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Professional News

Terrorist-Suspect Questioning Prompts APA Ethics Review

APA leaders will meet next month to begin developing guidelines for psychiatric involvement in national security interrogations, such as those the U.S. has conducted at Guantanamo Bay naval station.

BY MARK MORAN

Can a psychiatrist ethically participate in the interrogation of a detainee who may have information vital to the safety and security of the nation? If so, what is an appropriate role for a psychiatrist in such a setting—advisor on overall strategy? behind-the-scenes consultant on individual cases? active participant in questioning?

And when does "psychological pressure" cross the line into torture?

Those are just some of the ethical and professional dilemmas raised by recent allegations that behavioral health professionals, including psychiatrists, have participated in interrogation of detainees at the U.S. naval station at Guantanamo Bay, Cuba. Worldwide attention has been focused on allegations of abuse during interrogation of detainees there, as well as in Iraq and Afghanistan.

The nature and extent of involvement by psychiatrists in interrogations are not clear, but the charges have galvanized an effort to clarify ethical and professional boundaries and establish guidelines for psychiatrists' conduct in such settings.

APA is "troubled by recent reports regarding alleged violations of professional medical ethics by psychiatrists at Guantanamo Bay," the Association said in a statement issued at the end of June. "APA is not neutral on physician practices and clearly recommends that psychiatric physicians practice in accordance with the APA ethics guidelines, which are also in accordance with the medical code of ethics set forth in the American Medical Association's *Principles of Medical Ethics.*"

The statement noted that APA's *Principles of Medical Ethics With Annotations Especially Applicable to Psychiatry* states the following:

- A physician shall be dedicated to providing competent medical care with compassion and respect for human dignity and rights.
- A physician shall respect the law and also recognize a responsibility to seek change in those requirements that are contrary to the best interests of patients.
- Ethical considerations in medical practice preclude the psychiatric evaluation of any person charged with criminal acts prior to access to, or availability of, legal counsel. The only exception is the rendering of care to the person for the sole purpose of medical treatment.
- A physician shall respect the rights of patients, colleagues, and other health professionals and shall safeguard patient confidences and privacy within the constraints of the law.

Past APA President Paul Appelbaum, M.D., chair of the Council on Psychiatry and Law, told *Psychiatric News* that APA leaders began delineating the issues last year, before allegations about psychiatrists at Guantanamo had become public.

"The council and the Committee on Judicial Action met with a number of psychiatrists who have relationships with the military or with national security to talk about their experiences and the kinds of ethical issues they perceive in their work and how they deal with them," he said. "It was aimed at educating ourselves about these issues

please see ***Ethics Review*** *on page 34*

Photo by Joe Raedle/Getty Images

This is an interrogation room at Camp Delta at Guatanamo Bay, Cuba, for detainees from the war in Afghanistan. Approximately 600 prisoners remain in detention.

Government News

Two Reports Point Government To More Effective MH System

The 2003 report of the New Freedom Commission on Mental Health leads to an agenda for coordinating federal efforts to reform the country's mental health system. National advocacy organizations unite to propose more government action to address the problems.

BY AARON LEVIN

Better coordination and more federal action could transform the nation's fragmented system of mental health care, according to two major reports, one issued by the U.S. government and the other by a coalition of national mental health organizations.

"The federal government is aligning its resources so that people will have the opportunity for recovery," said Charles G. Curie, M.A., administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA), at a press conference last month at the Capitol in Washington, D.C.

"We must send a message that mental illness is an illness and not a scandal," said Curie. "Recovery should be an expectation, not an exception."

SAMHSA's report is titled "Transforming Mental Health in America. The Federal Action Agenda: First Steps." Just a few days later, the Campaign for Mental Health Reform (CMHR), a coalition of 16 national mental health advocacy organizations, including APA, set out its own list of goals in a 32-page report titled "Emergency Response: A Roadmap for Federal Action on America's Mental Health Crisis."

"The proof of these reports will appear if things actually change in the real world of care and support for people with mental illness," said APA President Steven Sharfstein, M.D., in an interview.

SAMHSA's agenda is an outgrowth of the 2003 report of President Bush's New Freedom Commission on Mental Health, titled "Achieving the Promise: Transforming Mental Health Care in America" *(Psychiatric News,*

please see ***Two Reports*** *on page 28*

Association News

APA Recruitment Video Wins Prestigious Industry Award

APA's video "Real Psychiatry: Doctors in Action" goes beyond being a successful recruitment tool for minority psychiatrists—it is also a finely crafted documentary.

BY EVE BENDER

A documentary video developed by APA's Department of Minority and National Affairs that follows the lives and psychiatric practices of four community psychiatrists has won plaudits—and a prestigious award—from the film and video industry.

"Real Psychiatry: Doctors in Action" won the CINE Spring 2005 Golden Eagle Award in the Science and Technology category.

CINE is an organization based in Washington, D.C., dedicated to fostering excellence in documentary film and video production through its semi-annual awards. This year's awardees will be honored in a ceremony in April 2006 in Washington, D.C.

Juries of CINE "media specialists" review thousands of entries to decide the winners of the CINE Golden Eagle Award and other awards.

"Real Psychiatry" provides a glimpse into the day-to-day practices of Curtis Adams, M.D., Mary Roessel, M.D., Mercedes Martinez, M.D., and Lowell Tong, M.D. Each of the psychiatrists treats racial and ethnic minority patients in a variety of settings (*Psychiatric News*, November 19, 2004).

The aim of the video is to encourage minorities to choose psychiatry as a career path, thereby leading to a reduction in mental health care disparities for minority patients.

"We're delighted that 'Real Psychiatry' has won the CINE award," said Annelle Primm, M.D., M.P.H., director of APA's Department of Minority and National Affairs. "Clearly, the video appeals not just to aspiring psychiatrists, but to the world at large."

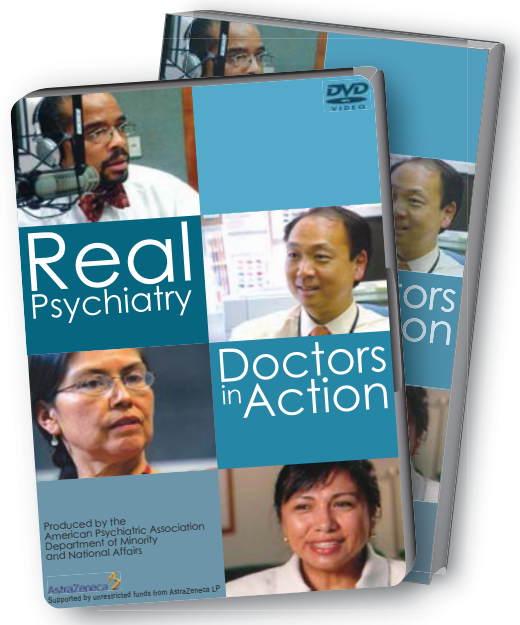
The idea for the video was conceived by Marilyn King, the department's senior program manager, who noted that with the CINE award, "response to the video exceeded our expectations." She also credited her APA colleagues with "pulling together as a team to make the video a success."

Primm and King praised the creative mastery brought to the project by filmmaker and producer Ginny Durrin, of Durrin Productions, a Washington, D.C.–based film and video company.

Durrin commented that before making the video, she didn't realize "how community oriented the role of a psychiatrist can be," and, like many, conjured up an image of the stereotypical couch when she thought about psychiatry.

"Each of the stars of the video took me on a fascinating journey in the course of their daily lives, whether it was doing a radio talk show, going into family health clinics in Chicago, practicing on Indian reservations in the Southwest, or teaching classes in San Francisco," she said.

A free copy of "Real Psychiatry: Doctors in Action" may be requested by phone at (888) 35-PSYCH or by e-mail at apa@dvd.org. Each additional copy of the video costs $10 for VHS and $15 for DVD. APA members can also view the video on APA's Web site at <www.psych.org/members/omna/diavideo.cfm?>. ■



Professional News

Suicide Prevention Day

World Suicide Prevention Day will be held Saturday, September 10. This is an international outreach sponsored by the World Health Organization and endorsed by APA. In the United States, Screening for Mental Health Inc. hosts the campaign Web site <www.StopASuicide.org>.

The Stop A Suicide Today! campaign outlines specific steps to take when someone is worried that a friend or relative is depressed and possibly suicidal. The Web site features the Suicide Risk Questionnaire, which identifies the warning signs of suicide, along with action steps, facts sheets, and help resources.

Campaign cosponsors include the Suicide Prevention Action Network, American Association of Suicidology, American Foundation for Suicide Prevention, Harvard Medical School Department of Psychiatry, and several other educational and prevention organizations. ■

Big Pharma and American Psychiatry: The Good, the Bad, and the Ugly

BY STEVEN S. SHARFSTEIN, M.D.

APA's annual meeting is one of the largest medical meetings in the United States and the largest psychiatric meeting in the world. There is something for everyone at our wonderful meeting, but many have commented to me on the extraordinary presence of the pharmaceutical industry throughout the scientific programs and on the exhibit floor.

The U.S. pharmaceutical industry is one of the most profitable industries in the history of the world, averaging a return of 17 percent on revenue over the last quarter century. Drug costs have been the most rapidly rising element in health care spending in recent years. Antidepressant medications rank third in pharmaceutical sales worldwide, with $13.4 billion in sales last year alone. This represents 4.2 percent of all pharmaceutical sales globally. Antipsychotic medications generated $6.5 billion in revenue.

When the profit motive and human good are aligned, it is a "win-win" situation. Pharmaceutical companies have developed and brought to market medications that have transformed the lives of millions of psychiatric patients. The proven effectiveness of antidepressant, mood-stabilizing, and antipsychotic medications has helped sensitize the public to the reality of mental illness and taught them that treatment works. In this way, Big Pharma has helped reduce stigma associated with psychiatric treatment and with psychiatrists. My comments that follow on the pharmaceutical industry and its relationship to psychiatry bear this in mind.

The interests of Big Pharma and psychiatry, however, are often not aligned. The practice of psychiatry and the pharmaceutical industry have different goals and abide by different ethics. Big Pharma is a business, governed by the motive of selling products and making money. The profession of psychiatry aims to provide the highest quality of psychiatric care to persons who suffer from psychiatric conditions. There is widespread concern of the overmedicalization of mental disorders and the overuse of medications. Financial incentives and managed care have contributed to the notion of a "quick fix" by taking a pill and reducing the emphasis on psychotherapy and psychosocial treatments. There is much evidence that there is less psychotherapy provided by psychiatrists than 10 years ago. This is true despite the strong evidence base that many psychotherapies are effective used alone or in combination with medications.

In my last column, I shared with you my experience, and APA's, in responding to the antipsychiatry remarks that Tom Cruise made earlier this summer as he publicized his new movie in a succession of media interviews. One of the charges against psychiatry that was discussed in the resultant media coverage is that many patients are being prescribed the wrong drugs or drugs they don't need. These charges are true, but it is not psychiatry's fault—it is the fault of the broken health care system that the United States appears to be willing to endure. As we address these Big Pharma issues, we must examine the fact that as a profession, we have allowed the biopsychosocial model to become the bio-bio-bio model. In a time of economic constraint, a "pill and an appointment" has dominated treatment. We must work hard to end this situation and get involved in advocacy to reform our health care system from the bottom up.

Furthermore, continuing medical education opportunities sponsored by pharmaceutical companies are often biased toward one product or another, and they are more akin to marketing than CME. APA has strict guidelines for the industry-sponsored symposia presented at our annual meetings; sanctions are applied when our rules are broken. Our guidelines have been held up as a standard for medical meetings in other specialties throughout the country. But there are many grand rounds, evening dinners, and lectures where such standards do not prevail.

Direct marketing to consumers also leads to increased demand for medications and inflates expectations about the benefits of medications. As a profession, we need to be concerned about advertising and the impact it has on the overmedicalization of our field. Of course, what is marketed to consumers are the highest-cost, on-patent products, and the cost of medications is something rarely considered by prescribing clinicians. When doctors don't prescribe cheaper but equally effective drugs, it consumes money that could have been used to provide other psychiatric or medical services.

There are examples of the "ugly" practices that undermine the credibility of our profession. Drug company representatives will be the first to say that it is the doctors who request the fancy dinners, cruises, tickets to athletic events, and so on. But can we really be surprised that several states have passed laws to force disclosure of these gifts? So-called "preceptorships" are another example of the "ugly"; that is, drug companies who pay physicians to allow company reps to sit in on patient sessions allegedly to learn more about care for patients and then advise the doctor on appropriate prescribing.

Drug company representatives bearing gifts are frequent visitors to psychiatrists' offices and consulting rooms. We should have the wisdom and distance to call these gifts what they are—kickbacks and bribes. (For more thoughts on this topic, see Viewpoints on page 33.) If we are seen as mere pill pushers and employees of the pharmaceutical industry, our credibility as a profession is compromised.

Here are several suggestions for remedies in our relationship with the industry.

- We need to embrace a new professional ethic. The doctor-patient relationship should not be a market-driven phenomenon.

please see ***From the President*** *on page 4*

NCQA Announces Measures To Assess Health Plan Quality

For example, one measure asks what percentage of children who are prescribed an ADHD medication had an adequate number of follow-up visits during initiation and maintenance phases of treatment.

BY MARK MORAN

The National Committee for Quality Assurance (NCQA) has released "technical specifications" for the 2006 edition of its Health Plan Employer Data and Information Set (HEDIS), adding five new performance measures including one on use of medication in children with attention-deficit/hyperactivity disorder (ADHD).

That measure looks at whether children who have been prescribed ADHD medication have received systematic follow-up office visits to evaluate treatment response and ensure that potential adverse side effects of those medications are avoided.

The NCQA is a nonprofit organization that accredits and certifies health care organizations and manages the evolution of HEDIS, a tool used by health plans to measure and report on their performance.

Psychiatrist Richard Hermann, M.D., a member of the NCQA Behavioral Health Measurement Advisory Panel, told *Psychiatric News* that the new measure asks two questions: What percentage of children aged 6 to 12 who are prescribed a medication for ADHD had a follow-up visit within 30 days of treatment initiation? And what percentage of those children had two follow-up visits within the subsequent nine months?

"Conceptually, the point is to determine if children who are prescribed medications for ADHD are simply started on a medication and left to their own devices, or if they receive ongoing follow-up care that can address medication issues as well as psychosocial issues," Hermann said.

He is also chair of the APA Committee on Quality Indicators and an associate professor of medicine and psychiatry at Tufts University School of Medicine, where he is the director of the Center for Quality Assessment and Improvement in Mental Health.

Hermann said that the existing seven HEDIS measures developed for mental health care primarily focus on care of adults. The ADHD measure is the first that specifically evaluates care provided to children

"This is a start toward more broadly addressing the quality of mental health care for kids," Hermann said. Other areas that might be addressed in ADHD treatment include use of psychosocial treatments, quality of assessments, and accuracy of the resulting diagnosis.

He said ADHD was chosen as a starting point because it is one of the more prevalent psychiatric conditions of childhood and is associated with significant functional problems in academic achievement and social performance.

Hermann added that the condition is often treated by pediatricians, who don't necessarily have the same follow-up practices that a psychiatrist would have.

Other HEDIS mental health measures included in the new specifications are the following:

- **Follow-up after hospitalization for mental illness:** The percentage of [health plan] members aged 6 and older who were hospitalized for treatment of selected psychiatric disorders and who received ambulatory care from a mental health care provider within (1) seven days and (2) 30 days of hospital discharge.
- **Antidepressant medication management:** The percentage of members aged 18 years and older who were diagnosed with a new episode of depression and treated with antidepressant medication and who (1) remained on an antidepressant drug during the entire 12-week acute treatment phase; (2) remained on an antidepressant drug for at least six months; and (3) had at least three follow-up contacts with a primary care or mental health care practitioner that were coded with a mental health diagnosis during the 12-week, acute-treatment phase.
- **Initiation of alcohol and other drug treatment:** The percentage of adults diagnosed with alcohol or drug dependence who begin inpatient or outpatient treatment within 14 days of diagnosis.
- **Treatment engagement for alcohol and other drug dependence:** The percentage of adults diagnosed with alcohol or drug dependence who engage in treatment, with two treatments occurring within 30 days after initiating treatment.

The other medical measures included in the new specifications include use of spirometry in the diagnosis and assessment of chronic obstructive pulmonary disease, drugs to be avoided in the elderly, annual monitoring of patients on persistent medications, and antibiotic use in adults with acute bronchitis.

Information about quality measures for mental health care can be obtained from a new APPI book written by Hermann, *Improving Mental Healthcare: A Guide to Measurement-Based Quality Improvement*. It is available for purchase at <http://appi.org/book.cfm?id=62088>.

"HEDIS 2006, Volume 2: Technical Specifications" is available in print and electronic formats and can be ordered by phone at (888) 275-7585 or online at <www.ncqa.org/publications>. ■

from the president

continued from page 3

- Preceptorships should be considered unethical.
- Enticements, gifts, parties, and so on should be reined in because patients must believe that their doctor has their best interests in mind when a prescription is handed to them.
- We must re-evaluate single-sponsored medical education events and phase them out in favor of more general support for CME along with a careful policing of these events for bias.
- The amount and support received by individual clinicians and researchers from industry should be transparent and the information readily available.
- When we attend lectures at annual meetings and other educational events, and read journals and textbooks, we should know very clearly about the industry support given to presenters and authors.

As psychiatrists, we should all be grateful for the modern pharmacopia and the promise of even more improvements in the future. At the same time, however, we must be very mindful that we cannot accept gratuities in the new medical marketplace. ■

Candidates Sought For Evaluation On ABPN Oral Exam

APA is seeking candidates to participate in a pilot program that will help them evaluate their performance on an oral examination similar to Part 2 of the ABPN boards. Only candidates who have failed the oral examination (Part 2 of the ABPN examination) two or more times are eligible to participate.

This is the second year that APA has conducted the program.

Current and past board examiners will evaluate participants on their performance on a live patient interview and clinical vignettes and then provide feedback on factors that interfere with their performance.

The program will held on Saturday, October 29, at SUNY Downstate Medical Center, located at 450 Clarkson Avenue, Brooklyn, N.Y.

Tuition for the diagnostic assessment is $800. The deadline for applications is September 1.

The pilot program can accommodate only 24 candidates. Participants will be chosen by lottery from the applications received by the deadline. Remediation is the responsibility of participants.

Those interested in applying should contact Nancy Delanoche by e-mail at ndelanoche@psych.org or by phone at (703) 907-8663. The application can be downloaded from <www.psych.org/edu/res_fellows/program/pilot.cfm>. ■

Substance-Abuse Admissions Rise for Several Drugs

The total number of substance abuse treatment admissions has risen slightly in 10 years; however, the number of admissions for some substances, such as methamphetamine, has risen dramatically.

BY AARON LEVIN

Admissions to substance abuse treatment facilities for disorders related to the use of methamphetamines and narcotic pain medications rose in 2003, while those for alcohol, marijuana, and heroin use fell slightly, the Substance Abuse and Mental Health Services Administration (SAMHSA) reported.

The number of treatment admissions rose in the decade ending in 2003 from about 1.6 million in 1993 to 1.8 million in 2003, according to the highlights from Treatment Episode Data Sets, although that total represents a drop from the peak of 1.9 million admissions logged in 2002. The data cover annual admissions to drug and alcohol abuse treatment in facilities reporting to individual state administrative data systems.

Methamphetamine admissions rose about 10 percent, from 105,754 in 2002 to 116,604 in 2003. By comparison, there were only 20,776 methamphetamine admissions in 1993. Admissions for opiate abuse (including nonprescription methadone) rose 12 percent in the same period, increasing from 45,927 in 2002 to 51,071 in 2003. There were just 14,143 such admissions in 1993.

> **"There hasn't been a whole lot of change in 10 years despite increased research on using medications to treat substance abuse."**

"The alarming growth of methamphetamine use and, in part, its popularity can be explained by the drug's wide availability, ease of production, low cost, and highly addictive nature," said SAMHSA Administrator Charles Curie, M.A., in a statement accompanying release of the data.

The data are for admissions, not individuals, and cover only facilities receiving state or federal substance abuse treatment funds.

The general decline in substance abuse admissions from 2002 to 2003 resulted mainly from about 50,000 fewer persons entering treatment for alcohol abuse. Heroin-related admissions fell by about 17,000, while those for cocaine and marijuana each rose by about 5,000.

"Any decline [in treatment admissions] is of concern because only a small percentage of patients who need treatment get it," said Marianne Guschwan, M.D., a clinical assistant professor of psychiatry at New York University School of Medicine and past chair of APA's Corresponding Committee on Treatment Services for Patients With Addictive Disorders.

The number of admissions may well be driven by insurance status, even though the study data are drawn from government-funded treatment programs, she said.

SAMHSA's data do not mention payers, but do record that only 29 percent of patients over age 16 admitted for substance abuse treatment were employed, 31 percent were unemployed, and 40 percent were listed as not in the labor force.

When viewed as a primary substance of abuse, alcohol accounted for 42 percent of treatment admissions, but 44 percent of those alcohol-abuse patients reported abusing another drug as well.

Overall, men accounted for 70 percent of substance abuse admissions. About 59 percent of admissions were white, 24 percent black, and 13 percent Hispanic. Methamphetamine and opiate users were more evenly divided between men and women—just over half were male. In addition, 73 percent of methamphetamine users in treatment were white, and only 2.6 percent were black.

Nationally, 23.2 percent of admissions (426,720) were due to alcohol abuse alone, another 18.5 percent (341,278) to alcohol and a secondary drug, 2.8 percent (51,071) to nonheroin opiates, and 6.3 percent (116,604) to methamphetamine use.

There were, however, noticeable regional differences. For instance, in California alcohol abuse alone accounted for less than 10 percent of admissions (half the overall U.S. rate), while methamphetamines accounted for more than 30 percent (almost five times the national rate). In five other states—Arkansas, Idaho, Nevada, Oklahoma, and Utah—alcohol admissions were close to the national average, but methamphetamine admissions accounted for over 20 percent of all substance abuse admissions—three times the national rate.

About 36 percent of these admissions arrived at treatment as referrals from the criminal justice system, including more than half of all admissions for marijuana (57 percent) and methamphetamine/amphetamine (51 percent) abuse.

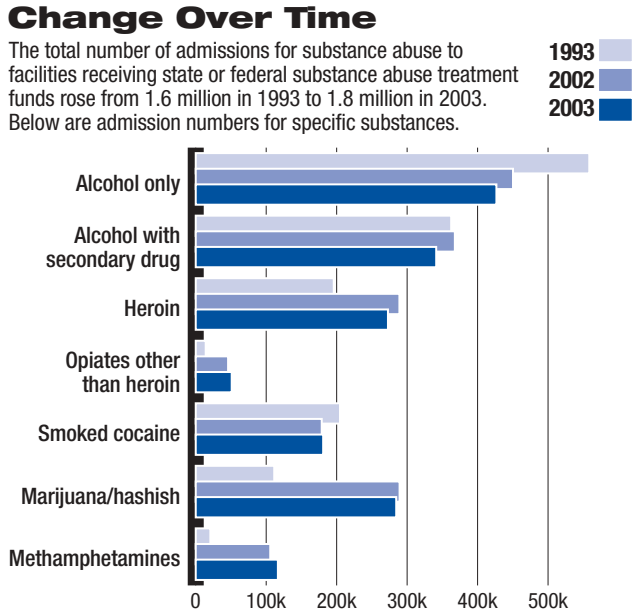
Sixty-one percent of admissions went to ambulatory care, 22 percent to detoxification, and 17 percent to residential treatment.

"We have to figure out why there has been such a slow expansion of care for these patients," said Guschwan. "There hasn't been a whole lot of change in 10 years despite increased research on using medications to treat substance abuse."

The "Treatment Episode Data Set Highlights–2003" are posted at <wwwdasis.samhsa.gov/teds03/2003_teds_highlights.pdf>. ■

Abused Substances Change Over Time

The total number of admissions for substance abuse to facilities receiving state or federal substance abuse treatment funds rose from 1.6 million in 1993 to 1.8 million in 2003. Below are admission numbers for specific substances.



Source: SAMHSA, Treatment Episode Data Set, 2005

APA*PAC* Supports New Jersey Congressman

Thomas Newmark, M.D. (right), a member of the New Jersey Psychiatric Association, presents New Jersey **Rep. Robert Andrews** (D) with a contribution from APA's political action committee, APA*PAC*. Andrews is the ranking minority member of the Subcommittee on Employer-Employee Relations of the House Education and the Workforce Committee. This subcommittee shares jurisdiction over the mental health parity issue for which APA advocates. The presentation was made locally and is part of an ongoing APA*PAC* program in which APA members educate federal legislators and policymakers about mental health issues.

Psychiatrist Reappointed Chair Of *CPT* Editorial Panel

The AMA first developed codes for medical services and collected them in a manual called *Current Procedural Terminology.* Eventually the insurance industry and federal government adopted them.

BY MARK MORAN

Psychiatrist Tracy Gordy, M.D., was reappointed by the AMA to a second term as chair of its *Current Procedural Terminology (CPT)* Editorial Panel.

The panel is responsible for maintaining and updating the manual of codes to which are attached descriptions of every kind of procedure that a physician may perform. The purpose of *CPT* is to provide a uniform language that accurately describes medical, surgical, and diagnostic services and thereby serves as an effective means for reliable nationwide communication among physicians, other health care providers, patients, and third-party payers, according to the AMA.

The codes are used for reimbursement by the insurance industry, but also for statistical and research purposes: health services researchers, for instance, may seek information on how many codes for a particular service have been submitted in a defined period of time.

As chair and the only psychiatrist on the panel, Gordy occupies a strategic position. "All of medicine looks to the panel if they have a new procedure," Gordy told *Psychiatric News.* "It is the body that is going to grant them a code that they will use to indicate a specific service or procedure has been performed."

Professional societies such as APA, individual physicians, and manufacturers of devices may submit procedures to the board for review. Gordy said that several hundred procedures are submitted every year and that anywhere from 80 to 100 "category 1" codes—codes that are specifically used for reimbursement—may be approved.

Codes for new services related to treatment of mental illness, such as vagus nerve stimulation, are in the works for approval, Gordy said.

The *CPT* was first developed by AMA as a descriptor of services in 1966. In time, the codes were adopted by the insurance industry, and in the 1980s the federal government adopted the codes for use in reimbursing services under Medicare.

The panel, which will meet three times this year, has 17 members. Of these, 11 are physicians nominated by the AMA Board of Trustees; other members of the board are nominated by the Blue Cross and Blue Shield Association, the Health Insurance Association of America, the American Hospital Association, and the Centers for Medicare and Medicaid Services.

Gordy has been on the *CPT* Editorial Panel for 15 years and has been chair for the last six. Recently retired from private practice in Austin, Texas, he continues to serve as a consultant to the Social Security Administration, testifying as a psychiatric expert for the Social Security Administration's Office of Hearings and Appeals. Along with psychiatrist Chester Schmidt, M.D., Gordy also conducts consultations to educate APA members and others about coding and documentation issues.

"I have thoroughly enjoyed my time with the panel," Gordy said. "Those of us who serve on the panel take off our specialty hats and review all kinds of things. It's like going back to medical school." ■

government news

APA Warns of Dangers In Rush to E-Prescribe

Adoption of e-prescribing by the physician community will be fraught with barriers unless CMS adopts a more cautious approach, according to APA Medical Director James H. Scully Jr., M.D.

BY MARK MORAN

Federal standards for electronic prescribing (e-prescribing) proposed by the Centers for Medicare and Medicaid Services (CMS) must be pilot tested first, APA informed CMS Administrator Mark McClellan, M.D., M.P.H., in a recent letter. Further, the deadline for compliance with the standards should be moved from January 1, 2006, to the end of 2007.

Those are just a two of the recommendations expressed in a lengthy comment letter signed by APA Medical Director James H. Scully, M.D., regarding the agency's proposed final standards for e-prescribing.

The proposed e-prescribing regulations, issued at the beginning of the year, are intended to hasten the adoption of e-prescribing by physicians. The effort is part of a global effort to move medicine toward electronic medical record keeping.

The regulations would establish standards for the following:

- Transactions between prescribers and dispensers for new prescriptions, prescription refill requests and responses, prescription change requests and responses, prescription cancellation requests and responses, and related messaging and administrative transactions.
- Eligibility and benefit inquiries and responses between drug prescribers and prescription drug plans.
- Eligibility and benefit inquiries and responses between dispensers and sponsors of the new Medicare prescription drug benefit under Part D.
- Formulary and benefit coverage information, including information on the availability of lower-cost, therapeutically appropriate alternative drugs, if certain characteristics are met.

Under the Medicare Modernization Act of 2003 (MMA), the National Committee on Vital and Health Statistics (NCVHS) was called upon to develop recommendations to CMS for uniform standards for e-prescribing. From March to September 2004, NCVHS heard testimony from 65 witnesses and industry experts including all stakeholder groups identified in the MMA, as well as e-prescribing networks, demonstration projects, software developers, and consumer advocacy organizations.

The proposed e-prescribing foundation standards are based on the NCVHS's recommendations to McClellan.

The letter from Scully outlined a series of concerns about the proposal focused on protection of patient privacy, the need to minimize the cost burden associated with acquiring technology for e-prescribing, development of regulations to protect physicians who accept in-kind technological assistance for e-prescribing, and policies to protect against manipulation of physician prescribing choices.

All of these concerns found expression in Scully's request that CMS reconsider the deadline for compliance and pilot test the standards in a subgroup of physicians before adopting them as final standards.

"APA maintains that the goals and mission of effectuating widespread adoption of e-prescribing with the physician community will be fraught with barriers, unless CMS adopts a more judicious, cautious approach," Scully wrote. "Pilot-testing of standards within their actual context of usage is imperative, along with a more realistic, workable effective date for e-prescribing compliance. . . .

"Only after evaluating the results of e-prescribing pilot projects using different systems across a spectrum of clinical settings will it be feasible to determine precisely which standards, process areas, or technologies require adjustment. It will take some time to discover how to perfect these systems, and CMS must not foreshorten this process or it will prove ultimately to be at the expense of patients."

Specifically, APA urges CMS to take these actions:

- Work with the Office of the Inspector General to draft a new "safe harbor" regulation for physicians to accept nonmonetary assistance freely to implement their e-prescribing infrastructure and to establish an effective temporary exemption from prosecution under the "Stark II" federal law. (That law regulates transactions between physicians and various other designated health services and entities).

- Establish clear policies prohibiting design bias in software and hardware for e-prescribing systems, as well as for streaming commercials and other superfluous information into e-prescribing systems.

- Adopt proposed standards as initial, rather than final, to determine their functionality and interoperability and pilot test all initial standards, preferably using several technology systems for comparative data.

- Move the effective date for e-prescribing rules to the end of 2007 to ease the burden of the transition into Medicare Part D of those beneficiaries who are "dually eligible" for Medicare and Medicaid. This will provide more time to issue national prescriber identifier numbers for physicians to obtain and implement grants and to finalize new laws protecting physicians from prosecution for accepting assistance with e-prescribing systems.

The CMS standards are posted online at <www.cms.hhs.gov/medicarereform/E-Prescribing.pdf>. The text of APA's comments to CMS is posted at <www.psych.org/members/advocacy_policy/reg_comments/APACommentsERxg.pdf>. ■

Positive Results Lead to Renewal Of Outpatient Commitment Law

Improved outcomes for people who have serious mental illness and a history of treatment noncompliance lead to a five-year extension of New York's Kendra's Law.

BY EVE BENDER

A law mandating outpatient psychiatric treatment for people with serious mental illness in New York has been renewed with the hope that it will continue to reduce hospitalizations, arrests, and homelessness.

On June 30, the date that the five-year-old Kendra's Law was set to expire, New York Gov. George Pataki (R) signed legislation to extend the program for another five years.

The law is named for Kendra Webdale, a 32-year-old woman who in January 1999 was pushed into the path of an oncoming subway train by a man with untreated schizophrenia.

Seven months after her death, Pataki signed Kendra's Law. As of March, there were 3,908 people who had received court-ordered outpatient treatment, or assisted outpatient treatment (AOT), under Kendra's Law.

The legislation is meant to benefit seriously mentally ill people who, due to a history of noncompliance with treatment, cycle in and out of hospitals, jails, prisons, and homeless shelters.

To be eligible for AOT, the person's noncompliance must have resulted in either two psychiatric hospitalizations or treatment in a correctional facility in the prior three years or at least one threat or act of violence toward self or others in the prior four years.

The new law expands the list of those who can petition the courts to ask that a person be evaluated for AOT eligibility to include psychologists and social workers. The initial list included psychiatrists, parents, spouses, adult siblings, adult roommates, directors of hospitals in which the individuals are hospitalized, the mental health director or social services official for the county where the person lives, and parole or probation officers.

After the petition has been filed, a county-designated physician conducts a clinical assessment of the person to determine whether it is appropriate to pursue a court order for AOT.

Those who are deemed eligible for services under Kendra's Law are court-ordered to receive AOT in the community for up to six months. The treatment is usually coordinated through an AOT intensive case manager and, in some cases, an assertive community treatment team.

County mental health directors operate, direct, and supervise AOT programs. In New York City, the Department of Health and Mental Hygiene oversees implementation of AOT, which is administered by teams of employees of the New York City Health and Hospitals Corporation.

The New York State Office of Mental Health (OMH) is responsible for statewide implementation and monitoring of the AOT program.

The updated legislation includes a number of changes designed to improve the coordination and delivery of assisted outpatient treatment (AOT) for eligible recipients.

For instance, to facilitate AOT in rural areas with few psychiatrists, the law authorizes OMH "to make available to counties with a population of less than 75,000 a physician employed by OMH for the purpose of making the affirmation or affidavit required when filing petitions."

The updated legislation also expands eligibility criteria somewhat by excluding the time a person spends in a psychiatric hospital or correctional facility from the period prior to the petition process.

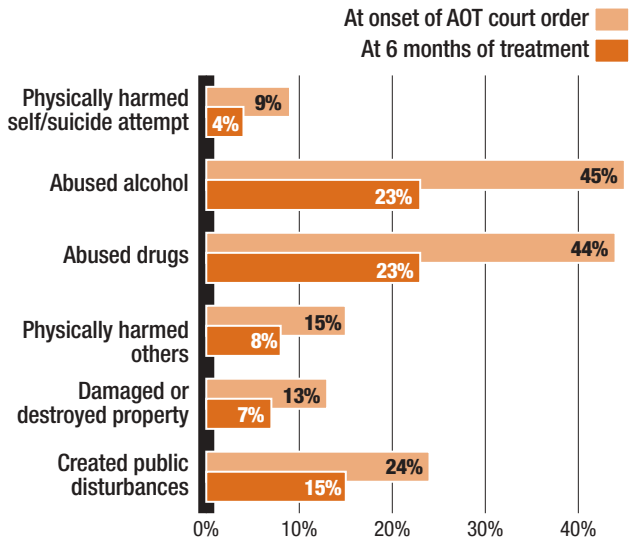
OMH has been evaluating outcomes for those in AOT from the start of the program to March, and the data were released in a report that OMH issued that same month.

The majority of the 2,745 recipients for whom data were available remained in treatment longer than the initial six-month court-ordered period. The average length of time in AOT was 16 months, according to the report.

please see ***Kendra's Law*** *on page 13*

Harmful Behaviors Decline Under Kendra's Law

Researchers at the New York Office of Mental Health analyzed data it collected on approximately 2,700 people who had received assisted outpatient treatment (AOT) under Kendra's Law since 1999. They found a significant decline in the percentage of people who reported harmful behaviors after receiving six months of AOT.



Source: New York State Office of Mental Health, March 2005

Readers Give *Psychiatric News* Favorable Report Card

BY JAMES P. KRAJESKI, M.D.

Are you being served? That was what the editors of *Psychiatric News (PN)* wanted to find out last fall as we surveyed APA members in our latest readership survey, the third we have conducted in the last six years.

Our readers told us that *PN* is in fact doing well, with 75 percent of respondents rating the newspaper as excellent or good in meeting their professional needs, and 81 percent rating the quality of articles as excellent or good. In addition, 75 percent of respondents were very satisfied or satisfied with *PN's* content.

David Hathcox

James Krajeski, M.D., editor in chief of *Psychiatric News,* presents the results of its 2004 readership survey to APA's Trustees at their July meeting.

Readers also indicated that they are pleased with the paper's design, with 70 percent of respondents agreeing or strongly agreeing that the overall design and layout make the newspaper easy to read.

Compared with our competitors, *PN* was deemed to be of more value to readers and was the preferred publication for information on mental health/psychiatric issues. It was also rated the best psychiatry-related newspaper for employment opportunities.

The survey obtained a 50 percent response rate from a random sample of 1,000 APA members. The demographic information obtained from the respondents closely parallels the demographics of APA members in general, so we are reasonably certain that the conclusions are representative of the broader membership.

The survey was also sent to all members of the Board of Trustees and Assembly. Because the random sample was expected to capture few Canadian members, a separate e-mail survey was sent to all Canadian members for whom APA had e-mail addresses. The results for those groups were tabulated separately from those of the random sample of members. The data in this article refer to the responses from the randomly sampled members. The confidence level of the results is +/- 4.4 percent.

Readers were also asked to rank their interest in the newspaper's regular features. They rated Viewpoints, From the President, Letters to the Editor, and the Medical Director's Desk (the medical director's column) highest. Reports of Board and Assembly actions and the Residents' Forum were ranked relatively low (see chart on page 22).

The feedback on topics of interest to readers paralleled closely the results of prior surveys. Readers were most interested in clinical news and information, psychopharmacology, psychotherapy, and research news. They were least interested in reading news about APA members and district branch activities. However, for even the lowest-ranked items a sizable portion of readers (about one-fourth to one-third) still indicated that these topics were of substantial interest to them (see chart on page 22).

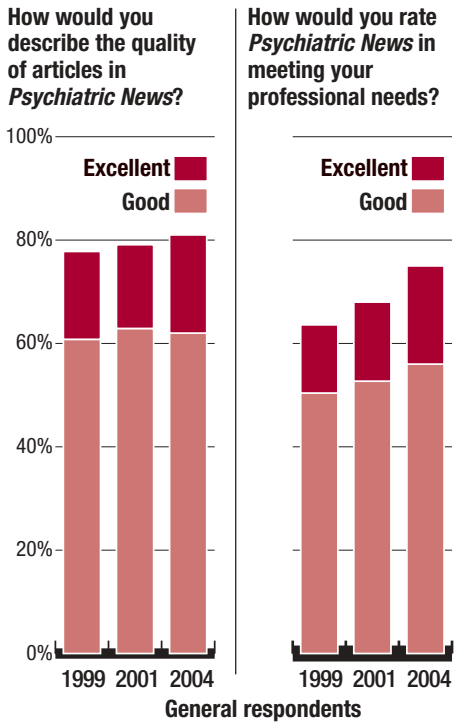
The survey also provided an opportunity for readers to comment on how *PN* could be improved, and numerous respondents took advantage of that forum.

As one might expect, there were some contradictory opinions—for example, some wanted articles to provide more details, though most readers who commented on article length preferred shorter articles. One of the most common requests was to reduce the number of articles that "jump" from one page to another. There were several requests to add an opportunity to obtain CME credit. A few respondents suggested in one way or another that *PN* was too much of a house organ. Some respondents felt there was too little focus on Canadian issues.

Readers may wonder how we use the results of these surveys. We have responded to past surveys by increasing considerably the amount of coverage of clinically related topics. We will continue to focus heavily on this area as the recent survey shows that reader interest in such topics remains strong.

The results also indicate that there is a diverse range of areas in which APA members are interested, so we will continue to provide coverage that fits the wide-rang-

please see ***Report Card*** *on page 22*



Source: *Psychiatric News* Readership Survey Report, 2005
Lewis & Clark Research

James P. Krajeski, M.D., is editor in chief of *Psychiatric News.*

Trustees Back Recognition Of Same-Sex Civil Marriage

Among issues on a wide-ranging Board agenda are a position statement on same-sex civil marriage, a report from APA's auditors, and the design for a new APA logo.

BY KEN HAUSMAN

The APA Board of Trustees took a historic step at its July meeting when it made APA the first medical specialty society to support legal recognition of same-sex civil marriage.

Such a position statement had been endorsed by the Assembly at its May meeting in Atlanta (*Psychiatric News*, June 17). It expands APA's existing position in support of same-sex civil unions and emphasizes the mental health consequences of denying same-sex couples the same legal rights as their heterosexual counterparts. The legal rights to which these couples do not have access can include visiting an ill partner in the hospital, making health care decisions for a disabled partner, financial and retirement planning to prepare for emergencies or a financially secure future, and, in the case of parents, being able to raise a child when the biological parent is unable.

The statement, which applies to civil and not religious marriage, notes that same-sex couples "experience several kinds of state-sanctioned discrimination that can adversely affect the stability of their relationships and their mental health." It also points out that "there is ample evidence that long-term spousal and family support enhances physical and mental health at all stages of development."

The position statement passed with 14 "yes" votes, one "no" vote, and two abstentions.

Area 6 Trustee Tom Ciesla, M.D., who supported the proposal, insisted that the issue is not discrimination, but tolerance. Despite the opposition that some members may register to the position statement, "supporting it is simply the right thing to do," he said.

David Hathcox

Area 3 Trustee Roger Peele, M.D., talks with new Board member Mary Helen Davis, M.D., who represents Area 5, at last month's Board of Trustees meeting in Baltimore.

Former APA President Paul Fink, M.D., stressed that the "social" component of the biopsychosocial approach to mental health to which APA is committed cannot be arbitrarily dismissed.

In explaining his opposition to the proposal, Member-in-Training Trustee Daniel Mamah, M.D., said that this is "a social issue that's weakly linked to mental health" in the research literature and is thus outside of psychiatrists' expertise. He noted that he was a supporter of the right of gay couples to marry.

Former APA President Paul Appelbaum, M.D., also maintained that APA should not take positions on such "divisive social issues," particularly when its agenda includes pressing matters more directly related to mental health care. He abstained from voting, however, explaining that he did not want a "no" vote to be interpreted as signaling his opposition to same-sex marriage, which, in fact, he supports.

Auditors Give Favorable Report

The Trustees received a very favorable auditors' report on APA's finances for the two years ending December 31, 2004, and how the Association is managing them.

APA's balance-sheet ratio, including investments, shows that it has $1.72 in assets to cover each dollar of liability. The auditors said this ratio was stronger on average than that of other not-for-profit associations.

The chief auditor, Wayne Berson of the independent auditing firm BDO Seidman, said that overall it gave APA an "excellent report," finding that, compared with similar associations, APA has "an extremely strong balance sheet" and that a very high percentage of its budget goes to program activities.

Other Board Actions

The Board of Trustees also deliberated on several other issues. It voted to

- **appoint a work group to review a proposal from the Assembly to give that body the right to override Board votes that ignore or overrule actions approved by the Assembly.** This proposal would require an APA Bylaws change and apply only to issues without a fiduciary impact on APA. Seventy-five percent of Assembly members would have to vote in favor for an override of a Board action to be implemented. This work group, part of whose charge is to review the proposal's legal implications, will report back to the Board in October.
- **defeat a proposal to put APA on record in support of ending Medicaid's Institution for Mental Disease (IMD) exclusion.** The rule bars federal Medicaid payments for adult inpatient psychiatric care in institutions with more than 16 beds if those facilities are primarily for psychiatric treatment, which thus exempts general hospital psychiatric units from the exclusion. There is concern that ending the exclusion would impose severe financial hardship on general hospital psychiatric units while it benefits large, specialized hospitals, which have lower costs than general hospital units. Others opposed to removing the exclusion noted that the effects are likely to vary by geographic region, and thus it might be more appropriate for some district branches rather than APA to take a position. Proponents of terminating the exclusion, however, viewed it as one more form of discrimination against people who need treatment for mental illness.
- **obtain feedback from Assembly members and APA members in general about adopting a new logo for APA.** This was in response to a proposal to make the logo used in APA's Healthy Minds, Healthy Lives campaign the APA logo (see below). The logo is a stylized staff of Aesculepius, and the blue figure is a stylized letter "P" for psychiatry.

AMERICAN PSYCHIATRIC ASSOCIATION

- **increase registration fees in all categories by 10 percent for the 2006 APA annual meeting in Toronto** to compensate for the meeting's several years of steadily

please see ***Board*** *on page 10*

APA Board Finds TSPP Noncompliant

At its July meeting, the APA Board of Trustees determined that APA's Texas district branch, the Texas Society of Psychiatric Physicians (TSPP), has violated the APA policy of requiring membership in both a district branch and the national organization by supporting and promoting an organization that is in direct competition with both TSPP and APA and is therefore out of compliance with APA policies. The determination came after extensive negotiation between APA and TSPP.

At the October 2004 Board meeting, at the invitation of then-APA President Michelle Riba, M.D., M.S., current and former TSPP officers explained the details of and answered questions about the controversial establishment of two new psychiatric organizations in the state: the Federation of Texas Psychiatry and the Texas Academy of Psychiatry *(Psychiatric News,* November 19, 2004).

TSPP officers stated that the federation is an umbrella body whose members are psychiatric and mental health organizations and other medical organizations in the state. The academy—one of the federation's members—is an organization for psychiatrists who do not belong to TSPP, which as a district branch requires dual membership in the branch and in the national APA.

APA officials said at the time that TSPP's relationships with and support of competing organizations appeared to violate APA's longstanding dual-membership requirement. By its most recent action, the Board has determined that TSPP is, in fact, out of compliance with established APA policy.

In a letter sent to APA members in Texas after the Board meeting, APA President Steven S. Sharfstein, M.D., and President-elect Pedro Ruiz, M.D., assured them that the status of their APA membership and benefits will remain unchanged. "Despite serious differences between APA and TSPP leadership which could result in changing the relationship between the organizations," they wrote, "we want to assure you that APA . . . will continue to provide the benefits and services that support your professional development and patient care."

They pointed out that in addition to the many benefits that individual members receive—access to free and discounted CME programs and the Managed Care Help Line, as well as such periodicals as the *American Journal of Psychiatry* and *Psychiatric News*—APA provides much support to district branches and state associations. For example, APA provides grants to DBs/SAs for advocacy work, which have totaled almost $1.4 million since 2000, including $110,000 for TSPP.

"APA is committed to preserving both its strong partnership with its district branches and the dual-membership requirement," Sharfstein and Ruiz stated in their letter. "We remain hopeful that TSPP's leadership will change its position and modify its current relationships to conform to established APA policies."

District Branch Presidents Report to Board

David Hathcox

Two district branch presidents, **Victoria Dreisbach, D.O.,** of the Connecticut Psychiatric Society and **Nestor Galarza, M.D.,** of the Puerto Rico Psychiatric Society described several key initiatives for APA Trustees at last month's Board meeting.

Dreisbach described a successful effort to make sure a psychologist-prescribing bill never made it out of committee in the Connecticut legislature. She noted that alliances with other physician groups played a large role in the bill's demise. She noted that the district branch is building a "proactive network" to be ready to go into battle when the bill resurfaces in a future session.

Galarza noted that the district branch has joined with the Puerto Rico Bar Association to fight the death penalty, has upgraded its presence in the media and improved its Web site, and is gearing up to respond to an anticipated bill to allow psychologists to prescribe. He also noted that due to several financial factors unique to Puerto Rico and sharply declining membership, the district branch will be sending APA a request to lower its dues for Puerto Rican psychiatrists.

New Fellows Selected for APA's Minority Fellowships

APA has announced the names of the 29 minority psychiatry residents selected to participate in the APA Minority Fellowships Program as either an APA/SAMHSA fellow or an APA/AstraZeneca fellow.

2004-2005 APA/SAMHSA Minority Fellows

Tyson Boudreaux, M.D., New York University School of Medicine
Adrian Buckner, M.D., East Tennessee State University
Delane Casiano, M.D., University of Pennsylvania Health System
Lois Choi-Kain, M.D., Massachusetts General Hospital/McLean
Susanna Dhaliwal, M.D., Thomas Jefferson University
Navdeep Dhaliwal, M.D., University of Louisville
Kelvin Exum, M.D., Howard University
Ayodele Green, M.D., Columbia University, Harlem Hospital Center
Dauda Griffin, M.D., Harvard Medical School
Nisba Husain, M.D., St. Vincent Hospital, New York City
Fatima Imara, M.D., University of California, San Francisco
Karen Liaw, M.D., Massachusetts General Hospital/McLean
Brian Rothbert, M.D., University of Colorado Health Sciences Center
Tina Tonnu, M.D., University of California at Davis
M. Renee Valdez, M.D., Ph.D., University of California, San Francisco

SAMHSA Substance Abuse Fellows

Daniel Dickerson, D.O., Yale University
William Huang, M.D., Cedars Sinai Medical Center
Moddy Kiluvia, M.D., Yale University
Varinder Rathore, M.D., Albert Einstein College of Medicine

2005-2007 APA/AstraZeneca Fellows

Mary Ann Barnovitz, M.D., University of California at Davis
Kimberly Bush, M.D., Medical University of South Carolina
Takesha Cooper, M.D., San Mateo County Mental Health Services
Leah Fennell, M.D., University of South Florida
Alphonso Nichols III, M.D., University of Louisville
Johanna Paulino-Woolridge, M.D., Howard University
Jennifer Pender, M.D., University of South Carolina
Rene Valles, M.D., University of Utah
Sudeepta Varma, M.D., New York University School of Medicine
Monisha Vasa, M.D., Cedars Sinai Medical Center

Two APA/SAMHSA fellows were elected chair and vice chair by their peers to represent the fellowship on the APA Board of Trustees and the Joint Reference Committee. The chair is Sherri Simpson, M.D., who is training at Baylor College of Medicine, and the vice chair is Yanni Rho, M.D., who is training at Harvard University. ■

Board

continued from page 9

rising cost increases and to reduce dependence on industry financial support. Registration fees for most member categories have not been increased in three years. The increase means, for example, that most APA members will pay $220 to register for the 2006 annual meeting, compared with $200 for the 2005 annual meeting.

• **endorsed an APA position statement urging use of the concept of recovery** in the care of adults with serious and persistent mental illness being treated in "community-based and other public-sector mental health systems." It explains that the recovery concept promotes a "resumption of normal development" and stresses "a person's capacity to have hope and lead a meaningful life and suggests that treatment can be guided by attention to life goals and ambitions. . . . It focuses on wellness and resilience and encourages patients to participate actively in their care, particularly by enabling them to help define the goals of psychopharmacologic and psychosocial treatments."

In executive session, the Board voted to take action on the controversy concerning the Texas district branch and the establishment of two new psychiatric organizations in Texas (see box on page 9).

Also in executive session, Trustees approved grant requests for activities related to scope-of-practice issues from the Alaska, Wyoming, and Illinois district branches.

The Board was also informed that prior to last month's meeting the Executive Committee agreed to sign on to amicus curiae briefs in three cases.

One case, *Airwohi v. Hawaii*, involves that state's use of its manslaughter statute to prosecute a woman who used methamphetamine while she was pregnant. The state charges that her son died two days after he was born as a direct result of her drug use. The case is before the Hawaii Supreme Court, and APA signed onto a brief written by National Advocates for Pregnant Women. APA issued a position statement in March 2001 opposing prosecution of pregnant or newly delivered women on child abuse charges based solely on use of drugs during their pregnancy, pointing out that many women will shun treatment out of fear that they are risking arrest. The position statement is posted at <www.psych.org/edu/other_res/lib_archives/archives/200101.pdf>.

In *Goodman v. Georgia* and *United States v. Georgia* the key issue is whether prisons are required to comply with the Americans With Disabilities Act. The two cases argue a similar issue, and APA is concerned that disabled prisoners, including those with mental illnesses, are not being accommodated as the law mandates for public services.

Trustees also heard *Psychiatric News* Editor in Chief James Krajeski, M.D., report on the results of a readership survey (see page 8).

A draft summary of all the Board actions taken at its July meeting will be posted soon in the Members' Corner area of APA's Web site, <www.psych.org>. ■

Suicide-Prevention Program Linked to Reduced Attempts

A New Mexico Indian tribe with a high suicide rate launched a suicide prevention program 15 years ago. The program appears to have led to a decline in suicide attempts, but not in suicides.

BY JOAN AREHART-TREICHEL

In 1988 an Indian tribe located in the back country of New Mexico experienced annual rates of suicide and of suicide attempts that were 15 times higher than for the rest of the United States. The rates were five times higher than for other New Mexico Indian tribes, and suicidal activity was increasing among the tribe's youth.

So in 1990, the tribal council, with the aid of the U.S. Indian Health Service, launched a suicide prevention program directed toward its adolescents. Five years later, 20- to-24-year-olds were targeted as well.

The goals of the program included identifying suicide risk factors specific to the tribe, focusing on specific individuals or families at high suicide risk, providing such individuals and families with mental health services, and confronting suicide-related issues such as alcoholism, domestic violence, unemployment, and so forth. By 2002, the program had a staff of 57. Today, its annual budget is about $1 million.

Researchers have conducted a study to determine whether the program has reduced suicidal behaviors among members of this tribe, which, to protect the tribe's privacy, they refer to as the Western Athabaskan Tribal Nation. It appears that it has, the investigators reported in the July *American Journal of Public Health*.

The lead researcher was Philip May, Ph.D., a professor of family and community medicine at the University of New Mexico.

May and his colleagues gathered data documenting the tribe's annual number of suicide attempts and completed suicides two years before the suicide prevention program began—that is, in 1988—as well as after it started, with the last follow-up conducted in 2002. The group then analyzed the data to determine whether there were any changes in the number of suicide attempts or suicides during these years.

There were 20 suicide attempts a year on average before the program got underway in 1990, the researchers found. This average dropped to nine by the program's second year and then to four by 2002.

Moreover, the group aged 19 to 24 experienced the greatest decline in suicide attempts. The annual frequency of 11 attempts before the program got under way remained unchanged during the first two years after the program was launched, but subsequently declined to three in 2000 and one in 2002.

Youth aged 11 to 18 experienced a significant drop in suicide attempts as well. The annual frequency of attempts before the program began was 15. It decreased to two by the second year of the program, rose briefly to five in 1996, but returned to two during the period 2000 to 2002.

In contrast to the suicide-attempt findings, the annual frequency of completed suicides did not fall during the years of the study. The number of suicides for the tribe was one or two a year before the suicide prevention program was launched, and it remained the same even by the 2002 follow-up.

The suicide prevention program can probably be credited with the decline in suicide attempts that occurred during the period of the study, May and his colleagues concluded, especially since the dip occurred among tribal members under age 25—the age group primarily targeted by the program.

Concomitantly, it may be that the program was unsuccessful in reducing suicides per se during the years of the study, May and his team acknowledged. Because most suicides among New Mexico Indians have historically occurred among tribal members younger than age 35 years, have frequently involved alcohol, have been instigated by firearms or hanging, and have been characterized as impulsive, they said, "one would expect suicide completions to be more resistant to programmatic intervention and prevention than gestures and attempts."

Nonetheless, they pointed out, it could be that the suicide prevention program is halting suicides to some degree since "no increase in suicide completions occurred on the reservation during the period of the program" and since "there is some evidence that suicide completions may have decreased for the target population, although the numbers are too small for statistical inference."

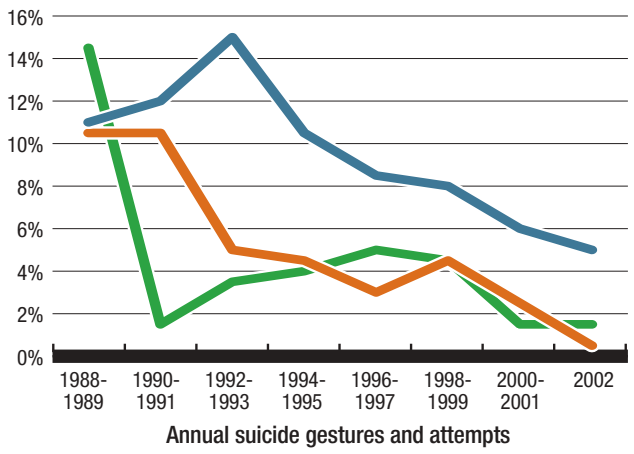
May told *Psychiatric News* that other tribal communities and Indian Health Service officials have contacted him and his coauthors for more details about the program so that they can try to replicate it.

The study was funded by the U.S. Indian Health Service, Centers for Disease Control and Prevention, and the Indian tribe that implemented the suicide prevention program.

An abstract of "Outcome Evaluation of a Public Health Approach to Suicide Prevention in an American Indian Tribal Nation" is posted at <www.ajph.org/cgi/content/abstract/95/7/1238>. ■

Prevention Effort Cut Attempts

An Indian tribe in New Mexico has experienced a sharp decline in suicide attempts since a suicide-prevention program was initiated in 1990.



Source: May et al., *American Journal of Public Health,* July 2005

Patients Benefit From CMHC, Medical School Partnership

Yale University and Connecticut's Department of Mental Health joined forces 39 years ago to establish a community mental health center that has brought multiple benefits to patients, students, researchers, psychiatrists, and mental health professionals.

BY KATE MULLIGAN

Each night outreach workers from the Connecticut Mental Health Center (CMHC) and collaborating agencies work at New Haven's Town Green encouraging homeless people to accept help for their mental illness and substance abuse problems.

By day, at the center itself, Yale Department of Psychiatry faculty members and other researchers conduct clinical and basic neurobiological research in a very different kind of effort to mitigate the damage of those disorders.

The range and variety of expertise that the CMHC brings to the alleviation of mental illness result in large part from its administrative structure.

The CMHC is a state-owned community mental health center that operates under a memorandum of agreement between Connecticut's Department of Mental Health and Addiction Services (DMHAS) and Yale University. That arrangement, which began 39 years ago, poses obvious challenges and offers great opportunities.

Like other mental health centers, the CMHC serves an economically disadvantaged population who suffer from serious mental illness, often with a co-occurring substance abuse disorder.

"We take that responsibility seriously," said CMHC Director Selby Jacobs, M.D. "This is not an ivory tower. We serve exactly the same kind of people you find at other community mental health centers."

With a budget of more than $1 million, the CMHC operates its Outreach and Engagement Project, bringing treatment and rehabilitative services to people who traditionally are among the most reluctant to accept them (see article below).

Staff provide services at three satellite clinics, one of which offers bilingual and bicultural services to Spanish-speaking people, in addition to outpatient and hospital treatment at its main facility.

Photo courtesy of Connecticut Mental Health Center

Members of the Community Services Network are turning two historic buildings into the Park Street Inn, to be used to transition patients in a state psychiatric hospital back into community life.

Outreach to the community is enhanced by virtue of the CMHC's role as the lead agency for the Community Services Network (CSN). Sixteen community-based organizations work as a consortium to address the needs of people with serious mental illness and co-occurring substance use disorders.

Tom Styron, Ph.D., CSN's executive director, said CSN provides a "remarkably diverse, innovative, and comprehensive set of services." They include vocational and social rehabilitation programs, crisis and respite services, and opportunities for various kinds of supported housing.

He pointed to the Park Street Inn as an example of collaboration. Funded by DMHAS, the facility will provide transitional housing to persons who might otherwise need to remain in a state psychiatric hospital. Coordinated medical and rehabilitative services will be offered by four of the CSN member agencies in an effort to prepare residents for permanent homes in the community.

Jacobs is a professor of psychiatry and Styron is an associate professor in the Department of Psychiatry at the Yale University School of Medicine. Those affiliations are key to some of the CMHC's strengths.

DMHAS Commissioner Thomas Kirk, Ph.D., described the advantages of Yale University's involvement with the CMHC.

"It's a win-win situation," he said. "Patients benefit from the improved quality of care that comes from the application of new research, and faculty members gain the experience of treating people with challenging forms of mental illness in a well-run facility."

He pointed out that the university affiliation also enhances the state's capability to benefit from federal research and development grants.

Jacobs said, "DMHAS provides about $3 million in research money to the CMHC each year. Faculty members leverage that figure about six times because of their ability to obtain competitive research grants."

He believes that success in translating research into practice is a defining characteristic of an academic mental health center. The Institute of Medicine has estimated the time for such translation typically to be 15 or more years.

Staff have begun a multiphase effort to build on their successful experience conducting large-scale research projects to bring the results of that research more quickly to patients.

They reviewed lists of ongoing research projects and interviewed research program directors to identify projects that lend themselves to translation. One of the three projects identified will incorporate the results of neurocognitive research that enhances brain functioning into an existing program that provides psychosocial supports for people with disabilities who are preparing for employment.

Greater use of evidence-based medicine and of best practices will also support the goal of improving the translation of research.

Jacobs also mentioned a collaborative effort between DMHAS and the Yale Program for Recovery and Community Health (PRCH).

With support from a five-year, $2.3 million grant from the National Institutes of Health to the DMHAS, PRCH researchers will examine the effectiveness of various interventions, such as peer-support services and collaborative treatment planning, that are part of "person-centered care." (Collaborative efforts between DMHAS and

please see ***CMHC*** *on facing page*

Project Finds Successful Strategy To Reach Difficult Population

By developing methods to engage a hard-to-reach population, Connecticut Mental Health Center staff win the support of city and state officials for efforts to resolve problems associated with homelessness.

BY KATE MULLIGAN

Staff of the Outreach and Engagement Project (O&E) at the Connecticut Mental Health Center (CMHC) in New Haven can claim a number of successes.

Not the least of these victories is that both city and state officials agreed to fund the program after a six-year federal grant ended in 1999.

The Substance Abuse and Mental Health Services Administration funded the project, then called ACCESS, in 1993 as part of a multicity demonstration effort to determine the effects of service integration on care for homeless people with mental illness.

Frequently, the end of federal funding for a demonstration program results in the end of services and a staff left with no resources to implement the lessons learned. The O&E Project is one of only three of the original 18 ACCESS demonstration projects still in operation.

The project, in fact, has expanded because of support from the Connecticut Department of Mental Health and Addiction Services (DMHAS) and the city of New Haven and now has a budget of over $1 million.

Project Director Deborah Fisk, who was one of the first three outreach workers, described an evolutionary process in which staff tried different approaches to persuade homeless people to seek treatment for mental illness and to access supportive services.

They faced issues that had received little attention in the literature about outreach to this population.

"We had problems related to professional boundaries and ethics," she said. "We would approach a client in a soup kitchen, not realizing that we were 'outing' him as a user of our services to the other people there."

Staff were giving their own money to clients because of the level of need.

Today more than half of the O&E staff are recovering from mental illnesses, including addiction disorders. Many of these staff members, who are called peer specialists or workers, have also been homeless.

Fisk initially was skeptical about adding a peer specialist to the team, but did so because it was a condition of the grant. She recognized the power of the concept when she heard a homeless woman tell the peer specialist, "I want to be like you. What do I have to do to get a job like yours?"

Integrating peer specialists into the team and other aspects of the program brought new challenges.

"Workplace discrimination is pervasive against people with mental illness," Fisk said. It can even occur at a setting such as a community mental health center.

Peer specialists told about instances of overt discrimination, such as being the only team member expected to make coffee and of being excluded from routine social events such as lunch gatherings.

They also talked about more subtle problems. "I feel cut off from both groups," one specialist told Fisk. "I'm alone in the middle."

A peer specialist might find herself in a professional role at a meeting with her therapist or former therapist.

Fisk advocates open discussion and exploration about these issues and recognizes the need for training staff about them.

She and other staff members began to publish articles about various issues concerning the employment of peer specialists and providing outreach in journals such as *Psychiatric Rehabilitation Journal*.

Staff also established closer relationships with city officials and agencies providing relevant services. Two new programs resulted from the collaboration.

New Haven funds a project that provides subsidies for homeless men and women to enter housing that is "substance free."

A second program, jointly funded by the DMHAS and New Haven, provides a range of services, including outreach, case management, and vocational services, through a multidisciplinary team to people with substance abuse disorders.

Fisk herself has gone through an evolutionary process in terms of her career in mental health services.

She began as a night attendant doing custodial work and bed checks at a public psychiatric hospital and joined the CMHC 18 years ago as a psychiatric aid in the inpatient unit.

Fisk took particular satisfaction in helping people cope with the trauma of acute illness and hospitalization and watching them gain hope. She has since earned an M.S.W. and is working toward a Ph.D. ■

community news

CMHC

continued from facing page

PRCH to implement a recovery model throughout Connecticut will be described in a later issue.)

Commissioner Kirk cited the CMHC's work in forensic psychiatry as another important contribution. Staff from the Law and Psychiatry Program consult with courts and community groups, conduct research, and train psychiatry residents.

The CMHC's overall budget is approximately $50 million a year for research, services, and costs attributed to teaching, but the figure fluctuates with the availability of research funds.

Medicaid funds constitute approximately 2 percent of the budget for clinical services, considerably less than the percentage at most community mental health centers.

One result is greater flexibility in terms of services offered and eligibility for those services. The CMHC also has limited protection from the kinds of funding cuts that are occurring throughout the country.

Jacobs said, however, that DMHAS funding has been "flat" for several years, which results in a decrease in resources because of the effect of inflation.

"We are not claiming to do more with less," he said. "We are going to maintain quality and balance in the kinds of clinical services we offer."

Nonetheless, Jacobs is identifying cost-effective ways of providing good care. A clinic that will offer early intervention at the time of the first episode of psychosis is one such method. The result, he expects, will be better quality of life for the patients and lower costs for the mental health system because of diminished need for repeated hospitalizations and other kinds of expensive long-term treatment.

He also continues to find ways to sell the value of the CMHC to state officials and other audiences.

"We are training the future generation of medical directors, doctors, and psychiatric nurses who will be responsible for the health care of Connecticut residents," Jacobs said.

He can show that the CMHC secured federal grants that nearly doubled the amount of money that the DMHAS targeted to the provision of supported-housing opportunities for people with serious mental illness.

New Haven city officials and DMHAS offered financial support for the CMHC's outreach program because of its success in addressing problems of homelessness and substance abuse (see article on facing page).

Jacobs believes strongly in the importance of advocacy at the national level for adequate funding for public psychiatry. He is chair of APA's Committee on Public Funding for Psychiatric Services.

"During his presidency, Dr. [Paul] Appelbaum highlighted the problems associated with the systematic defunding of the mental health system," he said. "Data from SAMHSA for 1991-2001 support his view and show a shift in costs to the public sector. Medicaid has become the most important single source of funds for mental health services. Now that program is the target of a government commission established to control and cut costs. Any cuts will hurt the most needy and vulnerable of psychiatric patients. I believe that responding to Dr. [Steven] Sharfstein's recent call for increased advocacy is crucial." Sharfstein is APA's current president.

Information about the Connecticut Mental Health Center is posted at <www.communityservicesnetwork.org/agencies/cmhc.html>. ■

government news

Kendra's Law

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When OMH researchers analyzed outcomes for recipients who completed AOT, they found that 23 percent had been incarcerated at least once in the three years before receiving AOT, while just 3 percent were incarcerated during their court-ordered treatment.

When researchers looked at the same three-year period preceding AOT treatment, they found that the vast majority (97 percent) had been hospitalized at least once, while just 22 percent were hospitalized while receiving AOT.

In addition, 19 percent of AOT recipients had been homeless before receiving AOT, while 5 percent were homeless during their treatment.

According to Mary Zdanowicz, J.D., director of the Arlington, Va.-based Treatment Advocacy Center, Kendra's law has "greatly improved quality of life" for its recipients in addition to reducing arrests and hospitalizations of seriously mentally ill people in New York.

She also credited AOT with improving New York's mental health system by ensuring that those who are eligible for treatment under Kendra's Law, a population she called "too often ignored and often underserved," have a safety net.

Barry Perlman, M.D., president of the New York State Psychiatric Association (NYSPA) and director of psychiatry at St. Joseph's Medical Center in Yonkers, said that the OMH data indicate that Kendra's Law is promising. While NYSPA supports a time-limited continuation of the law, he said, "we think additional research on services and financing is warranted" before a permanent renewal is legislated.

He noted that early OMH data suggested that most of the referrals to AOT from hospitals were coming from those operated under the auspices of local governments, such as municipal or county hospitals, rather than from the inpatient units of general, not-for-profit voluntary hospitals.

"This may be due to the expenses related to sending a staff psychiatrist to evaluate patients and attend court hearings to obtain AOT for patients," which detracts from hospital revenue, he noted.

"NYSPA approved the change in the law that provided assistance in counties with 75,000 or less," he said. "We hope that in the future the funding will be extended to all counties in the state regardless of population size."

He said that such funding would provide strong encouragement for greater use of AOT by the staff of inpatient units of general hospitals.

More information on Kendra's Law is posted on the Web at <www.omh.state.ny.us/omhweb/Kendra_web/KHome.htm>. The legislation is posted at <assembly.state.ny.us/leg/?bn=A08954>. "Kendra's Law: Final Report on the Status of Assisted Outpatient Treatment" is posted at <www.omh.state.ny.us/omhweb/Kendra_web/KHome.htm>. ■

connections

How to Make Social Networking On the Internet Work for You

BY JOHN LUO, M.D.

Social networking is a natural extension of the connectivity provided by the Internet. Many of our patients, for example, have made new acquaintances, found a support group for their particular problems, and even met their spouse via the Internet.

"Social networking" on the Internet refers to a category of applications to help connect friends, business partners, or other individuals using a variety of tools. These tools range from Web logs, instant messaging chat clients, and online databases. In the business context, social networking allows individuals to expand upon existing relationships to make new business contacts.

This process is based on the experiment by Stanley Milgram, a Yale University psychologist who conducted the "small world experiment" to test the theory of "six degrees of separation" proposed by Hungarian writer Frigyes Karinthy in a short story called "Chains." The theory states that anyone can be connected to any other person via a chain of acquaintances with no more than five intermediaries. Milgram tested the theory by randomly selecting people in the Midwest to send a letter to a stranger located in Massachusetts. The senders were given the target's name, occupation, and general location and were instructed to send the letter to someone they believed was most likely to be able to reach the target. The participants expected the chain to include at least a hundred intermediaries; however, it took an average of only six intermediaries.

Social networking Web sites work by assisting each member in creating a network of business associates. Each contact is encouraged to expand his or her own network by inviting other colleagues to join. There is some overlap of similar contacts in the network, but usually such overlap is minimal. The power of the system depends upon the extent of the network created by the members. Each member also creates a personal profile, which highlights information such as description of current job, areas of expertise, former employment, and educational background. The information is captured in a searchable database.

This business network can now be mined to find jobs, service professionals, and people of interest based on key words such as location, area of expertise, or company.

Once a desired contact is determined, a request for contact is then made and routed through the network. Each intermediary has the ability to approve or deny the contact request, which is done anonymously. Once the request has been approved and passed along by all of the intermediaries, the appropriate contact information is granted to the requesting member.

The advantage of the social networking system is that members have access to services and people whom they do not know personally. Potential employers can list jobs within the social networking system that often partner with job sites. One advantage for applicants is the ability to utilize their network contacts in applying for the position.

Another good use of social networking systems is finding referrals for patients who are moving to locations where they do not know any of the local providers. Many professionals use the AMA's DoctorFinder and make an educated guess on which professionals are the best match. Using the social networking system for this purpose could give patients more assurance that a referral is appropriate and less a shot in the dark.

I have been successful in contacting various technology manufacturers to donate items for the American Association for Technology in Psychiatry Fellowship. In addition, I have made several contacts to help test new PDA software products in exchange for licenses for my resident physicians. The majority of contacts whom I have made are in the context of technology, but with growing members in different fields, the possibilities are expanding.

One of the problems with social networking systems with regard to the health care industry is that medical professionals have not yet joined these sites in large enough numbers to create a rich network. Many business professionals, especially in the technology sector, have embraced this technology, but less than 1 percent of users are currently in medical practice.

One of the reasons for the low-utilization rate is that physicians do not understand how the service works and what benefits can be gained. I have had to explain to invitees to my network that this service is not "spam" but a business tool.

In addition, there are numerous professional-based social network sites such as LinkedIn, Ryze, ReferNet, Ecademy, Spoke, and Knowmentum, and it may be too time consuming to create memberships and networks in all of them. Some sites such as Doostang and Orkut are by invitation only, which limits access; however, an Orkut invitation can be purchased on eBay.

I encourage readers to e-mail me at jsluo@mednet.ucla.edu to join my network. ■

John Luo, M.D., is an assistant professor of psychiatry at the UCLA Neuropsychiatric Institute and Hospital in Los Angeles and president of the American Association for Technology in Psychiatry.

New Sleep Drug Binds To Melatonin Receptors

With a unique mechanism of action, ramelteon enters a crowded market as a new option for people who suffer from insomnia.

BY JIM ROSACK

The U.S. Food and Drug Administration late last month granted final approval to ramelteon, the first insomnia medication in 35 years to offer a unique mechanism of action that allows long-term use and is not designated as a controlled substance by the Drug Enforcement Administration.

The drug will be marketed in the United States as Rozerem (rose-AIR-em) by Takeda Pharmaceuticals North America Inc. It should be on pharmacy shelves in September, a Takeda spokesperson confirmed. While pricing is expected to be "competitive," it had not been set at press time.

Ramelteon was approved by the FDA "for the treatment of insomnia characterized by difficulty with sleep onset" in those aged 18 and older.

"Rozerem represents a breakthrough in sleep medicine because it is truly a novel medication in terms of how it works," said Louis Mini, M.D., medical director for neuroscience at Takeda Pharmaceuticals North America, a subsidiary of Takeda Pharmaceutical Company of Japan. "It approaches the treatment of insomnia in a completely different way from all other currently available prescription agents."

According to FDA approval documents, ramelteon's most significant characteristic is its "highly selective and specific receptor-binding profile." The medication has a very high affinity for two specific melatonin receptors, MT_1 and MT_2. While melatonin receptors are found throughout the body, MT_1 and MT_2 are localized in the brain's supra-chiasmatic nucleus (SCN)—a small group of neurons in the hypothalamus referred to as the brain's "master clock." Ramelteon has very low or no detectable affinity for virtually all other receptors in the central nervous system.

This highly selective binding is in stark contrast to nearly all other available insomnia medications, which target some component of the GABA-A–benzodiazepine receptor complex. Binding to the GABA-A complex results in sedation due to central nervous system depression.

However, the GABA-A complex is widespread throughout the CNS. The resulting widespread sedation from CNS depression is associated with adverse effects commonly seen with many sleep medications, including memory problems, cognitive blunting, and the general "sleeping pill hangover."

In contrast, the FDA-approved labeling for ramelteon indicates the drug has no detectable affinity for the GABA-A complex. Rather, by targeting the MT_1 and MT_2 receptors in the brain's SCN, the drug is aimed at regulating the brain's intrinsic sleep-wake cycle.

Drug Regulates Master Clock

"As the day goes on," Mini explained, "an individual's need for sleep—or 'sleep load'—increases, reaching a peak somewhere around 9 p.m. or 10 p.m., for most who are sleeping normally."

However, people do not generally fall asleep as their sleep load increases, Mini said, because the SCN balances that load with an "alerting signal" that promotes wakefulness.

"In individuals who are sleeping normally, the body begins to produce melatonin in response to the onset of darkness," Mini continued. Melatonin binds to receptors throughout the central nervous system, including the MT_1 and MT_2 receptors in the SCN. "When melatonin binds to [these two] receptors, the alerting-signal is dampened, allowing the accumulated sleep load to do its job, and the individual falls asleep."

By binding specifically and selectively to the melatonin receptors in the SCN, ramelteon is thought to achieve the same end point: a reduction of the brain's normal alerting signal and the promotion of sleep.

"While we've learned from the advances of understanding the science of melatonin, this drug itself is not melatonin," Mini emphasized. The drug's chemical structure is different from melatonin; the drug is "more selective, specific, and potent" in its binding to MT_1 and MT_2 receptors than the natural hormone. This would suggest that the new medication might benefit even those with sleep-onset insomnia who may have tried melatonin but saw no benefit.

The drug, however, is not likely to benefit patients with insomnia characterized by multiple night-time awakenings. In clinical trials, Mini told *Psychiatric News*, "total sleep time was increased, but when it came to awakening after sleep onset, we did not show statistical significance."

Drug May Be Useful for Elderly

Ramelteon was discovered by scientists at Takeda's headquarters in Japan in 1996. The development program for the drug has been "extensive," including more than 100 preclinical studies and "43 clinical studies involving more than 4,200 patients," Mini said.

Takeda studied the drug in specific populations, including the elderly, who tend to be especially prone to side effects related to CNS depression, such as memory problems and respiratory depression. Mini, who practiced geriatric psychiatry prior to joining Takeda, said clinical trials showed the drug was indeed effective in elderly patients. In addition, there were no differences in the safety profile of the drug in the trials with elderly patients compared with those in adults aged 18 to 65.

The company also studied the drug in elderly patients with chronic obstructive pulmonary disease and patients with sleep apnea. Again, researchers found no differences in either efficacy or safety. The FDA-approved labeling discusses the use of ramelteon in both of these special populations.

In phase IV postmarketing studies, the company plans to look also at the safety and efficacy of the drug in patients with cognitive impairments, including those with Alzheimer's disease. In addition, the FDA is requiring Takeda to undertake pediatric efficacy and safety trials.

Prescribing Guidelines

The recommended dosing for ramelteon is 8 mg taken 30 minutes before bedtime. The FDA chemical and medical reviews of the drug indicate that ramelteon is rapidly absorbed from the stomach and extensively broken down by first-pass metabolism in the liver. Ramelteon should not be taken with foods high in fat, which significantly decrease the drug's absorption.

Because the drug is metabolized mostly in the liver, approved labeling advises physicians to prescribe the drug with caution to those with moderate liver impairment and not at all to those with severe liver failure. Since ramelteon is principally metabolized in the liver by the CYP1A2 enzyme, it should not be used in conjunction with any known strong inhibitor of the enzyme, such as fluvoxamine (Luvox).

In clinical trials of ramelteon, the most

please see ***Sleep Drug*** *on page 21*

Vagus Nerve Stimulation Device Approved With Multiple Cautions

Choosing to side with patients whose treatment options are dwindling, the FDA has granted a controversial approval for a surgically implantable device to treat severe, treatment-resistant depression.

BY JIM ROSACK

The U.S. Food and Drug Administration has approved the vagus nerve stimulation (VNS) device as a new therapeutic option for patients who have severe depression and who have not responded to multiple courses of standard antidepressant therapies.

In a rare move, Daniel Schultz, M.D., director of the FDA's Center for Devices and Radiological Health, signed the approval letter to Houston-based Cyberonics Inc. Approval letters are usually signed by the appropriate director or deputy director of the division that has jurisdiction over the device's or drug's class.

The VNS system has been the focus of controversy almost from the point that Cyberonics submitted its original application to the FDA in October 2003. FDA staff reviewers working under Schultz originally deemed the device "nonapprovable." Reviewers were concerned about the company's data from the short-term clinical trials indicating relatively low levels of response to the VNS system and several suicide attempts, including at least one completed suicide.

Cyberonics appealed the nonapprovable decision, submitting supplemental data on longer-term efficacy and safety. The FDA's Neurological Devices Panel—an advisory group of outside experts—then voted 5-2 in June 2004 to recommend approval of the device *(Psychiatric News*, July 16, 2004).

The disagreement between the FDA's internal review and the advisory group's recommendation prompted outrage from the patient advocacy group Public Citizen and sparked a review of the FDA's handling of the application by the Senate Finance Committee *(Psychiatric News*, June 17).

In the end, the FDA approved the VNS device "for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments."

The VNS system requires surgical implantation of the stimulator—similar to a cardiac pacemaker—in the patient's left shoulder. The surgeon must tunnel an electrode from there to the neck through the subcutaneous tissues to the vagus nerve. The electrode is then wrapped around the left vagus nerve, and the opposite end is attached to the device and turned on. The device is programmable with a handheld computer that communicates with the device by radio signals.

Because of the complexity of the procedure and skills required to implant and program the VNS device, the FDA's final approval included several of the recommendations made by the Neurological Devices Panel. The panel had strongly recommended a very narrowly defined treatment population in which VNS could be used and stipulated that the device could be implanted and monitored only by physicians specifically trained and qualified to do so.

Adverse reactions associated with the surgical implantation procedure include bleeding, infection, pain at the incision site, failure of the incision to heal, possible eruption of the device through the skin, possible breakage or disconnection of the lead, and vagus nerve damage.

The most common treatment-emergent adverse effects noted in clinical trials of VNS for depression included (after nine to 12 months of therapy) voice alterations (54.1 percent), shortness of breath (16.3 percent), neck pain (12.9 percent), cough (6.2 percent), and pharyngitis (5.3 percent).

The FDA's approval was based on data from four clinical trials submitted by Cyberonics. For example, one trial was a 12-week, acute-phase feasibility study with long-term follow-up. Fifteen percent of the subjects were responders, having achieved at least a 50 percent reduction in their depression scale scores. At the one-year mark, 27 percent were responders, and at two years, 21 percent were responders.

The FDA's Schultz was not available for an interview with *Psychiatric News;* however, he told the *Wall Street Journal* that in the clinical trials he saw a "consistent, long-term response that is quite striking" for a "very, very sick, end-stage population" of patients who have "run out of standard options for the treatment of a serious condition."

FDA information on the Cyberonics VNS Therapy System, including the approval order and a summary of safety and effectiveness, is posted at <www.fda.gov/cdrh/pdf/p970003s050.html>. ■

Generic Antipsychotic Is Equivalent To Brand Product, Data Show

Generic versions of clozapine continue to be plagued by rumors of low quality or lack of bioequivalence to the brand-name product, in spite of data and FDA determinations to the contrary.

BY JIM ROSACK

When patients taking Novartis's Clozaril were switched to a generic clozapine, no statistically significant changes were seen in a wide array of outcomes measuring patient stability and resource utilization, according to a study published in the August *Community Mental Health Journal*.

Concerns about the bioequivalence of generic and brand-name clozapine have existed nearly as long as the generic versions of the second-generation antipsychotic have been available. The first generic version of Clozaril was approved by the U.S. Food and Drug Administration (FDA) on November 26, 1997. Within roughly a year, clinicians were expressing concerns that that first generic, made by Zenith-Goldline Pharmaceuticals, was not, in fact, bioequivalent to the brand-name product. There were numerous reports of patients whose symptoms became worse and even some reports of full relapse after being switched from the branded product to the generic.

The issue became so heated that Novartis and Ivax Corp. (which makes the Zenith-Goldline brand of generic products) threatened reciprocal legal action in 2000 (*Psychiatric News*, December 15, 2000). By February 2001, the FDA publicly stated that the data the agency had seen indicated there was no bioequivalence problem. The FDA also said, however, that it would continue to monitor reports of bioequivalence problems and recommended that Ivax conduct a new complete bioequivalence study. Ivax subsequently did so, and the FDA confirmed the drug's AB bioequivalence rating to Clozaril.

> "These data demonstrate that there was no increase in service utilization by patients converted to generic clozapine."

The latest study, completed by Daniel Healy, M.D., a clinical assistant professor of psychiatry at the University of Michigan, and his colleagues, looked at 108 adult patients aged 18 and above in a clozapine clinic at the Washtenaw County Community Mental Health Center (CMHC) in Michigan. These 108 patients constituted all the patients being followed in the clozapine clinic at the time.

In an attempt to reduce pharmaceutical costs, the CMHC, along with the University of Michigan Pharmacy Service, decided to switch patients from Clozaril to a specific generic equivalent, made by Mylan Pharmaceuticals. The CMHC chose Mylan, the researchers noted, because of the company's strong data on bioequivalence.

For each patient, serum clozapine levels were obtained two weeks before and after the switch from brand to generic. A one-year retrospective examination of each patient's records was completed prior to the switch.

Information about outpatient psychiatric visits, emergency room visits, inpatient hospitalizations, partial-hospital or day-program utilization, crisis-center utilization, dose of clozapine, and use of any adjunct antipsychotic medications were collected for each patient. The same information was collected for one year following the patients' switch to clozapine.

Of the 108 patients, 62 were men and 46 women, and the average age was 42.5 years. The patient sample was overwhelmingly Caucasian; only two were Hispanic, and 14 African American. The average daily dose of Clozaril taken by patients prior to the switch was 452 mg (+/- 177 mg). The average dose of clozapine after the switch was 451 mg (=/- 176 mg). No statistically significant differences were found in serum blood levels achieved with oral doses of clozapine compared with Clozaril.

In the year after the switch, 16 patients required an increase in dose, and 11 required a decrease in dose. Nine patients required the addition of an adjunct antipsychotic, and three patients who were already on a second antipsychotic had to be changed to a different antipsychotic.

Overall, there were no statistically significant differences between Novartis's Clozaril and Mylan's clozapine as measured by inpatient hospital days, crisis-center utilization, admissions for inpatient treatment, and outpatient psychiatric visits for the periods studied—that is, one year before the switch and one year after the switch. The only statistically significant finding was a decrease in psychiatric emergency room visits—69 for Clozaril compared with 32 for clozapine.

"These data demonstrate that there was no increase in service utilization by patients converted to generic clozapine. In fact, all of our measures of utilization decreased, although the decrease was significant only for ER visits," the authors concluded.

Healy and his colleagues suggested that the lack of increase in service utilization and the significant decline of ER use "may reflect gradual stabilization of these patients over time or the gradual reductions of patients using inpatient or psychiatric emergency room services in general."

The switch, they added, "was cost-effective, as the reduction in pharmacy costs was not offset by increased utilization costs."

The researchers conceded that they used "proxy measures of utilization" that "did not reflect increasing symptoms." The researchers also noted that because patients' clinical status was not assessed before and after the switch, "it is possible that patients did exhibit symptom change with the switch."

An abstract of "Clinical Equivalence of Generic Clozapine" can be accessed at <springerlink.metapress.com> by clicking on "Browse Publications," "C," "Community Mental Health Journal," and "August." ■

Do Dopamine Agonists Spark Gambling Compulsion?

If dopamine agonists can trigger pathological gambling, then they may do so by supercharging dopamine receptors in an area of the brain known to give rise to craving and pleasure.

BY JOAN AREHART-TREICHEL

Forty-one-year-old "Derrick" and 63-year-old "George" had two things in common: both had Parkinson's disease and both, within one to two months after starting to take a dopamine-agonist medication, felt a strong urge to gamble.

George had gambled at casinos about four times a year, and he had never overspent his self-allotted gambling limit. Now, he said, he felt an "incredible compulsion" to gamble two or three times a week, even when he "logically knew it was time to quit."

As for Derrick, he had never gambled before, but began gambling on the Internet and lost $5,000 within a few months.

The cases of Derrick and George were reported July 11 on the Web site of *Archives of Neurology*, along with those of nine other individuals who also had Parkinson's disease and had started to show signs of pathological gambling after taking a dopamine agonist. The report came from a group of psychiatrists and neurologists at the Mayo Clinic. The lead author was M. Leann Dodd, M.D., a psychiatrist and senior associate consultant in Mayo's Department of Psychiatry and Psychology.

Dodd and her group also conducted a MEDLINE search for any mention of Parkinson's patients engaging in pathological gambling after getting a dopamine agonist. They found 17, they stated in their report.

Twenty-eight cases hardly constitute compelling evidence that there is a connection between dopamine agonists and pathological gambling. Moreover, most Parkinson's patients who take dopamine agonists do not experience the desire to gamble excessively, Dodd told *Psychiatric News*. In fact, she said, she has never heard of any other medication having been linked with pathological gambling.

Hypotheses Offered

Nonetheless, she and her colleagues suspect that dopamine agonists triggered the pathological gambling in the cases they reported and hypothesized why this may have occurred.

For example, they were able to follow up eight of the 11 individuals they cited, and once these individuals tapered or stopped taking a dopamine agonist, their urge to engage in pathological gambling ceased as well.

Also, after taking dopamine agonists, six of the patients felt a strong desire not just to gamble but also to engage to excess in other behaviors such as eating, drinking alcohol, having sex, and making purchases. And once these patients stopped taking the drug or took less, their urges in all of these domains declined dramatically. One of these patients was George. He stopped taking his dopamine agonist abruptly. Two days later, he felt his longings to engage in such behaviors rapidly resolve. It was "like a light switch being turned off," he said.

Authorities Weigh Evidence

Two pathological gambling authorities—Suck Won Kim, M.D., a professor of psychiatry at the University of Minnesota, and Jon Grant, M.D., an associate professor of psychiatry there—told *Psychiatric News* that they have little doubt that dopamine agonists can trigger an impulse to gamble. Indeed, Grant said, "Those of us who treat pathological gamblers have also seen many movement-disordered patients who report pathological gambling onset secondary to starting dopamine agonists."

And the reason why dopamine agonists might trigger pathological gambling, Kim explained, is that they exert their pharmacological actions not only in the basal ganglia that govern Parkinson's symptoms, but in the nucleus accumbens. The nucleus accumbens is known to give rise to craving and pleasure, which in turn are mediated by dopamine. Thus, if a dopamine agonist overly excites dopamine receptors in the nucleus accumbens, it might well "trigger cravings to gamble and excitement when winning," Kim speculated.

Specific Version of Receptors May Matter

But if dopamine agonists can truly ignite the urge to gamble, then why do they awaken it in only a few patients who take them? Dodd suspects that the answer may lie in which genetic version of dopamine receptors one has inherited.

In other words, one version of the receptors might be more receptive to dopamine stimulation than another. In fact, Dodd said, she and her colleagues may be "doing a genetic study looking for possible polymorphisms in the gene that codes for the dopamine D_3 receptors that may be contributing to the way this small population of patients is responding to the dopamine agonists."

Grant believes that in addition to genetic research, functional brain imaging could help answer an even more intriguing question: Why did the patients who only gambled secondary to taking dopamine agonists not also develop problems with sex, alcohol, or eating?

"Pathological Gambling Caused by Drugs Used to Treat Parkinson Disease" can be accessed at <http://archneur.ama-assn.org> by searching on the study title. ■

Cholesterol-Alzheimer's Link Backed by New Data

Several cholesterol-related genes, not just the APOE one, have been implicated in Alzheimer's disease and may eventually be used to predict who is going to develop the illness.

BY JOAN AREHART-TREICHEL

The e4 variant of the APOE gene has been strongly linked with susceptibility to Alzheimer's disease. Indeed, one-fourth of the population is estimated to carry this variant. What fewer people are aware of, however, is that the APOE gene is also known to be the major transporter of cholesterol in the blood and central nervous system and a risk factor for coronary disease.

Now a number of other genes involved in cholesterol metabolism appear to be involved in Alzheimer's susceptibility as well, a new study suggests. However, the APOE gene still seems to be the biggest culprit.

The study was led by Andreas Papassotiropoulos, M.D., a psychiatrist and research professor at the University of Zurich in Switzerland. Results appeared in the July *Journal of Clinical Psychiatry*.

Papassotiropoulos and his colleagues enrolled more than 500 older persons from Switzerland and Greece. Half had been diagnosed with Alzheimer's disease; the other half did not have the illness. The researchers then analyzed DNA samples from these subjects to assess 12 single nucleotide polymorphisms—that is, variants in genetic material—from 11 genes related to cholesterol metabolism and previously linked to Alzheimer's disease. One of the single nucleotide polymorphisms was the APOE e4 variant.

The scientists also examined the DNA samples to see whether they contained 48 single nucleotide polymorphisms that had never been linked with either cholesterol or Alzheimer's.

Finally, they looked for links between any of the single nucleotide polymorphisms and the presence of Alzheimer's.

They found that nine of the 12 single nucleotide polymorphisms previously implicated in cholesterol metabolism and Alzheimer's were also significantly associated with Alzheimer's in their study.

In contrast, they were not able to find any association between Alzheimer's and the 48 single nucleotide polymorphisms not previously tied to cholesterol and Alzheimer's.

Moreover, they found that some of the nine single nucleotide polymorphisms were more strongly associated with Alzheimer's than the others were. The APOE e4 gene variant headed the list. Then came material from a gene called SOAT1. Then came material from the APOE promoter.

"This study is potentially important for several reasons," Eric Reiman, M.D., a professor of psychiatry at the University of Arizona and deputy editor of the *Journal of Clinical Psychiatry*, asserted in an editorial accompanying the report. For example, "It implicates a cluster of genes, including, but not limited to, the APOE e4 allele, in the susceptibility to late-onset Alzheimer's disease."

Also, he added, "It provides further support for the role of higher cholesterol levels in the pathogenesis of Alzheimer's disease and the potential role of cholesterol-lowering strategies in the treatment and prevention of this disorder."

However, as Reiman cautioned in an interview with *Psychiatric News*, the findings will not be used clinically any time soon to predict Alzheimer's for several reasons—they have not yet been replicated, "they do not predict with sufficient certainty whether or when a person might develop symptoms," and "they don't yet tell the person what he or she might be able to do to prevent the disorder."

In fact, he said, testing for the APOE e4 variant alone to predict Alzheimer's risk is not recommended for clinical use at this point because of the danger of triggering false alarms or creating false reassurances, and because no preventive measures are available.

Josepha Cheong, M.D., an associate professor of psychiatry at the University of Florida and chair of the APA Council on Aging, told *Psychiatric News* that the study impressed her for several reasons. For one, the researchers attempted to identify the interplay of a cluster of genes that may be involved in the etiology and clinical presentation of Alzheimer's disease instead of looking for the effect of a single gene at a time, which is more common. For another, she believes that the study "represents a continuation in the discovery of genes involved in the pathogenesis of Alzheimer's disease." And finally, whereas the "research results may not be acutely clinically relevant, they portend significant possibilities for diagnosis and treatment."

Meanwhile, Papassotiropoulos said, "I anticipate that several genetics groups will attempt to replicate the findings, among others Dr. Jonathan Prince from the Karolinska Institute in Sweden. There are [also] several [other] lipid-related genes to be looked at. In addition, it will be important to combine this genetic information with data on brain activation patterns by means of PET or fMRI."

The study was funded by the Swiss National Science Foundation, the Early Diagnosis of Alzheimer's Disease and Related Dementia Program in Switzerland, and the National Center for Competence in Research in Switzerland.

"A Cluster of Cholesterol-Related Genes Confers Susceptibility for Alzheimer's Disease" can be accessed online at <www.psychiatrist.com/toc.htm> by searching on the article title in the July issue. ■

World MH Day

Professional News

The theme for this year's World Mental Health Day, to be held October 10, is "Mental and Physical Health Across the Life Span." The theme reflects the growing recognition by physicians and researchers in all parts of the globe that mental and physical health are inextricably linked.

The World Federation for Mental Health, which sponsors the campaign, hopes participants will be better equipped to "change policy, practice, and service-delivery systems to ensure that mental health needs and concerns receive the level of priority necessary to reduce the burden of disease associated with serious mental disorders." The federation notes in a press release that inadequate attention to and integrated services for co-occurring physical and mental disorders are problems in affluent countries as well as undeveloped ones.

Information about World Mental Health Day, including fact sheets and educational material, is posted at <www.wmhday.net>. ■

Memory-Skills Training May Benefit Schizophrenia Patients

Asking patients with schizophrenia to remember and recognize words by considering their meanings improves recall and may offer approaches to helping patients with the disorder.

BY AARON LEVIN

A growing body of research on the intersection of schizophrenia and memory illuminates both the nature of the disease and practical issues for patients.

"Subtle memory deficits in schizophrenia can lead to difficulty in functioning independently in real life, even more than the severity of the hallucinations and delusions that affect patients," said Deana Barch, Ph.D., an associate professor of psychology, radiology, and psychiatry at Washington University in St. Louis and coauthor of a new study on episodic memory and cortical activity. Study results are published in the July 1 *Biological Psychiatry*.

The researchers recruited 17 patients with schizophrenia and 26 healthy controls. They were shown anonymous faces and a series of printed words in the first phase of the study and then quizzed on their ability to recall or answer questions about what they had seen.

Their brains were scanned with a functional magnetic resonance imaging (fMRI) system while they completed these tasks. All but one of the patients in the schizophrenia group were taking medications.

"Past research has shown that [people with schizophrenia] have deficits in memory, but the question is whether these are permanent, or if some strategies might improve their memory," said lead author Aaron Bonner-Jackson, a graduate student in psychology at Washington University, in an interview with *Psychiatric News*.

The researchers did not describe the study to the subjects as a memory test, but the questions asked and the way they were presented allowed them to test how well the subjects learned and recognized information.

"They were not explicitly memorizing each word, but the deep semantic processing they were doing helped them to recognize a good percentage of those words later on," said Bonner-Jackson. "I believe that knowing they were going to be tested later would probably affect their strategy in some way, which in turn probably would have affected their brain activity and subsequent recognition of the words. However, it was not necessary for them to know about the later memory test in order to obtain consent, since the brief deception was minor and necessary for our experiment."

The researchers asked two kinds of questions. "Deep" questions required the subjects to think about the semantic meaning of the words, that is, if they were abstract or concrete. "House" is concrete, while "love" is abstract, for instance.

"The point is, you've asked them to think about the word," said Barch. "If you think about what words mean, you remember them better later."

"Shallow" processing meant simply asking about the arrangement of letters in the word: Did the first or last letter of the word come earlier in the alphabet?

Study subjects weren't specifically trained in techniques for remembering words or images or for answering test questions, but the structure of the study demanded certain strategies to process the information, said Bonner-Jackson.

"The advantage of using deep versus shallow processing is that patients don't have to generate a strategy for memory," commented J. Daniel Ragland, Ph.D., an associate professor of neuropsychology in psychiatry at the University of Pennsylvania School of Medicine, in an interview. "And it's gratifying to see research taking strategy into account during imaging."

Subjects with schizophrenia in the Washington University study performed worse than controls on both the shallow (alphabetical judgments) and deep (abstract/concrete) encoding tasks. Members of both groups did better on shallow than deep tasks.

In the recognition phase of the trial, subjects with schizophrenia were less accurate than were control subjects, but the difference was not statistically significant.

Compared with shallow encoding, deep encoding of words resulted in significant memory performance benefits among the schizophrenia subjects. Those subjects "benefit from deep encoding, just like controls do," said Bonner-Jackson. "They don't have a generalized memory deficit; they can do what controls do."

The fMRI imaging delineated areas of the brain in both subject groups that showed more activity during deep than shallow encoding. Both groups showed effects in regions typically active during deep semantic encoding. However, schizophrenia subjects showed greater activity for deep versus shallow encoding in three other regions: the left inferior frontal, right inferior frontal, and left middle frontal. These regions were not usually engaged by control subjects.

Two hypotheses might explain the involvement of these added brain areas seen in the fMRI.

please see ***Memory*** *on page 21*

JANSSEN RISPERDAL

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JANSSEN RISPERDAL
P4C

Sleep May Be Athletes' Best Performance Booster

Chronobiology studies are giving athletes and coaches valuable information on sleep strategies that could help ensure that an athlete's performance doesn't become a victim of too little sleep.

BY LYNNE LAMBERG

Athlete A or team X, the top performers in their sport, sometimes lose to less-adept competitors. Lower-ranked athletes or teams, at their peak, may perform better than top-ranked ones at their worst. Even elite athletes aren't always at the top of their game.

Variations in sports performance may reflect normal ebb and flow of biological rhythms. Marked differences between time of training and time of competition—as commonly occur in figure skating and football—also may dent an athlete's performance, noted Teodor Postolache, M.D., an associate professor of psychiatry at the University of Maryland School of Medicine.

Postolache served as guest editor of the June *Clinics in Sports Medicine*, which explores applications of body-time research to sports performance. (This issue was published as a book, *Sports Chronobiology*, by Saunders.)

Normal mid-afternoon drowsiness, jet travel, seasonal and menstrual-cycle variations in body rhythms, and lack of sleep can take the edge off athletic skills, Postolache said. Chronobiology lab findings can help athletes perform at their peak and reduce their risk of injury.

Psychiatrists and psychologists working in medical school psychiatry departments report their research in some of the book's 18 articles.

Psychomotor Vigilance Declines

Hans Van Dongen, Ph.D., and David Dinges, Ph.D., of the University of Pennsylvania, described studies assessing psychomotor vigilance performance after sleep deprivation. This skill involves reaction time and sustained attention. It is needed for not only sports performance but also everyday activities such as driving. It is highly sensitive to sleep loss, often experienced by athletes on road trips, particularly after they cross multiple time zones.

Such performance deteriorates markedly after 88 hours of continuous wakefulness, a duration comparable to staying up for three nights and long enough to show circadian patterns of alertness and sleepiness. Performance is consistently better in the day than at night, a reflection of humans' innate programming to stay alert in the day and sleep at night. Two-hour nap opportunities every 12 hours can blunt deficits in psychomotor vigilance.

Naps have a downside, though. Right after awakening, people often manifest performance deficits termed "sleep inertia." They're foggy and clumsy. This effect intensifies with progressive sleep loss, especially at night, Van Dongen and Dinges found. Very short naps—roughly 10 minutes—may offer some recuperative benefit when people are sleep deprived, they said, without producing noticeable levels of sleep inertia.

'Sleep Debt' Snowballs

Chronic sleep restriction, widespread among American adults, has serious adverse consequences for physical and mental performance, asserted sleep researcher William Dement, M.D., Ph.D., a professor of psychiatry at Stanford University. The most important aspect of the body's homeostatic regulation of sleep, he said, is that sleep loss is cumulative. "When total nightly sleep is reduced by exactly the same amount each night for several consecutive nights," he reported, "the tendency to fall asleep in the daytime becomes progressively stronger each day."

Dement calls this phenomenon "sleep debt." As he explains, the brain records as a debt every hour of sleep that is less than a person's nightly requirement. This snowballing debt may include an hour of sleep lost a week or month ago, as well as the hour lost last night, he speculated. A large sleep debt can be reduced only by extra sleep.

In a landmark 1994 National Institute of Mental Health study, subjects stayed in bed in the dark 14 hours every night for 28 consecutive nights. At first, they slept as long as 12 hours a night, suggesting they entered the study with sizeable sleep debts, Dement said. By the fourth week, their sleep stabilized at a nightly average of eight hours and 15 minutes—a figure interpreted to mean that most adults need this amount of sleep each night.

Does 'Secret' Advantage Accrue?

When subjects slept until "slept out," their mood, energy level, and sense of well-being as indicated on daily questionnaires all improved. Athletes who obtain all the sleep they need, Dement suggested, might have a "secret" advantage over their competition.

The adage "practice makes perfect," long a truism of athletic training, has been modified by sleep and chronobiology studies in the past decade, according to Matthew Walker, Ph.D., and Robert Stickgold, Ph.D., of Harvard Medical School. After initial training, the human brain continues to learn in the absence of further practice, they said. The improvement develops in sleep.

These findings have a direct application to athletes' training schedules, they asserted. Athletes who train consistently across the day and then cut short their sleep to get up early the next morning for practice might shortchange their brains of sleep-dependent consolidation and plasticity.

Studies of bright light's beneficial impact on mood hold relevance for the depressed athlete who experiences adverse effects from antidepressant medications or needs to avoid psychoactive substances entirely, said Postolache and Dan Oren, M.D., of Yale University School of Medicine. Bright light's antidepressant effects start sooner than those of most antidepressant medications, they noted. They suggest light exposure could be used to hasten antidepressant response.

> **"Athletes who obtain all the sleep they need might have a 'secret' advantage over their competition."**

Injured athletes simultaneously may experience diminished feelings of competence and self-worth and undergo an abrupt decrement in light exposure due to reduction in outdoor training. Postolache and Oren recommended that sidelined athletes continue to get bright-light exposure, either natural or artificial.

The contents of and ordering information for* Sports Chronobiology *is posted at <www.intl.elsevierhealth.com/catalogue/title.cfm?ISBN=1416027696>. ■

Memory

continued from page 17

"If greater activity appeared in better-performing subjects, it may mean that these regions are compensating for some deficit," said Bonner-Jackson. "Or, if the increased activity appeared in lower-performing subjects, it could simply represent wasted effort and indicate greater pathology."

Seeking evidence for either of these two alternatives, the researchers compared high- and low-performing subgroups among the schizophrenia patients. The effect size for the deep versus shallow contrast was greater in the low-performing group. Thus, people with schizophrenia who perform worse on the encoding tasks use more (and bilateral) brain regions, while high performers require a smaller set of regions to complete the same tasks, a set more like those activated in control subjects.

The "pathological" explanation seems more likely, given the results of this study, said Bonner-Jackson. Schizophrenia is associated with a deficit in the use of effective strategies to influence memory performance, and those abnormalities are not fully overcome by use of those strategies, said the authors.

Nevertheless, the study outcome also suggests avenues for clinical improvement of patients, Bonner-Jackson said: "People with schizophrenia have more memory capability than we thought."

Such insights derived from the current state of basic research might influence ways to improve their lives.

"Patients with schizophrenia in a new learning situation tend to take a rather passive approach to processing stimuli, not actively organizing information," said Ragland, whose related research is now in press with the *American Journal of Psychiatry*. "With the shallow/deep paradigm you can compensate by giving them a strategy, but the real challenge is teaching patients to do it for themselves, without a person in a white coat standing at their shoulder."

"It won't help to tell people with schizophrenia just to work harder or emphasize rote rehearsal of information," said Barch. "Rather than practice the same inefficient methods, it would be better to help them understand how they're learning by stressing the meanings and relationships of the things they encounter."

An abstract of "The Influence of Encoding Strategy on Episodic Memory and Cortical Activity in Schizophrenia" can be accessed at <www.elsevier.com/locate/biopsychiat> under the July 1 issue. ■

Sleep Drug

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often reported adverse effects that occurred more frequently and at a statistically significantly higher rate than placebo were somnolence, fatigue, and dizziness.

At extremely high doses (roughly 200 times the approved dosage) in animal studies the drug was shown to be a developmental teratogen. The drug is classified as Pregnancy Category C by the FDA and therefore should be used in women who are pregnant "only if the potential benefit justifies the potential risk to the fetus."

Physicians are also cautioned in the approved labeling that the drug was associated with increased serum prolactin levels in women during clinical trials. Prolactin levels increased on average 34 percent in women taking the drug compared with a 4 percent decrease in those on placebo. No differences in serum prolactin were seen in male patients during clinical trials.

Complete prescribing information on ramelteon is posted online at <www.rozerem.com>. ■

IPS Forum Will Help Psychiatrists Explain Medicare Part D

APA Institute

A forum that will provide APA members with the practical information they need to help their patients navigate Medicare's new Part D pharmaceutical benefit has been added to the schedule of APA's 2005 Institute on Psychiatric Services.

The institute will be held in San Diego from October 5 to 9 (see box on page 27 for registration information).

The forum, "Readying for the New Medicare Pharmacy Benefit: The Part D Challenge," will be sponsored by APA's Office of Healthcare Systems and Financing and chaired by Director Irvin "Sam" Muszynski. It is part of APA's ongoing effort to educate members about Medicare's new prescription drug benefit, which begins on January 1, 2006.

The forum will be held on Thursday, October 6, from 10 a.m. to 11:30 a.m.

Said Muszynski, "Deciding which Part D pharmacy plan to participate in will be a daunting task for almost all Medicare beneficiaries, but especially for dual-eligible beneficiaries, whose drug benefit will be transferred from their state's Medicaid program to Medicare. We anticipate that patients will be very dependent on their physicians to help them make the right decision." ■

at your service

Hiring a Nurse Practitioner Enhances Practice When Done Carefully

Q. I am considering a contract arrangement with a nurse practitioner. The nurse practitioner would come to my office two days a week to assess patients and handle routine medication refills. The individual would be an independent contractor, and I would function as his or her supervisor. I am a participant in the APA-endorsed Psychiatrists' Professional Liability Insurance Program. Is there coverage under my policy for this arrangement? Will my professional liability risk increase?

A. Utilization of allied health care professionals can be an effective solution to the problem of limited psychiatric resources. As such, more and more psychiatrists are incorporating nurse practitioners in their practices. As with all practice arrangements, you are wise to take steps against potential professional malpractice exposure.

First, entering into a practice agreement with a nurse practitioner constitutes an important change in your practice. Therefore, you should notify your professional liability insurance carrier of the change and discuss coverage issues with your underwriter.

Second, there are some steps you can take to minimize professional malpractice risks. The scope of a nurse practitioner's practice, including prescribing authority, is defined by each state. You should have a clear understanding of what is required by the state's nursing board. You should also verify the nurse practitioner's education, training, licensing, and credentialing, as well as inquire about any administrative complaints or lawsuits that may have been filed against the individual. Contact your state Board of Medicine and review the practice of medicine statutes and any regulations regarding the relationship between physicians and nurse practitioners.

You and the nurse practitioner should have a clear agreement and understanding, preferably in writing, about some specific aspects of the practice relationship including (1) the frequency and type of supervision and record review, (2) notification by the nurse practitioner of any changes in his or her professional status, and (3) information to be given to patients about the respective roles of yourself, the nurse practitioner, and the patient. Other elements may be indicated by the statutes and rules of your state or jurisdiction. In addition, various third-party payers and facilities where you practice may have their own rules about practice relationships with nurse practitioners.

Adequate supervision and involvement in the new treatment delivery arrangement are necessary to maintain high-quality patient care. You should tailor your level of involvement to the nurse practitioner's education, training, and skills, as well as to the clinical needs of patients. Do not make assumptions about the nurse practitioner's knowledge; assess the person's skills carefully. You want to ensure good, ongoing communication between yourself, the nurse practitioner, and patients, especially with regard to the appropriate threshold for notification of material changes in the status of patients—for example, emergencies, crises, and medication side effects. If the nurse practitioner will be prescribing on his or her own, be sure the individual has complied with regulatory requirements and has obtained a DEA number and prescription pads.

Program participants may contact the Risk Management Consultation Service help line for additional guidance on reducing and managing risk in this area.

This column is provided by PRMS, manager of the Psychiatrists' Program, for the benefit of members. More information about the Program is available by visiting its Web site at www.psychprogram.com>; calling (800) 245-3333, ext. 389; or sending an e-mail to TheProgram@prms.com. ■

letters to the editor

Here's One Answer

As APA President Steven Sharfstein, M.D., wrote in his July 1 column, "Where Does the Money Come From and Where Does It Go?": "[P]rivate insurance has cut back dramatically on paying for the treatment of our patients as the carveout behavioral health care companies *have been successful in reducing costs* (emphasis mine). More and more patients have become uninsured and/or qualified for care under public programs, especially Medicaid."

Health care coverage is not analogous to manufacturing. In manufacturing, there are only two ways to lower what are considered "costs": increase production per unit time, while holding quality and expenses relatively constant (productivity, throughput) or controlling prices favorably by driving competitors out of (narrowing) the field, as with antitrust violations.

What Dr. Sharfstein does not explain is that being in a purely cash-flow business, these companies have not reduced "costs" at all but successfully increased premium profits. Insurance manufactures nothing and, with the managed-care additive, stabilizes or increases premiums. His admission that "people with mental illness are at more risk than ever" concedes that there's no free lunch in medical economics.

Since my good friend Dr. Sharfstein only indirectly answers the questions he raises, I will make an attempt. My answer to his first question, "Where Does the Money Come From," is that it still comes from private insurance premiums, Social Security's FICA taxes for Medicare, and general revenue (federal and state) income taxes earmarked for Medicaid. My answer to his second question, "Where Does It Go?" lies in the reduction of the amount of care each "managed" patient now gets, passing those savings (not costs) from health care services to stockholders, improving nothing, while churning increasingly subacute patients through the system.

JACK C. SCHOENHOLTZ, M.D.
Mamaroneck, N.Y.

Gender Genetics Complex

At its meeting last month, the Board of Trustees voted to have APA support the legal recognition of same-sex civil marriage. This vote came after the Assembly had approved the same position at its May meeting. The position statement emphasizes a variety of psychological and social reasons for recognizing same-sex couples. I would like to add a biological imperative to the arguments.

Opposition to same-sex marriages rests on the assumption that gender is unambiguously divided into male and female. However, various studies have found that up to 2 percent of live births—as many as 80,000 annual births—vary from the standard definitions of chromosomal, genital, gonadal dimorphism. At the chromosomal level a multitude of genetic patterns is possible. For example, instead of XY, there are males with XXY, XXYY, XXXY, XXXXY, and XYY. Among females, there are some who have only one X chromosome, those who have three, and others who have a mosaic of one X mixed with XX. There are also autosomal (non-sex gene) mutations that can affect gender. The most common form is called "pseudo-hermaphroditism," which includes congenital adrenal hyperplasia in females and testicular feminization syndrome due to androgen insensitivity in males.

Last, there are persons who have normal chromosomal and anatomical makeup, and yet their gender does not conform to standards. They include a range of persons who are clinically diagnosed as having gender identity disorder. These persons have a strong and persistent cross-gender identification.

Thus, our traditional dichotomous classification poses problems at the chromosomal, anatomical, and psychological levels.

In reality, there is neither an absolute "genetic" male or "genetic" female, nor is there an absolute "male" or "female" gender identity, just a spectrum of expressions. Because gender cannot be easily categorized, it renders laws about sex and marriage illusory. As physicians and psychiatrists, we have

please see ***Letters*** *on page 28*

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

association news

Report Card

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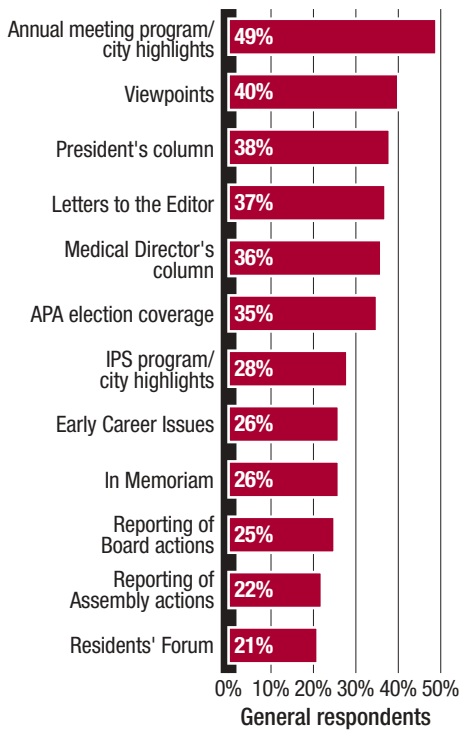
ing interests of the various subgroups of the membership.

We are aware from this and previous surveys of readers' dislike of articles that jump from one page to another. We do make considerable effort to keep these to a minimum in each issue. The section heads that are a key feature of *PN's* design, however, prevent us from eliminating jumps entirely.

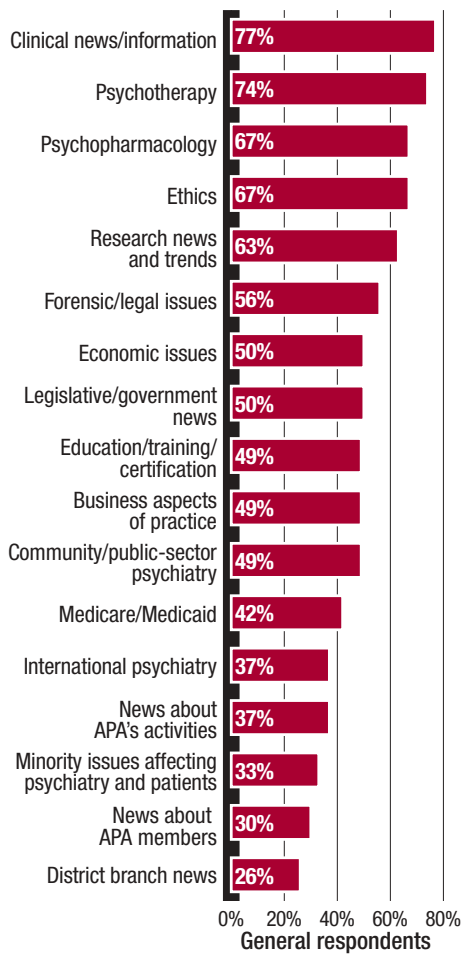
We will also explore the possibility of offering CME credit within *PN* ways to better address issues that may be of greater interest to Canadian members.

All of us on the staff thank the members who participated in the survey. I invite all readers to help shape our coverage by providing ideas and feedback to me and our staff. Please contact us at pnews@psych.org. ■

Respondents rated their interest in features, using a scale from 5 (very interested) to 1 (not at all interested). This chart shows the percentage of respondents who rated their interest as 4 or 5.



Respondents rated their interest in topics, using a scale from 5 (very interested) to 1 (not at all interested). This chart shows the percentage of respondents who rated their interest as 4 or 5.



Source: *Psychiatric News* Readership Survey Report, 2005 Lewis & Clark Research

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Two Will Be Honored for Battle Against War's Trauma

BY GARY B. MELTON, PH.D.

At APA's 2005 Institute of Psychiatric Services in San Diego, the American Orthopsychiatric Association will present awards to two mental health professionals who have courageously assisted civilians traumatized by armed conflict. Both winners will also deliver lectures.

Gary B. Melton, Ph.D., is president of the American Orthopsychiatric Association and director of the Institute on Family and Neighborhood Life at Clemson University.

The Max Hayman Award will be presented to Ferid Agani, M.D., a psychiatrist who is a member of the parliament of Kosovo, for his development of a system of mental health services to facilitate the recovery of people traumatized in the civil war in Kosovo. In addition to serving as a legislator, Agani is an assistant professor of neuropsychiatry and psychodynamics at the University of Prishtina.

The Hayman Award honors distinguished scholarship in the mental health disciplines that contributes to the elimination of genocide and the remembrance of the Holocaust.

Michael Wessells, Ph.D., a professor of psychology at Randolph-Macon College in Ashland, Va., and senior child protection specialist for the Christian Children's Fund, will receive the Marion Langer Award. Wessells will be honored for his exemplary work to build systems of support and to preserve family and community relationships for children in numerous zones of armed conflict or natural disaster.

The Langer Award is presented annually in recognition of distinction in social advocacy and the pursuit of human rights.

Colloquially known as "Ortho," the American Orthopsychiatric Association is a multidisciplinary organization of mental health professionals dedicated to the pursuit of social justice. The presentations and lectures will occur in a symposium cosponsored by Ortho and the American Association of Community Psychiatrists in the Fairbanks Ballroom in the West Tower of the Sheraton San Diego Hotel and Marina on Saturday, October 8, from 7:30 p.m. to 10 p.m. The symposium will include a reception in honor of Agani and Wessells.

I will chair the session and present the awards. Noting Ortho's current emphases, I will also offer some introductory comments about the significance of the honorees' work for the pursuit of justice around the world.

These remarks will be elaborated by Robin J. Kimbrough-Melton, J.D., director of Clemson's National Center for Rural Justice and Crime Prevention and cochair of Ortho's Task Force on Mental Health and Human Rights. Specifically, Kimbrough-Melton will address the importance of protection of children's rights to personal security and of family relationships.

Ortho's other major annual award, the Blanche F. Ittleson Award, will be presented this year to Sandra Christenson, Ph.D., and Joyce Epstein, Ph.D., for their groundbreaking scholarship and public service to strengthen parents' participation in the schools.

Christenson is the Birkmaier Professor of Educational Leadership at the University of Minnesota, where she also directs the School Psychology Program. Epstein is a research scientist and director of the Center on School, Family, and Community Partnerships at Johns Hopkins University.

The award recognizes outstanding achievement in the delivery of children's services and the promotion of children's mental health. Christenson and Epstein will receive the award in ceremonies at their home institutions on September 15 and October 19, respectively. The Ittleson Award recipients will also lecture at the First Annual Ortho Summer Institute, to be held June 26 to July 1, 2006, in conjunction with the Cape Cod Institute (www.cape.org). Its theme is "Helping Children and Families Where They Are: Caring for Children in Schools, Pediatric Clinics, Places of Worship, and Other Community Settings." ■

57th Institute on Psychiatric Services
APA's Leading Educational Conference on Public and Community Psychiatry

How to Register

APA's 2005 Institute on Psychiatric Services will be held in San Diego from October 5 to 9. There are two ways to register:

- Register online for the 2005 Institute on Psychiatric Services at <www.psych.org/edu/ann_mtgs/ips/05/index.cfm>.
- Use the registration form found in the preliminary program booklet and mail or fax the completed form to APA. The booklet can be obtained by calling (888) 357-7924.

Register before September 6 and save on fees. A discounted fee is available for residents; medical students attend free.

Two Reports

continued from page 1

August 15, 2003). The agenda was developed in discussion with six cabinet departments—Health and Human Services, Education, Justice, Labor, Housing and Urban Development, and Veterans Affairs—and the Social Security Administration.

"The Action Agenda is not a quick fix," Curie emphasized. "It's a living document to transform mental health care and hold the federal government accountable."

Following the guidelines for the New Freedom Commission, which required that initiatives have no impact on federal budgets, the Action Agenda proposes coordination of ideas but requests no new funding.

"The underlying assumption is of budget neutrality, but strategic use of new funds to make changes could make a big difference," said Sharfstein.

According to the SAMHSA report, the role of the federal government should be to lead and to facilitate change in mental health care at the federal, state, and local levels as well as in the private sector. The Action Agenda lists 31 separate items covering clinical outcomes, community models of care, cost-effectiveness, and dissemination of research (see box).

Observers said the agenda appeared belatedly but praised its intent.

"Advocates were nervous and dismayed at the time it took to get the Action Agenda cleared for release, but we are pleased with its breadth and depth," Michael Hogan, Ph.D., director of the Ohio Department of Mental Health and chair of the New Freedom Commission on Mental Health, said in an interview with *Psychiatric News*.

The next step for the federal government is to set up an executive steering committee from all the concerned departments to plan "ongoing stewardship . . . to guide the collaborative work of mental health system transformation. . . ," in its words.

"The Action Agenda is really an inventory of what all federal agencies are doing now and how they have pledged to act together in an agreed way," said A. Kathryn Power, M.Ed., director of SAMHSA's Center for Mental Health Services, in an interview. "It's the first step—that's all it is. I hope we can convene the steering committee by the end of the year."

"The steering committee creates a high-level, organized body on mental illness that has been strikingly absent in the federal government," said Hogan. "I am pleased to see the involvement of the Labor Department, Veterans Affairs, and Social Security."

He noted that the Social Security Administration wasn't even represented on the New Freedom Commission, but that rules for its Social Security Disability Insurance and Supplemental Security Income programs affect how people with disabilities can work their way out of poverty.

Termed a "roadmap" for federal action, the CMHR's document calls for new legislation to ensure mental health parity in insurance coverage, allow families with mentally ill children and incomes up to 250 percent of the federal poverty line to buy into Medicaid, end discrimination in Medicare, and fund the diversion of mentally ill people who have committed nonviolent crimes into treatment rather than prison (see box).

"The Action Agenda is focused on what the federal government bureaucracy can do, while the CMHR report addresses what Congress still needs to do," said Hogan. "Having the two appear within days of each other leaves me hoping we're moving toward a critical mass."

"The roadmap," Sharfstein commented, "provides a constructive set of doable steps that would improve opportunities for persons with mental illness to receive effective treatment and support."

Representing APA at the CMHR report's unveiling at the Capitol in Washington, D.C., were James H. Scully Jr., M.D., APA medical director; Eugene Cassel, J.D., director of APA's Division of Advocacy; and Jessica Mikulski, a communications specialist in APA's Office of Communications and Public Affairs.

"APA's involvement in the campaign," Hogan told *Psychiatric News*, "is very important because it brings professional credibility to CMHR."

A bipartisan group of senators and representatives spoke at the CMHR press conference. While both Democrats and Republicans have supported many mental health bills, some were passed without sufficient funding being authorized, said Sen. Mike DeWine (R-Ohio). DeWine recalled his days as a county prosecutor, when jail was the only option for mentally ill offenders. Fully funding the Mentally Ill Offender Treatment and Crime Reduction Act of 2004 would offer alternatives to prison for mentally ill persons who commit nonviolent crimes, he said.

Opposition to mandating better mental health benefits in private plans has come largely from corporations, which fear adding to already high health care costs, explained Sen. Edward Kennedy (D-Mass.).

"If people faced the reality of the statistics, there would be no difficulty in passing parity legislation," said Rep. Patrick Kennedy (D-R.I.), the senator's son. "The American people don't understand the extent of mental illness, so we're dealing with the symptoms of the problem—overcrowded jails, family separations, depressed senior citizens trapped in their apartments."

The biggest challenge is Medicaid funding, said Rep. Kennedy. Funding for mental health services will probably be the first to be cut, especially if there is a shift to block grants.

"The Action Agenda and the CMHR roadmap were complementary documents and together can serve to bring about needed changes to the country's mental health system," said CMHR Director Charles S. Konigsberg, J.D. "We look forward to sitting down with SAMHSA to develop a common agenda."

SAMHSA's Action Agenda is posted at <www.samhsa.gov/Federalactionagenda/NFC_TOC.aspx>. The CMHR's roadmap is posted at <www.mhreform.org/emergency/index.htm>. ■

Reports Outline Roadmap To Reform Mental Health System

Two major reports were released last month in response to the 2003 report of President Bush's New Freedom Commission on Mental Health. The first report, by the Substance Abuse and Mental Health Services Administration, is titled "Transforming Mental Health in America. The Federal Action Agenda: First Steps." The other report, "Emergency Response: A Roadmap for Federal Action on America's Mental Health Crisis," was prepared by the Campaign for Mental Health Reform, of which APA is a member.

SAMHSA's Action Agenda Sets Goals

The following are among the goals for federal agencies to work toward as they lead and facilitate change in mental health care at the federal, state, and local levels and in the private sector:

- Reinforce the message that mental illnesses and emotional disturbances are treatable and that recovery is the expectation.
- Act immediately to reduce the number of suicides in the nation through implementation of the National Strategy for Suicide Prevention, launched by HHS in 2001.
- Help states develop the infrastructure necessary to formulate and implement comprehensive state mental health plans that include the capacity to create individualized plans of care that promote resilience and recovery.
- Develop a plan to promote a mental health workforce better qualified to practice mental health care that is culturally sensitive and based on evidence-based practices in both specialty settings and at the primary care level.
- Initiate a national effort focused on the mental health needs of children and promote early intervention with informed parental consent for children identified to be at risk for mental disorders. Prevention and early intervention can help forestall or prevent disease and disability.
- Expand the "Science-to-Services" agenda to develop new toolkits outlining evidence-based practices for use by providers, administrators, educators, and consumers.
- Increase the employment of people with psychiatric disabilities.
- Design and initiate an electronic health records and information system that will help providers and consumers better manage mental health care and that will protect the privacy and confidentiality of consumers' health information.

CMHR Lays Out Roadmap

These are among the 28 action items included in CMHR's "Emergency Response" roadmap:

- End discrimination by health insurance plans through enactment of parity legislation this year.
- Better utilize Medicaid dollars by providing cost-effective home- and community-based care in lieu of institutional care and permitting states to utilize Medicaid dollars for comprehensive treatment plans.
- Allow families to buy into Medicaid to access services for a child with a disability, including emotional and behavioral disorders.
- End the unconscionable and costly "warehousing" of youth with mental disorders.
- End discrimination against mental health treatment in Medicare, which requires higher copayments for mental health outpatient care and limits inpatient hospital coverage for mental health treatment.
- Provide early identification and effective treatment for returning veterans at risk of post-traumatic stress disorders and their families.
- Provide early detection and intervention services to mothers and children who receive health care at federally funded maternal and child health clinics.
- Permit presumptive eligibility for Supplemental Security Income and Medicaid for people who are homeless and have a serious mental illness.
- Fund programs to divert mentally ill people who have committed nonviolent crimes into treatment instead of jail or prison.

letters to the editor

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an obligation to clarify this issue for policymakers and the general public.

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Clarification

The article "Good Intentions Often Miss Disaster Relief Targets" in the July 1 issue reported on a session held at APA's 2005 annual meeting in Atlanta titled "Global Disasters: Psychiatric Medicine and Public Health Challenges." The article did not name the organizations that collaborated on the session, which was held at the Carter Center. APA's Council on Global Psychiatry and the World Psychiatric Association's Conflict Management and Resolution Section organized the session. The other groups involved were the World Psychiatric Association's sections on Military and Disaster Psychiatry and Occupational Psychiatry, the World Health Organization, and the Centers for Disease Control and Prevention.

The session, said Eliot Sorel, M.D., chair of the WPA Conflict Management and Resolution Section, was "a model of cooperation essential not only for scientific meetings but also for the practical development of responses to and interventions in disasters" occurring anywhere in the world. ■

Narrowing the 'Credibility Gap'

I have been following the issue of black-box warnings for antidepressant medications since it came on the scene last year and would like to present some observations and concerns knowing that APA is actively involved in the safety and effectiveness of treatment for children and adolescents with depression as was described in the March 4 issue.

Last year the data being presented by the Food and Drug Administration involved a review of 4,400 subjects who were said to be "on" or "taking" antidepressant medication. What struck me at the time was that there was no reference to blood-level studies to prove that the subjects actually ingested the medication and/or developed any kind of blood level, that is, absorbed the medication and were not rapid metabolizers, for example. I would hope that APA and the American Academy of Child and Adolescent Psychiatry will pursue this particular aspect of the issue.

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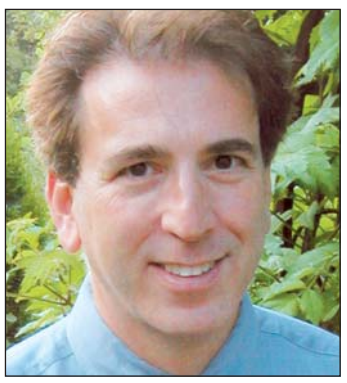
Thoughts on Pharmaceutical Companies and Gifts to Physicians

BY CHARLES ATKINS, M.D.



Whenever the feds—the Office of the Inspector General (OIG) in particular—investigate an issue in health care, it's good to pay attention. That's why I've been thinking more about the relationship between pharmaceutical companies and physicians. For me, this is personal; the drug companies and I go way back, and the phrase "Don't look a gift horse in the mouth" comes quickly to mind, followed by "There's no such thing as a free lunch."

It's gotten to the point that it's impossible not to partake of drug-company largesse when I attend a conference. Drug companies underwrite many of the talks, and even the buses that move us from lecture to lecture at no charge carry ads for popular drugs. Sure, I'll turn down the theater tickets and box seats at sporting events and the expensive tours, wine tastings, and meals, but it's impossible not to receive some form of freebie, however inadvertent.

Back at home, there's the community detailing with expensive luncheons and dinners, mostly with lectures attached, but not always. I receive invitations daily, and it's all free—not to mention the magazines and brochures that show up in my mail, without my having requested them. I can't tell who's been sending them; I wish they'd stop.

There's more too, for example, invitations to cruises, on which I could be paid as a consultant, to discuss "how I prescribe antidepressants." I was even gifted with a pricey, inscribed Mont Blanc pen when I became a medical director—I did not keep it—and the drug rep was upset, because who wants a pen with my name in gold?

As I try to distance myself from the pharmaceutical companies, I'm confronted with complex ethical issues. Or maybe they aren't so complex, but they make me squirm.

For instance, many of us who've tried to maintain some boundaries with the drug companies have gone with the party line: "It's O.K. for them to provide an educational event with a small lunch." Well, I'm not so sure. I do a fair amount of consulting and lecturing—I don't do this for free. Likewise, when the drug companies hire a respected professor to speak to a small group of docs, it costs. I remember one speaker quipping how the drug companies were putting his children through college. If we think about the real price tag for the event, the lunch, which might just be a sandwich, cookies, and soda, isn't the issue; it's the $1,500 or more, plus travel and lodging, that the speaker gets. So if I have 10 or even 20 doctors in the room, the gift per person is not just the $10 for lunch, but could be a couple hundred dollars.

Why would someone give me a gift worth hundreds of dollars? Either they love me, want to sleep with me, or want something else. They are giving a quid and would like a pro quo, which brings me to the line I've heard many colleagues spout: "I'm not influenced by the drug companies; the dinners, the gifts, and the marketing campaigns don't affect my prescribing practices."

I can't make that statement. This becomes even more knotty when we see how much research and how much publishing in the professional journals are either fully sponsored or underwritten by drug companies. Of course I'm influenced by them, I'm just not sure how much and in what ways. I have my suspicions, which are reflected in such questions as, Why are we so quick to abandon old medications when the new ones come out? If people spent the same amount of time, energy, and money extolling the virtues of off-patent medications, would we switch so quickly?

As the federal government has set about publishing compliance guidelines and studying the relationship between pharmaceutical companies and physicians—paying particular attention to pricing, kickbacks, and free samples—a process has started that will have far-reaching implications. But while increased federal scrutiny and internal guidelines will—and have—created change, I'd urge everyone in the medical profession to spend some time thinking through each interaction with a drug company. Ask yourself a few questions. I'd start simply with, How much did this company just spend on me? What do they want from me? And how has this interaction influenced me?

The OIG's "Compliance Program Guidelines for Pharmaceutical Manufacturers Published in the* Federal Register" *is posted at <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>. ■

Charles Atkins, M.D., is a psychiatrist, freelance writer, and member of the Yale clinical faculty. His latest novel, *The Cadaver's Ball* (St. Martin's Press), will be released in fall 2005.

Readers are invited to submit opinion pieces on issues facing psychiatry for possible publication in this column. They may be on an original topic or in response to previous "Viewpoints" articles. Those interested should contact Ken Hausman at *Psychiatric News* at (703) 907–7861; e-mail: KHausman@psych.org.

Ethics Review

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and trying to determine whether an APA statement was needed, and what form it should take."

Appelbaum said that at next month's fall component meetings the council and the committee, as well as representatives from the APA Committee on Ethics and the Committee on Misuse and Abuse of Psychiatry, will begin the process of developing guidelines for psychiatric involvement in national security interrogations.

What Is Legitimate Role?

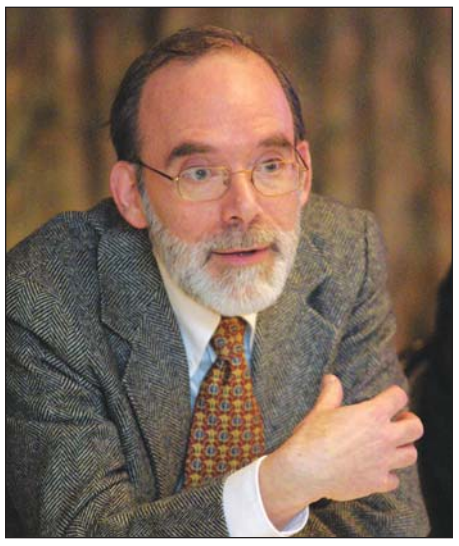
"The issues we will need to address include whether it is legitimate for a psychiatrist to be involved in an investigative process and, if so, in what ways," Appelbaum said. "As part of the interrogation itself? Providing advice in real time behind a one-way mirror? Advising in advance on interrogation techniques, including the vulnerabilities of a particular suspect? Or advising more generally? Those seem to be key questions raised by the Guantanamo experience that we will have to come to grips with."

He echoed other APA leaders in saying that the controversy had launched the profession into uncharted territory.

"The current APA ethical principles and annotations certainly have elements that can be drawn on to answer those questions," Appelbaum said. "But never having been faced so starkly with these issues, I think the Association has not had an opportunity to formulate relevant guidelines."

Spencer Eth, M.D., chair of APA's Ethics Committee, agreed. "This is a relatively new issue," he said. "Making a statement is itself an important step, rather than simply saying our existing guidelines cover it. Military practice is very different from civilian practice, just as is correctional psychiatry. We need to be mindful of the variety of types of practice our members are engaged in and not jump to conclusions."

APA leaders declined to comment on specific allegations of psychiatrist involvement at Guantanamo given the difficulty of determining the veracity of accounts and the extent and nature of psychiatric involvement.



Paul Appelbaum, M.D.: "We always need to think carefully about [psychiatrists'] nonpatient care roles and whether they so compromise that perceived allegiance to patients' interests that they ought not to be considered legitimate."

Involvement of MH Experts Acknowledged

A Department of Defense report on the subject of detainee abuse, led by Vice Admiral Albert Church III, director of Navy staff, was ordered by Defense Secretary Donald Rumsfeld last year and released in March.

Predictably, that report downplayed reports of widespread abuse, but the investigation did find inconsistencies regarding the development, promulgation, and dissemination of interrogation techniques. These techniques "migrated" from Guantanamo Bay to Afghanistan, and then to Iraq, the report stated.

The Church report stated that "behavioral science personnel" assisted in interrogations.

"[I]t is a growing trend in the Global War on Terror for behavioral science personnel to work with and support interrogators," the report stated. "These personnel observe interrogations, assess detainee behavior and motivations, review interrogation techniques, and offer advice to interrogators. This advice can be effective in helping interrogators collect intelligence from detainees; however, it must be done within proper limits.

"We found that behavioral science personnel were not involved in detainee medical care (thus avoiding any inherent conflict between caring for detainees and crafting interrogation strategies) nor were they permitted access to detainee medical records," the Church report concluded. "However, since neither the Geneva Convention[s] nor U.S. military medical doctrine specifically addresses the issue of behavioral science personnel assisting interrogators in developing interrogation strategies, this practice has evolved in an ad hoc manner."

Alan Stone, M.D.: "I am unprepared to say that in a situation of great consequence, a psychiatrist who might have some ability to help our military should claim some ethical obligation that transcends all other obligations."

More recently, a report in the July 7 *New England Journal of Medicine* stated that a psychiatrist and a psychologist had each headed Behavioral Science Consultation Teams (BSCT, pronounced "biscuit") to assist interrogators in questioning Guantanamo detainees.

"BSCT consultants prepared psychological profiles for use by interrogators," according to article. "They also sat in on some interrogations, observed others from behind one-way mirrors, and offered feedback to interrogators."

Moreover, the journal report stated—in a contradiction to the Church report—that BSCT teams did have access to medical records.

"An internal, May 24, 2005, memo from the Army Medical Command, offering guidance to caregivers responsible for detainees, refers to the 'interpretation of relevant excerpts from medical records' for the purpose of 'assistance with the interrogation process,' " said the journal article. "The memo, provided to us by a military source, acknowledges this nontherapeutic role, urging health professionals who serve in this capacity to avoid involvement in detainee care, absent an emergency. This acknowledgment is consistent with other accounts of information flow from caregivers to behavioral science consultants to interrogators."

Implications for Medicine Profound

APA leaders say the issue is fraught with implications for medicine generally.

"From a broader perspective, physicians in general retain the trust of the general population because of a perception that they are committed to the well-being of their patients," Appelbaum said. "We always need to think carefully about other nonpatient care roles and whether they so compromise that perceived allegiance to patients' interests that they ought not to be considered legitimate."

At the same time, the ethics of psychiatric participation in interrogation of detainees who may have information vital to the security of the nation are not clear-cut.

"I am unprepared to say that in a situation of great consequence, a psychiatrist who might have some ability to help our military should claim some ethical obligation that transcends all other obligations," said Alan Stone, M.D., a past APA President and current member of the Committee on Judicial Action. "There could come a time when I thought a person knows something, and I could help find out what that is. I would certainly think it strange for me to rest on an ethical principle when there is so much greater harm [at stake]."

Stone, a professor of law and psychiatry at Harvard, has written extensively about issues related to the misuse of psychiatry. He said the issue of psychiatric involvement in nonpatient care roles has surfaced before—as in the case of clinicians who provide the government "profiles" of foreign leaders—but the professional and ethical boundaries of such conduct have not been clarified.

The current controversy about Guantanamo interrogations adds the dilemma of determining when psychological pressure turns into torture. "These are issues that psychiatry hasn't faced up to or resolved," Stone said.

The American Psychological Association has issued detailed guidelines on the subject that allow for the involvement of psychologists in interrogations (see box).

Appelbaum noted that in contrast to psychiatry, psychology has a history of participation in a range of nontherapeutic functions and that there are distinct differences between the two professions.

"It's fair to say that psychology and psychiatry have a different ontogeny," he said. "Psychology has historically played many roles other than direct patient care, including consulting to organizations and businesses and the like, to a much greater extent than psychiatry has. So practices that we might as physicians find more problematic may seem acceptable to psychologists who are coming from this alternative tradition."

An unclassified version of the Church report is posted at <www.defenselink.mil/news/Mar2005/d20050310exe.pdf>. The journal report is posted at <http://content.nejm.org/cgi/content/full/353/1/6>. ■

Psychologists Outline Interrogation Ethics

There is a role for psychologists in the interrogation of detainees by the American military and government, according to the American Psychological Association.

In the light of reports that psychiatrists and psychologists have participated in interrogations of detainees at Guantanamo Bay naval station, the psychological association released a statement from its Presidential Task Force on Psychological Ethics and National Security that broadly outlines the ethical obligations of psychologists in such settings.

The task force was established earlier this year. Its charge did not include an investigative or adjudicatory role, nor did it render any judgment about events that may have happened in national security related settings.

The report states, "It is consistent with the [American Psychological Association] Ethics Code for psychologists to serve in consultative roles to interrogation and information-gathering processes for national security–related purposes, as psychologists have a long-standing tradition of doing in other law enforcement contexts."

The report listed the following 12 statements concerning psychologists' ethical obligations in national security work:

- Psychologists do not engage in, direct, support, facilitate, or offer training in torture or other cruel, inhuman, or degrading treatment.
- Psychologists are alert to acts of torture and other cruel, inhuman, or degrading treatment and have an ethical obligation to report these acts to the appropriate authorities.
- Psychologists who serve in the role of supporting an interrogation do not use health care information from an individual's medical record to the detriment of the individual's safety and well-being.
- Psychologists do not engage in activities that violate the laws of the United States, although psychologists may refuse for ethical reasons to follow laws or orders that are unjust or that violate basic principles of human rights.
- Psychologists are aware of and clarify their role in situations where the nature of their professional identity and professional function may be ambiguous.
- Psychologists are sensitive to the problems inherent in mixing potentially inconsistent roles such as health care provider and consultant to an interrogation and refrain from engaging in such multiple relationships.
- Psychologists may serve in various national security roles, such as consultant to an interrogation, in a manner that is consistent with the Ethics Code, and when doing so psychologists are mindful of factors unique to these roles and contexts that require special ethical considerations.
- Psychologists who consult on interrogation techniques are mindful that the individual being interrogated may not have engaged in untoward behavior and may not have information of interest to the interrogator.
- Psychologists make clear the limits of confidentiality.
- Psychologists are aware of and do not act beyond their competencies, except in unusual circumstances, such as set forth in the Ethics Code.
- Psychologists clarify for themselves the identify of their client and retain ethical obligations to individuals who are not their clients.
- Psychologists consult when they are facing difficult ethical dilemmas.

"Report of the American Psychological Association Presidential Task Force on Psychological Ethics and National Security" is posted at <www.apa.org/releases/PENSTaskForceReportFinal.pdf>.