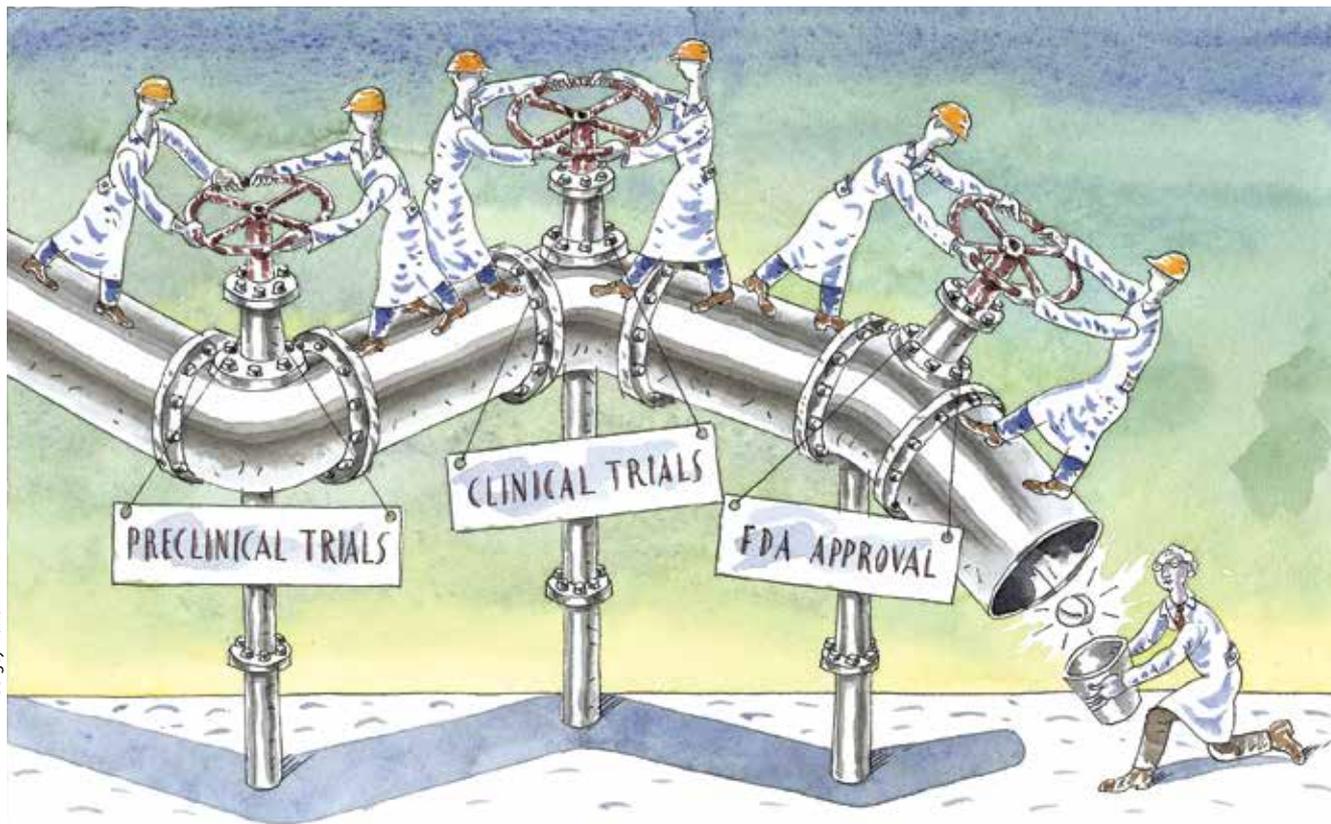


PSYCHIATRIC NEWS

The First and Last Word in Psychiatry

ISSN 0033-2704



Psychiatrists' Pay To Rise at Veterans Health Administration

Advocacy by APA in collaboration with veterans' organizations helps boost salary rates for psychiatrists working in the Veterans Health Administration.

BY AARON LEVIN

Beginning November 30, pay rates for physicians in the Veterans Health Administration (VHA)—including psychiatrists—will rise to more competitive levels, one of several measures intended to recruit and retain badly needed medical personnel to the giant health system.

The new pay scales bring the VHA, a part of the Department of Veterans Affairs, more closely in line with the private sector and other federal government agencies, said VHA psychiatrist Jenny Boyer, M.D., Ph.D., J.D., speaker of the APA Assembly and co-chair of the APA VA Caucus.

The range has moved up a notch from (in the VHA's jargon) Pay Table 1 to Pay Table 2, which in turn has three "tiers." Annual salaries begin at \$98,967 and top out at \$260,000.

"The VHA couldn't compete with other federal entities that could pay more, like the Department of Defense or the Indian Health Service," added Lizbet Boroughs, deputy director of APA's Department of Government Affairs.

The increased pay, combined with new legislation that doubles the amount of medical school debt relief from a maximum of \$60,000 to \$120,000, is

see **Pay** on page 38

Candidates, Innovation Missing From Psychotropic Drug Pipeline

There is a need for more innovative psychotropic drug development, but there is a dearth of new products on the horizon.

BY VABREN WATTS

In 2011, Pharmaceutical Research and Manufacturers of America (PhRMA)—the trade association representing major drug manufacturers—reported that 240 drugs intended to treat psychiatric disorders were in development, compared with more than 3,000 for cancer and 750 for infectious disease. A study published

in September in *Psychiatric Services in Advance* may provide some explanations as to why the pipeline for psychotropic medicines is nearly empty.

Researchers from Brandeis University and Truven Health Analytics led an investigation of the current state of psychotropic drugs in the pipeline and potential barriers that may keep these drugs from reaching distribution in the United States.

"Though current medications help many persons with mental health conditions, existing antidepressants, antipsychotics, and other psychotropic medicines on the market do not work well for all individuals," said the study's lead author, Peggy O'Brien, Ph.D., research

leader of Behavioral Health and Quality Research at Truven Health Analytics, in an interview with *Psychiatric News*. Given that studies have shown that many patients do not respond initially to antidepressants and that schizophrenia is treatment refractory in one-fifth to one-third of those affected, O'Brien and colleagues emphasized that the need to develop innovative treatment is obvious.

"We often read that there are hundreds or thousands of drugs in development, when, in fact, very few of those drugs reach the clinic," O'Brien explained. "This is not to say that companies are not performing innovative

see **Pipeline** on page 35

PERIODICALS: TIME SENSITIVE MATERIALS

14



26

INSIDE

Military turns to integrated care to treat soldiers with PTSD, depression.



Psychiatrist couple makes sure insurers follow the law on mental health parity.

28



Psychiatrists describe the lures, frustrations of treating patients in the VA system.

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CONTENTS



PROFESSIONAL NEWS

13 Collaborative Care Shows Success With Depressed Cancer Patients

A collaborative care approach for cancer patients with depression is found to be very effective—and the strategy works regardless of the patient's prognosis.

20 Lack of Cultural Awareness Can Compromise Mental Health Care

An advocate for better health care for Hispanic Americans discusses how critical cultural competence is when treating mental illness in patients of Hispanic descent.

GOVERNMENT NEWS

21 Public Now Has Access to Sunshine Act Data on Payments From Industry

Amid serious concerns about the accuracy of the data, the Centers for Medicare and Medicaid Services launched the Open Payments database.

LEGAL NEWS

22 How Might a Case Involving Tooth Whitening Impact Psychiatry?

A Supreme Court case over whether nondentists can provide tooth-whitening services raises scope-of-practice issues that could eventually affect physicians.

MEMBERS IN THE NEWS

28 VA Psychiatrists Explain Why They Chose to Follow That Career Path

A mix of practical and idealistic reasons motivates psychiatrists who specialize in treating America's veterans.

CLINICAL & RESEARCH NEWS

31 Kandels Accrue Evidence for 'Gateway Hypothesis' of Drug Use

Eric Kandel, M.D., and Denise Kandel, Ph.D., explore the link between nicotine and cocaine use as they study why addicts arrive at their drug of choice.

32 Antipsychotic Use Need Not Be Deterrent to Weight-Loss Efforts

A lifestyle modification program called STRIDE shows that given the right tools and comprehensive support, people with serious mental illness can lose weight and improve their metabolism.

Don't Miss This Exclusive Opportunity!



APA members will have an exclusive opportunity to register, enroll in courses, and make hotel reservations for APA's 2015 annual meeting in Toronto from **Tuesday, December 2, through Monday, December 15**. Nonmembers will have access beginning Tuesday, December 16. The meeting runs from May 16 to 20. To access the annual meeting website, go to www.psychiatry.org/annualmeeting. More information is available by calling the APA Meetings and Conventions Department at (703) 907-7822 or by e-mailing apa@psych.org.

Departments

12 | FROM THE PRESIDENT

14 | PSYCHIATRY & INTEGRATED CARE

30 | JOURNAL DIGEST

33 | MED CHECK

34 | LETTERS TO THE EDITOR

Advertisement

Advertisement

Advertisement

Advertisement

Advertisement

Advertisement

Advertisement

Advertisement

Advertisement

Advertisement



FROM THE PRESIDENT

The Practice of Medicine

BY PAUL SUMMERGRAD, M.D.

On October 14, the United States Supreme Court heard oral arguments in a case, which APA joined as an amicus curiae with other medical organizations, that arose from disagreement about what constitutes the “practice of dentistry” in North Carolina and challenged the role of the state dental board in the regulation of dentistry (see page 22). In oral arguments, some of the justices recognized the value of having medical specialists make decisions that impact medical care. Both Justice Scalia and Justice Breyer, uncommonly allied, acknowledged that regardless of the result of the antitrust question before them, both would want to see physicians, rather than a group of bureaucrats, deciding who should practice brain surgery. Psychiatrists clearly understand that the oversight of medical practice is not a small matter.

The justices’ comments arrived on the heels of recent discussions about scope of practice and legislation proposing pathways to “prescriptive” privileges. So it’s timely to consider these important issues, which have engaged the medical community in general and psychiatrists, among others, in particular. My use of quotation marks around the term “prescriptive” is purposeful, as I think it misconstrues the issues surrounding the mid-level practice of medicine, and the practice of medicine more broadly of which, of course, psychiatry is a part.

The licensure of physicians in the United States is often described as a full or unlimited license to practice medicine. While this is usually limited by training, hospital privileges, and other forms of credentialing, it nevertheless contains an important concept: that physicians evaluate and diagnose patients and prescribe treatment without an *a priori* requirement for supervision or oversight by another professional. Now obviously this does not prevent physicians from seeking consultation from others—indeed, good practice mandates such efforts when clinical circumstances warrant—but the core of the independent practice of medicine remains.

The prescription of pharmaceutical agents is, however, only one step, and a late one at that, in the clinical reasoning that must begin with the comprehensive evaluation of patients and a consideration of the differential diagnosis of what could be causing a patient’s symptoms. This can be followed by laboratory testing, physical and neurologic exams, radiologic studies, and continued clinical assessment and reassessment. This process of ongoing evaluation fully applies to patients with psychiatric symptoms as much as

any other patient group, and perhaps more so. We know that patients with psychiatric illness have higher rates of medical illness than cohorts without



psychiatric illness and that many general medical disorders can cause psychiatric symptoms or can directly influence the course and response to care of psychiatric illnesses. And all of this is the practice of medicine that psychiatrists perform daily before they ever decide whether a pharmaceutical agent should be prescribed. Thus, prescribing represents only one component of the practice of medicine, and one that is dependent upon broad and detailed medical knowledge.

Perhaps two clinical examples, disguised to protect confidentiality, will help illustrate my point:

A 42-year-old man was seen in the emergency room of a large general hospital. After an initial examination by the internal medicine house staff, a psychiatry resident was called to evaluate the patient for hysterical blindness. On examination, the patient was cooperative with the examiner, had fluent and coherent speech, and was concerned that he couldn’t see. He failed to track the examiner and on closer inspection had widely dilated pupils bilaterally and no impairment of level of consciousness or peripheral long track signs. Babinski’s reflex was not present. The patient’s pupils did not react to light, and the patient had no blink reflex to vigorous confrontation, suggesting he could not see. The psychiatry resident suspected a drug effect and, on gathering further history, discovered that the patient had access to quinine of which he had taken an overdose. Quinine is known to produce “quinine blindness” by binding in a reversible but toxic way to the retina, essentially disconnecting the retina from the central nervous system and rendering the patient temporarily, but actually, blind. He fully recovered without treatment 12 hours later.

A second—but more common—problem confronted a resident caring for a 63-year-old woman. The patient had had recurrent major depression for which a combination of psychotherapy and medication had been highly effective, allowing her to return to her normal work and social commitments. However, she began to experience lower abdominal distress, eventually accompanied by low-grade fevers and night sweats. Despite the resident’s concern, her patient’s complaints were dismissed at a local walk-in clinic,

see **From the President** on page 19

PROFESSIONAL NEWS

Integrated Care Improves Depression Symptoms in Cancer Patients

Two multicenter clinical studies find a collaborative care approach to cancer treatment is much more effective than usual care, even in patients with poor prognosis.

BY NICK ZAGORSKI

In 2008, the Institute of Medicine issued a report recommending that cancer care include provisions for a patient's psychological and social well-being. While challenges to implementing an integrated "whole-person" system do exist at the patient, provider, and institutional levels, they should not be insurmountable. Indeed, studies have shown that integrating psychiatric care into a standard care regimen can improve the well-being of cancer patients with depressive symptoms.

A pair of related clinical trials in the United Kingdom has now advanced the potential of integrated care in cancer

therapy even further. The two studies, SMaRT Oncology-2 and SMaRT Oncology-3, not only provided some of the most striking data on the positive impact of integrated care compared with usual care, but also showed that it can alleviate depression even in people with a poor cancer prognosis.

"Depression gets frequently overlooked in cancer patients because the main business of cancer care is prolonging life," said Michael Sharpe, M.D., a professor of psychological medicine at the University of Oxford and principal investigator of the Oncology-2 trial. "We need to balance that quantity of life with a better quality of life for these patients."

The SMaRT Oncology-2 trial findings, which were published in *Lancet*, enrolled 500 adults from three cancer centers in Scotland who were diagnosed with both depression and a cancer with a good prognosis (more than a year life expectancy). The group was randomly divided to receive either usual care or an approach known as Depression Care for People with Cancer (DCPC).

DCPC is a multicomponent program that provides both antidepressants and psychological therapy in a systematic fashion, bringing cancer specialists, psychiatrists, and primary care physicians together on the same page. The cogs in



Michael Sharpe, M.D., led the SMaRT Oncology-2 trial, which found a 45 percent difference in response to treatment between patients receiving an integrated program of depression care versus those receiving usual care.

University of Oxford

Key Points

- In cancer patients with good prognosis, 62 percent of patients receiving DCPC reported at least a 50 percent reduction in depression severity compared with 17 percent receiving usual care.
- In cancer patients with poor prognosis, these treatment response values were 51 percent for patients receiving DCPC compared with 15 percent of those receiving usual care.

Bottom Line: An integrated approach to cancer therapy such as DCPC can reduce symptoms and improve the quality of life of people with cancer, regardless of prognosis.

this collaborative machine are specially trained oncology nurses who establish relationships with the patients and continually oversee their progress.

"The patients told us that they wanted the focal point to be someone who understands cancer, knows what they are going through, and will help them stick through this intensive depression treatment regimen," Sharpe said.

After 24 weeks, 62 percent of patients see **Cancer Patients** on page 36

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Military Turns to Collaborative Care to Treat PTSD, Depression

BY CHARLES ENGEL, M.D.

Much has been written and discussed regarding the elevated rates of posttraumatic stress disorder (PTSD), depression, alcohol misuse, sexual assault, suicide, and other mental health problems in the military after 13 years of armed conflict in Iraq and Afghanistan. Indeed, these issues are widely viewed as among the most serious military health problems in need of science-based solutions.

Any solution faces health system challenges including stigma, barriers to care, and quality of care for military personnel and their families. The military's health system (MHS) serves a diverse spectrum of families and patients: wealthy and poor, infants to elderly, and men and women in similar proportions. It includes virtually every medical discipline, profession, and

ing those innovations, starting at the beginning of the program in 2003. That is when I first connected with investigators from the MacArthur Foundation Initiative on Depression in Primary Care, most importantly Alan Dietrich, Tom Oxman, John Williams, and Kurt Kroenke.

The MacArthur Initiative group called their approach the Three Component Model: (1) prepared primary care practices, which meant equipping clinics with process tools such as screening instruments and diagnostic aids and informatics enhancements; (2) a care manager resource, usually a registered nurse,

added to each participating primary care clinic; and (3) an enhanced specialty care interface, usually a psychiatrist meeting weekly with care managers to review patients' status and together formulate specific recommendations for the primary care clinician.

With the generous assistance of MacArthur Initiative experts and funding assistance from the Department of Defense, we adapted the initiative's model for depression, added a PTSD-specific module, and then successfully piloted the program during 2004-2005 at a large Army primary care clinic at Fort Bragg in North Carolina.

Lt. Gen. Kevin Kiley, then Army surgeon general, learned of our efforts.



Before we could say, "Careful what you ask for," we were funded, staffed, and armed with an Army health system OPOD (operations order) mandating implementation at 15 large, high-deployment installations (42 primary care clinics) worldwide. We called our modified MacArthur approach RESPECT-Mil (Re-Engineering Systems of Primary Care for PTSD and Depression in the Military) and started scrambling to make it happen beginning in January 2007.

The military health system was laboring to support two wars, so it was hardly unanimous among leaders and rank-and-file military health system clinicians that collaborative care was a step in the right direction. We had to be credible and persuasive champions. We traveled to every implementing facility, talked with leaders and staff at all levels, walked the clinics, saw with our own eyes what processes work, and learned lessons from implementation variation when it was unavoidable.

For maximum effect, we gave each installation's implementing team some room to make it its own, to take pride in the fact that its version of RESPECT-Mil was better than any other. For example, one site was proud of its unique and streamlined screening process, and another was proud of its business model of successfully generating RVU credit for the care facility. However, as a worldwide implementation team, we had to remain steadfast in maintaining the conceptual pillars of collaborative care, training and reinforcing them to ensure improved clinical outcomes.

By 2010, RESPECT-Mil was running in all 42 assigned clinics. A Web-based care management support system based on the one used for the IMPACT trial, one of the first large, multisite trials of collaborative care for primary care patients with depression, was fielded. We sent installation-specific reports comparing each site's performance with all others. On a set schedule, we were "boots down" at installations and facilities.

Our progress was rewarded. A new OPOD was issued that year, directing the expansion of RESPECT-Mil to 37 installations responsible for 92 primary care clinics. We had the trust of leaders, which helped when competing models emerged.

For example, the Army is moving to the patient-centered medical home. Some clinics and leaders preferred primary care mental health co-location, the placement of a mental health specialist in each clinic. The results of this strategy, however, are costly and fail to improve outcomes: while putting a specialist in each

clinic is easy to do and see, this approach unnecessarily restricts the work of the specialist to a single clinic. Unless there are changes to the process of care, primary care clinicians often miss patients with mental health needs and do not link them to a mental health specialist. Other times, the primary care clinician may identify and link them to a specialist, but without a care manager working actively to keep the patient engaged in some form of intensified treatment, the patient may drop out of care.

So we successfully stuck with our message: improving outcomes requires more than moving a mental health specialist into primary care—it takes broader and more active changes such as the use of a care manager to fully engage patients as well as their primary care teams, and it takes routine use of valid measurement tools such as the PHQ-9 and PTSD Checklist to help clinics identify, track, and regularly review patients' treatment needs.

Just before the OPOD was expanded, we were awarded a large research grant to complete a five-year, randomized, effectiveness trial of a second-generation approach to RESPECT-Mil, a model we are calling STEPS-UP (Stepped Enhancement of PTSD Services Using Primary Care). Several new innovations were added, such as centralized implementation assistance, stepped psychotherapies making use of Internet and telephone, care-manager training in intensive patient-engagement strategies for greater continuity, and routine use of automated registries to identify patients in need of treatment changes. Doug Zatzick, Jürgen Unützer, Wayne Katon, Lisa Jaycox, and Terri Tanielian are key collaborators in this exciting study, the results of which should be out next spring.

When I retired from the Army last fall, RESPECT-Mil was running in 88 Army primary care clinics and had improved care in more than 3 million patient visits. The program has helped tens of thousands of military personnel with PTSD and depression, including thousands who screened positive for suicidality. From my new position at the RAND Corporation, I feel fortunate for the opportunity to contribute in this way. Collaborative care has presented a once-in-a-lifetime opportunity to bring a science-based solution to an essential military problem. It has helped thousands of men and women in uniform in ways that also nudge our larger mental health system toward greater effectiveness for all Americans. **PN**

Collaborative care has presented a once-in-a-lifetime opportunity to bring a science-based solution to an essential military problem.

level of training. The MHS costs \$52 billion a year and covers some 9.6 million beneficiaries, including 1.4 million uniformed personnel.

Collaborative care has been an important part of Army efforts to reach out to those struggling with PTSD and depression. For years I had the privilege of lead-

Charles Engel, M.D., is a senior health scientist at the RAND Corporation.

Get Ready to Cast Your Vote!

The names of the candidates running for office in APA's 2015 election were announced after this issue went to press. The list is posted on APA's website at www.psychiatry.org and will appear in the next issue. Here are some important dates to keep in mind:

- **November 15:** Deadline for petition candidates.
- **December 19:** Candidates' photos and website addresses will be published in *Psychiatric News*.
- **January 2:** Voting begins at 5 a.m. (EST). All members for whom APA has a valid e-mail address on file will receive an electronic ballot. Other members will receive a paper ballot along with instructions on how to vote online if they so choose. Information on the candidates will be posted online and appear in a booklet accompanying the paper ballot.
- **January 20:** Deadline for ballot requests.
- **February 2:** Voting ends at 11:59 p.m. (EST).
- **Early to mid-February:** Election results will be announced.



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PROFESSIONAL NEWS

Depression Care Manager Key To Integrated Care Success

A full-time care manager dedicated to depression care is crucial to successful collaborative care programs, but the educational level of those managers is not.

BY MARK MORAN

Hiring care managers who are dedicated exclusively to depression care appears to be associated with better enrollment and remission rates among primary care patients receiving treatment for depression in a collaborative care model.

Moreover, outcomes did not differ depending on the educational level of care managers, suggesting that more highly trained—and more costly—care managers may not be necessary to provide cost-effective collaborative care. The findings were published October 1 in *Psychiatric Services in Advance*.

“Given a choice between high-cost part-time and lower-cost full-time individuals, clinicians working in collaborative care should choose the latter,” said senior author Richard Brown, M.D., M.P.H., in an interview with *Psychiatric News*. “Our study shows that lower-cost care managers can be effective, and payers need to be willing to support reimbursement based on outcomes rather than service delivery.”

Brown is a professor of family medicine at the University of Wisconsin School of Medicine and Public Health. He is also CEO of Wellsys, a health care consulting firm.

Care Managers Have Multiple Roles

In a collaborative care model, a care manager educates patients about depression, coordinates referrals, promotes behavior changes that decrease depression symptoms, supports adherence to treatment regimens, administers serial depression symptom questionnaires, and notifies primary care providers when responses to those questionnaires indicate inadequate improvement and a possible need to revise the treatment plan. Psychiatrists work as consultants to primary care physicians and to the care managers and more directly manage the care of the most severely ill patients.

From 2008 to 2012, the Institute for Clinical Systems Improvement (ICSI) helped 87 primary care clinics implement collaborative care through the Depression Improvement Across Minnesota, Offering a New Direction (DIAMOND) initiative. Brown and colleagues at ICSI

and the Department of Family Medicine at the University of Wisconsin School of Medicine and Public Health collected data from depression-care registries at 63 primary care clinics that participated in the initiative through early 2012.

They also surveyed project leaders at the 12 medical groups that operate the clinics about the background of care managers and clinic characteristics.

A total of 9,179 patients enrolled in DIAMOND as of early 2012. Enrollment rates varied from 1 percent to 55 percent across the participating clinics. Clinics with a dedicated care manager had higher enrollment rates than clinics in which the care manager had multiple roles, they found.

Training Level Showed No Impact

There were no significant differences in enrollment based on whether care managers were registered nurses, certified medical assistants, or licensed practical nurses.

Across the clinic sites, 7,438 enrolled patients were eligible for six-month PHQ-9 follow-up. Of these patients, 2,323 attained remission at six months. There was a trend for sites with a dedicated care manager to have higher remission rates, and again remission rates did not differ significantly based on the training level of the care manager.

“It’s important for care managers to see patients face to face on the day of their initial assessment and evaluation,” Brown told *Psychiatric News*. “If you are trying to bring patients back to the clinic by phone, you don’t get a very good enrollment yield.”

He said care managers need to invest a significant amount of time providing feedback, education, and emotional support for depressed patients. “They help make referrals for psychotherapy or pharmacotherapy or both, and that sometimes involves being on the phone for long periods,” he said. “They also help engage patients in behaviors that by themselves can lift depression—exercise, scheduling enjoyable activities, establishing healthier sleep hygiene, eating healthier.”

Psychiatrist Lori Raney, M.D., a leader in integrated care who reviewed the report, said the finding that outcomes do not differ depending on the training level of the care manager is welcome news to collaborative care leaders seeking to save costs. “Not everyone can have a psychologist or a social worker, and it’s good to know that a medical assistant or nurse can deliver these services,” she said. “You may not need to hire the most expensive people in the field to get a good outcome.”

Brown said he believes a fundamental



Richard Brown, M.D., says that the high demand for mental health care means that reliance on collaborative care is necessary to extend the reach of psychiatrists and primary care physicians.

barrier to adoption of collaborative care is cultural. “The idea of team care runs counter to the culture of health care and physician education,” he said. “Physicians are trained to believe they need to need to personally deliver these services.”

But he said the realities of the demand for mental health treatment in primary care mean psychiatrists and primary

From the President

continued from page 12

especially after her psychiatric history became known. It was only when the patient presented with worsening abdominal symptoms that the psychiatry resident accompanied her patient to the emergency room and spoke directly to the ER attending. She made sure her patient’s full clinical history was understood and assisted in the diagnosis of an abdominal abscess, at risk for rupture, which was surgically removed, allowing the patient to fully recover. Despite the involvement of other physicians in the care of these patients, absent the direct role of psychiatrists, the proper diagnosis and care of these patients would not have occurred.

The practice of medicine is far more complex, and fraught with risk, than the antiseptic phrase “prescriptive privileges” would suggest. Indeed, those who



Psychiatrist Lori Raney, M.D., says that the study findings are welcome news to collaborative care leaders who need to watch costs.

care physicians will need to rely on collaborative care team members to extend the reach of clinicians.

Beyond that, he said reimbursement continues to be a barrier. “There is no billing code to support reimbursement for collaborative care,” he said. “And if we did have a code, which individuals could be reimbursed? My fear is that reimbursement will be so low that it will not provide adequate incentive to make sure these services are provided consistently. Ultimately what we need are rigorous quality measures and strong financial incentives to excel on those measures.” **PN**

➤ “Effects of Staffing Choices on Collaborative Care for Depression at Primary Care Clinics in Minnesota” is posted at <http://ps.psychiatryonline.org/Article.aspx?ArticleID=1912428>.

would seek to obtain authority for that component of medical practice, without at a minimum the training and education that physician assistants and nurse practitioners undergo, reveal their fundamental failure to understand the nature of disease, psychiatric and otherwise. As well, they show their lack of understanding of the complexity of the process of evaluation and decision making in the practice of medicine and *inter alia* demonstrate why they should not have the privileges they seek without comprehensive biomedical training.

As Hippocrates reminded us, *ars longa, vita brevis ... iudicium difficile*—the art is long, life is short, judgment difficult. Indeed. We need to make sure his warning, and the complexity of real clinical care, is well understood by all who would make policy in this very important area. Our patients and their families deserve no less. **PN**

Lack of Culturally Competent Care Keeps Hispanics From Seeking Help

With Hispanic Americans likely to make up more than one-fourth of the U.S. population by 2050, advocates are asking for more cultural competence from mental health clinicians, as well as more efforts to diversify clinical trials.

BY VABREN WATTS

As the United States becomes more ethnically diverse, there is a call for physicians and health care professionals to develop greater cultural competency so they can provide more effective care to patients of different ethnic backgrounds. Prominent among these are people of Hispanic descent, the fastest growing minority population in the country.

“Currently, 1 in 6 [56 million] people in the U.S. is Hispanic,” said President and CEO of the National Alliance for Hispanic Health (NAHH) Jane Delgado, Ph.D., M.S., who was the guest speaker at a program in September sponsored by

APA’s Diversity at Work project. “This number is just 2 million people less than the population of both Australia and Canada combined.” Her presentation was held in observance of National Hispanic Heritage Month, which falls from September 15 to October 15.

Delgado, a Cuban-born American, immigrated to the United States at age 2 with her parents and sister. She overcame difficulties with English in

her youth to become one of the most respected figures in clinical psychology and health policy—serving as senior policy advisor in the Immediate Office of the Secretary of Health and Human Services, which coordinates the secretary’s policies and includes health *see Hispanics on page 42*



Jane Delgado, Ph.D., M.S., says that there should be increased efforts to include subjects of diverse races, ethnicities, and genders in clinical trials involving potential psychiatric medicines.

Words That Hispanic Patients May Use To Describe Psychiatric Symptoms

People in some Latino cultures describe mental illnesses in ways that are different from other ethnic groups in the United States. Below is a list of terms of which clinicians should be aware when asking patients of Hispanic descent to describe their symptoms.

- **Ataque:** A feeling of being out of control, anxious, and deeply distressed. Common symptoms include shouting, crying, trembling, heat in the chest rising into the head, and aggressive behaviors.
- **Nervios:** A general sense of vulnerability and stress brought on by difficult events. Symptoms include headaches and “brain aches,” irritability, stomach pains, sleep problems, nervousness, easy tearfulness, and mareos (dizziness or spells of lightheadedness).
- **Susto:** An illness due to a frightening event resulting in unhappiness and sickness. Typical symptoms include changes in appetite, troubled sleep and dreams, headaches and stomach aches, sadness, and lack of motivation.
- **Mal de ojo:** The concept of being the target of an “evil eye.” Children are believed to be especially at risk. Symptoms include fitful sleep, crying without apparent cause, diarrhea, vomiting, and fever.

For other common terms that may be used to describe illness symptoms by patients of Hispanic descent, see *Mental Health: A Guide for Latinos and Their Families* at <http://www.psychiatry.org/File%20Library/Practice/Diversity/Diversity%20Resources/APA-Latino-Mental-Health-Book-FINAL-2-6-09.pdf>.

Culturally Focused Consultation Enhances Integrated Care

For patients receiving culturally focused consultations, clinicians provided a psychiatric assessment, psychoeducation, cognitive-behavioral tools, and tailored treatment recommendations and used the DSM-IV-TR cultural formulation model.

BY MARK MORAN

A culturally informed short-term consultation with Latinos who are experiencing depressive symptoms may augment treatment as part of an integrated approach to depression in the primary care setting, according to a study published in the October *Psychiatric Services*.

“We found that a brief psychiatric consultation with a cultural focus can positively impact depressive symptoms among these Latino primary care patients,” principal investigator Nhi-Ha Trinh, M.D., M.P.H., of Massachusetts General Hospital and Harvard Medical School, told *Psychiatric News*.

Study participants included 118

Latino adults attending four primary care clinics affiliated with Massachusetts General Hospital who screened positive for likely depression. Clusters of participating primary care providers at each of the four clinics were randomly selected to administer either a two-session culturally focused psychiatric consultation (CFP) or enhanced usual care. Randomization was based on the clinic rather than the patient, as a way to prevent providers from being exposed to the intervention and then unintentionally providing it to usual-care study subjects.

For CFP intervention participants, study clinicians (psychologists or psychiatrists) provided a mental health assessment, psychoeducation, cognitive-behavioral tools, and tailored treatment recommendations; primary care provid-

ers were given a consultation summary. The DSM-IV-TR cultural formulation model and Engagement Interview Protocol were applied to engage the patient, inform culturally appropriate diagnosis, and provide tailored treatment recommendations. Study clinicians also had access to participants’ electronic health records.

Participants were also offered a second visit within two weeks, during which the clinician addressed participants’ questions and adherence to recommendations.

In enhanced usual care, primary care providers were notified via e-mail of positive depressive symptom screens, and participants received usual care for depression through their primary care practice.

Although depressive symptoms remained in the moderate range for both groups from baseline to six months, symptom reduction was greater among CFP intervention participants than those in usual care. Statistical analysis indicated that participation in the CFP intervention predicted lower depressive symptoms at follow-up, independent of baseline depressive symptoms, clinic site, age, gender, and employment status.

Trinh said the majority of participants were foreign-born, monolingual Spanish speakers, with half receiving some type of treatment for depression prior to participating in the study.

He said a number of cultural barriers may call for a culturally sensitive approach to care of depression in Latino patients.

“On the provider level, it may be challenging for a primary care provider to assess depression in a patient with whom they differ in ethnicity or culture,” he said. “This may be due to variation in symptom presentation or the terms used by Latinos to describe their experience with depression. Primary care providers may also have varying levels of experience in treating depression, and this may be complicated when working with patients with complex comorbid psychosocial problems.”

At the patient level, Latinos may lack knowledge about depression symptoms and treatment options and may be especially affected by a cultural stigma surrounding mental illness. Patient treatment preferences may differ from standard treatment recommendations, and Latinos may generally lack experience with the U.S. mental health care

see Consultation on page 41

GOVERNMENT NEWS

Open Payments Database Debuts For Public Scrutiny

APA members are urged to register on the Open Payments system so they can review information that may have been reported about their financial transactions with industry.

BY MARK MORAN

The first round of data reported by the pharmaceutical and medical-device industries regarding payments that physicians and teaching hospitals may have received from them is now open to the public.

The information, collected and reported by industry in accordance with the Physician Payment Sunshine Act, a part of the Affordable Care Act, is available on a database known as Open Payments, managed by the Centers for Medicare and Medicaid Services (CMS). According to CMS, its purpose is to increase transparency and accountability in health care.

At the time of its launch on September 30, the database included information collected from August to December 2013 on more than 4 million payments valued at nearly \$3.5 billion to 546,000 physicians and almost 1,360 teaching hospitals.

Physicians had an opportunity to review their data and dispute incorrect information for a 45-day period ending September 11; records whose problems were not resolved by the launch date were not published. Physicians still have until December 31 to dispute 2013 data, but disputes will not be flagged in the public database until the next publication cycle in June 2015.

Among the categories of payments that appear in the database are consulting fees; compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program; honoraria; gifts; entertainment; food and beverage; travel and lodging; education; research charitable contributions; royalty or license; current or prospective ownership or investment interest; compensation for serving as faculty or a speaker for an unaccredited and non-certified continuing education program; compensation for serving as faculty or a speaker for an accredited or certified continuing education program; grants; and space rental or facility fees (teaching hospitals only).

In the days after the launch, CMS said

that it expected to add “enhancements” to the database sometime this month that will allow the public to more easily review information and search on criteria such as specialty, location, or types of payments received. Beginning in June 2015, reports will be published annually and will include 12 months of payment data.

At press time, 40 percent of the records in the database did not carry personally identifiable information—that is, the name of the physician or

institution and other vital information—because the records did not meet CMS’s integrity standards for consistency of information when matched across other databases. Other records were not published because disputes over the reported data had not been resolved, and some manufacturers and group purchasing organizations were eligible to request a delay in publication of their data.

CMS announced that it will refresh

the 2013 data at least once prior to the publication of 2014 data. This refreshed 2013 data will include records whose disputes have been resolved, as well as records that were not matched to a single physician or teaching hospital and were corrected and resubmitted after the data publication deadline. Physicians and teaching hospitals will be given time to review the corrections.

APA members who have not yet registered on the Open Payments system and reviewed their data are encouraged to do so now. (See end of article for registration information.)

CMS acknowledged that financial ties between industry and individual physicians or institutions that may appear on the database do not necessarily signal wrongdoing; many payments to physicians or institutions may reflect legitimate contributions to research and other appropriate activities. “Given the importance of discouraging inappropriate relationships without harming beneficial ones, CMS is working closely with stakeholders to better understand the current scope of the interactions among physicians, teaching hospitals, and industry manufacturers,” the agency said in a statement on its website. “CMS encourages patients to discuss these relationships with their health care providers.”

Here are some examples of appropriate interactions:

see *Open Payments* on page 40

Key Points

The Open Payments database listing information about industry-reported financial transactions with physicians and teaching hospitals as part of the Physician Payment Sunshine Act is now open to the public.

- The database includes information, collected from August to December 2013 on more than 4 million payments to 546,000 physicians and about 1,360 teaching hospitals.
- However, 40 percent of the records have been “de-identified” because they did not meet CMS’s integrity standards for consistency of information when matched across other databases.
- Being listed in the database does not necessarily indicate wrongdoing, and there are many financial transactions listed supporting research and education that are appropriate.
- Physicians are encouraged to track their financial transactions with industry; a free mobile app called Open Payments Mobile for Physicians is available to facilitate such tracking (see page 41).

Bottom Line: Physicians need to be aware that data collected from industry under the Physician Payment Sunshine Act are open to the public, and those who have not registered at the Open Payments database to review their information should do so immediately.

Progress Is Erratic as Lawmakers Debate Veterans’ Legislation

Prodded by a scandal involving care and wait times at the Veterans Health Administration, federal lawmakers move forward piece by piece on veterans’ health issues.

BY AARON LEVIN

Legislative action affecting provision of mental health care in the Veterans Health Administration (VHA) is moving through Congress, but not always as quickly as veterans’ advocates would like.

In a remarkable display of bipartisanship and speed, for example, the Veterans Access, Choice, and Accountability Act of 2014 became law in August. The law was in part a response to the

appointment-scheduling scandal that led to the resignation of Veterans Affairs Secretary Eric Shinseki last May.

The new law allows veterans who face a waiting time for an appointment of more than 30 days or who live more than 40 miles from a VHA facility to obtain care for service-connected issues outside the VHA system. This program will end in three years or when the \$10 billion allocated for it is used up.

The act also provides for hiring new medical personnel in several fields, including mental health, and adds 1,500 graduate medical education residency slots.

“APA is pleased because the act will expand health scholarship education programs for shortage professions—including psychiatry—and increase the loan repayment limit from \$60,000 to

\$120,000,” said Lizbet Boroughs, deputy director of APA’s Department of Government Relations. Pay increases for all VHA physicians and dentists will go into effect November 30 (see page 1).

The law also mandates a series of study reports from the VA Office of the Inspector General. These will cover details on staffing levels at each VHA medical facility, including plans for addressing issues such as wait times, workload levels, staffing models, staffing shortage areas, and the VHA’s use of direct appointment authority to fill staffing shortages. Another study will detail the top five professional vacancy areas, which almost certainly will include psychiatry, given prior studies of medical staff shortages.

One thing that hasn’t happened yet is a long-dreamed-of but so far unrealized “seamless” connection between the medical systems of the Department of Defense and the VHA that would make the transition from care during active service to civilian life easier for veterans.

see *Veterans* on page 35

Dentists' Scope-of-Practice Case Getting Physicians' Attention

The Supreme Court weighs in on a case involving dentists that arises from a controversy over who can whiten teeth.

BY AARON LEVIN

Oral arguments about oral care rang through the Supreme Court in mid-October, but the outcome may or may not have much bite when the justices hand down their ruling next spring.

The case at hand hinges on who gets to whiten people's teeth in North Carolina—dentists or other people. Several medical groups, including APA, are taking an interest in the potential scope-of-practice implications of the case for other professions.

In court, the Federal Trade Commission (FTC) argued that the North Carolina Board of Dental Examiners violated antitrust laws when it sent cease-and-desist letters to nondentists who operated tooth-whitening businesses. The latter say their work should be considered cosmetic, not dental, and thus outside of the dental board's purview.



schegi/Shutterstock

State regulatory bodies are exempt from antitrust liability. However, the FTC said that because four of the six members of the board were dentists elected by their professional peers, the board lacked sufficient supervision to be a true part of the state government and thus was merely seeking to eliminate competition.

Furthermore, while the board might regulate dentistry, it had no legal authority to send out the cease-and-desist letters, the FTC said.

The dental board's attorney

responded that it was indeed a state body not subject to antitrust law and that it was also concerned about the safety of patients receiving the peroxide-based treatments.

APA joined the AMA and other medical and dental organizations in an amicus curiae brief supporting the North Carolina Board of Dental Examiners.

The Supreme Court justices addressed the scope-of-practice question during the session, at least in a hypothetical way. Justice Stephen Breyer opined that he wanted deci-

sions about practicing brain surgery to be made by people who knew something about brain surgery. Medical decisions ought to be made by medical professionals, other justices agreed from the bench.

The value of having practitioners on regulatory boards because of their professional expertise has to be counterbalanced by their unwillingness to accept personal liability. The medical and dental groups argued that if North Carolina's board were deprived of the state's sovereign umbrella, professionals would not serve on the boards.

The justices' views were not clear by the end of the oral arguments. A decision broadly in favor of the position of the FTC and the nondentist tooth whiteners might affect similar state boards regulating professions and trades. However, a more narrowly construed decision that addresses just the facts in this specific case would be unlikely to have a wider legal impact, according to experts.

The Supreme Court is expected to hand down its decision in the case by late next spring. **PN**

➔ The transcript of the oral arguments before the Supreme Court in *North Carolina State Board of Dental Examiners v. FTC* is posted at http://www.supremecourt.gov/oral_arguments/argument_transcripts/13-534_8nj9.pdf.

Oklahoma Court Rules Against Key ACA Provision

The ruling, which makes it likely the Supreme Court will weigh in on the decision, threatens a key provision of the ACA that makes subsidies for health insurance available to millions.

BY MARK MORAN

An Oklahoma district court has ruled that the Internal Revenue Service (IRS) does not have the authority to issue health insurance tax credits to offset premium costs for some low-income people, including those in states that have not established state-based health exchanges as part of the Affordable Care Act (ACA).

The U.S. District Court for the Eastern District of Oklahoma became the third to rule on the controversial ACA provision. Earlier this year, two courts of appeal issued conflicting opinions—

on the same day—about an IRS rule that allows the agency to distribute premium subsidies to people insured through federally run health exchanges. The subsidies are critical to the ACA, with millions of people enrolled in the health exchanges whose premiums are made more affordable because of the subsidies.

In the Oklahoma case, Judge Ronald White said, "The court holds that the IRS Rule is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law ... in excess of statutory jurisdiction, authority, or limitations, or short of statutory right ... or otherwise is an invalid implementation of the ACA, and is hereby vacated."

The ruling makes it likely that the Supreme Court will weigh in on the issue.

Oklahoma Attorney General Scott Pruitt (R), the plaintiff in the case on

behalf of the state of Oklahoma, hailed the ruling in a statement on his website. "Today's ruling is a consequential victory for the rule of law," he said. "The

administration and its bureaucrats in the IRS handed out billions in illegal tax credits and subsidies and vastly expanded the reach of the health care law because they didn't like the way Congress wrote the Affordable Care Act. That's not how our system of government works."

Oklahoma's lawsuit challenges an IRS rule issued in May 2012 that called for tax subsidies to be issued in states like Oklahoma that have not chosen to establish a state-based health care exchange and assessed "large employer" penalties in such states.

Pruitt asserted—and the Oklahoma district court agreed—that the IRS rule contradicts the language of the ACA, which he says "plainly states" that tax subsidies can be issued, and tax penalties can be assessed, only in states that established state-based health care exchanges.

"This is a case of statutory interpre-

tation," White wrote. "[T]he court is upholding the [Affordable Care] Act as written. Congress is free to amend the ACA to provide for tax credits in both state and federal exchanges, if that is the legislative will."

But White said that the ACA as presently written does not permit the distribution of subsidies for individuals in the federal—as opposed to a state-run—health exchange and cited earlier law stating that "vague notions of a statute's 'basic purpose' are ... inadequate to overcome the words of its text regarding the specific issue under consideration" and further that it is a "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate."

In July, the U.S. Court of Appeals for the District of Columbia Circuit issued a similar ruling. "Within constitutional limits, Congress is supreme in matters of policy, and the consequence of that supremacy is that our duty when interpreting a statute is to ascertain the meaning of the words of the statute duly enacted through the formal legislative process," Judge Thomas Griffith wrote

see *Oklahoma* on page 41



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New York Psychiatrists Work to Hold Insurance Carrier Accountable

Hal Rubin, M.D., advises psychiatrists to read contracts carefully and to use the leverage provided by the federal parity law to hold companies accountable.

BY MARK MORAN

Psychiatrist Hal Rubin, M.D., knows how to talk to an insurance company, and he knows how to say “no.”

Rubin, an adult and geriatric psychiatrist, is in practice with his wife, Lorna Clark-Rubin, M.D., an adult and child and adolescent psychiatrist, in the rural, upstate New York town of Plattsburgh. Through remarkable diligence, he has scored impressive victories in negotiations with a statewide subcontractor that manages the mental health and substance abuse benefits for a large employer.

They came to Plattsburgh with their children in 1990, drawn to the mountains, lakes, and streams where they could pursue their love of nature and practice psychiatry in a region that was short on mental health clinicians.

“For the first 11 years we were variably 40 percent to 60 percent of the local regional hospital psychiatric staff, as well as conducting a very busy outpatient practice,” Rubin told *Psychiatric News*. In 2001, they shifted to an entirely outpatient practice.

“Our practice is a business partnership, and we see patients from early childhood through the closing years of life,” he said. “Practicing in a small community, we see students, tradesmen and women, blue-collar workers, business professionals, CEOs, professors, doctors, teachers, unemployed and disabled individuals, and many others. Many patients with longstanding relapsing conditions have been under our care for 15 to 20 years and have maintained their highly functional abilities in family and work with our assistance.”

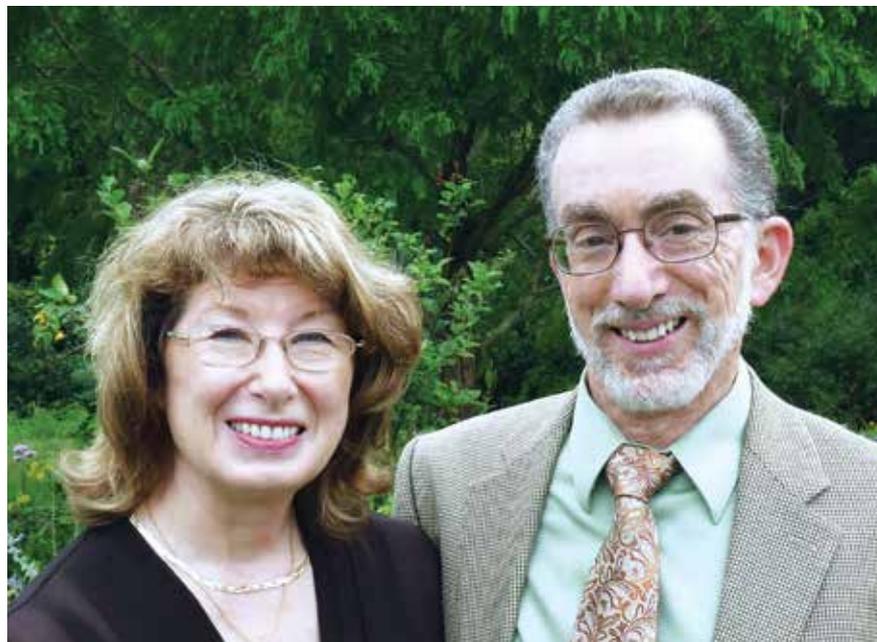
“Around the same time as we transitioned to all outpatient work, it struck me that the insurance companies needed us more than we needed them, since this is a psychiatrist-scarce region, and we have always received from many sources more referrals than we can possibly see. I began to read the proposed contracts and relevant state insurance laws carefully. It is not difficult to find these laws. You don’t need an attorney at this level.”

New Yorkers have been fortunate in

having an activist attorney general in Eric Schneiderman, who in July announced a settlement with New York City–based EmblemHealth Inc., requiring the insurer to reform its behavioral health claims–review process, cover residential treatment, and revise its copayment policies for outpatient visits to mental health and substance abuse treatment providers. The settlement also requires the company—which has 3.4 million members, 1.2 million of whom are New York City employees and retirees—to submit previously denied mental health and substance abuse treatment claims for independent review. That review could

allow a new psychotherapy add-on code. The change allows psychiatrists to bill for their services as other physicians can, with the added result of being reimbursed for their services at a rate comparable to all other physicians. (The old 908xx psychotherapy codes were traditionally reimbursed at a lower rate than the comparable E&M codes.)

But Fernbach said that instead of using the enhanced RVU values to establish reimbursement rates for the new combination codes, some managed care plans have simply manipulated the fees for the add-on codes so that the new total fee is no more than the comparable 2012



Psychiatrist Hal Rubin, M.D., and his wife, Lorna Clark-Rubin, M.D., also a psychiatrist, have been diligent in holding insurance companies accountable to the mental health parity law.

result in more than \$31 million being returned to members wrongfully denied benefits, according to a statement from the attorney general’s office (*Psychiatric News*, August 1).

But Rachel Fernbach, J.D., deputy director and assistant general counsel of New York State Psychiatric Association (NYSPA), told *Psychiatric News* earlier this year that in addition to pursuing violations of parity by New York insurers, NYSPA has been looking into ways that companies may be manipulating reimbursement rates to deny psychiatrists adequate payment for psychotherapy.

She noted that effective January 1, 2013, the old 908xx psychotherapy codes were eliminated from the Current Procedural Terminology (CPT) manual and replaced with new combination codes, consisting of an evaluation and management (E&M) code plus

fee, thereby discouraging psychiatrists from providing this service.

It was against this practice by the statewide subcontractor—and other alleged violations of the Mental Health Parity and Addiction Equity Act (MHPAEA)—that Rubin and his wife waged a protracted fight.

In the last days of 2013, Rubin—who is diligent about reading contracts he signs—received a memo from the company indicating that it was assuming the mental health subcontractor position for a large employer. Other memos and the subcontractor’s provider website stated that outpatient treatment reports would continue to be required after 10 visits and that clinicians should expect retrospective reviews of visits when an E&M code and a psychotherapy add-on code were billed together.

In addition, he said the provider

reimbursement schedules did not arrive with any memos and were nowhere to be found on the company’s secure provider website. This was unlike most other insurance companies with which he and his wife participated, he said.

“After numerous phone calls and emails, we did receive a copy of the fee schedule, and the rates were abysmal,” he said. “In fact, I found a fee schedule for our practice from 1998, and the rates were almost identical.”

Rubin said he believes the absence of many CPT codes now legitimately billable by psychiatrists, the continuation of treatment plans and other restrictive requirements, and rates that appeared to be determined by financial factors rather than methodology comparable to other physicians were bound to result in a reduction in the number of providers in local networks.

“Psychiatrists would not be willing to accept rates that were 30 percent to 60 percent below market for other physicians and would either not join the plan or withdraw,” he said. “This would ultimately lead to reduced patient access to care, reduced follow-up, greater suffering—precisely what MHPAEA was designed to correct.”

Rubin and Clark-Rubin began an untiring campaign to force the company to amend its policies as they pertain to his and his wife’s participation. Cut to the finale—as a result of Rubin’s diligence, he succeeded in negotiating for his practice that standard E&M codes absent from the initial fee schedule are now included, prior authorization for outpatient psychiatric visits is no longer required, and reimbursement rates including the additional E&M codes have been adjusted to reflect the complexity of the work.

So what is Rubin’s advice to other clinicians confronted with similar insurance company practices? “They have more leverage than they think they do,” he said. “With the MHPAEA in place, now is the time to use that leverage. A contract is a matter between two parties—it’s not the insurance company telling you what to do. Each party wants something the other party has. They write the contract, and I look at it as a proposal, which it is until you and the other party sign it. You have to be willing to say ‘no’ and demand a better contract if you are going to stick by what you think is right. Many people, including lawmakers, insurance commissioners, subscriber employers and unions, patients, and the state attorney general are interested in ensuring that insurance companies, which often do not respond to logic, reason, or patient needs, are compliant with the MHPAEA, and physicians and patients should not be shy in bringing them into the discussion.” **PN**

Advertisement

Idealism, Pragmatism Attract Psychiatrists to the VA

Three psychiatrists who practice in the Veterans Health Administration describe the ups and the downs of working in the nation's largest medical system.

BY AARON LEVIN

As salaries and loan repayment levels rise in the Veterans Health Administration (VHA) at the end of this month, the agency hopes to attract more psychiatrists and mental health personnel to its ranks.

What is it like to work for a large federal health agency charged with the care of millions of fellow citizens

After some thought, he also decided that the business, marketing, and insurance aspects of private practice were not for him. "I liked being part of a team in a system of care," he said, reflecting his military experience. "And I see that in both small and broad terms."

In the VHA, he could work within a circle that included a full complement of behavioral health staff: nurses,

but having a military background is not necessary to be effective with veterans, he said. "We have other psychiatrists on staff without military backgrounds. The key to their success is their competency and compassion."

Flexibility, Good Benefits Were Key

Jenny Boyer, M.D., Ph.D., J.D., in Tulsa, Okla., had some pretty down-to-earth reasons for moving to the VHA.

"When I had children, I needed a job with defined hours, and I wanted to be in academia," said Boyer, speaker of the APA Assembly and co-chair of the APA Caucus of VA Psychiatrists. "If you went to the VA, you could get

ter of Excellence for Substance Abuse Treatment and Education at the VA Puget Sound Health Center in Seattle and a professor of psychiatry and behavioral science at the University of Washington.

His training complete, Saxon took a full-time job in the addiction treatment program at the Puget Sound facility, intending to stay only a year or two until other opportunities opened up.

"Then everything clicked for me," he said in an interview. "I enjoyed seeing the tremendous gains in patients who turned their lives around."

Some patients were more successful than others, of course, but Saxon enjoyed the challenge and has been there ever since. There were other reasons too.

He came to prefer the VA's team approach to care over solo practice, and he liked the VA's economic model. "It is



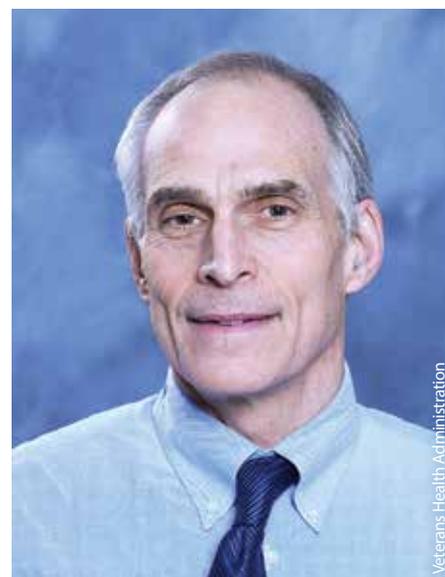
Veterans Health Administration

Competency and compassion, but not necessarily prior military experience, are the keys to working with veterans in the VHA, says Alan Hines, M.D.



David Hathcox

Jenny Boyer, M.D., Ph.D., J.D., went to work for the VA initially because it provided good work-life balance. She appreciates the sense of community and opportunity to serve people who had served their country.



Veterans Health Administration

Andrew Saxon, M.D., says that working in the VA gives him freedom to focus on patient care.

while also under heavy congressional and public scrutiny?

Three psychiatrists working for the VHA say that their choice to practice psychiatry in the VHA is a multifaceted mix of the pragmatic and idealistic. (All three emphasized that they spoke as individuals and not as representatives of the VHA.)

Teamwork Was a Lure

Alan Hines, M.D., joined the VHA in 2001 after medical school at Loma Linda University, residency at Walter Reed Army Medical Center, and four years in the U.S. Army as a psychiatrist at Ft. Campbell, Ky. Once out of the Army, he faced a choice of how and where to practice, he said.

Hines chose the northern Rocky Mountain region to be closer to his parents in Montana and found an opening at the VHA hospital in Boise, Idaho.

chaplains, attendants, IT experts, legal counsel, and medical colleagues from other specialties. At the same time, he could also draw on the experience and resources of a national organization.

"The flip side is you also have the obligations of a team member, which includes limited autonomy in some circumstances," he said. For instance, he found the VHA's treatment planning software hard to get used to initially. "But you have to roll with it and learn to pick your battles."

Today he works primarily as an administrator, but the frontline psychiatrists in his center have their own clinics and panels of patients. New patients get an hour of face-to-face time, with follow-up sessions of 30 minutes. The rest of the day is filled with collaborative work with colleagues, supervising, writing up notes, team meetings, and training.

His military experience gives him a little extra credibility with his patients,

incredibly good benefits, especially retirement, and you could be affiliated with a university and teach students. Once the workday ended, you could go home and take care of your other job, which is your family."

Once she got into the job, however, she also came to value the sense of community she found in the VHA and the opportunity to serve people who had served their country.

"The price of freedom can be seen at the VA," she said. "It's very rewarding, and it's never boring."

He Could Witness 'Tremendous Gains'

Andrew Saxon, M.D., did not have a military background before he completed a psychiatric residency at the University of Washington that included several rotations through the Seattle VA hospital and a stint as chief resident there.

Saxon is now the director of the Cen-

not based on fee-for-service," he said. "I can focus on patient care and not worry about insurance coverage."

Because the VA is a national system, Saxon also knows he has a large group of colleagues who share his professional interests and stand ready to offer their experience and advice when needed. The well-known electronic health records system is another plus, in his eyes.

He noted, however, that working in a large, national system may not be ideal for someone with a low tolerance for bureaucracy, he said.

"But it is not an unresponsive bureaucracy, even if the response happens slowly," he said. "There are some limitations of choice and freedom, but the trade-off is worth it."

Ultimately, the bottom line for Saxon is working with his patients: "Serving veterans who put their lives on the line for our country." **PN**

CLINICAL & RESEARCH NEWS

Symposium Addresses Mental Health Of Ethnic Minority College Students

Unaddressed racial discrimination on college campuses may be one predictor of adverse mental health consequences in students.

BY VABREN WATTS

The challenges associated with excelling academically can be stressful for any college student, but for students of color, particularly at institutions that have a majority white student population, these stresses can be exacerbated, experts suggest.

Last month, the Center for the Study of Race and Ethnicity in America (CSREA) at Brown University held “Young, Gifted, and @ Risk,” a symposium focusing on the mental health of high-achieving college students of color.

“Race and ethnicity, as well as structural racism and inequality, saturate every aspect of every human being’s life in the United States,” said Tricia Rose, Ph.D., a professor of Africana studies at Brown and director of CSREA, in an interview with *Psychiatric News*. “Young people of color are particularly at risk—no matter how gifted they may be—for not being understood about these challenges.”

The symposium was sponsored in conjunction with the Stephen C. Rose (SCR) Legacy Fund, a fund commemorating the life of a young African-American graduate of Harvard University who died by suicide on February



Annelie Primm, M.D., M.P.H., discusses her experience as a minority student at an Ivy League institution.

6 at age 29. Stephen was a nephew of Tricia Rose.

“Stephen was very intelligent,” Evan Rose, Stephen’s brother, said in addressing the audience. “As an African-American male, he was trying to figure out where he was going in life. ... The issues that he dealt with were issues similar to what other gifted African Americans deal with [throughout young adulthood].”

After Stephen’s death, the Rose family began to push for more dialogue concerning mental health awareness among young people. “When doing our research on the population of young people who are served and underserved [by mental health services], it was clear that young people of color were very

much underserved,” Stephanie Bell-Rose, J.D., M.P.A., mother of Stephen and co-administrator of the SCR Legacy Fund, told *Psychiatric News*. “When we examined the population more closely, it was clear that young people of color who were high achievers were even more underserved,” making this population vulnerable to adverse mental health consequences.

“There is an added pressure of being in the minority, numerically, ... which may cause someone to feel isolated,” said Alfee Breland-Noland, Ph.D., M.H.Sc., a speaker at the meeting and an associate professor of psychiatry



Tricia Rose, Ph.D., welcomes guests to the symposium “Young, Gifted, and @ Risk.”

at Georgetown University Medical Center. Breland-Noble explained to *Psychiatric News* that often more pressures can be applied to first-generation minority college students who are striving to become an inspirational figure for younger family members, in addition to fighting racial stereotypes regarding intelligence and overt and covert racism from students, faculty, and the campus administration.

A study published last year in the *Journal of Multicultural Counseling and Development* showed that of 240 minority college students interviewed at the University of Texas at Austin, African Americans were more likely to report feeling “minority-status stress” (that is, distress caused by discrimination) when compared with other ethnic minority groups, whereas Asian Americans were most likely to report imposter feelings, a psychological phenomenon in which people believe that they do not deserve successes that they have achieved. Both

feelings were predictors of psychological distress, with imposter-related ones being the strongest.

Kevin Cokley, Ph.D., M.Ed., lead author of the study and a professor of psychology at the University of Texas, said that racial stereotypes for intelligence may play a role in both of these situations, with African Americans feeling as though people are expecting them to underachieve, while the expectation for Asian Americans is to achieve or overachieve—causing both minority groups to be singled out. Cokley stressed that there is substantial need for psychological interventions that are specifically targeted to the diverse demands of all ethnic minorities.” APA Deputy Medical Director Annelie Primm, M.D., M.P.H., agreed.

“It’s very important for psychiatrists and other mental health professionals to be cognizant of the experiences of high-achieving ethnic minority students. It’s an aspect of cultural competence,” Primm told *Psychiatric News*.

Primm, who spoke about being an African-American student at an Ivy League university during the beginning stages of desegregation, said that the symposium exposed realities about issues that many students of color face throughout their academic careers, including isolation, self-doubt, and the feeling of not belonging—all emotions that she acknowledged feeling as a student. With support from family and friends, Primm said she was able to prevail.

Primm said that she is confident that the issues that were addressed at



Alfee Breland-Noland, Ph.D., M.H.Sc., says that minority students may experience feelings of isolation on college campuses with a majority white student population.

the symposium will have some impact on improving the experiences of high-achieving students of color and prompt “institutions of higher learning to put measures into place that will be relevant and culturally tailored for students of racially diverse backgrounds to not only attend, but to graduate and achieve success.” **PN**



Stephanie Bell-Rose, J.D., M.P.A., and Christopher Rose, Ph.D. (right), are the parents of Stephen Rose, a high-achieving graduate of Harvard University who died by suicide last February. With them are Stephen’s brother, Evan.



marilynnowicz/Shutterstock

BY NICK ZAGORSKI

Gut Bacteria Implicated In Eating Disorders

Intestinal bacteria may contribute to certain eating disorders, reports a new study in *Translational Psychiatry*.

Researchers at INSERM identified ClpB, a protein produced by *E. coli* and other intestinal flora, as the potential culprit. The immune system produces antibodies against ClpB when it is present, but these antibodies can also bind to melanotropin—the primary satiety hormone. When the antibodies bind to melanotropin, they affect its ability to regulate fullness.

As a test, mice were injected with *E. coli* in their gut; at first, these mice reduced their eating, but later the animals altered their habits and ate smaller meals, but ate more frequently than normal. This was not due simply to the introduction of new bacteria, as mice receiving an *E. coli* strain that did not produce ClpB did not differ from control mice in weight gain, food intake, or feeding pattern at any time.

The researchers also found that higher levels of anti-ClpB antibodies that also reacted to melanotropin were present in blood samples of people with anorexia nervosa, bulimia, and binge eating disorder, suggesting that melanotropin disruption is relevant in human feeding habits.

➤ Tennoune N, Chan P, Breton J, et al. Bacterial ClpB heat-shock protein, an antigen-mimetic of the anorexigenic peptide α -MSH, at the origin of eating disorders. *Transl Psychiatry*. 2014;4:e458. <http://www.nature.com/tp/journal/v4/n10/full/tp201498a.html>

Reducing Substance Use Reduces Risk of Aggression

People with both a serious mental illness and a substance abuse problem are at risk for increased aggression. Both conditions contribute to this

risk, but according to an analysis of 278 patients who were admitted to an outpatient dual-diagnosis treatment program, reducing substance abuse may be more influential in reducing future violence.

Researchers followed the patients for six months and found that the level of participation in the dual-diagnosis program did correlate with reduced aggression. However, further analysis found that the severity of the patient's psychiatric symptoms was not related to his or her aggression. Rather, substance use was the mediator; greater involvement in the program was associated with reduced substance use and lower aggression.

Study co-author Clara Bradizza, Ph.D., a researcher at the University at Buffalo Research Institute on Addictions, commented that the findings highlight the importance of reducing substance abuse among people with mental illness. "This not only improves the lives of affected individuals and their families, but also provides a safer environment for society as a whole," she said.

The study findings were published in the *Journal of Substance Abuse Treatment*.

➤ Zhuo Y, Bradizza C, Maisto S. The influence of treatment attendance on subsequent aggression among severely mentally ill substance abusers. *J Subst Abuse Treat*. 2014;47(5):353-61. <http://www.sciencedirect.com/science/article/pii/S0740547214001202>

Physical Activity Helps Purge Depression-Associated Chemical From Body

Physical exercise helps protect the body from stress-induced depression, though a new study in *Cell* suggests the mechanism is not what many people might think. Rather than boosting the production of pro-health compounds, exercise stimulates the production of an enzyme that breaks down a stress-related substance known as kynurenine.

Kynurenine is found at elevated levels in people with mental illnesses such as

schizophrenia and depression, though the contributing role of kynurenine isn't known.

Jorge Ruas, an investigator at Sweden's Karolinska Institutet, and his team subjected two sets of mice to stressful stimuli like loud noises or flashing lights; after five weeks of stress, regular mice showed depressive symptoms, whereas mice genetically modified to have well-trained muscles remained normal.

These "muscle mice" had higher levels of an enzyme called KAT in their skeletal muscle, which converts kynurenine into kynurenic acid. Unlike kynurenine, kynurenic acid does not pass the blood-brain barrier and thus can be excreted from the body.

As Ruas explained, "In this context the muscle's function is reminiscent of that of the kidney or liver."

➤ Agudelo L, Femenía T, Orhan F, et al. Skeletal muscle PGC-1 α modulates kynurenine metabolism and mediates resilience to stress-induced depression. *Cell*. 2014 Sep 25;159(1):33-45. <http://www.cell.com/cell/abstract/S0092-8674%2814%2901049-6>

Study Highlights Potential Link Between Stress, Social Dysfunction

Stress frequently brings about emotional and cognitive issues such as irritability and forgetfulness. Researchers at the EPFL (the Swiss Federal Institute of Technology) Brain Mind Institute discovered a biological mechanism behind this connection, which involves some overeager cutting by an enzyme called MMP-9.

Chronic stress triggers a release of the chemical glutamate, which activates NMDA receptors on neurons. As published in *Nature Communications*, Carmen Sandi, Ph.D., and colleagues found that the NMDA receptors in turn activate MMP-9 (matrix metalloproteinase-9), an enzyme that chops up other proteins, in the brain's hippocampus.

This MMP-9 proceeded to cleave nectin-3, an adhesion protein that keeps adjacent neurons close together so they can have an effective synaptic connection. The stress was, in effect, breaking synapses apart.

The process could be reversed, however, as researchers could restore the sociability of stressed rats through drugs that inhibited either MMP-9 or NMDA receptors.

"The identification of this mechanism is important because it suggests potential treatments for neuropsychiatric disorders related to chronic stress, particularly depression," Sandi said.

➤ Van der Kooij M, Fantin M, Rejmak E, et al. Role for MMP-9 in stress-induced down-

regulation of nectin-3 in hippocampal CA1 and associated behavioural alterations. *Nat Commun*. 2014; 5:4995. <http://www.nature.com/ncomms/2014/140918/ncomms5995/full/ncomms5995.html>

Early Progression to Intoxication Contributes To Heavy Drinking

Drinking at an early age is considered a leading risk factor for subsequent alcohol abuse, yet research in this area has produced inconsistent findings. A new study of high-school-age drinkers suggests that not only is the age when alcohol consumption began is relevant, but also how quickly a young drinker becomes intoxicated.

This analysis, published in *Alcoholism: Clinical & Experimental Research*, anonymously surveyed 295 teens about their drinking history and habits. The results showed that both age of drinking onset and the time between first drink and first intoxication (delay) were both determinants of future alcohol use in teens.

A short delay by itself did not significantly influence future binge drinking, but when considered in concert with age of onset, it was a strong predictor of risk—more so than age of onset alone.

As study author Meghan Morean, Ph.D., an assistant professor of psychology at Oberlin College, explained, "We would expect a teenager who had his first drink at age 14, and who got drunk at 15, to be a heavier drinker than a teenager who had his first drink at 14 and waited to get drunk until 18."

➤ Morean M, Kong G, Camenga D, et al. First drink to first drunk: age of onset and delay to intoxication are associated with adolescent alcohol use and binge drinking. *Alcohol Clin Exp Res*. September 24, 2014. [Epub ahead of print] <http://onlinelibrary.wiley.com/doi/10.1111/acer.12526/abstract;jsessionid=803F697A91D924D797C7E86F6485C9D8.f03t03>

Mini-Stroke May Increase Risk of PTSD

New research in the journal *Stroke* suggests that transient ischemic attacks (TIAs), also known as "mini-strokes," may increase the risk of developing posttraumatic stress disorder (PTSD).

Researchers in Germany and Great Britain assessed and surveyed 108 people who had experienced a TIA, which is a short-term restriction of blood flow in the brain that does not cause permanent damage. They found that 29.6 percent of TIA patients had symptoms consistent with PTSD—about 10 times the prevalence of the general population in Germany. Many

continued on facing page

CLINICAL & RESEARCH NEWS

Evidence Backs Gateway Hypothesis In Drug Addiction

A study in mice adds insights to epidemiological research on ways in which users arrive at their drugs of addiction.

BY AARON LEVIN

Chickens or eggs? It's an old argument, but addiction specialists are still scrapping over which drug of abuse users adopt first.

Do people with addiction just latch onto the first drug that comes their way, or is there a predictable escalation in their choice of substance?

"The debate is still going on," said Denise Kandel, Ph.D., a professor of sociomedical sciences in psychiatry at Columbia University and chief of the Department of the Epidemiology of Substance Abuse at the New York State Psychiatric Institute.

Kandel is a longtime proponent of the "gateway hypothesis" of drug use: "a well-defined developmental sequence of drug use occurs that starts with a legal drug and proceeds to illegal drugs."

Her epidemiological studies have shown that 87.9 percent of 18- to-34 year-old cocaine users had smoked cigarettes before using cocaine, but only 3.5 percent used cocaine before smoking cigarettes.

A second model of addiction posits a "common liability" to drug use—that is, an underlying general vulnerability for drug use.

Now, a combination of epidemiological and molecular research demonstrates a priming effect of nicotine on the brain that enhances the physiological response to cocaine, supporting the gateway model, according to Kandel and her husband, psychiatrist Eric Kandel, M.D., the Nobel Prize-winning profes-

sor of neuroscience and psychiatry at Columbia University and a senior investigator at the Howard Hughes Medical Institute, writing together in the September 4 *New England Journal of Medicine*.

"If you give an animal nicotine before you give it cocaine, it dramatically enhances the effects of cocaine, while cocaine has no effects on nicotine," said Eric Kandel in an interview with *Psychiatric News*. "We showed this at the levels of gene expression and chromatin structure."

"This is a very provocative study that asks questions with important public-health implications," said Joni Rutter, Ph.D., director of the Division of Basic Neuroscience and Behavioral Research at the National Institute on Drug Abuse.

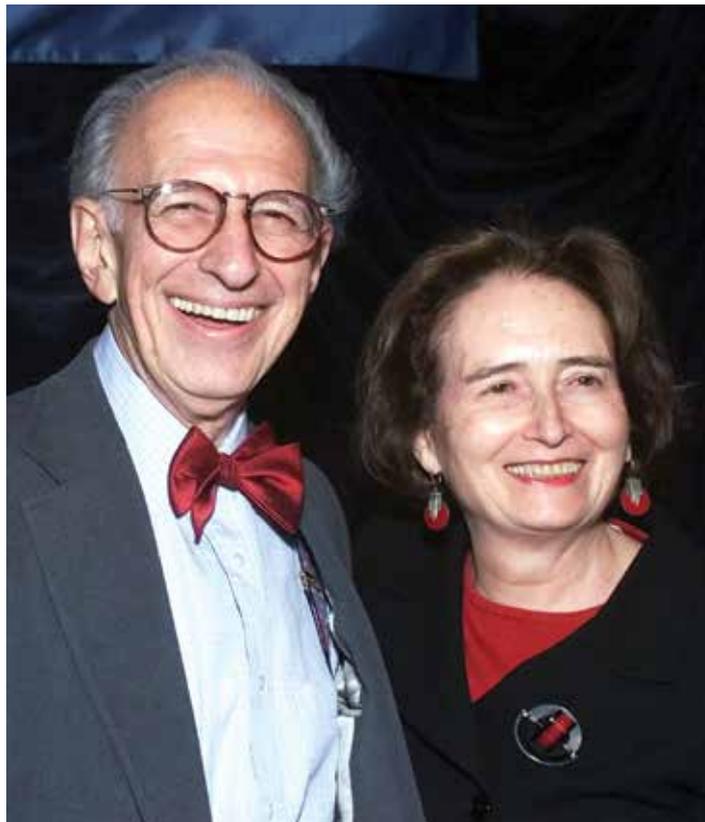
"In this specific drug pair, this may be a model that works," Rutter told *Psychiatric News*. "It may not in other drugs of abuse, but the questions certainly could be asked. The molecular mechanisms they studied are intriguing and are certainly testable."

Eric Kandel, his longtime collaborator Amir Levine, Ph.D., and their colleagues set out to examine several parameters of drug-use sequence.

One behavioral test, locomotor sensitization, showed that mice given nicotine in their drinking water for seven days, followed by co-administration of nicotine and cocaine for four days, displayed increased activity compared with both

patients with better counseling about the realistic risks of future ischemic events along with more positive adaptive strategies could prove beneficial to TIA patients. **PN**

➤ Kiphuth I, Utz K, Noble A, et al. Increased prevalence of posttraumatic stress disorder in patients after transient ischemic attack. *Stroke*. October 2, 2014. [Epub ahead of print] <http://stroke.ahajournals.org/content/early/2014/10/01/STROKEAHA.113.004459.abstract>



"Common factors will explain the use of drugs in general, and specific factors will explain why young people use specific drugs and do so in a particular sequence," according to Nobel Prize-winning psychiatrist Eric Kandel, M.D., and his wife and collaborator, sociologist Denise Kandel, Ph.D., about their research on how tobacco use can serve as a "gateway" to cocaine addiction.

"For all the measures we studied—locomotor sensitization, conditioned place preference, long-term potentiation, and expression—reversing the order of nicotine and cocaine exposure was ineffective: cocaine did not enhance the effect of nicotine," noted the Kandels.

"This shows that smoking is not only dangerous in its own right, but it's capable of potentiating at least one more dangerous drug," said Eric Kandel. "We're now looking at whether alcohol has a similar effect or whether nicotine has similar effects on other drugs."

The Kandels suggested that perhaps the two hypotheses about the route to addiction can be reconciled. "[W]e believe that the gateway hypothesis and the common liability model are complementary," they concluded. "Common factors will explain the use of drugs in general, and specific factors will explain why young people use specific drugs and do so in a particular sequence."

Their research must be replicated by independent labs but, if validated, might change the way cocaine abuse is treated, said Rutter.

"Providers treating cocaine addiction would also address nicotine use," she said. "Nicotine replacement therapy thus might not be a good choice, and behavioral approaches might work better. The Kandels have done a nice job of setting the table for asking those kinds of questions."

Those questions might involve gender or age, since the Kandels' lab work was carried out only in adult male mice, she said.

Rodents starting nicotine in adolescence consume more than those who start as adults, so a study of nicotine priming should also extend to adolescents, said both Rutter and the Kandels.

"And if nicotine primes the brain for cocaine, and if that holds up in real-world settings, does it also prime for other risky, impulsive behaviors or addictions, like obesity?" she asked, referring to the fact that many women gain weight when they quit smoking.

The Kandels' cross-disciplinary work adds new insights into the process of addiction and, if one is needed, yet another reason to keep young people from starting to smoke. **PN**

➤ "A Molecular Basis for Nicotine as a Gateway Drug" is posted at <http://www.nejm.org/doi/full/10.1056/NEJMs1405092>.

Journal Digest

continued from facing page

of the patients also reported decreased levels of mental and physical health.

The authors believe that while mini-strokes cause no permanent damage, fears of a subsequent larger stroke may lead to the onset of PTSD. The risk of PTSD following TIA also correlated with younger age and people who had poor coping behaviors in general.

They suggested that providing

Lifestyle-Modification Program Helps People On Antipsychotics Improve Health

A program known as STRIDE was able to help people with serious mental illness lose weight, improve glucose metabolism, and reduce hospital visits.

BY NICK ZAGORSKI

People with serious mental illness are at greater risk for obesity and the numerous health problems associated with obesity, such as diabetes. These risks are then compounded by metabolic side effects that antipsychotic drugs can cause.

This significant vulnerability should make those with mental illness prime candidates for intensive weight-loss interventions, but as Carla Green, Ph.D., M.P.H., a senior investigator at the Kaiser Permanente Center for Health Research in Portland, Ore., pointed out in an interview with *Psychiatric News*, “We

have so little data on how people with mental illnesses respond to weight-loss programs, because they are typically excluded from clinical studies.”

To remedy this, Green and her colleagues developed a comprehensive lifestyle intervention program known as STRIDE. In a study published September 15 in *AJP in Advance*, they demonstrated that STRIDE can help people taking antipsychotics lose weight and improve their glucose levels over the long term.

STRIDE seeks to promote healthy behaviors through weekly group sessions that teach participants important self-management skills, like creating activity logs, while also fostering social support and a sense of ownership. The program uses techniques and exercises to overcome cognitive barriers or other potential



Carla Green, Ph.D., and colleagues demonstrated that lifestyle modification programs can be adapted for people with mental illness to help them lose weight related to their illness and medications.

obstacles for people dealing with serious mental illness, while also educating the participants on how their mental and physical states were connected.

“This study filled an important gap in evidence by testing a lifestyle intervention that was adapted for delivery to individuals with serious mental illness,” said Christine Hunter, Ph.D., director of behavioral research at the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), which funded STRIDE. “Research to evaluate lifestyle approaches to reduce diabetes risk that are effective and tailored to the needs of high-risk populations is a priority for NIDDK.”

The study enrolled 200 adults who were taking antipsychotic medication and with a body mass index of at least 27. The volunteers were then randomly assigned to receive the STRIDE intervention for 12 months—split into a six-month intensive phase followed by a six-month maintenance phase—or a control group that received only usual care.

After six months, participants in the STRIDE intervention lost an average of nearly 10 pounds more than control group participants.

After the maintenance phase, intervention participants maintained, on average, a six-pound greater weight loss than the control group. Nearly half of the STRIDE participants lost at least 5 percent of their baseline body weight, with nearly one-fourth losing at least 10 percent. STRIDE participants also reduced their fasting blood glucose levels from around 106.3 to 100.4 mg/dL after 12 months, whereas blood glucose among the control group rose from 106.0 to 109.5 mg/dL.

This improved lifestyle showed some immediate benefits, as significantly fewer people in the STRIDE program reported nonpsychiatric medical hospitalizations than did controls during the study period—6.7 percent vs. 18.8 percent.

“We hope that demonstrating payoffs like fewer hospital visits will help convince organizations to fund these kinds of intervention programs,” Green said.

“It’s also a reason why we focused on antipsychotic use and not a particular disease,” she added. “This way we could make the intervention more broadly applicable and increase the chances of adoption.” She noted that STRIDE participants included people with schizophrenia, bipolar disorder, and posttraumatic stress disorder, and there were no discernable differences in how they responded to the intervention.

One outcome that did not differ
see **Lifestyle Modification** on page 34

BRAIN Initiative Gets New Participants, Financial Commitments

An ambitious project aimed at mapping the human brain brings in more than \$300 million in new investments, as well as new partners from industry, academia, and scientific foundations.

BY NICK ZAGORSKI

The BRAIN Initiative (for Brain Research through Advancing Innovative Neurotechnologies) was launched by President Obama in April 2013 to paint a new, dynamic picture of the brain and enable more thorough research on the most complex of human organs and the disorders that affect it.

As this bold endeavor enters its second year, the White House held a conference September 30 to review the progress already made by the BRAIN Initiative, discuss future goals and challenges, and announce new partners that have joined the fold in response to the President’s call to action for support of this ambitious undertaking.

Among the new groups aligning with the BRAIN Initiative are major industry leaders including Google and General Electric, signaling a promising “buy-in” from the commercial sector for this project. They joined with dozens of academic, medical, and private organizations to

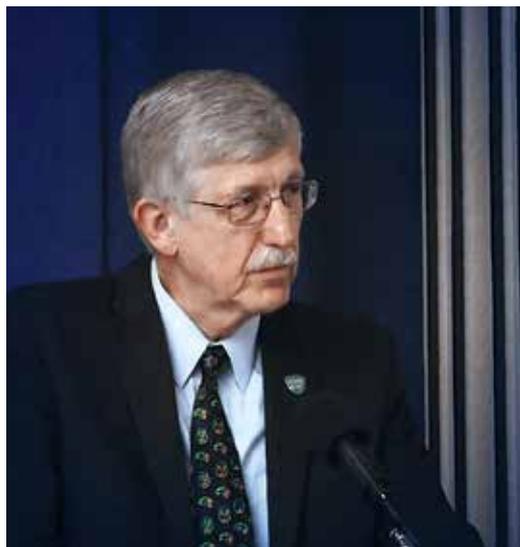
commit more than \$270 million for the BRAIN Initiative over the coming years.

“The administration has been delighted by this thoughtful response,” said Thomas Kalil, deputy director for policy in the White House Office of Science and Technology Policy and senior advisor for science, technology, and innovation at the National Economic Council, during the conference.

“We’re going to be much more likely to achieve the ambitious goals of this initiative if we have a broad coalition of individuals and organizations, both inside and outside the federal government, that are providing their ideas, financial support, and expertise.”

During the conference, the National Institutes of Health (NIH) also announced that it had finalized its first wave of grants totaling \$46 million for the BRAIN Initiative; this funding will support 58 projects and more than 100 investigators.

see **BRAIN Initiative** on page 42



NIH Director Francis Collins, M.D., Ph.D., highlights some of the exciting projects being funded by \$46 million in grants for the BRAIN Initiative.

CLINICAL & RESEARCH NEWS

CBT May Be Best Treatment for Social Anxiety Disorder, Study Finds

A network-based analysis of more than 100 clinical trials and 40 treatments for social anxiety disorder finds that CBT and serotonin inhibitors offer the most pronounced benefits.

BY NICK ZAGORSKI

Social anxiety disorder is emerging as one of the most prevalent mental illnesses in the United States, affecting an estimated 15 million people. While social anxiety disorder can be debilitating, the good news is that many psychological and pharmacological therapies have been shown to work.

However, the big picture of social anxiety interventions remains a bit murky; some studies have reviewed and analyzed existing data, but these meta-analyses generally focus on comparing one approach with another.

Evan Mayo-Wilson, D.Phil., an assistant scientist at the Johns Hopkins School of Public Health, told *Psychiatric News*, “When you do a pairwise comparison, you’re not really looking at

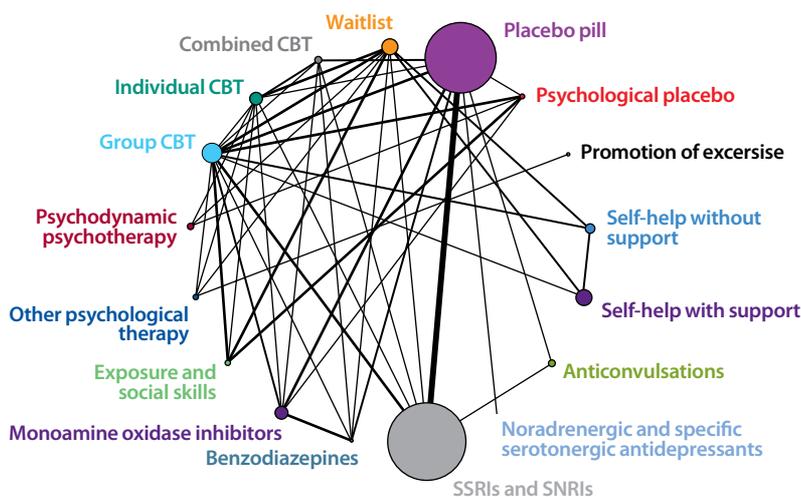
all the evidence you have available.”

So to get a better understanding of how the disorder is treated, Mayo-Wilson and his colleagues in the United Kingdom (where he worked before going

to Johns Hopkins) turned to an emerging methodology—a network meta-analysis, which can compare the effectiveness of multiple treatment options relative to each other and to a common reference.

Different Therapies Tested in the Meta-Analysis

Using a network meta-analysis, Evan Mayo-Wilson, D.Phil., and colleagues compared 41 interventions representing 17 classes of therapies and controls (pictured) relative to each other. In the model, the size of each circle represents the number of people who received the designated treatment, while the width of the lines represents the number of trials that had a direct comparison of the connected treatments.



Source: Evan Mayo-Wilson, D.Phil., et al., *Lancet Psychiatry*, Vol. 1, Issue 5, 368–376, 2014

Key Points

- A networked meta-analysis compared 41 interventions and control conditions for social anxiety disorder.
- When compared with waitlist (no intervention) as a reference, almost every intervention showed a patient benefit.
- When compared with an appropriate placebo, only cognitive-behavioral therapy (CBT) and selective serotonin or serotonin-norepinephrine reuptake inhibitors (SSRI/SSNI) remained significantly more efficacious.

Bottom Line: According to this analysis, CBT should be regarded as the best initial intervention for social anxiety disorder, given its strong benefit, coupled with the risks of side effects and relapse in medication therapies.

They combined the results of 101 clinical studies for social anxiety disorder and compared 41 therapies: 15 using drugs, 18 using psychotherapies, five using a combined approaches, and three types of controls.

The findings, which were published in *The Lancet Psychiatry*, reinforced see *Anxiety Disorder* on page 34

MED CHECK

BY VABREN WATTS

Drug Shows Promise for Agitation in Alzheimer's

Avanir Pharmaceuticals recently announced positive results from its phase 2 clinical trials examining the safety and efficacy of *AVP-923* for treatment of agitation in patients with Alzheimer's disease (AD).

“This is an exciting advancement in Alzheimer's disease research,” said Jeffrey Cummings, M.D., director of the Cleveland Clinic Lou Ruvo Center for Brain Health and chair of the study's steering committee. “Dementia-related neuropsychiatric symptoms such as agitation are extremely distressing to patients and their families.”

The study was a 10-week, double-blind trial with 220 patients with AD who were given either *AVP-923* or placebo. The analysis showed that usage of *AVP-923* was significantly associated with reduced agitation, measured by the Neuropsychiatric Inventory, when compared with placebo. It was also associ-

ated with a reduction of scores on scales measuring caregiver burden. The most common side effects reported were falls, diarrhea, and urinary tract infection—occurring in less than 10 percent of the patients taking *AVP-923*.

AVP-923 key components are dextromethorphan, a commonly used ingredient in cough medicines, and quinidine, used to control irregular heartbeats.

New Monitoring Test Created To Detect 'Z-Drugs'

Dominion Diagnostics, a provider of drug testing and medication monitoring, is marketing a laboratory-based urine test for the detection of Z-drugs—*nonbenzodiazepine-derived medications* used to treat insomnia.

Z-drugs, promoted as “benzodiazepine-like” drugs with fewer potential side effects such as residual daytime sedation and rebound insomnia, have become popular among recreational users—with *zolpidem* (a Z-drug and the key ingredient in Ambien) accounting for 11.5 percent of all emergency department visits made by adults aged 18 and older

for adverse events related to psychiatric medicines, according to the Centers for Disease Control and Prevention.

Dominion's testing for Z-drugs uses a system of ultra-performance liquid chromatography and tandem mass spectrometry to detect the metabolites of commonly prescribed nonbenzodiazepines, including *zolpidem*, *eszopiclone*, and *zaleplon*.

“Z-Drugs are chemically distinct from benzodiazepine medications and will not be detected in a benzodiazepines screening test or confirmatory procedure,” said Lawrence Andrade, manager of research and development at Dominion.

Antipsychotic Adherence Study Shows Positive Results

Janssen Pharmaceuticals has released results of its study involving the Janssen Connect program, which is designed to increase adherence to antipsychotic regimens in patients with schizophrenia. The results were presented at the U.S. Psychiatric and Mental Health Congress in September.

The study involved 9,354 individuals with schizophrenia who were prescribed Janssen's *Invega Sustenna (paliperidone palmitate)*, an injectable, long-acting antipsychotic, and enrolled in Janssen Connect from December 2010 to April 2014. Participants could receive the injections at an “injection center,” typically a pharmacy, in lieu of going to a health care practice.

The results showed that those opting for the injections were 4.5 times more likely to adhere to their medication than those who chose not to receive injections at the centers. Patients were considered to be adherent if they were administered their medication at least 80 percent of the time during the study.

“These results are proof that we're moving in the right direction,” said Catherine Piech, vice president of health economics and outcomes research at Janssen Scientific. “[This] program was born out of our dedication to helping people living with schizophrenia navigate through the difficulties ... [associated with] staying on medication as prescribed by their health care provider.”

see *Med Check* on page 42

 LETTERS TO THE EDITOR

SAMHSA to Build on Partnership With Psychiatry

We thank the estimated nearly 400 individuals and more than 55 organizations that engaged in a robust dialogue with the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop our new strategic plan, titled “Leading Change 2.0: Advancing the Behavioral Health of the Nation.”

APA President Paul Summergrad, M.D., offered his critique of our new plan in the September 11 online *Psychiatric News* (September 19 print edition). His support for our efforts to reduce disparities and the number of people with mental illness in the criminal justice system and recognition of our leadership on integrated care are greatly appreciated. He goes on to call into question our focus on the appropriate medical care of patients with serious mental illness and the development of a physician workforce that is essential for their care.

SAMHSA does not believe we can accomplish what is set forth in our new strategic plan without a focus on the appropriate medical care of patients with serious mental illness and the development of a physician workforce that is essential for their care. Meeting the psychiatric treatment needs for Americans with mental illness and substance use disorders is essential to helping people

attain and sustain recovery.

Our Recovery Support strategic initiative specifically notes the critical role that medical treatment plays in attaining and sustaining recovery for people with serious mental illnesses such as depression, schizophrenia, and bipolar disorder. This strategic initiative will include action steps such as the implementation of a new \$25 million effort, in partnership with the National Institute of Mental Health, to fund early treatment for those with first episodes of serious mental illness via our Mental Health Block Grant program. Further, our Health Care and Health Systems Integration strategic initiative includes the objective to promote “integrated treatment delivery for people with mental illness and substance use conditions” and again specifies the need for medical treatment for people with serious mental illnesses.

We are also excited about our new Workforce Development strategic initiative and how we can strengthen and expand the behavioral health workforce of the nation—including psychiatry. SAMHSA is already partnering with APA to achieve this goal via our 40-year partnership on the Minority Fellowship Program, the HIV/AIDS Training Program, the Recovery to Practice (RTP) ini-

tiative, and other efforts. The RTP effort includes a new component to provide clinical-decision support to practicing psychiatrists specifically on medication practices.

The Health Resources and Services Administration, along with SAMHSA, just announced \$99 million in new grant awards to train mental health providers, help teachers and others recognize mental health issues in youth and connect them to help, and increase access to mental health services for young people. These funds were included in the President and Vice President’s “Now Is the Time” plan to reduce gun violence by keeping guns out of dangerous hands, increasing access to mental health services, and making schools safer. This announcement comes on the heels of an additional \$54.6 million in Affordable Care Act funding to support 221 health centers in 47 states and Puerto Rico to establish or expand behavioral health services for over 450,000 people nationwide. Health centers will use these new funds for efforts such as hiring new mental health professionals, adding mental health and substance use disorder health services, and employing integrated models of primary care.

These new investments in workforce, along with the largest expansion of men-

Letters Invited

Readers are invited to submit letters up to 500 words long for possible publication. *Psychiatric News* reserves the right to edit letters and to publish them in all editions, print, electronic, or other media. Receipt of letters is not acknowledged. Letters should be sent by mail to *Psychiatric News*, APA, Suite 1825, 1000 Wilson Boulevard, Arlington, Va. 22209 or by e-mail to cbrown@psych.org. Clinical opinions in letters are not peer reviewed and thus should be independently verified.

tal health and substance abuse insurance benefits made possible by the Affordable Care Act and the Mental Health Parity and Addiction Equity Act, will help millions of Americans receive needed medical and preventive care.

SAMHSA looks forward to building on these partnerships with psychiatry so that we can achieve our mission of reducing the impact of substance abuse and mental illness—including serious mental illnesses—on America’s communities.

PAMELA S. HYDE, J.D.
Administrator

Substance Abuse and Mental Health
Services Administration

Anxiety Disorder

continued from page 33

the wide range of options available to people with social anxiety disorder, as almost every intervention showed some benefit compared with waitlist, a type of control group that effectively means no intervention; exercise promotion, interpersonal therapy, supportive therapy, and mindfulness training were the exceptions.

“A big take-home message from this study would be that we need to improve patient access and ensure that we have enough trained clinicians available,” said Mayo-Williams. “These results show the worst thing you can do to patients is to make them wait.”

Having enough therapists trained in psychotherapy is of particular importance, noted Mayo-Williams, because of all the options his group analyzed, individual cognitive-behavioral therapy (CBT) came out on top.

When compared with waitlist, CBT had an overall effect that corresponded to number-needed-to-treat (NNT) of fewer than two. NNT measures how many people need a treatment to ben-

efit one person, so values closer to one are more ideal.

CBT was also one of only two interventions that still showed significant benefits when pharmacological or psychological placebo controls were used as the comparison instead of waitlist. The other effective treatment was selective serotonin reuptake inhibitors/serotonin-norepinephrine reuptake inhibitors (SSRIs/SNRIs).

The investigators noted that since SSRIs/SNRIs can cause side effects, and since people can relapse once they stop taking the medication, CBT should be considered as a first-line treatment option, though they acknowledged that many people with social anxiety disorder may not have a desire for, or access to, CBT. In such cases, they suggested that patients should be given SSRIs if they prefer pharmacological treatment, while a CBT-based self-help therapy with support would be recommended for those who want a psychological intervention.

“We hope that this analysis will start steering therapists away from prescribing suboptimal treatments for social anxiety disorder,” Mayo-Williams said.

“The U.K. has done a good job of developing treatment guidelines based off of our group’s research, and we hope the U.S. will follow suit. Psychiatrists and psychologists need to come together to help get this done.”

While this network analysis has provided a more clear hierarchy of treatment effectiveness for social anxiety disorder, Mayo-Williams noted that gaps still remain. For example, the analysis only included five clinical trials that used both pharmacology and psychotherapy, and none of the studies used the same combination, so the possible additive value of combining medicine and talk therapy could not be accurately determined.

This study was funded by England’s National Institute for Health and Care Excellence, which develops “public health guidance to help prevent ill health and promote healthier lifestyles.” **PN**

 “Psychological and Pharmacological Interventions for Social Anxiety Disorder in Adults: A Systematic Review and Network Meta-Analysis” is posted at <http://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366%2814%2970329-3/abstract>.

Lifestyle Modification

continued from page 32

between the STRIDE and control groups was the rate of psychiatric hospitalizations, which was around 15 percent in both groups. “One concern of our program was that the health education might destabilize the patients and they would stop taking their medication to prevent weight gain,” she said. “But we didn’t see any indication of that.”

Green noted that some areas of the program still could use some improvement, such as recruiting more men and minority patients—a common issue for such intervention programs—and minimizing the regaining of weight during the maintenance phase. However, this should not diminish the broad message that people with serious mental illness, given the right tools and support, can handle an intensive lifestyle program and lose weight just like anyone else. **PN**

 “The STRIDE Weight Loss and Lifestyle Intervention for Individuals Taking Antipsychotic Medications: A Randomized Trial” is posted at <http://ajp.psychiatryonline.org/Article.aspx?ArticleID=1906048>.

Pipeline

continued from page 1

and important research. However, it is important to remember that because of the long pathway of drug development, medications currently in the research and development phase, even if they are ultimately FDA-approved, will not enter the market for many years.”

Tiny Fraction Make It to Phase 1

For many pharmacotherapies, the drug-approval process begins with preclinical trials that rely on a series of animal studies. PhRMA reports that for every 5,000 compounds for which companies begin development, only five (0.001 percent) proceed to phase 1 clinical trials, which are conducted with human subjects and overseen by the Food and Drug Administration (FDA). During phase 1 through phase 3 clinical studies, the pharmacotherapy is examined for safety, side effects, and effectiveness. Once phase 3 trials are successfully completed, the drug's sponsor seeks FDA approval for marketing and distribution—which may or may not be granted.

To investigate the current state of psychiatric drugs in the pipeline and why their development is moving at a snail's pace, O'Brien and colleagues gathered information from academic literature and nonacademic sources—such as industry reports, company press releases, and the National Institutes of Health clinical trials website—on phase 3 trials for drugs being developed to treat major psychiatric disorders, including alcohol use disorder, schizophrenia, and depression. The studies were conducted in the United States as

of the final research date of November 14, 2013, and involved adults aged 18 or older.

The analysis showed that the pipeline for psychotropic drug development—99 clinical trials were included—is limited, with little product innovation evident. Most of the examined drugs were a com-

“We often read that there are hundreds or thousands of drugs in development, when, in fact, very few of those drugs reach the clinic.”

bination of existing of FDA-approved medicines or individually approved medicines that were being tested for new indications or delivery-system approaches (such as an injectable version that is similar to an approved oral form).

Only Three Considered Innovative

Of the drugs being tested, only three differed substantially from existing medications. These included a serotonin-norepinephrine-dopamine reuptake inhibitor for treatment of depression (amitifadine), a drug targeting glycine receptors to address negative symptoms of schizophrenia (bitopertin), and a nicotinic alpha-7 agonist for adjunctive treatment for cognition in schizophrenia (EVP-6124).

Among the barriers that hindered development of psychotropic drugs were incentives that encourage firms to focus on incremental innovation—such as a new version with fewer associated side effects—rather than taking a risk on radically new molecular approaches, the failure of animal studies to translate

well to human trials, and drug-approval thresholds set by the FDA that developers and manufacturers may perceive as too high to attain.

In an interview with *Psychiatric News*, Alan Schatzberg, M.D., a professor of psychiatry at Stanford University and a former APA president, said that the departure by pharmaceutical companies from programs to develop innovative psychotropic medicines could result in serious problems for the field of psychiatry, especially for patients.

“There are a number of initiatives by various organizations to help with this problem, including the European College of Neuropsychopharmacology, which is working with companies to provide investigators with compounds that have been shelved, and NIMH's Research Domain Criteria program, which promotes research on specific [and new] biological targets,” he said. Schatzberg emphasized that it will take a concerted effort on the part of

government agencies, industry, as well as APA to advocate for investment in innovative psychiatric drug development. “Silence will not be helpful to our patients,” he stressed.

As for O'Brien, she hopes that the current study will provide psychiatrists and other clinicians with a better understanding of the process of drug development and the potential obstacles that may stand in the way of their having new and more effective medications to prescribe for patients with mental illness. To avoid some of these obstacles, she concluded, clinicians, researchers, and pharmaceutical and health care leaders must work together with policymakers to improve the current regulatory framework guiding the drug-approval process. This could “help promote innovation and increase the availability of safe, effective, and innovative medications for those with behavioral health conditions.” **PN**

 The abstract of “The Diminished Pipeline for Medications to Treat Mental Health and Substance Use Disorders” is posted at <http://ps.psychiatryonline.org/article.aspx?articleID=1901666&resultClick=1>.

Veterans

continued from page 21

APA has worked closely with several veterans' service organizations, including Vietnam Veterans of America and the Iraq-Afghanistan Veterans of America, to craft the Ensuring Veterans' Resiliency Act (EVRA). This measure was not passed on its own, but much of its language was incorporated into other legislation, Boroughs pointed out. Still other elements are likely to work their way into other measures in the next session of Congress, she said.

A more subtle transformation has occurred inside the VHA as well, noted Boroughs. Formerly, psychologists dominated the high-ranking mental health “consultant” positions at the VHA's Washington, D.C., headquarters. Now, four of those offices are run

by psychiatrists: APA members Ira Katz, M.D., Ph.D., Harold Kudler, M.D., Marsden McGuire, M.D., and Dean Krahn, M.D.

In addition, APA continues to work with the veterans' service organizations on two legislative packages whose aim is to improve vets' mental health—HR 5059, the Clay Hunt SAV Act, and S 2182, the Suicide Prevention for American Veterans Act.

Both legislative packages have widespread bipartisan support and contain language originally in EVRA, said Boroughs. The House bill has more than 107 cosponsors and is sponsored by the Republican chair of the House Veterans Affairs Committee. If not passed in the lame-duck session between the November 4 election and the start of the next Congress in January, both package bills will likely be reintroduced. **PN**

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Cancer Patients

continued from page 13

receiving DCPC responded to treatment—classified as at least a 50 percent reduction in depression severity—compared with only 17 percent receiving usual care. DCPC recipients also reported less anxiety, fatigue, and pain.

“That 45 percent difference in response to care is astounding,” Sharpe told *Psychiatric News*. “And all we did was just package together some of the evidence-based treatments we already have available on the shelf.”

Sharpe was particularly surprised by the low numbers for usual care. “These people all attended specialist cancer clinics,” he said, “and the primary physician and oncologist were both informed of the major depression diagnosis. This definitely shows that simple awareness of the diagnosis of depression among cancer patients is not enough to improve their outcomes.”

Patients With Poor Prognosis Benefit

But would DCPC work for depressed patients who have less to fight for? SMaRT Oncology-3 enrolled 142 lung cancer patients, a diagnosis that has an average six-month life expectancy, and assigned them to usual care or DCPC, which was adapted to factor in the physical deterioration of these patients and achieve a quicker response. However, DCPC enrollees still reported greater improvements, with 51 percent achieving a treatment response after 12 weeks, compared with 15 percent for usual care. This study was headed by Sharpe’s colleague at Oxford, Jane Walker, M.D., and published in *Lancet Oncology*.

“What makes these studies unique is that the patients were closely monitored so that the depression treatment could be intensified or otherwise adjusted as needed, which may have influenced the

strong results,” said Jesse Fann, M.D., M.P.H., a professor of psychiatry and behavioral sciences at the University of Washington. “It’s also the first time collaborative care has integrated the specialty cancer clinic in addition to the primary care setting.”

It’s an important aspect to the study, since starting in 2015, the American College of Surgeons will require all

cancer centers in the United States to evaluate cancer patients for psychosocial issues that could negatively impact care and to provide resources or referrals for psychosocial care.

While there are differences in the U.K. and U.S. health systems, a model like DCPC should work stateside. “Every cancer center is different in structure and staffing, but the core components of

DCPC can be effectively adopted at any location,” said Fann. “Each center can then make small adaptations that better fit its specific situation.”

Fann pointed to an integrated care model at the Seattle Cancer Care Alliance (SCCA), where he serves as director of psychiatry and psychology services, as an example. The SCCA model is similar to Sharpe’s, though it uses social work-

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Jane Walker, M.D., was the principal investigator of SMaRT Oncology-3, which found that a modified model of integrated depression care worked well even in lung cancer patients with a poor prognosis.

ers instead of oncology nurses as the care managers. It also goes beyond depression to help patients with psychosocial and physical aspects of cancer, such as increased anxiety, fatigue, pain, substance abuse, and sleep disorders.

More DCPC Uses Being Studied

Back in the United Kingdom, Sharpe and his team are exploring further

uses for DCPC as well. He envisions it could be integrated into palliative care and used more broadly in end-of-life situations. His group will also tackle the critical issue of cost-effectiveness, though a preliminary analysis of SMaRT Oncology-2 found that DCPC added about only \$1,000 in costs per patient, which is a small fraction of the average total cancer care costs.

The SMaRT Oncology trials were funded by Cancer Research UK, with additional support from the Chief Scientist Office of the Scottish Government. **PN**

 An abstract of "Integrated Collaborative Care for Comorbid Major Depression in Patients With Cancer (SMaRT Oncology-2): A Multicentre Randomised Controlled Effec-

tiveness Trial" is posted at <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2814%2961231-9/abstract>. An abstract of "Integrated Collaborative Care for Major Depression Comorbid With a Poor Prognosis Cancer (SMaRT Oncology-3): A Multicentre Randomised Controlled Trial in Patients With Lung Cancer" is posted at <http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2814%2970343-2/fulltext>.

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Pay

continued from page 1

expected to help attract more psychiatrists to the VHA (see story on page 28).

“These changes are good not only for psychiatrists but for a population that deserves good care,” said Boyer, who noted that she was speaking as an individual and not as a representative of the VHA.

APA’s support for the changes derived in part from an action paper passed by the APA Assembly, Boyer noted.

“We looked at open positions for psychiatrists across the government and found 156 in the VHA and just one in the Department of Defense, because the DoD had a higher pay scale,” she said in an interview. “This shows that individual APA members can offer an idea and

make significant changes.”

Psychiatry is considered together with other medical specialties like emergency medicine, pulmonology, and oncology in the VHA pay scheme.

Higher rates will apply to both newly recruited psychiatrists and those already serving in the VHA, said Boyer. “Boosting pay for new hires alone would actually have a reverse effect. People would

leave one facility and apply at another one to get better pay.”

Actual pay within each tier is governed by the applicant’s credentials, experience, and assigned tasks within the system. For instance, supervisors and psychiatrists who choose to work in rural areas may earn more, said Boyer.

“Competitive compensation for psychiatrists serving in the VHA has been a

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top advocacy priority for APA,” said Boroughs. APA has worked on three tracks to that end. Official statements and letters to Congress and the VHA have addressed the subject. Advocacy by APA members has educated Congress, while APA’s Department of Government Relations has worked with veterans’ service organizations (like Vietnam Vets of America, Iraq and Afghanistan Veterans of America, and

Disabled American Veterans) to amplify the need to improve the VHA’s retention and recruitment of psychiatrists.

Formerly, gaining higher pay was determined by a system of exceptions to salary caps or the use of hiring bonuses, both of which require often lengthy internal approval processes, said Boroughs. While that system will be replaced, the VHA will still take time to verify applicants’ creden-

tials and experience and conduct background checks. Applicants must also pass physical examinations and have valid, up-to-date certifications. Those requirements will still take time to meet and verify, continuing to slow the hiring process. [PN](#)

[▶](#) APA’s summary of the Veterans’ Access, Choice, and Accountability Act is posted at <http://www.psychiatry.org/File%20Library/Advocacy%20and%20Newsroom/08-08-2014-H-R-3230-Summary.pdf>.

APA’s letter to the House Committee on Veterans’ Affairs regarding the Ensuring Veterans Resiliency Act is posted at <http://www.psychiatry.org/File%20Library/Advocacy%20and%20Newsroom/6-20-2014---APA-Letter-to-Rep--Jeff-Miller-Regarding-the-Ensuring-Veterans--Resiliency-Act.pdf>.

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Open Payments

continued from page 21

- **Advancing medical knowledge:** Physicians in academic medical centers and other organizations receive funding from industry as investigators in clinical research and as consultants who help design and evaluate clinical trials or

develop new medical technologies.

- **Advancing physician knowledge:** Industry also supports physician education, and in some instances that will be reported as payments to individual physicians, even if the physicians are not aware of it. For example, a physician may receive an honorarium from his or her

medical society for being on the faculty of an educational program put on by the society. If the society received a grant from industry to help support the program, that honorarium may be reported as indirect payment from industry through the Open Payments system, even though the physician received the honorarium directly

from the medical society and wasn't aware of the industry support.

Additionally, CME courses funded by industry and visits from pharmaceutical representatives to physician offices or health care organizations to talk about new research and treatment options can also supplement physicians' knowledge about new advances in medicine. Indus-

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try sometimes also provides physicians with reprints of peer-reviewed medical journal articles and medical textbooks, which likewise help physicians stay abreast of the latest medical treatments.

CMS advises physicians to keep track of financial interactions with the health care industry and work with drug and device manufacturers to make sure submitted information is correct.

A free mobile app to help physicians track payments that might be reportable can be downloaded at the Google Play app store or iOS Apple app store. For more information, go to Open Payments Mobile for Physicians at <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Apps-for-Tracking-Assistance>.

html. According to CMS, the app serves as an information depository only; it does not interact with CMS systems or CMS contractors and cannot be used directly for data reporting to CMS or its contractors.

From its inception, the database has been plagued with problems. In August APA joined the AMA and more than 100 other medical specialty organizations in signing a letter to CMS registering “seri-

ous concerns with implementation of the Physician Payment Sunshine Act and ... request[ing] an expanded timeframe to allow recipients to register, review, and dispute [physician] data.” **PN**

➤ Registration information for the Open Payments system is posted at <http://www.psychiatry.org/advocacy--newsroom/advocacy/sunshineact>.

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Consultation

continued from page 20

system, Trinh said.

He noted that the findings from the study support the use of a short-term consultation focusing on cultural factors that may influence Latino patients’ perception of depression and treatment and an integrated approach to care of depression in primary care. “Such findings add to a growing literature on the benefits of collaborative care among primary care and mental health specialists,” he said. **PN**

➤ “Impact of a Culturally Focused Psychiatric Consultation on Depressive Symptoms Among Latinos in Primary Care” is posted at <http://ps.psychiatryonline.org/article.aspx?articleid=1878682>

Oklahoma

continued from page 22

in the majority opinion for the three-judge panel.

(A dissenting voice in that ruling, Judge Harry Edwards, said the court’s ruling ignores the overall statutory intent of Congress in passing the ACA, which was to expand affordable health insurance.)

On the same day, the U.S. Court of Appeals for the 4th Circuit for the Eastern District of Virginia, echoing Edwards’ dissent in the D.C. court decision, ruled that Congress clearly intended to make subsidies as widely available as possible as part of the effort to make insurance more affordable (*Psychiatric News*, August 11). **PN**

➤ The Oklahoma decision is posted at <http://www.ok.gov/oag/documents/Oklahoma%20v%20Burwell%20ruling.pdf>. The decision of the District of Columbia appeals court is posted at [http://www.cadc.uscourts.gov/internet/opinions.nsf/10125254d91f8bac85257d1d004e6176/\\$file/14-5018-1503850.pdf](http://www.cadc.uscourts.gov/internet/opinions.nsf/10125254d91f8bac85257d1d004e6176/$file/14-5018-1503850.pdf). The decision of the Virginia appeals court is posted at <http://www.ca4.uscourts.gov/opinions/published/141158.p.pdf>.

Med Check

continued from page 33

AstraZeneca and Lilly Team Up On Alzheimer's Drug

Pharmaceutical giants AstraZeneca and Eli Lilly are joining forces to commercialize and further develop **AZD3293**, an oral beta secretase cleaving enzyme (BACE) inhibitor, as a potential treatment for Alzheimer's disease (AD). The newly developed pharmacological agent, which functions to prevent amyloid plaque formation, is currently in early-stage testing.

"We are looking forward to working with Lilly, an organization with a long-term commitment to and expertise in treating Alzheimer's disease," said Mene Pangalos, an executive vice president at AstraZeneca. "By combining the scientific expertise from our two organizations and ... sharing the risks and cost of late-stage development, we will be able to accelerate the advancement of ... a promising new approach to treating AD.

Under the agreement, Lilly will pay AstraZeneca up to \$500 million in development and regulatory milestone payments—with the first milestone payment of \$50 million to be received in 2015. The companies will share all future developmental costs, as well as global revenue, equally.

The companies plan to rapidly move AZD3293 into phase 2 and phase 3 trials in patients with early AD.

Transcranial Therapy Shows Long-Term Benefits For Refractory Depression

Neuronetics Inc. conducted the largest study to date on long-term effectiveness of its NeuroStar TMS Therapy (NSTT) in adults with major depressive disorder who have failed to benefit from treatment with antidepressant medication. NSTT is a by-prescription transcranial magnetic therapy that regulates mood via a nonsystematic (that is, independent of the circulatory system) and noninvasive approach. It is

administered in the office five days a week for four to six weeks.

The study, published in the *Journal of Clinical Psychiatry*, showed that at the end of acute treatment (four to six weeks) with NSTT in 257 patients, 62 percent achieved symptomatic improvement, while 41 percent reported complete remission. These results were maintained after one year, with 68 percent achieving symptomatic improvement and 45 percent reporting remission. The most common side effect reported was pain or discomfort at or near the treatment site.

Neuronetics is studying the effectiveness of NSTT in patients with postpartum depression. **PN**

 Dunner, D, Aaronson, S, Sackeim, H, et al. A multisite, naturalistic, observational study of transcranial magnetic stimulation for patients with pharmacoresistant major depressive disorder: durability of benefit over a 1-year follow-up period. *J Clin Psychiatry*. September 16, 2014. [Epub ahead of print] <http://www.psychiatrist.com/JCP/article/Pages/2014/aheadofprint/13m08977.aspx>

Hispanics

continued from page 20

care reform initiatives, and a member of the National Advisory Council for the Carter Center Mental Health Task Force founded by Former First Lady Rosalynn Carter. Delgado, the first woman to serve as president and CEO of NAHH, has dedicated her career to improving the health of Hispanic and Latino Americans.

"Mental health involves more than the brain," Delgado noted. "We really need to understand the people who we serve ... and listen to them." During an interview with *Psychiatric News*, she said a crucial factor that keeps Hispanic Americans from accessing mental health care, as well as other health care, is the fear of not being understood due to language barriers and the lack of cultural competence by clinicians who may not fully understand the symptoms that these patients are describing.

Delgado described one situation in which a person of Hispanic descent visited the emergency department and repeatedly said "débil" when asked to describe his symptoms. Under the assumption that the patient was trying to convey that he was seeing the devil, the medical staff concluded that the patient's illness was related to mental illness. "Débil" means 'weak' in Spanish," Delgado explained. "This is but one of many examples of how misunderstandings of patients' ethnic background and language can affect the health care they receive.

Other obstacles that keep Hispanic Americans from accessing mental health services include lack of insurance and stigma. "We, as a country, are still working on decreasing stigma," said Delgado. "People still think that the issue of mental health is something that you should get over and is a sign of weakness. We have to recast this way of thinking, not just for Hispanics but for everyone."

Delgado, who advocates for minority health issues on Capitol Hill, also stressed the importance of increasing the diversity of subjects participating in clinical trials, particularly involving psychiatric drugs.

"Hispanics metabolize fat differently from the general population, making certain medications intended for diabetes more effective in this population, for example. Certain heart medications are more effective in African Americans," she said. "Does this [concept] hold true for psychiatric medication that we give patients? We need to know."

She added that "mental health professionals must push for better and more diverse data to make the best decisions for our patients." **PN**

BRAIN Initiative

continued from page 32

NIH Director Francis Collins, M.D., Ph.D., noted that these awards are just the first installment of a 12-year scientific plan focused on developing the tools needed to make the next leap in understanding the brain.

With the new partners and resources coming in, conference leaders also took the opportunity to highlight federal involvement in the project, with two new government agencies joining NIH, the Defense Advanced Research Projects Agency, and the National Science Foundation on the initiative.

The Intelligence Advanced Research Projects Activity, a program in the Office of the Director of National Intelligence, will sponsor applied-research projects that use multidisciplinary approaches to advance the knowledge of cognition and computation in the brain. And the Food and Drug Administration will work to enhance the transparency of the regulatory landscape for the—it is hoped, many—neurological medical devices that will be developed from BRAIN Initiative advances. **PN**

 More details about the new investments highlighted during the conference are posted at http://www.whitehouse.gov/sites/default/files/microsites/ostp/brain_fact_sheet_9_30_2014_final.pdf. Information about the BRAIN Initiative is posted at <http://www.braininitiative.nih.gov/index.htm>.

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