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Newspaper of the
American
Psychiatric
Association

PSYCHIATRIC NEWS

www.psychnews.org

inside

PERIODICALS:
TIME-SENSITIVE MATERIALS

Credit: WLIW-21

Rep. Patrick Kennedy (left) is interviewed by psychiatrist Jeffrey Borenstein, M.D., during Borenstein's public television series "Healthy Minds." Kennedy talked about the ambitious campaign he is launching at a conference later this month to harness knowledge and resources for the development of effective new treatments for brain disorders. At far left is Garen Staglin, co-chair of the campaign. See story below.

Kennedy Launches Initiative To Promote Brain Research

Rep. Patrick Kennedy is following in the footsteps of his uncle in asking the nation to rally together in a grand scientific undertaking.

BY RICHARD FAUST

APA has joined an impressive list of government officials, mental health advocacy groups and experts, scientists, and clinicians to launch former Congressman Patrick Kennedy's campaign to support the development of effective new treatments for neurological and mental disorders and dramatically increase funding for and coordination of brain research.

The American Psychiatric Foundation has stepped up with a $50,000 grant to support the conference that will launch the campaign, known as "The Next Frontier: One Mind for the Brain." The conference will be hosted by the Massachusetts General Hospital Starr Center from May 23 to 25.

On May 25, the conference will culminate with a gala event at the John F. Kennedy Library. That date marks the 50th anniversary of President Kennedy's speech rallying the nation to land a man on the moon by the end of the 1960s. The symbolism is no accident. Co-chairs Kennedy and Garen Staglin are referring to the Next Frontier campaign as a "moonshot to the mind," and its goal is to map what Kennedy calls the "inner space of the mind" within the next decade. And, of course, "Next Frontier" derives from the name that was given to John F. Kennedy's administration—"New Frontier." It came from a phrase in Kennedy's speech when he accepted the nomination for the U.S. presidency: "[W]e stand today on the edge of a New Frontier."

Patrick Kennedy's co-chair is a successful California businessman, wine maker, and philanthropist. The common experience of mental illness and health advocacy brought them together.

During 16 years in the U.S. House of Representatives, Kennedy wrote and cosponsored dozens of bills on issues related to mental illness and improving the lives of people with psychiatric disorders. Also, he used his position and profile to raise understanding of these disorders, includ-

please see ***Brain Research*** *on page 23*

Army Gets Closer To Pinpointing Soldiers at Risk For Suicide

NIMH researchers are sifting through mountains of data from the U.S. Army to determine why soldiers die by their own hand.

BY AARON LEVIN

Preliminary findings from a massive study of U.S. Army data reveal patterns of risk factors associated with suicide and suggest further avenues of inquiry, according to the National Institute of Mental Health (NIMH).

The report covered data on 900,000 soldiers who served at some time in Iraq or Afghanistan from 2004 to 2008. All were regular, active-duty troops, not members of the National Guard or Reserve. In that period, 389 soldiers killed themselves.

The Army accumulated information about suicide, accidental, and combat deaths as part of a dozen administrative and health-related datasets that it combined into one large research database. The data were then given to NIMH for analysis.

From the start of the Army Study to Assess Risk and Resilience in Servicemembers (referred to as Army STARRS), researchers planned to release data periodically, first to the Army and then publically, said study co-director Robert J. Ursano, M.D., a professor of psychiatry

please see ***Army Study*** *on page 28*

Need Help With Parity Law?

The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act has been in effect since January 1, 2010, and the law and the regulations implementing it are complicated. To help APA members and patients better understand the law and its impact on benefits, APA's Office of Healthcare Systems and Financing has created <www.mentalhealthparitywatch.org>. Also, the federal agencies monitoring the law have asked APA and its members to identify insurance plans not in compliance with the act. APA members can help by visiting the site to learn more and report any concerns.

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Lawmakers Seem Reluctant to Enact Scope-of-Practice Expansions

State activity on granting prescribing privileges to psychologists heats up, with some bills already dead and others awaiting action.

BY RICHARD FAUST

Bills that would grant psychologists prescription-writing authority are effectively dead for the current legislative sessions in Montana and Hawaii, joining bills defeated in Arizona and Utah. Similar legislation is still pending in New Jersey, Oregon, and Tennessee.

Staff in APA's Department of Government Relations (DGR) have been closely monitoring the various state prescribing bills. They also have been working with the state psychiatric associations, as well as allies such as the AMA, the National Alliance on Mental Illness (NAMI), and members of the Scope of Practice Partnership to defeat these bills and protect patients.

In Montana, the House Human Services Committee tabled Senate Bill 272 by a vote of 14 to 1. The lopsided vote is a strong indicator that the measure is dead for this legislative session. There is a procedure in Montana called a blast that can resurrect a bill and move it out of committee and straight to the full house. This procedure has been tried several times by supporters, but to no avail.

Hawaii has long been a key battleground over prescription privileges. Some form of legislation to give psychologists the authority to write scripts for psychotropic drugs has been proposed in the Hawaii legislature every year since 1985. Such legislation was passed in 2007, but vetoed by then Gov. Linda Lingle. This history made the latest Hawaii bill one of most closely watched in the nation. Senate Bill 597 was referred to the House Health Committee, where the chair announced that the bill would not be heard. This action would have killed the bill, except for a procedural rule allowing supporters to get a waiver to move the bill to the full House. Supporters had 20 days to secure the support of one-third of the House for the waiver. The deadline passed on March 30, killing the bill for the year.

This is the first year that a psychologist prescribing bill has been introduced in New Jersey. Assembly Bill 3745 was introduced relatively late in the legislative session and is still in the Regulated Professions Committee. Tim Martin, lobbyist for the New Jersey Psychiatric Association, told *Psychiatric News* that the "schedule doesn't bode well for this bill. The calendar is its biggest enemy." At this time the bill does not even have a counterpart in the state senate. The New Jersey Psychiatric Association has partnered with APA, the AMA, and the Medical Society of New Jersey to provide a steady stream of literature and facts to legislators in an effort to defeat the bill.

In Tennessee, a scope-of-practice bill was introduced in both legislative chambers, Senate Bill 0390 and House Bill 0749. The Senate has taken the lead on the bill, with no action to this point in

please see ***Scope of Practice*** *on page 6*

Are You Missing Our Extra Features?

Many APA members may not realize that the news that comes to them every two weeks in *Psychiatric News* is also available on the Web at <psychnews.org> or <pn.psychiatryonline.org>. While there are a number of advantages to receiving the print edition—and our research has shown that a majority of members still prefer receiving a hard copy—the online version offers many features that readers may find useful and timesaving.

For one, you'll get the news earlier—the online version of each issue is posted on the issue's date. (For example, the June 3 issue will be posted by noon on June 3.) It can take up to two weeks for most APA members to receive their copy in the mail.

Also, all the articles in each issue are linked to a central content site, with related articles identified at the end of each article. Most articles contain hyperlinks to the studies or documents they cover, making it easy for readers to access the source documents and review the material for themselves. Also, readers can sign up for RSS feeds and e-mail alerts as well as download a version of the newspaper that can be read on PDAs. And perhaps you'd like to see what your colleagues are reading—just click on "Most Read Articles" and you'll find out.

Later this year, you'll see a greatly improved, expanded, and interactive version of *Psychiatric News* online. Here you will find in one location all the news of relevance to you and your practice. More information about this initiative will be published in *Psychiatric News.* We look forward to receiving your feedback.

APA RESOURCES

- ***Psychiatric News* Web Site:** psychnews.org
- **APA and the APA Answer Center:**
  (888) 35-PSYCH in the U.S. and Canada; in other countries: (703) 907-7300. The Answer Center is open Monday through Friday, 8:30 a.m. to 6 p.m. Eastern time. All APA departments and staff may be reached through the Answer Center.
  Fax: (703) 907-1085
  E-Mail: apa@psych.org
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  Web Site: www.PsychFoundation.org
- **Mental Health Parity Watch**
  Phone: (866) 882-6227
  Web Site: www.Mentalhealthparitywatch.org

Reflections at Year's End

BY CAROL A. BERNSTEIN, M.D.

How time flies! One of the paradoxes about getting older is that time goes by much more quickly than it used to. It is difficult for me to believe that my year as your president is almost over. I thought I would use this column to reflect on the experience, as many of you have asked what it is like to be president of APA.

Stepping into the job last May, I soon learned that any fantasies I may have had about the APA presidency were just that—fantasies. The experience was not what I had expected, but I can certainly say that it has been phenomenally educational and growth enhancing. I feel truly privileged to have been able to serve the psychiatric community in this capacity and hope to continue to make valuable contributions in the coming years.

I first became involved in APA when I was a resident—struggling with the usual issues residents face, such as trying to find a bed for a patient needing admission from our emergency room (how little has changed in this regard through the years!). I enjoyed meeting residents from across New York City through the New York County District Branch Residents' Committee, and even though we didn't have the clout to increase our bed capacity, working together helped ease some of the tension.

Following completion of my training, I continued my involvement with the district branch Executive Committee, the Area 2 Public Relations Committee, and ultimately the APA Assembly and the Board of Trustees. I also had the opportunity to chair APA's medical student and graduate medical education components, and through these experiences, I developed both an interest in and appreciation for the role of organized psychiatry in advancing the agenda on behalf of our patients and our profession.

One of the most interesting aspects of serving as APA president-elect and president has been representing the field in both the national and international arenas. Speaking with legislators, advisors to the executive branch of government, the public, and reporters and other media personnel has been so important for our effectiveness as an organization and profession. In addition, the experience has greatly improved my ability to articulate our concerns more clearly and convey the essence of our work. Reviewing the many letters and statements that APA receives as well as writing my twice-monthly columns in *Psychiatric News* have honed my focus on issues important to our members and to the community at large. The experience has had the added bonus of improving my writing ability and has enabled me to contemplate future writing about graduate medical education.

I have most enjoyed meeting with our younger colleagues and feeling the energy of their hopes and commitment. To those of you who know me, that's not surprising. In my "day job" as vice chair for education in psychiatry and associate dean for graduate medical education at New York University School of Medicine, I appreciate every opportunity I have to inspire the next generation of psychiatrists about the rewarding career they have chosen, the dramatic advances in our understanding of the brain and behavior that have enabled us to improve treatments, and the importance of being active advocates for those suffering from psychiatric and substance abuse disorders. Our residents and early career psychiatrists are the future leaders of our field. Their use of ever-evolving electronic communication vehicles (we have so much to learn from them!), their insistence on a true work-life balance, and their focus on deliverables and outcomes can only help psychiatry move forward in a positive direction.

On the other end of the age spectrum in psychiatry are those of us who hail from the baby-boom and World War II generations. We are the backbone of APA, and this past year, I was constantly reminded of the great wisdom and experience we generously share. We continue to forge on despite—or perhaps because of—the setbacks and disappointments we have experienced. We have seen many of our values and practices in medicine turned upside down. We worry about the future of the doctor-patient relationship and how our ethical and humanitarian values will be maintained in a professional specialty where regulation seems out of control. While we are proud of our hard-fought victory for parity, we wonder if the economic climate will preclude our patients' benefiting from it.

Along the way, I have also learned that you cannot please all of the people all of the time. I came into the APA presidency with high hopes about our ability to communicate effectively about the issues that matter to us and about our capacity to come together as an organization to advocate for outstanding science, exceptional treatments, access to care, and high-quality educational opportunities for our members. For the most part, my hopes have been realized, but I have come to see how easy it is for information to be misrepresented and how difficult it is to get our messages across accurately and effectively.

I continue to believe that the organization must function at the grass-roots level to move forward. We must use new electronic media to transmit information—but in a personal way. And while posting news and information on our Web site and publishing them in *Psychiatric News* and DB and Area newsletters are essential, they are no substitute for a personal connection. I believe our national leaders must work locally to mentor and develop our recent graduates.

Finally, I don't see the close of my presidency as an end, but as a beginning. You have my pledge that I will continue to work to advance the mission of APA. I look forward to our continuing collaboration on behalf of all those who suffer from psychiatric disorders. ■

CMS Issues Rule Describing Standards ACOs Must Meet

The AMA expresses concern about the ability of private practice and small-group physicians to form accountable care organizations that can compete with larger hospitals and health systems and raises antitrust questions regarding the referral of patients.

BY MARK MORAN

The federal Centers for Medicare and Medicaid Services (CMS) has issued a proposed rule governing the nature and function of "accountable care organizations (ACOs)," including performance measures that the organizations would be required to meet.

ACOs are a model for coordinated delivery of medical care within a reformed health care system and were designated for a demonstration project in the Patient Protection and Affordable Care Act signed by President Obama last year. The project is known as the Medicare Shared Savings Program.

Generally, ACOs are coalitions of physicians and hospitals responsible for coordinating medical care for populations of patients across the continuum of care; they agree to be accountable for improving the health and experience of care for individuals, as well as the health of populations, while reducing the growth rate in health care spending.

Under the Shared Savings Program, participating ACOs that meet performance measures would share in those savings, while those that fall short could be liable for financial penalties. According to the proposed rule issued by CMS, a physician participating in an ACO would be required to notify a beneficiary that he or she is participating in an ACO and that the physician will be eligible for additional Medicare payments for improving the quality of care the beneficiary receives while reducing overall costs or may be financially responsible to Medicare for failing to provide efficient, cost-effective care. The beneficiary may then choose to receive services from the provider or seek care from another provider that is not part of the ACO.

The CMS Web site has a page devoted to the Shared Savings Program, <www.cms.gov/sharedsavingsprogram>.

In the proposed rule, CMS outlined 65 performance measures for establishing the standard ACOs must meet under the Shared Savings Program. The 65 measures span five quality domains: patient experience of care, care coordination, patient safety, preventive health, and at-risk population/frail elderly health. Included in the preventive-health domain is a measure for depression screening.

The health reform law specifies that an ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- ACO professionals (that is, physicians and hospitals meeting the statutory definition) in group-practice arrangements.
- Networks of individual practices of ACO professionals.
- Partnerships or joint-venture arrangements between hospitals and ACO professionals, or hospitals employing ACO professionals.
- Other Medicare providers and suppliers as determined by the secretary of Health and Human Services.

The lengthy proposed rule, published in the *Federal Register* on April 7, spells out numerous regulations governing the makeup and operation of ACOs. For instance, to participate in the Shared Savings Program, an ACO would have to complete an application providing information on how the ACO plans to deliver high-quality care at lower costs for the beneficiaries it serves. The ACO must agree to accept responsibility for at least 5,000 ben-

please see ***ACOs*** *on page 26*

Principles for Accountable Care Organizations

At the Interim Meeting of the AMA House of Delegates in November 2010, delegates approved the follow ing 13 principles for how accountable care organizations would be configured and operate. Here is a summary of those principles:

- The goal of an accountable care organization (ACO) is to increase access to care, improve the quality of care, and ensure the efficient delivery of care. Within an ACO, a physician's primary ethical and professional obligation is the well-being and safety of the patient.
- ACOs must be physician-led to ensure that a physician's medical decisions are not based on commercial interests but rather on professional medical judgment that puts patients' interests first. Where a hospital is part of an ACO, the governing board of the ACO should be separate and independent from the hospital governing board.
- Physician and patient participation in an ACO should be voluntary. Any physician organization or other entity that creates an ACO must obtain the written affirmative consent of each physician to participate in the ACO. Physicians should not be required to join an ACO as a condition of contracting with any public or private payer or being admitted to a hospital medical staff.
- Any savings and revenues of an ACO should be retained for patient care services and distributed to the ACO participants. (Savings might accrue if, for instance, an ACO provides care for a defined population for less than the capitated amount or the expenditure target established by a payer.)
- Federal and state anti-kickback and self-referral laws should be sufficiently flexible to allow physicians to collaborate with hospitals in forming ACOs without being employed by the hospitals or ACOs.
- Additional resources should be provided up-front to encourage ACO development, and the Centers for Medicare and Medicaid Services should provide grants to physicians to finance up-front costs of creating an ACO.
- The ACO spending benchmark should be adjusted for differences in geographic practice costs and risk adjusted for individual patient risk factors.
- Quality performance standards must be consistent with AMA policy regarding quality, including the use of nationally accepted, physician specialty–validated clinical measures developed by the AMA Physician Consortium for Performance Improvement (in which APA is a participant).
- An ACO must be afforded procedural due process if a contract with any payer—public or private—is terminated because of ACO failure to meet quality performance standards.
- ACOs should be allowed to use different payment models, including fee-for-service, capitation, partial capitation, medical homes, care management fees, and shared savings. Any capitation payments must be risk-adjusted.
- The Consumer Assessment of Healthcare Providers and Systems Patient Satisfaction Survey should be used as a tool to determine patient satisfaction and whether an ACO meets the patient-centeredness criteria required by the ACO law.
- Interoperable health information technology and electronic health record systems are key to the success of ACOs. Medicare must ensure systems are interoperable to allow physicians and institutions to effectively communicate and coordinate care and report on quality.
- If an ACO bears risk (as may be possible in a capitated payment arrangement), the ACO must abide by the financial solvency standards pertaining to risk-bearing organizations.

The full text of the AMA's principles for ACOs is posted at <www.ama-assn.org/assets/meeting/2010i/i-10-ref-comm-j.pdf>.

Vermont Psychiatrists Back State's Single-Payer Insurance Plan

The legislation being considered by the Vermont Senate was originally conceived by Harvard economist William Hsaio, Ph.D., who helped create Taiwan's single-payer system.

BY MARK MORAN

The Vermont Psychiatric Association (VPA) is supporting legislation in its state to create a "single-payer" system covering all Vermonters for general medical and mental health and substance abuse services.

At press time, the legislation, which originated in the Vermont House of Representatives as "an act relating to a single-payer and unified health system" (H 202), had passed in the House and Senate. Gov. Peter Shumlin (D), who has championed the bill, has said he will sign it.

The proposal requires a federal waiver for the state to pursue its own alternative health reform proposal in place of the federal Patient Protection and Affordable Care Act (ACA), signed by President Obama last year. Three new organizations would be created to help control health care costs and increase health insurance coverage: a new Green Mountain Care Board to oversee cost-containment strategies, the Vermont Health Benefit Exchange as required under the ACA for helping to achieve

please see ***Vermont*** *on page 28*

Credit: Kate McAllister, State Legislative Field Representative, APA

Vermont Gov. Peter Shumlin (center in suit and yellow tie) came to the Vermont Psychiatric Association (VPA) spring meeting to discuss Vermont's single-payer health reform legislation and other issues. Pictured with the governor are members and staff of the VPA.

A Symposium Held During the APA 2011 Annual Meeting

Enhancing Outcomes in Schizophrenia: New Treatment Approaches

Monday, May 16, 2011

5:30PM Dinner and Sign-in
6:00PM-8:00PM Educational Activity

Sheraton Waikiki

Second Level, Hawaii Ballroom, Kauai and Maui Rooms
Honolulu, Hawaii

Don't Miss This Important Educational Activity!

5:30PM
Dinner

6:00PM
Welcome and Overview
Stephen M. Stahl, MD, PhD
Activity Chairperson
Adjunct Professor of Psychiatry,
School of Medicine
University of California, San Diego
Chairman, Neuroscience Education Institute
Carlsbad, California

6:05PM
Mechanism of Action of Atypical Antipsychotics: Are There Any Meaningful Differences?
Stephen M. Stahl, MD, PhD
Activity Chairperson

6:25PM
New Atypical Agents for Schizophrenia: What Have We Learned?
Rona J. Hu, MD
Clinical Associate Professor,
Stanford University School of Medicine
Medical Director, Acute Psychiatric Inpatient Unit
Stanford Hospital and Clinics
Stanford, California

6:45PM
Switch Strategies in Patients With Schizophrenia: What Works Best?
John W. Newcomer, MD
Senior Associate Dean for Clinical Research,
Leonard M. Miller Professor of Psychiatry
and Behavioral Sciences,
Leonard M. Miller School of Medicine
University of Miami
Miami, Florida

7:05PM
Enhancing Long-Term Outcomes in Schizophrenia: The Role of Cognitive Remediation
Alice Medalia, PhD
Professor of Psychology (in Psychiatry),
College of Physicians and Surgeons
Director of Psychiatric Rehabilitation,
Columbia University Medical Center
New York, New York

7:25PM
Question and Answer Session

8:00PM
Adjournment

Who Should Participate
This activity is designed for clinical psychiatrists and other healthcare professionals interested in the management and treatment of schizophrenia.

Overview
Although numerous new therapeutic agents have been introduced as approved treatments for schizophrenia, several questions remain. Do the new drugs differ substantially from each other or from older antipsychotics? Receptor pharmacology shows that no two of the new antipsychotics share the same profile, but is this clinically meaningful? The antipsychotic drugs and doses patients receive are frequently changed—is this a good aspect of treatment or not, and how best should this be done? Comparing theoretical pharmacology with practical clinical use can be meaningful in determining whether distinctions among the antipsychotics are clinically relevant and how to exploit such differences in a practical manner. In addition, the actions of antipsychotic drugs must be leveraged with additional therapeutic efforts, including combining them with therapies such as cognitive remediation. This symposium will review the various antipsychotic drugs, their pharmacologic properties, their differential clinical properties, how to use them, and how to leverage their efficacy with cognitive remediation.

Learning Objectives
At the conclusion of this activity, participants should be able to

1. Describe the role of receptor actions in therapeutic effects as well as side effects of current antipsychotic agents.
2. Evaluate what we have learned about the risks and benefits of specific agents in clinical practice, including how to select and switch from one agent to another.
3. Discuss how to leverage the actions of medications with cognitive remediation for best outcomes in schizophrenia.

Accreditation Statement
The American Psychiatric Association (APA) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Credit Designation Statement
The APA designates this live activity for a maximum of 2 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Faculty Disclosure Statement
Participating faculty will disclose any industry affiliations, sponsorships, honoraria, monetary support, and other potentially biasing factors to the audience.

Attendees must be registered for the APA Annual Meeting to attend this symposium. Seating is limited and will be on a first-come, first-served basis. For more information about the meeting, please visit the APA Web site at www.psych.org or contact the APA toll free at 1.888.357.7924 (within the US or Canada) or 703.907.7300.

Sponsored by the American Psychiatric Association

SUNOVION

Supported by an educational grant from Sunovion Pharmaceuticals Inc.

State Considers Major Reform Of Health Care System

"Coordinating care organizations" in Oregon will be charged with delivering care to citizens within a geographic region and with prioritizing services for those with special needs, including mental illness and drug dependence.

BY MARK MORAN

The state of Oregon is moving toward a sweeping transformation of general health and mental health services, including the creation of regional "coordinating care organizations (CCOs)" responsible for organizing the delivery of all health services for citizens in each region of the state.

CCOs are the state's designated term for what have elsewhere been called "accountable care organizations" (ACOs)—the coalitions of hospitals, health systems, physicians, and other health care providers envisioned as a new model for providing coordinated, cost-effective care across populations. In the Patient Protection and Affordable Care Act, for instance, ACOs have been designated as a model for providing care under a demonstration project within the Medicare program (see page 4).

The proposal for delivery system change is still in the planning stages and will require legislative approval in the state as well as a federal Medicaid waiver.

Oregon psychiatrist David Pollack, M.D., who is on the board of the American Association of Community Psychiatrists, told *Psychiatric News* that the plan for regional CCOs in Oregon would essentially create something like a single-payer system for each region. In some cases a region may have more than one CCO, but the CCOs would—in the manner of a single-payer system—be responsible for the financing, organization, and delivery of all health services, and in time they would cover all citizens within the region.

"These CCOs would obtain and utilize the funds from public and private sources to coordinate a diverse panel of providers for a wide range of health services, including general medical, mental health, addiction, and dental services, as well as the health services required by persons in long-term-care settings," Pollack said. "They would coordinate care through delivery-system refinements that would attend to the comprehensive needs of patients and the interdependence of health conditions and health providers associated with those conditions.

"There will be major emphasis on clinical integration of behavioral health and primary care and the implementation of person-centered primary care homes," he said. "[The delivery system transformation] will also involve promoting more systematic prevention and chronic-care efforts, efforts to increase health literacy, culturally competent policies and methods, and increased active participation by patients in their own care and in the overall operation of the health system."

Pollack is also a professor of public policy in the Department of Psychiatry and the Division of Management at Oregon Health and Sciences University.

Like the ACOs envisioned in the Medicare demonstration project, Oregon's CCOs would be charged with creating savings through coordination of care, and participating provider panels would share in those savings.

In 2009, Oregon approved a health system reform bill that anticipated in many ways the features of the federal health care reform law, creating health insurance exchanges for the state and a new Oregon Health Policy Board responsible for implementing the health care reform provisions.

However, the state—still reeling from the economic downturn that began in 2008—is facing a $3.6 billion deficit, and Gov. John Kitzhaber (D) came into office arguing that sweeping changes in the delivery system were needed before the state could move toward universal health coverage of its citizens envisioned in the state's reform bill.

(Kitzhaber is an emergency physician who was instrumental in passage of the Oregon Basic Health Services Act in 1989, which received national attention for its effort to prioritize health and mental health services for the state's Medicaid population.)

A Transformation Team was created in December 2010 and charged with devising a comprehensive redesign of Oregon's health delivery system. A timeline has been established that envisions implementation of a newly designed delivery system by January 2013.

A March report by the Transformation Team to the legislature outlined the composition and function of CCOs. According to the report, a CCO is "an organization that serves as a single point of accountability for the cost of health care within a global budget and for access to and quality of a coordinated system of physical health, behavioral health, and oral health services delivered to the specific population of patients enrolled with the organization."

Notably, the team report stated that CCOs should prioritize services for patients "with high needs and multiple chronic conditions, mental illness, or chemical dependency to involve them in accessing and managing appropriate preventive, remedial, and supportive care and services. . . ."

Pollack told *Psychiatric News* that Medicare and Medicaid populations would be blended together and would be the first to be covered by the CCOs, followed by state employees and later privately insured individuals.

"The vision of the transformation team heavily promotes the use of primary care providers and primary care medical homes, and we have articulated very clearly that mental health has to be included in these primary care homes," he said.

Information about Oregon's initiative is posted at <www.oregon.gov/OHA/OHPB/members.shtml>. ■

Isaac Ray Award

The American Psychiatric Association and the American Academy of Psychiatry and the Law invites nominations for the Isaac Ray Award for 2012. This Award honors Dr. Isaac Ray, one of the original founders and the fourth President of the American Psychiatric Association, and is presented to a person who has made outstanding contributions to forensic psychiatry or to the psychiatric aspects of jurisprudence. The Award, which will be presented at the Convocation of Fellows at the Annual Meeting of the American Psychiatric Association in Philadelphia, PA, in May 2012, includes an honorarium of $l,500. The recipient obligates him or herself to deliver a lecture or series of lectures on these subjects and to present the manuscript for publication.

Nominations are requested as follows: (1) a primary nominating letter (sent with the consent of the candidate), which includes a curriculum vitae and specific details regarding the candidate's qualifications for the Award, and (2) a supplemental letter from a second nominator in support of the candidate. Additional letters related to any particular candidate will not be accepted or reviewed by the Award Committee. Nominators should not submit letters on behalf of more than one candidate. The deadline for receipt of nominations is **July 1, 2011**. Nominations will be kept in the pool of applicants for two years.

Nominations, as outlined above, should be submitted to:

Renee L. Binder, M.D., Chairperson
c/o Lori Klinedinst, Staff Liaison
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Scope of Practice

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the House Health and Human Resources Committee.

In speaking with the legislative representative of the Tennessee Psychiatric Association (TPA), Greg Keyser, M.D., *Psychiatric News* learned that members of TPA members and the Tennessee Medical Association spoke at a hearing of the Senate General Welfare, Health, and Human Resources Committee and subsequently the bill was "taken off notice." The bill could be brought back up, but at this point, said Keyser, "we feel fairly confident with where we are with the bill, at least in this legislative session." Bills in Tennessee carry over from one legislative year to the next, so APA continues to be vigilant about developments regarding this bill.

Oregon is the state currently receiving the most attention by opponents and proponents alike of extending prescribing authority to psychologists. Just last year Oregon passed such a bill, but it was vetoed by then Gov. Ted Kulongoski. That bill was passed during a special legislative session, and Kulongoski noted in his veto statement that he did not believe there was "opportunity for citizens and interested stakeholders to be adequately involved in the development of those proposed major policy changes."

This year's legislation, House Bill 3523, was passed by the Health Committee on April 14. The bill is now in the House Ways and Means Committee pending action. As of press time, the schedule for further action had not been set. ■

APA Creates Forum On Integrated Care

APA members interested in learning more about integrated care and how it relates to psychiatry are invited to join a new electronic forum created by APA's Council on Healthcare Systems and Financing. "Integrated care" refers to treatment-delivery models in which physicians work together to coordinate their patients' care. Examples of integrated care models are patient-centered medical homes, accountable care organizations, medical neighbors, and health homes.

There are about 160 APA members and staff participating in the electronic forum so far. It is being staffed by Karen Sanders of APA's Office of Healthcare Systems and Financing.

More information is available by contacting Sanders at (703) 907-8590 or ksanders@psych.org. ■

High-Profile Friends Work Toward Common Goal

Longtime friends Bill Cosby and psychiatrist Alvin Poussaint, M.D., receive accolades for their extensive efforts to improve the lives of children through their work with the media.

BY EVE BENDER

A psychiatrist shared the spotlight with a legendary entertainer in February at Tufts University in Medford, Mass., as they were honored for their efforts to better the lives of children through their commitment to creating responsible media.

Bill Cosby, who starred as Cliff Huxtable in the long-running TV series "The Cosby Show" and who has used humor to bring families together through his comedy routines, television appearances, and books, also holds a doctorate in education. Cosby shared a podium with his longtime friend Alvin Poussaint, M.D., who is a professor of psychiatry and the faculty associate dean for student affairs at Harvard Medical School and an expert on child development. Cosby and Poussaint were at Tufts to accept Eliot-Pearson Awards for Excellence in Children's Media.

The Eliot-Pearson Awards, co-sponsored by the Communications and Media Studies Program and the Eliot-Pearson Department of Child Development at Tufts, are given biennially to organizations, individuals, or companies that have demonstrated a commitment to innovation, diversity, nonviolence, and developmentally appropriate media. Nominations are made in categories that include television, film, interactive media and media literacy, and advocacy.

"The Eliot-Pearson Award started in recognition that children today are growing up in a world of wall-to-wall media. However, a greater quantity of media does not mean that it is all good. We want to honor those who create quality children's media and inspire others to create to this standard," said Julie Dobrow, director of the media studies program. "Bill Cosby was a natural choice for this award based on his ability to educate audiences through humor and compassion, as was Alvin Poussaint for his understanding of children's developmental differences," noted a press release.

Poussaint is an expert on race relations, families, and parenting, and is a crusader in the fight against exploitation of children in the media. He served as a production consultant to "The Cosby Show" and consults to the media on a wide range of social issues. He has also worked to reduce racial stereotyping in script writing.

He currently serves as senior advisor for the Campaign for a Commercial-Free Childhood and previously was the media center director for the Harvard-affiliated Judge Baker Children's Center.

Dobrow further praised Poussaint, noting that, "In addition to his long and distinguished career as a psychiatrist and as an academic physician, Dr. Poussaint has long been an advocate for quality children's media. He has written and spoken on behalf of media that are free of gender and ethnic or racial stereotypes, media that promote and model positive, prosocial and healthy interactions. . . . We were very proud to welcome Dr. Poussaint back to Tufts, where he'd had his first academic appointment in the Tufts Medical School, and to award him the 2011 Eliot-Pearson Award for Excellence in Children's Media."

Both Poussaint and Cosby emphasized the importance of producing educational children's television during their acceptance speeches, and Poussaint said that placing limits on children's consumption of television programming was essential to healthy development. "Children do best by doing," he remarked, stressing that too much time in front of the television could hamper academic performance.

In an interview with the *Tufts Daily* before the ceremony, Cosby said that many viewers found "The Cosby Show" entertaining, but that they also learned something from the show: "I think that in giving parents different choices of how to behave while raising their children and still making the stories funny and the characters human and wonderful, we were able to have many people realize that it wasn't necessary to execute physical violence on a child, or even verbal yelling." ■

Credit: Alonso Nichols/Tufts University

Bill Cosby (right) laughs at the end of an interview before receiving the Eliot-Pearson Award from the Department of Child Development at Tufts University. Looking on is fellow award recipient psychiatrist Alvin Poussaint, M.D. The duo were recognized for their contributions to excellence in children's media and commitment to innovation, diversity, nonviolence, and developmentally appropriate media.

BPD Researcher Searches For Puzzle's Missing Piece

John Gunderson, M.D., believes the future of BPD research lies in uncovering the unifying pathway—some X factor of dysregulation—that accounts for the symptoms that present as borderline personality. This is the last of a four-part series on BPD researchers.

BY MARK MORAN

In the early 1970s, John Gunderson, M.D., was assistant chief at the National Institute of Mental Health (NIMH) Center for Studies of Schizophrenia, with plans to devote a career to understanding and treating psychosis, when Otto Kernberg, M.D., published reports on the intrapsychic structure of patients who presented with what came to be known as borderline personality disorder (BPD).

From his earliest days in training, Gunderson had seen patients who matched Kernberg's description—emotionally volatile, impulsive, and potentially aggressive, with a history of unstable relationships and frequent self-harming. Recalling his early exposure to the disorder, he admitted to an "almost voyeuristic fascination" with these patients, who were considered uniquely "difficult" and whose lives were often spectacularly chaotic.

He started to collect descriptive accounts of patients with a condition that had garnered the name "borderline," because it was believed at the time to inhabit a border between psychosis and neurosis. "The Schizophrenia Center was a good place to be doing this," he recalled, "because at the time the disorder was considered an atypical form of schizophrenia."

Photo courtesy of John Gunderson, M.D.

John Gunderson, M.D., began his career as a schizophrenia researcher, but a fascination with the troubled lives of BPD patients turned him into a leading expert on borderline personality disorder.

WORKING ON THE BORDERLINE

Largely because of Kernberg's influence, BPD became a topic of interest within the psychoanalytic community—Gunderson had trained at the Boston and Washington psychoanalytic institutes and worked as a research fellow at Chestnut Lodge, famed for its long-term psychodynamic approach—and in 1980 BPD entered *DSM*.

The criteria adopted at that time for BPD have remained largely the same to this day, with only minor modifications: intense, unstable relationships marked by idealization and devaluation; fears of abandonment; unstable self-image; impulsive behavior; brief but intense episodes of depression, irritability, and/or anxiety; chronic feelings of emptiness; intense anger; episodic stress-related paranoia and/or dissociative symptoms; recurrent suicidal behavior; and recurrent acts of self-mutilation.

By the mid-1980s, Gunderson had begun to attract referrals to care for patients who met the criteria, and almost in spite of himself, the schizophrenia expert-to-be became an expert on BPD. In 1984 he published a textbook, *Borderline Personality Disorder* (American Psychiatric Press Inc.), that would be followed by some 15 other books and monographs on BPD and personality disorders (among other topics) and more than 200 peer-reviewed research publications.

From 1996 through 2009, he was a principal investigator and chair of the steering committee for the Collaborative Longitudinal Personality Disorders Study (CLPS), a multisite NIMH study that has markedly advanced the understanding of BPD and other personality disorders as hybrids of stable personality traits and intermittently expressed symptomatic behaviors and of their long-term course.

Today, he is staff psychiatrist at McLean Hospital, where he has spent all of his career since leaving NIMH. What began as intellectual fascination has evolved into a passion for the appropriate treatment of people with a disorder that Gunderson believes has for too long been stigmatized by clinicians themselves.

"Here at McLean, the culture is one in which all of our people are extensively trained in the treatment of BPD and other personality disorders," he said. "Patients with this diagnosis have suffered so much stigma and discrimination; they really deserve the best treatment by skilled clinicians."

Symptoms Improve, but Not Functioning

The period since Gunderson first became fascinated with BPD has witnessed enormous expansion in the understanding of the heritability of the disorder and of its longitudinal course.

Among the more startling findings from CLPS and from the McLean Study of Adult Development (another longitudinal study of personality disorders, led by Gunderson's colleague at McLean, Mary Zanarini, Ed.D.), is that over time patients with BPD tend to get better symptomatically though they may not improve functionally. In an extension of the McLean Study of Adult Development that appeared online in *AJP in Advance* in April 2010, Zanarini and colleagues found that a substantial majority of patients with BPD experience remission of symptoms and that their remission tends to be stable over time compared with patients with other mental disorders *(Psychiatric News*, May 7, 2010).

But crucially, the study also found that only half of patients achieve good social and vocational functioning. So, for instance, while patients may cease cutting themselves or exhibiting other self-harming behaviors, some may remain unable to maintain close long-term relationships or a job.

"These patients experience significant remission in their psychopathology," Gunderson told *Psychiatric News*. "The remission in BPD occurs more slowly than for bipolar disorder or major depressive disorder, but about 85 percent of patients over a 10-year period will remit, which no one ever thought to be the case. And when they remit, they rarely relapse. But at the same time, many remain dysfunctional so that their public-health cost to society remains high, even though they may stop needing some treatment."

The finding has important implications for long-term outcome of treatment, since many of the psychotherapies for BPD are focused on specific domains of pathology but may not address long-term functioning.

Unifying Pathway for "BPD-ness"

Today, that insight is being advanced in a paper by Gunderson and colleagues in press with the *Archives of General Psychiatry*. The authors suggest that the separate domains of pathology that have been used diagnostically to identify BPD—emotional instability, impulsive aggression, interpersonal hypersensitivity—may be expressions of a common, as-yet-to-be-identified pathway, some X factor of dysregulation that is the core of "BPD-ness."

The study assessed the familial aggregation of BPD and its four major symptom "sectors" (defined as affective, interpersonal, behavioral, and cognitive) and tested whether the relationship of the familial and nonfamilial associations among the sectors can be accounted for by a "latent BPD construct" or unifying pathway.

What they found was substantial familial aggregation for BPD; they also found that all four sectors of psychopathology aggregated significantly in families. But the level of familial aggregation of BPD itself was higher than that of the individual sectors, suggesting that the relationship among the sectors must be explained by some common, unifying pathway.

The study suggests that efforts should be made to identify endophenotypes associated not only with individual sectors of BPD, but also with a more global tendency toward dysregulation that involves the several sectors of symptoms that together present as BPD.

Gunderson believes that the future of BPD research lies in unearthing this X factor, the common pathway for the behavioral endophenotypes that show up as the disorder.

"There is some kind of core to borderline pathology that is not about being either impulsive or emotional or interpersonally sensitive, something that isn't wholly captured by any of these characteristics," he told *Psychiatric News*. "This is important because our treatments that target one or another sector of behavior in BPD are not likely to get at the core."

"Time to Attainment of Recovery From Borderline Personality Disorder and Stability of Recovery: A 10-Year Prospective Follow-Up Study" is posted at <http://ajp.psychiatryonline.org/cgi/content/abstract/167/6/663>. ■

Nominations Invited for Child Psych Awards

APA invites applications for the Blanche F. Ittleson Research Award, Agnes Purcell McGavin Award for Prevention, and Agnes Purcell McGavin Award for Distinguished Career Achievement in Child and Adolescent Psychiatry. These awards are given to psychiatrists who have made significant contributions to child and adolescent psychiatry. They will be presented at APA's 2012 annual meeting in Philadelphia.

The Blanche F. Ittleson Research Award recognizes research that promises to foster important advances in promoting the mental health of children and adolescents. A psychiatrist or a group of psychiatric investigators must have published this research within five years or have it officially accepted for publication in the near future.

The Agnes Purcell McGavin Award for Prevention recognizes a psychiatrist who has been successful in research or policy that is recognized as contributing to primary prevention of mental illness among children and adolescents.

The Agnes Purcell McGavin Award for Distinguished Career Achievement in Child and Adolescent Psychiatry recognizes a psychiatrist whose career demonstrates success in research, teaching, publications, clinical care, or policy.

The deadline for nominations is August 1. Detailed information about the materials required for nomination and the address for submission can be accessed at <www.psych.org/Share/OMNA/AwardsandFellowships.aspx> or obtained from Alison Bondurant at abondurant@psych.org or (703) 907-8639. ■

College MH Caucus

APA members with a special interest in college mental health issues are invited to participate in a meeting of APA's College Mental Health Caucus at this year's annual meeting in Honolulu. Participants will have an opportunity to discuss issues, raise concerns, and share information. The meeting will be held Tuesday, May 17, from 9:30 a.m. to 11:30 a.m. in the Kona Room of the Sheraton Waikiki Hotel. ■

Finding Job Isn't Direct Path To Better Mental Health

While employment is generally better than unemployment for mental health, the wrong job can be worse than no job. However, policy prescriptions for dealing with the impact of bad jobs are hard to come by.

BY RICHARD FAUST

Credit: Sergey Ivanov

Can having a bad job be more detrimental to mental health than no job? A study published in March in the Australian journal *Occupational and Environmental Medicine* says yes.

Peter Butterworth, Ph.D., an associate professor at the Centre for Mental Health Research at the Australian National University, and colleagues started from the long-established premise that employment is associated with myriad health (including mental health) benefits compared with unemployment. They said, however, that there has been "little direct comparison between the health effects of unemployment and [those] of jobs of varying psychosocial quality, especially longitudinally." They noted that "averse psychosocial work conditions such as high job demands, low decision latitude or control, job strain, a lack of social support at work, effort-reward imbalance, and job insecurity are well-established risk factors for poor health." The authors then sought to examine these characteristics in a longitudinal study of 7,155 working-age respondents to determine if poor-quality jobs continue to maintain a stronger association with mental health than unemployment does.

As hypothesized, researchers found that the relationship between labor-force status (employed, unemployed, and not participating in the labor force) and mental health was significant. Those employed have better mental health than the unemployed.

In discussing the study findings with *Psychiatric News*, Butterworth noted that "work provides a range of benefits over unemployment: not only access to financial and material resources, but also a sense of purpose and identity."

In an interview with *Psychiatric News*, Daven Morrison III, M.D., president of the Academy of Organizational and Occupational Psychiatry, echoed these thoughts, saying that work supports an individual's identity, and earnings tell the individual that he or she has value.

The longitudinal nature of the study enabled the authors to look at the link between employment circumstances and mental health over time and for individuals. This approach led to the finding that even when including a range of covariates—such as physical health, education, and experience of hardship—there was no difference in the mental health of unemployed individuals and individuals in the poorest quality jobs.

Butterworth told *Psychiatric News*, "Not all work is equal. . . . [The] findings show that the common assumption that any job offers mental health benefits for individuals over unemployment is not universally true."

The adverse mental effects of jobs with poor psychosocial conditions became starker when researchers looked at those going from unemployment into a new job. The results again confirmed that those moving from unemployment into a good job showed improved mental health. However, "those respondents who moved into poor-quality jobs showed a worsening in their mental health compared with those who remained unemployed."

This last finding raised some questions for Morrison. He was curious about the people who returned to work in a bad job. He would have liked the authors to ask whether the subjects previously had a better job and whether they were missing something from the previous job that the new position was unable to match, such as income, prestige, or security.

He noted that there is a lot of discussion in psychiatry about the difference between loss and grief and depression. He wondered whether respondents who returned to work in a bad job were mourning the loss of a better position as opposed to simply having difficulties with the new job.

While not the focus of this study, other questions about the mental health repercussions of a bad job revolve around the individual. Stephen Heidel, M.D., president of Heidel and Associates, told *Psychiatric News* that "individuals bring their own vulnerabilities to a situation." Some people are not a good fit for certain jobs. For example, perhaps someone with PTSD should not work in a convenience store where robberies have occurred.

The question remains, however, about what to do with what Heidel calls an "obvious truism." The authors contended that history has shown that the worst aspects of poor-quality jobs can be addressed through societal intervention and pressure and government policy. They pointed to previous regulatory changes geared toward ensuring worker safety and improving work conditions. Butterworth told *Psychiatric News* that the next step is to focus on the psychosocial aspects of employment.

"In the same way that we no longer accept workplaces that are physically unsafe or in which employees are exposed to dangerous substances, there could be a greater focus on ensuring a more positive psychosocial environment at work."

Heidel was skeptical that there is an easy fix. He doesn't believe that there is a magic number of criteria that can be modified to stop a job from having a negative impact on mental health. "Any one egregious element can make a job unbearable," and for a given individual, that element may be unknowable. Figuring out how to find and eliminate that one item for divergent individuals may not be a prescription for policymaking.

"The Psychosocial Quality of Work Determines Whether Employment Has Benefits for Mental Health: Results From a Longitudinal National Household Panel Survey" is posted at <http://press.psprings.co.uk/oem/march/oem59030.pdf>. ■

Data Sound Alarm on Gay Teens' Heightened Suicide Risk

The disparity in suicide risk between gay and nongay youth appears to increase with each level of severity—ideation, intent with a plan, actual suicide attempts, and attempts requiring medical attention.

BY MARK MORAN

Gay adolescents are three times as likely to report a history of suicidal ideation, suicidal intent, or suicidal attempts that require medical attention than are their straight peers.

The finding is from a meta-analysis of 19 studies looking at depression and suicide among children and adolescents that appears in the April 4 *Journal of Adolescent Health*, a publication of the Society for Adolescent Health and Medicine.

"The results underscore the need for clinicians treating youth and adolescents, whether they are gay or straight, to ask about sexual orientation and about suicidal thoughts or intentions, and to make sure that there are resources to intervene," lead author Michael Marshal, Ph.D., told *Psychiatric News*.

He is an assistant professor in the Department of Psychiatry at the University of Pittsburgh.

In the analysis, Marshal and colleagues conducted a systematic search of PsychInfo and MedLine to identify all studies published in 2009 or earlier using various combinations of key terms including "suicide," "depression," "gay," "lesbian," "LGB," and "adolescent." There were two criteria for the inclusion of studies in the meta-analyses: the studies must have reported rates of depression and/or suicidality among sexual minority and heterosexual youth, and their study samples had a mean age of 18 or less, with an upper boundary of the age range not exceeding 21 years.

Researchers identified and reviewed 378 abstracts to determine their eligibility, with the majority of ineligible studies excluded because they either focused on those aged 18 to 25, did not include a heterosexual comparison group, or were review papers.

Analysis of the 19 studies that met inclusion criteria revealed that, on average, 28 percent of gay teens reported a history of suicidality—including suicidal ideation, suicidal intent (defined as having a plan to commit suicide), actual suicide attempts, and attempts that required medical attention. This figure contrasts with 12 percent of heterosexual teens.

The analysis also showed that even after controlling for variables such as depression, low self-esteem, substance use, and conflict with family, gay and lesbian youth were still more than twice as likely to report a history of suicidality as were heterosexual youth.

Moreover, Marshal told *Psychiatric News* that the disparity in suicidality between gay and nongay youth increased with each level of severity—from ideation to actual attempts requiring medical attention. The odds ratio for suicidality among gay youth was 1.9 for ideation, 2.2 for intent, 3.18 for a history of attempts, and 4.17 for attempts requiring medical attention.

Overall, the odds ratio for any level of suicidality was 2.92 for youth who identified as being gay, according to the report.

Marshal told *Psychiatric News* that he had worked for several years in a clinic for adolescents with depression, many of whom had a history of suicidal thoughts or attempts, and was struck by the number of gay youth among his caseload. He added that he was intrigued to know whether the recent spate of news stories about suicide among gay youth were sensationalized or the reports represented a real trend.

The analysis would appear to confirm the markedly higher risk for suicidal thoughts, plans, or attempts among gay teenagers. He noted that all of the effect sizes for the various comparisons leaned in the direction of a higher risk for gay teens.

He emphasized the need for psychi-

please see ***Gay Teens*** *on page 28*

Mission to Libya Triggers Wide Range of Emotions

In 1999, a young physician fled Libya for political reasons and eventually became an American psychiatrist. He recently returned to help the Libyan people gain their freedom from dictator Muammar Gaddafi.

BY JOAN AREHART-TREICHEL

The date July 8, 1999, is one that Omar Reda, M.D., will never forget.

He was working as an emergency room physician in his hometown of Benghazi, Libya. When he arrived home that evening, his father told him that rumors were circulating that Omar would be imprisoned and perhaps even executed. The reason? He had delivered food and supplies to the families of people imprisoned by Libya's dictator, Col. Muammar Gaddafi.

His father urged him to flee the country. Taking his father's advice, he took a boat the next day to Malta, where he remained for several months until he obtained a visa to the United Kingdom. He made the right decision to leave Libya when he did; shortly thereafter, several of his physician friends who had provided similar help were arrested and imprisoned.

Credit: Omar Reda, M.D.

Omar Reda, M.D.: "Mr. Gaddafi had used aircraft missiles to fire on people. So there were people who were cut in half, there were people missing their extremities, there were people missing their brains."

Thus started Reda's odyssey—first to the United Kingdom, where he was a political refugee for three years—and then to the United States—where he did a psychiatry residency at the University of Tennessee and where he obtained a master's degree in disaster psychiatry from Harvard University. Today, 12 years after fleeing Libya, he lives in Portland, Ore., and works as an assistant professor of psychiatry at Oregon Health and Sciences University. He is married to a woman originally from Libya, and they have three daughters.

A Return Reconsidered

After Reda fled Libya, he didn't think he would ever return as long as Gaddafi remained in power. But then the Libyan revolution started last February 15. Thousands of Libyans, inspired by prodemocracy uprisings in Tunisia, Egypt, and other parts of the Arab world, attempted to liberate their country from Gaddafi. "I wanted to help them in some way," Reda said in an interview. "But how could I do that while living and working in Portland, Oregon?"

He looked for organizations that might be sending medical supplies to Libya and found one right in Portland. It was Medical Teams International, a nonprofit humanitarian aid and global health organization founded in 1979. He offered to help as a volunteer, and the organization was delighted to accept. He was told, "We are ready to send a shipment of medical supplies worth $421,000 to Libya right now. Would you be willing to distribute it?" He said yes.

His wife was anxious about his going to a combat zone, but agreed to support him in his effort. His disaster psychiatry training helped him prepare mentally for what he was about to undertake.

On February 26, Reda flew to Cairo. The medical supplies that he was supposed to distribute in Libya had been shipped to Cairo from the Netherlands. However, due to logistical problems, he couldn't obtain access to them right away. Nonetheless, "the Egyptian army and people were very kind, very sympathetic with the Libyan cause," he said, and some Libyan freedom fighters agreed to bring the medical supplies to him in Libya once the supplies had cleared Egyptian customs.

In Cairo, Reda also met a group of Libyans who agreed to take him along when they drove across the Egyptian border into Libya on March 1. Once across the border, he hitched a ride with still other Libyans to his former hometown of Benghazi, located in the eastern, liberated part of Libya.

Although he was exhausted from his long trip, he was exhilarated at the thought of being back on Libyan soil—especially soil "where I could smell the fresh air of freedom and share in Libyans' high spirits. There was a sense of community everywhere, even among strangers."

Shortly after he arrived in Benghazi, the freedom fighters delivered the medical supplies to him. He had initially planned to distribute the supplies in Benghazi, but then learned that a city some 100 miles to the south, Ajdabiya, had just been bombed. There were many casualties, so he decided to take the supplies to that city instead. He got one of his brothers to come along to help. They took the supplies to the city's main hospital. As they tore open the boxes of anesthesia supplies, pain-control narcotics, antianxiety medications, and other items, "people were very excited, very grateful," Reda said.

He Helped in Emergency Room

After that, Reda helped out as an emergency room physician in the Ajdabiya hospital. It was overcrowded with patients, and some of their injuries were horrific, Reda said. And because of patients' severe injuries, many hospital staff were overwhelmed emotionally, so Reda put his disaster psychiatry knowledge to work as well. He let them know that "what they were experiencing were normal reactions to abnormal situations and that he was available to listen if they wanted to share a thought, emotion, or story" with him. Indeed, stories he heard convinced him that the violence and casualties had been a lot worse than reported by the Western media and humanitarian organizations.

Reda likewise met with the head of the psychiatric hospital in Benghazi. He learned that admissions to the hospital had quadrupled since the start of the revolution, with most cases designated as acute stress disorder, brief psychotic disorder, or hysteria. Both he and the hospital chief agreed that there were probably going to be many cases of posttraumatic stress disorder in the months to come, especially among children who had been raped or who had witnessed their loved ones die.

In Benghazi, Reda also managed to reunite with his parents and some of his nine siblings, to meet some nieces and nephews for the first time, and to help his family with their emotional needs since one of his brothers had been kidnapped and two cousins killed since the revolution started.

On March 15, Reda returned to the United States. His two-week trip had flooded him with myriad emotions—anxiety, relief, joy, heartbreak, anger, and survivor's guilt—and he felt emotionally spent. He still feels emotionally depleted to some extent, he said.

"I am grateful to the Libyan people who fought and sacrificed their lives so that there is a free part of Libya and particularly so that I could return and see my family there," he explained. "The Libyan people are currently cautiously optimistic, especially since the United Nations declared a no-fly zone in Libya on March 17 and the United States spearheaded a military coalition to impose it. But almost every family in Libya has lost at least one loved one through this revolution, and no one feels safe as long as Gaddafi is in power."

Reda now dreams of returning to Libya and helping the Libyan people build a mental health care infrastructure. Currently, mental health care in Libya, even for minor disorders, is provided exclusively in the country's three mental hospitals. There is no outpatient follow-up care, and there are only about 20 psychiatrists to serve a population of 6 million people. "Maybe I can go there three months every year," said Reda. "I'm working with my university on how I can achieve that." ■

Learning From Spirit of Aloha

BY KAYLA POPE, M.D., J.D.

The APA annual meeting will mark the completion of my two-year term on the APA Board of Trustees. It has been a remarkable experience in many ways, and it has been a privilege to serve as your representative.

Kayla Pope, M.D., J.D.

I have been impressed by many aspects of the organization, chief among them the dedication and commitment of the members who serve on the Board, in the Assembly, and on the councils and other APA components. With all of our lives as busy as they are, to find those few extra hours to draft a resolution, meet with a member of Congress, or respond to a media request is no small task, and these volunteers deserve our appreciation.

I have also been impressed by the dedication and skills of the APA staff and the array of programs and issues they deftly manage for the Association's membership. Not infrequently, an impassioned argument would be made during a Board of Trustees meeting for this program or that initiative, only to have it come to light that the staff already had it covered.

While the Association has many strengths, there was one aspect of the experience that was disheartening and even perplexing, especially given our profession—how we manage conflict.

While I appreciate that we live in a world with finite resources and competing interests, too often it seemed that pushing for a particular position was more important than preserving the sense of our belonging to a community. Examples that come to mind are the invitation of Desmond Tutu to speak at the annual meeting Convocation, concerns about ABPN certification requirements, and the development of *DSM-5*. With all of these issues, there are very good reasons that colleagues may hold opposing views. But conflict is all in how you manage it, and we too often manage it in a way that discourages communication and erodes our group identity. We can do better than that, and the field, our patients, and our communities would be better served if we did.

Where better to reaffirm our sense of community than in Hawaii, where this year's annual meeting will soon begin and where Lauren Hodges, M.D., a local MIT, describes things getting done the "aloha way." Aloha meaning peace, kindness, and compassion. May our time in Hawaii renew our commitment to cooperation, communication, and community. Aloha. ■

Kayla Pope, M.D., J.D., is APA's member-in-training trustee, the Robert L. Stubblefield AACAP resident member to the AMA, and a clinical research fellow at NIMH and Children's National Medical Center.

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BOXED WARNING

1. AGRANULOCYTOSIS
BECAUSE OF A SIGNIFICANT RISK OF AGRANULOCYTOSIS, A POTENTIALLY LIFE-THREATENING ADVERSE EVENT, CLOZAPINE SHOULD BE RESERVED FOR USE IN (1) THE TREATMENT OF SEVERELY ILL PATIENTS WITH SCHIZOPHRENIA WHO FAIL TO SHOW AN ACCEPTABLE RESPONSE TO ADEQUATE COURSES OF STANDARD ANTIPSYCHOTIC DRUG TREATMENT, OR (2) FOR REDUCING THE RISK OF RECURRENT SUICIDAL BEHAVIOR IN PATIENTS WITH SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER WHO ARE JUDGED TO BE AT RISK OF RE-EXPERIENCING SUICIDAL BEHAVIOR.
PATIENTS BEING TREATED WITH CLOZAPINE MUST HAVE A BASELINE WHITE BLOOD CELL (WBC) COUNT AND ABSOLUTE NEUTROPHIL COUNT (ANC) BEFORE INITIATION OF TREATMENT AS WELL AS REGULAR WBC COUNTS AND ANCs DURING TREATMENT AND FOR AT LEAST 4 WEEKS AFTER DISCONTINUATION OF TREATMENT.
CLOZAPINE IS AVAILABLE ONLY THROUGH A DISTRIBUTION SYSTEM THAT ENSURES MONITORING OF WBC COUNT AND ANC ACCORDING TO THE SCHEDULE DESCRIBED BELOW PRIOR TO DELIVERY OF THE NEXT SUPPLY OF MEDICATION.

2. SEIZURES
SEIZURES HAVE BEEN ASSOCIATED WITH THE USE OF CLOZAPINE. DOSE APPEARS TO BE AN IMPORTANT PREDICTOR OF SEIZURE, WITH A GREATER LIKELIHOOD AT HIGHER CLOZAPINE DOSES. CAUTION SHOULD BE USED WHEN ADMINISTERING CLOZAPINE TO PATIENTS HAVING A HISTORY OF SEIZURES OR OTHER PREDISPOSING FACTORS. PATIENTS SHOULD BE ADVISED NOT TO ENGAGE IN ANY ACTIVITY WHERE SUDDEN LOSS OF CONSCIOUSNESS COULD CAUSE SERIOUS RISK TO THEMSELVES OR OTHERS.

3. MYOCARDITIS
ANALYSES OF POSTMARKETING SAFETY DATABASES SUGGEST THAT CLOZAPINE IS ASSOCIATED WITH AN INCREASED RISK OF FATAL MYOCARDITIS, ESPECIALLY DURING, BUT NOT LIMITED TO, THE FIRST MONTH OF THERAPY. IN PATIENTS IN WHOM MYOCARDITIS IS SUSPECTED, CLOZAPINE TREATMENT SHOULD BE PROMPTLY DISCONTINUED.

4. OTHER ADVERSE CARDIOVASCULAR AND RESPIRATORY EFFECTS
ORTHOSTATIC HYPOTENSION, WITH OR WITHOUT SYNCOPE, CAN OCCUR WITH CLOZAPINE TREATMENT. RARELY, COLLAPSE CAN BE PROFOUND AND BE ACCOMPANIED BY RESPIRATORY AND/OR CARDIAC ARREST. ORTHOSTATIC HYPOTENSION IS MORE LIKELY TO OCCUR DURING INITIAL TITRATION IN ASSOCIATION WITH RAPID DOSE ESCALATION. IN PATIENTS WHO HAVE HAD EVEN A BRIEF INTERVAL OFF CLOZAPINE, i.e., 2 OR MORE DAYS SINCE THE LAST DOSE, TREATMENT SHOULD BE STARTED WITH 12.5 mg ONCE OR TWICE DAILY.
SINCE COLLAPSE, RESPIRATORY ARREST AND CARDIAC ARREST DURING INITIAL TREATMENT HAS OCCURRED IN PATIENTS WHO WERE BEING ADMINISTERED BENZODIAZEPINES OR OTHER PSYCHOTROPIC DRUGS, CAUTION IS ADVISED WHEN CLOZAPINE IS INITIATED IN PATIENTS TAKING A BENZODIAZEPINE OR ANY OTHER PSYCHOTROPIC DRUG.

5. INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS TREATED WITH ANTIPSYCHOTIC DRUGS ARE AT AN INCREASED RISK OF DEATH. ANALYSES OF SEVENTEEN PLACEBO-CONTROLLED TRIALS (MODAL DURATION OF 10 WEEKS), LARGELY IN PATIENTS TAKING ATYPICAL ANTIPSYCHOTIC DRUGS, REVEALED A RISK OF DEATH IN THE DRUG-TREATED PATIENTS OF BETWEEN 1.6 TO 1.7 TIMES THE RISK OF DEATH IN PLACEBO-TREATED PATIENTS. OVER THE COURSE OF A TYPICAL 10 WEEK CONTROLLED TRIAL, THE RATE OF DEATH IN DRUG-TREATED PATIENTS WAS ABOUT 4.5%, COMPARED TO A RATE OF ABOUT 2.6% IN THE PLACEBO GROUP. ALTHOUGH THE CAUSES OF DEATH WERE VARIED, MOST OF THE DEATHS APPEARED TO BE EITHER CARDIOVASCULAR (e.g., HEART FAILURE, SUDDEN DEATH) OR INFECTIOUS (e.g., PNEUMONIA) IN NATURE. OBSERVATIONAL STUDIES SUGGEST THAT, SIMILAR TO ATYPICAL ANTIPSYCHOTIC DRUGS, TREATMENT WITH CONVENTIONAL ANTIPSYCHOTIC DRUGS MAY INCREASE MORTALITY. THE EXTENT TO WHICH THE FINDINGS OF INCREASED MORTALITY IN OBSERVATIONAL STUDIES MAY BE ATTRIBUTED TO THE ANTIPSYCHOTIC DRUG AS OPPOSED TO SOME CHARACTERISTIC(S) OF THE PATIENTS IS NOT CLEAR. CLOZAPINE IS NOT APPROVED FOR THE TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.

BEFORE INITIATING CLOZAPINE, IT IS STRONGLY RECOMMENDED THAT A PATIENT BE GIVEN AT LEAST 2 TRIALS, EACH WITH A DIFFERENT STANDARD DRUG FOR SCHIZOPHRENIA, AT AN ADEQUATE DOSE AND DURATION.

PATIENTS WHO ARE BEING TREATED WITH CLOZAPINE MUST HAVE A BASELINE WBC AND ANC BEFORE TREATMENT INITIATION, AND EVERY WEEK FOR THE FIRST 6 MONTHS. IF WBC LEVELS ≥ 3,500/MM³ AND ANC ≥ 2,000/MM³ ARE MAINTAINED DURING THE FIRST 6 MONTHS OF CONTINUOUS THERAPY, WBC AND ANC CAN BE MONITORED EVERY 2 WEEKS FOR THE NEXT 6 MONTHS. IF THE WBC LEVELS AND ANC ARE MAINTAINED DURING THE SECOND 6 MONTHS OF CONTINUOUS THERAPY, WBC AND ANC CAN BE MONITORED EVERY 4 WEEKS. WHEN CLOZAPINE TREATMENT IS DISCONTINUED (REGARDLESS OF REASON), WBC AND ANC MUST BE MONITORED WEEKLY FOR AT LEAST 4 WEEKS FROM THE DAY OF DISCONTINUATION OR UNTIL WBC ≥ 3,500/MM³ AND ANC ≥ 2,000/MM³.

Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery including agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, and feeding disorder in these infants. These complications have varied from self-limited to intensive care support and prolonged hospitalization. Clozapine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The safety and effectiveness of Clozapine has not been established in pediatric patients. Women receiving Clozapine should not breastfeed.

Because of risks associated with Clozapine, patients failing to show an acceptable level of clinical response should avoid continuing therapy. Patients taking benzodiazepines, anitihypertensives, citalopram, caffeine, tobacco smoke, and inhibitors or inducers of the cytochrome P450 1A2, 2D6, and 3A4 isozyme systems, should be carefully monitored upon Clozapine initiation and during therapy. Because of initial sedation, dose should be gradually escalated.

Patients with compromised cardiovascular function should be monitored since tachycardia, which may be sustained, has been observed in approximately 25% of patients taking Clozapine. Clozapine should be used with caution in patients with dementia or risk factors for stroke because of increased risk of cerebrovascular adverse events in dementia patients treated with some atypical antipsychotics.

Rare instances of eosinophilia, which can be substantial, have been reported. There are several reports of Neuroleptic Malignant Syndrome with Clozapine alone or in combination with lithium or other CNS-active agents. Tardive Dyskinesia is associated with use of antipsychotic drugs, with a low incidence of occurrence when Clozapine is used alone. Dystonia may occur in the first few days of treatment, especially in males and younger age groups. Symptoms include spasm of the neck muscles sometimes progressing to tightness of the throat, difficulty swallowing and breathing, and protrusion of the tongue. This may occur with low doses, but more frequently and with greater severity at higher doses.

Clozapine is contraindicated in patients diagnosed with myeloproliferative disorders, uncontrolled epilepsy, paralytic ileus, Clozapine-induced agranulocytosis, or severe granulocytopenia. Clozapine is also contraindicated in patients with severe CNS depression and in patients in a comatose state. Clozapine should not be administered concomitantly with drugs known to cause agranulocytosis.

Clozapine has potent anticholinergic effects and care should be exercised in using this drug. Patients should be observed for instances of cardiomyopathy, fever, pulmonary embolism, hepatitis, narrow angle glaucoma, impairment of intestinal peristalsis, prostate enlargement, impaired cognitive and motor performance, and when undergoing general anesthesia. Hyperglycemia, sometimes leading to ketoacidosis, has been associated with atypical antipsychotics such as Clozapine. Diagnosed diabetics should be monitored for worsening glucose control.

Common adverse events include drowsiness/sedation, dizziness, headache, tremor, syncope, tachycardia, visual disturbances, and hypotension. Patients should not drink alcohol or drive, and should avoid hazardous activity while taking Clozapine.

BRIEF SUMMARY

CLOZAPINE TABLETS USP

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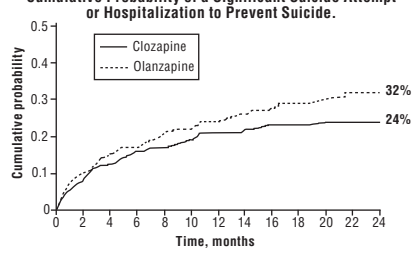
Clinical Trial Data (Reducing the Risk of Recurrent Suicidal Behavior in Patients with Schizophrenia or Schizoaffective Disorder Who are Judged to be at Risk of Re-experiencing Suicidal Behavior)
The effectiveness of clozapine in reducing the risk of recurrent suicidal behavior was assessed in the International Suicide Prevention Trial (InterSePT™), which was a prospective, randomized, international, parallel-group comparison of clozapine vs. olanzapine in patients with schizophrenia or schizoaffective disorder (DSM-IV) who were judged to be at risk for re-experiencing suicidal behavior. Only about one-fourth of these patients (27%) were considered resistant to standard antipsychotic drug treatment, and the remainder were not. Patients met one of the following criteria:

- They had attempted suicide within the 3 years prior to their baseline evaluation.
- They had been hospitalized to prevent a suicide attempt within the 3 years prior to their baseline evaluation.
- They demonstrated moderate-to-severe suicidal ideation with a depressive component within 1 week prior to their baseline evaluation.
- They demonstrated moderate-to-severe suicidal ideation accompanied by command hallucinations to do self-harm within 1 week prior to their baseline evaluation.

Dosing regimens for each treatment group were determined by individual investigators and were individualized by patient. Dosing was flexible, with a dose range of 200 to 900 mg/day for clozapine and 5 to 20 mg/day for olanzapine. For the 956 patients who received clozapine or olanzapine in this study, there was extensive use of concomitant psychotropics: 84% with antipsychotics; 65% with anxiolytics; 53% with antidepressants, and 28% with mood stabilizers. There was significantly greater use of concomitant psychotropic medications among the patients in the olanzapine group.
The primary efficacy measure was time to (1) a significant suicide attempt, including a completed suicide, (2) hospitalization due to imminent suicide risk (including increased level of surveillance for suicidality for patients already hospitalized), or (3) worsening of suicidality severity as demonstrated by "much worsening" or "very much worsening" from baseline in the Clinical Global Impression of Severity of Suicidality as assessed by the Blinded Psychiatrist (CGI-SS-BP) scale. A determination of whether or not a reported event met criterion 1 or 2 above was made by the Suicide Monitoring Board (SMB, a group of experts blinded to patient data).

A total of 980 patients were randomized to the study and 956 received study medication. Sixty-two percent of the patients were diagnosed with schizophrenia, and the remainder (38%) were diagnosed with schizoaffective disorder. Only about one-fourth of the total patient population (27%) was identified as "treatment resistant" at baseline. There were more males than females in the study (61% of all patients were male). The mean age of patients entering the study was 37 years (range 18 to 69). Most patients were Caucasian (71%), 15% were Black, 1% were Oriental, and 13% were classified as being of "other" races.
Data from this study indicate that clozapine had a statistically significant longer delay in the time to recurrent suicidal behavior in comparison with olanzapine. This result should be interpreted only as evidence of the effectiveness of clozapine in delaying time to recurrent suicidal behavior, and not a demonstration of the superior efficacy of clozapine over olanzapine.
The probability of experiencing (1) a significant suicide attempt, including a completed suicide, or (2) hospitalization due to imminent suicide risk (including increased level of surveillance for suicidality for patients already hospitalized) was lower for clozapine patients than for olanzapine patients at Week 104: clozapine 24% vs. olanzapine 32%; 95% C.I. of the difference: 2%, 14% (**Figure 1**).

Figure 1. Kaplan-Meier Estimates of Cumulative Probability of a Significant Suicide Attempt or Hospitalization to Prevent Suicide.



INDICATIONS AND USAGE
Treatment-Resistant Schizophrenia
Clozapine is indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia. Because of the significant risk of agranulocytosis and seizure associated with its use, clozapine should be used only in patients who have failed to respond adequately to treatment with appropriate courses of standard drug treatments for schizophrenia, either because of insufficient effectiveness or the inability to achieve an effective dose due to intolerable adverse effects from those drugs (see **WARNINGS**).
The effectiveness of clozapine in a treatment-resistant schizophrenic population was demonstrated in a 6-week study comparing clozapine and chlorpromazine. Patients meeting DSM-III criteria for schizophrenia and having a mean BPRS total score of 61 were demonstrated to be treatment resistant by history and by open, prospective treatment with haloperidol before entering into the double-blind phase of the study. The superiority of clozapine to chlorpromazine was documented in statistical analyses employing both categorical and continuous measures of treatment effect.
Because of the significant risk of agranulocytosis and seizure, events which both present a continuing risk over time, the extended treatment of patients failing to show an acceptable level of clinical response should ordinarily be avoided. In addition, the need for continuing treatment in patients exhibiting beneficial clinical responses should be periodically re-evaluated.
Reduction in the Risk of Recurrent Suicidal Behavior in Schizophrenia or Schizoaffective Disorders
Clozapine is indicated for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behavior, based on history and recent clinical state. Suicidal behavior refers to actions by a patient that puts him/herself at risk for death.
The effectiveness of clozapine in reducing the risk of recurrent suicidal behavior was demonstrated over a 2-year treatment period in the InterSePT Trial (see **Clinical Trial Data** under **CLINICAL PHARMACOLOGY**). Therefore, clozapine treatment to reduce the risk of suicidal behavior should be continued for at least 2 years (see **DOSAGE AND ADMINISTRATION**).
The prescriber should be aware that a majority of patients in both treatment groups in InterSePT received other treatments as well to reduce suicide risk, such as antidepressants and other medications, hospitalization, and/or psychotherapy. The contributions of these additional measures are unknown.
CONTRAINDICATIONS
Clozapine is contraindicated in patients with a previous hypersensitivity to clozapine or any other component of this drug, in patients with myeloproliferative disorders, uncontrolled epilepsy, paralytic ileus, or a history of clozapine-induced agranulocytosis or severe granulocytopenia. As with more typical antipsychotic drugs, clozapine is contraindicated in severe central nervous system depression or comatose states from any cause.
Clozapine should not be used simultaneously with other agents having a well-known potential to cause agranulocytosis or otherwise suppress bone marrow function. The mechanism of clozapine-induced agranulocytosis is unknown; nonetheless, it is possible that causative factors may interact synergistically to increase the risk and/or severity of bone marrow suppression.
WARNINGS
General
INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS TREATED WITH ANTIPSYCHOTIC DRUGS ARE AT AN INCREASED RISK OF DEATH. CLOZAPINE IS NOT APPROVED FOR THE TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS (SEE BOXED WARNING).
AGRANULOCYTOSIS
BECAUSE OF THE SIGNIFICANT RISK OF AGRANULOCYTOSIS, A POTENTIALLY LIFE-THREATENING ADVERSE EVENT (SEE FOLLOWING), CLOZAPINE SHOULD BE RESERVED FOR USE IN THE FOLLOWING INDICATIONS: 1) FOR TREATMENT OF SEVERELY ILL SCHIZOPHRENIC PATIENTS WHO FAIL TO SHOW AN ACCEPTABLE RESPONSE TO ADEQUATE COURSES OF STANDARD DRUG TREATMENT FOR SCHIZOPHRENIA, EITHER BECAUSE OF INSUFFICIENT EFFECTIVENESS OR THE INABILITY TO ACHIEVE AN EFFECTIVE DOSE DUE TO INTOLERABLE ADVERSE EFFECTS FROM THOSE DRUGS. CONSEQUENTLY, BEFORE INITIATING TREATMENT WITH CLOZAPINE, IT IS STRONGLY RECOMMENDED THAT A PATIENT BE GIVEN AT LEAST 2 TRIALS, EACH WITH A DIFFERENT STANDARD DRUG PRODUCT FOR SCHIZOPHRENIA, AT AN ADEQUATE DOSE, AND FOR AN ADEQUATE DURATION. 2) FOR REDUCING THE RISK FOR RECURRENT SUICIDAL BEHAVIOR IN PATIENTS WITH SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER WHO ARE JUDGED TO BE AT RISK OF RE-EXPERIENCING SUICIDAL BEHAVIOR.
CLOZAPINE IS AVAILABLE ONLY THROUGH A DISTRIBUTION SYSTEM THAT ENSURES MONITORING OF WHITE BLOOD CELL (WBC) COUNT AND ABSOLUTE NEUTROPHIL COUNT (ANC) ACCORDING TO THE SCHEDULE DESCRIBED BELOW PRIOR TO DELIVERY OF THE NEXT SUPPLY OF MEDICATION.
AS DESCRIBED IN TABLE 1, PATIENTS WHO ARE BEING TREATED WITH CLOZAPINE MUST HAVE A BASELINE WBC COUNT AND ANC BEFORE INITIATION OF TREATMENT, AND A WBC COUNT AND ANC EVERY WEEK FOR THE FIRST 6 MONTHS. THEREAFTER, IF ACCEPTABLE WBC COUNTS AND ANC (WBC ≥3500/mm³ and ANC ≥2000/mm³) HAVE BEEN MAINTAINED DURING THE FIRST 6 MONTHS OF CONTINUOUS THERAPY, WBC COUNTS AND ANC CAN BE MONITORED EVERY 2 WEEKS FOR THE NEXT 6 MONTHS. THEREAFTER, IF ACCEPTABLE WBC COUNTS AND ANC (WBC ≥3500/mm³ and ANC ≥2000/mm³) HAVE BEEN MAINTAINED DURING THE SECOND 6 MONTHS OF CONTINUOUS THERAPY, WBC COUNT AND ANC CAN BE MONITORED EVERY 4 WEEKS.
WHEN TREATMENT WITH CLOZAPINE IS DISCONTINUED (REGARDLESS OF THE REASON), WBC COUNT AND ANC MUST BE MONITORED WEEKLY FOR AT LEAST 4 WEEKS FROM THE DAY OF DISCONTINUATION OR UNTIL WBC ≥3500/mm³ AND ANC ≥2000/mm³.
Agranulocytosis
Background
Agranulocytosis, defined as an ANC of less than 500/mm³, has been estimated to occur in association with clozapine use at a cumulative incidence at 1 year of approximately 1.3%, based on the occurrence of 15 U.S. cases out of 1,743 patients exposed to clozapine during its clinical testing prior to domestic marketing. All of these cases occurred at a time when the need for close monitoring of WBC counts was already recognized. Agranulocytosis could prove fatal if not detected early and therapy interrupted. Of the 149 cases of agranulocytosis reported worldwide in association with clozapine use as of December 31, 1989, 32% were fatal. However, few of these deaths occurred since 1977, at which time the knowledge of clozapine-induced agranulocytosis became more widespread, and

close monitoring of WBC counts more widely practiced. In the U.S., under a weekly WBC count monitoring system with clozapine, there have been 585 cases of agranulocytosis as of August 21, 1997; 19 were fatal (3%). During this period 150,409 patients received clozapine. A hematologic risk analysis was conducted based upon the available information in the Clozaril® National Registry (CNR) for U.S. patients. Based upon a cut-off date of April 30, 1995, the incidence rates of agranulocytosis based upon a weekly monitoring schedule, rose steeply during the first two months of therapy, peaking in the third month. Among clozapine patients who continued the drug beyond the third month, the weekly incidence of agranulocytosis fell to a substantial degree. After six months, the weekly incidence of agranulocytosis declines still further, however, it never reaches zero. It should be noted that any type of reduction in the frequency of monitoring WBC counts may result in an increased incidence of agranulocytosis.

Risk Factors

Experience from clinical development, as well as from examples in the medical literature, suggest that patients who have developed agranulocytosis during clozapine therapy are at increased risk of subsequent episodes of agranulocytosis. Analysis of WBC count data from the Clozaril® National Registry also suggests that patients who have an initial episode of moderate leukopenia (3000/mm³ >WBC ≥2000/mm³) are at an increased risk of subsequent episodes of agranulocytosis. Except for bone marrow suppression during initial clozapine therapy, there are no other established risk factors, based on world-wide experience, for the development of agranulocytosis in association with clozapine use. However, a disproportionate number of the U.S. cases of agranulocytosis occurred in patients of Jewish background compared to the overall proportion of such patients exposed during domestic development of clozapine. Most of the U.S. cases of agranulocytosis occurred within 4 to 10 weeks of exposure but neither dose nor duration is a reliable predictor of this problem. Agranulocytosis associated with other antipsychotic drugs has been reported to occur with a greater frequency in women, the elderly, and in patients who are cachectic or have a serious underlying medical illness; such patients may also be at particular risk with clozapine, although this has not been definitely demonstrated.

WBC Count and ANC Monitoring Schedule

Table 1 provides a summary of the frequency of monitoring that should occur based on various stages of therapy (e.g., initiation of therapy) or results from WBC count and ANC monitoring tests (e.g., moderate leukopenia). The text that follows should be consulted for additional details regarding the treatment of patients under the various conditions (e.g., severe leukopenia).

Patients should be advised to report immediately the appearance of lethargy, weakness, fever, sore throat or any other signs of infection occurring at any time during clozapine therapy. Such patients should have a WBC count and ANC performed promptly.

Table 1. Frequency of Monitoring based on Stage of Therapy or Results from WBC Count and ANC Monitoring Tests

Situation	Hematological Values for Monitoring	Frequency of WBC and ANC Monitoring
Initiation of therapy	WBC ≥3500/mm³ ANC ≥2000/mm³ Note: Do not initiate in patients with 1) history of myeloproliferative disorder or 2) clozapine-induced agranulocytosis or granulocytopenia	Weekly for 6 months
6 months to 12 months of therapy	All results for WBC ≥3500/mm³ and ANC≥2000/mm³	Every 2 weeks for 6 months
12 months of therapy	All results for WBC ≥3500/mm³ and ANC≥2000/mm³	Every 4 weeks ad infinitum
Immature forms present	N/A	Repeat WBC and ANC
(continued) Discontinuation of Therapy	N/A	Weekly for at least 4 weeks from day of discontinuation or until WBC ≥3500/mm³ and ANC >2000/mm³
Substantial drop in WBC or ANC	Single Drop or cumulative drop within 3 weeks of WBC ≥3000/mm³ or ANC ≥1500/mm³	1. Repeat WBC and ANC 2. If repeat values are 3000/mm³ ≤WBC ≤3500/mm³ and ANC <2000/mm³, then monitor twice weekly
Mild Leukopenia ---------- Mild Granulocytopenia	3500/mm³ >WBC ≥3000/mm³ and/or 2000/mm³ >ANC ≥1500/mm³	Twice weekly until WBC >3500/mm³ and ANC >2000/mm³ then return to previous monitoring frequency
Moderate Leukopenia ---------- Moderate Granulocytopenia	3000/mm³ >WBC ≥2000/mm³ and/or 1500/mm³ >ANC ≥1000/mm³	1. Interrupt therapy 2. Daily until WBC >3000/mm³ and ANC >1500/mm³ 3. Twice-weekly until WBC >3500/mm³ and ANC >2000/mm³ 4. May rechallenge when WBC >3500/mm³ and ANC >2000/mm³ 5. If rechallenged, monitor weekly for 1 year before returning to the usual monitoring schedule of every 2 weeks for 6 months and then every 4 weeks ad infinitum
Severe Leukopenia ---------- Severe Granulocytopenia	WBC <2000/mm³ and/or ANC <1000/mm³	1. Discontinue treatment and do not rechallenge patient 2. Monitor until normal and for at least 4 weeks from day of discontinuation as follows: • Daily until WBC >3000/mm³ and ANC >1500/mm³ • Twice weekly until WBC >3500/mm³ and ANC >2000/mm³ • Weekly after WBC >3500/mm³
Agranulocytosis	ANC ≤500/mm³	1. Discontinue treatment and do not rechallenge patient 2. Monitor until normal and for at least 4 weeks from day of discontinuation as follows: • Daily until WBC >3000/mm³ and ANC >1500/mm³ • Twice weekly until WBC >3500/mm³ and ANC >2000/mm³ • Weekly after WBC >3500/mm³

***WBC = white blood cell count; ANC = absolute neutrophil count**

Decrements in WBC Count and/or ANC

Consult Table 1 above to determine how to monitor patients who experience decrements in WBC count and ANC at any point during treatment. Additionally, patients should be carefully monitored for flu-like symptoms or other symptoms suggestive of infection.

Non-Rechallengeable Patients

If the total WBC count falls below 2000/mm³ or the ANC falls below 1000/mm³, bone marrow aspiration should be considered to ascertain granulopoietic status and patients should not be rechallenged with clozapine. Protective isolation with close observation may be indicated if granulopoiesis is determined to be deficient. Should evidence of infection develop, the patient should have appropriate cultures performed and an appropriate antibiotic regimen instituted.

Patients discontinued from clozapine therapy due to significant granulopoietic suppression have been found to develop agranulocytosis upon rechallenge, often with a shorter latency on re-exposure. To reduce the chances of rechallenge occurring in patients who have experienced significant bone marrow suppression during clozapine therapy, a single, national master file (i.e., Non-rechallengeable Database) is maintained confidentially.

Treatment of Rechallengeable Patients

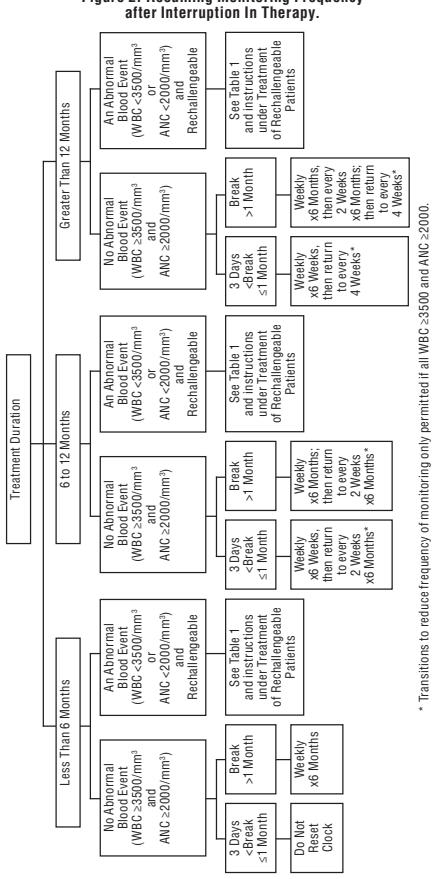
Patients may be rechallenged with clozapine if their WBC count does not fall below 2000/mm³ and the ANC does not fall below 1000/mm³. However, analysis of data from the Clozaril® National Registry suggests that patients who have an initial episode of moderate leukopenia (3000/mm³ >WBC ≥2000/mm³) have up to a 12 fold increased risk of having a subsequent episode of agranulocytosis when rechallenged compared to the full cohort of patients treated with clozapine. Although clozapine therapy may be resumed if no symptoms of infection develop, and when the WBC count rises above 3500/mm³ and the ANC rises above 2000/mm³, prescribers are strongly advised to consider whether the benefit of continuing clozapine treatment outweighs the increased risk of agranulocytosis.

Analyses of the Clozaril® National Registry have shown an increased risk of having a subsequent episode of granulopoietic suppression up to a year after recovery from the initial episode. Therefore, as noted in Table 1 above, patients must undergo weekly WBC count and ANC monitoring for one year following recovery from an episode of moderate leukopenia and/or moderate granulocytopenia regardless of when the episode develops. If acceptable WBC counts and ANC (WBC ≥3500/mm³ and ANC ≥2000/mm³) have been maintained during the year of weekly monitoring, WBC counts can be monitored every 2 weeks for the next 6 months. If acceptable WBC counts and ANC (WBC ≥3500/mm³ and ANC ≥2000/mm³) continue to be maintained during the 6 months of every 2 week monitoring, WBC counts can be monitored every 4 weeks thereafter, ad infinitum.

Interruptions in Therapy

Figure 2 provides instructions regarding reinitiating therapy and subsequently the frequency of WBC count and ANC monitoring after a period of interruption.

Figure 2. Resuming Monitoring Frequency after Interruption In Therapy.



* Transitions to reduce frequency of monitoring only permitted if all WBC ≥3500 and ANC ≥2000.

Eosinophilia

In clinical trials, 1% of patients developed eosinophilia, which, in rare cases, can be substantial. If a differential count reveals a total eosinophil count above 4,000/mm³, clozapine therapy should be interrupted until the eosinophil count falls below 3,000/mm³.

Seizures

Seizure has been estimated to occur in association with clozapine use at a cumulative incidence at one year of approximately 5%, based on the occurrence of one or more seizures in 61 of 1,743 patients exposed to clozapine during its clinical testing prior to domestic marketing (i.e., a crude rate of 3.5%). Dose appears to be an important predictor of seizure, with a greater likelihood of seizure at the higher clozapine doses used.

Caution should be used in administering clozapine to patients having a history of seizures or other predisposing factors. Because of the substantial risk of seizure associated with clozapine use, patients should be advised not to engage in any activity where sudden loss of consciousness could cause serious risk to themselves or others, e.g., the operation of complex machinery, driving an automobile, swimming, climbing, etc.

Myocarditis

Post-marketing surveillance data from four countries that employ hematological monitoring of clozapine-treated patients revealed: 30 reports of myocarditis with 17 fatalities in 205,493 U.S. patients (August 2001); 7 reports of myocarditis with 1 fatality in 15,600 Canadian patients (April 2001); 30 reports of myocarditis with 8 fatalities in 24,108 U.K. patients (August 2001); 15 reports of myocarditis with 5 fatalities in 8,000 Australian patients (March 1999). These reports represent an incidence of 5.0, 16.3, 43.2, and 96.6 cases/100,000 patient-years, respectively. The number of fatalities represent an incidence of 2.8, 2.3, 11.5, and 32.2 cases/100,000 patient-years, respectively.

The overall incidence rate of myocarditis in patients with schizophrenia treated with antipsychotic agents is unknown. However, for the established market economies (WHO), the incidence of myocarditis is 0.3 cases/100,000 patient-years and the fatality rate is 0.2 cases/100,000 patient-years. Therefore, the rate of myocarditis in clozapine-treated patients appears to be 17 to 322 times greater than the general population and is associated with an increased risk of fatal myocarditis that is 14 to 161 times greater than the general population.

The total reports of myocarditis for these four countries was 82 of which 51 (62%) occurred within the first month of clozapine treatment, 25 (31%) occurred after the first month of therapy and 6 (7%) were unknown. The median duration of treatment was 3 weeks. Of 5 patients rechallenged with clozapine, 3 had a recurrence of myocarditis. Of the 82 reports, 31 (38%) were fatal and 25 patients who died had evidence of myocarditis at autopsy. These data also suggest that the incidence of fatal myocarditis may be highest during the first month of therapy.

Therefore, the possibility of myocarditis should be considered in patients receiving clozapine who present with unexplained fatigue, dyspnea, tachypnea, fever, chest pain, palpitations, other signs or symptoms of heart failure, or electrocardiographic findings such as ST-T wave abnormalities or arrhythmias. It is not known whether eosinophilia is a reliable predictor of myocarditis. Tachycardia, which has been associated with clozapine treatment, has also been noted as a presenting sign in patients with myocarditis. Therefore, tachycardia during the first month of therapy warrants close monitoring for other signs of myocarditis.

Prompt discontinuation of clozapine treatment is warranted upon suspicion of myocarditis. Patients with clozapine-related myocarditis should not be rechallenged with clozapine.

Other Adverse Cardiovascular and Respiratory Effects

Orthostatic hypotension with or without syncope can occur with clozapine treatment and may represent a continuing risk in some patients. Rarely (approximately 1 case per 3,000 patients), collapse can be profound and be accompanied by respiratory and/or cardiac arrest. Orthostatic hypotension is more likely to occur during initial titration in association with rapid dose escalation and may even occur on first dose. In one report, initial doses as low as 12.5 mg were associated with collapse and respiratory arrest. When restarting patients who have had even a brief interval off clozapine, i.e., 2 days or more since the last dose, it is recommended that treatment be reinitiated with one-half of a 25 mg tablet (12.5 mg) once or twice daily (see DOSAGE AND ADMINISTRATION).

Some of the cases of collapse/respiratory arrest/cardiac arrest during initial treatment occurred in patients who were being administered benzodiazepines; similar events have been reported in patients taking other psychotropic drugs or even clozapine by itself. Although it has not been established that there is an interaction between clozapine and benzodiazepines or other psychotropics, caution is advised when clozapine is initiated in patients taking a benzodiazepine or any other psychotropic drug.

Tachycardia, which may be sustained, has also been observed in approximately 25% of patients taking clozapine, with patients having an average increase in pulse rate of 10 to 15 bpm. The sustained tachycardia is not simply a reflex response to hypotension, and is present in all positions monitored. Either tachycardia or hypotension may pose a serious risk for an individual with compromised cardiovascular function.

A minority of clozapine-treated patients experience ECG repolarization changes similar to those seen with other antipsychotic drugs, including S-T segment depression and flattening or inversion of T waves, which all normalize after discontinuation of clozapine. The clinical significance of these changes is unclear. However, in clinical trials with clozapine, several patients experienced significant cardiac events, including ischemic changes, myocardial infarction, arrhythmias, and sudden death. In addition there have been postmarketing reports of congestive heart failure, pericarditis, and pericardial effusions. Causality assessment was difficult in many of these cases because of serious preexisting cardiac disease and plausible alternative causes. Rare instances of sudden death have been reported in psychiatric patients, with or without associated antipsychotic drug treatment, and the relationship of these events to antipsychotic drug use is unknown.

Clozapine should be used with caution in patients with known cardiovascular and/or pulmonary disease, and the recommendation for gradual titration of dose should be carefully observed.

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including clozapine. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Neuroleptic Malignant Syndrome (NMS)

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmias).

The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system (CNS) pathology.

The management of NMS should include 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, 2) intensive symptomatic treatment and medical monitoring, and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS.

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

There have been several reported cases of NMS in patients receiving clozapine alone or in combination with lithium or other CNS-active agents.

Tardive Dyskinesia

A syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of treatment, which patients are likely to develop the syndrome.

There are several reasons for predicting that clozapine may be different from other antipsychotic drugs in its potential for inducing tardive dyskinesia, including the preclinical finding that it has a relatively weak dopamine-blocking effect and the clinical finding of a low incidence of certain acute extrapyramidal symptoms, e.g., dystonia. A few cases of tardive dyskinesia have been reported in patients on clozapine who had been previously treated with other antipsychotic agents, so that a causal relationship cannot be established. There have been no reports of tardive dyskinesia directly attributable to clozapine alone. Nevertheless, it cannot be concluded, without more extended experience, that clozapine is incapable of inducing this syndrome.

Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic drug treatment is withdrawn. Antipsychotic drug treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptom suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, clozapine should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. As with any antipsychotic drug, chronic clozapine use should be reserved for patients who appear to be obtaining substantial benefit from the drug. In such patients, the smallest dose and the shortest duration of treatment should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on clozapine, drug discontinuation should be considered. However, some patients may require treatment with clozapine despite the presence of the syndrome.

PRECAUTIONS

General

Because of the significant risk of agranulocytosis and seizure, both of which present a continuing risk over time, the extended treatment of patients failing to show an acceptable level of clinical response should ordinarily be avoided. In addition, the need for continuing treatment in patients exhibiting beneficial clinical responses should be periodically re-evaluated. Although it is not known whether the risk would be increased, it is prudent either to avoid clozapine or use it cautiously in patients with a previous history of agranulocytosis induced by other drugs.

Cardiomyopathy

Cases of cardiomyopathy have been reported in patients treated with clozapine. The reporting rate for cardiomyopathy in clozapine-treated patients in the U.S. (8.9 per 100,000 person-years) was similar to an estimate of the cardiomyopathy incidence in the U.S. general population derived from the 1999 National Hospital Discharge Survey data (9.7 per 100,000 person-years). Approximately 80% of clozapine-treated patients in whom cardiomyopathy was reported were less than 50 years of age; the duration of treatment with clozapine prior to cardiomyopathy diagnosis varied, but was >6 months in 65% of the reports. Dilated cardiomyopathy was most frequently reported, although a large percentage of reports did not specify the type of cardiomyopathy. Signs and symptoms suggestive of cardiomyopathy, particularly exertional dyspnea, fatigue, orthopnea, paroxysmal nocturnal dyspnea, and peripheral edema should alert the clinician to perform further investigations. If the diagnosis of cardiomyopathy is confirmed, the prescriber should discontinue clozapine unless the benefit to the patient clearly outweighs the risk.

Fever

During clozapine therapy, patients may experience transient temperature elevations above 100.4°F (38°C), with the peak incidence within the first 3 weeks of treatment. While this fever is generally benign and self-limiting, it may necessitate discontinuing patients from treatment. On occasion, there may be an associated increase or decrease in WBC count. Patients with fever should be carefully evaluated to rule out the possibility of an underlying infectious process or the development of agranulocytosis. In the presence of high fever, the possibility of Neuroleptic Malignant Syndrome (NMS) must be considered. There have been several reports of NMS in patients receiving clozapine, usually in combination with lithium or other CNS-active drugs. (see **Neuroleptic Malignant Syndrome (NMS)**, under **WARNINGS**).

Pulmonary Embolism

The possibility of pulmonary embolism should be considered in patients receiving clozapine who present with deep vein thrombosis, acute dyspnea, chest pain or with other respiratory signs and symptoms. As of December 31, 1993, there were 18 cases of fatal pulmonary embolism in association with clozapine therapy in users 10 to 54 years of age. Based upon the extent of use observed in the Clozaril® National Registry, the mortality rate associated with pulmonary embolus was 1 death per 3,450 person-years of use. This rate was about 27.5 times higher than that in the general population of a similar age and gender (95% Confidence Interval; 17.1, 42.2). Deep vein thrombosis has also been observed in association with clozapine therapy. Whether pulmonary embolus can be attributed to clozapine or some characteristic(s) of its users is not clear, but the occurrence of deep vein thrombosis or respiratory symptomatology should suggest its presence.

Hepatitis

Caution is advised in patients using clozapine who have concurrent hepatic disease. Hepatitis has been reported in both patients with normal and preexisting liver function abnormalities. In patients who develop nausea, vomiting, and/or anorexia during clozapine treatment, liver function tests should be performed immediately. If the elevation of these values is clinically relevant or if symptoms of jaundice occur, treatment with clozapine should be discontinued.

Anticholinergic Toxicity

Eye

Clozapine has potent anticholinergic effects and care should be exercised in using this drug in the presence of narrow angle glaucoma.

Gastrointestinal

Clozapine use has been associated with varying degrees of impairment of intestinal peristalsis, ranging from constipation to intestinal obstruction, fecal impaction and paralytic ileus (see **ADVERSE REACTIONS**). On rare occasions, these cases have been fatal. Constipation should be initially treated by ensuring adequate hydration, and use of ancillary therapy such as bulk laxatives. Consultation with a gastroenterologist is advisable in more serious cases.

Prostate

Clozapine has potent anticholinergic effects and care should be exercised in using this drug in the presence of prostatic enlargement.

Interference with Cognitive and Motor Performance

Because of initial sedation, clozapine may impair mental and/or physical abilities, especially during the first few days of therapy. The recommendations for gradual dose escalation should be carefully adhered to, and patients cautioned about activities requiring alertness.

Cerebrovascular Adverse Events

An increased risk of cerebrovascular adverse events has been observed in dementia patients treated with some atypical antipsychotics. The mechanism for this increased risk is not known. An increased risk cannot be excluded for dementia patients or other patients treated with clozapine. Clozapine should be used with caution in patients with dementia or risk factors for stroke.

Use in Patients with Concomitant Illness

Clinical experience with clozapine in patients with concomitant systemic diseases is limited. Nevertheless, caution is advisable in using clozapine in patients with renal or cardiac disease.

Use in Patients Undergoing General Anesthesia

Caution is advised in patients being administered general anesthesia because of the CNS effects of clozapine. Check with the anesthesiologist regarding continuation of clozapine therapy in a patient scheduled for surgery.

Information for Patients

Physicians are advised to discuss the following issues with patients for whom they prescribe clozapine:

- Patients who are to receive clozapine should be warned about the significant risk of developing agranulocytosis. Patients should be advised to report immediately the appearance of lethargy, weakness, fever, sore throat, malaise, mucous membrane ulceration or other possible signs of infection. Particular attention should be paid to any flu-like complaints or other symptoms that might suggest infection.
  - Patients should be informed that clozapine tablets will be made available only through a special program designed to ensure the required blood monitoring in order to reduce the risk of developing agranulocytosis. Patients should be informed that their WBC count and ANC will be monitored as follows:
    - ☒ Weekly blood tests are required for the first 6 months.
    - ☒ If acceptable WBC counts and ANCs (WBC ≥3500/mm³ and ANC ≥2000/mm³) have been maintained during the first 6 months of continuous therapy, then WBC counts and ANCs can be monitored every 2 weeks for the next 6 months.
    - ☒ Thereafter, if acceptable WBC counts and ANCs have been maintained during the second 6 months of continuous therapy, WBC counts and ANCs can be monitored every 4 weeks.
- Patients should be informed of the significant risk of seizure during clozapine treatment, and they should be advised to avoid driving and any other potentially hazardous activity while taking clozapine.
- Patients should be advised of the risk of orthostatic hypotension, especially during the period of initial dose titration.
- Patients should be informed that if they miss taking clozapine for more than 2 days, they should not restart their medication at the same dosage, but should contact their physician for dosing instructions.
- Patients should notify their physician if they are taking, or plan to take, any prescription or over-the-counter drugs or alcohol.
- Patients should notify their physician if they become pregnant or intend to become pregnant during therapy.
- Patients should not breastfeed an infant if they are taking clozapine.

Drug Interactions

The risks of using clozapine in combination with other drugs have not been systematically evaluated.

Pharmacodynamic-Related Interactions

The mechanism of clozapine-induced agranulocytosis is unknown; nonetheless, the possibility that causative factors may interact synergistically to increase the risk and/or severity of bone marrow suppression warrants consideration. Therefore, clozapine should not be used with other agents having a well-known potential to suppress bone marrow function.

Given the primary CNS effects of clozapine, caution is advised in using it concomitantly with other CNS-active drugs or alcohol.

Orthostatic hypotension in patients taking clozapine can, in rare cases (approximately 1 case per 3,000 patients), be accompanied by profound collapse and respiratory and/or cardiac arrest. Some of the cases of collapse/respiratory arrest/cardiac arrest during initial treatment occurred in patients who were being administered benzodiazepines; similar events have been reported in patients taking other psychotropic drugs or even clozapine by itself. Although it has not been established that there is an interaction between clozapine and benzodiazepines or other psychotropics, caution is advised when clozapine is initiated in patients taking a benzodiazepine or any other psychotropic drug.

Clozapine may potentiate the hypotensive effects of antihypertensive drugs and the anticholinergic effects of atropine-type drugs. The administration of epinephrine should be avoided in the treatment of drug-induced hypotension because of a possible reverse epinephrine effect.

Pharmacokinetic-Related Interactions

Clozapine is a substrate for many CYP 450 isozymes, in particular 1A2, 2D6, and 3A4. The risk of metabolic interactions caused by an effect on an individual isoform is therefore minimized. Nevertheless, caution should be used in patients receiving concomitant treatment with other drugs that are either inhibitors or inducers of these enzymes.

Concomitant administration of drugs known to induce cytochrome P450 enzymes may decrease the plasma levels of clozapine. Phenytoin, tobacco smoke, and rifampin may decrease clozapine plasma levels, resulting in a decrease in effectiveness of a previously effective clozapine dose.

Concomitant administration of drugs known to inhibit the activity of cytochrome P450 isozymes may increase the plasma levels of clozapine. Cimetidine, caffeine, citalopram, ciprofloxacin, and erythromycin may increase plasma levels of clozapine, potentially resulting in adverse effects. Although concomitant use of clozapine and carbamazepine is not recommended, it should be noted that discontinuation of concomitant carbamazepine administration may result in an increase in clozapine plasma levels.

In a study of schizophrenic patients who received clozapine under steady state conditions, fluvoxamine or paroxetine was added in 16 and 14 patients, respectively. After 14 days of co-administration, mean trough concentrations of clozapine and its metabolites, N-desmethylclozapine and clozapine N-oxide, were elevated with fluvoxamine by about three-fold compared to baseline concentrations. Paroxetine produced only minor changes in the levels of clozapine and its metabolites. However, other published reports describe modest elevations (less than two-fold) of clozapine and metabolite concentrations when clozapine was taken with paroxetine, fluoxetine, and sertraline. Therefore, such combined treatment should be approached with caution and patients should be monitored closely when clozapine is combined with these drugs, particularly with fluvoxamine. A reduced clozapine dose should be considered.

A subset (3% to 10%) of the population has reduced activity of certain drug metabolizing enzymes such as the cytochrome P450 isozyme P450 2D6. Such individuals are referred to as "poor metabolizers" of drugs such as debrisoquin, dextromethorphan, the tricyclic antidepressants, and clozapine. These individuals may develop higher than expected plasma concentrations of clozapine when given usual doses. In addition, certain drugs that are metabolized by this isozyme, including many antidepressants (clozapine, selective serotonin reuptake inhibitors, and others), may inhibit the activity of this isozyme, and thus may make normal metabolizers resemble poor metabolizers with regard to concomitant therapy with other drugs metabolized by this enzyme system, leading to drug interaction.

Concomitant use of clozapine with other drugs metabolized by cytochrome P450 2D6 may require lower doses than usually prescribed for either clozapine or the other drug. Therefore, coadministration of clozapine with other drugs that are metabolized by this isozyme, including antidepressants, phenothiazines, carbamazepine, and Type 1C antiarrhythmics (e.g., propafenone, flecainide, and encainide), or that inhibit this enzyme (e.g., quinidine), should be approached with caution.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenic potential was demonstrated in long-term studies in mice and rats at doses approximately 7 times the typical human dose on a mg/kg basis. Fertility in male and female rats was not adversely affected by clozapine. Clozapine did not produce genotoxic or mutagenic effects when assayed in appropriate bacterial and mammalian tests.

Pregnancy

Teratogenic Effects

Pregnancy Category B

Reproduction studies have been performed in rats and rabbits at doses of approximately 2 to 4 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to clozapine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, and in view of the desirability of keeping the administration of all drugs to a minimum during pregnancy, this drug should be used only if clearly needed.

Non-teratogenic Effects

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

Antipsychotic drugs, including clozapine, should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Animal studies suggest that clozapine may be excreted in breast milk and have an effect on the nursing infant. Therefore, women receiving clozapine should not breast-feed.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies of clozapine did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects.

Orthostatic hypotension can occur with clozapine treatment and tachycardia, which may be sustained, has been observed in about 25% of patients taking clozapine (see **BOXED WARNING**, **Other Adverse Cardiovascular and Respiratory Effects**). Elderly patients, particularly those with compromised cardiovascular functioning, may be more susceptible to these effects.

Also, elderly patients may be particularly susceptible to the anticholinergic effects of clozapine, such as urinary retention and constipation (see **PRECAUTIONS, Anticholinergic Toxicity**).

Dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Other reported clinical experience does suggest that the prevalence of tardive dyskinesia appears to be highest among the elderly, especially elderly women (see **WARNINGS, Tardive Dyskinesia**).

ADVERSE REACTIONS

Associated with Discontinuation of Treatment

Sixteen percent of 1,080 patients who received clozapine in premarketing clinical trials discontinued treatment due to an adverse event, including both those that could be reasonably attributed to clozapine treatment and those that might more appropriately be considered intercurrent illness. The more common events considered to be causes of discontinuation included: CNS, primarily drowsiness/sedation, seizures, dizziness/syncope; cardiovascular, primarily tachycardia, hypotension and ECG changes; gastrointestinal, primarily nausea/vomiting; hematologic, primarily leukopenia/granulocytopenia/agranulocytosis; and fever. None of the events enumerated accounts for more than 1.7% of all discontinuations attributed to adverse clinical events.

Extrapyramidal Symptoms

Dystonia

Class Effect

Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups. Clozapine, an atypical antipsychotic, is associated with a low incidence of dystonia (see **WARNINGS, Tardive Dyskinesia**).

Commonly Observed

Adverse events observed in association with the use of clozapine in clinical trials at an incidence of greater than 5% were: central nervous system complaints, including drowsiness/sedation, dizziness/vertigo, headache and tremor; autonomic nervous system complaints, including salivation, sweating, dry mouth and visual disturbances; cardiovascular findings, including tachycardia, hypotension and syncope; and gastrointestinal complaints, including constipation and nausea; and fever. Complaints of drowsiness/sedation tend to subside with continued therapy or dose reduction. Salivation may be profuse, especially during sleep, but may be diminished with dose reduction.

Incidence in Clinical Trials

The following table enumerates adverse events that occurred at a frequency of 1% or greater among clozapine patients who participated in clinical trials. These rates are not adjusted for duration of exposure.

Treatment-Emergent Adverse Experience Incidence Among Patients Taking Clozapine in Clinical Trials (Excluding the InterSePT™ Study) (N = 842) (Percentage of Patients Reporting)

Body System	
Adverse Event[a]	**Percent**
Central Nervous System	
Drowsiness/Sedation	39
Dizziness/Vertigo	19
Headache	7
Tremor	6
Syncope	6
Disturbed sleep/Nightmares	4
Restlessness	4
Hypokinesia/Akinesia	4
Agitation	4
Seizures (convulsions)	3[b]
Rigidity	3
Akathisia	3
Confusion	3
Fatigue	2
Insomnia	2

(cont'd)

Treatment-Emergent Adverse Experience Incidence Among Patients Taking Clozapine in Clinical Trials (Excluding the InterSePT™ Study) (N = 842) (Percentage of Patients Reporting)

Body System	
Adverse Event[a]	**Percent**
Hyperkinesia	1
Weakness	1
Lethargy	1
Ataxia	1
Slurred speech	1
Depression	1
Epileptiform movements/Myoclonic jerks	1
Anxiety	1
Cardiovascular	
Tachycardia	25[b]
Hypotension	9
Hypertension	4
Chest pain/Angina	1
ECG change/Cardiac abnormality	1
Gastrointestinal	
Constipation	14
Nausea	5
Abdominal discomfort/Heartburn	4
Nausea/Vomiting	3
Vomiting	3
Diarrhea	2
Liver test abnormality	1
Anorexia	1
Urogenital	
Urinary abnormalities	2
Incontinence	1
Abnormal ejaculation	1
Urinary urgency/frequency	1
Urinary retention	1
Autonomic Nervous System	
Salivation	31
Sweating	6
Dry mouth	6
Visual disturbances	5
Integumentary (Skin)	
Rash	2
Musculoskeletal	
Muscle weakness	1
Pain (back, neck, legs)	1
Muscle spasm	1
Muscle pain, ache	1
Respiratory	
Throat discomfort	1
Dyspnea, shortness of breath	1
Nasal congestion	1
Hemic/Lymphatic	
Leukopenia/Decreased WBC/Neutropenia	3
Agranulocytosis	1[b]
Eosinophilia	1
Miscellaneous	
Fever	5
Weight gain	4
Tongue numb/sore	1

[a] Events reported by at least 1% of clozapine patients are included.
[b] Rate based on population of approximately 1,700 exposed during premarket clinical evaluation of clozapine.

The following table enumerates adverse events that occurred at a frequency of 10% for either treatment group in patients who took at least 1 dose of study medication during their participation in InterSePT, which was an adequate and well-controlled 2 year study evaluating the efficacy of clozapine relative to olanzapine in reducing the risk of emergent suicidal behavior in patients with schizophrenia or schizoaffective disorder. These rates are not adjusted for duration of exposure.

Treatment-Emergent Adverse Experience Incidence[1] Among Patients Taking Clozapine or Olanzapine in the InterSePT™ Study (Percentage of Patients Reporting)

	Clozapine N = 479 % Reporting	Olanzapine N = 477 % Reporting
Adverse Events		
Salivary hypersecretion	48%	6%
Somnolence	46%	25%
Weight increased	31%	56%
Dizziness (excluding vertigo)	27%	12%
Constipation	25%	10%
Insomnia NEC	20%	33%
Nausea	17%	10%
Vomiting NOS	17%	9%
Dyspepsia	14%	8%

[1] AEs are listed by frequency in clozapine group, and included in the table are those for which the risk ratio of clozapine over olanzapine or of olanzapine over clozapine was greater than 1.5.
NEC - not elsewhere classified
NOS - not otherwise specified

Other Events Observed During the Premarketing Evaluation of Clozapine

This section reports additional, less frequent adverse events which occurred among the patients taking clozapine in clinical trials. Various adverse events were reported as part of the total experience in these clinical studies; a causal relationship to clozapine treatment cannot be determined in the absence of appropriate controls in some of the studies. The table above enumerates adverse events that occurred at a frequency of at least 1% of patients treated with clozapine. The list below includes all additional adverse experiences reported as being temporally associated with the use of the drug which occurred at a frequency less than 1%, enumerated by organ system.

Central Nervous System: loss of speech, amentia, tics, poor coordination, delusions/hallucinations, involuntary movement, stuttering, dysarthria, amnesia/memory loss, histrionic movements, libido increase or decrease, paranoia, shakiness, Parkinsonism, and irritability.

Cardiovascular System: edema, palpitations, phlebitis/thrombophlebitis, cyanosis, premature ventricular contraction, bradycardia, and nosebleed.

Gastrointestinal System: abdominal distention, gastroenteritis, rectal bleeding, nervous stomach, abnormal stools, hematemesis, gastric ulcer, bitter taste, and eructation.

Urogenital System: dysmenorrhea, impotence, breast pain/discomfort, and vaginal itch/infection.

Autonomic Nervous System: numbness, polydipsia, hot flashes, dry throat, and mydriasis.

Integumentary (Skin): pruritus, pallor, eczema, erythema, bruise, dermatitis, petechiae, and urticaria.

Musculoskeletal System: twitching and joint pain.

Respiratory System: coughing, pneumonia/pneumonia-like symptoms, rhinorrhea, hyperventilation, wheezing, bronchitis, laryngitis, and sneezing.

Hemic and Lymphatic System: anemia and leukocytosis.

Miscellaneous: chills/chills with fever, malaise, appetite increase, ear disorder, hypothermia, eyelid disorder, bloodshot eyes, and nystagmus.

Postmarketing Clinical Experience

Postmarketing experience has shown an adverse experience profile similar to that presented above. Voluntary reports of adverse events temporally associated with clozapine not mentioned above that have been received since market introduction and that may have no causal relationship with the drug include the following:

Central Nervous System: delirium; EEG abnormal; exacerbation of psychosis; myoclonus; overdose; paresthesia; possible mild cataplexy, and status epilepticus, and obsessive compulsive symptoms.

Cardiovascular System: atrial or ventricular fibrillation and periorbital edema.

Gastrointestinal System: acute pancreatitis; dysphagia; fecal impaction; intestinal obstruction/paralytic ileus; and salivary gland swelling.

Hepatobiliary System: cholestasis; hepatitis; jaundice.

Hepatic System: cholestasis.

Urogenital System: acute interstitial nephritis and priapism.

Integumentary (Skin): hypersensitivity reactions: photosensitivity, vasculitis, erythema multiforme, and Stevens-Johnson syndrome.

Metabolic and Nutritional Disorders: hypercholesterolemia, hypertriglyceridemia and new onset diabetes.

Musculoskeletal System: myasthenic syndrome and rhabdomyolysis.

Respiratory System: aspiration, pleural effusion, and pneumonia and lower respiratory tract infection which may be fatal.

Hemic and Lymphatic System: deep vein thrombosis; elevated hemoglobin/hematocrit; ESR increased; pulmonary embolism; sepsis; thrombocytosis; and thrombocytopenia.

Vision Disorders: narrow angle glaucoma.

Miscellaneous: CPK elevation; hyperglycemia; hyperuricemia; hyponatremia; and weight loss.

DOSAGE AND ADMINISTRATION

Treatment-Resistant Schizophrenia

Upon initiation of clozapine therapy, up to a 1 week supply of additional clozapine tablets may be provided to the patient to be held for emergencies (e.g., weather, holidays).

Initial Treatment

It is recommended that treatment with clozapine begin with one-half of a 25 mg tablet (12.5 mg) once or twice daily and then be continued with daily dosage increments of 25 to 50 mg/day, if well-tolerated, to achieve a target dose of 300 to 450 mg/day by the end of 2 weeks. Subsequent dosage increments should be made no more than once or twice weekly, in increments not to exceed 100 mg. Cautious titration and a divided dosage schedule are necessary to minimize the risks of hypotension, seizure, and sedation.

In the multicenter study that provides primary support for the effectiveness of clozapine in patients resistant to standard drug treatment for schizophrenia, patients were titrated during the first 2 weeks up to a maximum dose of 500 mg/day, on a t.i.d. basis, and were then dosed in a total daily dose range of 100 to 900 mg/day, on a t.i.d. basis thereafter, with clinical response and adverse effects as guides to correct dosing.

Therapeutic Dose Adjustment

Daily dosing should continue on a divided basis as an effective and tolerable dose level is sought. While many patients may respond adequately at doses between 300 to 600 mg/day, it may be necessary to raise the dose to the 600 to 900 mg/day range to obtain an acceptable response. (Note: In the multicenter study providing the primary support for the superiority of clozapine in treatment-resistant patients, the mean and median clozapine doses were both approximately 600 mg/day.)

Because of the possibility of increased adverse reactions at higher doses, particularly seizures, patients should ordinarily be given adequate time to respond to a given dose level before escalation to a higher dose is contemplated. Clozapine can cause EEG changes, including the occurrence of spike and wave complexes. It lowers the seizure threshold in a dose-dependent manner and may induce myoclonic jerks or generalized seizures. These symptoms may be likely to occur with rapid dose increase and in patients with preexisting epilepsy. In this case, the dose should be reduced and, if necessary, anticonvulsant treatment initiated.

Dosing should not exceed 900 mg/day.

Because of the significant risk of agranulocytosis and seizure, events which both present a continuing risk over time, the extended treatment of patients failing to show an acceptable level of clinical response should ordinarily be avoided.

Maintenance Treatment

While the maintenance effectiveness of clozapine in schizophrenia is still under study, the effectiveness of maintenance treatment is well established for many other drugs used to treat schizophrenia. It is recommended that responding patients be continued on clozapine, but at the lowest level needed to maintain remission. Because of the significant risk associated with the use of clozapine, patients should be periodically reassessed to determine the need for maintenance treatment.

Discontinuation of Treatment

In the event of planned termination of clozapine therapy, gradual reduction in dose is recommended over a 1 to 2 week period. However, should a patient's medical condition require abrupt discontinuation (e.g., leukopenia), the patient should be carefully observed for the recurrence of psychotic symptoms and symptoms related to cholinergic rebound such as headache, nausea, vomiting, and diarrhea.

Reinitiation of Treatment in Patients Previously Discontinued

When restarting patients who have had even a brief interval off clozapine, i.e., 2 days or more since the last dose, it is recommended that treatment be reinitiated with one-half of a 25 mg tablet (12.5 mg) once or twice daily (see **WARNINGS**). If that dose is well tolerated, it may be feasible to titrate patients back to a therapeutic dose more quickly than is recommended for initial treatment. However, any patient who has previously experienced respiratory or cardiac arrest with initial dosing, but was then able to be successfully titrated to a therapeutic dose, should be re-titrated with extreme caution after even 24 hours of discontinuation.

Certain additional precautions seem prudent when reinitiating treatment. The mechanisms underlying Clozapine-induced adverse reactions are unknown. It is conceivable, however, that re-exposure of a patient might enhance the risk of an untoward event's occurrence and increase its severity. Such phenomena, for example, occur when immune mediated mechanisms are responsible. Consequently, during the reinitiation of treatment, additional caution is advised. Patients discontinued for WBC counts below 2000/mm^3 or an ANC below 1000/mm^3 must *not* be restarted on clozapine (see **WARNINGS**).

Reducing the Risk of Recurrent Suicidal Behavior in Patients with Schizophrenia or Schizoaffective Disorder

The dosage and administration recommendations outlined above regarding the use of clozapine in patients with treatment-resistant schizophrenia should also be followed when treating patients with schizophrenia or schizoaffective disorder at risk for recurrent suicidal behavior.

The InterSePT study demonstrated the efficacy of clozapine in treatment of patients with schizophrenia or schizoaffective disorder at risk for recurrent suicidal behavior where the mean daily dose was about 300 mg (range 12.5 to 900 mg).

Patients previously treated with other antipsychotics were cross-titrated to clozapine over a one-month interval; the dose of the previous antipsychotic was gradually decreased simultaneous with a gradual increase in clozapine dose over the first month of the study. Patients on depot antipsychotic medication began clozapine after one full dosing interval since the last injection.

Recommendations to Reduce the Risk of Recurrent Suicidal Behavior in Patients Who Otherwise Previously Responded to Treatment of Schizophrenia or Schizoaffective Disorder with Another Antipsychotic Medication

The results of the InterSePT study demonstrated that, for a 2-year treatment period, the probability of a suicide attempt or a hospitalization due to imminent suicide risk is stable at approximately 24% after one year of treatment with clozapine (**Figure 1**, **Clinical Trial Data** section). A course of treatment with clozapine of at least 2 years is therefore recommended in order to maintain the reduction of risk for suicidal behavior. After 2 years, it is recommended that the patient's risk of suicidal behavior be assessed. If the physician's assessment indicates that a significant risk for suicidal behavior is still present, treatment with clozapine should be continued. Thereafter, the decision to continue treatment with clozapine should be revisited at regular intervals, based on thorough assessments of the patient's risk for suicidal behavior during treatment. If the physician determines that the patient is no longer at risk for suicidal behavior, treatment with clozapine may be discontinued (see recommendations above regarding discontinuation of treatment) and treatment of the underlying disorder with an antipsychotic medication to which the patient has previously responded may be resumed.

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Psychiatrists Among M.D.s Honored as Future Leaders

Three young psychiatrists are recognized by the AMA for their leadership activities and potential to grow into even stronger leaders.

Three psychiatrists are among only 30 physicians who were singled out this year to receive the 2011 AMA Foundation Leadership Award.

The psychiatrists are Jacob Behrens, M.D., a resident at the University of Wisconsin Hospital and Clinics; Jonathan Joel Shepherd, M.D., a fellow at Johns Hopkins University School of Medicine; and Ray Chih-Jui Hsiao, M.D., co-director of the Adolescent Substance Abuse Program at Seattle Children's Hospital.

The AMA Foundation presents the award to medical students, residents/fellows, and early career physicians from around the country who have demonstrated outstanding nonclinical leadership skills in advocacy, community service, and education. The award, given in association with Pfizer Inc., includes special training to develop their skills as future leaders in organized medicine and community affairs.

This year's winners were honored at a ceremony in Washington, D.C., in February.

"As our nation continues to struggle with issues of access, disease prevention, and disparities in care, encouraging the next generation of leaders is critical," said AMA Foundation President Barney Maynard, M.D., in a press statement. "We need individuals like these award recipients who are taking the initiative to tackle health care's most difficult challenges."

Behrens is pursuing a career using technological advances that provide new treatment modalities and improved geographic access to quality psychiatric care within Wisconsin and perhaps beyond. He was recently selected to join the Clinical Educator Track at the University of Wisconsin and hopes to continue to be involved with the education and mentorship of fellow colleagues and students and with public education. Behrens, who is active within APA and the county, state, and national

please see ***Future Leaders*** *on page 26*

APPI's Longtime CEO Retires

Ron McMillen built and directed American Psychiatric Publishing Inc. since its founding in 1981. He recently ended his 35-year APA career.

In an era in which people don't plan to spend long spans of time with one employer, Ron McMillen's 35 years at APA certainly stand out. As he retired at the end of March, he could look back with satisfaction on his significant contributions to APA, particularly his three decades as chief executive officer and publisher of American Psychiatric Publishing Inc. (APPI)—the only one it has had.

He began his APA career in 1976 as assistant director in the Office of Public Affairs. In 1981 he was tapped to head APA's new book-publishing endeavor—American Psychiatric Press Inc.—while still carrying out his duties as director of publications and marketing. In 1983 APPI published 12 titles—by 1991 that had expanded to 43 titles and annual sales of nearly $7.7 million.

McMillen helped that publishing enterprise grow into the world's largest publisher of books, journals, and multimedia products in the psychiatric field. He also guided APPI's leap into the Internet era with development of the highly regarded PsychiatryOnline Web site and APPI's presence on both Facebook and Twitter.

In addition to his APPI work, McMillen has held leadership positions in several organizations in the scholarly publishing arena, including the American Medical Publishers Association, for which he served as secretary-treasurer, and the Association of Learned and Professional Society Publishers.

APA Medical Director James H. Scully Jr., M.D., commented to *Psychiatric News* that "Ron 'is' APPI. He built it into the most important psychiatric publishing house in the world. His has been a very impressive career."

Melvin Sabshin, M.D., who was APA's medical director when APPI was founded, said in a letter read at McMillen's retirement reception at APA headquarters in March, "APA has been very fortunate to have had the skills and the commitment of such a marvelous manager. We thank him for all he has done for APA." ■

Credit: Robert Eubanks

APPI Publisher Ron McMillen poses with APA President Carol Bernstein, M.D., at McMillen's retirement celebration at APA headquarters.

Mixed Verdict Delivered On Autism Treatments

Despite a growing focus on autism spectrum disorders by the public and the medical community, evidence to support specific interventions for treating these disorders is thin and requires more and better research.

BY AARON LEVIN

Some treatments for autism help a little, some should be used rarely, and at least one should never be used.

Three systematic reviews in the May issue of *Pediatrics* offer limited news for the parents of children with autism spectrum disorders (ASD), mainly because so many of the studies examined were poorly designed or underpowered, said corresponding author Jeremy Veenstra-Vander Weele, M.D., an assistant professor of psychiatry, pediatrics, and pharmacology and director of the Treatment Resistant Autism Consultation Clinic at Vanderbilt University.

"To be clear, some available interventions that have been incompletely studied may be helpful, including various social-skills interventions and behavioral therapies," Veenstra-Vander Weele told *Psychiatric News*. "As Carl Sagan said, 'Absence of evidence is not evidence of absence.' "

The reviews were funded by the Agency for Healthcare Research and Quality and carried out by the researchers at Vanderbilt.

"Some early intensive behavioral interventions did appear to produce significant gains in language and cognitive skills, at least in some children," said longtime autism researcher Sir Michael Rutter, M.D., a professor at the Institute of Psychiatry, King's College London, in an interview. He was not involved in the systematic reviews. "I think all three reviews are good, and I support their conclusions."

Veenstra-Vander Weele; lead author Zachary Warren, M.D.; and their colleagues looked at studies of medical and behavioral interventions intended to improve the cognitive or behavioral performance of children with ASDs.

One purported remedy they rejected outright was secretin, a polypeptide neurotransmitter used in assessing pancreatic function and treating peptic ulcers.

In 1998, researchers reported that three children with ASDs given secretin to help diagnose gastrointestinal problems showed improvements in social, cognitive, and communications symptoms.

Secretin then gained some popular, off-label attention as a treatment for autism, despite several studies showing little effect.

The Vanderbilt group reviewed eight studies of the compound. None revealed significant improvement in language, cognition, or autistic symptoms compared with placebo, they wrote. New clinical trials were unlikely to change these findings, so "[f]urther studies of secretin in children with ASDs are not warranted," said the authors.

Evidence Scant for SSRI Efficacy in ASDs

There were problems with studies of other medical treatments, too. In fact, insufficient evidence existed to even evaluate the use in autism of selective serotonin-reuptake inhibitors or stimulants, said the researchers.

They did find sufficient evidence to support the use of the antipsychotic drugs risperidone and aripiprazole for "challenging and repetitive behaviors," such as irritability, aggression, and self-injurious behavior.

But the benefits of those drugs came with a high price—increased risk for weight gain, sedation, and extrapyramidal symptoms—that may confine the medications' use to patients whose severe impairment or injury risk outweighs the potential adverse effects.

Poorly designed and inadequately powered trials generally limited the value of studies on other medical interventions for ASDs, and the two strongly positive trials the authors identified were funded by drug companies. "[M]ore publicly funded studies of medications for ASDs are warranted," they said.

Behavioral Data More Encouraging

Not all the news was gloomy, Veenstra-Vander Weele told *Psychiatric News*.

"The early intensive behavioral intervention data are actually somewhat encouraging, just not as clear or as specific as we might hope," he said. "Despite the absence of certainty, this is the area where interventions seem most likely to have a large impact on educational outcomes."

The researchers looked at studies of three categories of behavioral therapy: the early intensive behavioral intervention (EIBI) pioneered by the late University of California at Los Angeles clinical psychologist Ole Lovaas, Ph.D.; comprehensive approaches for children under age 2, including the Early Start Denver Model (ESDM); and parent training.

Both the Lovaas model and ESDM use teaching strategies that are based on learning strategies called applied behavior analysis. Of the 23 EIBI studies assessed, 15 were rated as having poor quality and eight as fair, including one randomized controlled trial. Children in the treatment group in that trial improved their IQ test scores, but selection of the ASD patients was not uniform. Most study participants who showed considerable improvement were diagnosed with pervasive developmental disorder not otherwise specified, but most of those who did poorly in the trial were diagnosed with "classically defined autism disorder," said the authors.

In the second category, involving comprehensive approaches, only four studies of treatments for very young patients (younger than age 2) met the reviewers' standards for inclusion, and just one of those, the ESDM, was a randomized controlled trial.

"In the ESDM model, the teaching strategies are delivered as part of interactive play activity that is child-directed and provides an opportunity for the child's choice of materials and activities," said Geraldine Dawson, Ph.D., chief science officer of the advocacy group Autism Speaks and principal investigator of the ESDM randomized controlled trial, in an interview. "Skills such as making eye contact, gesturing, and responding to a request, are not taught in isolation . . . [but] within shared playful activity."

The trial indicated that children in the intervention arm showed greater gains over a two-year period in IQ (17.6 points) than did a comparison group (7.0 points) that received a less-intensive intervention.

Other studies of potentially promising comprehensive interventions had methodological flaws such as a lack of baseline comparisons, poor case definitions of included patients, or inadequate documentation, the authors pointed out.

Results Mixed for Parent Interventions

The third category of programs reviewed covered seven home-based interventions delivered by parents. Results were mixed, the authors determined. Criteria assessed in some studies seemed to improve, but others did not. Again, methodological problems (sample size, lack of randomization, and lack of standardized measures of performance) limited the studies' utility.

Other issues detract from the utility of many of these clinical trials as well.

For one thing, definitions of autistic disorder and autism spectrum disorders have changed significantly over the past 30 years and may continue to change with the development of *DSM-5*, making it hard to compare studies over time, he said. In addition, individual children with ASDs may differ substantially from one another in their symptoms, diagnoses, and response to treatment.

"It is therefore extremely important that studies fully characterize the participant population so that clinicians and families can evaluate whether a particular child is likely to benefit," he said.

Outcomes must be standardized as well. Autism Speaks has already adopted that approach, said Dawson.

"We recently funded seven clinical trials of early interventions for infants and toddlers with autism, and required that all investigators use the same outcome measures so that the data could be compared and combined across trials," she said. "Similarly, NIH now requires that investigators use common diagnostic, IQ, adaptive behavior, and language measures so that outcomes can be compared across different studies."

Another problem with autism studies is that the research sometimes stops with an initial clinical trial of a treatment performed by its developers.

"That is perfectly appropriate, so long as the study is appropriately controlled, but replication of research findings is critical," said Veenstra-Vander Weele. "It is also difficult to know how a treatment will translate into the real world without knowing that it has succeeded in multiple places."

Finally, how well improvements are sustained over time is poorly understood, he said.

"As far as I know, there are no long-term follow-up studies of intervention effects, but clinical experience suggests that continuing (but possibly occasional) treatment activity is needed," Rutter agreed.

Participants in the recently published trial of the ESDM model are being followed with the help of NIH funding, said Dawson. She expects publication within the next few years.

An abstract of "A Systematic Review of Medical Treatments for Children With Autism Spectrum Disorders" is posted at <http://pediatrics.aappublications.org/cgi/content/abstract/peds.2011-0427v1>. An abstract of "A Systematic Review of Early Intensive Intervention for Autism Spectrum Disorders" is posted at <http://pediatrics.aappublications.org/cgi/content/abstract/peds.2011-0426v1>. An abstract of "A Systematic Review of Secretin for Children With Autism Spectrum Disorders" is posed at <http://pediatrics.aappublications.org/cgi/content/abstract/peds.2011-0428v1>. ■

Call for Award Nominations

APA members are asked to identify individuals who are deserving of recognition for their professional contributions and achievements.

Nominations are now being accepted for the following 2012 APA Awards. The deadline for nominations is June 1.

- **John Fryer Award,** which honors an individual whose work has contributed to the improvement of the mental health of member of sexual minorities.

- **Solomon Carter Fuller Award**, which honors a black citizen who has pioneered in an area that has significantly benefited the quality of life for black people.

- **Oskar Pfister Award,** which honors an outstanding contributor in the field of psychiatry and religion.

- **Kun-Po Soo Award,** which recognizes an individual who has made significant contributions toward understanding the impact and import of Asian cultural heritage in areas relevant to psychiatry.

- **Alexandra Symonds Award,** which recognizes a woman psychiatrist who has made significant contributions to promoting women's health and the advancement of women.

- **George Tarjan Award,** which honors a physician who has made significant contributions to the enhancement of the integration of international medical graduates into American psychiatry.

More information is available at <www.psych.org/share/OMNA/MURawards.aspx> or from Alison Bondurant at abondurant@psych.org or (703) 907-8639. ■

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Sweeping Plaques From Brain Studied as Alzheimer's Strategy

Enhancing a natural cellular process for removing debris in the brain may constitute a novel and effective treatment strategy for Alzheimer's and other neurodegenerative diseases.

BY JOAN AREHART-TREICHEL

Enormous efforts have been expended in the search to discover an effective treatment for Alzheimer's disease that involves inhibiting the production of plaques in the brain—that is, by targeting the enzymes that make amyloid protein. But all of the candidate drugs that once showed promise have proven disappointing in clinical trials.

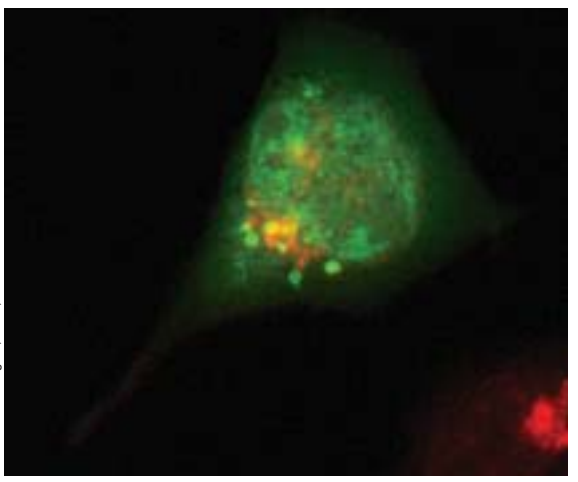
Therefore another tack for treating the disease may be needed—for example, the removal of plaques from the brain after they have already formed. Indeed, scientists at Rockefeller University have found a molecule that can do just that—at least in cultured rodent neurons.

The senior investigator was Paul Greengard, Ph.D., a professor and head of the Laboratory of Molecular and Cellular Neuroscience at Rockefeller University and a Nobel laureate in medicine. The lead investigator was Yuan Tian, Ph.D., a postdoctoral associate in Greengard's laboratory. Their findings were published online March 2 in the *FASEB Journal*, a publication of the Federation of American Societies for Experimental Biology.

Cells contain a pathway for degrading long-lived, aggregated proteins in a process called autophagy. So Greengard and his colleagues wondered whether the artificial induction of autophagy might be used to remove from the brain the proteins of which Alzheimer's plaques are made.

They tested various small-molecule enhancers of autophagy on cultured rodent neurons containing clumps of amyloid protein and found that one—SMER28—was successful in removing the clumps.

"At this point it is not clear if SMER28 is appropriate for animal studies [because of issues surrounding] bioavailability and brain permeability, but we would like to test its impact using animal models," Greengard told *Psychiatric News*. Regarding human clinical trials with SMER28, "it is too early to predict" whether they will be possible, he said.



Credit: Paul Greengard, Ph.D., et al.

A cell's autophagy process attacks a protein from which Alzheimer's plaques are made.

In any event, Greengard and his colleagues believe that their cell-culture success with SMER28 points to the potential of small-molecule enhancers of autophagy as effective treatments for Alzheimer's.

Gerald Weissmann, M.D., editor-in-chief of the *FASEB Journal*, pointed out in an accompanying press release, "Autophagy has been called the cell's equivalent of urban renewal. The Rockefeller group shows that strategies to remove the blight in cells that causes Alzheimer's disease are not only worth pursuing, but so far appear to be very promising."

Autophagy enhancers may hold treatment promise for some other neurodegenerative diseases as well, Greengard and his colleagues noted. For example, some small-molecule autophagy enhancers have been found to degrade, in cell culture, aggregates of mutant huntingtin proteins, the hallmark of Huntington's disease. And even more intriguingly, when mice were fed an autophagy enhancer called rapamycin, it extended their lifespan by about 10 percent, David Harrison, Ph.D., a professor at Jackson Laboratory in Bar Harbor, Maine, and colleagues reported in the July 16, 2009, *Nature*.

"SMER28 stands for 'small-molecule-enhancer-of-rapamycin-28,' but it really has nothing to do with the actual rapamycin molecule," Greengard explained to *Psychiatric News*. "It is called that because it was initially discovered as an enhancer of the effect of rapamycin to stimulate autophagy. In fact, we now know that SMER28 works through a pathway independent of rapamycin."

The research was funded by the National Institutes of Health and the Fisher Center for Alzheimer's Research Foundation.

An abstract of "A Small-Molecule Enhancer of Autophagy Decreases Levels of Amyloid Beta and APP-CTF Via Atg5-Dependent Autophagy Pathway" is posted at <www.fasebj.org/content/early/2011/03/02/fj.10-175158.abstract>. ■

Dramatic Cognitive Decline Seen Years Before Alzheimer's Diagnosis

Five to six years before people meet clinical criteria for an Alzheimer's diagnosis, they have already experienced a major downward spiral in cognition, a finding that has crucial public-health implications.

BY JOAN AREHART-TREICHEL

Cognition has already declined sharply five to six years before Alzheimer's disease is usually diagnosed.

This is a key finding from a study headed by Robert Wilson, Ph.D., a professor of neuropsychology at Rush University Medical Center in Chicago. The study's senior investigator was David Bennett, M.D., director of the Rush University Alzheimer's Disease Center. Their findings were published in the March *Archives of Neurology*.

Their study included more than 2,000 subjects. At baseline, the subjects had an average age of 77 and did not have Alzheimer's or any other kind of dementia, according to results of a structured clinical evaluation. That evaluation included a medical history, complete neurological examination, and cognitive-performance testing. The subjects underwent an identical structured clinical evaluation each year after that until they died or until termination of the study 16 years later. The subjects were followed up for an average of seven years.

During the follow-up period, 462 of the participants were diagnosed with Alzheimer's disease. Thus the investigators were able to examine the clinical evaluation results from previous years for these 462 individuals and to determine the state of their cognition prior to their Alzheimer's diagnosis. (Twenty subjects who developed types of dementia other than Alzheimer's were excluded from the analysis.)

Five to six years before their Alzheimer's diagnosis, the cognitive abilities of these 462 individuals had already started declining, the researchers found. Specifically, the results of these individuals' annual cognitive examinations showed that, on average, their semantic memory started deteriorating at 76 months before diagnosis, their working memory at 75 months, their perceptual speed at 70 months, their visuospatial ability at 65 months, and their episodic memory at 63 months.

Moreover, the downward spiraling of these individuals' cognition from baseline to diagnosis was dramatic, having accelerated 15-fold. In contrast, study subjects who did not develop Alzheimer's during the follow-up period evidenced little decline in cognitive function.

"These data show that by the time individuals meet clinical criteria for a diagnosis of Alzheimer's, they have already experienced many years of accelerating cognitive decline," the researchers stated in their report. The data also show, they said, that while certain types of cognition start eroding earlier than others, "cognition is clearly globally affected in the prodromal phase of Alzheimer's."

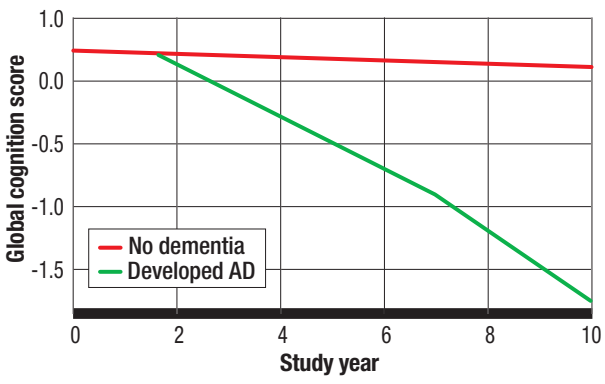
These findings have "important public-health implications," they concluded, "because it is generally assumed that treatments for Alzheimer's will be more effective if introduced before this prodromal period begins and cognitive systems are manifestly dysfunctional."

The study was funded by the National Institute on Aging and the Illinois Department of Public Health.

An abstract of "Cognitive Decline in Prodromal Alzheimer Disease and Mild Cognitive Impairment" is posted at <http://archneur.ama-assn.org/cgi/content/abstract/68/3/351>. ■

Dramatic Difference Seen In Cognition as Years Go By

This figure shows the cognitive trajectory of two subjects during a 10-year follow-up period—one who remained free of Alzheimer's and one who was diagnosed with Alzheimer's in year 7 of the follow-up. The former showed little cognitive decline during the 10-year period, whereas the latter had already been declining for more than five years before the diagnosis.



Source: Robert Wilson, Ph.D., et al., *Archives of Neurology*, March 2011

Nominations Invited

APA is inviting nominations for its Jack Weinberg Memorial Award for Geriatric Psychiatry. The award, established in 1983 in memory of Jack Weinberg, M.D., honors a psychiatrist who has demonstrated special leadership or who has done outstanding work in clinical practice, training, or research in geriatric psychiatry.

Candidates for the award must be psychiatrists who are nominated by an APA member. The award winner will receive a $500 honorarium and a plaque at APA's 2012 annual meeting in Philadelphia.

Submissions must include six copies of a letter summarizing the accomplishments of the nominee, two letters of endorsement from APA members, a current curriculum vitae, and bibliography.

The deadline for nominations is July 31. Submissions should be sent to Diane Pennessi, Staff Liaison, Council on Psychosomatic Medicine and Geriatric Psychiatry, APA, 1000 Wilson Boulevard, Suite 1825, Arlington, Va. 22209-3901. More information is available by contacting Pennessi at (703) 907-8668 or dpennessi@psych.org. ■

Depression Should Be Considered When Treating Arthritis Pain

Patients were evaluated for severity of osteoarthritis of the knee and assessed for depression. Depressed patients reported more pain than radiographic changes in their knees indicated they should experience.

BY LESLIE SINCLAIR

Could knee pain in the elderly be due more to depression than to the physical symptoms of the disease? An investigation performed at Seoul National University Bundang Hospital in Seongnam, South Korea, and published in the March *Journal of Bone and Joint Surgery* suggests that this may be true, especially in those people with less radiographic evidence of knee osteoarthritis.

The information came to light as part of the Korean Longitudinal Study on Health and Aging (KLoSHA), a population-based prospective cohort study of health, aging, and common geriatric diseases.

One thousand elderly Koreans aged 65 or older participated in the study; 660 underwent a radiographic examination of their knee, symptom evaluation, and diagnostic interviews for depressive disorders. (Subjects who had already undergone total knee arthroplasty, those diagnosed with a major psychiatric disorder, and those with a neuromuscular disorder were excluded.)

Several grading systems and scales were used to evaluate KLoSHA participants for the severity of knee osteoarthritis and for depression. Blinded evaluations were performed of three knee radiographs using the Kellgren-Lawrence grading system. Symptom severity was evaluated on the basis of the Western Ontario and McMaster Universities Osteoarthritis Index, with symptomatic knee osteoarthritis defined as a score of 39 or higher.

Diagnostic interviews to assess for depressive disorders included the Korean version of the Mini-International Neuropsychiatric Interview and the Korean version of the Geriatric Depression Scale.

Discrepancies in the relationship between the degree of pain reported by patients and radiographic severity of joint osteoarthritis have frequently been reported, said the report's authors. They cited numerous shortcomings of previous studies, including few that have correlated radiographic findings with symptom severity, others that included multiple joints, and still others that may not have properly assessed the patellofemoral joint, possibly underestimating radiographic changes.

Unsophisticated methods of pain measurement also may have hindered evaluations in past studies, the researchers noted, and additional pain-related risk factors such as obesity may not have been considered.

The results of this study may explain why some patients appear to be in more pain than their radiographic findings would suggest.

Patients who exhibited minimal to moderate radiographic severity of knee osteoarthritis (Kellgren-Lawrence grade 0 to 3) and the presence of a depressive disorder had an increased likelihood of symptomatic knee osteoarthritis (pain, stiffness, and disability). The presence of a depressive disorder was not associated with the likelihood of symptomatic knee osteoarthritis in subjects with severe osteoarthritis (Kellgren-Lawrence grade 4).

"These findings suggest that depression contributes substantially to the discrepancy between symptoms and radiographic degenerative changes that have been observed in patients with knee osteoarthritis," said the researchers. "This bidirectional relationship between pain and depression suggests that both should be considered as simultaneous therapeutic targets during the management of patients with knee osteoarthritis. Assessment and management of coexisting depression should be integrated with the assessment and management of knee osteoarthritis, particularly when radiographic changes of osteoarthritis in the knee joint are not severe."

This study was supported by Pfizer Global Pharmaceuticals and Seongnam City Government in Korea.

An abstract of "Association Between Comorbid Depression and Osteoarthritis Symptom Severity in Patients With Knee Osteoarthritis" is posted at <www.ejbjs.org/cgi/content/abstract/93/6/556>. ■

Study Illuminates Cocaine's Direct Effect on Cognition

When rules of the response-reward challenge were reversed, monkeys who were given cocaine showed more difficulty in adapting, suggesting impairments in executive function that guide goal-directed behavior.

BY MARK MORAN

Cocaine use appears to contribute directly to the development of cognitive deficits such as impairments of visual working memory and difficulty adapting to rule changes in reward tasks, according to an animal study reported in the March 30 *Journal of Neuroscience*.

A wide range of cognitive difficulties is seen among cocaine users, but it hasn't been clear whether these problems reflect preexisting traits that made them more susceptible to drug abuse or are caused by the drug itself, according to lead author Charles Bradberry, Ph.D., an associate professor of psychiatry at the University of Pittsburgh School of Medicine, and colleagues.

In the study, the researchers assessed cognitive skills in 14 rhesus monkeys, six of whom learned to touch an abstract shape on a touch screen to receive a sip of water, while eight used the touch screen to receive a cocaine infusion via a special access port into a blood vessel. Self-administration took place on four consecutive days over nine months.

A total of 36 weekly cognitive assessments were conducted on Mondays after a 72-hour drug-free period.

On each cognitive assessment day, three novel, visually distinct stimuli were used that required the subjects to learn a new stimulus-reward association for receiving water at the beginning of each session. The task began with presentation of a blue square that the animal had to touch, thereby indicating it was attending to the task; touching the blue square led to random presentation of two of the three stimuli, associated with a high, medium, or low water reward.

The researchers found that the cocaine group learned the initial rules as quickly and at first responded as accurately as the water-only group, but only five of the eight achieved the threshold of correct responses, defined as 27 correct responses out of 30 trials. The researchers then increased the difference between high and low rewards, which allowed the remaining three monkeys in the cocaine group to get to threshold.

Bradberry and colleagues said that the experiment demonstrates that cocaine users have a hard time maintaining focus and attention, but if the reward value associated with learning tasks is increased, it may be possible to overcome cognitive deficits.

When the researchers changed the rules so that the images associated with high- or low-water reward were reversed, they found that the cocaine group had much greater difficulty learning and adapting to the change in rules. This difficulty indicates a deficit in cognitive-control processes or executive brain functions that require focus and that guide volitional, goal-directed behavior, according to the study.

"These results represent a unique study in which a broad range of cognitive domains were studied longitudinally in nonhuman primates to determine the effects of chronic cocaine self-administration," wrote the researchers. "The results strongly suggest that, in addition to the substantial literature indicating the contribution of inherent differences between individuals for risk of addiction, cocaine use by itself causes cognitive deficits. Understanding the neurobiological basis of these deficits may help in the development of therapeutic approaches to address them."

The study was funded by the National Institute on Drug Abuse and the Veterans Affairs Medical Research Service.

An abstract of "Chronic Cocaine Self-Administration in Rhesus Monkeys: Impact on Associative Learning, Cognitive Control, and Working Memory" is posted at <www.jneurosci.org/content/31/13/4926.abstract>. ■

Nitric Oxide Gene Variant May Affect Depression Risk

Who would have guessed a quarter-century ago that the gas nitric oxide would be found to be a neurotransmitter and implicated not just in depression, but in other illnesses as well?

BY JOAN AREHART-TREICHEL

Back in 1989, Solomon Snyder, M.D., a professor of neuroscience, pharmacology, and psychiatry at Johns Hopkins University, and colleagues reported a provocative discovery—that the gas nitric oxide functions as a neurotransmitter in the brain. Since then, nitric oxide has emerged as an important player in various cognitive, emotional, and behavioral processes.

Nitric oxide also seems to be implicated in depression. For example, major depression has been linked with increased expression of two enzymes that make nitric oxide—neuronal nitric oxide synthase (nNOS) and inducible nitric oxide synthase (iNOS)—as well as with increased nitric oxide levels in the brain. Inhibitors of nNOS and iNOS produced antidepressant-like effects in mice. And now a variant of the gene that makes nNOS and a variant of one that makes iNOS appear to increase depression susceptibility.

The findings were reported in the March *Journal of Affective Disorders* by a team of Polish scientists. The lead investigator was Piotr Galecki, M.D., Ph.D., vice chair of the Department of Adult Psychiatry at the Medical University of Lodz, Poland.

Galecki and his colleagues wanted to find out whether any variants in the genes that make nNOS and iNOS contribute to the risk of developing depression. They tested their hypothesis in a study that included 181 subjects being treated for recurrent depression and 149 control subjects. The former had had on average four depressive episodes over the prior eight years. The control subjects had never been diagnosed with depression or another psychiatric disorder.

The scientists found that a variant of genetic material within the gene that makes nNOS and a variant of genetic material within the gene that makes iNOS were present significantly more often in the depressed subjects than in the control subjects. Thus these variants appeared to contribute to the risk of developing depression, just as the variants that the controls possessed appeared to protect against the risk of developing depression.

Specifically, the T/T or T/C variant of the nNOS gene appeared to increase vulnerability to depression, whereas the C/C variant of that gene seemed to decrease risk for it. The G/G or G/A variant of the iNOS gene appeared to increase susceptibility to depression, whereas the A/A variant of that gene seemed to decrease risk for it.

The relationship between nitric oxide and depression is also interesting in that some variants of the genes that code for nNOS and iNOS have been linked to other illnesses—for example, Alzheimer's disease, autism, bipolar disorder, high blood pressure, Parkinson's disease, rheumatoid arthritis, and schizophrenia. Indeed, the iNOS gene variant that Galecki and his team found protective against depression—the A/A variant—has also been found by other researchers to be protective against Parkinson's.

The reason or reasons why nitric oxide is implicated in so many illnesses is not clear at this point. But inflammation could be one possible explanation, various lines of research suggest. For example, nitric oxide is a free radical that may contribute to the development of pro-inflammatory compounds. Rheumatoid arthritis and high blood pressure, like depression, are characterized by the overproduction of free radicals and inflammatory reactions, and in addition, depression often coexists with these disorders. The iNOS gene is located on chromosome 17, as is a gene involved in inflammation; a variant of the latter has also been linked with depression.

> **"Anti-inflammatory treatment should be seriously considered in the treatment of major depression."**

These findings, plus his own, suggest that "anti-inflammatory treatment should be seriously considered in the treatment of major depression," Galecki told *Psychiatric News*.

The study was funded by the Department of Psychiatry of the Medical University of Lodz.

An abstract of "Association Between Inducible and Neuronal Nitric Oxide Synthase Polymorphisms and Recurrent Depressive Disorder" is posted at <www.sciencedirect.com/science/journal/01650327>. ■

Brain Volume Shrinkage Parallels Rise in Antipsychotic Drug Dosage

A magnetic imaging study of people with schizophrenia indicates that their brain volume decreases with use of antipsychotic medication. But what does that mean?

BY AARON LEVIN

Magnetic resonance imaging of the brains of patients with schizophrenia suggests that while treatment with an antipsychotic drug may alleviate symptoms, it may also contribute to reductions in brain volume.

"It is possible that, although antipsychotics relieve psychosis and its attendant suffering, these drugs may not arrest the pathophysiological processes underlying schizophrenia and may even aggravate progressive brain tissue volume reductions," said Beng-Choon Ho, M.D., an associate professor of psychiatry at the University of Iowa Carver College of Medicine, and colleagues in the February *Archives of General Psychiatry*.

The reduction in brain volume in schizophrenia occurs not because brain cells die off but rather because dendrites shrink and dendritic spines shrink, causing shrinkage in the synaptic connections in the cortex, explained Jeffrey Lieberman, M.D., another schizophrenia researcher not affiliated with the Iowa study.

"That's why in people with schizophrenia, thinking becomes more stereotyped, routinized, and concrete," said Lieberman, a professor and chair of the Department of Psychiatry at Columbia University College of Physicians and Surgeons and director of the New York State Psychiatric Institute.

"They don't have the elaborate richness of synaptic connections to allow for the cognitive and intellectual processes to occur," he said in an interview with *Psychiatric News*.

To see what effect antipsychotic drug treatment might have on the brain, the Iowa researchers performed a series of magnetic resonance imaging scans on 211 patients at baseline and an average of three years later. Most patients (n=139) had an additional scan about three years after that, and some had fourth (n=82) and fifth (n=31) scans at similar intervals.

During the course of the study, patients were given "treatment as usual" in the community by their own physicians using typical or atypical antipsychotic drugs or clozapine. Ho and colleagues controlled for dose, illness severity, and substance use.

They also used alternative ways of accounting for any treatment variations.

"Since our findings do not change when we analyze the data using different measures of illness severity, it suggests that our results are fairly robust," Ho told *Psychiatric News*. "The potential confounding influence from more severely ill patients needing higher doses of antipsychotics becomes less likely."

The longer the patients were followed up, the greater their changes in brain volume. As time passed, they lost total cerebral tissue, gray matter, and subcortical tissue, but saw enlargement of parietal white matter, lateral ventricles, and sulcal cerebrospinal fluid.

Brain volume changed not only over time but also in parallel with antipsychotic medication treatment. Patients who got the highest mean daily doses of antipsychotics had smaller frontal gray matter volumes and larger lateral ventricles.

"Antipsychotic treatment had a significant influence on brain volumes," even after adjusting for illness duration, illness severity, and substance misuse, the researchers noted.

The meaning of reduced brain volumes associated with antipsychotic drug use among patients with schizophrenia is unclear, they pointed out.

Some prior research seems to indicate that changes visible after treatment are similar to those attributable to the effects of the disease. Other studies disagree.

"Medications may reduce the volume in a healthy brain [as seen in primate studies], but disease is also a contributor," said Lieberman. "If you compared treated and untreated patients, the untreated patients might show a greater volume reduction."

Ethical considerations prevented including an untreated control group in the Iowa study.

However, data are available from brain autopsies of untreated patients done in the first half of the 20th century, prior to the introduction of effective antipsychotic medications, said Lieberman. Those studies documented a variety of changes in the brains of people with schizophrenia—aplasia, atrophy, hydrocephalus, and others, he noted. "So it is likely the disease itself that contributes to those neuropathologies," he said.

An editorial by David Lewis, M.D., of the University of Pittsburgh accompanying the report of Ho's study offers another experimental alternative based on the increasing use of antipsychotics for nonschizophrenia diagnoses such as mood disorders. A long-term comparison of brain volume changes in patients with and without exposure to those drugs might reveal whether the illness of schizophrenia or the antipsychotics taken to treat it was responsible for the brain changes Ho and colleagues reported.

"[A] positive finding would suggest a conserved medication effect that is independent of diagnosis or underlying disease," said Lewis. The clinical significance of brain volume changes is also open for debate, he said. The changes may reflect a positive result of therapy and not an adverse effect.

Ho suggested that different pathways initiated by antipsychotic medications lead separately to alleviation of symptoms and brain volume changes.

He also pointed out that the study reports only an association but not a causal relationship between higher antipsychotic dosages and greater brain volume reductions. However, that association, along with animal studies by others, suggests that antipsychotic medication is a mediating factor.

"Our finding does not mean that the disease itself is not a contributing factor to brain anatomical differences in schizo-

please see ***Brain Volume*** *on page 22*

Ralph Hoffman, MD, and research assistant Joan Nye, view functional MR images of a patient's cortical activation during auditory hallucinations.

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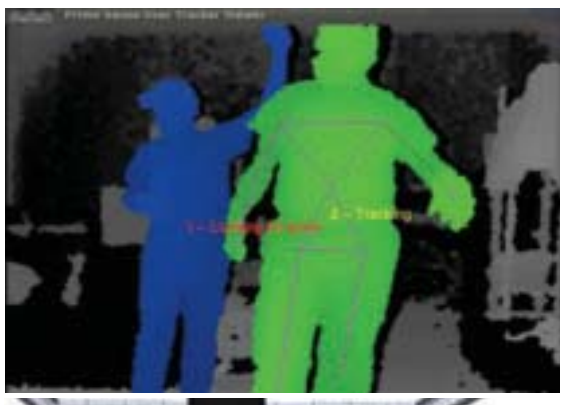
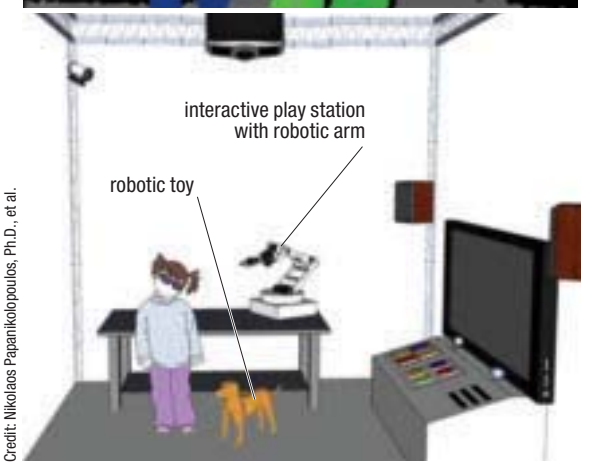
Movement Abnormalities Studied As Clue to Mental Illness Risk

Robots might be used to screen children for movement abnormalities that point to an increased risk for psychiatric disorders. A child who tests positive could then be evaluated further by a psychiatrist.

BY JOAN AREHART-TREICHEL

University of Minnesota scientists have an audacious goal—to use some of the latest computer software technology to see whether there are differences in movement between children who are healthy and children who will later develop a psychiatric disorder.





Credit: Nikolaos Papanikolopoulos, Ph.D., et al.

University of Minnesota scientists hope to use a Microsoft Kinect sensor (pictured in photo) to screen children for movement abnormalities that might indicate a psychiatric disorder. They are also planning to build an interactive play station with a robotic arm or robotic dog to screen children for such abnormalities (pictured in drawing).

The research team is headed by Nikolaos Papanikolopoulos, Ph.D., a professor of computer science and engineering at the university, and includes Kelvin Lim, M.D., a professor of psychiatry, and Kathryn Cullen, M.D., an assistant professor of psychiatry at the University of Minnesota Medical School.

The instrument that the scientists are using is a Microsoft product called a Kinect, which includes a camera and a computer. It shows the computer where a person is located in space and is able to track and analyze movements the person makes. Kinects are used in some computer games in which people can play golf, baseball, or other sports.

The scientists are just starting to use Kinects to study the movements of apparently healthy preschoolers at the University of Minnesota lab school (with the permission of the parents) to establish norms. They will then compare movement patterns between healthy children and those with various psychiatric disorders.

Once a set of movement patterns that are associated with common childhood psychiatric disorders is established, the next step will be to conduct longitudinal investigations to confirm whether such abnormalities represent risk markers for later development of psychiatric illness. Finally, once risk markers are established, children might be screened for such markers at an early age. Children who are ultimately identified in this manner could be evaluated by a clinician, and a plan for monitoring and/or early intervention could then be set into motion.

"We think that early intervention will lead to better outcomes," Cullen told *Psychiatric News*. "So we are brainstorming ways by which we might advance such early intervention."

She and her colleagues got some of their ideas from Elaine Walker, Ph.D., a schizophrenia researcher at Emory University, Cullen said. "She looked at home videos made of children who later developed schizophrenia and noted some movements and facial expressions that differentiated them from normal-developing children."

Meanwhile, Papanikolopoulos is planning to build robots that could be used to screen children for abnormal movements, behaviors, body positions, and/or facial expressions. The robots would contain Kinects plus other software and specialized detectors. The robots might even be built in the shape of items that would appeal to children, such as a pet or a sandbox, and by interacting with children and eliciting certain movements, they would potentially allow for even more detailed monitoring and measurement of complex movements.

Papanikolopoulos and his colleagues expect to have their first robot built within a year, he told *Psychiatric News*.

"This is a fascinating concept," David Fassler, M.D., a clinical professor of psychiatry at the University of Vermont and a child and adolescent psychiatrist, commented. "It's certainly plausible that children with subtle, but identifiable movement abnormalities could be at increased risk for the development of specific psychiatric disorders. The team deserves credit for thinking out of the box. I look forward to following their research."

Papanikolopoulos is credited with being the major driving force behind the Scout, a small reconnaissance robot now used by the U.S. Army. He and his team have also built a robotic scrub nurse and a robotic system that monitors a patient's movements during radiation therapy. He is also interested in using computer vision techniques for monitoring driver fatigue, monitoring safety in work zones, and tracking pedestrians and vehicles.

The scientists' research is being funded by two grants from the National Science Foundation (NSF) of more than $3 million. "I recently learned that NSF has awarded two even larger grants of $10 million to two other groups for similar projects," Cullen said.

More information about the research is posted at <www1.umn.edu/news/news-releases/2011/UR_CONTENT_304914.html> and at <www.cs.umn.edu/people/faculty/npapas>. ■

Brain Volume

continued from page 20

phrenia," he said. "There are likely multiple causes for smaller brain volumes in people with schizophrenia—genes, environmental factors, antipsychotics, street drugs, lifestyle, and so on."

Finally, Lieberman raised concerns that some patients or practitioners might draw unwarranted conclusions about the study's findings and decide to stop treatment.

Ho and colleagues also suggested avoiding precipitous changes in the use of antipsychotics to treat schizophrenia.

"We do not advocate that people stop taking their medications, because many patients with schizophrenia benefit from antipsychotic medications and from remaining on treatment," he said. He does, however, recommend using the lowest doses necessary to control symptoms.

Ho and colleagues recommended additional caution when antipsychotics are prescribed for patients diagnosed with disorders other than schizophrenia, such as bipolar or depressive disorders.

The study was supported by NIMH.

An abstract of "Long-term Antipsychotic Treatment and Brain Volumes" is posted at <http://archpsyc.ama-assn.org/cgi/content/abstract/68/2/128>. ■

New Assessment Tool May Help Determine Patients' Violence Risk

Only a comparative study will show whether a new tool for evaluating violence risk in patients discharged from a psychiatric unit appears to be superior to several others that are already available.

BY JOAN AREHART-TREICHEL

An easy-to-use tool for evaluating civilly committed patients' risk of violence toward others after discharge from an acute psychiatric ward has been developed by Norwegian researchers.

The lead investigator was John Olav Roaldset, M.D., Ph.D., of the Norwegian University of Science and Technology, and the study results were reported in the March *European Psychiatry*.

The tool is called the V-RISK-10. It includes 10 questions that address previous or current acts of violence, threats of violence, substance abuse, and severe mental illness, as well as personality disorders, lack of insight into the illness or behavior, suspiciousness, lack of empathy, unrealistic planning, and whether the patient will be exposed to future stress situations.

The clinician using the tool needs to answer each of the questions on a four-point scale indicating the extent to which a factor is present in the patient: 1, when the answer is no or not present; 2, maybe or moderately present; 3, definitely present; and 4, don't know, too little information.

The researchers screened some 1,000 patients with the V-RISK-10 before the patients were discharged from an acute psychiatric ward and attempted to follow them over the subsequent year to see whether any of them committed acts of violence. They were able to follow up with about a third of them. (Many subjects were lost to follow-up because one of the research assistants left and was not replaced.)

An evaluation of 327 patients at the three-month follow-up showed that 69 (21 percent) had committed an act of violence, and an evaluation of 367 patients at the 12-month follow-up showed that 101 (28 percent) had. (Some of the patients missing in the three-month evaluation were located and included in the 12-month one, Roaldset explained to *Psychiatric News*.)

The researchers then tested the V-RISK-10's predictive value in their cohort. They found that it had an overall accuracy of 0.80 for any violent behavior at three months and an overall accuracy of 0.75 for any violent behavior at 12 months, and that held true for both male and female patients. The tool was even more accurate in predicting severe violence—0.87 at three months and 0.86 at 12 months.

"This study indicates that the V-RISK-10 is an easy-to-use, valid, and feasible tool for screening risk of violence in acute psychiatric patients," the researchers concluded. However, a challenge in using this tool, or any risk-assessment tool, they noted, "is the almost-inevitable inverse relationship between false negatives and false positives. In screening procedures, it is important to keep rates of false negatives as low as possible without having too many false positives. . . ."

A leading forensic psychiatrist, Paul Appelbaum, M.D., a professor of psychiatry, medicine, and law at Columbia Uni-

please see ***Violence Risk*** *on page 26*


Schizophrenia
can tear
patients
apart

Table 7: Percentage of EPS Compared to Placebo

Adverse Event Term	Placebo (N=455) (%)	LATUDA 20 mg/day (N=71) (%)	LATUDA 40 mg/day (N=360) (%)	LATUDA 80 mg/day (N=282) (%)	LATUDA 120 mg/day (N=291) (%)
All EPS events	9	10	24	26	39
All EPS events, excluding Akathisia/ Restlessness	5	6	13	11	22
Akathisia	3	6	11	15	22
Dystonia*	1	0	4	5	7
Parkinsonism**	5	6	10	7	17
Restlessness	2	1	4	1	3

Note: Figures rounded to the nearest integer
*Dystonia includes adverse event terms: dystonia, oculogyric crisis, oromandibular dystonia, tongue spasm, torticollis, and trismus
**Parkinsonism includes adverse event terms: bradykinesia, cogwheel rigidity, drooling, extrapyramidal disorder, hypokinesia, muscle rigidity, parkinsonism, psychomotor retardation, and tremor

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

Dystonia

Class Effect: Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups.

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

6.5 Laboratory Test Abnormalities and ECG Changes in Clinical Studies

Laboratory Test Abnormalities

In a between-group comparison of the pooled data from short-term, placebo-controlled studies, there were no clinically important changes in total cholesterol measurements; triglycerides or glucose from Baseline to Endpoint [*see Warnings and Precautions (5.5)*]. There were also no clinically important differences between LATUDA and placebo in mean change from baseline to endpoint in routine hematology, urinalysis, or serum chemistry. LATUDA was associated with a dose-related increase in prolactin concentration [*see Warnings and Precautions (5.6)*]

Creatinine: In short-term, placebo-controlled trials, the mean change from Baseline in creatinine was 0.06 mg/dL for LATUDA-treated patients compared to 0.03 mg/dL for placebo-treated patients. A creatinine shift from normal to high occurred in 3.1% (30/977) of LATUDA-treated patients and 1.4% (6/439) on placebo. The threshold for high creatinine value varied from ≥ 1.1 to ≥ 1.3 mg/dL based on the centralized laboratory definition for each study [*see Dosage in Special Population; Use in Specific Populations*].

Transaminases: The mean changes in AST and ALT for LATUDA- and placebo-treated patients were similar. The proportion of patients with transaminases (AST and ALT) elevations ≥ 3 times ULN was similar for all LATUDA-treated patients (0.8% and 0.8%, respectively) to placebo-treated patients (0.9% and 1.1%, respectively).

ECG Changes

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

The effects of LATUDA on the QT/QTc interval were evaluated in a dedicated QT study involving 87 clinically stable patients with schizophrenia or schizoaffective disorder, who were treated with LATUDA doses of 120 mg daily, 600 mg daily, or ziprasidone 160 mg daily. Holter monitor-derived electrocardiographic assessments were obtained over an eight hour period at baseline and steady state. No patients treated with LATUDA experienced QTc increases > 60 msec from baseline, nor did any patient experience a QTc of > 500 msec.

6.6 Other Adverse Reactions Observed During the Premarketing Evaluation of LATUDA

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

Reactions are further categorized by MedDRA system organ class and listed in order of decreasing frequency according to the following definitions: those occurring in at least 1/100 patients (frequent) (only those not already listed in the tabulated results from placebo-controlled studies appear in this listing); those occurring in 1/100 to 1/1000 patients (infrequent); and those occurring in fewer than 1/1000 patients (rare).

Blood and Lymphatic System Disorders: ***Infrequent:*** *anemia;* ***Rare:*** *leukopenia, neutropenia*
Cardiac Disorders: ***Frequent:*** *tachycardia;* ***Infrequent:*** *AV block 1st degree, angina pectoris, bradycardia*
Ear and Labyrinth Disorders: ***Infrequent:*** *vertigo*
Eye disorders: ***Frequent:*** *blurred vision*
Gastrointestinal Disorders: ***Frequent:*** *abdominal pain, diarrhea;* ***Infrequent:*** *gastritis, dysphagia*
General Disorders and Administrative Site Conditions: ***Rare:*** *Sudden death*
Investigations: ***Frequent:*** *CPK increased*
Metabolic and Nutritional System Disorders: ***Frequent:*** *decreased appetite*
Musculoskeletal and Connective Tissue Disorders: ***Rare:*** *rhabdomyolysis*
Nervous System Disorders: ***Infrequent:*** *tardive dyskinesia, cerebrovascular accident, dysarthria, syncope;* ***Rare:*** *neuroleptic malignant syndrome, seizure*
Psychiatric Disorders: ***Infrequent:*** *abnormal dreams, panic attack, sleep disorder;* ***Rare:*** *suicidal behavior*
Renal and Urinary Disorders: ***Infrequent:*** *dysuria;* ***Rare:*** *renal failure*
Reproductive System and Breast Disorders: ***Infrequent:*** *amenorrhea, dysmenorrhea;* ***Rare:*** *breast enlargement, breast pain, galactorrhea, erectile dysfunction*
Skin and Subcutaneous Tissue Disorders: ***Frequent:*** *rash, pruritus;* ***Rare:*** *angioedema*
Vascular Disorders: ***Infrequent:*** *hypertension, orthostatic hypotension*

7 DRUG INTERACTIONS

Given the primary CNS effects of LATUDA, caution should be used when it is taken in combination with other centrally acting drugs and alcohol.

7.1 Potential for Other Drugs to Affect LATUDA

LATUDA is not a substrate of CYP1A1, CYP1A2, CYP2A6, CYP4A11, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6 or CYP2E1 enzymes. This suggests that an interaction of LATUDA with drugs that are inhibitors or inducers of these enzymes is unlikely.

LATUDA is predominantly metabolized by CYP3A4; interaction of LATUDA with strong and moderate inhibitors or inducers of this enzyme has been observed (Table 8). LATUDA should not be used in combination with strong inhibitors or inducers of this enzyme *[see Contraindications (4)]*.

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

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

5.14 Use in Patients with Concomitant Illness

Clinical experience with LATUDA in patients with certain concomitant systemic illnesses is limited *[see Use in Specific Populations (8.7, 8.8)]*. LATUDA has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from premarketing clinical studies *[see Warnings and Precautions (5.1, 5.8)]*.

6 ADVERSE REACTIONS

6.1 Overall Adverse Reaction Profile

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

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

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

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

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

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

6.2 Clinical Studies Experience

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

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

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

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

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

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

Note: Figures rounded to the nearest integer
*Somnolence includes adverse event terms: hypersomnia, hypersomnolence, sedation, and somnolence
**Parkinsonism includes adverse event terms: bradykinesia, cogwheel rigidity, drooling, extrapyramidal disorder, hypokinesia, muscle rigidity, parkinsonism, psychomotor retardation, and tremor
***Dystonia includes adverse event terms: dystonia, oculogyric crisis, oromandibular dystonia, tongue spasm, torticollis, and trismus

6.3 Dose-Related Adverse Reactions

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

Table 6: Dose-Related Adverse Events

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

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

6.4 Extrapyramidal Symptoms

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

Table 2: Change in Fasting Lipids

	Placebo	LATUDA 20 mg/day	LATUDA 40 mg/day	LATUDA 80 mg/day	LATUDA 120 mg/day
Mean Change from Baseline (mg/dL)					
	n=418	**n=71**	**n=341**	**n=263**	**n=268**
Total cholesterol	-8.5	-12.3	-9.4	-9.8	-3.8
Triglycerides	-15.7	-29.1	-6.2	-14.2	-3.1
Proportion of Patients with Shifts					
Total Cholesterol (≥ 240 mg/dL)	6.6% (23/350)	13.8% (8/58)	7.3% (21/287)	6.9% (15/216)	3.8% (9/238)
Triglycerides (≥ 200 mg/dL)	12.5% (39/312)	14.3% (7/49)	14.0% (37/264)	8.7% (17/196)	10.5% (22/209)

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

Weight Gain

Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Pooled data from short-term, placebo-controlled studies are presented in Table 3. The mean weight gain was 0.75 kg for LATUDA-treated patients compared to 0.26 kg for placebo-treated patients. In study 3 [*see Clinical Studies (14.1)*] change in weight from baseline for olanzapine was 4.15 kg. The proportion of patients with a ≥ 7% increase in body weight (at Endpoint) was 5.6% for LATUDA-treated patients versus 4.0% for placebo-treated patients.

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

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

In the uncontrolled, longer-term studies (primarily open-label extension studies), LATUDA was associated with a mean change in weight of -0.38 kg at week 24 (n=531), -0.47 kg at week 36 (n=303) and -0.71 kg at week 52 (n=244).

5.6 Hyperprolactinemia

As with other drugs that antagonize dopamine D_2 receptors, LATUDA elevates prolactin levels.

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

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

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

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

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

In the uncontrolled longer-term studies (primarily open-label extension studies), LATUDA was associated with a median change in prolactin of -1.9 ng/mL at week 24 (n=188), -5.4 ng/mL at week 36 (n=189) and -3.3 ng/mL at week 52 (n=243).

Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent in vitro, a factor of potential importance if the prescription of these drugs is considered in a patient with previously detected breast cancer. As is common with compounds which increase prolactin release, an increase in mammary gland neoplasia was observed in a LATUDA carcinogenicity study conducted in rats and mice *[see Nonclinical Toxicology]*. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans, but the available evidence is too limited to be conclusive.

5.7 Leukopenia, Neutropenia and Agranulocytosis

Leukopenia/neutropenia has been reported during treatment with antipsychotic agents. Agranulocytosis (including fatal cases) has been reported with other agents in the class.

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

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

5.8 Orthostatic Hypotension and Syncope

LATUDA may cause orthostatic hypotension, perhaps due to its α1-adrenergic receptor antagonism. The incidence of orthostatic hypotension and syncope events from short-term, placebo-controlled studies was (LATUDA incidence, placebo incidence): orthostatic hypotension [0.4% (4/1004), 0.2% (1/455)] and syncope [< 0.1% (1/1004), 0%]. Assessment of orthostatic hypotension defined by vital sign changes (≥ 20 mm Hg decrease in systolic blood pressure and ≥ 10 bpm increase in pulse from sitting to standing or supine to standing positions). In short-term clinical trials orthostatic hypotension occurred with a frequency of 0.8% with LATUDA 40 mg, 1.4% with LATUDA 80 mg and 1.7% with LATUDA 120 mg compared to 0.9% with placebo.

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

5.9 Seizures

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

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

5.10 Potential for Cognitive and Motor Impairment

LATUDA, like other antipsychotics, has the potential to impair judgment, thinking or motor skills.

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

Patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that therapy with LATUDA does not affect them adversely.

5.11 Body Temperature Regulation

Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing LATUDA for patients who will be experiencing conditions that may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration *[see Patient Counseling Information (17.9)]*.

5.12 Suicide

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

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

5.13 Dysphagia

Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia. LATUDA is not indicated for the treatment of dementia-related psychosis, and should not be used in patients at risk for aspiration pneumonia.

LATUDA® (lurasidone HCl) Tablets

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

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

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature.

Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear.

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

1. INDICATIONS AND USAGE

LATUDA is indicated for the treatment of patients with schizophrenia.

The efficacy of LATUDA in schizophrenia was established in four 6-week controlled studies of adult patients with schizophrenia *[see Clinical Studies]*.

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

4. CONTRAINDICATIONS

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

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

5. WARNINGS AND PRECAUTIONS

5.1 Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. LATUDA is not approved for the treatment of dementia-related psychosis [*see Boxed Warning*].

5.2 Cerebrovascular Adverse Reactions, Including Stroke

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

5.3 Neuroleptic Malignant Syndrome

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

Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

The diagnostic evaluation of patients with this syndrome is complicated. It is important to exclude cases where the clinical presentation includes both serious medical illness (e.g. pneumonia, systemic infection) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology.

The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for NMS.

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

5.4 Tardive Dyskinesia

Tardive Dyskinesia is a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements that can develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.

There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Given these considerations, LATUDA should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.

If signs and symptoms of tardive dyskinesia appear in a patient on LATUDA, drug discontinuation should be considered. However, some patients may require treatment with LATUDA despite the presence of the syndrome.

5.5 Metabolic Changes

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

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Because LATUDA was not marketed at the time these studies were performed, it is not known if LATUDA is associated with this increased risk.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

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

Table 1: Change in Fasting Glucose

	Placebo	LATUDA 20 mg/day	LATUDA 40 mg/day	LATUDA 80 mg/day	LATUDA 120 mg/day
Mean Change from Baseline (mg/dL)					
	n=438	**n=71**	**n=352**	**n=270**	**n=283**
Serum Glucose	-0.7	-0.6	2.5	-0.9	2.5
Proportion of Patients with Shifts to ≥ 126 mg/dL					
Serum Glucose (≥ 126 mg/dL)	8.6% (34/397)	11.7% (7/60)	14.3% (47/328)	10.0% (24/241)	10.0% (26/260)

In the uncontrolled, longer-term studies (primarily open-label extension studies), LATUDA was associated with a mean change in glucose of +1.6 mg/dL at week 24 (n=186), +0.3 mg/dL at week 36 (n=236) and +1.2 mg/dL at week 52 (n=244).

Dyslipidemia

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

LATUDA, a once-daily, oral atypical antipsychotic[1]

- The efficacy of LATUDA was established in 2 studies for each dose
- The safety and tolerability of LATUDA were evaluated in multiple studies
- The recommended starting dose is 40 mg/day taken with food (at least 350 calories) with no initial dose titration required. The maximum recommended dose is 80 mg/day
  - For patients with moderate and severe renal or hepatic impairment, the dose of LATUDA should not exceed 40 mg/day
  - When coadministered with a moderate CYP3A4 inhibitor such as diltiazem, the dose of LATUDA should not exceed 40 mg/day
  - LATUDA should not be administered with strong CYP3A4 inhibitors such as ketoconazole or strong CYP3A4 inducers such as rifampin

NEW

Latuda®

(lurasidone HCl) tablets

40mg and 80mg

INDICATION AND USAGE

LATUDA is an atypical antipsychotic agent indicated for the treatment of patients with schizophrenia. Efficacy was established in four 6-week controlled studies of adult patients with schizophrenia. The effectiveness of LATUDA for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Please see Important Safety Information below, including **Boxed Warning**, and accompanying Brief Summary.

Hyperprolactinemia: As with other drugs that antagonize dopamine D2 receptors, LATUDA elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia/neutropenia has been reported during treatment with antipsychotic agents. Agranulocytosis (including fatal cases) has been reported with other agents in the class. Patients with a preexisting low white blood cell count (WBC) or a history of drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy, and LATUDA should be discontinued at the first sign of a decline in WBC in the absence of other causative factors.

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

Seizures: LATUDA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold (e.g., Alzheimer's dementia).

Potential for Cognitive and Motor Impairment: In short-term, placebo-controlled trials, somnolence was reported in 22.3% (224/1004) of patients treated with LATUDA compared to 9.9% (45/455) of placebo patients, respectively. The frequency of somnolence increases with dose. Patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that therapy with LATUDA does not affect them adversely.

Body Temperature Regulation: Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing LATUDA for patients who will be experiencing conditions that may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.

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

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia. LATUDA is not indicated for the treatment of dementia-related psychosis, and should not be used in patients at risk for aspiration pneumonia.

DRUG INTERACTIONS

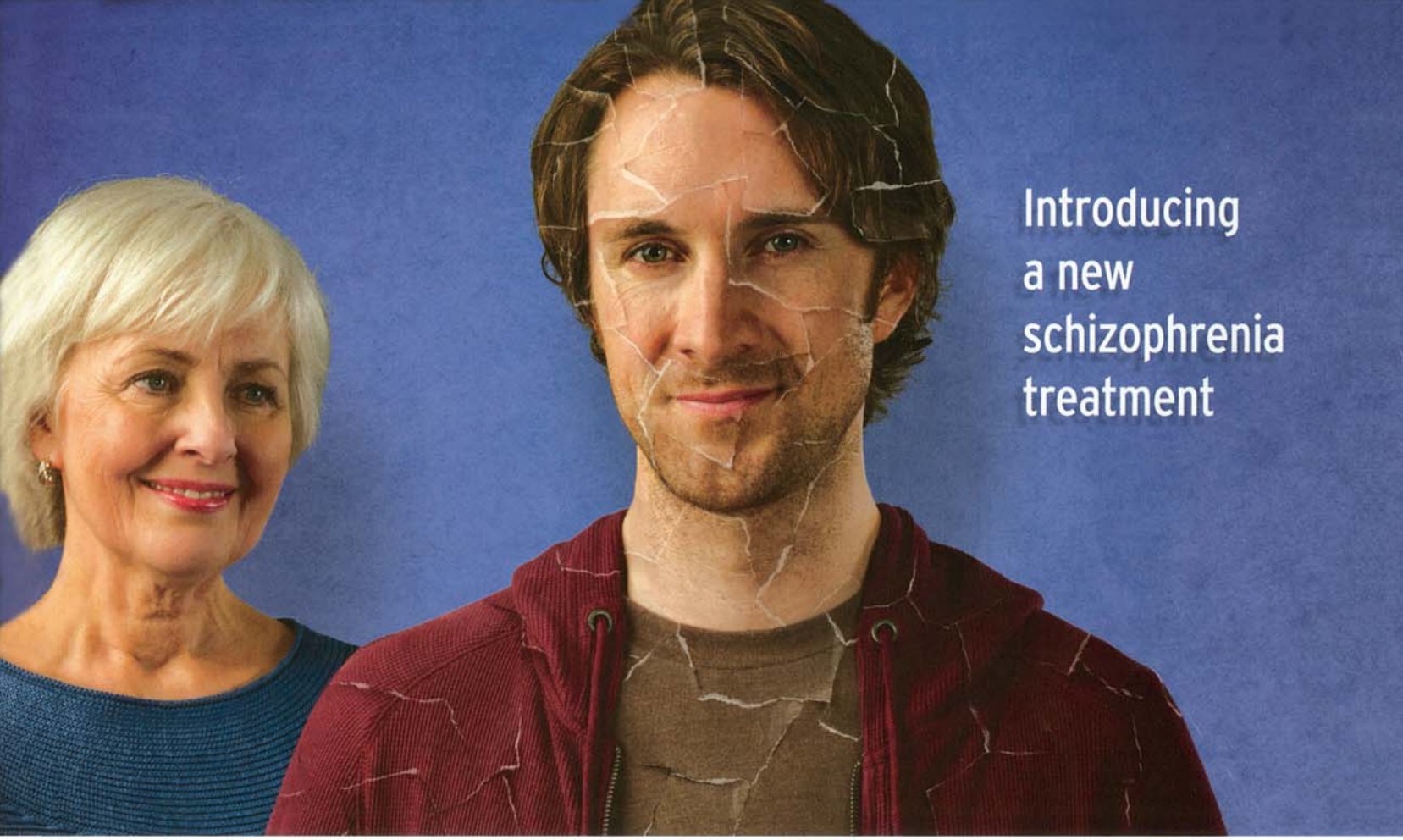
Drug Interactions: Given the primary CNS effects of LATUDA, caution should be used when it is taken in combination with other centrally acting drugs and alcohol.

ADVERSE REACTIONS

Commonly Observed Adverse Reactions (≥5% and at least twice that for placebo): The most commonly observed adverse reactions in patients treated with LATUDA in short-term clinical studies were somnolence, akathisia, nausea, parkinsonism, and agitation.

Reference: 1. LATUDA prescribing information. Sunovion Pharmaceuticals Inc. October 2010.

FOR MORE INFORMATION, PLEASE CALL 1-888-394-7377 OR VISIT **www.LatudaHCP.com**.



IMPORTANT SAFETY INFORMATION FOR LATUDA

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

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5% compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. LATUDA is not approved for the treatment of patients with dementia-related psychosis.

CONTRAINDICATIONS

LATUDA is contraindicated in any patient with a known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone. LATUDA is contraindicated with strong CYP3A4 inhibitors (e.g., ketoconazole) and strong CYP3A4 inducers (e.g., rifampin).

WARNINGS AND PRECAUTIONS

Cerebrovascular Adverse Reactions, Including Stroke: LATUDA is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported with administration of antipsychotic drugs, including LATUDA. NMS can cause hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Given these considerations, LATUDA should be prescribed in a manner that is most likely to minimize the occurrence of TD. If signs and symptoms appear in a patient on LATUDA, drug discontinuation should be considered.

Metabolic Changes

- **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

7.2 Potential for LATUDA to Affect Other Drugs

Digoxin (P-gp substrate): Coadministration of LATUDA (120 mg/day) at steady state with a single dose of digoxin (0.25 mg) increased C_{max} and $AUC_{(0-24)}$ for digoxin by approximately 9% and 13%, respectively relative to digoxin alone. Digoxin dose adjustment is not required when coadministered with LATUDA.

Midazolam (CYP3A4 substrate): Coadministration of LATUDA (120 mg/day) at steady state with a single dose of 5 mg midazolam increased midazolam C_{max} and $AUC_{(0-24)}$ by approximately 21% and 44%, respectively relative to midazolam alone. Midazolam dose adjustment is not required when coadministered with LATUDA.

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

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects

Pregnancy Category B

Lurasidone was not teratogenic in rats and rabbits. There are no adequate and well-controlled studies of LATUDA in pregnant women.

No teratogenic effects were seen in studies in which pregnant rats and rabbits were given lurasidone during the period of organogenesis at doses up to 25 and 50 mg/kg/day, respectively. These doses are 3 and 12 times, in rats and rabbits respectively, the maximum recommended human dose (MRHD) of 80 mg/day based on body surface area.

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

Non-teratogenic Effects

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

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

8.3 Labor and Delivery

The effect of LATUDA on labor and delivery in humans is unknown.

8.4 Nursing Mothers

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

8.5 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.6 Geriatric Use

Clinical studies of LATUDA in the treatment of schizophrenia did not include sufficient numbers of patients aged 65 and older to determine whether or not they respond differently from younger patients. In elderly patients with psychosis (65 to 85), lurasidone concentrations (20 mg/day) were similar to those in young subjects *[see Clinical Pharmacology]*. No dose adjustment is necessary in elderly patients.

Elderly patients with dementia-related psychosis treated with LATUDA are at an increased risk of death compared to placebo. LATUDA is not approved for the treatment of patients with dementia-related psychosis *[see Boxed Warning]*.

8.7 Renal Impairment

It is recommended that LATUDA dose should not exceed 40 mg/day in patients with moderate and severe renal impairment ($Cl_{cr} \geq 10$ mL/min to < 50 mL/min).

After administration of a single dose of 40 mg LATUDA to patients with mild, moderate and severe renal impairment, mean C_{max} increased by 40%, 92% and 54%, respectively and mean $AUC_{(0-\infty)}$ increased by 53%, 91% and 2- times, respectively compared to healthy matched subjects.

8.8 Hepatic Impairment

It is recommended that LATUDA dose should not exceed 40 mg/day in patients with moderate and severe hepatic impairment (Child-Pugh Class B and C). In a single-dose study of LATUDA 20 mg, lurasidone mean $AUC_{(0-last)}$ was 1.5-times higher in subjects with mild hepatic impairment (Child-Pugh Class A), 1.7-times higher in subjects with moderate hepatic impairment (Child-Pugh Class B) and 3-times higher in subjects with severe hepatic impairment (Child-Pugh Class C) compared to the values for healthy matched subjects. Mean C_{max} was 1.3, 1.2 and 1.3-times higher for mild, moderate and severe hepatically impaired patients respectively, compared to the values for healthy matched subjects.

8.9 Gender

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

8.10 Race

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

8.11 Smoking Status

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

10. OVERDOSAGE

10.1 Human Experience

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

10.2 Management of Overdosage

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

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

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

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

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

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Revised: October 2010
901456R01

FDA Finds Dangerous Drug In Counterfeit ED Product

Originally developed as an antidepressant, then approved as a weight-control drug, and later withdrawn from the market, the serotonin-norepinephrine reuptake inhibitor known as sibutramine keeps showing up in all the wrong places.

BY LESLIE SINCLAIR

On February 23, the Food and Drug Administration (FDA) announced that it had notified Biotab Nutraceuticals Inc. that two lots of a counterfeit product purporting to be Extenze, Biotab's over-the-counter herbal supplement marketed for "natural male enhancement," had been discovered. Not only were they counterfeit, but the lots also contained undeclared drug ingredients, including the erectile dysfunction drugs tadalafil and sildenafil (Cialis and Viagra), and sibutramine, formerly marketed as Meridia for weight control.

Although the counterfeit Extenze was not manufactured, distributed, or packaged by Biotab, it was falsely marked with the same lot numbers used by Biotab for its genuine product. So difficult was it to distinguish the counterfeit packages that Biotab voluntarily recalled the two affected lots it had manufactured, even as the FDA warned that other counterfeit formulations might still be circulating.

The discovery is cause for concern because, although tadalafil and sildenafil are approved for use, they can interact with nitrates found in some prescription drugs (such as nitroglycerin) and lower blood pressure to dangerous levels. Men with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates and also commonly experience erectile dysfunction and therefore might be enthusiastic consumers of "natural" products like Extenze. The inclusion of sibutramine in these products, however, might pose an even greater hazard.

Sibutramine had a respectable beginning. Originally eyed as an antidepressant, it was repositioned as a weight-control drug once its ability to suppress the appetite by inhibiting the reuptake of the neurotransmitters norepinephrine and serotonin was recognized. Indications that it had the ability to increase thermogenesis and decrease food intake made it that much more attractive for development. Sibutramine was given the trade name Meridia by Abbott Laboratories and approved by the FDA in November 1997 for weight loss and maintenance of weight loss in obese people, although its amphetamine-like properties led the Drug Enforcement Administration to classify it as a Schedule IV drug, capable of habit-forming results.

Severe Side Effects Soon Reported

But, like other once-promising weight-control drugs such as phentermine and orlistat, sibutramine had its downside, and it was a big one: reports of sudden death, heart failure, renal failure, and gastrointestinal problems led the FDA to question its safety. The Sibutramine Cardiovascular Outcomes Trial (SCOUT) was initiated as part of a postmarket requirement to look at the cardiovascular safety of sibutramine after its European approval. Results, published in the *European Heart Journal* in 2007, were daunting: The trial demonstrated a 16 percent increase in the risk of serious cardiac events, including nonfatal heart attack, nonfatal stroke, the need to be resuscitated once the heart stopped, and death in a group of patients given sibutramine compared with a group given placebo. Even more disappointing was the small difference in weight loss between the placebo group and the group that received sibutramine.

"Meridia's continued availability is not justified when you compare the very modest weight loss that people achieve on this drug to their risk of heart attack or stroke," said John Jenkins, M.D., director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research. "Physicians are advised to stop prescribing Meridia to their patients, and patients should stop taking this medication. Patients should talk to their health care provider about alternative weight loss and weight loss maintenance programs."

Under pressure from the FDA, Abbott Laboratories agreed to voluntarily withdraw Meridia from the U.S. market on October 8, 2010.

Subutramine Continued to Appear

The Extenze incident isn't the first time sibutramine has appeared, undeclared, in over-the-counter products. In December 2008, the FDA issued an alert to consumers naming 27 products marketed as dietary supplements for weight loss that illegally contained undisclosed amounts of sibutramine. An additional 34 sibutramine-contaminated products were recalled by the FDA on April 22, 2009.

In January 2010, the FDA warned the public about a counterfeit version of the weight-loss drug Alli being sold over the Internet, particularly at online auction sites. Authentic versions of Alli contain over-the-counter amounts of orlistat; the counterfeit versions contained high doses of sibutramine.

Despite the FDA's efforts, counterfeit and contaminated products containing sibutramine and other undeclared ingredients offered for weight loss and treatment of erectile dysfunction continue to be detected.

"These contaminants pose a risk precisely to the individuals for whom the product is advertised," said Gary Kennedy, M.D., a professor of psychiatry and behavioral science at Montefiore Medical Center, Albert Einstein College of Medicine. "Physicians should routinely ask patients about their use of supplements, especially in the context of a new prescription or when questions about side effects arise. When a patient uses an FDA-approved medication for erectile dysfunction, the risks are quantified and largely predictable. With nutraceuticals and supplements, the situation is 'buyer beware' because, as these recalls demonstrate, we don't know what is in those formulations." ■

Brain Research

conntinued from page 1

ing speaking openly about his own battles with mental illness and those of his family. Staglin, faced with his son's schizophrenia, decided to take the issue of mental illness head on, raising over $750 million for various charities, including co-founding the International Mental Health Research Organization, BringChange2Mind, and the Staglin Family Music Festival for Mental Health *(Psychiatric News*, June 3, 2005).

In an interview with *Psychiatric News*, Kennedy spoke of the power of bringing together the best scientists in government and the private sector. Working on the Appropriations Committee and the National Institutes of Health subcommittee, he often chaired or participated in hearings on research opportunities in the neurosciences and found it "a privilege to have a front-row seat with the best scientists and researchers." In working on the mental health parity act, he realized how these experts can help shape and normalize the way the public views brain disorders. "As someone who has seen and experienced mental and substance issues, I took comfort in how science could destigmatize and bring mental health into overall health."

Kennedy believes that the biggest challenge for neuroscience is getting its political science in order. The first prong of this effort is getting the best and brightest together to consolidate scientific research efforts. The second prong is to educate the public on the plight of the men and women in the U.S. military who are returning home with traumatic brain injuries and posttraumatic stress disorder.

Toward the first goal, an impressive collection of scientists and organizations have joined the effort. In addition to APA, they include the American Academy of Neurology, American Association of Neurological Surgeons, American Brain Coalition, Brain Trauma Foundation, and Mental Health America. Many more agencies have committed their support to the campaign objectives.

"A sustained national commitment to brain research could have transformative impacts on science and society," said Steven Hyman, M.D., provost of Harvard University, professor of neurobiology at Harvard Medical School, and chair of the program and planning committee for the May scientific meeting. "Based on relatively recent advances in knowledge and technology, the neuroscience field is on the cusp of revolutionary discoveries that can open new avenues for scientific understanding as well as for better human health and functioning. It is crucial that this effort begin with a thorough evaluation of opportunities for major advances, and a diverse group of leading scientists and physicians is working along with NIH scientific leaders to identify the most promising avenues for further investigation and progress."

Jeffrey Borenstein, M.D., chair of APA's Council on Communications, hosted Kennedy and Staglin on his public television "Healthy Minds" program. He told *Psychiatric News*, "I think the One Mind for Brain Research campaign is an important initiative. Research has resulted in tremendous advances in psychiatric care, and there is tremendous promise for continued progress. For this reason it is important to have efforts like Congressman Kennedy's and Garen Staglin's to raise the awareness and funds to move forward. We were proud to have Congressman Kennedy and Mr. Staglin on our show."

Paul Burke, interim executive director of the American Psychiatric Foundation, told *Psychiatric News* that when Kennedy and Staglin came to the foundation in February with ideas and plans for the conference and requested a grant, the foundation board and APA's Board of Trustees gave their enthusiastic approval.

APA Medical Director and CEO James H. Scully, M.D., told *Psychiatric News*, "The brain is the most interesting organ—and the most complicated. It's good to have a champion like Patrick Kennedy." Scully is also chair of the foundation's Board of Directors.

On the issue of building public support for brain research, both Kennedy and Staglin believe that the country has no choice but to make this a national-security issue. They believe that if the country cannot take care of and protect its soldiers, they cannot protect the American people.

"A sustained national commitment to brain research could have transformative impacts on science and society."

Kennedy said, "Brain issues are by far the most numerous injuries affecting our returning soldiers. Our heroes now need heroes of their own. The scientists doing the research that can unlock the cures to brain disorders can be those heroes."

Kennedy went on to point out that "the Next Frontier campaign will give soldiers the opportunity to be heroes all over again because the advances it may bring about will help them gain their lives back and serve as examples for others."

However, he continued, the Next Frontier campaign is not only about treating soldiers, but also about benefitting millions of other Americans as new treatments are developed and stigma is eradicated, once and for all.

The Next Frontier campaign Web site can be accessed at <www.moonshot.org/>. ■

med check

COMPILED BY LESLIE SINCLAIR

Regulatory Briefs

• In February the U.S. Food and Drug Administration (FDA) approved the selective alpha-2A agonist ***Intuniv (guanfacine) extended-release tablets*** for use as adjunctive therapy to stimulants for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17. Intuniv is the first once-daily nonstimulant to be approved for use alone or in combination with stimulants for treatment of ADHD. The approval is based on results from a nine-week, placebo-controlled study of Intuniv when given in combination with a stimulant to children and adolescents with ADHD.

The prescribing information is posted at <www.accessdata.fda.gov/drugsatfda_docs/label/2009/022037lbl.pdf>.

• In March the FDA announced that new data suggest that the drug ***Topamax (topiramate)*** and its generic versions increase the risk for the birth defects cleft lip and cleft palate in babies born to women who use the medication during pregnancy. Topiramate is approved to treat certain types of seizures in people who have epilepsy and to prevent (but not relieve) the pain of migraine headaches. Cleft lip and cleft palate, collectively called oral clefts, are birth defects that occur when parts of the lip or palate do not completely fuse together early in the first trimester of pregnancy, a time when many women do not know they are pregnant. The announcement was prompted by data collected from the North American Antiepileptic Drug Pregnancy Registry, which indicated the increased risk. Based on the data, topiramate will have a stronger warning in its prescribing information. The pregnancy category will be changed to Pregnancy Category D, meaning that there is positive evidence of human fetal risk based on human data, but the potential benefits of the drug in pregnant women may outweigh the risk in certain situations. The FDA previously designated the drug as Pregnancy Category C because of the lack of human data.

Details about the labeling change are posted at <www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm245777.htm>.

• In March the FDA convened a two-day meeting to seek the Molecular and Clinical Genetics Panel's expert opinion and input on scientific issues concerning genetic tests that make medical claims and are marketed directly to consumers. In particular the panel focused on test results that consumers can obtain without clinician involvement. Numerous molecular diagnostic tests have been developed based on genetic variations that are known or believed to contribute to a disease or that can help select appropriate treatment. The FDA's regulatory challenge is to assure that benefits of this work may be appropriately delivered to patients and consumers, while ensuring that risks are appropriately managed, said the agency in its executive summary of the meeting.

The executive summary is posted at <www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM245660.pdf>.

Research Briefs

• In February Forest Laboratories Inc. and Gedeon Richter Plc. announced preliminary top-line results from an eight-week, phase 2 clinical trial of the novel investigational antipsychotic agent ***cariprazine*** as an adjunctive therapy in treatment of major depressive disorder. Cariprazine is currently undergoing phase 3 trials for the separate and additional indications of schizophrenia and bipolar mania. The companies are considering conducting an additional phase 2 dose-response trial examining a wider range of doses.

The announcement is posted at <www.frx.com/news/PressRelease.aspx?ID=1347817>.

• Researchers evaluating the efficacy and tolerability of ***escitalopram***, a selective serotonin reuptake inhibitor, in alleviating the frequency and severity of menopausal hot flashes reported their results in the January 19 *JAMA*. The multicenter, eight-week, randomized, double-blind, placebo-controlled, parallel-group trial enrolled 205 women (95 African American, 102 white, and 8 other) from July 2009 to June 2010. Among healthy women, use of escitalopram (10-20 mg/d) compared with placebo resulted in fewer and less-severe menopausal hot flashes at the eight-week follow-up.

An abstract of the article is posted at <http://jama.aassn.org/content/305/3/267.abstract>.

• Transcept Pharmaceuticals Inc. announced in March that the first patient has been enrolled in a phase 2 clinical study to evaluate ***TO-2061***, a low-dose form of ondansetron, as an adjunctive treatment for obsessive-compulsive disorder (OCD) in patients who have responded inadequately to currently approved treatments.

Approximately 50 percent of patients do not respond adequately to standard first-line treatment with currently approved OCD medications, including the selective serotonin reuptake inhibitors and the tricyclic agent clomipramine. There is no FDA-approved augmentation therapy for these treatment-resistant patients.

More about the study is posted at <www.transcept.com/content/view/103/99/>.

• In March Euthymics Bioscience Inc. announced the initiation of an advanced clinical study of its lead product candidate ***EB-1010*** for the treatment of major depressive disorder. The TRIADE (Triple Reuptake Inhibitor Anti-Depressant Effects) trial is a phase 2b/3a clinical trial to assess the safety and efficacy of EB-1010, a novel serotonin-preferring triple reuptake inhibitor. The trial will be conducted at 25 centers throughout the United States, and the company plans to enroll about 300 subjects. Patient recruitment is under way, and top-line results are expected in mid-2012.

More information is posted at <www.euthymics.com/products.html>.

• A report in the March 9 *JAMA* by Michelle Roseman, B.A., of the Department of Psychiatry at McGill University in Montreal, and her colleagues stated that disclosure of conflicts of interest related to the funding of biomedical research disappear when study results are included in meta-analyses of trials of pharmacological treatments. Among a group of meta-analyses of pharmacological treatments published in high-impact biomedical journals, information concerning primary study funding and author conflicts of interest for the included randomized, controlled trials were only rarely reported, said the study's authors, who warned, "Without acknowledgement of conflicts of interest due to industry funding or author-industry financial ties from randomized, controlled trials included in meta-analyses, readers' understanding and appraisal of the evidence from the meta-analysis may be compromised."

An abstract of the report is posted at <http://jama.ama-assn.org/content/305/10/1008.short>. ■

book case

No Easy Escape From This Room

BY HELEN M. FARRELL, M.D.

Room
By Emma Donoghue
Little, Brown and Company
321 pages

"Jacker Jack" narrates a harrowing tale of love, anxiety, and fortitude in Emma Donaghue's novel *Room*. Through the voice of 5-year-old Jack, Donaghue creates a vivid image of a world filled with stark contrasts. Love, hate, hope, and despair characterize the emotions of Jack and his mother, not to mention the reader, as one experiences life for the two in one small room. While Jack loves his room and finds reassurance and dependency through inanimate objects such as Rug, Bed, and Room, his mother hates it. Nevertheless, she loves Jack and finds meaning in life and hope for a future through her son.

Jack joyfully describes his life as "easy peasy." Meanwhile, his mother feels trapped in the 11-by-11 space that has stifled her freedom. Still breast-feeding her son, "Ma" on the surface appears to have boundary issues, but she is actually a selfless character who struggles to meet the needs of her child in the most unusual of circumstances. Nevertheless, Ma's overwhelming desire for freedom causes a tremendous amount of separation anxiety for her son when he is separated from the objects that for years created an illusion of security and dependability for him.

Without revealing details of the book's suspenseful plot, readers should know that *Room* evokes feelings of confinement, confusion, and resentment. This is accomplished through Ma's neurotic usage of projective identification as a much-needed defense mechanism. This novel highlights the blurry lines defining closeness and autonomy. As the story unfolds, the reader is introduced to other people. Jack's belief system and knowledge of the world are turned upside down, while his mother strives to reclaim her own identity. Jack is forced to grapple with the concept of being a separate entity from his mother. Ma's own conflicts in their new world prohibit her from providing Jack with much needed mirroring and reassurance.

Both Jack and Ma will resonate with readers on multiple levels. The *New York Times* named *Room* one of the top-10 best books of 2010. Donaghue has successfully penned a tale that is rich in psychological, sociological, and political meaning. *Room* is a modern thriller filled with psychodrama that psychiatrists will thoroughly enjoy inhabiting alongside the resilient characters who learn there is more to life outside. ■

Helen M. Farrell, M.D., is a forensic psychiatry fellow at the University of Cincinnati School of Medicine.

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Being an APA fellow is an earned, honorary designation. While yearly dues rates for general members and fellows are the same, fellowship carries several benefits:

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• Fellows receive a lapel pin and an embossed certificate as a symbol of their status.

The major requirements are five years of general membership and Board certification.

A fellowship application form is posted at <www.psych.org/Resources/Membership/EnrollmentFormsApplications/FellowshipGuidelinesandNominationForm.aspx>. More information is available by calling (888) 357-7924 and asking for a Membership Department staff person. ■

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ACOs

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eficiaries. If the application is approved, the ACO must sign an agreement with CMS to participate in the Shared Savings Program for three years. An ACO will not be automatically accepted into the Shared Savings Program.

ACOs that meet the program's quality-performance standards would be eligible to receive a share of the savings they generate below a specific expenditure benchmark set by CMS for each ACO. But ACOs could also be required to repay Medicare for a portion of their expenditures that exceed the benchmark.

AMA Gives Qualified Backing

The AMA has generally endorsed the concept of ACOs but has expressed concern about the financial obstacles to joining or forming an ACO, particularly for doctors in private practice or small groups. The AMA has also expressed antitrust concerns; under existing laws governing the referral of patients to hospitals or other entities in which a physician has a financial interest, physicians cannot legally form an ACO.

At its Interim Meeting last November, the AMA House of Delegates approved a set of principles to guide the formation and function of ACOs that would have to be met to receive AMA support (see box on page 4).

"We need to have some form of antitrust relief," psychiatrist John McIntyre, M.D., a member of the AMA Council on Medical Services and an APA delegate to the AMA House of Delegates, told *Psychiatric News* after the November meeting. "Otherwise, physicians who try to bond together to form an ACO or clinical integration system will run afoul of existing laws. The Affordable Care Act addresses this subject in terms of so-called 'safe harbors' to protect physicians, and the principles approved by the house express the AMA's support for that kind of protection" (*Psychiatric News*, December 17, 2010).

In addition to the proposed rule on ACOs, CMS has issued—in conjunction with the Office of Inspector General (OIG), the Federal Trade Commission, the Antitrust Division of the Department of Justice, and the Internal Revenue Service—three documents related to the issue of antitrust:

- A joint CMS and OIG statement on waivers for ACOs participating in the Shared Savings Program with regard to the antitrust statutes.
- An IRS notice requesting comments regarding the need for guidance on participation by tax-exempt organizations in the Shared Savings Program through ACOs.
- A joint Federal Trade Commission and Department of Justice Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.

Because of the complexity and volume of the federal government's proposed rules and notices, physician organizations—including APA—were at press time still reviewing the documents. The rule comment period ends June 6, and the AMA said it intends to release its comments early so they can be used by state medical and specialty societies.

In a statement released after the publication of the proposed rule, psychiatrist Jeremy Lazarus, M.D., who is speaker of the AMA House of Delegates, said the AMA is reviewing the rule.

"ACOs offer great promise for improving care coordination and quality while reducing cost, but only if all physicians who wish to are able to lead and participate in them," Lazarus said. "For this to happen, significant barriers must be addressed, including the large capital requirements to fund an ACO and to make required changes to an individual physician's practice, existing antitrust rules, and conflicting federal policies.

"The AMA made recommendations to CMS on how to make it possible for physicians in all practice sizes and settings to successfully lead and participate in ACOs, including flexible requirements for ACO structure, transitional steps for ACO formation, increased access to loans and grants for small practices, easing of antitrust restrictions, and timely access to quality data. The AMA looks forward to working with the administration to develop physician-led new models of patient care."

The proposed rule is posted at <www.gpo.gov/fdsys/pkg/FR-2011-04-07/html/2011-7880.htm>. The joint CMS-OIG notice is posted at <www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1#special>. The proposed antitrust policy statement is posted at <www.justice.gov/atr/public/guidelines/269155.pdf>. IRS Notice 2011-20 will be posted at <www.irs.gov/pub/irs-drop/n-11-20.pdf>. ■

Violence Risk

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versity and a former APA president, told *Psychiatric News* that the study is "interesting and promising."

"But the numbers of patients who were actually violent were small, and if one focuses on the group whose violence caused injury—the group of greatest public and policy concern—there were only seven at three months and 17 at 12 months. So although the results are promising, they were based on very small numbers and really need to be confirmed with larger samples," Appelbaum said.

In addition, that some tools for evaluating violence risk have been designed for forensic populations doesn't mean that they wouldn't also be helpful for civil ones, Appelbaum pointed out. The major predictors of violence that apply to people without mental illness—for example, past violence or substance abuse—also apply to those with it, he noted, and several tools for evaluating violence risk in forensic patients have already been tested on civil outpatients and found to be about as accurate as the V-RISK-10. "So it would be really helpful to have a comparative study to explore whether this instrument does better than the others or is about the same in its level of accuracy," he said.

The study was funded by the Norwegian University of Science and Technology, Alesund Hospital, and Oslo University Hospital.

An abstract of "V-RISK-10: Validation of a Screen for Risk of Violence After Discharge From Acute Psychiatry" can be accessed at <www.sciencedirect.com/science/journal/09249338> by clicking on the March issue. The V-RISK-10 can be used and downloaded for free from <www.forensic-psychiatry.no>. ■

letters to the editor

Neuropsychoanalysis Exists

I read with great interest the front page article in the March 4 issue titled "Analysis Can Use Dose of Neuroscience, Says Kandel." I have profited from a number of wonderful workshops on various neuroscience topics that Dr. Kandel gave over the years at meetings of the American Psychoanalytic Association (APsaA).

The kind of integration between psychoanalytic understanding and the contributions of neuroscience that Kandel espouses has indeed been taking place. Weekly lectures on "neuropsychoanalysis" have been held at the Arnold Pfeffer Center of the New York Psychoanalytic Institute, under the leadership of Mark Solms, Ph.D., for a number of years. The lectures are available for viewing on the Internet. In January 2010, I chaired a session of the Workshop on Curriculum and Didactic Teaching for curriculum chairs of its constituent institutes on the topic "The Role of Neuroscience in the Psychoanalytic Curriculum." We learned, among other things, that 19 of the 30 APsaA institutes had already included such coursework in their curriculum and that other institutes were also planning to do so.

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.

Psychoanalysis was developed by a neurologist! Sigmund Freud's 1895 "Project for a Scientific Psychology" was an effort to explain human psychology in terms of central nervous system functioning. He abandoned it because he realized that the hydraulic model for the CNS's ridding itself of stimuli that he used, based on the very primitive state of neuroscience at that time, was untenable. He expressed hope that one day progress in neurological understanding would enable us to achieve the goal whose pursuit he was forced to abandon. It would appear that that day has come.

MARTIN A. SILVERMAN, M.D.
Maplewood, N.J.

Future Leaders

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chapters of the AMA, works with Savory Sunday, a mission in Madison, Wis., that provides hot meals and transportation services to those in need.

Hsiao is an assistant professor at the University of Washington School of Medicine. He serves on the Executive Committee of the Washington State Medical Association as the assistant secretary-treasurer and is a past president of the Washington State Psychiatric Association (WSPA). For his outstanding contributions to WSPA, Hsiao was honored with APA's William Sorum Award for members-in-training in 2008. He is also one of APA's delegates to the Young Physician Section of the AMA. In addition to his advocacy efforts through organized medicine, Hsiao is working closely with state and local government agencies, health service providers, and community organizations to transform prevention and treatment services for adolescents with co-occurring psychiatric and substance use disorders in Washington state. His leadership in advancing the field of adolescent addiction treatment and education has led to international recognition; he was recently named a Presidential International Consultant for National Chung Cheng University in Taiwan.

Shepherd, who is a second-year child and adolescent psychiatry fellow at Johns Hopkins, has been selected for the inaugural edition of *Who's Who in Black Baltimore: Celebrating African-American Achievements* for his dedication to launching programs that address the social ills of youth. He is trying to provide national leadership in the advocacy of quality mental health services for all children. His professional leadership activities include service as co-chair of the Community Relations Committee for the historic Monumental City Medical Society in Baltimore. His civic involvement includes community-based projects through the Office of Culture and Diversity Competence at the Johns Hopkins University School of Medicine and consultation for the Mario Do Right Foundation, a nonprofit serving the needs of children with substance-addicted parents. Shepherd is an ordained minister in the Church of God in Christ Inc., and he serves in many leadership capacities at his local church.

The AMA Foundation, a 501(c)(3) tax-exempt foundation, is the philanthropic arm of the AMA. According to the foundation, it is committed to improving the health of Americans through support of quality programs in public health and medical education. Programs include grants for free clinics and healthy-lifestyle projects, medical student scholarships, and health literacy initiatives. ■

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Army Study

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and neuroscience, chair of the Department of Psychiatry, and director of the Center for the Study of Traumatic Stress at the Uniformed Services University of the Health Sciences in Bethesda, Md.

"We're using an adaptive design meant to provide real-time information to the Army as soon as it's available in order to inform potential interventions," said Ursano in an interview.

During the study period, Army suicide rates rose significantly, from about 10 per 100,000 to more than 20 per 100,000.

"Each of these is a tragic event, especially when death occurs because of something you consider preventable," said NIMH demographer Michael Schoenbaum, Ph.D., who works on and is a spokesperson for the Army STARRS study.

Suicide was a "rare statistical outcome" no matter whether the soldier was deployed to Iraq or Afghanistan, had returned from a deployment, or had never been deployed, Schoenbaum told *Psychiatric News*. However, potential patterns have emerged from the preliminary study.

In one widely reported statistic, for instance, suicide rates among deployed women soldiers appeared to rise dramatically, from 5.1 in 2004 to 15.2 per 100,000 in 2008. However, the rate must be viewed with caution. The number of deployed women is relatively low, so that rate is based on a total of 22 women who committed suicide during that period, including eight of the 113 suicides that occurred during deployment.

Nonetheless, the rates for women were still lower than for men before, during, and after deployment, although they rose much higher while in the war zones, he said. Women represented 10 percent of deployed soldiers but accounted for 7 percent of suicides of deployed soldiers.

Asian ethnicity appeared initially to be a risk factor, too. The Army asks recruits to identify themselves as white, black, Asian, Native American, or other. So U.S. soldiers who call themselves Asian might have ancestors from China, Japan, Korea, Vietnam, India, Pakistan, or other countries—covering a wide geographic, genetic, and cultural swath. They might be born in the United States or they might be immigrants, adding another variable to their background.

While these self-identified Asians make up 3.5 percent of the Army, they accounted for 9.5 percent of the suicides, although again the absolute number was small—37 individuals in the four-year period. The disparity was evident before, during, and after deployment.

Among protective factors, researchers found that being married appeared to protect soldiers against death by any means, including accidents and combat, as well as suicide, said Schoenbaum. Married soldiers on deployment commit suicide at a rate of 15 per 100,000, compared with 24.5 per 100,000 among never-married troops.

"But we don't know why, even after we control for age, family composition, rank, and time in service," he said. "The Army doesn't treat married soldiers differently."

Combining multiple risk and protective factors may eventually permit more precise targeting of suicide prevention interventions, said Schoenbaum.

In the current analyses, the researchers looked at the statistical association between suicide death and soldiers' age, sex, marital status, race, religion, education, rank, promotions, demotions, "stop-loss" status (soldiers who are involuntarily retained beyond their contracted enlistments), and length of Army service, he said.

To examine the concentration of risk posed by numerous variables, they estimated that "predicted" annual suicide risk ranged between three and more than 400 suicides per 100,000 persons for soldiers with the lowest- and highest-risk patterns of characteristics, respectively. They calculated that the 5 percent of soldiers with the highest predicted suicide risk based on this analysis accounted for some 22 percent of the actual suicide deaths from 2004 to 2008.

This early finding suggests it may be possible to develop and apply empirical methods to identify a relatively small number of soldiers who are at particularly high suicide risk, to aid prevention and treatment efforts, said Schoenbaum.

Still under study are the effects of military specialty, unit assignment and casualty rates of units, personal weapons or vehicles owned, disciplinary problems, failed drug tests, and involvement with the criminal-justice system. In addition to suicide deaths, researchers will review nonsuicide deaths, nonfatal suicide attempts, suicidal ideation, depression, and posttraumatic stress disorder.

"We will have more refined information in less than a year," said Schoenbaum.

However, there is a limit on the value of predictive factors.

"Most people with risk factors never attempt to hurt themselves, and a minority of people who commit suicide have no risk factors," he said. "Our challenge is to help the Army focus its preventive efforts on empirically identified risk groups. Ultimately our task is to provide 'actionable' results—practical, useful information that the Army can use to help real people."

Much more work remains to be done in the study, said Ursano. The researchers will eventually draw on "massive" datasets covering thousands of soldiers.

"This is an early, cross-sectional look at single variables that leaves us with a number of potential explanations," he said. "There are limitations attached to the data released now, but there is always a challenge between science and the need for making decisions about national security."

"Army STARRS Preliminary Data Reveal Some Potential Predictive Factors for Suicide" is posted at <www.nimh.nih.gov/science-news/2011/army-starrs-preliminary-data-reveal-some-potential-predictive-factors-for-suicide.shtml>. ■

Vermont

continued from page 4

universal insurance coverage, and the evolution by 2017 of the Health Benefit Exchange into Green Mountain Care as the state's single-payer plan.

In testimony before the state legislature in March, VPA President Alice Silverman, M.D., told lawmakers that members of the association support the effort.

"Every day our members witness the suffering of their patients and devastating consequences of the lack of access to psychiatric care as a result of aggressive insurance practices that unfairly limit and deliberately create obstacles to care," Silverman testified. "They have watched as a nonprofit insurance company, Blue Cross/Blue Shield of Vermont, 'carved out' the benefits for their most vulnerable and stigmatized patients to a for-profit, out-of-state managed care company called Magellan, whose primary fiduciary responsibility is to stockholders and not patients. They have watched their patients struggle to meet high copays and deductibles and forgo needed tests and treatment. And they have watched too many of their under- and uninsured patients suffer an unexpected illness and have to declare bankruptcy. And all this has occurred while the CEO of Vermont Blue Cross/Blue Shield retired with millions of dollars, as have other executives from insurance companies all over the country.

"Our members believe that a single-payer health care system that provides comprehensive care with full parity for the treatment of psychiatric [disorders including substance abuse] is the best way to accomplish this, and we commend the legislature and Gov. Shumlin for your hard work thus far," Silverman said.

Though the effort appears to enjoy wide public support, political jockeying around the measure is intense, and even before the House approved the legislation, the phrase "single payer" was stricken from the title of the bill.

A statement from Physicians for a National Health Program (PNHP), which has long advocated for a Canadian-style single-payer health care system, argued that the Vermont legislation was not a true single-payer system because it would preserve the private insurance market alongside any universal public system that might emerge.

"We appreciate the enthusiasm for progressive health reform shown by Gov. Shumlin and the many dedicated single-payer supporters in Vermont," PNHP said in a statement in April. "However, it is important to note that the bill passed by the Vermont House falls well short of the single-payer reform needed to resolve the health care crisis in that state. . . . Indeed, as the bill moved through the House, the term 'single payer' was entirely removed, and restrictions on the role of private insurers were loosened. . . . The Vermont plan promises a public program open to all residents of the state in 2017, but even then it would allow a continuing role for private insurance. This would negate many of the administrative savings that could be attained by a true single-payer program and opens the way for the continuation of multitiered care."

Vermont's proposal was designed by Harvard economist William Hsiao, Ph.D., the principal investigator of the team who developed the Resource-Based Relative Value Scale. Hsiao was commissioned by the legislature to conduct a detailed examination of the health care system in Vermont. Hsiao was involved with development of the new single-payer health care system in Taiwan that covers everyone and includes comprehensive benefits.

Hsiao was charged with developing three options for reform. These are the three options:

- A state government-administered and publicly financed single-payer health benefits system.
- A state government-administered, public option that would allow Vermonters to choose between public and private insurance coverage.
- A public/private single-payer system, which would provide an "essential" benefits package, would be administered by an independent board with diverse representation, and would employ a competitively selected third party to manage provider relations and claims adjudication and processing.

In a lengthy and detailed January 11 report to the legislature examining the advantages and disadvantages of each proposal, including political ramifications, Hsiao concluded that the third option—the public-private system—would be optimal.

"If Vermont implements the structure contemplated under Option 3, it will set in place a policy that controls the long-range escalation of health care costs, affords every Vermont resident coverage with an essential benefits package, creates jobs by allowing employers to better plan for the costs associated with their workers' coverage, attracts new workers to Vermont with better health care and higher wages, and, finally, creates a healthier and more productive citizenry," Hsiao stated in his report.

Information about the bill, H 202, and its current status can be accessed at <www.leg.state.vt.us/>. Hsiao's report is posted at <www.leg.state.vt.us/jfo/healthcare/FINAL%20VT%20Hsiao%20Written%20Statment%20for%20Jan1911_1.pdf>. The statement by PNHP is posted at <www.pnhp.org/news/2011/april/vermont-health-bill-mislabeled-single-payer-doctors-group>. ■

Gay Teens

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atrists and mental health professionals treating adolescents to create a safe place for teens to talk about sexual orientation.

"All of us involved in care of adolescents have to provide a clinical context that is safe for young people to come out and to talk with their clinicians about sexual orientation without fear that they might be 'outed' to parents or other family members who might be involved in the clinical care of their teenagers."

"Suicidality and Depression Disparities Between Sexual Minority and Heterosexual Youth: A Meta-Analytic Review" is posted at <www.journals.elsevierhealth.com/periodicals/jah/home>. ■

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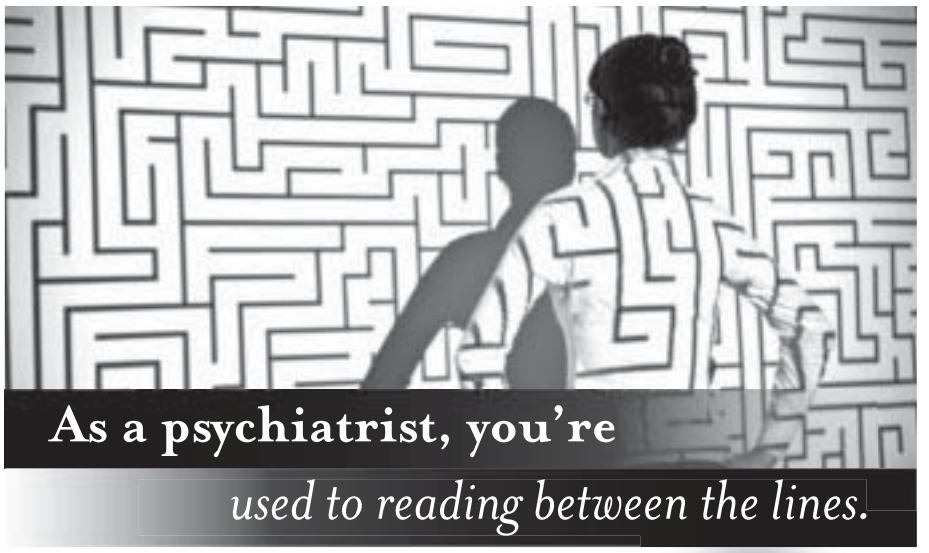

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The University of Wisconsin's Department of Psychiatry seeks an academic Child and Adolescent Psychiatrist to lead and further develop innovative training, clinical care and translational research programs. As Director of the Division of Child and Adolescent Psychiatry, you will have access to a unique set of resources supporting the early detection, treatment, and prevention of major psychiatric illnesses. Additional faculty positions are available to the Director to recruit to the Division.

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For additional information, please contact

Ned H. Kalin, M.D.
Chair and Hedberg Professor
NKALIN@WISC.EDU

Inpatient Psychiatry

HealthPartners Medical Group is a successful multispecialty physician practice in metropolitan Minneapolis/St. Paul, Minnesota and neighboring western Wisconsin. Our dynamic Behavioral Health team provides patients with top psychiatric care at Level 1 trauma center Regions Hospital in St. Paul. We encourage BC/BE psychiatrists to consider these opportunities:

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In this more traditional 5 days/week practice, you'll team with our Behavioral Health residents, therapists, social workers, NPs/PAs, nursing staff and psychiatrists to provide care to psychiatric inpatients at Regions Hospital. Shared call and rounding are part of this practice.

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Assistant Medical Director, Behavioral Health – Inpatient Care

HealthPartners Medical Group is a successful multispecialty physician practice in Minneapolis/St. Paul, Minnesota. Our Behavioral Health Division seeks a high-energy, visionary leader for our hospital-based psychiatric facilities at Regions Hospital, the largest and most innovative psychiatric resource in St. Paul and the east metro area.

This high-profile position is responsible for the design, implementation and ongoing improvement of inpatient psychiatric services within our 80-bed inpatient unit and 16-bed short stay unit; co-management of behavioral health emergency room patients; and coordination of our consult and liaison team.

In addition to maintaining substantive patient care responsibilities, this position supervises our inpatient psychiatrists, advanced practice providers and other key clinicians; participates in psychiatric resident and medical student teaching; measures quality of inpatient psychiatric care and patient flow; develops and implements inpatient mental health policies/procedures; and ensures compliance with hospital regulatory requirements.

The ideal candidate is a strong, engaging, adaptable leader who focuses on collaboration and creativity and is forward-thinking, able to effectively analyze national benchmarks and care trends regarding quality of care and patient satisfaction. The position requires board certification in Psychiatry with at least two (2) years of experience leading and motivating hospital-based inpatient psychiatric care teams, and five (5) years of recent, successful inpatient practice experience.

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Interested Candidates should send a cover letter and detailed resume via e-mail to (email preferred):

Dr. Robert Eilers, Medical Director
Division of Mental Health and Addiction Services
P.O. Box 727, 50 E. State Street
Trenton, NJ 08625
mhsresume@dhs.state.nj.us

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CONSULTATION-LIAISON PSYCHIATRIST / PSYCHO-ONCOLOGIST

University Hospitals Case Medical Center

University Hospitals Case Medical Center seeks psychiatrists to join our expanding Division of Medicine and Psychiatry. As primary affiliate of Case School of Medicine, University Hospitals provides a rich academic and educational environment, and is both nationally and internationally known for emphasis on patient care, teaching and research. Our division currently encompasses an inpatient consultation teaching service at the 1000-bed University Hospitals main campus, outpatient general psychosomatic medicine clinics, and specialty clinics in psycho-oncology, women's health, psychodermatology, transplant psychiatry, HIV/psychiatry and bariatric surgery. The department has recently integrated with the UH Neurological Institute which allows for collaboration with neurology and neurosurgery in areas such as brain tumor, stroke, movement disorders, epilepsy, neuromuscular disorders and memory disorders. Excellent consultation opportunities are on the horizon with the opening of our new flagship suburban hospital, the UH Ahuja Medical Center, as well as the new UH Seidman Cancer Hospital.

This faculty position affords the flexibility to blend inpatient and outpatient consultation practices throughout our hospital system and will be created based upon candidate's areas of expertise, experience and personal interests. We preferentially seek a candidate with interest and experience in psycho-oncology to split time between Seidman Cancer Center and other consultation-liaison roles in the division, however, those with interest in general consultation-liaison psychiatry may also apply. Academic appointment at Case School of Medicine is anticipated at a rank consistent with level of experience. Applicants should be Board eligible or Board certified. Fellowship training or Board certification in Psychosomatic Medicine is highly desirable. Salary is commensurate with qualifications. Please send your inquiries to Dr. Joseph Locala at: Joseph.Locala@uhhospitals.org or call 216-844-3883

MOODS DISORDERS PROGRAM

The Department of Psychiatry at University Hospitals Case Medical Center is expanding its Mood Disorders Program. The Program seeks Board-certified or Board-eligible academic psychiatrists to join one of the premier mood disorders programs in the country. These are full-time positions in either the tenure or non-tenure tracks. Candidates with academic and research interests and teaching experience are preferred. Academic appointment at Case Western Reserve University School of Medicine is anticipated at a rank consistent with level of experience. Candidates with academic and research interest, and teaching experience are preferred.

Responsibilities include a varied mix of research and clinical services; possibly including routine outpatient clinical care, ECT, intensive outpatient program, and/or investigational treatments as well as teaching medical students, training psychiatric residents, and supervising skilled mental health professionals. Salary is commensurate with qualifications. Please send your inquiries to Dr. Keming Gao at Keming.Gao@uhhospitals.org or call 216-844-2865

Requirements for both positions are: Qualified candidates for Instructor should hold a doctoral degree and completed at least several post-doctoral or fellowship years. Candidates for Assistant Professor should demonstrate promise for research and teaching excellence: candidates for Associate Professor should have established a significant professional reputation; candidates for Professor should be internationally recognized for leadership and scholarship in their discipline.

In employment, as in education, Case Western Reserve University is committed to Equal Opportunity and Diversity. Women and members of underrepresented minority groups are encouraged to apply. Case Western Reserve University provides reasonable accommodations to applicants with disabilities. Applicants requiring a reasonable accommodation for any part of the application and hiring process should contact the Office of Inclusion, Diversity and Equal Opportunity at 216-368-8877 to request a reasonable accommodation. Determinations as to granting reasonable accommodations for any applicant will be made on a case-by-case basis.

Academic Psychiatrist

BRIGHAM AND WOMEN'S HOSPITAL
FAULKNER HOSPITAL

Our vibrant Department of Psychiatry is seeking an academic psychiatrist for a 0.75-1.00 FTE outpatient psychiatry faculty position. The department has specialty programs in Women's Mental Health and Neuropsychiatry, provides care to a diverse population with high medical co-morbidity, and is a major teaching site for the Harvard Longwood Residency Training Program. The successful candidate will be exceptionally skilled at complex diagnostic assessment, psychopharmacologic management and focused psychotherapy, collaborative with a multidisciplinary team, inspiring to trainees, and interested in engaging with care innovation and clinical research.

Academic rank at Harvard Medical School will be commensurate with experience, training and achievements.

If interested, please send CV by 6/1/2011 to:

Arthur Barsky, MD
Vice-Chair for Psychiatric Research
Department of Psychiatry
Brigham and Women's Hospital,
75 Francis Street
Boston, MA 02115
abarsky@partners.org

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DEPARTMENT OF PSYCHIATRY
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CLINICAL DIRECTOR, BIPOLAR CLINICAL AND RESEARCH PROGRAM

The MGH Department of Psychiatry is recruiting for a Clinical Director of our Bipolar Clinical and Research Program.

Candidates should be:

- Board certified/board eligible psychiatrists or licensed Ph.D. psychologists with expertise in the care of patients with bipolar disorder.
- Dedicated to excellence in the clinical care, research, teaching and mentorship.
- Committed to clinical quality assurance and improvement and innovation.
- Qualified for an academic appointment at Harvard Medical School at the rank of Instructor or above. Previous administrative/clinical leadership experience as well as experience with clinical research is highly desirable.

Interested individuals should apply to Andrew Nierenberg MD, Director of the Bipolar Clinical and Research Program (anierenberg@partners.org). The Massachusetts General Hospital is an affirmative action/equal opportunity employer. Minorities and women are strongly urged to apply.

HARVARD MEDICAL SCHOOL

MGH 1811

CHAIR, DEPARTMENT OF PSYCHIATRY
New York, NY

The Department of Psychiatry at Lenox Hill Hospital on Manhattan's Upper East Side is pleased to announce an exciting opportunity for a chair to lead our multi-faceted department that is composed of a 28-bed adult inpatient service; child, adolescent and adult outpatient services; consultation-liaison services; and Emergency Department services. This leader will have opportunities to participate in and help shape initiatives in quality improvement, clinical research, education, and behavioral health service delivery; as well as an opportunity for academic appointment since the Department also serves as a training site for NYU medical students and psychiatry residents. Candidates must be Board Certified and have 10 years of experience that includes at least 5 years in a progressive leadership capacity.

With over 150 years of service to New York City, Lenox Hill Hospital and its Department of Psychiatry are envisioned as the Manhattan hub of an extended behavioral health network since recently becoming part of North Shore-LIJ – the nation's second-largest, non-profit, secular healthcare system. We offer a competitive salary and benefits package. For more information please contact Laura Screeney, FASPR, Office of Physician Recruitment, at **lscreeney@nshs.edu** or **(888) 685-7545**. An equal opportunity employer. M/F/D/V

North Shore LIJ Lenox Hill Hospital

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The Department of Psychiatry at Maine Medical Center is seeking to hire a Board Certified/Board Eligible adult psychiatrist for Outpatient Adult Services. MMC, located in the beautiful and historic city of Portland, is the area's major tertiary and academic medical center, with adult and child psychiatric residency training programs, comprehensive outpatient treatment programs in adult, child and geriatric psychiatry, as well as inpatient, intensive outpatient and partial hospital programs.

Physician – Adult Psychiatry

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ASSISTANT or ASSOCIATE PROFESSOR
(Medical Center Line)
PSYCHIATRY AND BEHAVIORAL SCIENCES

The Department of Psychiatry and Behavioral Sciences at Stanford University School of Medicine is seeking a full-time Assistant or Associate Professor in the Medical Center Line. This is a clinical teaching and research position. The position will be based at the Department of Psychiatry and Behavioral Sciences.

The successful candidate will provide expert compassionate clinical care, teach and supervise Stanford trainees in psychiatry, clinical psychology, as well as medical students. Excellent clinical training and related post-training work experience in an academic setting are expected. In depth understanding of eating disorders, including cognitive neuroscience, imaging, and genetic research, is desired.

Applicants must possess doctoral level training in General Psychiatry, Psychology, Child and Adolescent Psychiatry, and/or Child Psychology. In addition, candidates must be currently licensed or fully eligible for a California medical license or a California license to practice clinical psychology, as well as either board-certified or board eligible in one of the above mentioned areas by July 2011.

General criteria for the Medical Center Line (MCL) are:
"The major criteria for appointment, reappointment and promotion for faculty in the MCL shall be excellence in the overall mix of clinical care, clinical teaching, scholarly activity that advances clinical medicine, and institutional service."

Stanford University is an equal opportunity employer and is committed to increasing the diversity of its faculty. It welcomes nominations of and applications from women and members of minority groups, as well as others who would bring additional dimensions to the university's research, teaching and clinical missions. I would appreciate your forwarding this announcement to individuals whom you feel would be particularly suited for this position. Interested candidates should send a copy of their curriculum vitae, a brief letter outlining their interests and the names of three references via e-mail only to:

Stewart Agras, M.D.
c/o Jessica Yu, jsyu@stanford.edu
Department of Psychiatry
and Behavioral Sciences
Stanford University School of Medicine
401 Quarry Road
Stanford, CA 94305
Phone: (650) 723-2242 / Fax: (650) 725-5737

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We have openings in our adult and child/adolescent programs for BE/BC psychiatrists and nurse practitioners, who are interested in working with a growing, collegial group. These are employed positions which provide a full benefit package and a competitive compensation package.

Our Program Director will be available during the meeting to speak with candidates. Please call Nicole Chamberlain, 505-823-8785 to meet with our Director or get additional information.

nchamberl@phs.org, www.phs.org

PRESBYTERIAN
THE FIRST 100 YEARS

North Shore-LIJ is the nation's second-largest, non-profit, secular healthcare system that cares for people of all ages throughout Long Island, Queens, Manhattan and Staten Island, NY — a service area encompassing more than seven million people. With us, your skills will have a tremendous impact on transforming care and transforming lives. Consider joining us in the following roles:

PSYCHIATRISTS

We are seeking energetic Psychiatrists with excellent clinical and teaching skills to join our faculty and support the education of physicians-in-training at The Zucker Hillside, Long Island Jewish, North Shore University and Staten Island University Hospitals. Positions available on our inpatient, ambulatory care, consultation-liaison and geropsychiatry services. Our psychiatrists support a diverse patient population and as such, successful candidates must be clinically flexible and versatile, and be interpersonally engaging. Eligibility for an academic appointment at the new Hofstra North Shore-LIJ School of Medicine is commensurate with qualifications. A NYS license is required.

Our facilities are known for their pioneering work in diagnosis, treatment and research of mental illness. Additionally, The Zucker Hillside Hospital has been recognized by *U.S.News & World Report* as one of the nation's top psychiatric facilities.

Whatever your interests, or lifestyle, you can find it here at North Shore-LIJ — located in NYC and the surrounding suburbs — our area has something to offer for everyone. Depending on your interest, you can easily access mid-town Manhattan by train within 30 minutes to catch a Broadway show, or drive to our beautiful Long Island beaches within 20 minutes. You will also have the opportunity to work in a supportive, progressive, academic environment amongst high quality staff and colleagues. In return, we'll provide you with a competitive salary and benefits package.

For consideration, please submit your CV and letter of interest to: **John M. Kane, MD, Chairman, Department of Psychiatry at JKane2@nshs.edu or Laura Screeney, FASPR, Corporate Director of Physician Recruitment at lscreeney@nshs.edu**. Call **888-685-7545** for more information.

North Shore LIJ

www.nslij.com

North Shore-LIJ is the proud recipient of the 2010 National Quality Forum (NQF) National Quality Healthcare Award for our ongoing commitment to providing high-quality, transparent, patient-centered healthcare. We are the first and only New York metropolitan area hospital to receive such an honor. An equal opportunity employer. M/F/D/V

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For more detailed information about all locations and positions contact: Joy Lankswert, In-house Physician Recruiter @ 866-227-5415 ext: 222 or email joy.lankswert@uhsinc.com

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MedOptions offers a flexible schedule at locations close to where you live or work. Our psychiatrists are supported by a clinical team that includes nurse practitioners, clinical psychologists and licensed clinical social workers. The work shares many similarities with consultation liaison psychiatry, especially in that medical colleagues are most appreciative of our efforts.

We offer a competitive compensation package, full benefits starting at 24 hours/week and relocation assistance.

For consideration, please contact:
Marianne Wright
MedOptions
Phone: 800.370.3651, ext 1164
Email: mwright@medoptionsinc.com
Website: www.medoptionsinc.com

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PROVIDERS WANTED - Established telemedicine company is currently recruiting psychiatrists to provide online and telephonic consultations within the states in which they are licensed. For additional information, please contact Kate at 800.200.5202 or kmayes@copetoday.com.

ARIZONA

Northern Arizona, gorgeous mountain community at 7000 feet!
PSYCHIATRIST NEEDED -
HOSPITAL EMPLOYED MODEL

We are searching for a BC/BE Psychiatrist to admit and manage Adult and Adolescent Inpatients and participate in an outpatient clinic. Flagstaff Medical Center is a non-profit, 270+ bed hospital with 17 adult and 5 adolescent psychiatric beds.

FMCs Behavioral Health Unit is the only private inpatient facility in all of Northern Arizona. The acuity of the inpatient population, frequent medical considerations and proximity to numerous Native American populations presents opportunities for intellectual challenge and growth.

Primary responsibility is to attend psychiatric inpatients (adult and adolescent) along with consultation to general hospital patients. Duties also include outpatient management of discharged patients when appropriate. Will be expected to perform admission assessments including physical examination. Hospitalist co-management readily available when indicated.

Flagstaff Medical Center is located in Northern Arizona, at 7000 feet elevation in the ponderosa pines. 2 hours north of Phoenix, 23 miles north of Sedona and an hour from the Grand Canyon. The lifestyle is casual and family oriented, a university and mountain town with great recreational opportunities (Snowbowl ski resort is located in town.)

Recruitment is based on salary, bonus opportunity, benefits and relocation expenses are included.

Visit our website at www.flagstaffmedicalcenter.com and contact the physician recruiter, Maggie Lewis at 928-214-3531 or Maggie.lewis@nahealth.com.

This is not an H1-B or J-1 opportunity.
No outside recruiting firms **please.**

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Visit the Job Bank Booth at the APA Annual Meeting to find out how you can set up face-to-face interviews with candidates and/or employers in attendance.

The University of Arizona **Department of Psychiatry** is recruiting for several professional positions to join a progressive and growing academic department located in the beautiful Southwest, with over 300 days of sunshine every year! These positions will support residency and fellowship expansion and new facilities opening in 2011. Candidates must have current credentials to practice medicine in the United States and be Board-certified or Board-eligible in Psychiatry.

Assistant/Associate Professor, Psychiatry (NTE) - Inpatient/Outpatient Psychiatrist -Job #46987

Successful candidates will join our psychiatrists providing inpatient services at the brand new 62 bed behavioral health pavilion on the Kino campus. Position is affiliated with our adult residency program offering direct supervision of psychiatry residents, interns and other trainees. Other duties may include participation in committees and department services as directed by the Department Head. Opportunities may also exist for work in a new ambulatory Crisis Response Center. Salary: $185-200K+ (DOE)

Assistant/Associate Professor, Psychiatry (NTE) — Child Psychiatrist-Job #43272

We are seeking a dynamic, academically-oriented psychiatrist to join our expanding child and adolescent program! Responsibilities include providing clinical services in an academic outpatient setting, offering consultation/liaison support to the University hospitals, and contributing to the didactic and supervisory component of residency and fellowship programs. Opportunities may exist for community-based contract work. Individuals must be Board-Certified or Board-Eligible in Child & Adolescent Psychiatry. Salary: DOE

For additional information and/or to apply visit www.uacareertrack.com and reference specific title from above. If you have questions, please contact:

Jessica Bodzioch
Human Resources Representative
Dept. of Psychiatry
1501 N. Campbell Avenue,
P.O. Box 245002
Tucson, AZ 85724-5002
(520) 626-3819 or
bodzioch@email.arizona.edu.

Review of applications is ongoing until positions are filled. **The University of Arizona** is an EEO/AA Employer- M/W/D/V.

Neuropsychiatrist - Phoenix, Arizona

The Barrow Neurological Institute at St. Joseph's Hospital and Medical Center, recognized by U.S.News & World Report as one of the top 10 neuroscience programs in the country, is currently seeking a Neuropsychiatrist to join our new Center for Neuromodulation. Our neuromodulation program is already one of the busiest in the West, having performed more than 1,000 Deep Brain Stimulation (DBS) procedures in the last 10 years. With a very active clinical research program, we're exploring new indications for DBS, such as depression, bipolar disorder, Tourette syndrome, autism, anxiety, dementia and obesity. To ensure this endeavor is successful, we're looking for extensive support from a talented psychiatric professional like you.

As part of a multidisciplinary team, you will be involved with the application of neuromodulatory procedures (including DBS, rTMS, ECT and VNS) to neuropsychiatric disorders. You'll contribute to existing programs focused on the clinical and experimental use of neuromodulation through animal studies or human neuroimaging. You will also provide support with the establishment of an outpatient neuropsychiatry clinic, the recruitment of candidates for clinical trials, and the preoperative screening of candidates for neuromodulation procedures.

Qualifications include an M.D. or D.O. degree, board certification or eligibility for board certification in psychiatry, eligibility for Arizona psychiatry licensure, BNI credentials, and membership with relevant professional associations and societies. You also must be active academically and have a strong interest in expanding your clinical research base and increasing scholarly productivity. Academic faculty appointment is available at the Creighton University School of Medicine.

To apply, send your curriculum vitae along with a cover letter and the names of three references to: Jason Caplan, M.D., Chairman of Psychiatry, St. Joseph's Hospital and Medical Center, 500 W. Thomas Road, Phoenix, AZ 85013; or e-mail Jason.caplan@chw.edu.

CALIFORNIA

Outpatient Adult Psychiatrist needed for a progressive county mental health system, in the Central Valley less than two hours from San Francisco and Yosemite. Recovery-oriented treatment provided in a multidisciplinary setting. Excellent salary scale with steps starting from 179K to 217K; additional 5% differential for board certification. No call requirements at this time. Full benefit package including medical, vision/dental, vacation, sick time. Excellent retirement package with deferred comp. plan avail.

Fax CV to Uday Mukherjee, MD at 209-525-6291 or call 209-525-6119; e-mail at umukherjee@stanbhrs.org.

BE/BC Psychiatry: DMH ASH $187-$192 per hour. DMH Coalinga $190 per hour. CDCR $171-$173 an hour and $45 an hour on call. (805) 703-3729. www.intuitivehealthservices.com.; intuitivehealthservices@intuitivehealthservices.com.

San Francisco Bay Area or Sacramento: J1 and H1 applicants welcome.

Adult and child psychiatrists in out-patient or hospital practices in or near the San Francisco Bay Area or Sacramento, California. Locations meet criteria for designated shortage area. Please view our web site at CommunityPsychiatry.com or call (800) 244-5807, Fax: (916) 285-0338, Email StephaniMartinez@communitypsychiatry.com.

Atascadero & Coalinga state hospitals and CA Prisons looking for BE/BC Psychiatrists. $160-185/hr. Up to $44k/mo. 8-12hr/day. Wknds $42/on call. Alameda Co. up to 270k/yr. H1/J1 Welcome. Tel. (707)694-6890/(707)226-2426/(707)694-3805; Fax(415)814-5764. bayareadoctors@gmail.com

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California Locums positions AVAILABLE NOW!

FT or PT work available.Contract Psychiatry Remunerations Starting from:

- $187.50 + /hour - Atascadero State Hospital
- $180.00 + /hour - Coalinga State Hospital
- $150.00-165.00 /hour - CA Dept. of Corrections

Please contact ExMed Inc.
800-822-9434
connect@exmedinc.com
www.exmedinc.com

Coalinga & Napa state hospitals need full time contract psychiatrists. No call. No weekends. $180/hr + malpractice. Call 661-274-9674. Fax CV to 800-758-7013 or **e-mail decy@hahacorp.com.**

MEDICAL DIRECTOR

The San Diego County Psychiatric Hospital is a free-standing adult facility located in the heart of the County and is a key component in the County Behavioral Health Division's continuum of care. The Medical Director can play a leading role in the development of the overall County safety net health system, and is a key medical leader in the dynamic, innovative Health & Human Services Agency. Teaching opportunities available. Requires proven leadership and supervisory skills. Interest in primary care integration helpful. Salary competitive.

CV and letter of interest can be submitted online at www.sdcounty.ca.gov/hr. For questions about the application process, please contact Gloria Brown, Human Resources Analyst at (619) 531-5117 or **Gloria.Brown@sdcounty.ca.gov**. Questions about the position may be directed to Marshall Lewis, MD, Behavioral Health Clinical Director, HHSA at **Marshall.Lewis@sdcounty.ca.gov**

LICENSED CA. PSYCHIATRIST wanted for part-time PRIVATE PRACTICE POSITION. Flexible hours. Already on insurance panels a must. No inpatient work. Very little on call. AVERAGE $200 PER HOUR. Fax CV to 760-946-1215 or email desertbehavioralhlth@msn.com.

COUNTY OF SANTA CRUZ PSYCHIATRIST
Salary: $173,930 - 188,178 Annually

Santa Cruz County is seeking staff Psychiatrist to join their Mental Health and Substance Abuse Services (MHSAS) division to ensure new community resources and opportunities for recovery and resiliency in this small coastal community in Northern California. MHSAS is part of a large Health Services Agency that provides a broad range of services for mental health care. The County is known for having many innovative programs and a strong history of effective collaboration.

For job details and/or to apply, please visit www.santacruzcountyjobs.com and click on the Psychiatrist job title. For any questions and/or to learn more about this position contact Dr. Charles Lewis Johnson, M.D. by calling (831) 454-5468.

CONNECTICUT

BEAUTIFUL SUBURBAN CT
1 1/4 HRS FROM NYC

CT licensed BC/BE Psychiatrist to join a 30 year well established multi-disciplinary practice providing adult psychiatric services. Excellent Compensation. Send CV/cover letter by fax 203-797-0877 or email: afrymd@yahoo.com.

FULL TIME CHILD PSYCHIATRIST CENTRAL CONNECTICUT

The child psychiatry division of Saint Francis Hospital and Medical Center, in **Hartford Connecticut**, is seeking a full time outpatient child psychiatrist (BE/BC). The child psychiatry service works collaboratively with a large group of pediatric primary care practices in Connecticut. These outpatient positions involve psychiatric evaluation and management of children and adolescents with a variety of disorders, and are supported by skilled social workers and therapists in our outpatient division. Our psychiatric service includes 4 inpatient units, including two child and adolescent units, a large outpatient psychiatric service, and a consult-liaison service. The hospital is a teaching site for University of Connecticut Medical School and The University of Hartford.

For more information about this opportunity, please contact Christine Bourbeau in the Recruitment Office at 855.894.5590 or fax/email your CV to 860.714.8894.

Email address: CBourbea@stfranciscare.org
Visit our Website at:
www.saintfranciscare.com
EEO/AA-M/F/D/V,
Pre-employment drug testing

VA Connecticut Healthcare System is recruiting a **Staff Research Psychiatrist** in the field of addiction and dual diagnosis at the West Haven Campus. This facility is affiliated with the Yale University School of Medicine, Department of Psychiatry. The candidate will be responsible for the development of a research program in the field of dual diagnosis and addiction psychiatry. This person will also function as a staff psychiatrist, providing psychiatric care to veterans within the psychiatry service and will work with a team of psychiatrists, psychologists and other members of a multidisciplinary team at the VA Connecticut Healthcare System.. Applicants must have successfully completed psychiatric residency training in an accredited, U.S. program, be board certified (or eligible), licensed to practice in CT and legally employable. Applicants must have independent grant funding and be in a position to grow a research program.

Interested applicants send CV and 3 letters of recommendation no later than **June 6, 2011** to Ismene Petrakis, Professor of Psychiatry, Yale School of Medicine, Chief of Psychiatry and Mental Health Service Line Manager, VA Connecticut Healthcare System, 950 Campbell Avenue, West Haven, CT, 06516.

Yale University is an affirmative action, equal opportunity employer. Yale values diversity in its faculty, students and staff and especially encourages applications from women and underrepresented minority scholars.

VA Connecticut Healthcare System and Yale University School of Medicine, Department of Psychiatry is recruiting a **Staff Psychiatrist** in the field of **Mood Disorders and Geriatrics**. The candidate will be responsible for clinical work at VA CT Healthcare System: this person will function as a staff psychiatrist, providing psychiatric care to veterans within the psychiatry service and will work with a team of psychiatrists, psychologists and other members of a multidisciplinary team at the VA Connecticut Healthcare System. For academic endeavors, applicants will be expected to develop scholarly work related to clinical work or education. Applicants must have successfully completed psychiatric residency training in an accredited, U.S. program, be board certified (or eligible), licensed to practice in CT and legally employable. Preference will be given to applicants who have completed training in geriatric psychiatry and who have shown promise in academic work (teaching, presenting in meetings, articles etc) and be in a position to continue to contribute to the academic mission.

Interested applicants send CV and 3 letters of recommendation no later than **June 1, 2011** to Ismene Petrakis, Professor of Psychiatry, Yale School of Medicine, Chief of Psychiatry and Mental Health Service Line Manager, VA Connecticut Healthcare System, 950 Campbell Avenue, West Haven, CT, 06516.

Yale University is an affirmative action, equal opportunity employer. Yale values diversity in its faculty, students and staff and especially encourages applications from women and underrepresented minority scholars.

Staff and Principal Psychiatrists and Psychiatrists Per Diem

The Department of Mental Health & Addiction Services has challenging opportunities for Staff Psychiatrists, Principal Psychiatrists and Psychiatrists-Per Diem at Capitol Region Mental Health Center, Hartford, CT, Western Connecticut Mental Health Network, Waterbury, CT and Connecticut Valley Hospital, Middletown, CT. Qualified H1B Visa Candidates encouraged to apply. Application closing date: June 30, 2011. Email Audrey.Bongiorno@po.state.ct.us or call (860) 262-6740.

For more information log on to www.ct.gov/dmhas/employmentopportunities. DMHAS is an Affirmative Action/Equal Opportunity Employer. Members of protected classes and/or individuals in recovery are encouraged to apply.

Yale Department of Psychiatry, Yale-New Haven Psychiatric Hospital (YNHPH) is recruiting an inpatient attending with adolescent fellowship experience and interest in affective disorders of adolescents and young adults. The successful candidate must have extensive experience in imaging, inpatient experience and have solid evidence of teaching effectiveness and extra-mural grant support potential. Must be knowledgeable and effective in grantsmanship and research methodology and design. Must be board eligible or certified by ABPN, license eligible in CT and able to obtain credentials at YNHPH and the Yale School of Medicine. Academic appointment will be at the rank of Assistant Professor.

Please send a CV and 3 references by **June 1, 2011** to William Sledge, MD, Medical Director Yale New Haven Psychiatric Hospital, 184 Liberty Street., New Haven, CT, 06506. Direct inquiries to William.sledge@yale.edu. Yale University is an affirmative action, equal opportunity employer. Yale values diversity in its faculty, students, and staff, and especially encourages applications from women and underrepresented minority scholars.

DELAWARE

Mental Health-Psychiatrists Child/Adol (BC/BE) to provide evaluations, medication management and consult with staff in a highly regarded,private, not-for-profit child guidance clinic in **Wilmington, DE and Lewes/Seaford, DE**.

These two positions provide services to our continuum non-residential mental health services for children & families. Full-time. No weekends. Competitive package. Send cover letter and resume to: Delaware Guidance Services, HR, 1213 Delaware Ave., Wilmington, DE 19806. Fax: 302-652-8292, www.delawareguidance.org. EOE.

DISTRICT OF COLUMBIA

The Department of Psychiatry and Behavioral Sciences at The George Washington University Medical Faculty Associates, an independent non-profit clinical practice group affiliated with The George Washington University, is seeking an academic psychiatrist for a full time appointment. The position will include: 1) outpatient practice of clinical psychiatry; 2) medical student and resident education. Basic Qualifications: Applicants must be license eligible in the District of Columbia and be Board Certified or Board Eligible in General Psychiatry. Academic rank and salary will be commensurate with qualifications. Preferred Qualifications: Teaching and administrative experience in psychiatry residency education; Background in global mental health, cross-cultural psychiatry, and human rights advocacy; Masters Degree in Public Health or background in mental health policy and advocacy.

Review of applications begins June 6, 2011, and will continue until the position is filled. Application procedure: To be considered, interested applicants should send a letter of interest, curriculum vitae and three letters of recommendation (including one from the Fellowship Director, if applicable) to:

James L. Griffith, MD
Interim Chair and Professor
Department of Psychiatry and Behavioral Sciences

2150 Pennsylvania Avenue, NW
Washington, DC 20037

Only complete applications will be considered. The George Washington University Medical Faculty Associates is an Equal Opportunity/Affirmative Action Employer.

Basic Qualifications: Applicants must be license eligible in the District of Columbia. Applicants must be Board Certified or Board Eligible in General Psychiatry.
Preferred Qualifications: Teaching and administrative experience in psychiatry residency education; Background in cross-cultural psychiatry and human rights; M.P.H. degree or background in mental health policy and advocacy.

Applicants should allow the Search Committee to contact their training/fellowship director or more recent mentors for reference.

FLORIDA

PSYCHIATRISTS: Renaissance Behavioral Health Systems (RBHS), a Joint Commission accredited, comprehensive behavioral health center, is seeking Psychiatrists for its inpatient and outpatient programs in Jacksonville and Gainesville, Florida. Full-time positions with competitive salary and excellent benefits package. Must be Board Certified or Board Eligible and possess Florida medical license.

For more information, contact: Robert Sommers, Ph.D., President/CEO, RBHS, P.O. Box 19249, Jacksonville, FL 32245-9249. Phone: 904-743-1883, ext. 7103. Fax: 904-743-5109. Email: rbhspres@bellsouth.net.

SEEKING OP ADULT PSYCHIATRIST. Well established, successful practice. Will help with ins. panels. Paid P/T hospital C&L work possible. Central FL beachside loc. Low crime, excellent schools, golf, fishing & surfing. Must be FL licensed. Email CV: vmehtamd@gmail.com or fax: 321-951-1204.

Florida Licensed BE/BC Psychiatrist and advanced registered nurse practitioner (ARNP) needed for a Joint Commission Accredited community mental health center and psychiatric hospital in West Palm Beach. Excellent benefits package and location. Contact: Suresh P. Rajpara, M.D., Chief Medical Officer, Oakwood Center of the Palm Beaches, 1041 45th street, West Palm Beach, Fl 33407. Phone: (561) 383-5917; Fax: (561) 514-1504. E-mail: srajpara@oakwoodcenter.org.

PSYCHIATRIST; FULL TIME, FL LICENSE REQUIRED; Aventura, FL; private practice located equidistant between Miami and Ft. Lauderdale; children/adolescent/adult/geriatric pts; email CV to aventuraoffices@bellsouth.net or FAX to Dusty: 305-935-1717.

Psychiatrist for CSU and Detox Facility

Punta Gorda is an attractive waterfront community on Charlotte Harbor leading to the Gulf of Mexico. CBHC is the local community mental health and substance abuse provider.

CBHC is seeking a full-time FL Licensed Psychiatrist to provide psychiatric services to consumers in an 18-bed crisis stabilization unit (adults and adolescents) and a 15-bed adult detox/res facility, as well as providing some outpatient services. Work schedule is full time Monday through Friday, with some flexibility in scheduling; typically on call M-TH nights. Responsibilities include working as part of a team and documenting to an electronic medical record. Prefer exp treating co-occurring disorders; exp. in inpatient setting is also preferred. CBHC prefers that candidates be bc ~ adults and children. Competitive pay and good benefits. Must have or obtain certification to prescribe Suboxone.

For consideration, please email, mail or FAX your CV. For more information, call Dr. Matthews-Ferrari @ (941) 347-6408.

Charlotte Behavioral Health Care, Inc.
1700 Education Avenue;
Punta Gorda, FL 33950
Phone: (941) 639-8300; Fax: (941) 347-6493
Email: jvanderweele@cbhcfl.org;
www.cbhcfl.org
An Equal Opportunity Employer.

DAYTONA - MELBOURNE - ORLANDO - OCALA-
Psychiatrists needed for rapidly expanding Nursing Home Service. Great support. No call. Average Salary 210K + benefits. Part-time available. Some travel required. Must have FL Medicare & FL Medicaid individual provider #s. No Restrictions (H1B Candidates Considered). Call our Clinical Coordinator, Linda at 866-936-5250.

GEORGIA

PSYCHIATRIST to join a well-established multi-disciplinary private M/H practice in St. Marys, GA, 35 miles north of Jacksonville, FL. No start up money required. Full office & billing services provided for an immediate ft/pt caseload. We are a US Health Service Corp site with up to $170,000 in student loan forgiveness possible. For information, call Bryan P. Warren, M.D., DLFAPA at 912-882-4994. Email CV to practicemgr@tds.net.

Augusta, Georgia
Growing Department Seeks General Psychiatrists for New Academic Partnership

With expanding programs and financial stability, the Department of Psychiatry and Health Behavior at Georgia Health Sciences University (GHSU) now seeks BC/BE psychiatrists to lead the expansion of a new public psychiatry partnership with the Georgia Department of Behavioral Health and Developmental Disabilities. Position will manage medical and clinical care at East Central Regional Hospital-Augusta (located only five miles from the medical school campus), a GHSU teaching facility with a 150 bed psychiatric facility, 71 forensic beds and a developmental disabilities facility caring for 300 individuals. Position will enhance teaching throughout the department by expanding the GHSU presence and enhancing core didactic and residency practical instruction in psychiatry. Teaching components include oversight of medical and nursing students, psychiatry residents, forensic and psychotic disorders fellows, psychology interns and post-doctoral candidates. Additional educational and clinical research opportunities constitute a significant portion of the position's time. The candidate will also be expected to contribute to activities related to public policy and the regulation of psychiatry in the state of Georgia. A detailed description of the department structure, programs, research and education is provided on the departmental website. The desired candidate will have ABPN certification, be eligible for a Georgia license and possess medical management experience. The successful candidate will be appointed to the academic faculty at GHSU at a rank commensurate with experience and previous academic achievements.

Augusta, home of the Master's golf tournament and a charming Southern city, is a superb place to live! Low cost of living, close to Georgia/Carolina mountains and Georgia/Florida coast. Salary and fringe benefits package are highly competitive. GHSU is an equal employment, equal access and equal educational opportunity and affirmative action institution. It is the policy of the university to recruit, hire, train, promote and educate persons without regard to age, disability, gender, national origin, race, religion, sexual orientation or veteran status. See http://www.mcg.edu/som/psychiatry/ for more information. Contact: Stewart Shevitz, M.D., MSHA, Professor and Interim Chair, sshevitz@georgiahealth.edu (706) 721-6719.

Adult Mental Health & Forensic BE/BC Psychiatrists needed to join our large, interdisciplinary, inpatient facilities at Southwestern Regional Hospital in Thomasville, GA and Central State Regional Hospital in Milledgeville, GA. Great schedules, complete benefit package including malpractice, relocation assistance, and more! CBS News singled out Thomasville as top city with **"outstanding in climate, housing prices and entertainment opportunities."** Milledgeville has wonderful lakefront communities with plenty of water recreation and beautiful historic homes. Please email CV to ctwormley@dbhdd.ga.gov Indicate PN job to find out more!

Georgia Health Sciences University (formerly Medical College of Georgia) Augusta, GA
Growing Department Seeks New Faculty in Adult Psychiatry Program

With expanding programs and financial stability, the Department of Psychiatry and Health Behavior at Georgia Health Sciences University (GHSU) now seeks BE/BC adult psychiatrists to provide medical and clinical services in acute care areas. Positions are needed to fill clinical needs in the delivery of outpatient services, contract care with the state and local correctional facilities and to assist in the organization of emergency psychiatry services. Clinician-educator positions are available. The department, which has sustained growth and financial stability, has strong, nationally recognized training programs in general, child and adolescent, and forensic psychiatry, an internship program in health psychology, and competitively funded clinical and preclinical research. The department has inpatient adult geriatric and child units and outpatient programs of child and adolescent, schizophrenia and mood disorders, and health behavior programs. The Department of Psychiatry has a prominent role in the community, with GHSU being the only academic medical center for the region. Multiple collaborative opportunities exist. Our new public psychiatry partnership with the Georgia Department of Behavioral Health and Developmental Disabilities to manage and provide clinical care to the regional state hospital (located only five miles from the medical school campus), expands our faculty recruitment, educational and clinical research opportunities. GHSU has a strong research infrastructure including core laboratories, statistical consultation and core genetics facilities. Extensive research training program for junior faculty includes a master's program in clinical translational research and internal grant programs with generous career development awards.

Augusta, home of the Master's golf tournament and a charming Southern city, is a superb place to live! Low cost of living, close to Georgia/Carolina mountains and Georgia/Florida coast. Salary and fringe benefits are highly competitive. GHSU is an equal employment, equal access and equal educational opportunity and affirmative action institution. It is the policy of the university to recruit, hire, train, promote and educate persons without regard to age, disability, gender, national origin, race, religion, sexual orientation. Contact: Stewart Shevitz, MD, MSHA, Professor and Interim Chair, sshevitz@georgiahealth.edu; (706) 721-6719.

IDAHO

Twin Falls, Idaho
Psychiatry Opportunities

Are you currently practicing psychiatry in an unparalleled environment? Are you working with a collegial group of physicians in an area with little to no managed care and great income potential? Do you and your family have a quality of life including time and access to limitless outdoor recreation including skiing, biking, fishing, golfing, and white water rafting?

If you answered no to any of the questions above and are looking for an outstanding psychiatry opportunity, then St. Luke's Magic Valley Regional Medical Center and Canyon View Psychiatric and Addiction Services in Twin Falls, Idaho is the place for you!!

Below are a few key points about this practice opportunity that make it stand out from all other Psychiatry positions:

- Highly Competitive First Year Salary and Employment Benefits
- Future Income Potential $175K-$225K
- Little to no managed care
- 1:5 Call Schedule(with additional income potential for extra call coverage, plans to move to a 1:6 rotation)

For details on this exceptional opportunity please call:
Caryn Grossman
St. Lukes Health System Physician Recruitment
1-800-723-4852 or email drcareers@slhs.org
stlukesonline.org

ILLINOIS

SPRINGFIELD - Medical Director - Child Psychiatric Hospital. Academic affiliation & training site. Salary, benefits and bonus opportunity. Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

STAFF PSYCHIATRIST

A successful mental health group practice est. 1993, located in Chicago's north shore is seeking a staff psychiatrist to provide medication management services for patients. Referrals will come from staff psychologists and surrounding communities which includes a large network of referring physicians, hospitals, and other professionals. Our staff currently works with patients of all ages (children, adolescents, adult and geriatric). This is an excellent private practice opportunity in a congenial and energetic work environment. Hours are flexible; compensation is based on collection for services provided. Practice is supported with excellent billing, answering service, and administrative staff. Qualified individuals must be board eligible or certified and eligible for licensure in the State of Illinois.

Send c.v. or inquiries to: Physician Inquiry, P.O. Box 975, Northbrook, IL. 60065.

TEACHING FACULTY POSITIONS
UNIVERSITY OF ILLINOIS
COLLEGE OF MEDICINE AT PEORIA
METHODIST MEDICAL CENTER OF ILLINOIS

SEVERAL FULL TIME FACULTY POSITIONS AVAILABLE IN SUPPORT OF NEW PSYCHIATRY RESIDENCY TRAINING PROGRAM:

- Primary Responsibilities include education, supervision, and clinical care. Administrative, program development, & scholarship roles are also available.
- Directorship Opportunities available in the following clinical service areas: Adult Inpatient, Geriatrics, and Partial Hospitalization Program.
- Associate Program Director position is also available to persons interested in advancement to full Program Director.
- Competitive salary & benefits. Academic rank commensurate with experience.

The Methodist Medical Center of Illinois is a 329-bed teaching institution affiliated with the University of Illinois College of Medicine and provides complete support of the residency. Five state-of-the art inpatient behavioral health units, comprised of 63 patient beds, provide a positive environment and productive learning experience for residents and faculty.

The University has successfully hired several new faculty. The new positions are perfect opportunities for motivated educators interested in curriculum development, supervision of residents and medical students, and entry into academic medicine.

Please contact: Ryan Finkenbine, MD, Department of Psychiatry, University of Illinois College of Medicine at Peoria, 221 NE Glen Oak Ave., Peoria, IL 61636. Phone: 309-671-8393, Fax: 309-671-8384, e-mail: ryanf@uic.edu.

Seeking a board certified psychiatrist for the Medical Director position at **McFarland Mental Health Center, Springfield, Illinois**, a Joint Commission accredited state psychiatric inpatient hospital serving forensic and civil adults. Candidate must possess strong clinical and administrative skills and experience. Compensation is competitive with comprehensive benefit package.

Interested candidates contact Karen Schweighart, Hospital Administrator, at 217-786-6994 or E-mail: Karen..Schweighart@illinois.gov.

MENTAL HEALTH SOLUTIONS, P.C., a multidisciplinary group private practice seeks part-time board certified PSYCHIATRIST, licensed in Illinois, to work in outpatient office(s) in Barrington, IL and/or Mundelein, IL. Flexible hours. Competitive compensation. Office space, referrals, supplies, and support staff provided.

For more information call (847)566-0164 Ext. 619. Fax Resume to (847)566-0375 or email bfellowes@ilmentalhealthsolutions.com.

KANSAS

Psychiatrist for Kansas Outpatient Community Mental Health Center. No on-call. Integrated model with primary care. NHSC loan repayment eligible. Benefits package with KPERS retirement. KS licensure preferred and Board eligible. EOE. Contact Blair at 620-332-1996. See us at **www.fourcounty.com**.

LOUISIANA

FORENSIC PSYCHIATRY FELLOWSHIP DIRECTOR

The Department of Psychiatry and Behavioral Sciences at Tulane University School of Medicine is recruiting a forensic psychiatry fellowship training director for a full-time faculty position. The candidate selected for this position will assume the responsibilities for the Directorship of the fully accredited Forensic Fellowship Program. He/she will lead the forensic team responsible for supervision of residents, forensic fellows, and medical students during their rotations at Feliciana Forensic Facility and in various state mental health facilities where they will provide clinical services. He/she must be professionally competent and be board certified in general psychiatry and in forensic psychiatry. She/he must be eligible for medical licensure in the State of Louisiana and have a current state and federal narcotics number. In addition, candidates must be eligible for clinical privileges at Tulane University Hospital and Clinic under the appropriate staff category and must agree to abide by those privileges as outlined by the current bylaws of the institution. Salary will be competitive and commensurate with the level of the candidate's academic appointment. We will continue to accept applications for this position until a suitable qualified candidate is identified.

Qualified applicants should send email of interest, updated CV and list of references to John W. Thompson, Jr, MD, Professor and Vice Chair for Adult Psychiatry, Director of the Division of Forensic Neuropsychiatry at jthomps3@tulane.edu.

Tulane is strongly committed to policies of nondiscrimination and affirmative action in student admissions and in employment.

CHILD PSYCHIATRISTS

THE DEPARTMENT OF PSYCHIATRY AND BEHAVIORAL SCIENCES, TULANE UNIVERSITY SCHOOL OF MEDICINE in New Orleans, LA, is recruiting for BE/BC child psychiatrists at the instructor or assistant professor level, salary commensurate with experience. Clinical responsibilities available in the areas of consultation liaison psychiatry, community based child and adolescent psychiatry, and early childhood mental health. Teaching responsibilities include the supervision of residents, clinical psychology fellows and interns, and medical students rotating through the clinical facilities serviced by this position as well as the presentation of grand rounds and participation in the didactic series in child psychiatry. Clinical research is strongly encouraged. The persons selected must be professionally competent and be board eligible/certified in general psychiatry. She/he must be eligible for medical licensure in the State of Louisiana and have a current state and federal narcotics number. In addition, candidates must be eligible for clinical privileges at TulaneUniversity Hospital and Clinic under the appropriate staff category and must agree to abide by those privileges as outlined by the current bylaws of the institution. Applications will be accepted until a suitable qualified candidate is found.

Send CV and list of professional/academic references to Charley Zeanah, Jr, MD, Professor and Vice Chair, Child and Adolescent Psychiatry, Tulane University School of Medicine, Department of Psychiatry and Behavioral Sciences, 1440 Canal Street TB52, New Orleans, LA 70112 (czeanah@tulane.edu).

Tulane is strongly committed to policies of nondiscrimination and affirmative action in student admission and in employment.

MARYLAND

Springfield Hospital Center is seeking Board-certified or Board-eligible **general psychiatrists** for our 350-bed MHA adult inpatient facility. Salary is negotiable, within MHA guidelines. Our rural, tobacco-free campus is 22 miles west of Baltimore, convenient to the Chesapeake Bay, Washington, and a variety of cultural, historic, sports, and recreational venues. Benefits include 27 paid days off in the first year, subsidized health insurance, free parking, a generous retirement program, and a truly pleasant workplace. A Medical Services physician is always on campus to attend to patients' somatic needs. Staff psychiatrists are not expected to work after hours, but some choose to supplement their salary by providing evening and weekend/holiday coverage under contract. In addition, we offer after-hours coverage contracts to psychiatrists who are not full-time staff members. Please send CV to **Jonathan Book, M.D., Clinical Director, SHC, 6655 Sykesville Road, Sykesville, MD 21784. For questions, call (410)970-7006 or e-mail JBook@dhmh.state.md.us.** EOE

Eastern Shore Hospital Center, Cambridge, Maryland is seeking both a Clinical Director and a Board-certified psychiatrist for this 76-bed, state-of-the-art Joint Commission accredited state psychiatric facility located on Maryland's Eastern Shore. ESHC provides outstanding care to those with chronic/severe mental illness, including many who are court committed for evaluation/treatment. Live near the Chesapeake Bay where you can enjoy sailing, crabs, beaches, quaint towns, and the best of country living, all within 90 minutes of the academic and cultural resources of Baltimore and Washington, D.C. Clinical Director is responsible for the development, maintenance, and supervision of all clinical service operations, including recruitment, training, supervision, and evaluation of medical staff and clinical department heads; overseeing the process of credentialing and privileging; providing leadership in performance improvement activities; establishing policies and procedures; and ensuring that patient care is delivered in accordance with Joint Commission standards. Board-certified psychiatrist provides direct patient care on a 20-bed inpatient unit and leads a multidisciplinary team to provide patient-centered, recovery-based case. Clinical Director - minimum 3-5 years of administrative or supervisory experience. State benefits and leave package. EOE. Facility is located in designated Health Professional Shortage Area.

Please send CV to Cassandra Stanley, Personnel Administrator, Eastern Shore Hospital Center, P. O. Box 800, Cambridge, MD 21613. For questions call 410-221-2330 or e-mail cstanley@dhmh.state.md.us.

PSYCHIATRIST

BE/BC Child/Adolescent Psychiatrist/Medical Director needed 20-40 hours a week for outpatient community mental health facility on Maryland's Eastern Shore, approximately one hour fifteen minutes from the Balto-Wash. Area.

Send resume/vitae with cover letter to Michael Campbell, LCSW-C, Director, Caroline Co. Mental Health Clinc, P.O. Box 10 Denton, Md. 21629, phone 410-479-3800 ext 117, fax 410-479-0052 or e-mail mikecampbell@dhmh.state.md.us EOE.

MASSACHUSETTS

The Department of Psychiatry at the University of Massachusetts Medical School/UMass Memorial Medical Center is seeking a **BC/BE Psychiatrist** for its **University Hospital Outpatient Clinic**. Candidates should have an interest in available academic opportunities in either training or research. Academic rank commensurate with experience.

Interested applicants send CV to Alan P. Brown, M.D., Vice Chairman for Clinical Services, Department of Psychiatry, UMass Memorial Medical Center, 55 Lake Avenue North, Worcester, MA 01655 or email BrownA01@ummhc.org. AA/EOE.

Starr Psychiatric Center seeks a 20-40 hr psychiatrist for dynamic established psychiatric practice On Boston's South Shore. Medical model, multi-disciplinary staff. Stimulating environment, good pay. Clinic has a reputation for successful care, where others have failed. Email davidzstarr@juno.com or call 508.580.2211.

Academic Psychiatrist
BRIGHAM AND WOMEN'S HOSPITAL
FAULKNER HOSPITAL

Our vibrant Department of Psychiatry is seeking an academic psychiatrist for a 0.75-1.00 FTE outpatient psychiatry faculty position. The department has specialty programs in Women's Mental Health and Neuropsychiatry, provides care to a diverse population with high medical co-morbidity, and is a major teaching site for the Harvard Longwood Residency Training Program. The successful candidate will be exceptionally skilled at complex diagnostic assessment, psychopharmacologic management and focused psychotherapy, collaborative with a multidisciplinary team, inspiring to trainees, and interested in engaging with care innovation and clinical research. Academic rank at Harvard Medical School will be commensurate with experience, training and achievements.

Academic rank at Harvard Medical School will be commensurate with experience, training and achievements.

If interested, please send CV by 6/1, 2011 to: Arthur Barsky, MD, Vice-Chair for Psychiatric Research, Department of Psychiatry, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115; abarsky@partners.org.

Harvard Medical School and **Brigham and Women's Hospital** are Affirmative Action/Equal Opportunity Employers. We strongly encourage applications from women and minorities.

CAMBRIDGE: Consultation Liaison Psychiatry Position

PSYCHIATRIST: Cambridge Health Alliance is seeking a half- to full-time psychiatrist to join our Consultation-Liaison Psychiatry Service serving a multi-ethnic and diverse patient population. The position will include some inpatient work but will be focused on outpatient work and program development within Women's Health, Medical Specialty, and Primary Care Clinics. The Department of Psychiatry at Cambridge Health Alliance is an appointing department at Harvard Medical School. Our public health commitment coupled with a strong academic tradition and existing collaboration with medicine, make this an ideal opportunity for candidates interested in integrated medical and psychiatric care with underserved populations. We have strong training programs in Primary Care, Adult and Child Psychiatry, and Psychosomatic Medicine and innovative educational programs for medical students. These programs provide many opportunities for teaching and research. Academic appointment is anticipated, as determined by the criteria of Harvard Medical School.

Qualifications: BC, strong clinical skills, commitment to public sector populations, team oriented, problem solver, interested in working closely with primary care and medical specialists. Fellowship training in Psychosomatic Medicine, as well as bilingual and/or bicultural abilities, is desirable. Interest and experience with substance use disorders preferred. We offer competitive compensation and excellent benefits package.

Cambridge Health Alliance is an Equal Employment Opportunity employer, and women and minority candidates are strongly encouraged to apply. CV & letter to Susan Lewis, Department of Psychiatry, 1493 Cambridge Street, Cambridge, MA; Fax: 617-665-1204. **Email preferred:** SLewis@challiance.org.

Unique Career / Financial Opportunity

The Figman Psychiatric Group is a multidiscipline, for profit, out patient clinic in the Raynham Woods Medical Center (near Boston and Providence) with over 2,000 active patients and, on average, fifteen to twenty new referrals each week. I seek a highly qualified, energetic psychiatrist with entrepreneurial skills and a long term vision to become partner and within ten years, as I retire, owner of the practice.

Contact **Robert Figman, M.D.** at nfigman@gmail.com or 617-201-8935 to learn of a very lucrative, creative financing plan resulting in ownership. This is not an offer to sell the practice.

Boston area—Northeast Hospital Corp, a local nonprofit medical and psychiatric system on Boston's North Shore, has openings for full time and part time inpatient attending psychiatrists and night/weekend on call psychiatrists at Bay-Ridge Hospital and Beverly Hospital. The Hospitals are teaching sites for Boston University School of Medicine, and for the inpatient psychiatrist positions, there is no required night call, a competitive salary, and a full benefit package including generous time off as well as reimbursement for malpractice insurance and CME expenses. The lucrative night/weekend on-call opportunities can be scheduled to fit your needs, and both on-site and call from home options are available.

Contact Barry Ginsberg, M.D., Chief and Administrative Director, NHC Dept. of Psychiatry, 60 Granite Street, Lynn MA 01904. Phone (781) 477-6964, Fax (781) 477-6967, email bginsber@nhs-healthlink.org.

vinfen
helping to transform lives

Vinfen Corporation, headquartered in Cambridge, MA is a leading nonprofit human services organization that provides a comprehensive array of services to adolescents and adults with psychiatric, developmental and behavioral disability. With an annual operating budget of $100 million, Vinfen supports thousands of individuals in 197 programs in eastern Massachusetts and northern Connecticut. Through a variety of programs including assertive community treatment, community living, day and vocational services, club house as well as peer and family supports, Vinfen promotes the recovery, resiliency, habilitation and self determination of the people we serve.

External Relations (5-10%)
The Medical Director is responsible for representing Vinfen, broadly and clinically, to a variety of external stakeholders. In this particular capacity, the MD is focused on broad policy, regulatory or strategic issues. The position may also involve, on a limited basis, consultations on individuals needing review and/or planning for special resources or interventions. The Medical Director is tasked with both representing the interests, needs and concerns of Vinfen, as well as systematically bringing information back to inform others. The list of external organizations with whom the Medical Director interfaces is broad and includes, but is not limited to MA and CT state and federal regulatory bodies including EOHHS, DPH, DMAS and DDS, organizations within our field, and a broad range of health care entities including hospitals, health systems and insurers.

Clinical Expertise (35%)
The Medical Director will handle a case load. He/she will be expected to respond to requests of senior management and/or the DON to review and plan for services for individuals with special needs or concerns.

Supervisor (20%)
In this role, the MD will recruit, supervise and mentor the appropriate clinical staff including the newly recruited Assist Medical Director.

Strategic and Operational Planning (5%)
The Medical Director is responsible for partnering and problem solving on a growing range of topics of strategic importance to Vinfen.

Training (10%)
In his/her role with the team, the MD will continue to provide ongoing education as part of clinical rounds or case reviews. In addition, he/she will partner with the SVPs, VP of CT, DON, and the training Department to develop a series of ongoing educational materials for a variety of audiences within Vinfen.

Quality Oversight (15%)
The Medical Director will provide broad oversight to all requisite clinical activities, including leading any clinical reviews required by the State or as determined by him/her or others within Vinfen, including client deaths.

Research (5%)
The Medical Director will participate in the development of innovative approaches to assessment and interventions for populations served by Vinfen.

If interested, please apply online at https://www2.apply2jobs.com/vinfen/ProfExt/index.cfm?fuseaction=mExternal.showJob&RID=1915&CurrentPage=1.

Exceptional Professional Opportunity for psychiatrist to provide high quality care as part of a well respected multidisciplinary private group practice loacted 2 hours north of NYC in Columbia County/Hudson Valley, NY and **neighboring Berkshire County, MA**. Inpt/outpt. Flexible hours.

Excellent salary packages $200,000 + (with opportunity for additional income). **Call Dennis Marcus, M.D.** at (413)528-1845, fax CV to (413)528-3667 or email to scppcmd@yahoo.com.

Women's Mental Health Psychiatrist

Brigham and Women's/Faulkner Hospitals (BW/F) Department of Psychiatry is seeking a psychiatrist to provide clinical care and teaching within our outpatient Women's Mental Health service. Research experience is desirable; research opportunities are available. BW/F is an international leader in women's health. Academic rank at Harvard Medical School will be commensurate with experience, training and achievements. If interested, please send CV to Laura Miller MD, Vice-Chair for Academic Clinical Services, Department of Psychiatry, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115; lmiller23@partners.org.

Harvard Medical School and Brigham and Women's Hospital are Affirmative Action/Equal Opportunity Employers. We strongly encourage applications from women and minorities.

Psychiatrist, Concord, Massachusetts

Full-time psychiatry salaried position for growing general hospital department of Psychiatry. Position includes inpatient responsibility for patients on our 31-bed inpatient unit, consultation and liaison services to the medical units, and shared on-call responsibilities as a member of the department of Psychiatry. Emerson Hospital is a recognized provider of high quality mental health and substance abuse services. We provide a stimulating and collegial atmosphere for the career-minded psychiatrist. Competitive salary and benefit package. Additional compensation available for added call responsibilities. The Concord area is an excellent environment to develop a vibrant supplemental private practice. Please contact Robert Stern, MD, chair, department of Psychiatry, 978-287-3512 or by email at rstern@emersonhosp.org. Geriatric expertise and ECT experience a plus.

Weekend coverage - Also seeking moonlighters to cover the inpatient service one weekend per month. Includes rounding on all inpatients and phone coverage from home. Please contact Robert Stern, MD, chair, department of Psychiatry, 978-287-3512 or by email at rstern@emersonhosp.org.

MICHIGAN

Live and Work in an Amazing Vacation Destination

20K sign-on, and Relocation Assistance. Mostly Outpatient. You choose all adult or a combination of Adult/Child/Adolescent. See 7-8 patients per day. Enjoy this gorgeous harbor town right on Lake Michigan.

Contact: Courtney Tripp - ASA Partners
Courtney@asapartners.net
800-473-5460 Ext 112.

J1 and H1 Opportunities near Ann Arbor, Michigan

Adult and child psychiatrists in out-patient or hospital practices, near Ann Arbor, Michigan. Locations meet criteria for designated shortage area. Please view our web site at Community-Psychiatry.com or call (800) 244-5807, Fax: (916) 285-0338, Email StephaniMartinez@communitypsychiatry.com.

Hiawatha Behavioral Health is seeking a **Psychiatrist/Medical Director** to provide direct psychiatric services to adults, psychiatric assessments, and medication management as part of a multi-disciplinary team; assuring that all clients receive appropriate evaluation, diagnosis, treatment, medical screening, and psychiatric evaluation whenever indicated; and that clinical staff receives appropriate clinical supervision. Position may be full or part-time (negotiable with the successful applicant).

Hiawatha Behavioral Health is a progressive, nationally accredited Agency that provides a comprehensive array of services to persons with serious mental illness, developmental disabilities, and children with severe emotional disturbances in a rural setting. The Agency values opportunities to contribute to the growing body of knowledge of most effective treatments and supports toward recovery for individuals challenged by serious and persistent mental illness.

Applicants should be a **Board Certified/Board Eligible adult Psychiatrist**; and have, or the ability to obtain, State of Michigan licensure.

Hiawatha Behavioral Health is a Community Mental Health Agency that covers Chippewa, Mackinac, and Schoolcraft Counties in the picturesque Upper Peninsula of Michigan. The Upper Peninsula is a wonderful place to live and work, with great schools, family friendly communities, year-round recreational opportunities and natural beauty.

Send letter of interest and resume to: Hiawatha Behavioral Health, Human Resources Manager, 3865 S. Mackinac Trail, Sault Ste. Marie, fax to 906-635-3760, or e-mail: kjuda@hbhcmh.org. Applications will be accepted until position is filled. E.O.E.

MINNESOTA

Community-University Health Care Center, UMN is seeking two Psychiatrists (one full-time and one part-time) to provide psychiatric evaluation and follow-up to clinic patients, provide clinical consultation to Advanced Practice Registered Nurses, and participate in quality assurance activities.

For further information or to apply:
Full-time position (#171565):
employment.umn.edu/applicants/Central?quickFind=94377
Part-time position (#171566):
employment.umn.edu/applicants/Central?quickFind=94378

MISSISSIPPI

Horizon Health seeks **Psychiatrists** for weekend call coverage for Adult and Geriatric inpatient psychiatric programs in **Batesville, MS.** For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

MERIDIAN: Addiction Services Director - Inpatient and Outpatient Services. Top range salary, benefits and bonus opportunity. Private treatment facility. Great leadership opportunity. Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com

MISSOURI

Psychiatrists needed in **Charleston & Bowling Green, MO** with MHM Services, Inc. A leader in Correctional Mental Health, we offer highly competitive, guaranteed salaries, paid malpractice insurance, and an excellent benefits package. Utilize your skills in a unique, challenging practice opportunity where you can make a difference. To apply or inquiry, contact **Mark Hyde: 877-861-7993** or email CV to: **mark@mhmcareers.com**.

NEBRASKA

Part-time MEDICAL DIRECTOR

Excellent opportunity, Medical Director for our Managed Care Organization. The physician in this MD position will have opportunity for creative clinical thinking and decision making, and along with a team of clinical and medical leaders, will have oversight of UM and QI programs. This position provides a key interface between the MCO and the providers, members and MCO customers. It provides the opportunity to develop clinical programs based on evidence based practices and to monitor clinical outcomes in service delivery across the membership. This position uses excellent clinical skills in an innovative way.

Position requires Nebraska licensure and ABPN Board Certification in Psychiatry. Excellent base salary, paid benefits, and flexible hours within normal business hours.

Please apply to our Recruiter Terri Holub, Phone 916-859-5162 or e-mail tmholub@magellanhealth.com; www.magellanhealth.com.

NEVADA

Horizon Health, in partnership with **Northeastern Nevada Regional Hospital in Elko, NV**, has an exciting opportunity for a **Medical Director** for a **16-bed** Geriatric Inpatient Psychiatric Program. Excellent income and quality of life! State-of-the-Art facilities, and complete program support with full complement of staffing to include: Nursing, Social Work, Therapy, and Marketing. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

NEW JERSEY

Attending Psychiatrist

Bergen Regional Medical Center, in **Paramus, NJ**, one of the largest psychiatric resources providing a continuum of behavioral health care in the community, has an exceptional opportunity for an Attending Psychiatrist.

The incumbent will deliver psychiatric care including evaluations, treatment, family meetings and discharge planning as part of a multidisciplinary team, provide consults on in- and outpatients medical units, and participate in resident training and supervision. Weekday and night on-call required; weekend coverage optional.

Requirements: MD or DO, completed Psychiatric residency, NJ licensure in Psychiatry, DEA and CDS. Board certification preferred.

Please submit your CV for confidential consideration to:
apply@bergenregional.com
or fax to: (201) 967-4109.
EOE

PSYCHIATRIST- Elizabeth - Part-time Positions in our Psychiatric Emergency Service, and Adult and Child Psych Services. Sought by the largest and most comprehensive behavioral health and psychiatric service in a general hospital in New Jersey (JCAHO accredited) Board Certified and Bi-lingual preferred. Urban hospital setting.

Contact Jim Lape, Senior Vice President of Psychiatry, Trinitas Regional Medical Center, 655 E. Jersey St., Elizabeth, N.J. 07206. Interested parties can E-Mail their resume to Mr. Lape @ Jlape@Trinitas.org and/or fax your resume to (908)994-7457.

OPPORTUNITY to start private practice @ no cost, Summit NJ. Office with a great view in a prestigious medical center adjacent to Overlook Hospital. Psychiatrist in pre retirement phase needs easy transition for patients. TURN KEY. 908/522-3099, tedshah@gmail.com.

NEW MEXICO

LAS CRUCES: Medical Director -Private behavioral health hospital with I/P, RTC and O/P services. Highly competitive salary, benefits and bonus opportunity package. Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

NEW YORK CITY & AREA

BC/BE Psychiatrists to provide Consultation services in Long Term Care Facilities (NH, SNF). Locations: Manhattan and NYC Metro Area. PT/FT Well above average salaries/benefits, flexible hours. Recent graduates encouraged to apply.

Please email CV to
mdassistant@neuropsychllp.com
or via Fax: 718-239-0032Tel: 718-239-0030.

PSYCHIATRISTS

The City of New York Human Resources Administration's Customized Assistance Services is recruiting Psychiatrists for a unique program providing home-based psychiatric evaluation and crisis-intervention services. In this role, you will utilize a team approach to provide consultative evaluations throughout the City's five boroughs. This will often involve working on geriatric, emergency, and consult/liaison issues.

Psychiatrists must have completed an approved residency training program in Psychiatry, be Board Eligible/Certified and possess a valid license to practice medicine in the State of New York.

This position offers regular hours, competitive pay, a collegial atmosphere, a minimum of paperwork, no managed care, and optional on-call duties for additional pay. Fringe benefits include health insurance, 401K, 457, defined benefit pension plans, and paid vacations and sick leave. Physician Loan Forgiveness programs may be available to eligible candidates.

Interested individuals should submit their curriculum vitae and a copy of their New York State Registration(s) to:

Johnny Bon, Director of Personnel Services
NYC Human Resources Administration
Customized Assistance Services
2 Washington Street - 17th Floor
New York, New York 10004
E-mail: bonj@hra.nyc.gov
Fax: (212) 495-2931

ALBERT EINSTEIN COLLEGE OF MEDICINE
Of Yeshiva University
Department of Psychiatry and Behavioral Sciences

The Sound View Throgs Neck Community Mental Health Center

PSYCHIATRISTS - Two Full-Time - Adult Outpatient Program. This Program seeks psychiatrists experienced in diagnostic evaluation and psychopharmacology to provide clinical care, supervise a team and teach medical students, psychiatry residents and clinical fellows. New York State License, Board Certified/Board Eligible in Psychiatry. DEA Registration. These positions carry a faculty appointment. Knowledge of Spanish a plus.

In return for your expertise, we offer a competitive salary, outstanding benefits package and a professional work environment offering career growth potential.

For consideration, please submit your CV with salary history to: Thomas F. Betzler, M.D., Executive Director, Sound View Throgs Neck Community Mental Health Center, 2527 Glebe Avenue, Room 304, Bronx, NY 10461; Fax: (718) 931-7307; Email: thomas.betzler@einstein.yu.edu. Equal Opportunity Employer.

PHS

Work for the national leader in correctional healthcare services.
PRISON HEALTH SERVICES...

The largest correctional healthcare provider in the U.S. provides healthcare services for inmates at **Rikers Island in Queens, NY.**

Correctional medicine offers work independence, diversity of duties, continuity of care and an opportunity to provide care to the underserved and in need of help.

Make a Difference...
- Looking for new challenges?
- Want to make a real difference?
- Have questions about this unique environment?

PSYCHIATRISTS
FULL TIME/PART TIME/PER DIEM.
FLEXIBLE SHIFTS

Prison Health Services Medical P.C. invites you to join its substantial, comprehensive, multidisciplined M.H. team at Riker's Island.

Tours: 8am-4pm; 4pm-12am; 12am-8am with some flexibility. Salaries and benefits are competitive.

For more info please contact: David Rosenberg MD, Supervising Psychiatrist, Tel: 646 717 4061, or email us your resume: PHSNYC@riepf.com.

PRISON HEALTH
MEDICAL SERVICES, PC
49-04 19th Ave., Astoria, NY 11105
PHS is an Equal Opportunity Employer
M/F/D/V

Exceptional Career Opportunity!
Long Island College Hospital
Department of Psychiatry
97 Amity Street, Brooklyn, NY. 11201

Long Island College Hospital, a 500 bed general hospital located in Brooklyn Heights, seeks BC/BE psychiatrists for the following:

- Moonlighting Positions Available: Weekdays, Nights, and Weekends!

We seek highly motivated and committed physicians; and offer a competitive salary/benefits package. Please email your resume to: cluther@chpnet.org, or fax to: (718) 780-1827; Attn: Charles Luther, M.D.

We are committed to diversity and equal opportunity.

Child and Adolescent Psychiatrist
P/T - 10-15 hours per week (evenings and/or weekends) in a Child and Family Mental Health Center in Brooklyn. Excellent compensation. No call. Fax resume to (718) 553-6769, or email to clinicaldirector@nypcc.org

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PSYCHIATRIST-OUTPATIENT

The highly regarded **Pederson-Krag Center** offers a position of Staff Psychiatrist in our **Smithtown Clinic** 20 HRS seeing patients in our Mental Health and Addiction Recovery Programs.

Flexible schedule. Excellent benefits. Mail CV to Roger Kallhovd, M.D., Pederson-Krag Center. 55 Horizon Drive, Huntington, NY 11743, or fax 631-920-8165 EOE/AA.

NEW YORK STATE

PSYCHIATRIST OPENINGS at **CENTRAL NEW YORK PSYCHIATRIC CENTER**, a State-operated, forensic, JCAHO Accredited Facility, is seeking full time Psychiatrists for our Inpatient Facility in Marcy, NY, and for our Correction-based programs in various locations throughout the state.
- Board Certified: $181,790
- Licensed: $168,421.
- Limited Permit: $111,611-$124-227

NY State provides a generous and comprehensive benefits package including an outstanding Pension Plan; opportunities may exist for additional compensation and for NHSC Loan Forgiveness.

Contact: Dr. Jonathan Kaplan, Clinical Director (Code 312)
Call at: 845-483-3443, Fax: 845-483-3455.
E-mail: Jonathan.Kaplan@omh.ny.gov.

ST. JOSEPH'S Hospital Health Center

Loan Forgiveness is NOW Available at St. Joseph's Hospital Health Center in Syracuse, NY

The Comprehensive Psychiatric Emergency Program (CPEP) is seeking a **BE/BC Psychiatrist** to work in a busy state of the art ER setting. CPEP is a licensed Psychiatric ER open 24/7 - www.sjhsyr.org.

The Position
- Competitive base salary & generous benefits package (Employed by the Hospital).
- 1 - 2 MD per 8 hour shift (8-4, 4-12, 12-8) with 24/7 Clinical team.
- 7200 patient presentations per year.
- 17-18 new presentations per 24 hour period.
- 80% adult patients, 20% under the age of 18.
- Departmental call (no CPEP call) is approximately 1:13 eve/night, 1:8 weekends.

The Location-Syracuse, NY
- Voted #1 by CNNMoney.com as the most affordable housing market in U.S. major metropolitan areas.
- Voted #4 by Forbes Magazine as "Americas Best Places to Raise a Family".
- No traffic jams.
- In addition there are various recreation opportunities including sporting lakes, as well as museums, historical sites, and cultural attractions including a symphony, museum, zoo and other attractions.
- Located in the heart of NYS, close to the Adirondacks, the Finger Lakes, Ontario, Canada, and unparalleled opportunities for those interested in outdoor life.
- For those who crave a visit to a large city, the hospital is 4 1/2 hours from New York City, 5 hours from Boston, and 6 hours from Washington, D.C.

Forward your CV and Cover Letter to john.cerniglia@sjhsyr.org or call 315-396-4364 for more information.

Practice In the Perfect Place:
Saratoga Springs, NY

Saratoga Hospital seeks BE/BC, NYS-licensed psychiatrists for a full time inpatient position. This is an opportunity to work with a close-knit, experienced, multi-disciplinary care team on a 16-bed adult inpatient unit and with emergency department and hospital staff for consultation liaison service. Participate in reasonable hospital inpatient call schedule, 1:6, with plans to expand call pool. The compensation and benefit package is competitive.

Our Location is a destination, just a half hour from Albany, three hours from New York City, Montreal and Boston. Saratoga Springs is a family-oriented community known for its restaurants and local shops, neighborhoods, and excellent schools. World-class entertainment, culture, and recreational opportunities are abundant in and around Saratoga Springs!

Contact: Denise Romand, Saratoga Hospital (518) 583-8465, email: docfind@saratogacare.org. Visit us at www.saratogahospital.org or our community at www.saratoga.org.

Exceptional Professional Opportunity for psychiatrist to provide high quality care as part of a well respected multidisciplinary private group practice loacted 2 hours north of NYC in Columbia County/Hudson Valley, NY and **neighboring Berkshire County, MA**. Inpt/outpt. Flexible hours.

Excellent salary packages $200,000 + (with opportunity for additional income). **Call Dennis Marcus, M.D.** at (413)528-1845, fax CV to (413)528-3667 or email to scppcmd@yahoo.com.

St. Lawrence Psychiatric Center, a fully accredited NYS Office of Mental Health facility, is seeking Licensed Psychiatrists for our Children and Youth, Forensics and Adult services. In addition to salary ($168,421 to $174,798) and guaranteed additional compensation for voluntary participation in an on-call program, benefits package includes medical/dental/vision insurance, paid vacation, holiday and sick time, an excellent retirement plan, and educational and professional leaves. SLPC is an EO/AAE, federally designated as MHPSA.

Located on the scenic St. Lawrence Seaway in northern New York, St. Lawrence Psychiatric Center is located within reasonable driving distance of many cultural, educational and economic opportunities, including metropolitan Ottawa and Montreal, Canada and Syracuse, NY. Close proximity to the Adirondack Mountains, including Lake Placid, offers easy access to a wide variety of unspoiled natural areas and provides abundant recreational opportunities throughout the year.

Submit letter of interest to: Rosella Turnbull, St. Lawrence Psychiatric Center, One Chimney Point Drive, Ogdensburg, NY 13669 or at Rosella.Turnbull@omh.ny.gov. If you have questions, please call (315) 541-2189.

Western New York-Chautauqua Region: Jamestown Psychiatric PC is seeking a Psychiatrist to join our rapidly growing Adult and Child Psychiatric team. Competitive salary and flexible growth opportunities are offered. We will offer a starting bonus to eligible candidates. Loan repayment, J1 or H1 assistance available. Please contact Mrs. Linda Jones, office manager @ lj@psychwebmd.com or Phone 716-483-2603. Fax CV and qualifications to 716-483-2828.

NORTH CAROLINA

CARF accredited, fast growing, private psychiatric practice is seeking a psychiatrist to join six other psychiatrists, five nurse practitioners, one physician assistant, five doctorate level psychologists, and sixteen master level therapists. Candidate must be a MD or equivalent and have North Carolina Medical License; completed residency in an accredited psychiatry program and be Board eligible or (maintained) Board certified with the American Board of Neurology and Psychiatry. All psychiatry specialists or subspecialists are welcome - adult, child or adolescent. J-1 / H1 Visa applicants are welcome. Outpatient, in-patient, and combination of both are available. Psychiatrists will also provide consults; on-call and some weekend duty may be required.

Our Coastal Community:

- Close to the beach
- Growing Population of 154,579
- 30 Miles of Wide, Unspoiled Beaches on Atlantic Ocean
- Coastal Activities Offer Unique Shopping and Family Entertainment
- Ranked 24th Out of 301 Surveyed Metropolitan Areas as **"Best Place to Raise a Family"** According to Reader's Digest
- 6 Private Schools Available and Excellent Public Schools

Benefits:
- Competitive salary; range of $200K to $350K annually
- Excellent benefit package, including professional liability insurance.

Send CV's to blind.ad.nc@gmail.com.

Live and work near beautiful Lake Gaston, NC!

Employment opportunity with partnership potential. Adult, primarily outpatient. Admit to 20-bed behavioral health unit at **Halifax Regional**.

- **Paid vacation / CME**
- **Relocation package**
- **401(K)**
- **Competitive Salary**

Location: I-95 corridor, northeastern NC. 2.5 hours to Outer Banks, centrally located 1.5 hours from Raleigh-Durham, NC, Richmond, VA, and Norfolk, Va. Outstanding water recreation. Area population: 85K.

Send letter and CV to Pam Ballew
pballew@halifaxrmc.org
252-535-8795
www.halifaxregional.org
www.visithalifax.com

Adult Staff Psychiatrists

Charlotte, NC

Carolinas HealthCare System has unique opportunities for Adult Staff Psychiatrists at its Behavioral Health Center. The center is part of a 874- bed regional teaching facility nestled in the heart of Charlotte. Join an outstanding team of psychiatrists in a very collegial working environment.

Adult Staff Positions - Inpatient and outpatient work.

Excellent benefits package which includes:
- **Two weeks CME**
- **Paid vacation**
- **Short and long-term disability**
- **401K, 457B and pension plan**

Opportunity for extra income by seeing private patients or by taking shifts in the ER
Interested applicants should email their CV to Elaine Haskell at: elaine.haskell@carolinashealthcare.org for more information.

EOE/AA

NORTH DAKOTA

North Dakota - Sanford Health Fargo Region is expanding its Child/Adolescent Behavioral Health Services and currently seeking a **Child/Adolescent Psychiatrist** interested in a rewarding practice as well as department chair leadership. The department is staffed with three child psychiatrists, four child psychologists, one child and adolescent trained psychology resident and one master level therapist. Located in Fargo, ND, this outpatient practice includes opportunity for practice in both the behavioral health clinic and in a collaborative model with Sanford pediatricians at two clinic locations. Sanford psychiatrists also have the opportunity to teach University of North Dakota psychiatry residents. To learn more about Sanford Health Fargo visit: **www.sanfordhealth.org**.

Fargo, ND is a metropolitan, tri-college community of 190,000 where high quality elementary and secondary education is a priority. Close proximity to Minnesota lake country offers access to a multitude of four season outdoor activities. To learn more about the Fargo community visit: www.culturepulse.org and www.fmchamber.com.

Contact:
Jean Keller, Physician Recruiter
Sanford Physician Placement
Phone: 701-280-4853, Fax: 701-280-4136
Email: Jean.Keller@sanfordhealth.org.
EOE/AA Not subject to H1 Caps

OHIO

CLEVELAND: Child Psychiatrist - Inpatient Services. Salary, benefits, bonus opportunity. Phone call only 1:5. Establised programs and collegial staff. Contact Joy Lankswert, In-house recruiter @ 866-227-5415; OR email joy.lankswert@uhsinc.com.

Addiction Psychiatrist

The Department of Psychiatry at The MetroHealth System, a major teaching hospital of Case Western Reserve University, is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) addiction psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a top1% ranked hospital. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

Child and Adolescent Psychiatrist

The Department of Psychiatry at The MetroHealth System, a major teaching hospital of Case Western Reserve University, is expanding under the leadership of the new Chair, Ewald Horwath, M.D. We are currently seeking a board-certified (or board eligible) child and adolescent psychiatrist, who will provide clinical care, teaching of residents and students and have the opportunity for academic and career development at the largest medical research institution in Ohio and a top1% ranked hospital. Benefits include a competitive salary, incentive potential, health insurance, paid time off, liability insurance, an academic appointment and CME opportunities.

In employment, as in education, MetroHealth System and Case Western Reserve University are committed to Equal Opportunity and World Class Diversity. Please send CV and a letter outlining clinical and academic interests to ehorwath@metrohealth.org.

OKLAHOMA

Psychiatrist (BE) or (BC)
Announcement #2011-09
DMHSAS/Oklahoma Forensic Center (OFC)-Vinita, OK
Salary Range: $184,000-$215,500

Minimum Qualifications: Must be licensed to practice medicine by the State of Oklahoma and be Board Eligible or Board Certified.
Benefits include: Insurance, Retirement, Vacation, Holiday & Sick Leave. Must be able to pass drug screen and OSBI background check. Reasonable accommodations to individuals with disabilities may be provided upon request. To apply contact Human Resources at 918-713-5549. OFC is an EOE.

OREGON

Chief Medical Officer (CMO)
Oregon State Hospital (OSH)
Salem, Oregon

Oregon State Hospital is looking for a BC psychiatrist to assume the role of its CMO. This position is responsible for the administrative oversight of the Oregon State Hospital medical staff, medical department and clinical practice. This position reports to the Superintendent and plays a key leadership role in hospital-wide strategic planning, quality improvement, risk management, business development and outreach.

Work in a brand new hospital that incorporates modern architecture, treatment spaces, and technologies. This is an Executive Service position with a salary up to $274,000 annually depending upon qualifications. A generous and comprehensive benefit and PERS retirement package is included as well as opportunities to have an academic appointment with the Oregon Health Sciences University. Requires six years' management experience in mental health development, an unrestricted Oregon license, or the ability to obtain one by the time of appointment. Phone: (503) 945-2887; email: lila.m.lokey@state.or.us; fax: (503) 945-9910; www.oregon.gov/DHS/mentalhealth/osh. The State of Oregon is an Equal Opportunity Employer.

BC/BE Psychiatrists
Oregon State Hospital (OSH)
Salem, Oregon

Oregon State Hospital is looking for BC/BE psychiatrists. You will work in a brand new hospital that incorporates modern architecture, treatment spaces, and technologies. Salary is very competitive and includes psychiatric differential, board certification pay, and opportunities for additional on-call work. OSH offers opportunities in our general adult, geriatric, and forensic programs. A generous and comprehensive benefit and PERS retirement package is included as well as opportunities to have an academic appointment with the Oregon Health Sciences University.

Phone: (503) 945-2887; email: lila.m.lokey@state.or.us; fax: (503) 945-9910; www.oregon.gov/DHS/mentalhealth/osh. The State of Oregon is an Equal Opportunity Employer.

PENNSYLVANIA

Psychiatrist
Philadelphia Area Behavioral Health

NHS Human Services ("NHS"), and its subsidiaries, is a major provider of community-based behavioral healthcare, serving the special needs of over 50,000 children and adults annually.

Currently, NHS is seeking full time and part time Psychiatrists for its **Outpatient** and **Residential** programs located throughout **Philadelphia** and the **surrounding counties**. Service lines include: Adult Mental Health; Substance Abuse; Children's; and I/DD. Successful candidates will have the following: **Board Certified or Board Eligible in PA** and must have successfully completed an **approved Psychiatry Residency**.

Please submit CV to: MD@NHSonline.org
www.NHSonline.org
NHS is an EOE

PENNSTATE HERSHEY
Milton S. Hershey Medical Center

The Penn State Department of Psychiatry is recruiting psychiatrists for its growing department. With our clinical partner, Pennsylvania Psychiatric Institute, the Department staffs four clinics, with outpatient and partial hospital programs for children and adults, 58 adult and 16 child/adolescent beds, ECT and other neurostimulation services, and psychiatric consultation for 3 hospitals. Our current psychiatry faculty numbers 52, with planned increases, plus 24 residents and fellows. We have a growing research portfolio, with basic and clinical research and close collaboration with allied neuroscience disciplines at several Penn State campuses. We plan expansion in teaching programs as well.

Successful candidates should have strong clinical and teaching skills and, optimally, potential for scientific and scholarly achievement.

Candidates with interest and skills in these areas should send a curriculum vitae and cover letter to:

Alan J. Gelenberg, M.D.
Professor and Chair
Penn State Hershey Medical Center
Department of Psychiatry, H073
500 University Drive, P.O. Box 850
Hershey, PA 17033
Phone: 717.531.8516
Fax: 717.531.6491
agelenberg@hmc.psu.edu

Penn State Hershey Medical Center is committed to affirmative action, equal opportunity and the diversity of its workforce.

Stroudsburg, PA

Full time outpatient Adult/Child Psychiatrist, ISL Psychiatric Services is looking to recruit additional psychiatrists to join our excellent group of 20 psychiatrists and other mental health workers. Starting salary of 170k and an excellent benefit package. Please send CV to (570) 424-6271, or call (570) 424-6187.

PITTSBURGH Assertive Community Treatment - Opportunity for a FT ACT psychiatrist at Mercy Behavioral Health. Our financially solid organization, with 24 psychiatrists, offers competitive compensation and an excellent benefits package. Contact Jim Jacobson, MD at 412-488-4927 physician@mercybh.org.

Psychiatrists:

Currently we have exciting full- and part-time positions in a rapidly expanding department. Opportunities include responsibilities in and outside our five-hospital health system. There are immediate openings for child/adolescent, adult and addictions psychiatrists.

There are also practice options in a traditional psychotherapy model. Psychiatric Hospitalist positions are available for weekday and weekend rounding and Crisis. Excellent salaries, no on-call nor rounding responsibilities ever and exceptional benefits package offered. Send CV to Kevin Caputo, M.D., Vice President and Chairman, Department of Psychiatry, Crozer-Keystone Health System, One Medical Center Blvd., Upland, PA 19013 or contact the department manager, Kathy Waring at 610-619-7413.

RHODE ISLAND

CL/Outpt position available for board eligible/certified psychiatrist in the Behavioral Health Division of Women and Infants Hospital, a major teaching affiliate of the **Alpert School of Medicine at Brown University, Providence, RI**. Qualified applicants will have a demonstrated interest in teaching and perinatal /women's behavioral health. Clinical faculty appointment and salary commensurate with experience. Please send CV and letter of interest to Steven Rasmussen, M.D., Chair of Psychiatry and Human Behavior, 345 Blackstone Blvd., Providence, RI 02906 or email Steven Rasmussen @ Brown.edu.

Full-time position available for board eligible/certified day hospital psychiatrist interested in clinical faculty position at **Butler Hospital**. This outstanding opportunity offers a collegial academic environment in the major psychiatric teaching facility of the Warren Alpert School of Medicine at Brown University, located in Providence, RI. Salary and clinical faculty appointment commensurate with experience. Apply by sending CV to Lawrence_Price_MD@brown.edu.

SOUTH CAROLINA

Hospital seeking to employ a Psychiatrist!!

McLeod Health is seeking a Full-Time BC/BE Adult Psychiatrist for our Behavioral Health Psychiatric Center located in a beautiful rural setting in Darlington, SC, just minutes away for the main flagship hospital, McLeod Regional Medical Center in Florence, SC. We have an extensive support staff for the hospital and ED consults and a twenty-four hour Access Center. Our state-of-the-art 23 bed crisis intervention in-patient facility was built and designed specifically for the needs of the psychiatric patient. We also provide out-patient therapy for patients in a private practice setting. We offer a competitive salary, comprehensive benefits and retirement package, paid professional liability insurance, CME allowance, relocation assistance, and sign on bonus.

McLeod Regional Medical Center is a 453 bed, tertiary care, and teaching facility serving a primary market of 6-counties, and receiving tertiary referrals from 12 counties for a total population of 1 million people.

McLeod, 2010 American Hospital Association Winner, is leading the way in the nation for patient care by improving quality and safety. We are committed to developing patient-centered,

evidence-based, physician-led quality health care in a not-for-profit hospital system that values each individual patient.

If you are interested in joining this nationally recognized hospital, please contact Angela Stukes at 843-777-7046 or by email at astukes@mcleodhealth.org. Go to mcleodphysicianrecruiting.org for more details regarding this position.

TENNESSEE

Horizon Health, in partnership with **Livingston Regional Hospital in Livingston, TN**, near beautiful **Dale Hollow Lake**, has an exciting opportunity for a **Medical Director** at our 10-bed Geriatric Inpatient Psychiatric Program. Excellent income with great quality of life! 2 hours from Nashville and Knoxville and one of the lowest costs of living in the U.S. For more information contact: Mark Blakeney, Voice: 972-420-7473, Fax: 972-420-8233; email: mark.blakeney@horizonhealth.com EOE.

Can you go home and leave your work behind?

Your relocation comparison checklist:

- Paid malpractice coverage
- 37.5 hour work week
- 100% employer funded pension
- 80% of health insurance premiums covered
- No state or city income tax
- Most competitive state for business
- 5th best state in the nation for Quality of Life
- 2nd best state in the nation for the business climate
- **2009 "State of the Year"** for the number of new jobs created

Lakeshore offers all this and more. Lakeshore has a full-time position open for a BC/BE Psychiatrist in a 115-bed facility with a mountain view setting overlooking the picturesque Tennessee River. Lakeshore is located in Knoxville, Tennessee, one of the most affordable cities in the U.S.

Nestled in the foothills of the Great Smoky Mountains National Park, rugged mountains, lush valleys, abundant fresh-water fishing streams and lakes and breath-taking vistas plus miles of hiking trails, dozens of campsites and boundless opportunities to "get away from it all" are just minutes from downtown.

Knoxville is also home to a rich arts community, diverse range of restaurants and entertainment, shopping and sporting events, and the Southeast's booming high-tech Innovation Valley. Knoxville and the Innovation Valley truly provide cosmopolitan amenities with a hometown atmosphere. With several of the state's top ranked primary/secondary schools, and the highly rated flagship campus of the University of Tennessee, East Tennessee offers a topnotch education for everyone.

Earn extra money through voluntary on-call coverage. Excellent benefits which includes malpractice coverage, 100% employer funded pension, 401k tax deferred retirement with employer contribution, health insurance, paid sick leave, paid vacation, paid time off for CME, and 11 paid holidays per year.

Contact Bert Simpson, MD, Clinical Director, today to discuss this unique opportunity at (865) 583-8768. Come enjoy your work and enjoy your life. Pre-employment drug testing required. The State of TN is an Equal Opportunity, Equal Access, Affirmative Action Employer.

PSYCHIATRIST

Western Mental Health Institute, a Joint Commission accredited psychiatric hospital with an all board certified medical staff, has an opening for a full time BE/BC psychiatrist. All patient services are delivered in a newly built state of the art hospital located in a beautiful country setting only 65 miles east of Memphis, TN. Competitive salary: 37.5 hour work week, opportunity to earn significant additional income through voluntary on-call system. Excellent State benefits including an employer funded benefit pension plan. Contact Rita Kennedy at 731-228-2028 or e-mail to rita.kennedy@tn.gov.

TEXAS

San Antonio, Texas

Large, private mental health group seeks a bright, energetic Psychiatrist who is looking for long-term growth. Training / experience in Child / Adolescent, Geriatric or Addiction welcome. Set your own hours and practice parameters. 100% Outpatient available. Potential to rapidly establish and maintain a thriving practice drawing from a large referral base. Income potential will exceed $250,000. Located in San Antonio Texas a cultural gateway into the American Southwest the area is famous for its culture and is home to theme parks, museums and major league sports teams.

Contact Chris Gluz, **Alpha Medical Group**, 800.584.5001 or cgluz@alphamg.org. **Visit www.alphamg.org.**

Senior PsychCare is seeking **MD/DO Psychiatrist throughout Texas**. Will consider BC Psychiatrist or Neurologist with strong interest in Geriatrics and TX license. Full and Part-time positions available in San Antonio, Dallas, Houston and Austin. Multidisciplinary team, full benefits, excellent compensation, flexible schedule. lmatthews@seniorpsychiatry.com or call 713-850-0049. www.seniorpsychiatry.com.

VERMONT

Inpatient/Outpatient Psychiatry

Exciting opportunity to practice in a well established, hospital based Psychiatry Department. Fulltime, employed position with excellent benefits at second largest hospital in the state, and among the highest salaries offered in the state. 19 bed inpatient unit, and new outpatient program. Weekend call 1:6, week nights 1:5 with overnight phone call only. Strong crisis team covers intake in ED.

Enjoy the magic of classic New England towns, quiet roads, and make Vermont your year round home. Imagine yourself in the vibrant beauty of our fall foliage, the warmth of ending a day of skiing by a roaring fire, or a lazy summer day on a lake. Only hours from NYC, Boston & Montreal. Send CV to Rebecca Banco, Inhouse Physician Recruiter for Rutland Regional Medical Center, bbanco@rrmc.org.

VIRGINIA

Assistant Commissioner for Quality Management and Development/Medical Director

The Virginia Department of Behavioral Health & Developmental Services (DBHDS) is seeking an accomplished executive who will serve as Assistant Commissioner for Quality Management & Development/Medical Director. Position leads the development, implementation, & evaluation of systems, policies, & processes that ensure the highest quality of care, patient-centeredness, safety, effectiveness, timeliness, equity, efficiency, & evidence based medical standards. In addition, it will develop, implement, & administer a plan for a centralized QM & accreditation model to be applied across the organization. This position requires comprehensive knowledge of state & local government human services operations that serve individuals in need of behavioral health or substance abuse & addiction, or developmental disability treatment & supports. Knowledge of state of the art program treatment methodologies for individuals w/ mental illness, substance abuse & addiction or developmental disabilities. Knowledge of NCQA & URAC accreditation requirements & QI process implementation; & program/project management, data analysis & reporting. Medical license in State of Virginia & Board Certification in psychiatry required. Extensive executive level experience in leadership, administrative management (especially health or human services) & policy development is desired. We offer a competitive salary & benefit package. Pos #180. Open until filled. For more info & to apply online, go to http://jobs.virginia.gov/. Contact: Stacy Pendleton, HR Mgr @ stacy.pendleton@dbhds.virginia.gov. www.dbhds.virginia.gov. EOE

CSB/District 19 - Community Psychiatrist Position: F3211

ACADEMIC AMBULATORY PSYCHIATRY: VA Commonwealth University recruiting BE/BC Psychiatrist with community psychiatry and academic career interests to provide outpatient clinical care and supervise/teach residents/medical students. The clinical experiences include: City community psychiatry clinic and hospital-based teaching clinic. VCU Department of Psychiatry employs over 80 fulltime faculty and has well-funded research in genetics, addictions, child and women's mental health and psychopharmacology. VCU is a large urban university with robust health science campus and 750-bed university hospital. Richmond, the State Capital, has moderate climate and rich mix of history with modern facilities, excellent suburban housing, public/private schools. J-1 applicants welcome.

Send CV to Tammy M. Newcomb, Human Resources, Department of Psychiatry, VCU, Box 980710, Richmond, VA 23298 (Fax 804-628-1247). VCU is an Equal Opportunity/Affirmative Action employer. Women, minorities, and persons with disabilities are encouraged to apply.

GEROPSYCHIATRIST: Virginia Commonwealth University, Department of Psychiatry is recruiting a Virginia license eligible and board-eligible/certified Geropsychiatrist to be a program leader in providing clinical care, education and scholarship. Geropsychiatry fellowship and funded research preferred. J-1 will be considered. Clinical facilities include 12-bed geriatric inpatient team at the University hospital, geriatric clinic and large base of nursing home residents. Strong educational program with medical students, psychiatry residents and other trainees. Opportunity for collaborative and independent research available. Demonstrated experience working in and fostering a diverse faculty, staff, and student environment or commitment to do so as a faculty member at VCU.

VCU is a large urban university with robust health science campus and 700-bed university hospital. Department of Psychiatry employs over 80 full time faculty members and is nationally ranked in federally funded research. Richmond, the State Capital, has moderate climate, rich mix of history, culture and modern facilities, and nearness to beaches, mountains, and Washington, DC. Excellent suburban housing and quality public/private schools. Internet provides comparative cost of living. Competitive salary support and bonus plan for faculty.

Send CV to Tammy Newcomb, Human Resources, Department of Psychiatry, VCU/MCV, Box 980710, Richmond, VA 23298. Virginia Commonwealth University is an equal opportunity/affirmative action employer. Women, minorities, persons with disabilities encouraged to apply.

WASHINGTON

Summit Research Network (Seattle) LLC is seeking a licensed, board certified Psychiatrist to work with adult and pediatric/adolescent populations in clinical research trials. Must be comfortable working in a team environment as a Sub Investigator and Principal Investigator in primarily psychiatric pharmaceutical research at our site in beautiful **Seattle, WA.**

This position can be either part time or full time, or a combination of part time research and private practice. Summit offers competitive salary based on experience/credentials with an excellent benefit package.

Please send inquiries and CV to: James R. Hockley, MBA, Summit Research Network Management, Inc., 2701 NW Vaughn St., Ste.350; Portland, OR or via email: jhockley@summitnetwork.com.

Interfaith Community Health Center seeks a Psychiatrist or Psychiatric Nurse Practitioner to support PCPs & other BH professionals with their patients' BH issues & perform assessments, treatment, & medication management. ICHC is a federally qualified community health center providing medical, dental, and behavioral health services in the beautiful Pacific NW. Providing access to high quality affordable health care for all is our mission.

Please view our website and application process at **www.interfaithchc.org** or call HR at 360-788-2623.

WEST VIRGINIA

Child and Adolescent Psychiatrist (J-1 slot available)

Westbrook Health Services, a Comprehensive Community based, not for profit behavioral health center located in the Mid-Ohio Valley is recruiting a Child and Adolescent Psychiatrist.

Metro area of 150,000. A great place to raise a family. Good schools, including colleges and universities. Very low crime rate. Practice where you are wanted and appreciated. HPSA approved for educational loan repayment.
For details, call or send your CV to:

Dr. Amelia McPeak, Medical Director
Westbrook Health Services
2121 Seventh Street, Parkersburg, WV 26101
Phone: 304-485-1721 ext 273
Fax 304-422-0908
E-mail: amcpeak@westbrookhealth.com

HUNTINGTON: General or Child Psychiatrists. - Fulltime, Part-time and Locums. Residential & Inpatient Services at River Park Hospital. Highly competitive salary, benefits, and bonus opportunity. Little call - great team support. College town community with many amenities for quality of life. J1 & H1 eligible. Contact Joy Lankswert, In-house recruiter @ 866-227-5415 OR email joy.lankswert@uhsinc.com

WISCONSIN

Eau Claire, Wisconsin: Luther Midelfort - Mayo Health System, seeks a BC/BE Adult Psychiatrist with interest in inpatient and outpatient work. Opportunity could include Medical Directorship of outpatient addictions program. Call of 1:7. Outpatient unit attached to 20 bed inpatient unit. Luther Midelfort - Mayo Health System, vertically integrated, physician directed hospital and multi-specialty clinic of 250 physicians owned by Mayo Clinic. Eau Claire, a university community with metro area of 95,000, located 90 minutes east of Minneapolis. Outstanding schools, family-oriented community, state with favorable malpractice climate, strong compensation and benefits package may be expected.

Contact Cyndi Edwards: 800-573-2580, fax 715-838-6192, or edwards.cyndi@mayo.edu . Visit our website www.luthermidelfort.org. EOE

WISCONSIN DEPARTMENT OF HEALTH SERVICES
Mendota Mental Health Institute
Psychiatrist

Mendota Mental Health Institute is seeking to hire Psychiatrists to work at their facility in **Madison, WI**. These positions function as unit psychiatrists, providing direct medical and psychiatric services to patients of the Mendota Mental Health Institute (MMHI) in accordance with established institution policy, treatment methods, goals of patients and unit policy. Duties include performing physical exams, prescribing medications and treatments, psychiatric consultation with patient and family; participation in and/or conducting in-service meetings, staffing, case conferences; providing consultation to community agencies; and participation in training of residents, medical students, and unit staff. Special requirements are possession of a license to practice medicine in the State of Wisconsin or the ability to obtain the license prior to appointment, plus a minimum of 3 years in an approved residency in psychiatry. ABPN (American Board of Psychiatry and Neurology) Board certification in General Psychiatry is expected within three (3) years of hire.

For further information, including salary, additional job duties, knowledge, skills and abilities, and application information, please see the job announcements at http://wiscjobs.state.wi.us/public/index.asp. EOE.

Fellowships

Post-doctoral Research Fellowship Positions for Physicians at the Philadelphia VAMC MIRECC

Two-year research fellowship position focusing on dual diagnosis of medical, psychiatric, and addictive disorders in an established center with a specific focus on co-morbidities. Start date is July 1, 2011, but is negotiable. Pilot funding available to fellows to initiate projects in the etiology, diagnosis, clinical course, and treatment of dual disorders. Fellowship provides 75% time for research and 25% for clinical training in dual disorders. Medical degree from an accredited medical school and eligibility to practice medicine in any state in the U.S. required. Applications to Henry R. Kranzler, M.D., MIRECC/116, Philadelphia Veterans Affairs Medical Center, 3900 Woodland Ave., Philadelphia, PA 19104. henry.kranzler@va.gov.

Residencies

PGY 4/5 Residency Positions at Yale University

The Yale University Department of Psychiatry has PGY 4/5 positions available for July 2011. Sites include Silver Hill Hospital, VA Connecticut Healthcare System and Yale New Haven Hospital. Positions include inpatient and outpatient. Each position offers clinical and academic opportunities.

Interested applicants should contact Ann Cohen DePalma at 203.785.2095.

Practice for Sale

PSYCHIATRIC PRACTICE FOR SALE

- Near Seattle, Washington
- $400,000 annual revenue.
- Financing is available.
- Asking $225,000.

Annual cash flow to doctor is $150,000 - $200,000. No Medicaid. Psychiatric Care in this area considered limited and underserved.

Contact Monte Zwang, Broker
Wellness Capital Management
Monte@WellnessCapital.com, 888.727.5489

Furniture

ANALYTIC COUCH COMPANY!

Handmade iconic couches. See our online catalogue at www.analyticcouch.com Contact Randy for fabric samples 206-855-6888. Some custom options available.

Publications & Tapes

Tenth Anniversary! A classic!
The book that said it first, unequivocally, and jolted the psychiatric community into recognizing the reality: Bipolar not ADHD: Unrecognized epidemic of manic depressive illness in children, by George Isaac, MD. A must read. Only $14.95 at amazon.com and bn.com.

Finally, an up-to-date, fair and balanced resource for your patients about antidepressant treatment. **Taking Antidepressants: Your Guide to Starting, Staying On, and Safely Quitting** is a new book by clinician/researcher Michael Banov MD. Available at Amazon, Barnes and Nobel. Bulk discount rates at www.takingantidepressants.com.

You care

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

So open up and have the important conversation about long-acting injections. You might be surprised by what comes of it.

Janssen™
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November 2010

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