lot of flexibility in terms of job and schedule. Please send C.V. to Paul Menitoff, M.D. Greater Lowell Psychiatric Associates, LLC 9 Acton Road Suite 25 Chelmsford, MA 01824.

**Starr Psychiatric Center seeks** a 20-40 hr psychiatrist for dynamic established psychiatric practice On Boston's South Shore. Medical model, multi-disciplinary staff. Stimulating environment, good pay. Clinic has a reputation for successful care, where others have failed. Email davidzstarr@juno.com or call 508.580.2211.

View the classifieds online at pn.psychiatryonline.org

# CAMBRIDGE: Consultation Liaison Psychiatry Position

PSYCHIATRIST: Cambridge Health Alliance is seeking a half- to full-time psychiatrist to join our Consultation-Liaison Psychiatry Service serving a multi-ethnic and diverse patient population. The position will include some inpatient work but will be focused on outpatient work and program development within Women's Health, Medical Specialty, and Primary Care Clinics. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment coupled with a strong academic tradition and existing collaboration with medicine, make this an ideal opportunity for candidates interested in integrated medical and psychiatric care with underserved populations. We have strong training programs in Primary Care, Adult and Child Psychiatry, and Psychosomatic Medicine and innovative educational programs for medical students. These programs provide many opportunities for teaching and research. Academic appointment is anticipated, as determined by the criteria of Harvard Medical School.

**Qualifications:** BC, strong clinical skills, commitment to public sector populations, team oriented, problem solver, interested in working closely with primary care and medical specialists. Fellowship training in Psychosomatic Medicine, as well as bilingual and/or bicultural abilities, is desirable. Interest and experience with substance use disorders preferred. We offer competitive compensation and excellent benefits package.

**Cambridge Health Alliance** is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. CV & letter to Susan Lewis, Department of Psychiatry, 1493 Cambridge Street, Cambridge, MA; Fax: 617-665-1204. Email preferred: SLewis@challiance.org.

#### Associate Director of Psychiatry Residency Training University of Massachusetts Medical School

Board certified Psychiatrist educator wanted to serve as Associate Director of Adult Psychiatry Residency Training at UMass Memorial Healthcare/University of Massachusetts Medical School. The Associate Director provides teaching and supervision to psychiatry residents, participates in residency administration, and has major responsibility for the residency curriculum. Candidates should have expertise in psvchotherapy and/or psychopharmacology education, excellent administrative experience, a desire to contribute to innovative program development, and an identified clinical or research interest in adult psychiatry. The Associate Director will be expected to devote half time to residency training and the other half to research or clinical work based on qualifications and interests. The position offers a competitive salary, excellent benefits, and a faculty appointment with the University of Massachusetts Medical School. UMMHC is an AA/EOE. Send letter of interest and curriculum vitae to: Sheldon Benjamin, M.D., Vice Chair for Education and Residency Training Director, University of Massachusetts Medical School Department of Psychiatry, Rm. S7-823, 55 Lake Avenue North, Worcester, MA 01655, Phone: 508-856-4087 Fax: 508-856-5000, Email: sheldon.benjamin@umassmed.edu.

The Department of Psychiatry at Mount Auburn Hospital, affiliated with Harvard Medical School, is recruiting for a full-time and a halftime 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. Position includes participating in the teaching activities of the Department. Academic appointment to the clinical faculty at Harvard Medical School is anticipated.

Please send letter of interest and cv to: Joseph D'Afflitti, M.D., Chair, Department of Psychiatry, Mount Auburn Hospital, 330 Mount Auburn Street, Cambridge, MA 02138; tel: 617 499-5008; email: jdafflit@mah.harvard.edu.

> Prefer to keep it confidential? \$35 extra for a confidential *Psychiatric News* blind box.

# MICHIGAN



Lakeland Healthcare, located in beautiful southwest Michigan, is currently seeking a Manager of Psychiatric Services for our hospital. Must be a RN with a Masters Degree in Psychiatric or Behavioral Health Nursing. Please apply at **www.lakelandhealth.org.** EOE.

Directorship Position - An Easy Income of \$220k to \$240k (Or More) - No long workdays necessary to make a great income. Clinical and part-time admin. responsibilities on adult psychiatric services in the Saginaw, MI area. C/A work is also available. Salary w/benefits or contract arrangement available. Close to Lake Huron. Only an hour and a half to Detroit and Ann Arbor. Staff Psychiatry position also available. Please call Terry B. Good at 1-804-684-5661, Fax #: 804-684-5663; Email: terry.good@ horizonhealth.com.

# **MISSOURI**

Very Lucrative Opportunity Right Near Springfield- Outpatient work and consults. Also share call for 10-bed geropsychiatric unit. Offering very attractive employment compensation package. Springfield is a great city (161,000 population)-not too large and not too small. Branson is an hour away. Please call Terry B. Good at 1-804-684-5661, Fax #: 804-684-5663; Email: terry.good@horizonhealth.com.

# MONTANA

Horizon Health invites you to consider an exciting practice opportunity for two NEW distinct Adult and Geriatric Inpatient Psychiatric Units, comprised of 26 total beds in Helena, MT. Nestled beneath the foothills of the Montana Rockies, Helena, the Capital of Montana, is alive with history and culture. This charming and beautiful Victorian city of 70,000 people provides a diverse attraction with many street festivals, theater, museums, symphonies, fairs and rodeos. There is truly something for everyone here! Excellent practice opportunity with great income (\$200K+) and unparalleled quality of life! For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@ horizonhealth.com EOE.

# **NEW JERSEY**

Westampton - East of Philadelphia. 2 positions. General/Addiction AND Geriatric Psychiatrists. Fulltime positions - no on site call! Contact Joy Lankswert, In-house recruiter @ 866-227-5415 or email joy.lankswert@uhsinc. com.



# FULL-TIME INPATIENT ADULT PSYCHIATRIST

**Carrier Clinic**, a private Psychiatric Hospital located 3 miles North of Princeton, NJ is looking for an inpatient Adult, General Psychiatry and Dual Diagnosis Psychiatrist. This staff psychiatrist coordinates and administers medical care to Adult Dual Diagnosis and General Psychiatry patients. Requires current NJ Medical license and DEA and CDS certifications. ASAM certification preferred. Must be board eligible or board certified in General Psychiatry, Addiction Psychiatry or Addiction Medicine preferred. Send CV to: **sladyman@carrierclinic. com** or fax to: Carrier Clinic 908-281-1470.

# **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

# **General Adult and Addiction Psychiatrists**

The Department of Psychiatry at The Mount Sinai Medical Center (MSMC) in Manhattan has openings for General Adult and Addiction Psychiatrists. The FT/PT positions include outpatient work at the World Trade Center Mental Health Program with opportunities for teaching and clinical research. An academic appointment will be offered at Mount Sinai School of Medicine (MSSM) commensurate with experience. Applicants who have completed their residency training prior to July 2005 must be certified in General Adult Psychiatry by The American Board of Psychiatry and Neurology. Qualified candidates must possess an MD or DO degree, be comfortable with using an electronic medical record, and preferably have experience in treating mood and anxiety disorders. Spanish and/or Polish speaking physicians are strongly encouraged to apply. The MSMC is a premier 1,171 bed tertiary-care facility internationally acclaimed for excellence in clinical care, education and scientific research in nearly every aspect of medicine. The MSMC/MSSM is an equal opportunity/affirmative action employer. We recognize the power and importance of a diverse employee population and strongly encourage applicants with various experiences and backgrounds.

Interested applicants should contact Fatih Ozbay, MD, Associate Medical Director of the WTC Mental Health Program by sending their CVs via email to natacha.lamour@mssm.edu.

# PSYCHIATRIST

Stony Brook University's Department of Psychiatry and Behavioral Science has a F/T or P/T position immediately available for a board certified/eligible psychiatrist in University-affiliated inpatient service located at Eastern Long Island Hospital, 23-bed adult unit in scenic Greenport, NY. Position includes faculty appointment and academic opportunities. N.Y. State license necessary. To apply, submit cover letter and CV to Mark J. Sedler, M.D., MPH, Department of Psychiatry and Behavioral Science, Health Sciences Center, T-10, Room 020, Stony Brook University, Stony Brook, NY 11794-8101; or fax (631) 444-1560. For a full position description or application procedures, visit www.stonybrook.edu/jobs (Ref. #F-6508-10-09).

**Stony Brook University/SUNY** is an equal opportunity/affirmative action employer.

# PSYCHIATRISTS Moonlighting/FT positions BEST IN BROOKLYN!

- Night/weekends/Holidays
- IP/ED/CL/ Detox/Assisted Living • Physician friendly staff!
- No insurance calls!
- Competitive hourly rates/salaries
- Additional pay per encounter possible

Please FAX 718.630.8594 or send CV to: Tracey Irvin, Dept. of Psychiatry, Lutheran Medical Center, Suite 2-41A, 150 55th St., Brooklyn, NY 11220. EOE/AA M/F/D/V. www.LutheranHealthCare.com.



**On Call Psychiatrists:** Psychiatrists, Fellows and Senior Residents to cover days, nights, weekends and Holidays in the Psychiatric Emergency Department at the Long Island College Hospital. Please fax resume to: THE LONG ISLAND COLLEGE HOSPITAL, DEPART-MENT OF PSYCHIATRY, 339 Hicks Street, FAX: (718) 780-1827. Attn: Deborah Dwoskin, 718-780-1159.

> View your ad online for free! All line classified ads are posted on the *Psychiatric News* web-site: pn.psychiatryonline.org

**Rockland Psychiatric Center**, a state psychiatric hospital affiliated with NYU and located 30 minutes north of NYC in the scenic lower Hudson Valley, has openings for inpatient psychiatrists. We offer regular hours, optional oncall for extra pay, excellent benefits including state retirement system. Weekly grand rounds, large medical staff, collegial atmosphere. With 430 inpatient beds and 11 clinics in 5 surrounding counties, there are many opportunities for movement and advancement once on staff.

# Send CV to Mary Barber, MD, Clinical Director rpmeb01@omh.state.ny.us.



# Medical Director - Opioid Treatment Program (OTP)

The Addiction Institute of New York at St. Luke's-Roosevelt Hospitals seeks an enthusiastic psychiatrist who is dedicated to helping patients with substance use and other psychiatric disorders.

You will deliver psychiatric care and, in collaboration with the clinic manager, provide overall leadership at the OTP. You will also supervise the Columbia University Addiction Fellows with eligibility for faculty appointment at Columbia University College of Physicians and Surgeons. The position is half-time and requires buprenorphine prescribing privileges (the bup waiver) and Board Certification (or Eligibility) in Psychiatry.

Competitive salary and full benefits offered. Interested applicants should send CV to: Petros Levounis, MD, MA, Director of The Addiction Institute of New York, 1000 Tenth Avenue, Suite 8C-02, New York, NY 10019. Tel: 212-523-6876. E-mail: PLevounis@chpnet.org. EOE.

# **NEW YORK STATE**

Assistant Attending Psychiatrist - (Elmhurst, NY) - Supervises clinical activities of housestaff (incl. chief resident, residents, & interns) & medical students in Psychiatry dept. Conducts direct patient care & manages assigned patient caseload. Conducts independent evaluation of patients seen by housestaff & med. students. Serves as consultant for housestaff & med. students regarding patient diagnostic eval., treatment plan, consultations, disposition, & followup care, util. knowledge of normal child development, psychopharmacology, psychotherapeutic modalities incl. play therapy, trauma-focused cognitive-behavioral therapy, & family therapy. Evaluates clinical performance & progress of housestaff & medical students. Req's: Doctor of Medicine or foreign equivalent, and 2 yr Fellowship in Child & Adolescent Psychiatry: Clinical training incl. normal child development, military psychiatry, family crisis intervention, psychotherapeutic modalities incl. play therapy, trauma-focused cognitive-behavioral therapy, & additional exposure treating children w/ mental retardation & developmental delays. Eligible for License w/ NY State Board of Medicine & American Board of Psychiatry and Neurology w/ specialty in Adolescent and Child Psychiatry, & passed FLEX examination or equivalent (i.e. NMBE III or USMLE III). Must have demonstrated excellence in teaching, research and clinical treatment.

> Contact: HR, IP Mount Sinai Medical Center 1 Gustave L. Levy Pl., Box 1514 NY, NY 10029. Ref. #: 1960847.

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. **Exceptional Professional Opportunity** for psychiatrist to provide high quality care as part of a well respected multidisciplinary private group practice loacted 2 hours north of NYC in Columbia County/Hudson Valley, NY and **neighboring Berkshire County, MA**. Inpt/ outpt. Flexible hours.

Excellent salary packages \$200,000 + (with opportunity for additional income). **Call Dennis Marcus, M.D.** at (518)697-8010, fax CV to (413)528-3667 or email to scppcmd@yahoo. com.

# Exciting Opportunity for a Child Psychiatrist.

Northeast Parent & Child Society, one of New York State's most innovative human service agencies, is seeking to add a highly energized and committed psychiatrist to its dynamic mental health team.

#### Meet the Challenge!

Located in Schenectady NY, Northeast is a \$40 million dollar, nationally accredited organization, which serves as the county's designated child and family mental health agency. Under the supervision of one the top psychiatrists in Upstate NY, the psychiatrist will work with a team of mental health therapists and psychiatric nurse practitioners dedicated to meeting the needs of children and families with a broad array of emotional and psychiatric challenges.

#### Live in a Great Community!

Offering a lifestyle for every personality, New York's Capital Region boasts unrivaled quality of life at a low cost of living. School systems, healthcare and recreational activities here are among the best in the country. Moreover, its central location places it only three hours from some of the top destinations in the world: **New York City, Boston and Montreal.** 

# Make a Difference!

Many children and families suffer from lack of access to mental health and psychiatric care. The new psychiatrist will work collaboratively with community leaders dedicated to improving the quality behavioral health care for Schenectady County's most vulnerable residents.

#### Salary & Benefits

NPCS offers a compensation package on par with large city providers. Moreover, the lower cost of living, option of city, suburban or countryside communities allows for a richer and better quality of life.

# Qualifications

Qualified MD/DO candidates will be able to meet the following requirements:

- Graduation from at an accredited US psychiatric residency
- Completion of specialty fellowship in child and adolescent psychiatry.Licensed/Eligible to practice in the State of
- New York. • Possess a current DEA registration.
- Be board certified/eligible.

Candidate must also have adesire toserve a high needs population, and be comfortable evaluating, diagnosing, and treating the mental, emotional, and behavioral disorders of children and adolescents.

**To Apply-** Email your cover letter and résumé to Christopher.Burky@NEParentChild.orgenter the title of interest in the subject field. Northeast Parent & Child Society is an equal opportunity, affirmative action employer.

**St. Lawrence County Mental Health Clinic** in Canton, NY seeks full time (35 hrs/week) BC/ BE psychiatrist to join interdisciplinary treatment team in providing outpatient mental health services to both children and adults. Competitive salary and excellent fringe package and malpractice coverage.

Canton is situated between the Adirondack foothills and the St. Lawrence River Valley with four universities nearby. St. Lawrence County is an EO/AAE, federally designated as MHPSA.

Submit letter of interest and CV to Dan Dodge, LCSW-R, St. Lawrence County Mental Health Clinic, 80 State Highway 310, Suite 1, Canton, NY 13617. Email: ddodge@co.st-lawrence. ny.us. If you have questions, please call 315-386-2167.

# Adult Staff Psychiatrist Emergency Room Psychiatrist Charlotte, NC

Carolinas HealthCare System has unique opportunities for Adult Staff Psychiatrists at its Behavioral Health Center. The center is part of a 874- bed regional teaching facility nestled in the heart of Charlotte. Join an outstanding team of psychiatrists in a very collegial working environment.

Adult Staff Position - Inpatient and outpatient. Emergency Room Psychiatry Position -Work in the facility's in-house emergency de-

- partment. Rotating shifts. Excellent benefits package which includes:
- Two weeks CME
- Paid vacation
- Short and long-term disability
- 401K, 457B and pension plan Opportunity for extra income by seeing private

patients or by taking shifts in the ER Interested applicants should email their CV to Elaine Haskell at: elaine.haskell@carolinashealthcare.org or call 800-847-5084 for more information.

# EOE/AA

**Carolina Partners in Mental HealthCare, PLLC** is seeking **BE/BC psychiatrists** for our practices in Wake Forest and Raleigh, NC. PAs and NPs also welcome to apply. Private outpatient practices, full partnership from day one no investment required. FT, PT flexible. Carolina Partners has ten offices in Raleigh, Durham, Cary, Chapel Hill, Burlington and Wake Forest, North Carolina. Good opportunity to control your life and clinical practice, while making a good income!

**Contact Executive Director or send CV to:** Carolina Partners in Mental HealthCare, 1502 W. Hwy 54, Suite 103, Durham, NC 27707. Phone 919-967-9567; Fax 919-882-9531; Email carolinapartners@bellsouth.net. Find us online at www.carolinapartners.com.

# OHIO

# **Geriatric Psychiatrist**

The Department of Psychiatry at The MetroHealth System, a major teaching hospital of Case Western Reserve University, is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) geriatric psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a top1% ranked hospital. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

# **Child and Adolescent Psychiatrist**

The Department of Psychiatry at The MetroHealth System, a major teaching hospital of Case Western Reserve University, is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) child and adolescent psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a top1% ranked hospital. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

#### Consultation-Liaison Psychiatrist

The Case Western Reserve University Department of Psychiatry at MetroHealth is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) consultation-liaison psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a hospital ranked in the top 1% for outcomes and efficiency. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

# Addiction Psychiatrist

The Department of Psychiatry at The MetroHealth System, a major teaching hospital of Case Western Reserve University, is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) addiction psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a top1% ranked hospital. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

# Psychiatrist. The Ohio State University, Columbus, OH.

Counseling and Consultation Service at The Ohio State University is seeking a board eligible/ board certified psychiatrist for a 1.0 FTE Senior Staff position. The psychiatrist will provide outpatient services to the student population, collaborate with a multidisciplinary staff, supervise trainees and consult with other campus units. State of Ohio benefits with no call or weekend duties. Ohio licensure and board eligibility/certification required at time of hire. To assure consideration, please apply by 01/02/2011 by visiting our web site at www. jobsatosu.com and search by requisition #354089. Candidates should submit a cover letter and curriculum vitae when they apply. To build a diverse workforce, Ohio State encourages applications from individuals with disabilities, veterans and women. EEO/AA employer.



# JOIN THE VA! - NORTHEAST, OHIO

Louis Stokes Cleveland VA Medical Center a teaching affiliate of Case Western Reserve University (CWRU) seeks quality board certified applicants for full or part-time **Psychiatrist** positions at the **Lorain**, **Mansfield**, **Sandusky** and **Youngstown** Community Outpatient Clinics. The primary responsibilities are providing ambulatory patient care in a multi-disciplinary setting. The VA offers a competitive salary with comprehensive health care and federal benefits package.

**Send CV to:** Judy Trepkowski, Human Resources Specialist, 05(B), Louis Stokes Cleveland VAMC, 10000 Brecksville Road, Brecksville, OH 44141, Fax: 440-740-2385. We are a diversified and Equal Opportunity Employer.

Bundle your *Psychiatric News* classified with a *Psychiatric Services* classified and receive 10% off. OREGON

#### BC/BE Psychiatrists Oregon State Hospital (OSH) Salem, Oregon

Oregon Department of Human Services (DHS), OSH is looking for Oregon BC/BE Psychiatrists. OSH offers FT, PT and flexible opportunities in our general adult, geriatric, and forensic programs. A generous and comprehensive benefit and PERS retirement package is included, as well as a new hospital in 2011 which will incorporate state-of-the-art architecture, treatment space and technology. Salary is very competitive and includes psychiatric differential, certification pay and opportunities for additional on-call work. Dr. Mark Diamond, CMO, invites you to call and/or send your CV to us today! Phone: (503) 945-2887; email: lila.m.lokey@ state.or.us; fax: (503) 945-9910; mail: Human Resources, 2600 Center Street NE, Salem, OR 97301-2682. Please visit our website at www. oregon.gov/DHS/mentalhealth/osh. The State of Oregon is an Equal Opportunity Employer.

# PENNSYLVANIA

**PHILADELPHIA:** Admission Services Physician (Mon-Fri)

PHILADELPHIA suburb Doylestown: Child Psychiatrist - Inpatient/RTC. STATE COLLEGE: Child OR General Psychiatrist - Inpatient OR All Outpatient (O/P J1 eligible). Salary & benefits. Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR

email joy.lankswert@uhsinc.com. Horizon Health, in partnership with St. Vincent Health Center (Voted 5th Best Place to work in Pennsylvania!), a 436-bed tertiary care hospital in Erie, PA, has an exciting opportunity for an Adult Psychiatrist for a 32-bed Adult and Geriatric Inpatient Psychiatric Program. Opportunities for input and growth, tertiary care, teaching opportunities in FP residency program and LECOM medical school. Excellent compensation package with full benefits. Located on the shores of Lake Erie with 7 miles of beaches, Erie is the fourth largest city in Pennsylvania with a metropolitan population of 280,000. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

# ASSOCIATE MEDICAL DIRECTOR

Excellent full time opportunity, Associate Medical Director for our Managed Care Organization. The physician in this AMD position will have opportunity for creative clinical thinking and decision making, and along with a team of clinical and medical leaders, will have oversight of UM and QI programs. This position provides a key interface between the MCO and the providers, members and MCO customers. It provides the opportunity to develop clinical programs based on evidence based practices and to monitor clinical outcomes in service delivery across the membership. This position uses excellent clinical skills in an innovative way.

Position requires Pennsylvania licensure and ABPN Board Certification in Psychiatry. Excellent base salary and performance bonus up to 10% of annual, paid benefits, and normal business hours Monday through Friday.

Please apply to our Recruiter Terri Holub, Phone 916-859-5162 or e-mail tmholub@ magellanhealth.com. www.magellanhealth.com.

# **Psychiatrists:**

Currently we have exciting full- and parttime positions in a rapidly expanding department. Opportunities include responsibilities in and outside our five-hospital health system. There are immediate openings for child/adolescent, adult and addictions psychiatrists.

There are also practice options in a traditional psychotherapy model. Psychiatric Hospitalist positions are available for weekday and weekend rounding and Crisis. Excellent salaries, no oncall nor rounding responsibilities ever and exceptional benefits package offered. Send CV to Kevin Caputo, M.D., Vice President and Chairman, Department of Psychiatry, Crozer-Keystone Health System, One Medical Center Blvd., Upland, PA 19013 or contact the department manager, Kathy Waring at 610-619-7413.

# PENNSTATE HERSHEY



# DIRECTOR OF NEUROSTIMULATION

The Penn State Department of Psychiatry is recruiting a psychiatrist to be its Director of Neurostimulation. Responsibilities include supervising and growing clinical services in ECT, DBS, rTMS, and VNS. Teaching and research are expected. There are opportunities for collaboration with other neuroscience departments.

With our clinical partner, Pennsylvania Psychiatric Institute, the Department staffs four clinics and an inpatient facility with 74 beds. Our current psychiatry faculty numbers 52, and we have 24 residents and fellows.

The successful candidate should have strong clinical and teaching skills and potential for scientific and scholarly achievement. An established program of research and a history of extramural grant funding are desirable. The successful candidate will also have a demonstrated ability to promote productive collaboration with colleagues in psychiatry and other disciplines.

Candidates with interest and skills in this area should send a curriculum vitae and cover letter to:

Alan J. Gelenberg, M.D.

Professor and Interim 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.

# TENNESSEE

# New Psychiatry Opportunity in well-known Southeastern City

- We offer stipend and medical school loan repayment
- Choice of employment or a guarantee
  NO STATE INCOME TAX
- Currently a **10 week waiting time** for new
- Full patient load and referrals from day one.
- Opportunity to join existing private practice and cover voluntary center care.
- Access to best public and private schools in Tennessee.
- Compensation package includes salary, signing bonus, relocation, customary benefits and retirement.
- Voted in the **TOP 20 PLACES TO LIVE** by three independent national magazines.
- Practice is backed by one of the top health systems in the country.

For More information contact Stephen Browning at 404-435-3190 or Stephen-browning@ att.net.



#### INPATIENT PSYCHIATRIST Vanderbilt University School of Medicine, Department of Psychiatry

The Department of Psychiatry is recruiting psychiatrists to lead teaching services at Vanderbilt Psychiatric Hospital, an 88-bed teaching hospital on the campus of Vanderbilt University Medical Center. The hospital offers specialized inpatient programs for children & adolescents and for adults with mood disorders, psychotic disorders, addictions, and cognitive disorders. Successful BE/BC candidates will receive a faculty appointment on the clinician-educator track, with rank and salary commensurate to experience.

Applicants should email or send letter of interest with an updated CV to Harsh K. Trivedi, MD, Executive Medical Director and Chief of Staff, Vanderbilt Psychiatric Hospital, 1601 23rd Avenue South, Nashville, TN 37212. Interested and eligible candidates may obtain further information by contacting Dr. Trivedi at 615-327-7024 or harsh.k.trivedi@vanderbilt.edu.

# TEXAS

# Interested in Life on the Texas Gulf Coast?

Corpus Christi State Supported Living Center is hiring a FT board certified or board eligible psychiatrist. Corpus Christi - on the beautiful Texas Gulf Coast has great fishing and beaches and offers easy access to Padre Island National Seashore. Corpus Christi, home to Texas A&M University-CC, Hooks baseball, & Ice Rays hockey, averages 288 days of sunshine a year with an average daily temperature of 71 degrees and an average July temperature of 84. Corpus Christi has an international airport and is a short drive to San Antonio, Houston, Austin and Mexico. The Corpus Christi State Supported Living Center is a developmental facility for people with mental retardation who may also have physical disabilities as well as mental illness. Typical work schedule is 8 a.m. to 5 p.m. M-F. Work environment is casual and medical problems are challenging. Strong support system with excellent benefits. 200K+, state funded pension plan, paid health insurance, paid vacation and sick days, longevity pay, up to 15 paid holidays per year, and more.

For more information, contact: Sandra G. Rodrigues, MD, Medical Director @ Sandra. Rodrigues@dads.state.tx.us or Gloria Grande, Administrative Assistant @ Gloria.Grande@ dads.state.tx.us.

# VIRGINIA

VIRGINIA COMMONWEALTH UNI-VERSITY: Department of Psychiatry, School of Medicine, in collaboration with the Hunter Holmes McGuire Veterans Administration Medical Center, and VCU Institute for Drug and Alcohol Studies, is recruiting an academic physician Chair for the Division of Addiction Psychiatry. Chair is responsible for developing research, teaching and clinical programs. Funded Addictions Fellowship. Strong programs in psychiatric genetics, epidemiology, pharmacology, toxicology, and women's health. State funded health practitioner impairment program, Behavioral Public Health, laboratory and community based research are active areas for collaboration. Wonderful work environment. Department of Psychiatry has over 75 full-time faculty, 39 residents, multiple fellowships and research centers including an addiction genetics research center. The Veterans Administration Medical Center has robust residential and outpatient addictions programming, and an outstanding program in Psychiatry and Primary Care. VCU is Virginia's largest university with robust health science campus and 750-bed university hospital. Richmond, the State Capital, has moderate climate, a rich history, cultural activities, excellent choices for urban, suburban, or country living, outstanding public/private schools.

Send applications to Joel J. Silverman, M.D., Chairman, c/o Takeya McLaurin, Department of Psychiatry, MCV/VCU Box 980710, Richmond, VA 23298. Please contact Dr. Joel Silverman at (804) 828-9156 or email jsilverman@ mcvh-vcu.edu.

Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Men, women, persons with disabilities, and minorities are encouraged to apply.

VIRGINIA COMMONWEALTH UNI-VERSITY, School of Medicine, is recruiting a BE/BC psychiatry educator to serve as Ambulatory Care Division Chair in large, financially stable department. Duties include development of new programs, resident and student education, direction of general and specialty clinics, clinical care and a significant role in overall departmental leadership. Experience in academic ambulatory care, psychiatric education and administration desired. Ambulatory Care Clinics are located at the VCU Medical Campus, and have an estimated 16,000 patient visits/year. Department of Psychiatry has over 75 full-time faculty, 39 residents, multiple fellowships and research centers including an addiction genetics research center. Richmond, the State Capital, has moderate climate and rich mix of history, a diverse multicultural community, excellent housing and public/private schools.

Send applications to Joel J. Silverman, M.D., Chairman, c/o Takeya McLaurin, Department of Psychiatry, MCV/VCU Box 980710, Richmond, VA 23298. Please contact Dr. Joel Silverman at jsilverman@mcvh-vcu.edu.

Virginia Commonwealth University is an Equal Opportunity/Affirmative Action employer. Men, women, persons with disabilities, and minorities are encouraged

to apply.

# PSYCHIATRIST - INPATIENT TREATMENT Southwestern Virginia Mental Health Institute

We invite you to consider our psychiatrist opening for inpatient treatment. Our hospital has 156 inpatient beds and is located in Marion, Virginia, in the heart of the *Blue Ridge Mountains*.

#### The position offers a new challenge and reward every day and includes:

- Competitive salary (Call and negotiate with us!).
- Sign-on bonus up to \$10,000.
- Relocation allowance up to \$8,000.
- Generous state benefits including low cost health, dental and vision insurance; employer paid long and short term disability, long-term care, life insurance, and malpractice insurance; employee contribution to defined benefit retirement; 457-b Deferred Compensation Plan available; and medical and family tax-deferred reimbursement accounts. Assuming a salary of \$185,000 the total compensation including benefits would amount to \$258,466. The amount would be approximately \$265,000 if health benefits included family coverage.
- No on-call required; compensated on-call available.
  Medical school affiliation.
- Monday through Friday 8-5 work day affords
- a work/life balance.

# Come and see all that Southwestern Virginia has to offer:

- A paradise for outdoor enthusiasts who enjoy kayaking, canoeing, hunting, fishing, hiking, biking, horseback riding, or camping.
- Five state parks in the Blue Ridge Highlands Region.
- Historic Barter Theater located in Abingdon, Virginia.
- Historic Lincoln Theater located in Marion, Virginia.
  Numerous arts, crafts, antique, and music fes-
- tivals.Several local wineries featuring outdoor sum-
- mer concerts and wine-tasting/tours.
- Local farmers' markets.
- Close to several metropolitan areas and airports.

I look forward to your call at (276) 783-1204 to discuss the job opportunity we have available, and share with you some of the wonderful things the region of Southwestern Virginia has to offer.

Ruby L. Wells, Human Resource Analyst Southwestern Virginia Mental Health Institute 340 Bagley Circle Marion, VA 24354 Phone: 276-783-1204 Fax: 276-783-0844 E-mail: Ruby.wells@dbhds.virginia.gov

Website: www.swvmhi.dbhds.virginia.gov Job Application Site: https://jobs.agencies.virginia.gov. EOE

# **BC/BE Psychiatrist - Forensic/Civil**

**Central State Hospital**, a JCAHO accredited 277 bed psychiatric hospital, located 30 miles south of Richmond, Virginia and within two hours from the Blue Ridge Mountains, the beaches and our Nation's Capital is seeking a BC/BE psychiatrist to provide state of the art behavioral health and medical care to forensic and civilly committed patients in need of a structured, secure environment. In addition to our civil units, CSH has the Commonwealth's only maximum security Forensic Unit. Excellent benefits offer malpractice, health and life insurance, vacation and sick leave, retirement plan and relocation assistance.

Contact: employment@csh.dbhds.virginia.gov.

Advertising in the *Psychiatric News Classifieds*, gets you free online exposure at www.pn.psychiatryonline.org. VIRGINIA COMMONWEALTH UNI-VERSITY: Department of Psychiatry, School of Medicine, in collaboration with the Hunter Holmes McGuire Veterans Administration Medical Center, and VCU Institute for Drug and Alcohol Studies, is recruiting an academic physician Chair for the Division of Addiction Psychiatry. Chair is responsible for developing research, teaching and clinical programs. Funded Addictions Fellowship. Strong programs in psychiatric genetics, epidemiology, pharmacology, toxicology, and women's health. State funded health practitioner impairment program, Behavioral Public Health, laboratory and community based research are active areas for collaboration. Wonderful work environment. Department of Psychiatry has over 75 full-time faculty, 39 residents, multiple fellowships and research centers including an addiction genetics research center. The Veterans Administration Medical Center has robust residential and outpatient addictions programming, and an outstanding program in Psychiatry and Primary Care. VCU is Virginia's largest university with robust health science campus and 750-bed university hospital. Richmond, the State Capital, has moderate climate, a rich history, cultural activities, excellent choices for urban, suburban, or country living, outstanding public/private schools.

Send applications to Joel J. Silverman, M.D., Chairman, c/o Takeya McLaurin, Department of Psychiatry, MCV/VCU Box 980710, Richmond, VA 23298. Please contact Dr. Joel Silverman at (804) 828-9156 or email jsilverman@ mcvh-vcu.edu.

Virginia Commonwealth University is an Equal Opportunity/Affirmative Action

employer. Men, women, persons with disabilities, and minorities are encouraged to apply.

# WASHINGTON

The University of Washington and Harborview Medical Center (HMC) in Seattle, WA is accepting applications for a hospital-based psychiatrist at the rank of Acting Instructor or Acting Assistant Professor. This position is 1.0 FTE and will work doing a combination of inpatient psychiatry and hospital psychiatry consultation work with a large team consisting of another psychiatrist, psychologist, nurse and social worker. Two half-days a week will be spent in an ambulatory outpatient setting seeing patients. There is an MD requirement for this position. The position will also be responsible for teaching residents and medical students. Application deadline is Sept 15, 2010. Start date Jan 2, 2011 (sooner is possible).

**Please send application and CV to:** Peter Roy-Byrne MD, Chief Psychiatry, Harborview Medical Center 325 9th Ave. Box 359911, Seattle, WA 98104 or email roybyrne@uw.edu. The UW is building a culturally diverse faculty and strongly encourages applications from females and minority candidates. The UW is and EOE/AA employer.

# Medical Director Western State Hospital

The University of Washington (UW) and Western State Hospital (WSH) in Tacoma, WA are accepting applications for Medical Director at WSH at the rank of Associate Professor (without tenure) or Professor (without tenure). Requirements include an MD, completion of an accredited psychiatry residency program, ABPN board certification, expertise in the treatment of individuals with chronic and serious mental health disorders, and significant leadership experience at a major institution. This is a fulltime position to provide medical oversight and direction to WSH treatment programs, assume the medical responsibility for all patients, and participate in strategic planning and program development. This position is a member of the hospital Executive Leadership Team and reports directly to the WSH Chief Executive Officer. The UW faculty engage in teaching, research, and service.

Please send CV and cover letter to Jess C. Jamieson, Ph.D., Chief Executive Officer, Western State Hospital, 9601 Steilacoom Blvd. SW, Lakewood, WA 98498-7213 or e-mail Jess. Jamieson@dshs.wa.gov. For questions concerning the faculty appointment, please contact Richard C. Veith, MD, Professor and Chair, **UW Psychiatry and Behavioral Sciences** at (253) 543-3752 or e-mail rcv@uw.edu.

The UW is building a culturally diverse faculty and strongly encourages applications from females and minority candidates. The UW is an EOE/AA employer.

Summit Research Network (Seattle) LLC is seeking a licensed, board certified Psychiatrist to work with adult and pediatric/adolescent populations in clinical research trials. Must be comfortable working in a team environment as a Sub Investigator and Principal Investigator in primarily psychiatric pharmaceutical research at our site in Seattle, WA.

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Please send inquiries and CV to: James R. Hockley, MBA, Summit Research Network Management, Inc., 2701 NW Vaughn St., Ste.350; Portland, OR or via email: jhockley@ summitnetwork.com.

# **WISCONSIN**

**Psychiatrists - Appleton, Wisconsin.** Affinity Medical Group an integrated health care organization in East Central Wisconsin is recruiting a **BC/BE Child/Adolescent and BC/BE Adult Psychiatrists** for our Appleton location. These opportunities will encompass the full scope of services that support the needs that a psychiatric patient may present. Benefit from an industry leading compensation and exceptional benefits package. The Appleton area offers a unique quality of family oriented living, all season recreation, a nationally acclaimed educational system, a diverse growing economy, and a host of cultural opportunities.

For information, contact Cookie Fielkow, Affinity Physician Recruitment; Phone: 800-722-9989; E-mail: cfielkow@affinityhealth.org; Fax: 920-727-4350. Visit our website at: www.affinityhealth.org. EOE. Not a J-1 opportunity. A partnership of Ministry Health Care and Wheaton Franciscan Healthcare.



WASHINGTON DC

Entering its 34th year, this ACGME-accredited fellowship on Psychosomatic Medicine is currently accepting applications for three PGY-5 positions to start July 1, 2011. Under the guidance of Dr. Thomas Wise and Dr. Catherine Crone, the fellowship offers consultation-liaison training in a wide variety of medical specialties in both inpatient and outpatient settings. This includes: oncology, ob/gyn, HIV, trauma, organ transplantation, pulmonary medicine, and cardiology. Didactic seminars address clinical, biological, and psychodynamic approaches to understanding the medically ill. Opportunities in teaching, research, and outpatient psychotherapy are readily available. Training is tailored to fellow's area of interest and career goals. The fellowship is based at Inova Fairfax Hospital, an 833-bed tertiary care teaching facility located in the suburbs of Washington, D.C.

#### Interested individuals should contact:

Catherine Crone, M.D. PM Fellowship Program Director George Washington University Medical Center c/o Inova Fairfax Hospital 3300 Gallows Road Falls Church, VA 22042 Phone: 703-776-3380 E-mail: cathy.crone@inova.org

#### PGY 5 Fellowship in University Student Mental Health at The University of Chicago

This post-residency training program focuses on teaching the knowledge and skills necessary to provide mental health care to a university student community. The program will train future student mental health psychiatrists, and includes mentorship by the faculty based at the Student Counseling and Resource Service at The University of Chicago, an active student mental health service staffed by six psychiatrists and over 20 non-physician psychotherapists serving a population of approximately 14,000 extraordinary students. Clinical skills for this fellowship include training in psychosocial treatments for students including short-term psychotherapy, crisis intervention, and group psycho-therapies that are particularly important in this population, such as cognitive behavioral procrastination groups and eating disorder groups. It will also include intensive training in the unique aspects of psychopharmacology in this setting, such as addressing target symptoms without impairing cognition. Other aspects of training would be treatment of Attention Deficit Hyperactivity Disorder, substance abuse, mood and anxiety disorders, and first break psychotic disorders. The fellowship will also include administrative aspects of student mental health. This includes an understanding of the university's processing of applications for mental health disability accommodation, consultation for students going on and off medical leave for psychiatric reasons, providing liaison to the Department of Psychiatry for services provided to students, and doing training sessions for groups around campus who are likely to deal with troubled students. The fellow will receive supervision and training on becoming a good consultant for behavioral health issues on campus. These consultations include inquiries by faculty, University staff, and peers about how to deal with troubled students. The fellow will have experience and education on how to be an effective mental health expert as a member of the team of student life and student services professionals.

Please send a personal statement, curriculum vitae, and three letters of recommendation by **February 4, 2011** to: Thomas A. M. Kramer M.D., Director, Student Counseling and Re-

source Service, The University Of Chicago, 5737 South University, Chicago, IL 60637.

For information about the Student Counseling and Resource Service at The University of Chicago: http://counseling.uchicago.edu.

# FELLOWSHIP PUBLIC PSYCHIATRY at YALE

Yale University School of Medicine is accepting applications for a one-year Fellowship in Public Psychiatry for July 2011, based at the Connecticut Mental Health Center [CMHC], for individuals interested in public mental health and administration. CMHC is a major site for training, research and clinical service within the Yale and State systems. As a state-funded, academic, urban mental health center it provides a unique setting for psychiatrists to obtain advanced training as they pursue careers as leaders in the field. Fellows spend 50% time in seminars, supervision, and administrative/policy meetings of CMHC and the CT Dept. of Mental Health and Addiction Services; and up to 50% effort providing direct clinical service and/ or consultation within public mental health settings in the New Haven area. Child & Adolescent trained psychiatrists may apply for a combined advanced fellowship position with CMHC and the Yale Child Study Center. All candidates must be eligible for board certification and CT licensure. Minority applicants are encouraged to apply.

For further information contact Jeanne Steiner, D.O. Medical Director, CMHC - Yale Univ., 34 Park St New Haven, CT 06519 or Jeanne. Steiner@yale.edu.

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Contact Lindsey Fox to receive a hard copy of our Media Kit by U.S. Mail or to request an electronic version. Fellowship at the Massachusetts General Hospital Center for Anxiety and Traumatic Stress Disorders and Home Base Program for Veterans

The Massachusetts General Hospital Center for Anxiety and Traumatic Stress Disorders and the MGH-Red Sox Foundation Home Base Program for Veterans and Their Families are offering a joint psychiatric fellowship program. The fellowship is designed to provide comprehensive training in the research investigation in anxiety related disorders including PTSD, panic disorder, social anxiety disorder, generalized anxiety disorder and complicated grief in the general population as well as PTSD and related disorders in veterans.

Interested MDs should forward a letter of interest, curriculum vitae and list of 3 references to **Mark Pollack, M.D**. Center for Anxiety and Traumatic Stress Disorders and the Home Base Program Massachusetts General Hospital; mpollack@partners.org.

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# GEODON<sup>®</sup> (ziprasidone HCI) Capsules GEODON<sup>®</sup> (ziprasidone mesylate) injection for intramuscular use 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 is indicated for the treatment of schizophrenia, as monotherapy for the acute treatment of bipolar manic or mixed episodes, and as an adjunct to lithium or valproate for the maintenance treatment of bipolar disorder. GEODON intramuscular is indicated for acute agitation in schizophrenic patients.

#### DOSAGE AND ADMINISTRATION

Schizophrenia GEODON Capsules should be administered at an initial daily dose of 20 mg twice daily with food. In some patients, daily dosage may subsequently be adjusted on the basis of individual clinical status up to 80 mg twice daily. Dosage adjustments, if indicated, should generally occur at intervals of not less than 2 days, as steady-state is achieved within 1 to 3 days. In order to ensure use of the lowest effective dose, patients should ordinarily be observed for improvement for several weeks before upward dosage adjustment. Efficacy in schizophrenia was demonstrated in a dose range of 20 mg to 100 mg twice daily in short-term, placebocontrolled clinical trials. There were trends toward dose response within the range of 20 mg to 80 mg twice daily, but results were not consistent. An increase to a dose greater than 80 mg twice daily is not generally recommended. The safety of doses above 100 mg twice daily has not been systematically evaluated in clinical trials. Maintenance Treatment—While there is no body of evidence available to answer the question of how long a patient treated with ziprasidone should remain on it, a maintenance study in patients who had been symptomatically stable and then randomized to continue ziprasidone or switch to placebo demonstrated a delay in time to relapse for patients receiving GEODON. No additional benefit was demonstrated for doses above 20 mg twice daily. Patients should be periodically reassessed to determine the need for maintenance treatment. Bipolar I Disorder Acute Treatment of Manic or Mixed Episodes-Dose Selection: Oral ziprasidone should be administered at an initial daily dose of 40 mg twice daily with food. The dose may then be increased to 60 mg or 80 mg twice daily on the second day of treatment and subsequently adjusted on the basis of tolerance and efficacy within the range 40 mg to 80 mg twice daily. In the flexible-dose clinical trials, the mean daily dose administered was approximately 120 mg. Maintenance Treatment (as an adjunct to lithium or valproate)-Continue treatment at the same dose on which the patient was initially stabilized, within the range of 40 mg to 80 mg twice daily with food. Patients should be periodically reassessed to determine the need for maintenance treatment. Acute Treatment of Agitation in Schizophrenia Intramuscular Dosing-The recommended dose is 10 mg to 20 mg administered as required up to a maximum dose of 40 mg per day. Doses of 10 mg may be administered every two hours; doses of 20 mg may be administered every four hours up to a maximum of 40 mg/day. Intramuscular administration of ziprasidone for more than three consecutive days has not been studied. If long-term therapy is indicated, oral ziprasidone hydrochloride capsules should replace the intramuscular administration as soon as possible. Since there is no experience regarding the safety of administering ziprasidone intramuscular to schizophrenic patients already taking oral ziprasidone, the practice of co-administration is not recommended. Ziprasidone intramuscular is intended for intramuscular use only and should not be administered intravenously. Intramuscular Preparation for Administration GEODON for Injection (ziprasidone mesylate) should only be administered by intramuscular injection and should not be administered intravenously. Single-dose vials require reconstitution prior to administration. Add 1.2 mL of Sterile Water for Injection to the vial and shake vigorously until all the drug is dissolved. Each mL of reconstituted solution contains 20 mg ziprasidone. To administer a 10 mg dose, draw up 0.5 mL of the reconstituted solution. To administer a 20 mg dose, draw up 1.0 mL of the reconstituted solution. Any unused portion should be discarded. Since no preservative or bacteriostatic agent is present in this product, aseptic technique must be used in preparation of the final solution. This medicinal product must not be mixed with other medicinal products or solvents other than Sterile Water for Injection. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Dosing in Special Populations Oral: Dosage adjustments are generally not required on the basis of age, gender, race, or renal or hepatic impairment. GEODON is not approved for use in children or adolescents. Intramuscular: Ziprasidone intramuscular has not been systematically evaluated in elderly patients or in patients with hepatic or renal impairment. As the cyclodextrin excipient is cleared by renal filtration, ziprasidone intramuscular should be administered with caution to patients with impaired renal function. Dosing adjustments are not required on the basis of gender or race.

# CONTRAINDICATIONS

**QT Prolongation** Because of ziprasidone's dose-related prolongation of the QT interval and the known association of fatal arrhythmias with QT prolongation by some other drugs, ziprasidone 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 ziprasidone and other drugs that prolong the QT interval have not been performed. An additive effect of ziprasidone and other drugs that prolong the QT interval cannot be excluded. Therefore, ziprasidone should not be given with dofetilide, sotalol, quinidine, other Class la and III anti-arrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl acetate, dolasetron mesylate, probucol or tacrolimus. Ziprasidone is also contraindicated with other 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**]. Ziprasidone 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 is not approved for the treatment of dementia-related psychosis (see BOXED WARNING).

**QT** Prolongation and Risk of Sudden Death Ziprasidone 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 ziprasidone. Ziprasidone should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias (see **CONTRAINDICATIONS**).

**QT Prolongation in Clinical Trials** A study directly comparing the QT/QT<sub>c</sub> prolonging effect of oral ziprasidone with several other drugs effective in the treatment of schizophrenia was conducted in patient volunteers. The mean increase in QT<sub>c</sub> from baseline for ziprasidone 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 ziprasidone on QTc length was not augmented by the presence of a metabolic inhibitor (ketoconazole 200 mg twice daily). In placebo-controlled trials, oral ziprasidone increased the QTc 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%) patients who received GEODON and 1/440 (0.23%) patients who received placebo revealed QTc intervals exceeding the potentially clinically relevant threshold of 500 msec. In the ziprasidone-treated patients, neither case suggested a role of ziprasidone. QT Prolongation and Torsade De Pointes Some drugs that prolong the QT/QTc 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/QTc prolongations may also increase risk, or increase it in susceptible individuals. Although torsade de pointes has not been observed in association with the use of ziprasidone in premarketing studies and experience is too limited to rule out an increased risk, there have been rare post-marketing reports (in the presence of multiple confounding factors) (see ADVERSE REACTIONS). A study evaluating the QT/QTc prolonging effect of intramuscular ziprasidone, 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 ziprasidone (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 ziprasidone is 50% higher than the recommended therapeutic dose. The mean change in QTc 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 QTc from baseline for ziprasidone was 4.6 msec following the first injection and 12.8 msec following the second injection. The mean increase in QTc from baseline for haloperidol was 6.0 msec following the first injection and 14.7 msec following the second injection. In this study, no patients had a QTc interval exceeding 500 msec. As with other antipsychotic drugs and placebo, sudden unexplained deaths have been reported in patients taking ziprasidone at recommended doses. The premarketing experience for ziprasidone did not reveal an excess risk of mortality for ziprasidone 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, ziprasidone's larger prolongation of QTc length compared to several other antipsychotic drugs raises the possibility that the risk of sudden death may be greater for ziprasidone 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 QTc interval, including (1) bradycardia; (2) hypokalemia or hypomagnesemia; (3) concomitant use of other drugs that prolong the QTc interval; and (4) presence of congenital prolongation of the QT interval. Electrolyte Disturbances May Increase The Risk of QT Prolongation It is recommended that patients being considered for ziprasidone 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 ziprasidone treatment. Persistently prolonged QTc 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, ziprasidone should be avoided in patients with histories of significant cardiovascular illness, e.g., QT prolongation, recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. Ziprasidone should be discontinued in patients who are found to have persistent QTc 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 A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients undergoing treatment 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. If signs and symptoms of tardive dyskinesia appear in a patient on ziprasidone, drug discontinuation should be considered. Hyperglycemia and Diabetes Mellitus Hyperglycemia-related adverse events, sometimes serious, have been reported in patients treated with atypical anti-psychotics. 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. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia.

#### PRECAUTIONS

Leukopenia, Neutropenia, and Agranulocytosis In clinical trial and postmarketing experience, events of leukopenia/neutropenia and agranulocytosis (including fatal cases) have been reported temporally related to antipsychotic agents. Possible risk factors for leukopenia/neutropenia include pre-existing low white blood cell count (WBC) and history of drug induced leukopenia/neutropenia. Patients with a pre-existing low WBC or a history of drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and should discontinue GEODON at the first sign of decline in WBC in the absence of other causative factors. Patients with neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000/mm3) should discontinue GEODON and have their WBC followed until recovery. Rash In premarketing trials with ziprasidone, about 5% of patients developed rash and/or urticaria, with discontinuation of treatment in about one-sixth of these cases. The occurrence of rash was related to dose of ziprasidone, although the finding might also be explained by the longer exposure time in the higher dose patients. Several patients with rash had signs and symptoms of associated systemic illness, e.g., elevated WBCs. Most patients improved promptly with adjunctive treatment with antihistamines or steroids and/or upon discontinuation of ziprasidone, and all patients experiencing these reactions were reported to recover completely. Upon appearance of rash for which an alternative etiology cannot be identified, ziprasidone should be discontinued. Orthostatic Hypotension Ziprasidone may induce orthostatic hypotension associated with dizziness, tachycardia, and, in some patients, syncope, especially during the initial dose-titration period, probably reflecting its  $\alpha_1$ -adrenergic antagonist properties. Syncope was reported in 0.6% of the patients treated with ziprasidone. Ziprasidone 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 which would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medications). Seizures In clinical trials, seizures occurred in 0.4% of patients treated with ziprasidone. There were confounding factors that may have contributed to the occurrence of seizures in many of these cases. As with other antipsychotic drugs, ziprasidone should be used cautiously in patients with a history of seizures or with conditions that potentially lower the that lower ner's der threshold may 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 ziprasidone and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia (see BOXED WARNING and Increased Mortality in Elderly Patients with Dementia-Related Psychosis in WARNINGS). Hyperprolactinemia As with other drugs that antagonize dopamine D2 receptors, ziprasidone 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 reaction in patients treated with ziprasidone. In the 4- and 6-week placebo-controlled trials, somnolence was reported in 14% of patients on ziprasidone compared to 7% of placebo patients. Somnolence led to discontinuation in 0.3% of patients in short-term clinical trials. Since ziprasidone 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 ziprasidone therapy does not affect them adversely. Priapism One case of priapism was reported in the premarketing database. Body Temperature Regulation Although not reported with ziprasidone 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. Prescriptions for ziprasidone should be written for the smallest quantity of capsules consistent with good patient management in order to reduce overdose risk. Patients With Concomitant Illnesses Clinical experience with ziprasidone in patients with certain concomitant systemic illnesses is limited. Ziprasidone 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 QTc prolongation and orthostatic hypotension with ziprasidone, 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 assure safe and effective use of GEODON, the information and instructions provided in the patient information should be discussed with patients. Laboratory Tests Patients being considered for ziprasidone treatment who are at risk of significant electrolyte disturbances should have baseline serum potassium and magnesium measurements. Low serum potassium and magnesium should be replaced before proceeding with treatment. Patients who are started on diuretics during Ziprasidone therapy need periodic monitoring of serum potassium and magnesium. Discontinue ziprasidone in patients who are found to have persistent QTc measurements >500 msec (see WARNINGS).

# **DRUG INTERACTIONS**

(1) Ziprasidone should not be used with any drug that prolongs the QT interval. (2) Given the primary CNS effects of ziprasidone, caution should be used when it is taken in combination with other centrally acting drugs. (3) Because of its potential for inducing hypotension, ziprasidone may enhance the effects of certain antihypertensive agents. (4) Ziprasidone may antagonize the effects of levodopa and dopamine agonists. Effect of Other Drugs on Ziprasidone Carbamazepine, 200 mg bid for 21 days, resulted in a decrease of approximately 35% in the AUC of ziprasidone. Ketoconazole, a potent inhibitor of CYP3A4, 400 mg qd for 5 days, increased the AUC and Cmax of ziprasidone by about 35-40%. Cimetidine, 800 mg qd for 2 days, did not affect ziprasidone pharmacokinetics. Co-administration of 30 mL of Maalox® did not affect ziprasidone pharmacokinetics. Population pharmacokinetic analysis of schizophrenic patients enrolled in controlled clinical trials has not revealed evidence of any clinically significant pharmacokinetic interactions with benztropine, propranolol, or lorazepam. Effect of Ziprasidone on Other Drugs In vitro studies revealed little potential for ziprasidone to interfere with the metabolism of drugs cleared primarily by CYP1A2, CYP2C9, CYP2C19, CYP2D6 and CYP3A4, and little potential for drug interactions with ziprasidone due to displacement. Ziprasidone 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. In vivo studies have revealed no effect of ziprasidone on the pharmacokinetics of estrogen or progesterone components. Ziprasidone 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 ziprasidone 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.

#### NONCLINICAL TOXICOLOGY

**Carcinogenesis, Mutagenesis, Impairment of Fertility** Lifetime carcinogenicity studies were conducted with ziprasidone 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. Ziprasidone 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** in **PRECAUTIONS**). *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:* Ziprasidone increase 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/m2 basis). Fertility rate was reduced at 160 mg/kg/day (8 times the MRHD on a mg/m2 basis). There was no effect on fertility at 40 mg/kg/day (2 times the MRHD on a mg/m2 basis). The retility of female rats was reduced.

#### **USE IN SPECIFIC POPULATIONS**

**Pregnancy** *Pregnancy Category C:* There are no adequate and well-controlled studies in pregnant women. Ziprasidone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Labor and Delivery** The effect of ziprasidone on labor and delivery in humans is unknown. **Nursing Mothers** It is not known whether ziprasidone or its metabolites are excreted in human milk. It is recommended that women receiving ziprasidone should not breastfeed. **Pediatric Use** The safety and effectiveness of ziprasidone in pediatric patients have not been established. **Geriatric Use** Of the total number of subjects in clinical studies of ziprasidone, 2.4 percent were 65 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Nevertheless, the presence of multiple factors that might increase the pharmacodynamic response to ziprasidone, 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 ziprasidone-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse reaction, compared with about 2.2% (6/273) on placebo. The most common reaction associated with dropout was rash, including 7 dropouts for rash among ziprasidone patients (1%) compared to no placebo patients (see PRECAUTIONS). Bipolar Mania: Approximately 6.5% 8/279) of ziprasidone-treated patients in short-term, placebo-controlled studies discontinued treatment due to an adverse reaction, compared with about 3.7% (5/136) on placebo. The most common reactions associated with dropout in the ziprasidone-treated patients were akathisia, anxiety, depression, dizziness, dystonia, rash and vomiting, with 2 dropouts for each of these reactions among ziprasidone 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 of ≥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 4-study pool revealed an apparent relation of adverse reaction to dose for the following reactions: 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 ziprasidone 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 (for EPS) and the Barnes Akathisia Scale (for akathisia) did not generally show a difference between ziprasidone and placebo. Dystonia Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. 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. Elevated risk of acute dystonia is observed in males and younger age groups. Vital Sign Changes Ziprasidone 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 ziprasidone (10%) compared to placebo (4%). A median weight gain of 0.5 kg was observed in ziprasidone patients compared to no median weight change in placebo patients. Weight gain was reported as an adverse event in 0.4% of both ziprasidone and placebo patients. During long-term therapy with ziprasidone, a categorization of patients at baseline on the basis of body mass index (BMI) revealed the greatest mean weight gain and highest incidence of clinically significant weight gain (>7% of body weight) in patients with low BMI (<23) compared to normal (23-27) or overweight patients (>27). There was a mean weight gain of 1.4 kg for those patients with a "low" baseline BMI, no mean change for patients with a "normal" BMI, and a 1.3 kg mean weight loss for patients who entered the program with a "high" BMI. ECG Changes Ziprasidone is associated with an increase in the  $QT_c$  interval (see **WARNINGS**). In the schizophrenia trials, ziprasidone 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 Ziprasidone in Schizophrenia 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 adverse events are those occurring in fewer than 1/1000 patients. 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 trans-peptidase 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 Findings Observed in Trials of Intramuscular Ziprasidone In these studies, the most commonly observed adverse reactions associated with the use of intramuscular ziprasidone (≥5%) and observed at a rate on intramuscular ziprasidone (in the higher dose groups) at least twice that of the lowest intramuscular ziprasidone group were headache (13%), nausea (12%), and somnolence (20%). Adverse Events at an Incidence of  $\geq$ 1% in Short-Term Fixed-Dose Intramuscular Trials The following list enumerates the treatment-emergent adverse events that occurred in  $\geq 1\%$  of patients during acute therapy with intramuscular ziprasidone: Body as a Wholeheadache, 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. Other Events Observed During Post-marketing Use Adverse reaction reports not listed above that have been received since market introduction include rare occurrences of the following-Cardiac Disorders: Tachycardia, torsade de pointes (in the presence of multiple confounding factors), (see WARNINGS); Digestive System Disorders: Swollen Tongue; Reproductive System and Breast Disorders: Galactorrhea, priapism; Nervous System Disorders: Facial Droop, neuroleptic malignant syndrome, serotonin syndrome (alone or in combination with serotonergic medicinal products), tardive dyskinesia; Psychiatric Disorders: Insomnia, mania/hypomania; Skin and subcutaneous Tissue Disorders: Allergic reaction (such as allergic dermatitis, angioedema, orofacial edema, urticaria), rash; Urogenital System Disorders: Enuresis, urinary incontinence; Vascular Disorders: Postural hypotension, syncope.

#### DRUG ABUSE AND DEPENDENCE

Controlled Substance Class Ziprasidone is not a controlled substance.

#### OVERDOSAGE

In premarketing trials in over 5400 patients, accidental or intentional overdosage of oral ziprasidone 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 (200/95).

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# **BIPOLAR I MAINTENANCE TREATMENT**

# GEODON + LITHIUM OR VALPROATE PROVENSUPERIOR TO LITHIUM OR VALPROATE ALONE IN PREVENTING RELAPSE



GEODON is indicated for acute treatment as monotherapy of manic or mixed episodes associated with bipolar I disorder and for maintenance treatment of bipolar I disorder as an adjunct to lithium or valproate. For full symptoms and diagnostic criteria, see the *DSM-IV-TR*<sup>®</sup> (2000).

# **IMPORTANT SAFETY INFORMATION**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death compared to placebo. GEODON is not approved for the treatment of patients with dementia-related psychosis.

GEODON is contraindicated in patients with a known history of QT prolongation, recent acute myocardial infarction, or uncompensated heart failure, and should not be used with certain other QT-prolonging drugs. GEODON has a greater capacity to prolong the QT interval than several antipsychotics. In some drugs, QT prolongation has been associated with torsade de pointes, a potentially fatal arrhythmia. In many cases this would lead to the conclusion that other drugs should be tried first. Hypokalemia may increase the risk of QT prolongation and arrhythmia.

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 durationdependent syndrome. If signs and symptoms appear, discontinuation should be considered since TD may remit partially or completely.

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

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

The most common adverse events associated with GEODON in bipolar mania were somnolence, extrapyramidal symptoms, dizziness, akathisia, and abnormal vision.

The most common adverse events ( $\geq$ 5%) associated with GEODON in the bipolar maintenance study were tremor and insomnia.

*Please see brief summary of prescribing information on adjacent page.* **For more information, please visit www.pfizerpro.com/GEODON**