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Government News

FDA Panel Rejects New Rule For Psychiatric Drug Testing

In a resounding rejection, an FDA advisory committee tells the agency that its heart might be in the right place, but its head clearly isn't.

BY JIM ROSACK

With a unanimous 12-0 vote, members of the U.S. Food and Drug Administration (FDA) Psychopharmacologic Drugs Advisory Committee (PDAC) told the agency to reverse its recently implemented requirement calling on drug companies to submit both short-term (eight to 12 week) and longer-term (more than six months) efficacy data as part of an initial application for approval to market a psychiatric medication.

The PDAC members expressed concern that the requirement would slow drug development and timely approval of new medications for the treatment of mental illness. In addition, they expressed concern over how longer-term data should be collected and by whom.

"We'll likely follow your advice," said Thomas Laughren, M.D., acting director of the FDA's Division of Psychiatry Products. Laughren officially spoke for the agency at a day-long public hearing late last month.

Legally, the FDA is not bound by the votes of its advisory panels. Historically, it has nearly always followed its committees' leads, although there have been notable exceptions recently in areas other than psychiatric drug products.

The unanimous "no" vote was in response to the first of a list of 12 questions Laughren had submitted to the PDAC for its consideration. Of the 12 questions (some multipart), formal votes were requested for four, with the remainder of the questions intended only to generate discussion. The PDAC's answer to the first question, "Is it a reasonable expectation that a sponsor would have accumulated data for both acute and longer-term efficacy trials at the time of filing of an application for a drug treatment for major depressive disorder?" seemed to be a foregone conclusion nearly from the outset of the hearing. Indeed, of those speaking throughout the hearing, Laughren seemed to be the only one who supported the notion.

Yet, several members of the PDAC expressed concern over how the public might view the panel's "no" vote. Some members said they feared that the panel's vote would be considered a rebuke to the FDA for attempting to require "a higher standard of evidence" for approval of psychiatric medications.

In an unusual move, the PDAC unanimously voted to approve the release of a public statement saying: "The advisory committee recognizes the need for evidence to inform clinical practice regarding long-term treatment efficacy, without potentially slowing progress of new drug development. We encourage collaborative efforts by industry, the National Institutes of Health, and the FDA to further research on long-term treatment."

At the end of the day, the remaining questions that the FDA had presented to the PDAC were not directly addressed, and no further votes were taken.

An unusual coalition involving 10 phar-

please see ***Drug Testing*** *on page 37*

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Allegations of arbitrary detention and "inhumane" use of electroconvulsive therapy must be addressed by Turkey's psychiatrists and health officials, an APA committee maintains. See page 18.

Elderly Patients Show Elevated Mortality Risk on Atypicals

Clinical & Research N

Researchers again are noting that along with potential benefit comes risk, especially for frail, elderly patients with dementia on antipsychotics.

BY JIM ROSACK

A new meta-analysis of clinical-trials data appears to confirm a small but statistically significant increase in risk of death associated with the use of second-generation (or "atypical") antipsychotic medications (SGAs) in elderly patients who have dementia.

SGAs have increasingly been prescribed off label in recent years to patients with dementia to help calm agitation and aggression or treat delusions and hallucinations, as well as other behavioral disturbances commonly associated with various forms of dementia, including Alzheimer's disease.

> Concern over the drugs' use in frail, elderly patients has been steadily growing, however, and this past April the U.S. Food and Drug Administration ordered revisions to the labels of all SGAs. Each of the drugs' labels now includes language on the increased risk of death in elderly demented patients within the labels' black-box warnings (*Psychiatric News*, May 6).

The new meta-analysis, completed by investigators at the University of Southern California (USC), appeared in the October 19 *Journal of the American Medical Association*. The meta-analysis was funded with grants from the Alzheimer's Disease Centers of California and the University of Southern California Alzheimer's Disease Research Center.

The report's lead author, Lon Schneider, M.D., M.S., a professor of psychiatry and behavioral sciences at USC's Keck School of Medicine, is also the coprincipal investigator (with the University of Rochester's Pierre Tarriot, M.D.) of the National Institute of Mental Health's Clinical Antipsychotic Trials of Intervention Effectiveness–Alzheimer's Disease (CATIE-AD) study.

CATIE-AD was designed to look at the effectiveness and safety of using antipsychotic medications to control the behavioral disturbances associated with dementia in "real-world" practice settings. Although data collection has been completed in CATIE-AD, results have yet to be

please see ***Atypicals*** *on page 36*

Government News

Part D Formularies Expected to Cover Most Psychiatric Medications

APA is anxious to verify that plan formularies do in fact cover the drugs relevant to treatment of mental illness and substance abuse.

BY MARK MORAN

Prescription drug plan (PDP) formularies under the new Medicare Part D program appear to cover all medications relevant to the treatment of mental illness, including substance abuse, according to a preliminary review of the plans by APA's Office of Health Systems and Financing.

But still there are many bugs in the system that the government has provided for ascertaining more detailed information about the availability of varying dosages, and the kind of restrictions—such as prior authorization or requirements for step therapy—that may apply.

At press time, Irvin Muszynski, J.D., director of APA's Office of Healthcare Systems and Financing, told *Psychiatric News* that the Formulary Finder—the online tool provided by the government at the Medicare Web site <www.medicare.gov>—appears to be deficient.

And Web pages offered by sponsoring PDPs also do not appear to provide sufficient information, he said.

"For us to help physicians and patients make informed decisions about the plans, we need a laundry list of information about plan formularies, including exactly what drugs are included, what restrictions may apply, and related details," Muszynski said. "But when you go to the formulary finder or to a sponsoring plan's homepage, you simply cannot extract all the data elements to provide informed decision support."

"The formularies are much more robust than we had expected. . . ."

A letter from APA to Mark McClellan, M.D., M.P.H., administrator of the Centers for Medicare and Medicaid Services (CMS), outlined concerns about the formulary finder.

In the meantime, Muszynski said the medications most relevant to patients with mental illness and substance abuse appear to be covered. "The plans seem to be relatively inclusive of all the relevant drugs," he said. "What we don't know is whether all dosages and all forms of a drug are available or where quantity limits, prior authorization, or step therapy is indicated."

In the weeks leading up to marketing of PDPs, APA and other advocacy organizations were bracing for potential problems concerning enrollment of "dual eligibles" (individuals who qualify for both Medicare and Medicaid), formulary restrictions, and copayments and deductibles associated with the complex new benefit *(Psychiatric News*, October 7).

More recently, some of those concerns have abated as it appears that the government has made good on its promise that "all or substantially all" medications necessary for the treatment of mental illness, including substance abuse, are included in plan formularies.

At APA's Institute on Psychiatric Services last month, Jeffrey Kelman, M.D., M.M.Sc., chief medical officer at the Center for Beneficiary Services of the CMS, told psychiatrists that "the formularies are much more robust than we had expected, and no class of disease or drug is discriminated against."

Moreover, Kelman said that psychiatrists should expect minimal problems with processing appeals and requests for exceptions to the formularies. He noted that the population requiring antipsychotic drugs, for instance, would be a small part of most PDPs' business and that the expensive and time-consuming process of appeals would make it unlikely that they would put up much resistance. *(Psychiatric News*, November 4).

Muszynski expressed confidence in the good faith of CMS to rectify problems with the Formulary Finder and with the formularies themselves. "We are just anxious to verify what looks to be a relatively inclusive set of formularies," he said.

More information on Part D from APA and its partners is posted at <www.mentalhealthpartd.org/>. ■

Professional News

Prevention Toolkit

As part of its suicide prevention focus, the Substance Abuse and Mental Health Services Administration, in conjunction with the National Suicide Prevention Lifeline (a project of the Mental Health Association of New York City), has produced a free toolkit for crisis centers and other mental health programs that want to increase their efforts in this area.

The toolkit includes press releases that programs can customize, materials to educate local media about suicide prevention programs and resources, and suggestions on how to build partnerships with others interested in suicide prevention.

More information about the toolkit is posted at <www.suicidepreventionlifeline.org/campaign/kit/default.aspx>. ■

Medical Ethics and the Detainees At Guantanamo Bay

BY STEVEN SHARFSTEIN, M.D.

On October 19 at 8 a.m., I climbed aboard a Navy jet with the surgeon general of the United States, the surgeon general of the Army, the assistant secretary of defense for health affairs, and a small group of U.S. medical and psychological leaders. Our destination was the detention camp for suspected terrorists at the U.S. Naval Station at Guantanamo Bay, Cuba.

This visit, in part, came about as a result of a letter I wrote last July to the Department of Defense expressing APA's significant concern about the participation of psychiatrists in providing consultation to military interrogators. I wrote that this participation "could be construed as facilitating treatment of prisoners in a manner inappropriate to psychiatry and possibly in violation of medical ethics." To its credit, the military responded by inviting me and other medical leaders to tour the detention camp firsthand and to have a frank discussion about medical ethics.

Our plane landed at 11 a.m. After a 20-minute boat ride to the naval installation at Camp Delta (a newly constructed prison for 505 detainees from Afghanistan, Iraq, and other Middle Eastern countries), we had a two-hour briefing and a question/answer period with the commander of the Joint Task Force at the base and other base leaders. We then walked through the prison complex, observed the detainee hospital, and viewed the newly opened, almost $3 million psychiatric wing. The med/surg hospital looked like a community hospital, and we met with the highly qualified staff. The psychiatric wing looked "state of the art" for a short-term psychiatric unit. We did not interview any detainees, speak to any detainees' lawyers, or witness any interrogations. We left Guantanamo by 5 p.m.

At 8 p.m. we returned to Andrews Air Force Base and began a spirited three-hour discussion over dinner. I distributed an APA position statement that is awaiting action by the Assembly regarding psychiatric participation on interrogation of detainees. This statement was developed by our Council of Psychiatry and Law, chaired by Paul Appelbaum, M.D., with input from the APA Ethics Committee, the Committee on Judicial Action, the Committee on Misuse and Abuse of Psychiatry, and representatives of military psychiatry. I read aloud from the third paragraph, "Psychiatrists should not participate in the interrogation of persons held in custody by military or civilian investigative or law enforcement authorities, whether in the United States or elsewhere, nor should they provide information or advice to military or civilian investigative or law enforcement authorities regarding the likely consequences of specific techniques of interrogation that are in any way particularized in its application to an individual detainee."

The role of Behavioral Science Consultation Teams in interrogation was a focus of widely read articles in the *New Yorker* and *New England Journal of Medicine* earlier this year.

It quickly became apparent that the APA position (supported by colleagues from the AMA) contrasted with the view of the American Psychological Association. The other APA has taken the position that "[p]sychologists may serve in various national security roles, such as consultant to 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 ethical consideration."

The military health leaders asked us to explain the difference. Why, they asked, might psychiatrists object to participating in interrogations but not psychologists?

In responding for psychiatry, I emphasized our Hippocratic training, our profound ethical obligation to patients, and our abiding concern that such consultation can involve psychiatrists in facilitating deception and cruel and degrading treatment. I argued that the other APA is wrong in permitting skills developed for healing to be used for gaining intelligence. (As the discussion wore on, I thought—but did not say—that such ethical differences between psychiatrists and psychologists are why limits are needed on the scope of practice of nonmedical professions.)

The surgeons general and other distinguished medical military leaders appeared to listen carefully. They were clearly not of the same mind on this subject. Their job is difficult, and they struggle under conflicting pressures. Yet, I continued to urge them to respect medical ethics and bar psychiatrists from interrogation teams as soon as possible.

The other issue we discussed at length was the handling of detainees, called "enemy combatants," who were on a hunger strike. Eleven of these were being fed via NG tubes and were being closely monitored medically. The ethics of forced feeding, the life-and-death issues being confronted, and the status of the detainees were all issues raised and debated.

I made it home at midnight. Soon after closing my eyes, I began to dream of a day when the detention center at Guantanamo Bay could close for good. ■

Professional News

Name Change

The organization long known as the National Alliance for the Mentally Ill (NAMI) changed its name last summer to the National Alliance on Mental Illness..

Bob Carolla, NAMI director of media relations, told *Psychiatric News* that "the change reflects NAMI's long-held commitment to people-first principles—we do not define anyone by their illness." ■

APA Working to Improve Your Membership Experience

BY JAMES H. SCULLY JR., M.D.

Thousands of hours were spent preparing for the implementation of APA's new Association Management System, and our Membership Department staff quickly realized that it was time well spent! It's been more than four months since APA "went live" with the new system, known specifically as TMA Resources Integrated Member Services Solution (TIMSS), and the Membership Department—one of the first groups of new users—quickly adapted to working in the new environment. There are many advantages to the membership component of the system, which gives staff the tools needed for more efficient work, enabling them to provide a higher quality of service to you, our members.

The Board of Trustees recently approved recommendations from the Membership Committee to automate the procedures for members who transfer between district branches, as well as member upgrades from member-in-training to general member status. Beginning in January, these automatic processes will simplify procedures that will now be uniform across all district branches and state associations (DB/SAs).

The automated process will allow our membership staff to contact residency training programs to verify residency completion, as well as verify licensure information. Members-in-training will no longer be required to submit paperwork to advance to general member status. In addition, any change in a member's preferred mailing address will trigger a change in the membership database. The member will also be notified that his or her district branch affiliation has changed. If eligible to continue membership in the former district branch, the member will be given the option to stop the automatic process. Members are not required to transfer, for example, if retired, living in an area other than where they practice, or are members of the Society of Uniformed Services Psychiatrists.

There are other exciting changes in the Membership Department, specifically in the areas of membership recruitment and retention. The Membership Department recently hired Kevin Mills for the new position of membership development manager. In this multifaceted position, Mr. Mills is responsible for all aspects of strategy development and implementation of membership recruitment campaigns, membership retention, and renewal initiatives. He will also develop and manage membership benefits and services. He will be working with district branches, as well as various member components and APA departments to identify collaborative efforts for membership recruitment and retention. He will also develop tools and resources that the district branches can use in their own recruitment efforts.

The Membership Committee has recently appointed work groups for membership recruitment and retention. These working groups will include representatives from the Assembly and the Council on Member and District Branch Relations. APA staff are working closely with them to identify short- and long-term goals and objectives.

One of APA's goals is to provide the highest level of service that consistently exceeds the expectations of our members and DB/SAs, as well the members of the public who contact us for information.

Last fall the Membership Department conducted an online survey of DB/SA staff to collect feedback on member services related to communication with DB/SA staff and membership transactions and processes. In general, most respondents agreed or strongly agreed that communication from the Membership Department was timely, concise, and informative. Most agreed or strongly agreed that membership transactions and processes are handled in a timely and accurate manner. Most also agreed or strongly agreed that the various membership and membership billing reports are meaningful and useful, are easy to read, and provided in a timely manner.

In an effort to further improve support offered to the DB/SAs, the District Branch Outreach Orientation program, developed and conducted by Amira Salinas Cranor, membership and special projects manager, was launched last year to provide membership training for new DB/SA executive staff. The training sessions are held locally, and materials pertinent to district branch membership operations are provided to give the DB/SA staff a complete overview of membership processing. Quick and accurate processing of all membership actions and better service to all current and new members have been the end result. Six DB/SA site visits have been conducted over the past year, and so far the feedback has been extremely positive. Several more visits are being planned for the fall.

We continue to look for ways to improve your membership experience and welcome your comments and suggestions. Please forward your recommendations or questions to me at medicaldirector@psych.org. ■

James H. Scully Jr., M.D., is medical director and CEO of APA.

Association News

Annual Meeting Attendees Can Go Online to Revisit Presentations

Among the speakers whose annual meeting presentations are preserved in the library are Eric Kandel, M.D., Thomas Insel, M.D., and Glen Gabbard, M.D.

BY MARK MORAN

In the digital age, anything that can be taped or filmed can be made to last, literally, forever.

And now some of the best speakers at APA's annual meeting are preserved online in the Association's Online Information Library. Clinicians can listen to and in some cases watch lectures and symposia they missed at APA's 2005 annual meeting in Atlanta, Ga., while receiving continuing medical education (CME) credits.

"Because of technological advances, we can now capture the audio and slides of important sessions at the annual meeting, as well as videos of some sessions, and preserve them as enduring materials for those who were not able to attend the meeting," said Deborah Hales, M.D., director of APA's Division of Education and Career Development.

Hales said even those clinicians who attended the live session and are viewing it online in the "library" for a second time can earn CME credit.

"If you're interested enough to review something again, you can get the CME credits," Hales said. "There's no penalty for studying something again."

Access to nine industry-supported symposia from the meeting is free, as is the special two-part symposium "Neuroscience for the Psychiatrist." APA members can access other materials for a fee of $65, and the nonmember fee is $125.

All of the material in the library is free to anyone who registered for and attended the annual meeting in Atlanta and can be accessed by keying in an annual meeting badge number. Those who attended the meeting but have lost or forgotten their badge number can receive it by calling (703) 907-8666.

Among the stellar presentations that have been preserved in the library are "Human Psychiatric Disorders: Genetic Models in Mice" by Eric Kandel, M.D.; "Stress and the Mind-Body Connection: Lessons From Neuroendocrinology" by Bruce McEwen, Ph.D.; "The Conflicting Worldviews of Sigmund Freud and Oskar Pfister: Keys to Understanding Patients" by Armand Nicholi Jr., M.D.; "Neurobiological Underpinnings of Psychotherapy" by Glen Gabbard, M.D.; and "Psychiatry in the Genomic Era" by Thomas Insel, M.D.

Hales said plans are under way to improve and expand the online library, with significantly more material to be added from APA's 2006 annual meeting in Toronto. "We are trying to move our technology into the 21st century to help our members keep up with what they need to know."

APA's Online Information Library can be accessed at <www.psych.org/am library>. ■

Association News

New Research Submissions Invited For 2006 Annual Meeting

The deadline for new research submissions for APA's 2006 annual meeting is December 2. The annual meeting will be held in Toronto from May 20 to 25, 2006.

The new research format comprises visual, self-explanatory poster presentations on a wide variety of research findings. Data must be generated from new or ongoing research using scientific methods and should not have been published prior to December 2.

All poster sessions will be held in the Toronto Convention Centre. Two are scheduled daily on Tuesday and Wednesday, May 23 and 24, from noon to 2 p.m., and from 3 p.m. to 5 p.m. One session will be held Thursday, May 25, from noon to 2 p.m.

A New Research Young Investigators' Poster Session will held on Monday, May 22, from 9 a.m. to 10:30 a.m. This session provides researchers beginning their careers with the opportunity to discuss their works in progress with colleagues and senior investigators. Research fellows, residents, and medical students who wish to have their work considered for this session should check the box titled "Young Investigators' Poster Session" on the new-research submission form.

The oral/slide format features the top-graded young investigator submissions in one of three special oral/slide sessions. In this format, young investigators will have the opportunity to give a 15-minute presentation and take questions from the audience. These sessions will be held on Monday, May 22, from 1 p.m. to 2:30 p.m.

More information on the new research format is posted at <www.psych.org/edu/ann_mtgs/am/06/2006formatdescript.pdf>. Submission forms can be accessed at <www.psych.org/edu/ann_mtgs/am/06/index.cfm>. ■

Governor Bypasses Legislature, Orders Commitments

New York's governor initiates an administrative program to commit sexual predators to public psychiatric hospitals indefinitely. It follows on the heels of similar changes in the laws of other states.

BY RICH DALY

New York became the first state to enact civil commitment for sexual offenders administratively—a move that has triggered strong concerns among psychiatrists.

After unsuccessfully pushing the New York state legislature since 1998 to pass legislation to allow the commitment of violent sexual offenders to state mental hospitals at the end of their prison terms, Gov. George Pataki (R) issued an executive order to state correction and mental health officials to begin assessing and detaining some convicted sexual offenders.

The move makes New York the first state to refer such prisoners to mental health facilities without a law that specifically authorizes such detentions, and mental health officials said that raises serious concerns.

"As citizens, most of us would be comfortable seeing people properly incarcerated if these are considered crimes," said Barry Perlman, M.D., president of the New York State Psychiatric Association (NYSPA). "What we are concerned about is using the mental health system to solve a problem that seems to spill over to it because the criminal justice system cannot adequately handle it."

Psychiatrists and other mental health advocates said the objections to the governor's initiative include the impact it will have on the already tight budgets of the state's public mental health programs and whether other patients in mental health facilities would be adequately protected from the sexual offenders moved directly from the prison system.

Officials in the governor's office and the Office of Mental Health would not provide details of the program beyond a statement released by the governor's office.

The governor "directed the Office of Mental Health [OMH] and the Department of Correctional Services to push the envelope of the state's existing involuntary commitment law because he couldn't wait any longer for the Assembly leadership to bring his legislation to the floor for a vote," according to the statement.

The governor's initiative "directed that every sexually violent predator in state custody be evaluated for involuntary civil commitment before being released from prison."

Diagnostic Specifics Unclear

State officials have not identified either the diagnoses that would trigger detention nor the types of medical or other personnel responsible for determining commitment. Richard Gallo, state government lobbyist for the NYSPA, was told by state health officials that two OMH psychiatrists must agree on committing an inmate before it can happen.

No figures have been released by the governor's office, but Gallo said state mental health officials told him that by late October, 14 inmates out of 70 evaluated were referred to the state mental health system under the initiative.

The state has begun to identify "appropriate models for treatment" and to hire staff to treat these patients, according to Steven Hoge, M.D., director of the division of forensic psychiatry at Bellevue Hospital Center in New York and a member of APA's Council on Psychiatry and Law, who has spoken informally with state mental health officials.

The patients, according to news reports, will be detained at the Manhattan Psychiatric Center until deemed "safe" by a physician or released by a judge. The state prison system houses more than 5,000 violent sex offenders.

Psychiatrists Have Several Concerns

Richard Rosner, M.D., chair of the NYSPA's Committee on Psychiatry and the Law, said much more information is needed before NYSPA can take a formal position on the initiative. He said government officials need to release more details, including which criteria meet the qualifications for commitment and which facilities will be designated to house committed individuals.

A major concern for Rosner is the budgetary impact this decision will have on the already strained state mental health system.

> **"There are questions about whether people with paraphilia are treatable, but the question of whether they are involuntarily treatable has never been answered."**

Psychiatrists who have spoken with OMH officials said that state officials estimate commitment costs about $200,000 annually for each patient, which includes facilities and personnel but not potential legal costs from court challenges to the program.

"To the extent that the mental hospital beds are filled by people for whom they were not intended, there are fewer of them available for people for whom they were intended," Rosner said. "On the surface it would appear that state psychiatric services are being used in the service of preventive detention, and that is something that is inconsistent with the American criminal justice system."

Another problem the program could create is the further stigmatization of mentally ill individuals, said Jeffery Metzner, M.D., chair of APA's Committee on Judicial Action, which has not taken a position on the initiative. His concern was that any program that mixes psychiatric patients with violent criminals will cause the public to associate mental illness with violent behavior and sexual violence in particular.

Will Treatment Help?

Psychiatrists interviewed for this article repeatedly questioned whether those committed to psychiatric care under the New York program are candidates for treatment.

Research has found widely varying levels of recidivism among sexual offenders, depending on the type of patient. However, no compelling research exists on whether involuntary treatment is effective for sexual predators, according to Gallo and Hoge.

"There are questions about whether people with paraphilia are treatable, but the question of whether they are involuntarily treatable has never been answered," Hoge said.

In 1999 APA's Task Force on Sexually Dangerous Offenders reported that the treatment approach most likely to have an effect on recidivism is multimodal and combines pharmacological, cognitive, and behavioral treatments along with relapse prevention.

To date, 16 states and the District of Columbia have enacted laws to allow author-

please see ***Commitment*** *on page 6*

Psychiatric Input Contributes To Law Restricting Video Games

California takes aim at violent video games with a new law that bans their sale to minors. Supporters hope the measure will remove one influence they believe encourages violence in children.

BY RICH DALY

California has enacted a law banning the sale of violent video games to children, based in part on the recommendation of psychiatrists and mental health professionals.

Last month California Gov. Arnold Schwarzenegger (R) signed legislation barring the sale and rental to people under age 18 of video games that depict serious injury to human beings in a manner that is especially "heinous, cruel, or depraved."

The means the law uses to determine applicable games includes whether a "reasonable person, considering the game as a whole, would find [that the game] appeals to a deviant or morbid interest of minors." Manufacturers distributing games in the future for sale in California will be required to mark games meeting the law's definitions for violence with a large "18."

Retailers who sell violent video games to minors, and manufacturers that do not mark such games, are subject to a $1,000 fine. The measure becomes effective on January 1, 2006.

Nationwide, video game manufacturers have followed the Entertainment Software Ratings Board's voluntary rating system and labeling system, which was instituted in 1994. Its ratings range from "EC" for early childhood to games rated "AO" for adults only.

The law was supported by the California Psychiatric Association (CPA), the California Academy of Pediatricians, and the AMA on the basis of research that showed a connection between depictions of violence and children acting violently shortly after viewing such portrayals.

"It depends on their developmental level, but kids who have not reached the level of formal operational thinking have trouble differentiating these games from reality," said George Fouras, M.D., who is chair of CPA's Child and Adolescent Committee and who testified in the state legislature in support of the bill. "These games teach the kids that certain things are permissible, and they are rewarded for actions that are illegal in our society."

Fouras said that little research has focused specifically on whether exposure to violent video games influences children's behavior, but studies have found connections between exposure to violent media content and short-term violent behavior in children.

Former U.S. Surgeon General David Satcher, M.D., noted in the 2000 "Report on Youth Violence" that a meta-analysis of studies on media violence indicated that "brief exposure to violent dramatic presentations on television or in films causes short-term increases in the aggressive behavior of youth, including physically aggressive behavior."

The surgeon general's report also indicated a small but significant long-term correlation between viewing television violence in children and later aggression. The report further noted that while some evidence suggests that more aggressive children watch more violence and might be more prone to violence, stronger evidence identifies viewing media portrayals of violence as a precursor of increased aggression.

The legislation, AB 1179, received a boost after hidden sex scenes were uncovered this summer in "Grand Theft Auto: San Andreas," and the game's manufacturer pulled it from stores, according to Assembly Speaker Pro Tem Leland Yee (D), a child psychologist and the bill's sponsor.

Randall Hagar, director of Government Affairs for the CPA, said its members supported the legislation because studies have consistently linked children's exposure to entertainment content with behavior.

Hagar said the industry was not effectively limiting minors' access to these violent games, and a February 14, 2004, study in the *Journal of the American Medical Association* found a consistent discrepancy between the voluntary rating system used by the industry and the games' violent content.

Video-game manufacturers opposed the legislation primarily on the basis that it would impinge on their free-speech rights and be difficult for retailers to enforce.

Two video-game trade groups, the Video Software Dealers Association and Entertainment Software Association, filed suit to overturn the law less than two weeks after it had been signed. Schwarzenegger said he will fight the suit.

Several other states, including Illinois and Michigan, enacted similar laws earlier this year, prompting legal fights with the $10 billion video-game industry. Courts have ruled against similar bans in other jurisdictions.

Information on AB 1179 is posted at <www.assembly.ca.gov/acs/acsframeset2text.htm>. ■

Grants Will Foster Integration Of Youth MH Services

SAMHSA grants support state, local, and tribal efforts to move child mental health services away from centralized hospitals and toward community-based mental health programs.

BY RICH DALY

Programs in 20 states that aim to reach more of the estimated 6.3 million youth who need access to community-based mental health services will receive grants totaling $184.5 million over six years, federal officials announced last month.

The Substance Abuse and Mental Health Services Administration (SAMHSA) awarded the grants through 25 "cooperative agreements" to state, local, and Native-American programs that provide community mental health services for children and adolescents with serious emotional disturbances and their families, according to SAMHSA. The program defines "emotional disturbance" as diagnosable disorders that severely disrupt the youngsters' daily functioning in the home, school, or community.

The aim of the grant program, which will distribute $23.5 million in Fiscal 2005, is to integrate a comprehensive array of mental health and support services into a coordinated network that addresses the clinical and functional needs of children and adolescents and provides support to their families. Congress approved the funding in 2004, after extensive APA lobbying.

"Unless provided with appropriate care, these youngsters often experience significant challenges in school and are at high risk of being removed from home and family to institutional settings," said Charles Curie, M.A., SAMHSA administrator, in a written statement.

The program, a component of the Comprehensive Community Mental Health Services for Children and their Families Program, was begun in 1992. It has been popular with federal legislators and the Bush administration, which have kept its funding stable in recent years despite cuts in other areas of mental health, according to Lizbet Boroughs, deputy director of APA's Department of Government Relations (DGR).

APA has long supported continued funding of this program in discussions with members of Congress and appropriations committee staff, Boroughs said. Moreover, each year the Mental Health Liaison Group, of which APA is a member, includes funding recommendations for the grants in its annual appropriations list of mental health services and programs.

The program is also well regarded by budget analysts and scores well in effectiveness in assessments by the federal Office of Management and Budget, according to Boroughs.

"We're very gratified that these grants continue to be funded and be a priority to the administration," said Boroughs. "These grants have been very, very successful."

Since the program was launched in 1992, more than 100 grants have been awarded to state, local, and tribal governments in 49 states, Washington, D.C., Guam, and Puerto Rico, according to SAMHSA; 11 grants were awarded in the past two years.

The largest number of grants were awarded to California, which received four of this year's 25 grants of up to $1 million. The county-administered Medicaid system in that state receives such a large number of the grants because the populous locales aggressively seek additional funding sources, Boroughs said.

Butte County, for example, received $992,919 for the first year to establish wraparound services, such as transportation, educational services, and other needs, as part of what SAMHSA officials described as a "complete system of care" for children with severe emotional disturbances.

Boroughs described the programs that are receivingz the grants as "low-budget, high-impact services" that are rarely funded by Medicaid.

The grants, which are renewable for up to six years, are awarded on the basis that state and local governments will continue to fund the programs themselves at the end of the grant term.

Although the Fiscal 2006 federal budget process remained in flux at press time, the funding for next year's grants appeared likely to remain at about the same level as in Fiscal 2005, according to Boroughs.

Further details on the grants are posted online at <www.samhsa.gov/news/newsreleases/051004_ChildMentalHealth.htm>. ■

Commitment

continued from page 5

ities to confine violent sexual offenders in psychiatric hospitals after their prison terms. Those laws were upheld by the U.S. Supreme Court in 1997 in *Kansas v. Hendricks*.

The APA task force issued a report that opposed these laws to "preserve the moral authority of the profession and ensure continuing societal confidence in the medical model of civil commitment." Such laws misuse psychiatry to detain a class of people preventively for whom confinement rather than treatment was the real goal, the task force stated.

John LaFond, an attorney and author of *Preventing Sexual Violence: How Society Should Cope With Sex Offenders*, told *Psychiatric News* that New York's use of the generic civil commitment statute for this purpose could open it to an "inexorable broadening" of the people to whom it is applied. "A crime becomes the reason to commit, and a past event speaks forever to the present and the future, which is really scary," LaFond said.

Mental health advocates expect a legal challenge eventually from one of the committed inmates affected by the New York program. The NYSPA would consider filing an amicus brief on their behalf, Perlman said.

Pataki's statement on the New York program is posted at <www.ny.gov/governor/press/05/oct24_05.htm>. ■

CEPHALON

P4C

Bills Target Abuses In Residential Facilities

A partially hidden industry offering a controversial approach to teens with psychological or behavioral problems needs better oversight.

BY AARON LEVIN

Residential treatment programs for young people with behavioral or emotional problems need increased state and federal oversight to eliminate abusive and unproven treatment practices, said mental health advocates at a meeting last month at the U.S. Capitol.

While many beneficial programs exist, many others are not accredited or licensed, according to psychologist Robert Friedman, Ph.D., a professor of child and family studies at the University of South Florida in Tampa. "Some of these programs are exploiting the desperation of parents and mistreating the youth they serve."

At a meeting for Capitol Hill staffers, Friedman and others supported one bill (HR 1738) to allocate funds to help states license and regulate these facilities and a second (HR 823, S 380) to end custody relinquishment as a requirement for coverage by public insurance programs.

Few data exist on the number of children sent to such programs or their effectiveness, said Friedman. Regulatory policies vary, with some states requiring licensing and others having no oversight at all. Fewer than 12 states regulate these programs.

At issue are unregulated facilities using methods with no grounding in research or conventional practice, said Charles Huffine, M.D., of Seattle, a past president of the American Association of Community Psychiatrists. These programs offer only cursory assessment of new residents, followed by issuing diagnoses that frighten parents into committing their children to the facility. Young people are isolated from their families and then get unproven, confrontational therapies. Several deaths have been reported, as well.

"Abuse is sold as treatment," said Huffine. "It's advertised as 'behavioral therapy' but as a researcher, I can tell you it has nothing to do with behavioral therapy."

> **"Some of these programs are exploiting the desperation of parents and mistreating the youth they serve."**

Parents often are so desperate for help that they fail to check the credentials of program staff and are easy prey for fearmongering sales tactics. They end up paying thousands of dollars a month in the hope that something will help their children.

Because these are private entities and not public institutions, they function as parental surrogates.

"Kids have no rights and no diagnosis and can be sent away to age 18," said Huffine.

The offending residential treatment programs inhabit a nebulous world where data are not easy to find. Many are set up to avoid regulation by mental health, drug abuse, education, or child welfare authorities, said Maia Szalavitz, a freelance journalist and the author of the forthcoming *Help at Any Cost: How the Troubled Teen Industry Cons Parents and Hurts Kids* (Riverhead Books, 2006), in an interview.

"We have more regulations for chickens then we do for these kids," said Szalavitz.

Even the numbers are hazy. There may be 100 programs of concern, housing 10,000 to 20,000 children, and bringing in $1 billion a year in fees, Szalavitz estimated. Many are based on outdated, abusive "attack therapies" popularized in the 1970s by organizations like Synanon. The programs often promote harsh discipline, deprivation, betrayal of peers, and isolation from family. Some set up branches outside the United States, both to escape regulation and to distance children from parents.

At present, any regulation is up to state attorneys general. In August, the New York attorney general ordered one such boarding school, Ivy Ridge, near the Canadian border, to refund $1 million to parents for "grossly misrepresenting academic credentials." Despite its claims, the school was not accredited and had no authority to issue the 113 high school diplomas it handed out to students. The school is affiliated with the World Wide Association of Specialty Schools, a group of seven schools in the United States and abroad that have been investigated for allegations of child abuse, according to the Salt Lake City *Deseret News*.

Passage of HR 1738, the End Institutional Abuse of Children Act, sponsored by Rep. George Miller (D-Calif.), would provide $50 million to the states to license and monitor programs, establish penalties for child abuse within them, and require the State Department to report any abuse of American children overseas, said Tammi Seltzer, senior staff attorney at the Bazelon Center for Mental Health Law in Washington, D.C. The Government Accountability Office should also investigate treatment practices and credentialing in the industry, said Seltzer.

"For the first time, mental health stood up and opposed these programs," said Szalavitz. "They need to be delegitimized by the psychological and psychiatric establishments."

More information on residential treatment programs for children is posted at http://cfs.fmhi.usf.edu/projects/ASTART.htm>. ■

APA's Minority Fellowships Program Invites Applicants

Psychiatry residents are invited to apply for APA's Minority Fellowships Program (MFP). The MFP provides educational opportunities not only to minority residents, but to all residents interested in providing quality and effective service to minorities and the underserved. The fellowships provide the funds necessary for psychiatry residents to experience a specialized educational program specifically geared toward building leaders in psychiatry. It is also designed to involve fellows in APA's work and give APA the perspective of young psychiatrists.

The MFP fellows are classified into three groups: APA/SAMHSA Fellows (funded by the Substance Abuse and Mental Health Services Administration), APA/SAMHSA Substance Abuse Fellows (funded by the Centers for Substance Abuse Treatment and Substance Abuse Prevention), and APA/AstraZeneca Fellows (funded by AstraZeneca).

SAMHSA and substance abuse fellows receive a fellowship stipend for twelve months based on their postgraduate year and availability of federal funds. AstraZeneca fellows do not receive a stipend; however, travel funds are available to attend specific APA meetings and special projects. AstraZeneca fellows serve for two years.

All applicants must be in their PGY-2 year by July 2006 or PGY-5 year for the substance abuse segment and must be APA members. SAMHSA applicants must be U.S. citizens or permanent residents at the time of application. AstraZeneca applicants need not be U.S. citizens or permanent residents or graduates of a U.S. medical school. Residents interested in the substance abuse segment must be in an addiction training program approved by the affiliated medical school or agency where a significant number of substance abuse patients are from minority and underserved groups.

The deadline for applications is January 31, 2006. More information is available by contacting Marilyn King by phone at (703) 907-8653 or by e-mail mking@psych.org or online at <www.psych.org/edu/other_res/apa—fellowship/cmhs_index.cfm. ■

SAMHSA Funds Efforts to Prevent Incarceration of Mentally Ill People

A jail-diversion grant program is committed to reducing the number of mentally ill persons arrested and tried each year.

BY RICH DALY

A new round of federal grants, long supported by APA, aims to reduce the nearly 800,000 arrests of people with mental illness made each year.

The federal Substance Abuse and Mental Health Services Administration (SAMHSA) will distribute $7.2 million in state grants over three years to divert individuals with mental illness away from the criminal justice system and into community-based mental health services, including substance abuse treatment .

"All too often individuals with mental illness, often with co-occurring substance abuse, are incarcerated instead of receiving treatment for their disorders," said SAMHSA Administrator Charles Curie, M.A., when the grants were announced last month.

The treatment and support services that the grants will fund can reduce the criminalization and incarceration of nonviolent adult offenders with mental illnesses, Curie said.

APA has been a strong advocate of the jail-diversion grant program, which has awarded 26 three-year grants since it began in 2002. The Mental Health Liaison Group (MHLG), which APA helps lead, has reported that research consistently shows that jail-diversion programs are effective and benefit not only individuals with mental illness but also their communities. Researchers estimate that 7 percent of the 11.4 million people arrested each year have current symptoms of mental illness. Three-quarters of those individuals have co-occurring substance use disorders, according to a study in the August 1996 *Archives of General Psychiatry*.

The SAMHSA jail-diversion grant program "should continue based not only on its efficacy, but also because, for people inappropriately warehoused in jails, appropriate and effective community-based treatment is needed now," stated the MHLG's recommendation for federal Fiscal 2006 appropriations.

In 2003 the President's New Freedom Commission on Mental Health recommended "widely adopting adult criminal justice and juvenile justice diversion. . . strategies to avoid the unnecessary criminalization and extended incarceration of nonviolent adult and juvenile offenders with mental illness."

SAMHSA lists more than 300 jail-diversion programs nationwide. The programs include efforts to divert people with mental illness into treatment before formal charges are brought and "postbooking" efforts to identify mentally ill individuals in jail or in court and divert them to mental health programs.

The grant recipients coordinate with social-service agencies to ensure that life-skills training, housing placement, vocational training, job placement, and health care are available to those who are diverted.

The grants funded six programs in five states.

Among the largest grant recipients, New York City will receive $400,000 annually for three years to help the Bronx expand its mental health court and serve 180 more mentally ill individuals annually who are charged with misdemeanor offenses. Services will include Assertive Community Treatment and wellness self-management programs that provide culturally and linguistically appropriate services.

A 2004 SAMHSA-funded study found that these programs reduce the time people with mental illness spend in jail and successfully link diverted inmates to community-based services, without increasing the safety risk to the public.

More information about the grant recipients is posted at <www.samhsa.gov/news/newsreleases/051007_JailDiversion.htm>. ■

HS--CALL FOR PAPERS
P4C

Psychiatrists' Children Often Find Parent's Profession a Mystery

BY SUDEEPTA VARMA, M.D.

I knew I had walked into the middle of something that morning when I saw my co-residents huddled over a computer. It was the Matt Lauer–Tom Cruise interview transcript. Although Tom Cruise still apparently had many women at "hello"—his often-quoted line from "Jerry Maguire"—he had lost me somewhere between break-ups with Nicole and Penelope. When I got to the line, "Psychiatry is a pseudoscience," I had read enough.

Some people say that psychiatry is one of the most misunderstood fields in medicine. But what I have learned is that even family members of psychiatrists fall prey to this misunderstanding. A joke I once heard involved a 10-year-old boy at a party who was asked "What does your father do for a living?" "I'm not sure," he responded. "He goes into his office with pretty women, and comes out with a lot of cash in his hands." The point of the joke was, of course, that his father turned out to be a Manhattan psychiatrist.

At the last APA annual meeting, I had the honor of presenting at a workshop titled Children of Psychiatrists, led by Dr. Michelle Riba, who was completing her term as APA president, and Dr. Leah Dickstein. It was an opportunity for me explore why the field of psychiatry is such an enigma for so many, particularly children of psychiatrists.

I stepped into the conference room and in front of an audience of about 100. There was little time for tachycardia, sweaty palms, or other signs of impending doom. I began with an anecdote that my father had shared with me. As he entered medical school, he envisioned himself a surgeon, but later decided to enter psychiatry. A senior faculty member responded, Satish, you don't have tuberculosis, and you're not mentally ill, so why would you want to go into psychiatry? Well, despite being told in that encounter that psychiatry was meant only for the disabled, my father entered psychiatry that year and never looked back. What is it that is so esoteric and even romantic about psychiatry, especially for children of psychiatrists? My hypotheses: 1) There are no tools of the trade children can hold in their hands, 2) Confidentiality concerns further obscure what little information children do have, 3) Many individuals lack information and understanding about mental illness. Let me further explain these hypotheses.

There are no tools of the trade. Cardiologists have stethoscopes and EKG machines. What do psychiatrists have? In Thomas Maeders's *Children of Psychiatrists and Psychotherapists*, he cites a vignette of a woman who describes an early experience in which she was told to bring something from her father's job to show and tell. She recalls thinking that her classmates had fathers with "real" jobs—the kids brought in drain pipes, circuit breakers, and blueprints. Her father gave her a pad of yellow legal paper, a pen, and a reflex hammer. "I knew that he didn't even use the hammer and was just trying to make himself seem important," the woman recounted. "I decided that my father didn't do anything at all." In psychiatry, there is no process that children can watch, no tools, no product. There is something intangible about psychotherapy for most of us children of psychiatrists, and we are left to wonder what exactly happens behind those closed office doors?

Issues of confidentiality and privacy make it difficult for psychiatrist parents to talk about specifics with their kids. Also, as children of psychiatrists visiting our parents at work, we often find it to be bland. Family pictures are absent. There are often special rules for home offices—children must be quiet when nearby. A couch replaces the more familiar examination table.

Stigma and misunderstanding present as additional barriers to understanding psychiatry. One of my supervisors, while taking her son to school, ran into a patient of hers. The child was surprised to find out that the woman was a patient. But mom, she looked so normal, the child responded. Many children—and not just those of psychiatrists—have the misperception that all patients with mental illness are locked away in wards and engage in bizarre behavior; they fail to see them as people with jobs and families—as people seeking help for an illness.

As my talk came to a conclusion on that hot Atlanta morning, I was glad I decided to participate, sweaty palms and all. I learned that for parents who are psychiatrists, communicating with one's child about mental health is extremely helpful in the demystification process. And I found that one of the most important things a parent can pass on to his or her child is their own passion in life. So even though your child may not become a psychiatrist, at least he or she will know that you gave them that gift. ■

Sudeepta Varma, M.D., is a PGY-3 psychiatry resident at New York University School of Medicine.

Directory Available

The 2006 *Membership Directory* of the National Association of Psychiatric Health Systems is now available. It is designed to identify sources of help for individuals with psychiatric and addictive disorders.

The directory includes the name, address, phone/fax, and names of officers of behavioral health systems throughout the country. The facilities operated by each system are also listed. Facilities are also listed according to geographic location.

Copies can be ordered by calling (202) 393-6700, ext. 106; the cost is $35, which includes shipping and handling. ■

Insurer Pays Millions to Settle Lawsuit by Physicians

In addition to monetary settlement, Humana has agreed to use a definition of medical necessity that acknowledges that patients are entitled to medically necessary care as defined by a physician.

BY MARK MORAN

Health insurer Humana Inc. reached an agreement with representatives of more than 700,000 physicians to settle a nationwide class-action suit pending in the U.S. District Court in Miami.

The suit was brought against several health plans under the Racketeer Influenced and Corrupt Organizations (RICO) Act and has been led by the California Medical Association (CMA). Filed five years ago, the class-action suit accuses several for-profit HMOs of using coercive, unfair, and fraudulent means to control physician-patient relationships.

In the ensuing years, physician associations in Connecticut, Georgia, Louisiana, Texas, Florida, and other states have joined with the CMA.

According to a statement released by the company, Humana has agreed to pay $40 million to physicians and up to $18 million in legal fees to be determined by the court.

"Humana is pleased that we have been able to reach an agreement to settle this litigation," said Michael McCallister, Humana's president and chief executive officer. "We have devoted significant time and resources to improving the quality and timeliness of our transactions with physicians who care for our health plan members. Humana has undertaken systems and infrastructure improvements in connection with how the company relates to providers, enhancing, among other things, the speed and accuracy of claims reimbursement to providers and setting the stage for real-time adjudication of claims filed electronically. This has all been part of Humana's ongoing efforts to strengthen its collaborative relationships with providers."

The Connecticut State Medical Society (CSMS) released a statement about the settlement noting that, in addition to the monetary component of the settlement, physician groups and Humana have agreed to "new levels of transparency and communication." Below are some of the provisions to which Humana has agreed, according to CSMS:

- A definition of medical necessity that ensures patients are entitled to receive medically necessary care as defined by a physician.
- Use of coding standards including use of the AMA's *CPT*.
- Establishment of an independent, external review board for resolving disputes with physicians concerning many common billing disputes.
- Payment of valid clean claims within 15 days for claims submitted electronically and 30 days for claims submitted on paper.

At press time, the agreement still had to be approved by U.S. District Judge Federico Moreno.

The settlement by Humana follows one in July by Wellpoint *(Psychiatric News*, August 5). In that settlement, Wellpoint agreed to use a patient-friendly definition of medical necessity and to cease using software programs that systematically lowball or deny payment for legitimate patient claims.

The Wellpoint settlement also provided $135 million in direct payments to physicians to resolve allegations of unfair reimbursement for more than a decade. Previous settlements had been reached with Aetna, Cigna, Prudential, and Health Net *(Psychiatric News*, July 16, 2004; October 15, 2004).

In addition, Wellpoint agreed to apply the "patient-friendly" definition of medical necessity outlined in the settlement to mental health care, including substance abuse, and to treat participating psychiatrists like other participating physicians with respect to provider directories and referrals.

"We have a good settlement in terms of psychiatric services being treated the same as other services," psychiatrist Catherine Moore, M.D., a member of the CMA Board of Trustees, told *Psychiatric News* at the time. "This kind of action shows the importance of physicians working together so that we can more effectively fight these huge businesses that are taking us to the cleaners." ■

Applications Invited

The APA Office of Children's Affairs welcomes applications for the 2006-07 APA/Shire Child and Adolescent Psychiatry Fellowships. The application deadline is December 9. The fellowships will be awarded to five residents to travel to two APA annual meetings and to work with mentors on issues in child and adolescent psychiatry.

This program is designed to promote interest in child and adolescent psychiatry by introducing residents to new clinical research and to successful public programs for the treatment of seriously mentally ill children and adolescents. Fellows will have opportunities to meet and network with leaders in child and adolescent psychiatry.

The APA/Shire Child and Adolescent Fellowship is open to PGY-1 through PGY-3 residents. Applicants must be an APA member and have approval by their training director or department chair.

Applications must include a completed application form; a statement of interest from the applicant that gives a detailed outline of his or her experience, knowledge, and interest in child and adolescent psychiatry; a curriculum vitae; and a letter of support from a residency training director or department chair that describes the resident's potential contribution to the field.

This program is supported by an unrestricted educational grant from Shire Pharmaceuticals, overseen by the APA Council on Children, Adolescents, and Their Families, and administered by Jane Edgerton, project manager of the Office of Children's Affairs.

Application materials are available online at <www.psych.org/edu/res_fellows/2006APAShire.pdf>. Additional information is available by phone at (703) 907-8579 or e-mail at kids@psych.org. ■

MH Education Should Be Tailored to Minorities' Values

Implementing culturally competent methods of helping families requires looking at the world through their eyes, says an award-winning psychologist.

BY KATE MULLIGAN

Christopher Amenson, Ph.D., offered a telling example of the hazards of assuming that Euro-American strategies to help families cope with mental illness will be universally applicable.

In many cultures, he said, people are reluctant to go to strangers when they are in trouble. Reaching out beyond the extended family for support or even information can be viewed as evidence that the entire family has failed. Yet self-help groups are premised on the idea that unrelated people who share a serious problem can provide valuable help to each other.

In the lecture "Outcomes for Psychoeducation for Diverse Patients," Amenson told attendees at APA's 2005 Institute on Psychiatric Services about the impact of the disconnect between Euro-American values and practices and those of other cultures on efforts to provide education to families affected by mental illness.

He is faculty chair of the Pacific Clinics Institute, which provides education and training promoting recovery for people with serious mental illness. The institute serves an ethnically diverse population in southern California.

The National Alliance on Mental Illness gave Amenson the Outstanding Psychologist award in 2001 for his work with families who are caring for a person with mental illness.

Amenson told the audience, "Remember a basic principle of psychotherapy: 'Begin where the patient is.' We need to apply that idea to family psychoeducation as well."

Disproportionately few families of color participate in family psychoeducation programs, he said, but outcomes can be as positive as those for Euro-American families when the programs are tailored to reflect the participants' cultural values and practices.

Such tailoring begins with methods of recruitment. Recognize the importance of personal connections in encouraging a family or individual to seek help, he advised.

Neither brochures nor invitations to educational meetings are effective outreach methods among members of some cultures, said Amenson. "Invite families to a 'get-acquainted' social event," he suggested. Working through community and religious leaders has been successful in his experience to encourage participation.

The need for a social exchange is important even at the first encounter with an agency. "The person who answers the phone should be willing to spend several minutes chatting with the caller rather than merely trying to schedule an appointment," he said. "You might get only one chance with that family."

Acknowledgement of the existence of cultural differences has also been an effective strategy for Amenson. He tells families on the first visit about an instance in which his well-intentioned actions offended a family because of his unfamiliarity with their significance in that family's culture.

Amenson contrasted Euro-American values of independence and autonomy with those of other cultures that emphasize harmony and family unity. Rather than trying to promote independence from the family for the person who is ill, a therapist should try to build on the family's strengths and use community supports to help the person find a more satisfying life within his or her cultural framework.

"It's hard to get into a family, but it's also hard to get out. . . . You are part of the family forever."

Amenson gathered more than 40 members of an extended Latino family together in a Los Angeles backyard to develop strategies to help a young man with schizophrenia. The man's sister realized that he could safely serve as a babysitter for her children. His brother arranged for him to become an unpaid manager of a soccer team.

A prayer group at the man's church "adopted" him and enabled him to sit through services without becoming a distraction. The priest gave him volunteer work as a gardener, after seeing changes in his behavior. After a year of improvement, a grocer, who had attended the initial backyard meeting, offered the young man a paid job stocking shelves.

"The young man never attended a session at the clinic," Amenson said. "Instead we used the natural supports in the environment."

Amenson pointed out one final challenge in working with some families of color. "It's hard to get into a family, but it's also hard to get out. . . . You are part of the family forever. People will come to you for advice because you have become the 'family helper.' "

The rewards, however, are "tremendous." A success with an extended family of color can be "greater and more profound," he said, because change affects such a large network of people.

Information about Pacific Clinics Institute is posted at <www.pacificclinics.org>. ■

Patient Advocate Crusades to Give 'Image Makeover' to Mental Illness

In the 1960s, Frederick Frese was warned to prepare for a lifetime in a psychiatric hospital. About 40 years later, he ended up on national television, educating millions of people about schizophrenia.

BY KATE MULLIGAN

Frederick Frese III, Ph.D., opened his plenary session speech at APA's 2005 Institute on Psychiatric Services by urging everyone in the audience with a serious mental illness to stand.

Nine or 10 people got to their feet in a crowded ballroom last month in San Diego.

Frese thanked his "fellow SMI friends" and said, "I know that. . . many others have it. That's where I was for many years. . . keeping a secret. But I'm not going to stand in the shadows. I'm not going to be belittled. I'm not going to be ashamed."

"Blending Consumer, Family, and Professional Perspectives on Recovery from Serious Mental Illness" was a call for an "image makeover" for those who have been subjected to various forms of stigma and discrimination and urged to reconcile themselves to the idea of a lifetime with a debilitating disease.

Frese was told to abandon hope of recovery from schizophrenia when he was hospitalized during the 1960s at a state psychiatric hospital in Ohio. He recounted the following conversation:

Doctor: "Have you ever been hospitalized for very long?"

Frese: "Yes, sir, for five months."

Doctor: (smiling) "I'm smiling because five months isn't long at all. You have a degenerative brain disease that will only get worse with time. You will spend the rest of your life under the care of the state hospital."

Thorazine was the only medication available at the time. Frese now suffers from tardive dyskinesia.

Look at the movies, he told the audience, if you want to understand why "we need a makeover."

The American Film Institute recently listed the 50 "greatest movie heroes" in the last 100 years. Leading the list were such iconic figures as Indiana Jones and Atticus Finch. No person with a mental illness was cited, but they were represented on the list of villains.

There are signs of change. Frese mentioned "A Beautiful Mind" and "The Aviator" as movies that suggest a more positive and accurate depiction of serious mental illness and the contributions of people who have it. He told the audience that "Proof," a play that offers a complicated portrayal of mental illness, currently is the most widely performed play in the world. Kay Redfield Jamison, Ph.D., has helped to destigmatize bipolar disorder with the book *An Unquiet Mind*, in which she describes her own experiences with mental illness.

Frese's own life provides evidence of changed attitudes toward those with serious mental illness and of the contributions a person diagnosed with schizophrenia can make *(Psychiatric News*, March 19, 2004).

He earned his Ph.D. in psychology and has worked for more than 30 years helping people with serious mental illness.

Frese founded the Community and State Hospital Section of the American Psychological Association and serves on the boards of the National Alliance on Mental Illness and the Treatment Advocacy Center.

He has appeared on CNN and "World News Tonight" with Peter Jennings and is featured in the video "I'm Still Here: The Truth About Schizophrenia."

Frese told the audience, "When I was hospitalized, I thought that someday I might write about this, but never in my wildest dreams did I expect to appear on national television."

He also has helped to develop crisis-intervention teams and other methods of improving the interaction between the criminal justice system and people with mental illness in Ohio.

Evelyn Lundberg Stratton, a member of the state's Supreme Court, spearheaded the activities when her 12-year-old son was hospitalized as a result of a serious mental illness and she began to learn about the various disorders and their effects on families.

Frese talked to "dozens of judges" about serious mental illness and helped with the training of police officers.

He termed his work with the Treatment Advocacy Center (TAC) "more controversial." The TAC has been active in promoting legislation such as Kendra's Law in New York, which permits involuntary outpatient treatment under certain conditions. ■

Ellen Dallager

Frederick Frese III, Ph.D.: "I'm not going to stand in the shadows. I'm not going to be belittled."

Professional News

Suicide-Prevention Film

A film aimed at preventing suicide among college students is available from the American Foundation for Suicide Prevention. "The Truth About Suicide: Real Stories of Depression in College" provides information about depression, including its symptoms and association with suicide, and encourages students to seek help if they suspect they have a problem.

The film is available in both DVD and VHS formats and comes with a facilitator's guide containing supplementary resource materials and recommendations for using the film effectively on campus.

Orders may be placed by calling (888) 333-AFSP, ext. 10. The cost is $19.95, including shipping and handling. More information and resources are posted online at <www.afsp.org/collegefilm>. ■

AACAP President Shifts Focus To 'Old-Fashioned Constructs'

A focus on sound basic principles will guide AACAP thru the next two years of challenges.

BY JIM ROSACK

The American Academy of Child and Adolescent Psychiatry (AACAP) teamed up last month with its counterpart to the north, the Canadian Academy of Child and Adolescent Psychiatry (CACAP) to host a joint annual meeting in Toronto.

With more than 3,500 in attendance, the meeting was one of the largest held in North America to focus on child and adolescent psychiatry. Joining more than 1,540 AACAP members were 180 CACAP members and nearly 1,800 nonmembers.

Once again this year a major challenge being faced by the two academies is the significant shortage of child psychiatrists, both above and below the border. Echoing previous AACAP meetings, a large number of sessions focused on the need to increase access to quality mental health services for children and teens through partnerships with primary care and family physicians as well as pediatricians.

As at prior AACAP meetings, several sessions focused on the need to improve diagnosis and treatment of seemingly burgeoning number of children with attention-deficit, depressive, and bipolar disorders. And issues of use of psychiatric medications in pediatric patients were paramount, with concerns about safety and efficacy of medications a topic of many sessions. (More coverage of these topics will apear in a subsequent issue of *Psychiatric News.*)

Returning to Core Principles

However, rather than remaking the child mental health care system to meet impending challenges, incoming AACAP president Thomas Anders, M.D., a professor of psychiatry at the University of California-Davis, declared he would devote his two-year term to "continuity and stability, rather than challenge and change. I would like," he said, "to focus on the importance of a few old-fashioned constructs that have served us well."

Anders proposed to "translate a few key constructs from psychiatry's early days into action plans for today." These translations, he said, "will sustain continuity and stability" in the field of child mental health services. Anders went on to invoke the memory of Sigmund Freud who, like Anders, was born in Vienna, Austria.

Freud, he said, was "first and foremost, a neurobiologist," and would, Anders said, "employ the latest available neuroscience technologies and techniques," had he been practicing today. While many of his theories have been "largely and appropriately discredited," Anders said, "Freud should be remembered as an astute clinician and an observant scientist whose constructs stimulated many of the baby-watchers, experimental psychologists, and developmental neuroscientists who have followed."

Freud, Anders continued, left three "enduring insights about the mind." The first was the notion that some behaviors and emotions were instinctive in origin—a concept furthered by others and expanded to say that some behaviors and emotions are genetically influenced. Second, Freud recognized "the importance of early childhood experience" and described "infantile traumas." Third, Anders concluded, Freud taught psychiatry much about the importance of transference.

All three constructs, Anders said, continue to shape the practice of child and adolescent psychiatry. "We remain mind-brain scientists who use models of mind to understand the complexities of behavior."

Stigma Still Stubborn Challenge

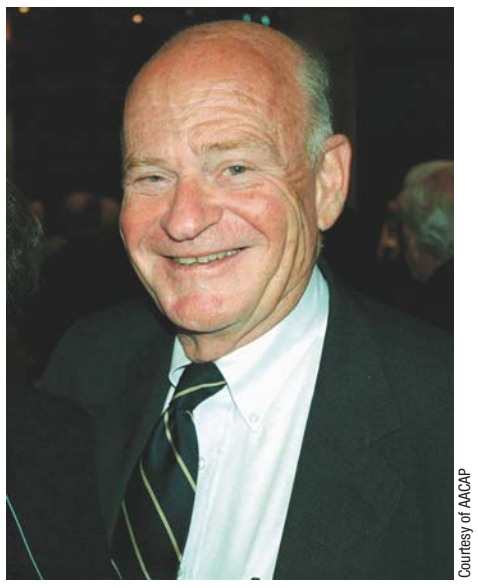
A primary "mind construct" challenging child and adolescent psychiatry today, Anders said, is stigma. "Is it not stigma that, in part, accounts for the lack of interest in, and understanding of, our field by our professional colleagues and the public at large?"

The stigma associated with "mental illness and with our profession is one likely reason for our workforce shortage." Stigma must be addressed directly, Anders said, by "educating all levels of society about the value of our work, the scientific foundations of our knowledge, and the efficacy of our treatments." One way to do this, he said, "is to ally ourselves with parent groups and self-help groups. We as professionals need to partner with a broad range of interest groups focused on reducing stigma."

The child and adolescent mental health profession, Anders declared, "must do something about this dire circumstance because we do know what is needed and what consequences result if our children's developmental needs are not met. We must become more successful, culturally sensitive, international activists."

Child and adolescent psychiatrists in the United States, Anders said, should be active advocates for passage of the Child Healthcare Crisis Relief Act (S 537), which would provide incentives for more professionals to enter the child and adolescent mental health field. In addition, current child and adolescent psychiatrists must "nourish our young," he stated, mentoring and guiding aspiring medical students and residents to choose child psychiatry as their subspecialty.

"Passing on our skills, love of our profession, and the excitement of our field remain critically important activities for each and every one of us," Anders said.



Courtesy of AACAP

Thomas Anders, M.D.: "Passing on our skills, love of our profession, and the excitement of our field remain critically important activities for each and every one of us."

During his two year term as AACAP president, Anders said he will work to reduce stigma, advocate for "psychologically healthy beginnings," and access to quality care for all children.

These goals, he said, are not new, but in fact quite old. However, they are perhaps, "all the better for their maturity."

More information on AACAP and its annual meeting are posted at <www.aacap.org>. ■

Suicidality Self-Reports May Be Key Component of Depression Evaluation

Rates of suicidal thinking among depressed adolescents on medication are comparable to those in their peers who are in psychotherapy. Self-reports strongly predict emergent suicidality.

BY AARON LEVIN

Depressed adolescent outpatients receiving psychotherapy but not medication displayed rates of emergent suicidality comparable to those reported in antidepressant trials, according to a new study.

Self-reported ideation at intake was the best predictor of eventual suicidality in that group, wrote Jeffrey Bridge, Ph.D., and four colleagues at the Western Psychiatric Institute and Clinic of the University of Pittsburgh Medical Center, in the November *American Journal of Psychiatry.* Self-report is often more accurate than interviews about sensitive topics like suicidal thoughts, sexual behavior, and substance use, they concluded. The study was funded by the National Institute of Mental Health (NIMH).

"Suicidality is fairly common among depressed kids, even when they are getting psychotherapy without SSRIs," said study coauthor David Brent, M.D., in an interview. "Many kids deny suicidality on interview but admit to it on self-report."

The researchers defined suicidality as a rating of at least 4 on the K-SADS suicide ideation item—suicidal ideation with a plan or an actual suicide attempt.

The emergence of suicidality probably could not be attributed to treatment, but rather to the "specific and systematic assessment" of self-reported suicidality, according to Bridge and his colleagues. Usually clinical trials rely on participants or investigators to report adverse events after they occur.

"These findings raise methodological issues for the design and interpretation of psychotherapy and pharmacotherapy treatment trials of depression in young patients," wrote the researchers.

Self-report is a reasonable source for information, but must be balanced by the knowledge that adolescents are notoriously volatile regarding suicidality, said Howard Sudak, M.D., a clinical professor of psychiatry at the University of Pennsylvania.

"We think of suicide as falling along a continuum from ideation, to planning, to attempt and completion," said Sudak in an interview. "The hardest to evaluate is ideation, but 60 percent of high school students have had ideation at some point."

Bridge and colleagues recruited 107 subjects aged 13 to 18 who were diagnosed with major depressive disorder and scored 13 or higher on the Beck Depression Inventory. Patients were randomized to cognitive-behavioral therapy, systemic behavioral therapy, or nondirective supportive therapy. Treatment assignment, age, sex, race, and socioeconomic status had no effect on outcomes. The only significant predictor of emergent suicidality was a higher score on Beck Depression Inventory item 9. Of the 107 patients, 88 denied current suicidality the week before evaluation, and 11 of that group developed suicidality during treatment. One attempted suicide.

Self-reported suicidality in the week before intake was a better predictor than information gained in the intake interview, treatment assignment, cognitive distortion, or depression severity, wrote the researchers. "Self-report may be a necessary component to the assessment of adolescent suicidal risk."

Future clinical trials of therapies for depression in adolescents should evaluate self-reported suicidality at intake and consider balancing treatment arms on that basis, they concluded.

Brent's study represents a useful starting point, said Sudak, but he would like to see larger, more definitive studies with matched controls in and out of therapy.

"I'd like to know what the base rate is in an untreated population and compare it to patients in therapy or on drugs," he said, especially in light of the U.S. Food and Drug Administration's black-box warning about suicidality among antidepressant users.

"The studies that produced the black-box warnings had nothing to do with deaths by suicide, just ideation and attempt," said Sudak, who favors using SSRIs and SSNIs in appropriate candidates for treatment. "I'm happy to see another study that seems to indicate that we are overreacting. I think more harm is done by discouraging practitioners from using these drugs when they should use them than would be engendered by using them."

"We are going to look at this type of analysis in a multisite study, called TORDIA (Treatment of Resistant Depression in Adolescents) funded by NIMH, which will be completed in about one year," he said. "One exciting thing about that study is that we will have drug and metabolite concentrations on almost all the subjects."

An abstract of "Emergent Suicidality in a Clinical Psychotherapy Trial for Adolescent Depression" is posted online at <http://ajp.psychiatryonline.org/cgi/content/full/162/11/2173?>. ■

Mental Health Issues on Agenda For Troops Back From Gulf Coast

BY ANNETTE MATTHEWS, M.D.

Over the course of a week I got almost daily e-mails asking me to help with a "reintegration session." The approximately 1,300 Oregon National Guardsmen who had been sent to Louisiana to help in the Hurricane Katrina efforts have been coming home in waves of 200-500 soldiers and needed a "debriefing," including information on the mental health effects of their experience. My role was to talk with them about mental health problems that might arise after their return.

Eager to volunteer, I found myself somewhat frustrated that the dates and times that they were to land and be debriefed kept changing. It made it hard to put into my not-so-flexible schedule. As I complained, someone said to me, "How do you think the guardsmen feel?"

Indeed, they have more to grouse about than I do. Their Louisiana call-up began right before the Labor Day weekend. Usually the last sunny weekend in Oregon, before the six months of darkness and rain that is our winter. This is the last time to go fishing, or heat up the barbecue, take that trip to the ocean, or go boating on the river. All this traded for the mission of going to Louisiana to help in rescue and recovery efforts.

I asked one of my colleagues if he wanted to go to the reintegration seminar with me. He asked, "What would we do?" I had to tell him that I really did not know. All I knew was that we had to talk about mental health, but the details of what we needed to say were unknown to me. I had never been a psychiatrist in a time of war or natural disaster. "Military reintegration" was not a rotation I had had in my residency training program. It occurred to me that professionally we may sometimes be challenged with experiences for which no amount of training will prepare us.

I had done my homework, however, by the time my day came. I drove out to the airport, to the National Guard Armory. The gymnasium-like drill floor was set up with stations: check-in, medical, travel pay, address change. All the stations had to be checked off, or the guardsmen would not be allowed to leave the building to return home. Tables were filled with lunch bags that included food donated by local organizations. The guardsmen landed in commercial airliners on the National Guard airfield and then were bused to the base.

They started to trickle in, and then flood. All of them were wearing uniforms in shades of sandbox tan. A few still wore their camel backs that allowed for instant access to water. Most carried machine guns, some had flags, one a map, and one a giant green stuffed frog with Mardi-Gras beads wrapped around its neck. Most were young, but some were older. Most were not veterans of any war, though a few had been to Iraq, Afghanistan, or even Vietnam. The vast majority were men, but interspersed among them were a few women.

In a classroom across from the gymnasium was the station where the guardsmen would be briefed by the judge advocate general about legal issues, an employment specialist about returning to previous jobs, the Department of Veterans Affairs about health services (including mental health services), and the chaplain. Groups of 50-75 cycled through. The theme of these talks was that if you are having a problem, it is better to get help sooner rather than later.

I presented my part five times during a period of about four hours, but the other presenters had been there for days repeating their information over and over. For my part, I described what some of the normal symptoms of readjustment are, including readjusting to home life and dealing with both good and bad memories of the mission. I also reviewed some of the symptoms, such as poor sleep, increased irritability, increased substance abuse, and marital and work problems that might signal the need for mental health care.

For psychiatry residents and others who are looking for ways to volunteer to help with the aftermath of the Katrina and Rita disasters there is a wealth of ideas and resources on the APA Web site at <www.psych.org/disasterpsych>, National Center for PTSD Web site at <www.ncptsd.org>, and others. One way to help is to support the work of first responders such as police, firefighters, search-and-rescue teams, and in this case, the National Guard.

It had started to rain in Oregon while the reservists were away. I watched them line up outside on the tarmac to get their mission ribbon. Welcome home and thank you. I heard on the news that the same guardsmen will be redeployed in nine months to Afghanistan. I thought that nine months seemed to be an awfully short time before they had to be ready to face even more crises and trauma. ■

Annette Matthews, M.D., is a psychiatrist at the Portland VA Medical Center, an APA/Bristol-Myers Squibb Fellow in public and community psychiatry, and an early career psychiatrist.

APA Awards Innovative MH Service Programs

APA presented its annual Psychiatric Services Achievement Awards at its 2005 Institute on Psychiatric Services last month in San Diego to innovative programs that deliver services to mentally ill or disabled people, have overcome obstacles, and can serve as models for other programs. This annual competition, begun in 1949, is supported by a grant from Pfizer Inc.

The 2005 awards, selected from a field of 54 applications, were presented by Debbie Carter, M.D., chair of the awards committee. All winning programs participated in a special workshop at the institute.

Gold Award winners were presented with a $10,000 check and plaque; Silver Award winners in the other categories received a plaque.

Ellen Dallager

Aaron Kuzemka (left) of Pfizer Inc. presents a check for $10,000 to Sam Tsemberis, Ph.D., executive director of Pathways to Housing Inc. in New York City, winner of the 2005 Gold Award for community-based programs. Alexa Whoriskey, M.D., Pathways' medical director, holds the plaque.

Ellen Dallager

Aaron Kuzemka (second from left) of Pfizer Inc. shakes hands with Andrew S. Pomerantz, M.D., chief of the Primary Mental Health Care Clinic of the White River Junction VA Medical Center in Vermont, the winner of the APA 2005 Achievement Award for academically or institutionally sponsored programs. Looking on are Debbie Carter, M.D., chair of APA's 2005 Achievement Awards Committee, and Brady Cole, codirector of the clinic.

Gold Awards

• **Primary Mental Health Care Clinic** at the White River Junction VA Medical Center in White River Junction, Vt., won in the category of academically or institutionally sponsored programs. The program was recognized for "its unique application of a model to provide comprehensive psychiatric care within a primary care setting and improve treatment engagement."

• **Pathways to Housing Inc.** in New York City won the Gold Award in the category of community-based programs. The award was accepted by Sam Tsemberis, Ph.D., and Alexa Whoriskey, M.D. Pathways to Housing was selected for the "exemplary success of [its] housing first program in the provision of permanent housing and treatment services for adults with severe mental illness and co-occurring substance use disorders."

Silver Awards

• **POPPA (Police Organization Providing Peer Assistance)** in New York City was recognized for "outstanding commitment to providing confidential peer-based counseling to police officers and families affected by traumatic events and work-related stressors." Frank Dowling, M.D., and Bill Genet accepted the award.

• **World Trade Center Healing Services/Child and Adolescent Program** at Saint Vincent Catholic Medical Center in New York City was recognized for "exemplary success in the provision of expert trauma treatment to students with stress-related symptoms and post traumatic stress disorder as a result of the terrorist attacks of September 11, 2001, and other traumatic events." Lea Defrancisci, M.D., accepted the award.

More information about the 2005 winners is posted at <http://psychservices.psychiatryonline.org/current.shtml#/ARTICLES>. Information about the 2006 Achievement Awards competition is available from Mary Ward at (202) 907-8592 or mward@psych.org. ■

Drug Maker Enhances Health Care Education Effort

Lilly's outreach effort benefits mental health advocacy and people with mental illness.

BY TARA BURKHOLDER

Eli Lilly and Co. has launched a public outreach initiative called Putting Patients First that promotes the company's desire to address the needs of patients and families in its health care initiatives.

As part of this campaign, visitors to Lilly's booth at APA's 2005 annual meeting were given a token that they could use to support one of several philanthropic organizations. Each token represented a $5 contribution to the chosen charity. The organizations that received contributions included the American Psychiatric Foundation, National Mental Health Association, National Alliance on Mental Illness, and World Federation for Mental Health and Families for Depression Awareness. The foundation received $20,000.

"We are extremely grateful to Eli Lilly and Co. and to all attendees at the annual meeting who participated in this effort. In addition to providing needed funds to further the foundation's mission, this effort helped to raise awareness of the foundation and our work to educate the public about mental illness," said Altha Stewart, M.D., president of the American Psychiatric Foundation.

The American Psychiatric Foundation is APA's philanthropic and educational arm. The mission of the foundation is to advance public understanding that mental illnesses are real and can be effectively treated.

More information is posted at <www.psychfoundation.org>. ■

Altha Stewart, M.D.: "This effort helped to raise awareness of the foundation and our work to educate the public about mental illness."

Tara Burkholder is the marketing communications manager of the American Psychiatric Foundation.

PSYCHIATRIC PRACTICE & MANAGED CARE
APA OFFICE OF HEALTHCARE SYSTEMS AND FINANCING

New Web Site Provides Guidance on Part D

A new Web site was launched by APA and its partners last month to provide information about the new Medicare Part D prescription drug benefit. The site, <www.mentalhealthpartd.org>, is concerned with the issues faced by enrollees who need medication for mental illness and by their families. It also provides information for two groups to whom patients will turn for assistance in selecting a prescription drug plan (PDP): psychiatrists and other physicians and providers at community behavioral health and integrated health centers.

In addition to APA, the Web site is a joint effort of the National Mental Health Association, National Council for Community Behavioral Healthcare, and the Treatment Effectiveness Now project; it is also sponsored by these organizations, along with the American Association of Community Psychiatrists, National Alliance on Mental Illness, National Association of State Mental Health Program Directors, and American Association for Geriatric Psychiatry.

Irvin L. "Sam" Muszynski, J.D., director of APA's Office of Healthcare Systems and Financing, was a prime mover behind the creation of the Web site.

Said Muszynski, "We've been working with other mental health groups for over two years, originally to do what we could to affect how medications for mental illness would be dealt with under Part D, and later to determine what we could do as a coalition to help our various constituencies cope with the changes that Part D will bring. A Web site seemed like the best way to keep everyone apprised of the latest information as it becomes available and to have a central place where clinicians can find provider decision support tools."

Muszynski noted that the coalition was apparently successful in getting the Centers for Medicare and Medicaid Services (CMS) to provide special protections for coverage of medications used to treat mental disorders. Antidepressants, antipsychotics, and anticonvulsants are among the six categories of medications that CMS has said should be represented on all PDP formularies by "all or substantially all" of the medications available. For other categories, PDPs are required to have only two drugs available in each.

Muszynski warned that "all or substantially all" may prove to be less inclusive than it sounds. He noted that CMS made it clear that this means that "all or substantially all" of the medications available must appear on each formulary in some form or other—it does not mean that every dosage and form of each medication have to be available. "We are hopeful that the actual formularies will match CMS's intent," said Muszynski.

On the up side, CMS made it clear in meetings with APA that PDPs are to assume that Part D enrollees who seek refills for drugs under their new drug coverage have been stabilized on their current regimen and should continue to be provided with these necessary drugs regardless of their formulary status. Again, Muszynski warned that this directive may not be quite as good as it sounds because CMS has not codified it, and it is unclear how it will be enforced.

In mid-October, the official Medicare Prescription Drug Plan Finder went live at <www.medicare.gov>. If you scroll down the homepage, you will find the options "Compare Medicare Prescription Drug Plans" and "Formulary Finder."

The option "Compare Medicare Prescription Drug Plans," also known as the Plan Finder, allows you to conduct either a personalized search for apppropriate PDPs for a specific patient by entering that patient's Medicare information or to conduct a general search that produces a list of available plans in your region. One search method does not appear to be superior to the other. At press time, neither option allowed a patient's current drugs to be entered.

The Formulary Finder allows you to enter the name of the state and the list of medications the patient is taking. It then produces a list of the available plans that will provide all or some of those drugs.

When the Plan Finder became operational on October 17, it was clear that it was still very much a work in progress—it was unable to do many of the comparison tasks it was supposed to perform before November 15, the date that enrollment begins. It is hoped that CMS will rectify the problems soon.

Muszynski recommends that filling out the patient portion of APA's Patient/PDP Assessment Form (available at <www.mentalhealthpartd.org>) will prove helpful in making the best use of the Plan Finder when it works properly. The form helps psychiatrists compile a complete list of the medications a patient is taking. This information can then be fed into the Plan Finder or Formulary Finder, which should produce a list of the PDPs that can provide all (or substantially all) of the patient's drugs. and another list that can provide a portion of them.

The transition to drug coverage under Part D promises to be most problematic for dual-eligible beneficiaries, that is, those who are now receiving their medications through state Medicaid programs but will be switched on January 1 to coverage under a low-premium Medicare PDP. The Office of Healthcare Systems and Financing is surveying low-premium plans with national coverage to identify the status of commonly used brand-name psychiatric drugs. Although dual eligibles will be autoenrolled into a low-income plan in their region, they have the option of selecting another plan that will better meet their needs. Unlike other enrollees, who may change plans only during open enrollment periods, dual eligibles and other enrollees who receive low-income subsidies may change plans at any time. If they select a plan that costs more than the subsidy provides, they will be expected to pay the difference, which will likely require charitable assistance.

Psychiatric Practice & Managed Care (PP&MC) provides news and updates on practice management issues to APA members. PP&MC is printed bimonthly in *Psychiatric News* and posted on the newspaper's Web site. Beginning with publication of the next PP&MC page, it will be posted in PDF format under "Psychiatric Practice" on APA's Web site.

Since Medicare Part D appears to be a work in progress—it's not just the Web site that's changing daily—APA will be monitoring the program carefully during its initial enrollment period and after the program begins in January to determine whether CMS is making good on its promises to enrollees with mental disorders.

Muszynski reports that APA has sent a letter to CMS asking officials to resolve problems in accessing plan information online and recommends checking in at <www.mentalhealthpartd.org> to keep up with the latest information. ■

Most States Have Laws For MCO Independent Review

As the number of consumers receiving their health care through managed care plans has grown, disagreements over covered services have multiplied. In response to concerns about the impartiality of health plan benefit coverage decisions coupled with the failure of passage of a Patients' Bill of Rights at the federal level, 44 states and the District of Columbia have enacted independent review laws. Only six states have yet to enact such laws (Idaho, Mississippi, Nebraska, North Dakota, South Dakota, and Wyoming).

URAC (formerly the Utilization Review Accreditation Commission) defines independent review as "a process, independent of all affected parties, to determine if a health care service is medically necessary, medically appropriate, or investigational. Independent review typically, but not always, occurs after all appeal mechanisms available within the health benefits plan have been exhausted. Independent review is sometimes referred to as external review."

The independent review process gives insureds an opportunity to have impartial expert medical professionals review disputes. The reviews are conducted by one expert or a panel of experts not affiliated with the health plan. Decisions are binding in most states. Approximately 50 percent of the coverage disputes taken to independent review result in a reversal of the previous denial.

While a Patients' Bill of Rights was considered by Congress in the 1990s, it never became law. Instead, most states moved ahead with legislation to allow consumers to appeal outside their health plans through external or independent review organizations (IROs). Thus, after exhausting internal appeals to the health plan, a patient or his/her physician may appeal to the state IRO in accordance with established procedures. State laws vary in how these appeal mechanisms are administered and funded and the extent to which they are prompt, binding, and truly independent.

Self-insured plans that are overseen by ERISA (the federal Employment Retirement Income Security Act) are the exception to this procedure, since they are exempt from all state regulation including that involving IROs. The appeal of denials under ERISA must be made within the plans; the only additional appeal beyond the internal review is a complaint filed with the U.S. Department of Labor Public Disclosure Office.

There seems to be a general lack of public awareness and education about the independent review process. Independent reviews have not achieved their potential of resolving coverage disputes because patients generally do not avail themselves of this right despite claims-denial letters advising them of its existence. The Kaiser Family Foundation and Consumers Union have put together a helpful guide for patients titled "A Consumer Guide to Handling Disputes With Your Employer or Private Health Plan, 2005 Update," posted at <www.kff.org/consumerguide/7350.cfm>. The guide provides specific information on how to access the IROs in each state that has established an independent review process.

In September APA's Council on Healthcare Systems and Financing accepted recommendations from the Committee on Managed Care for three actions dealing with the external review process: (1) ask the district branches in the six states that do not have an external review process if they are aware of or need model legislation to establish these mechanisms in their states, (2) survey all district branches with external review organizations about their satisfaction with the appeals mechanisms, and (3) educate district branches and members about appeal mechanisms.

By Paul H. Wick, M.D.
Chair, Committee on Managed Care ■

Q&A

CPT Q&A

Q: *If I perform an initial psychiatric interview and prescribe psychotropic medication, do I code 90801? Or do I code 90801 and 90862?*

A: We suggest you use 90801. It is unlikely that a carrier (Medicare or commercial insurance carrier) would pay you for a 90801 and a 90862 when done with the same patient on the same day. ■

Abuse Said to Be Rampant In Turkey's Mental Hospitals

Allegations of arbitrary detention and "inhumane" use of electroconvulsive therapy must be addressed by Turkey's psychiatrists and health officials, an APA committee maintains.

BY AARON LEVIN

An APA committee wants the Turkish Psychiatric Association to clarify allegations of human rights abuses in Turkey's public psychiatric facilities that were raised in a recent report by a Washington-based advocacy group.

"We're approaching [Turkish psychiatrists] as colleagues concerned about the quality of care that they provide, the ethical and other protections they have for patients, and how can we help them do something about it," said Alan Stone, M.D., a former APA president and the Touroff-Glueck Professor of Law and Psychiatry at Harvard, in an interview with *Psychiatric News*.

The report, issued in September by Mental Disability Rights International (MDRI), delineated the "pervasive" use of electroconvulsive therapy (ECT) as punishment, its use with children and adolescents, and "unmodified" by muscle relaxants, anesthesia, or oxygenation. It pointed to the lack of mental health laws that protect patients from arbitrary detention. The MDRI team also visited rehabilitation centers and orphanages and observed improper use of restraints and seclusion, lack of rehabilitation and medical care, and disabled children "emaciated from starvation."

"Inhuman and degrading conditions of confinement are widespread throughout the Turkish mental health system," said the report. "Locked away and out of public view, people with psychiatric disorders as well as people with intellectual disabilities, such as mental retardation, are subjected to treatment practices that are tantamount to torture."

Psychiatric Association Responds

In a statement issued in response, the Turkish Psychiatric Association and the Turkish Medical Association said that some information in the MDRI report was anecdotal, but they largely agreed with its findings.

"We have to regretfully acknowledge that the deficiencies and shortcomings pointed out. . .are consistent with the facts," said the two associations. "It is a well-known fact that psychiatric services in Turkey are well behind those in developed countries and even behind general health standards in our country."

A Turkish government representative disputed MDRI's assessment of conditions in Turkey, however.

"The report has been taken seriously in Ankara but the government does not consider it accurate," said Fatih Yildiz, first secretary of the Turkish Embassy in Washington, D.C. He said the report did not reflect the current situation and rejected claims of arbitrary detention. ECT was not performed on minors and was not used as punishment, he said, and according to the Ministry of Health, "it is not always medically possible to provide anesthesia for all patients receiving ECT."

MDRI investigators said they visited sites in Turkey in April 2005 and July 2005, and stood by the statements in their report.

APA's Corresponding Committee on the Misuse and Abuse of Psychiatry is seeking more information about the practices reported by MDRI and to find ways to support the Turkish Psychiatric Association's desire for reform of standards and quality of care in Turkey, while acknowledging the inadequate resources available there.

"My understanding is that the Turks have been aware of these concerns since 1997, but they have not modified the conditions since then," said Stone. "As colleagues, we're concerned about questions of care, what can be done, and how we can help them."

The MDRI investigators included American and Turkish members. MDRI has produced similar reports on the status of persons with mental disabilities in Peru, Kosovo, Paraguay, and Mexico.

"The problem does not seem to be a lack of resources," said investigator Robert Okin, M.D., a professor of clinical psychiatry at the University of California, San Francisco, chief of psychiatry at San Francisco General Hospital, and the only physician on the team. Okin cited the case of Mexico, which he has also visited on behalf of MDRI and where unmodified ECT is not used, despite modest available resources.

"The human rights violations we witnessed in Turkey are a result of government policies, not the personal or professional trespasses of Turkish psychiatrists," said Okin. "It is important that psychiatrists in the U.S. join with them as allies and colleagues to focus on the source of the problem."

Alan Stone, M.D.: "As colleagues, we're concerned about questions of care, what can be done, and how we can help them."

Chance to Have Impact

"We chose Turkey because it was where we could be most effective," said Laurie Ahern, associate director of MDRI and one of the report's co-authors, in an interview. Turkey is in the spotlight at the moment, pending its application to join the European Union (EU).

The Commission on Enlargement of the EU will release a report on the general progress made by Turkey on November 9, said Krisztina Nagy, an EU spokesperson in Brussels. "What we can say at this stage is that the commission follows very closely the situation of vulnerable groups in the candidate countries, including mentally disabled people. The commission's experts will study in detail the report of Mental Disability Rights International, but at this stage we have no particular comment to the content of this specific report."

After a two-year investigation, MDRI described human rights abuses in several aspects of psychiatric care. While most Turkish persons with mental disabilities live with family members, existing social or mental health services are not enough to cover treatment or support in the community. Lack of community-based care has filled state psychiatric facilities with chronic patients while draining resources for persons needing acute care for psychiatric crises.

Care at state facilities was largely custodial. At the Bakirköy and Erenköy hospitals in Istanbul, said co-authors Ahern and Eric Rosenthal, J.D., "people sat in beds or chairs or wandered the grounds of the facility with little to occupy them."

Legal protections for the mentally ill in Turkey are almost nonexistent, said the report. Persons facing confinement may be arbitrarily detained in psychiatric facilities, have no right to appeal of their commitment, and are denied the right to informed consent or to refuse treatment.

The country will need more than formal legal protections for the mentally ill, said Okin, in an interview. At present, Turkey lacks the judicial structures (such as hearing officers or special courts) to carry out laws and judges trained in human rights.

A total of 359 staff psychiatrists serve the 5,500 beds in five public psychiatric hospitals, said the report. Treatment is minimal and consists mainly of medications and ECT.

"The most widespread and serious human rights violation MDRI observed in Turkey's mental health system is the common practice of using electroconvulsive therapy (ECT) in 'unmodified' forms without anesthesia, muscle relaxants, or oxygenation," said the authors. ECT was used for children and the elderly and for a longer list of indications than the four that Turkish Ministry of Health agreed to with the European Committee for the Prevention of Torture in 1997.

"The misuses of ECT were already established as inhumane and degrading before we came along," said Ahern. MDRI was told that high use of ECT allowed institution officials to release patients and free up beds for new ones. Often, ECT was the only treatment these patients received. Patients sent home after ECT frequently had little access to psychiatric medications, either because they could not afford them or because they lived in rural areas where such drugs were not available or where there were no psychiatrists to write frequent prescriptions, as required under current regulations.

"I don't link it to Turkish culture or Turkish psychiatrists because it's not happening in university hospitals," said Okin. "There is some lack of recognition on the part of the Turkish government that this is a real human-rights violation."

Besides its findings, the report also includes MDRI's recommendations to improve Turkey's mental health system, including "ending the abuse of ECT; protecting against inhuman and degrading conditions in institutions; [and ending] improper and arbitrary detention."

MDRI also offered an assessment of a proposed mental health law drafted by the Turkish Psychiatric Association, lauding its goals but expressing concern for its perceived deficiencies and offering suggestions for improving it.

"We have reason to believe that Turkey has professionals who care about these issues and has the resources to make changes," said Ahern. "We had support from Turkish advocates, psychiatrists, and human-rights lawyers. Our goal is to support reform in Turkey."

The APA committee is drafting a letter of inquiry, urging Turkey to put international norms for ECT into effect immediately, not to use ECT on children, and to publish standards of care and make them available to the public, patients, and physicians. Perhaps the scheduled presence of a World Psychiatric Association congress in Istanbul in July 2006, will spur Turkey to institute reforms, said Stone.

"What Turkey really needs to do is create community alternatives, a legal framework and a legal structure, and make changes in its institutions," said Okin. "If the European Union is firm and vigorous in insisting that human-rights violations in parts of Turkey will be corrected, then Turkey will make the needed changes."

The report "Behind Closed Doors: Human Rights Abuses in the Psychiatric Facilities, Orphanages, and Rehabilitation Centers of Turkey" is posted at <www.mdri.org/projects/turkey/turkey%20final%209-26-05.pdf>. ■

At Bakirköy Psychiatric Hospital in Istanbul, patients lie about the grounds with little to occupy their time.

TAKEDA ROZEREM
P4C

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TAKEDA ROZEREM
PBW

Bipolar Disorder, Creativity Show Positive Correlation

The longer children with familial bipolar disorder are sick, the less perceptual creativity they demonstrate. Thus early bipolar treatment of such youngsters might prevent their loss of creativity.

BY JOAN AREHART-TREICHEL

Creativity and mood disorders are related, evidence has suggested. For example, some famous composers have been thought by psychiatrist-musician Richard Kogan, M.D., to have had mood disorders *(Psychiatric News*, April 19, 2002). Also, a number of living artists and writers have reported having mood disorders.

And now both adults with bipolar disorder and their children seem to show greater perceptual creativity than do healthy control subjects.

Kiki Chang, M.D., director of the pediatric bipolar disorders program at Stanford University, and colleagues gave the Barron-Welsh Art Scale (BWAS), a test that measures creativity, to 40 adults with bipolar disorder and 18 adults without the illness. The scoring of this test is based on "like" and "dislike" responses to figures of varying complexity and symmetry that provide a comparison with preferences indicated by artists. Thirty-eight simple and/or symmetrical figures disliked by artists and 24 more complex and/or asymmetrical figures liked by artists comprise the BWAS's Dislike and Like subscales, respectively; total scores combine responses to these subscales. People whose scores are more in accord with the likes and dislikes of artists are considered as having greater creativity.

Compared with healthy controls, bipolar subjects scored significantly higher on the BWAS Dislike Subscale and higher, although not significantly so, on the BWAS Like Subscale.

Chang and her colleagues also gave the test to 20 children who had a parent with bipolar disorder and who had the disorder themselves; to 20 children who had a parent with bipolar disorder and who had attention-deficit/hyperactivity disorder (ADHD) but no bipolar disorder (and who were suspected of showing possible early signs of bipolar disorder); and to 18 healthy control children.

The children with either bipolar disorder or ADHD scored significantly higher than did the healthy controls on the BWAS Dislike Subscale, and higher, although not significantly so, on the BWAS Like Subscale.

Thus, "the results of this study support an association between bipolar disorder and creativity and contribute to a better understanding of possible mechanisms of transmission of creativity in families with genetic susceptibility for bipolar disorder," the researchers concluded in their report in the November *Journal of Psychiatric Research.*

In other words, as Chang told *Psychiatric News*, "We were surprised that both offspring with ADHD and offspring with bipolar disorder had similar levels of this type of creativity. This might indicate that this is either a genetically mediated trait or that it is due to similar creative environments. However, it does not appear to be due to mania itself."

These results likewise have implications for clinical psychiatrists, Chang believes.

For example, she said, they should realize that children with bipolar disorder who are not doing well academically may have creative talents that can be developed.

Also, she pointed out, just as bipolar individuals seem to dislike the concrete and mildly prefer the complex and abstract, they also seem to have a chaotic lifestyle, since she and her colleagues found in another study that bipolar subjects often experience conflict and disorganization. Yet a simplified, structured lifestyle may be more beneficial to their mental health.

"Finally and most importantly," she added, "we found a negative correlation of illness duration with this type of creativity; the longer the children were sick, the less creative they were," Chang stressed. "That would imply that early intervention to prevent this illness. . .could prevent a loss of creativity over time."

The study was funded by the Heinz C. Prechter Fund for Manic Depression, National Alliance for Research on Schizophrenia and Depression, Klingenstein Third Generation Foundation, and National Institutes of Health.

An abstract of "Creativity in Familial Bipolar Disorder" can be accessed at <www.sciencedirect.com>, by clicking on "Browse A-Z," then "J," then "Journal of Psychiatric Research," then the November issue. ■

Research Forum

Professional News

A new Internet-based forum for schizophrenia researchers will allow them to share ideas with colleagues, keep abreast of developments in schizophrenia research, and learn about meetings and funding opportunities.

The Schizophrenia Research Forum, which is funded by the National Institute of Mental Health (NIMH), allows visitors to participate in live chats about schizophrenia research, for instance, and includes press coverage of interviews with leaders in the field.

The latest findings in schizophrenia research are posted in a section that lists citations of recent schizophrenia-related papers, with links to Pub-Med abstracts.

A section called "current hypotheses" reviews current thinking about causes and treatments of schizophrenia.

NIMH is providing $700,000 to fund the schizophrenia forum from 2005 to 2007.

The Mental Health Research Association and the National Alliance for Research on Schizophrenia and Depression cosponsor the forum.

The Schizophrenia Research Forum is posted at <www.schizophreniaforum.org>. ■

Disorder's Pessimistic Prognosis Not Always Justified

People with late-life schizophrenia appear to be relatively stable and may even experience some improvement in mental health and functioning.

BY MARK MORAN

Some patients who have had schizophrenia for decades may substantially improve in later life. So said Dilip Jeste, M.D., winner of APA's Research in Psychiatry Award, at the Association's 57th Institute on Psychiatric Services in San Diego last month.

"The prevalent concept of schizophrenia as a neurodegenerative disease with a downward course is not quite accurate," Jeste said. "Most people with the disease do not get demented as they age, and those [older patients with schizophrenia] living in the community show a slight improvement with age. Apart from the biological significance, this offers a ray of hope that even for people with schizophrenia who have been sick for decades, there can be a light at the end of the tunnel.

"The disease is not a lifetime sentence, and you can get better in later life."

"The disease is not a lifetime sentence, and you can get better in later life," he said.

Jeste is the Estelle and Edgar Levi Chair in Aging at the University of California, San Diego (UCSD) and director of the Sam and Rose Stein Institute for Research on Aging. He is also editor in chief of the *American Journal of Geriatric Psychiatry*.

Jeste also told psychiatrists at the institute that a body of research from around the world has shown that late-onset schizophrenia—occurring after the age of 40—is a valid diagnosis with unique attributes but also a number of similarities with the more common, early-onset form. He also presented study results showing that psychosocial treatments—especially cognitive-behavioral therapy and social-skills training—can support recovery in late life (see box).

Jeste said the emerging picture of late-life schizophrenia counters Emil Kraepelin's original formulation of dementia praecox (or precocious dementia) as a neurodegenerative disease whose onset is invariably during adolescence or early adulthood and that leads inevitably to dementia.

The concept was formulated in the late 19th century, when life expectancy was far shorter than it is today. Moreover, Jeste predicted that with the aging of the baby-boom population, many mental health clinicians will be practicing geriatric psychiatry.

He presented a recently completed analysis of data from research at UCSD on 1,156 middle-aged and elderly patients with schizophrenia or schizoaffective disorder and 215 healthy controls who were followed for the past two decades.

Of the 937 younger patients with schizophrenia (aged 40 to 60), 39 percent (or 365) were living independently in the community, and 49 percent (888) had ever been married. Of the 219 older patients (aged 60 or greater), 47 percent (103) were living independently in the community, and 70 percent (153) had ever been married.

While the figures for the older patients were well below those for the controls (they were in the 80 and 90 percentiles for independent living and marriage, whether old or young), they suggest that patients do not invariably decline in late life, Jeste said.

Moreover, scores on the SF-36, a 36-item self-rated physical health scale, showed that while people with schizophrenia experienced some decline in physical functioning over time, the decline was not as prominent as among the controls. Even more surprising was that while average self-reported mental status declined some among healthy controls, it appeared to improve in late life for those with schizophrenia, Jeste said.

Dilip Jeste, M.D., winner of APA's Research in Psychiatry Award.

Finally, while self-reported overall quality of life declined markedly among the controls, it remained stable for patients with schizophrenia in late life, he reported.

"This is definitely not dementia," Jeste said. "The course seems to be relatively stable and nondeteriorating. There appears to be improvement in mental health and functioning, and the quality of well-being does not decrease over the lifetime of these subjects."

Those results corroborate earlier published work by Jeste and colleagues at UCSD on rates of sustained remission in the community showing that of 145 middle-aged and elderly patients with schizophrenia living independently, 18 had been labeled "clinically remitted," while 12 others met criteria for remission established by the researchers.

Those criteria included no hospitalization for the previous five years and a level of psychopathology similar to that of normal subjects. Patients also had to be neuroleptic-free or on a low dose of an antipsychotic. The mean age was 58, and the length of follow-up since meeting criteria for remission was between two and 10 years, according to the study, which appeared in the August 2004 *American Journal of Psychiatry*.

Jeste told participants at APA's institute that the "real" rate of remission is likely higher since some patients who recover cease being seen by clinicians.

Possible predictors of remission include marital status, social support, and greater reserves of cognitive or personality function. Those patients with more severe paranoid or schizoid features in early life may be less likely to remit, Jeste said. Age or duration of illness does not appear to be associated with likelihood of remission.

On measures of cognition, remitted pa-

please see ***Prognosis*** *on page 35*

It's Never Too Late

Schizophrenia appears to respond to psychosocial treatments in mid- and late-life, according to Dilip Jeste, M.D.

At APA's 2005 Institute on Psychiatric Services, Jeste presented data from a study that he and his team had published earlier this year showing that community-dwelling patients with schizophrenia or schizoaffective disorder aged 42 to 72 may respond to psychosocial treatment.

In that study, 76 patients with schizophrenia or schizoaffective disorder were randomized to cognitive-behavioral therapy and social-skills training (CBSST) or treatment as usual. Patients were assessed using the Independent Living Skills Survey, Beck's Cognitive Insight Scale, Comprehensive Module Test to assess outcome of CBSST, and psychopathology (PANSS, HAM-D) at baseline, three months, and six months.

The treatment arm consisted of three modules of four weekly sessions each, for a total of 24 group sessions, on "thought challenging," "seeking social support," and "solving problems." Treatment was manualized with homework assignments after "classes." The patients had had schizophrenia or schizoaffective disorder for approximately three decades on average.

Eighty-six percent of the patients completed the treatment. While there was no significant change in psychopathology in these pharmacologically stabilized patients, there was significant improvement at three and six months on frequency of social activities, cognitive insight, and mastery of the skills taught in the three modules.

"Psychosocial treatments work in older persons with schizophrenia," Jeste concluded. "Successful aging is not an oxymoron, even in people with chronic schizophrenia."

The study, "A Randomized, Controlled Trial of Cognitive-Behavioral Social Skills Training for Middle-Aged and Older Outpatients With Chronic Schizophrenia," was published in the March American Journal of Psychiatry *and is posted at <http://ajp.psychiatryonline.org/gi/content/full/162/3/520>.*

Psychosocial Treatment Often Missing From Schizophrenia Regimens

Because of reimbursement issues, or lack of training on the part of mental health professionals in the field, treatment of schizophrenia is often confined to pharmacotherapy alone.

BY MARK MORAN

Psychosocial treatments are underutilized in the treatment of schizophrenia, despite proven efficacy when used in combination with antipsychotic medication, said Anthony F. Lehman, M.D., M.S.P.H., in a presentation at APA's 57th Institute on Psychiatric Services last month in San Diego.

Psychological and family interventions, assertive community treatment (ACT), and supported employment strategies have been found to be highly effective in the treatment of schizophrenia and are recommended in APA's treatment guidelines.

Ellen Dallager

Anthony F. Lehman, M.D., M.S.P.H., receives the American Psychiatric Foundation's Alexander Gralnick, M.D., Award for Research in Schizophrenia at the IPS from Jacqueline Feldman, M.D.

Yet because of reimbursement and funding issues, or because of lack of training in psychosocial interventions on the part of mental health professionals, treatment of schizophrenia is often confined to pharmacotherapy alone.

"All evidence-based psychosocial treatments for persons with schizophrenia are recommended within the context of appropriate pharmacotherapy," Lehman said at the institute. "Pharmacotherapy plus psychosocial interventions are generally more effective than pharmacotherapy alone, but there is a gap between what science tells us to do and what we do in actual practice.

"Most patients are offered some form of counseling, but the nature of the treatment is often ill defined. And typically the workforce is not adequately trained in evidence-based approaches."

Lehman is professor and chair of the department of psychiatry at the University of Maryland School of Medicine. And he was principal investigator for the Schizophrenia Patient Outcome Research Team, which originally released treatment recommendations, as well as a report on how patterns of usual care conformed to those recommendations, in 1998.

At the institute, he drew on those findings and some more recent research in an overview of psychosocial treatment including psychological interventions, family interventions, ACT, and supported employment.

please see ***Psychosocial*** *on page 37*

JANSSEN RISPERDAL
P4C

JANSSEN RISPERDAL

P4C

Racism's Sequelae Continue To Impact Black Patients

It's crucial that psychiatrists and mental health professionals treating African Americans establish a trusting relationship with the patients to help them overcome a "healthy cultural suspicion" of treatment.

BY EVE BENDER

It is incumbent upon psychiatrists and other mental health clinicians to empower some of their African-American patients to advocate for themselves as they navigate a complex maze of systems and agencies that can be disempowering.

This was one of the messages delivered to those at the Solomon Carter Fuller Award Lecture on the mental health treatment of African-American patients and their families at the APA Institute on Psychiatric Services in October in San Diego.

The award, which this year went to Nancy Boyd-Franklin, Ph.D., honors a black individual whose work has significantly benefited the quality of life for black people.

Boyd-Franklin is a professor at Rutgers University's Graduate School of Applied and Professional Psychology and author of several books, including *Black Families in Therapy: Understanding the African American Experience* and *Boys Into Men: Raising Our African American Teenage Sons*. Both books were co-authored by her husband, A.J. Franklin, Ph.D.

Ellen Dallager

Nancy Boyd-Franklin, Ph.D., pointed out that racism continues to impact African-American patients who receive mental health services.

During the session, Boyd-Franklin showed heart-wrenching video footage of psychiatrist Salvador Minuchin, M.D., counseling an African-American woman whose two children had been taken away from her.

Minuchin pioneered structural family therapy and supervised Boyd-Franklin in her studies.

Boyd-Franklin explained that the patient's infant had cerebral palsy and was "failing to thrive" due to the illness. A neighbor reported the mother to child protective services, which removed the infant and an older child from the home due to a suspicion that the mother was neglecting her children.

After the mother's children were removed, a psychiatrist misdiagnosed the grieving mother as psychotic, making it extremely difficult for her to reclaim her children in the courts. "When an African-American patient is misdiagnosed," said Boyd-Franklin, "it can stay with them forever."

She also called attention to "the power of these outside agencies," such as the courts and child-protective services on African Americans receiving mental health treatment.

Though Minuchin was able to advocate for the mother in her fight to get her children back, it is important that clinicians help African-American patients be able to advocate for themselves, she said.

Boyd-Franklin also spoke about some of the ways many African Americans perceive mental health treatment. For instance, mental health clinicians of any color working with African-American patients should be aware that their patients may be resistant to or have a "healthy cultural suspicion" of psychotherapy.

"In African-American communities," Boyd-Franklin said, "therapy and psychopharmacology are often seen as the domain of sick people, crazy people, white people, or rich people." This belief "impacts the way black patients and their families interact with our system," she added.

All mental health clinicians should know that "racism has absolutely impacted our [African-American] clients and continues to affect them, irrespective of class and education."

As a result, many African Americans have traditionally turned to family and church, or spirituality, which serve as "buffers" against racism, Boyd-Franklin explained.

In years past, psychiatry residency programs and graduate psychology programs either did not acknowledge these coping mechanisms, or worse, pathologized them, she said.

While training to receive her doctoral degree in the 1970s, Boyd-Franklin said "there was no mention of family in mental health training. . .we were seeing clients in a very Eurocentric, individualized frame-

please see ***Racism*** *on page 35*

Perceptions of Elderly Affect Care They Receive

Societal attitudes toward elderly people with mental illness—regardless of culture—are often stigmatizing and pessimistic, according to one proponent of "successful aging."

BY EVE BENDER

As the number of elderly minorities with mental illness increases substantially over the coming years, so too will the demand for culturally sensitive mental health services by psychiatrists.

Unfortunately, each minority group faces barriers to comprehensive psychiatric treatment, which include lack of insurance, stigma, and the cost of care, according to a group of psychiatrists who treat and conduct research with patients from diverse ethnic backgrounds. They spoke at the APA Institute on Psychiatric Services in San Diego last month.

"Whether we like it or not, most of us are going to be geriatric psychiatrists within the next few decades," said Dilip Jeste, M.D., Estelle and Edgar Levi Chair in Aging, director of the Sam and Rose Stein Institute for Research on Aging, and Distinguished Professor of Psychiatry and Neurosciences at the University of California, San Diego.

He pointed out that while there were about 6 million people over age 65 with psychiatric disorders in 1990, that number is expected to top 15 million in 2030.

Important issues to consider are how race and ethnicity play a role in risk for mental illness and whether an increased risk for a particular mental disorder is influenced by environment, genes, or the interaction between the two, he noted.

From left: Rodrigo Muñoz, M.D., Mary Roessel, M.D., Jagannathan Srinivasaraghavan, M.D., Warachal Faison, M.D., and Dilip Jeste, M.D., spoke about the importance of cultural competence in the treatment of elderly minority patients with mental illness.

For instance, the proportion of people with vascular dementia living in India and Japan is higher than in Western countries, and the World Health Organization has declared that 2 of every 3 people with dementia will soon live in developing countries, Jeste said.

By contrast, elderly people living in rural India may have a lower risk for Alzheimer's disease than their counterparts in Western countries. Jeste cited the research of Mary Ganguli, M.D., M.P.H., who came to this conclusion after studying a sample of 2,700 elderly Indian villagers. She also found a low prevalence of APO-E4, a gene variant associated with Alzheimer's.

Cultural Differences in Care, Attitudes

Across cultures there are differences in the quality of health care, societal attitudes toward the elderly in general, and attitudes toward elderly people with mental illness, Jeste noted.

Older people living in some Asian communities "may have an advantage in the sense that the elderly tend to be better respected than they are in Western cultures."

He described the concept of "successful aging," which occurs across many cultures and is characterized by socialization, engaging in physical activity, adapting well to change, and being satisfied with life. Physical exercise and mental stimulation are essential to achieve successful aging, he said.

There is evidence that even older people living with physical illnesses and serious mental illness such as schizophrenia can achieve successful aging, he said, which flies in the face of dominant attitudes toward elderly people with mental illness in our culture—that they are "not worth wasting time and energy on" because they are in advanced stages of life, and nothing more can be done for them. "Societal and scientific attitudes toward aging need to change," Jeste declared.

Stigma, Misdiagnosis Impede Treatment

A number of factors, including stigma and lack of insurance coverage, keep many African-American elderly from seeking mental health care, according to Warachal Faison, M.D., clinical director of the Alzheimer's Research and Clinical Programs at the Medical University of South Carolina and assistant director of the Institute for Research Minority Training on Mental Health and Aging.

"If you are African American and have a mental illness," she said, "you are considered to be a double minority." Faison is also vice chair of APA's Committee on Ethnic Minority Elderly.

African Americans who seek mental health services are more likely to be misdiagnosed with psychosis, less likely to be diagnosed with depression, and less likely to receive a selective serotonin reuptake inhibitor than are patients from other ethnic backgrounds, according to Faison.

please see ***Elderly*** *on page 35*

Can Pathological Liars Blame It on the Brain?

The biological basis of pathological lying may lie in white matter in the prefrontal brain region. Still unknown, however, is whether anatomy drives deception or whether deception drives anatomy.

BY JOAN AREHART-TREICHEL

The nose of the fairy-tale puppet Pinocchio may have grown longer with each lie he told. But what was going on in his head as he lied?

A new study may have the answer. It found a greater amount of prefrontal white matter in the brains of pathological liars.

"To our knowledge, this study is the first to show a brain abnormality in people who lie, cheat, and manipulate others," the investigators said in their study report, which was published in the October *British Journal of Psychiatry*.

The study was headed by Yaling Yang, a doctoral student in brain and cognitive science at the University of Southern California. His team included Adrian Raine, Ph.D., a professor of psychology at the University of Southern California and among America's leading scientists when it comes to peering into the brains of antisocial individuals to learn what is going on (*Psychiatric News*, June 17).

Yang and his colleagues recruited subjects by advertising at temporary-employment agencies. They did not tell people interested in participating that it had to do with antisocial behavior, and especially with lying, since they also wanted to include a number of subjects who did not engage in such behaviors.

They ended up with 49 subjects—21 normal subjects, who had neither antisocial personality disorder nor a history of pathological lying; 16 subjects with antisocial personality disorder, but no history of pathological lying; and 12 subjects with a history of pathological lying. Subjects were defined as pathological liars if they fulfilled criteria for pathological lying on the Psychopathy Checklist-Revised; criteria for conning/manipulative behavior on the same checklist; the deceitfulness criterion for *DSM-IV* antisocial personality disorder; or criteria for malingering as indicated by admitting to telling lies to obtain sickness benefits.

None of the groups differed significantly in social class, ethnicity, I.Q., handedness, history of head injury, height, head circumference, and *DSM-IV* diagnoses of alcohol/drug misuse/dependence.

Yang and his team then assessed the gray-matter and white-matter volumes of all 108 subjects with structural magnetic resonance imaging.

Compared with both antisocial and normal control subjects, liars had some 25 percent more prefrontal white matter and more than a 33 percent reduction in the ratio of prefrontal gray matter to prefrontal white matter.

Yang did not expect these results, he told *Psychiatric News*. "I was surprised by how significantly different the brains of pathological liars and the brains of controls were," he said. "And I was surprised that the answer to pathological lying may be in white matter. To date, neuroscientists still focus more on gray matter, which is the neural cell bodies of the brain, than on white matter, which is the connection between cells."

Indeed, since white matter is pivotal to the connectivity and cognitive function of the human brain, increased prefrontal white matter might confer a predisposition to lying, Sean Spence, M.D., a professor of psychiatry at the University of Sheffield in England and a deception authority, speculates in an accompanying editorial. On the other hand, he cautioned, "We do not know whether the findings reflect cause or effect (whether anatomy drives deception or is driven by its practice)."

Also unknown, he added, is whether the study results apply only to "a subgroup of unemployed antisocial people who resort to deception for instrumental gain, but who are not necessarily very good at lying" or also apply to "those successful social predators who lie and cheat and yet retain enormous influence in the world."

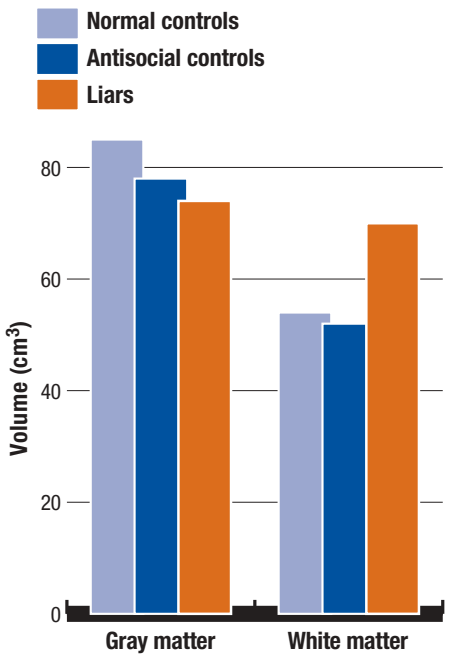
And as Spence told *Psychiatric News*, "I don't think the study changes what a psychiatrist would do in the clinic at the moment, but I think the scientific study of deception will gradually inform the way people think about practice that relies so heavily upon subjective accounts."

The study was funded by the National Institute of Mental Health and the Wacker Foundation.

An abstract of "Prefrontal White Matter in Pathological Liars" is posted at <http://bjp.rcpsych.org/cgi/content/abstract/187/4/320>. ■

White Lies, White Matter

The smallest ratio of prefrontal gray matter to white matter was found in liars; the next smallest in antisocial controls, and the largest in normal controls.



Source: Yang et al., *British Journal of Psychiatry*, November 2005

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Elderly

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Elderly African Americans are also more likely than whites to be misdiagnosed with dementia and Alzheimer's disease, she noted.

Faison cited research by J. Scott Roberts, Ph.D., of Boston University School of Medicine, who in 2003 found that African Americans were more poorly informed about Alzheimer's disease than were Caucasians. For instance, African Americans were much more likely than whites to believe that Alzheimer's is a normal part of aging.

Faison emphasized that there is a dearth of African Americans participating in clinical trials and an inadequate number of African-American investigators. A reversal of this trend will result in higher-quality treatment interventions and screening tools for older African Americans with mental illness, she noted.

According to Mary Roessel, M.D., a staff psychiatrist at the Santa Fe Indian Health Services Hospital and Clinic in Santa Fe, N.M., access to health care providers is difficult for many American-Indian elders. "Because most of our elders live on reservations, lack of transportation is a real issue for them," she said.

Unlike in many Western cultures, older American Indians are respected and looked to as keepers of cultural knowledge and tradition, she noted.

However, it is not uncommon for American-Indian elders to be financially exploited, abused, or neglected by younger family members charged with caring for them.

While working with American-Indian elders who served in World War II and the Korean War, she has noticed a high prevalence rate of posttraumatic stress disorder. "Many had never sought help before and have been suffering for as long as 50 years," said Roessel.

It is crucial that American Indians have access to culturally sensitive care and are provided with an interpreter, if necessary. At the hospital where she works, "there are native speakers who are available to conduct a mental status exam or psychiatric interview" in the patient's native language, Roessel said.

In American-Indian families, she explained, there is usually one family member who is designated to take care of an elderly relative and "will come to the office to offer more information about the patient or serve as an interpreter."

Health privacy laws have sometimes been detrimental to treating American-Indian elders with mental illness, especially in cases where overly cautious clinicians "isolate patients" by barring family members from treatment sessions, which is not necessary, Roessel said.

It may also be beneficial to combine various aspects of American-Indian healing traditions with mental health treatment, she noted. ■

Prognosis

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tients scored worse than normal controls but better than patients who were still symptomatic. This finding is consistent with the fact that deficits in cognition typically appear years before the first psychotic break, Jeste noted.

"Initially this appeared to be a disappointment," he said. "If we call these patients remitted, why would they have cognitive impairment? Yet the more one thinks about it, the more it makes sense. Schizophrenia is a neurodevelopmental disease, and most agree that the predisposition is present very early in childhood. Children who go on to develop schizophrenia show cognitive impairments years before they show psychotic symptoms or before they are diagnosed.

"If that's the case, and cognitive impairment predates schizophrenia, why would we expect cognition to be normal after remission?" he said. "Cognition is not related to psychopathology, so the best we can expect is to return to premorbid functioning, which is what we expect for any illness."

This outcome should hardly be considered a failure. "For someone to return to premorbid function after decades of illness is remarkable," Jeste said. ■

Racism

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work," she recalled.

"One thing they don't tell us in graduate or medical school is that in many African-American communities, the work we do in psychiatry and psychology is considered antispiritual," she said.

In the past, when African-American patients reported to their therapists that in order to survive a certain ordeal they "prayed to the Lord," Boyd-Franklin said, more often than not, clinicians were trained to write "religiosity" in their notes on the patient.

Boyd-Franklin also encouraged attendees to respond to African-American patients "from the gut" in the context of psychotherapy. "It is that response that will enable you to connect and establish therapeutic rapport with a client who is perhaps totally different from you in class and race," she emphasized. ■

Two Guidelines To Be Available For Review

The APA Assembly and other APA members are invited to review and comment on the drafts of two APA practice guidelines beginning next month and continuing through mid-January.

The Practice Guideline for the Treatment of Patients With Obsessive-Compulsive Disorder is a new guideline. The Practice Guideline for the Treatment of Patients With Alzheimer's Disease and Other Dementias of Late Life, Second Edition, is a revision of the guideline published in 1997.

The guidelines may be downloaded from "Members Corner" on APA's Web site at <www.psych.org/members/assembly/pg/pgdraft_reviewmembers.cfm>. APA members may also request a hard copy from their district branch.

Same-Sex Marriage

I am writing in support of the Board of Trustees' approval of the position statement in support of same-sex civil marriage. Those who say that APA should not involve itself in such matters have forgotten both our history and our responsibility to care for our patients' whole lives, not just symptoms which may be amenable to medication.

It is entirely appropriate for APA to make statements regarding civil rights issues. We know well that depriving people of civil rights has mental health consequences, as there is a strong scientific literature supporting this. With respect to civil rights for gay people, psychiatry has a special burden to speak loudly. Homosexuality was a diagnosis until 1973, and ego-dystonic homosexuality remained in the *DSM* until 1987; thus, our profession was used to help bolster discrimination in many arenas. For example, psychiatrists played a key role for years in screening gay people out of the military on the basis of being "paranoid" characters and therefore unfit to serve.

This position statement is a revision of APA's previous statement in support of civil unions. It acknowledges that civil unions are not portable across state lines and do not offer the same benefits as civil marriages. We are either for equal rights or we are not.

Civil marriage would help gay men and lesbians gain legal protections for themselves and their children. Supporting it is something that our profession should proudly do, and I applaud the Trustees for taking this step.

MARY E. BARBER, M.D.
Kingston, N.Y.

Thank you, thank you, thank you to APA President Steven Sharfstein, M.D. for his comments in his September 16 column. As someone approaching a 22-year anniversary in a long-term, committed, same-gender relationship, it was encouraging to have this important topic argued in such a cogent manner. This is precisely the kind of issue on which APA should take a stand, and I hope Dr. Sharfstein's well-considered comments set the standard for ongoing debate.

JEANETTE SCHEID M.D., PH.D.
Howell, Mich.

Thanks to APA President Steven Sharfstein, M.D., for his thoughtful, eloquent essay in the September 16 issue titled "Psychiatry and Legal Recognition of Same-Sex Civil Marriage." He addressed all the relevant mental health issues involved in this most important and positive decision by APA's Board of Trustees.

I am proud to be a member of an organization willing to take important humanitarian stands on questions of the day, controversial or not.

MARIANNE MAKMAN, M.D.
New Rochelle, N.Y.

I am writing in response to the September 16 column of APA President Steven Sharfstein, M.D., titled "Psychiatric and Legal Recognition of Same-Sex Civil Marriage."

Dr. Sharfstein's comments reflect the muddle-headed thinking that makes psychiatrists the butt of jokes in the community. His argument for APA's taking a stand on this issue "is based fundamentally on the research evidence." However, saying that homosexuality has strong links to biology and genetics is meaningless—so does Down's syndrome, schizophrenia, bipolar disorder, and attention-deficit/hyperactivity disorder. Saying that same-sex marriage is associated with clear benefits is irrelevant—premarital sex and divorce clearly have deleterious effects on adults and their children, yet APA has not taken a stand supporting abstinence and the sanctity of marriage. APA already endorsed the concept of same-sex civil unions in 2000; I don't believe that research has been done to demonstrate that same-sex marriages are even more beneficial than same-sex civil unions, and should therefore be recognized.

The reasons for recognizing same sex marriage are based on social and political beliefs, not scientific data. It does APA no good for its president to be disingenuous in this regard. Claiming that APA's position is based on scientific research only makes it easier for the community at large to question the science that has gone into developments in understanding of the human brain and mind. The arguments for recognition of same-sex marriage have more to do with opinions about human rights and societal order, and APA, as a scientific organization, should have refrained from taking a position on this issue.

GARY N. SWANSON, M.D.
Allison Park, Pa.

The August 19 *Psychiatric News* headlined that "APA Board Supports Same-Sex Marriage." The article explained that APA now supports legal recognition of same-sex civil marriages. There were details as to why it was believed that denying this legal right would have mental health consequences, and Paul Fink, M.D., stated that the "social" component of the biopsychosocial approach cannot be arbitrarily dismissed.

APA is an organization of medical specialists with a mission to promote the highest quality care and serve the professional needs of its membership. As such, APA's support of legal recognition of same-sex marriages is a dangerous "boundary violation." The issue of same-sex marriage is not an issue of psychiatric diagnosis or treatment.

The legalization of same-sex marriage is the agenda of a specific special interest group. It is a highly divisive issue in American politics and jurisprudence. APA's asserting any position on this issue would serve only to alienate potential supporters of our objectives that are fully consistent with our mission. APA should be working toward ensuring that there are sufficient resources available to make mental health care accessible, for example, ending discriminatory mental health benefits under Medicare and other insurance, or resolving the increasing limitations in access to medications. APA should remain vigilant to prevent increasing attempts to prescribe medication by legislation instead of proper medical education.

The assertion that denying legal same-sex marriages can result in mental health consequences is very problematic. Losing a job or failing a grade can cause mental health consequences. Will APA now support a national prohibition on job losses or insist on "A's for Everyone"? Such statements are ludicrous. Stating the same for same-sex marriages hurts the credibility and professionalism of APA.

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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.

No Suicide Decision

Thank you for the article in the July 1 issue in which Robert Simon, M.D., was interviewed: "Several Signs Should Alert Clinicians to Suicide Risk.

I have one small addition to make. Dr. Simon comments that there are no data to support the use of no-suicide contracts to prevent suicide. However, as Marcia Goin, M.D., pointed out in the July 18, 2003, issue, these contracts seem to have evolved from the no-suicide decision procedure published by me, Robert L. Goulding, M.D., and Mary E. Goulding M.S.W., in the February 1973 *American Journal of Psychiatry* in the article "No-Suicide Decisions: Patient Monitoring of Suicidal Risk."

This procedure, which is not a contract, has been used for more than 30 years internationally with only four reported fatalities. These data were reported at a workshop at APA's 2004 annual meeting in New York in which Dr. Simon was kind enough to participate. He said he agreed that this procedure was different and professionally sound.

I should emphasize that I entirely agree with Dr. Simon's cautions against contracts in general.

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Atypicals

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published. Researchers who conducted NIMH's companion CATIE-Schizophrenia study reported primary results in September *(Psychiatric News*, October 21).

In the current report, Schneider and his colleagues electronically searched MEDLINE from 1966 to April 2005 and the Cochrane Controlled Trials Register (January 1, 2005). In addition, they reviewed conference proceedings, abstracts, and poster presentations (1999 through April 2005) from geriatric medicine, psychiatric, neurological, and geriatric psychiatry meetings. Information was also requested from pharmaceutical manufacturers and the FDA.

In all, the team identified and analyzed 15 clinical trials in which the SGAs aripiprazole (Abilify), olanzapine (Zyprexa), quetiapine (Seroquel), or risperidone (Risperdal) were compared with placebo. (One study included both olanzapine and risperidone.) The studies encompassed 3,353 patients who received one of the four SGAs and 1,757 patients who received placebo.

During the active-treatment phase of a clinical trial of patients taking one of the four drugs, 118 deaths occurred, compared with 40 deaths among those on placebo. This difference was statistically significant (p=0.02). Patients taking an SGA were 1.54 times more likely to die (from any cause) than those patients assigned to receive placebo in the clinical trials studied. While available details were not plentiful, most of the reported deaths were cardiovascular in origin or from infections such as pneumonia.

When Schneider and his colleagues analyzed all the data they had available to estimate patients' total exposure to either drug or placebo (that is, dose as well as duration of drug/placebo therapy), they found that the overall relative risk of death was 1.65 times more likely in those taking drug compared with those taking placebo.

In this pooled, total-exposure analysis, each of the individual medications was associated with an increased relative risk of death from any cause, compared with placebo. However, the risk varied among the drugs, with the highest relative risk of death associated with olanzapine (RR=2.31) and the lowest with risperidone (RR=1.35). However, while the overall increase was highly statistically significant (p=0.003), none of the relative risks calculated for the individual medications reached statistical significance.

"Although the findings were consistent from trial to trial and from drug to drug," Schneider and his coauthors concluded in their *JAMA* report, "It is only when all trials are combined that a statistically significant effect is found. No drug is individually responsible for the effect, but rather each contributes to the overall effect."

In an editorial accompanying the report, Peter Rabins, M.D., M.P.H., and Constantine Lyketsos, M.D., M.H.S., both in the department of psychiatry and behavioral sciences at Johns Hopkins University School of Medicine, noted, "The results do not contraindicate the use of antipsychotic drugs in the treatment of patients with dementia," but rather, they write, "the results change the risk-benefit analysis such that antipsychotic drugs should be used only when there is an identifiable risk of harm to the patient or others, when the distress caused by the symptoms is significant, or when alternate therapies have failed, and symptom relief would be beneficial."

Rabins and Lyketsos also noted the difficulties that Schneider and his colleagues encountered in trying to identify all available data on the use of antipsychotics in elderly demented patients. Similar challenges have been encountered with research efforts involving other drug classes, they added.

"Because there is a significant likelihood that rare events will not be identified in the two [studies] required by the FDA for approval," Rabins and Lyketsos wrote, "the FDA must put more effort into formal post-marketing surveillance" and require public registry of all clinical-trials data.

An abstract of "Risk of Death With Atypical Antipsychotic Drug Treatment for Dementia" is posted at <http://jama.ama-assn.org/cgi/content/abstract/294/15/1934>. The accompanying editorial is posted at <http://jama.ama-assn.org/cgi/content/extract/294/15/1963>. ■

Drug Testing

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maceutical companies (all of which are direct competitors in the psychiatric drug market) provided nearly three hours of joint testimony on how the requirement for long-term data at the time of initial filing would effect the drug-development process. The overwhelming message was that the requirement would significantly slow down drug development, perhaps obstructing it altogether. Bringing psychiatric medications to the market would take longer and be more costly, the companies said.

"Both acute and long-term efficacy data are needed for psychiatric disorders that are recurrent or chronic; everyone agrees with that," said Frederick Goodwin, M.D., a professor of psychiatry at George Washington University, who introduced the companies' joint testimony. "But [an indication to treat an acute episode and an indication for maintenance treatment] are very different indications and should not be made interdependent."

Yet, FDA's Laughren argued throughout the day for requiring "longer-term data," saying at the outset that "most psychiatric illnesses are chronic, and all psychiatric illnesses for which psychiatric drugs have approved indications in the U.S. are chronic."

Even so, he emphasized, all of the drugs currently approved for psychiatric illnesses gained their approvals with short-term efficacy data (generally eight to 12 weeks). In contrast, he noted, "most treatment guidelines for chronic psychiatric illness" recommend between four and six months of medication treatment.

"Clinicians," he said, "have generally not had sufficient evidence base to support what is the standard of practice."

Regulatory Environment Shifting

Prior to six months ago, new medications for psychiatric indications were routinely approved on the basis of two randomized, placebo-controlled clinical trials, lasting eight to 12 weeks, that showed a drug was efficacious for the indication sought and safe to use.

Recognizing the need for longer-term data, the FDA increasingly over the last several years has added postmarketing research commitments (commonly known as Phase IV clinical trials) to drug-approval letters. Phase IV commitments have often included requests to complete longer-term studies generally ranging from six to 12 months and focused on maintenance of efficacy and/or relapse prevention.

On new drug applications (NDAs) for medications to treat mental illnesses, the FDA has often asked drug companies to complete "randomized withdrawal studies" in which patients receive initial treatment on an open-label basis for a minimum period. Those patients who meet response criteria and remain stable are then randomly assigned to either continue on medication or switch to placebo. The endpoint in this type of trial is usually either time to relapse or some measure of relapse rate.

However, beyond requirements for pediatric studies (imposed under the Pediatric Research Equity Act of 2003), Laughren reminded committee members, "I'm not aware of any regulatory way to enforce Phase IV requirements."

Simply put, the FDA can ask manufacturers to complete Phase IV commitments, but has no regulatory authority to require their completion. As a result, many requested studies have not been completed in a timely manner, and some have not been completed at all.

Laughren said he would estimate that "70 percent to 80 percent of requests for Phase IV studies are completed by manufacturers; however, it often takes three to five years for the FDA to get the data." Industry representatives at the hearing generally agreed with those statements.

Last spring, however, the FDA began asking drug manufacturers to submit evidence of both short-term and long-term efficacy for drugs intended to treat mental illness at the time the company submits its NDA, rather than on the tail end of the approval process.

"[The FDA] has been thinking about this issue for a long time," Laughren said. The agency, he continued, has over the last six months required data from a randomized withdrawal trial in which patients who have responded to the medication have been stable for at least six months prior to being randomized to continue medication or switched to placebo. After patients are randomized, they must be followed for at least six months, making the minimum duration of the clinical trial one year.

"This proposed policy has been met with considerable resistance and questions," Laughren told PDAC members, "and for this reason, we thought it would be useful to bring this general issue to the committee for discussion."

In essence, Laughren was asking the PDAC to endorse the proposed policy, giving the agency's efforts to collect long-term data more credence.

Longer-Term Studies Disease-Centric

The PDAC's discussion of the proposed up-front requirement for long-term data was so heavily weighted against endorsing the requirement that PDAC chair, Wayne Goodman, M.D., a professor of psychiatry at the University of Florida College of Medicine, challenged committee members to discuss any possible benefit to voting yes, "if only to play devil's advocate."

It appeared that no one discounted the need for long-term data on the effectiveness and safety of psychiatric medications; however, several PDAC members questioned Laughren on the intention behind bringing the question before the advisory committee. PDAC consumer representative Jean Bronstein, R.N., M.S., asked, "Is the intent here simply to give the FDA stronger teeth to require long-term data?"

Laughren responded, "The issue is [that] we know that clinicians are going to prescribe these medications long term, if they are working for a patient. Right now, that prescribing is done without the benefit of any data."

He noted that other countries already require drug manufacturers to submit long-term data, most notably the European Union (see box).

The majority of the discussion then appeared to center around two key questions: How should long-term data be collected? And who should be responsible for collecting it?

Nearly all of those who spoke at the meeting expressed concern that a blanket requirement for long-term data would prove problematic. The primary reason cited was the vast differences in treatment response both with different medications in the same disorder and between different disorders. Many expressed the need to tailor long-term research to specific disorders, using different methods or different types of studies in different disorders.

With respect to who should collect long-term data, PDAC members noted that it is already actively collected in large "real-world" effectiveness trials funded by the National Institute of Mental Health (NIMH), such as the recently reported data on antipsychotic medications from the CATIE trial *(Psychiatric News*, October 21). NIMH has conducted large effectiveness trials of medications for depression, bipolar disorder, schizophrenia, and Alzheimer's disease.

"That's what NIMH is for though, it fills that role," said PDAC Chair Goodman.

That prompted a quick, but light response from Matthew Rudorfer, M.D., acting chief of the Adult Treatment and Preventive Interventions Research Branch at NIMH. "They wouldn't let me bring the checkbook today," said Rudorfer, who is also a voting member of the PDAC.

More seriously, he continued, "Some forms of research are better at framing different questions. The regulatory setting is good for acute efficacy data, but maybe it is not the right venue for getting at the longer-term data."

Information on the public advisory committee hearing is posted at <www.fda.gov/ohrms/dockets/ac/cder05.html#Psychopharmacologic>. ■

Europe's Requirements Stricter

In contrast to the U.S. Food and Drug Administration (FDA), which is currently pondering requirements for both acute and long-term efficacy data at the time a drug-approval application is submitted, the European Agency for the Evaluation of Medicinal Products (EMEA) began requiring both datasets to be submitted in late 2002. EMEA oversees drug approvals in the European Union member countries; however, member countries now retain the right to final approval to market a drug within their borders. By 2010, drug approvals will be centralized and regulated by EMEA.

Between 1995 and 2002, EMEA issued a series of guidance documents covering research and development of psychiatric medications, with each guidance being specific to a particular disorder. EMEA, at the time of the first submission of a new drug application for approval, requires submission of data showing acute efficacy as well as long-term maintenance of response or relapse prevention. Generally, EMEA requires a trial of at least six months in which patients who have shown a significant response to the medication under review are randomly assigned to continue medication or be blindly switched to placebo.

The requirements are similar to those that the FDA proposed at the public hearing of the Psychopharmacologic Drugs Advisory Committee late last month (see story on page 1). However, some believe the more stringent European Union requirements have delayed or prevented approval of medications approved by the FDA using only acute-treatment data from eight- to 12-week clinical trials.

Detailed information on EMEA requirements are posted at <www.emea.eu.int/>.

Psychosocial

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Lehman noted that early research on psychotherapy of schizophrenia was grounded in psychoanalytic theories that have since been discounted as causal explanations for schizophrenia. But today, cognitive-behavioral therapy (CBT), social-skills training, and cognitive remediation—manualized strategies that have sometimes been referred to as "training the brain"—have a proven track record of efficacy.

Lehman said CBT appears to be most effective among outpatients with residual symptoms for reducing beliefs in delusions, distress associated with delusions, and overall level of symptoms. It may reduce depression and negative symptoms, but does not appear to reduce the likelihood of relapse.

Predictors of success with CBT include whether the patients have some level of "cognitive flexibility" regarding delusions—that is, the ability to question the validity of delusional thoughts—and insight about the condition.

Similarly, social-skills training does not appear to be substantially effective for symptom reduction or relapse prevention, but does have a reliable and significant effect on specific behavioral skills, with a positive impact on defined areas of functioning, Lehman said. And it has a positive effect on patient satisfaction and self-efficacy, he said.

A principal obstacle plaguing the use of social-skills training is the lack of generalizability from the laboratory to the community; patients may reliably learn the skills during training but fail to use them when they are on their own.

Cognitive remediation (CR) is a third psychological intervention that focuses on "thinking" skills, especially those cognitive abilities affected by the disease. Targets of CR have included verbal memory, problem solving and executive function, attention, social perception, and work performance.

CR generally involves five weeks to six months of training on self-guided computer tasks using commercially produced educational software, and intensive individual training using paper and pencil neurocognitive test materials.

Lehman presented evidence from studies showing that combining medication with family education substantially reduces the risk of relapse. Key elements of family education are duration of at least nine months, illness education, crisis intervention, emotional support, and training in how to cope with illness symptoms.

Finally, he presented data from 25 studies over the years comparing ACT with "usual care." On measures of time spent in hospital, housing stability, quality of life, and patient satisfaction, the number of studies that found ACT superior to usual care was greater by a wide margin than those that found no difference. However, on measures of symptom severity, social functioning, vocational functioning, and number of times people were arrested and jailed, the number of studies (among the 25) that found no difference between ACT and usual care was greater than the number that found any difference—but the margin was small, and on all of those measures there were some studies that found an advantage for ACT.

Pioneered by Leonard Stein, M.D., and Mary Ann Test, Ph.D., ACT employs a multidisciplinary team, including a psychiatrist, to provide services in the community. The strategy relies on a high frequency of patient contact and a focus on the most high-risk patients.

Success is dependent on a high degree of fidelity to the principles of ACT, funding arrangements, and the ability to step patients down to less-intensive treatment, Lehman said. ■

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