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# PSYCHIATRIC NEWS

## Malpractice Liability Cap Fails in Senate

Government News

“See” references appear on pages 1,32,37

The day before the Senate defeated a medical liability reform bill, the Agency for Healthcare Research and Quality reported that states that have enacted limits on noneconomic damages in malpractice suits have about 12 percent more physicians per capita.

BY MARK MORAN

Senate legislation that would have imposed limits on noneconomic damages in medical liability cases was defeated last month despite support from the American Medical Association, APA, and more than 50 other groups representing physicians, insurers, and patients.

The Patients First Act (S 11) would have capped noneconomic damages—also known as damages for “pain and suffering”—at \$250,000. The bill, introduced on June 27 by Sen. John Ensign (R-Nev.) with 10 co-sponsors, is similar to the HEALTH (Help Efficient, Accessible, Low-Cost, Timely Healthcare) Act (HR 5), which passed the House of Representatives by a 229-196 vote on March 13.

Senate Democrats, who opposed the bill to cap noneconomic damage awards, blocked an effort by Republicans to end debate and call the bill to the floor for consideration. The cloture vote failed by 49-48, short of the 60 votes required to limit debate.

Prior to the cloture vote, which essentially defeats the bill, the AMA had been

vigorously campaigning for it, drawing special attention to the opposition by the nation’s trial lawyers.

“Senators must understand that doctors are being forced to make hard choices to limit procedures, refer high-risk cases, and retire early,” AMA President Donald J. Palmisano, M.D., said before the vote. “Without federal legislation, patients will bear the brunt of this crisis as access to care in many high-risk medical specialties becomes limited.

“While the trial lawyers continue to hide behind smokescreens and roadblocks, liability-insurance premiums rise to staggering levels for many physicians,” Palmisano said.

As the debate in the Senate was progressing, the AMA was running medical liability radio ads in key states with key senators, including Alabama, Arkansas, Nebraska, Pennsylvania, and South Carolina. “In the last two months both patients and physicians have told Congress how important it is for them to pass medical liability reform,” Palmisano said. “Over 26,000 patients have

*please see **Malpractice** on page 43*

## Experts Outline Costs, Barriers To High-Quality Depression Treatment

Patients’ views about depression affect their treatment outcomes, as does the fragmented structure of the health care system.

Health Care Economics

BY KATE MULLIGAN

Researchers tackled a big issue about the treatment of depression at the June meeting of AcademyHealth in Nashville.

In the session titled “Integrating Behavioral Health and Medical Care: What Does it Take?,” they addressed clinical and economic strategies that promote or inhibit effective treatment of depression in primary care settings.

“It’s a win-win situation when high-quality treatment for depression pays for itself,” Kathryn Rost, Ph.D., said. But, she added, previous studies have not demonstrated a cost offset for health plans that fund high-quality depression treatment, despite many experts’ belief that such treatment reduces medical costs for comorbid physical disorders.

Rost is a professor in the department of family medicine at the University of Colorado Health Sciences Center at Fitzsimons. AcademyHealth is the professional organization for health services researchers, policy analysts, and practitioners and a resource on health research and policy.

Rost’s study focuses on costs to health plans only. A recent survey found that employers are losing an estimated \$44 billion a year in lost productivity directly related to depression (*Psychiatric News*, July 15).

Rost and her colleagues developed an intervention to encourage the delivery of high-quality depression treatment and tested it at 12 primary care clinics across the country from 1996 to 1999. With fund-

*please see **Depression** on page 37*



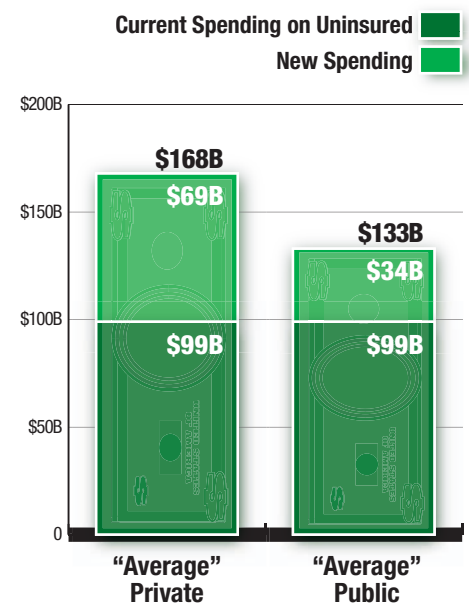
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**BOSTON**  
**Access to Integrated  
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October 29-November 2, 2003

Continuing  
information on  
APA’s fall meeting  
can be found on  
page 23.

### Universal Coverage Affordable

If currently uninsured individuals were given coverage under a universal expansion of health insurance, health care spending would increase from \$99 billion to \$168 billion. This scenario assumes that coverage would be similar to that in an average private insurance plan for lower- and middle-income Americans and includes all uncompensated care and out-of-pocket payment by the uninsured. If the expanded coverage were similar to the average public insurance plan, the estimated total spending would be about \$133 billion. This represents an increase in total health care spending of only 3 percent to 6 percent.



Source: Kaiser Commission on Medicaid and the Uninsured/Hadley and Holahan, June 2003

See story on the new report from the Kaiser Commission on Medicaid and the Uninsured about costs of expanded coverage on page 24.

# AMA Ad Campaign Targets Medicare Payment Formula

The AMA, with APA support, launches a campaign to get Congress to reform Medicare's "flawed" payment formula that penalizes physicians if patient services grow more rapidly than the gross domestic product.

Government News

BY MARK MORAN

**T**he American Medical Association has opened an advertising campaign to convince Congress to reform what it calls a "flawed" Medicare physician payment formula.

Advertisements in several prominent journals read in Washington and elsewhere by legislators and public-policy advocates—including *Roll Call*, *National Journal*, *Congress Daily*, and others—have appeared displaying the Medicare payment formula and posing the question, "Know What This Equals?"

The answer: "Bad News for America's Seniors."

Yank D. Coble Jr., M.D., the immediate past president of the AMA, explained that under the current formula, physicians are penalized if services to Medicare patients grow more rapidly than the nation's gross domestic product.

"At times of slow economic growth, it is likely that Medicare spending on physician services will exceed the target and trigger cuts in physician payments," Coble said. "But the health care needs of America's seniors don't change with the ups and downs of the U.S. economy. Patients and physicians lose under a formula that cuts Medicare payments when the overall economy slows and when more health care services are provided to seniors."

## Payments Could Plummet

He added, "Unless we change the physician payment formula, Medicare payments will continue to plummet, making it more difficult for our nation's seniors to get the health care they need and deserve."

Earlier this year, the Centers for Medicare and Medicaid Services (CMS) predicted that Medicare physician payments will likely be cut by 4.2 percent in January 2004.

But Coble noted that Congress's own Medicare advisory committee, MedPAC, has recommended that physicians get a 2.5 percent increase instead of a 4.2 percent cut in 2004 and that Congress replace the current Medicare payment formula.

Michael Strazzella, deputy director for congressional relations in APA's Division

of Government Relations, told *Psychiatric News* that APA is "extremely supportive" of the AMA's campaign and is backing adoption of provisions in the House of Representative's Medicare prescription drug bill that would amend the payment formula.

Those provisions would increase the Medicare fee schedule by at least 1.5 percent, Strazzella said.

"The administration needs to understand that this is not a matter of physicians lining their pockets, but an issue of patient access," Strazzella said. "If physicians are not appropriately reimbursed, they will not be able to serve their patients."

## CMS Backs Out

In related news, the CMS has cancelled plans to make automatic adjustments on claims for physician services that were provided in January and February 2003, but not paid for until after March 1.

According to the AMA, the adjustments were intended to rectify inaccurate payments stemming from computer errors that prevented carriers from varying payment according to whether a service was provided before or after payment changes took effect on March 1. Millions of claims were involved, and many physicians could have been hit with overpayment demands that required restitution to both Medicare and individual patients, according to the AMA.

Data from one multistate insurance carrier indicated that about 250,000 claims and 100,000 beneficiaries per state could have been affected. Carrier computers were incapable of handling the overload, and it was estimated that adjustments would take up to a year to complete.

A June 26 notice from the CMS canceled the plans for automatic adjustments and called for adjustments only if the physician brings a claim to the Medicare carriers' attention. In effect, physicians can seek adjustments for underpayments and avoid adjustments for overpayments.

CMS expects this approach to increase Medicare expenditures by \$50 million in 2003, according to the AMA. ■



from the president

## On Your Way to the Forum

BY MARCIA GOIN, M.D.

**T**rumpets blare! Drums roll! APA's Division of Government Relations (DGR) calls you to action. Are you quick to respond? Will you add your voice to answer APA's plea to advocate for our patients and our profession?

### If Not, Why Not?

If you have not been reacting to DGR's appeals, don't stop reading just yet. Many members are active advocates, but far fewer than we need. Why? The shortage of responders certainly does not reflect the depth of concern that we all have about the crumbling mental health system and the urgent need for renewal, reform, and change.

The answer may lie in the persona of those of us who chose to go into medicine. Most of us became physicians because we want to treat patients. We didn't enter politics; we chose medicine—we want to heal the sick, relieve physical and emotional suffering. Lobbying our legislators or leading a march to the steps of Congress is not in our job description; in fact, to some colleagues those roles seem to be discomforting or unseemly.

Early in my professional life, I believed APA should concern itself with treatment and education, not politics. While in this state of political naiveté, I was fortunate to be invited by a senior colleague in the department of psychiatry at the Los Angeles County/USC Medical Center to come along while he paid a visit to the local congressman. Influence and education were needed to block damaging reductions in



local funding. The meeting was a revelation. The congressman was gracious and welcoming, but he knew very little about the mental health system, including its precarious funding and how it functions in the treatment and care of emotionally ill children, adolescents, and adults. The news of the adverse effects of de-

pression in the workplace and its alarming impact upon families and the community and the ultimate economic costs to business and to the states' tax revenues illuminated his thinking about the psychosocial consequences of disability. Our mantra that mental illness is diagnosable and treatable and that its treatment is cost-effective was surprising news for him. He listened carefully to this detailed exposition by my psychiatric political mentor. In the days ahead, needed changes occurred in the political process guided by our congressman.

The meeting helped me to recognize that legislators are receptive to being, indeed in many cases are honored to be, sought out personally by informed physicians. Often you can assume that our legislators are uninformed about psychiatry and psychiatrists, but they are willing to learn. Of course, they want to win their next election, but they also want to be constructive along the way.

Since they may ask hard questions, we need to be prepared. A colleague recently described the following reaction from a legislator: "Doctor, I understand your position about proposed Medicaid cuts, but we

*please see **From the President** on page 43*



## the medical director's desk

# Membership Department: APA's Nerve Center

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

**W**hat are the requirements to become a distinguished fellow of APA? When will I reach life status? I am no longer a member-in-training; how do I become a general member? How can I become a fellow? I'm a new resident; is it true that dues are waived for the first year of membership?

I'm about to retire and can no longer afford dues but want to maintain my membership; what can I do? I'm moving to another state; how do I change my local affiliation?



These are the types of questions that staff in the Membership Department field on a daily basis. Did you know that on average more than 1,000 members change their district branch affiliation each year? Or that 600 members-in-training advance to general membership each year? Last year almost 650 members ap-

plied for the new category of fellowship, and there were more than 130 nominations put forward by district branches for distinguished fellowship. There are also more than 2,000 new members enrolled annu-

ally, which means that welcome packets must be sent; membership certificates must be sent as well to new general members.

The Membership Department is also responsible for sending more than 27,000 renewal notices in October each year and then every other month until dues are paid in full or the member is dropped for nonpayment. When members face financial hardship, there is a process by which they can request dues relief. Hundreds of such requests are processed annually.

The department has 12 staff members, with an annual budget of \$1.3 million. Membership dues represent 19 percent of APA's total revenue. Five membership coordinators are assigned to work with specific district branches and members in a geographic

area. These coordinators process new member enrollments and reinstatements, serve as the point of contact for district branch staff, and have overall responsibility for ensuring member inquiries are handled efficiently. Two project coordinators handle special functions such as coordinating the dues-relief process, fellowship applications and distinguished fellowship nominations, district branch transfers, and the process of resident advancement to general membership. Two other staff work directly with the membership database by adding new members and making member class and status changes, as well as coordinating the invoice renewal process, running statistical reports, and keeping member records up to date. One staff member provides administrative support to the department and ensures that membership cards are sent in a timely manner. Two staff members provide management and administration to the department's daily operations, as well as support the Membership Committee.

The department has the overall responsibility for membership business operations of the Association, including implementation of membership policies and procedures, processing membership transactions, responding to member inquiries, and working closely with district branch staff. The department manages the membership database, including the invoice renewal process, maintains the accuracy and integrity of the membership data, and reports on statistical data. A task force of members and staff has been studying a new association management system. Though there is always a risk that unforeseen problems will occur with the migration to a new computer system, this system, if it is put in place, should result in streamlining the membership process.

For years members have complained that the process for joining APA is too cumbersome. They believe that it should be easier to join, easier to become a general member after finishing residency, and easier to change local membership from one state to another when moving to a new locale. As a result of actions taken by both the Assembly and the Board of Trustees, the Membership Department staff is working with 14 district branches on a pilot project to streamline membership procedures.

Through the pilot project, membership applications are submitted directly to APA for the first phase of the application process before being sent to the district branch for review (outside of the pilot project, all applications are approved first by the district branch before being sent to APA). District branches in the pilot project are presented with completed applications that meet APA criteria for membership and have been verified and credentialed by staff in the national office. The branch has 45 days in which to approve the application or request additional time for review. Many branches take fewer than 45 days to approve an application; however, if the district branch does not respond to APA in 45 days, the applicant is enrolled as a member in both APA and the district branch.

If the pilot project is determined to be successful and the procedures receive final approval from the Board of Trustees, all future applications and other membership transactions will be handled in this manner. The outcome will be that all applications, transfers, and advancements will be processed in a timely and efficient manner.

I am continually looking for ways to improve the membership experience for our members and welcome your comments and suggestions. Please forward your comments and suggestions to me at [medicaldirector@psych.org](mailto:medicaldirector@psych.org). ■

# Medical Record Database Efficient but Troubling

The Department of Health and Human Services and two other federal agencies are involved in a plan to adopt common clinical terminology to facilitate the use of electronic medical records.

BY CHRISTINE LEHMANN

Imagine being able to retrieve a patient's electronic medical record that has been updated by every health care professional the patient visits. This scenario isn't science fiction and will raise more questions about whether the federal privacy rules sufficiently safeguard individual health information.

Last month the federal government announced two health information initiatives designed to build a unified electronic medical records system in the United States.

Health and Human Services (HHS) Secretary Tommy Thompson announced that HHS and the departments of Defense and Veterans Affairs (VA) will incorporate a common clinical terminology into their information systems to facilitate the exchange of health care information electronically.

The federal agencies will use SNOMED-CT, which stands for the Systemized Nomenclature of Medicine—Clinical Terms, owned by the College of American Pathologists (CAP). The HHS, VA, and Defense departments are subsidizing the \$32.4-million license that the National Library of Medicine (NLM) purchased from the College of American Pathologists for use of SNOMED-CT.

NLM, which is part of the National Institutes of Health, will incorporate the core content of SNOMED-CT in English and Spanish into its Unified Medical Language System (UMLS). The UMLS contains more than 100 biomedical and health vocabularies and classifications that are linked and distributed in a common format, according to UMLS advisor Carolyn Tilley of NLM's Bibliographic Services Division.

The UMLS contains *DSM-III* and *DSM-IV*, the ninth and 10th editions of the *International Classification of Diseases (ICD)*, and the Health Insurance Portability and Accountability Act (HIPAA) electronic transaction code sets, Tilley told *Psychiatric News*.

SNOMED-CT will be accessible through the UMLS database early next year, said Tilley. "We anticipate that SNOMED data will be incorporated into information

systems in hospitals and other health care institutions used by health care professionals," said Tilley.

While HHS plans to incorporate privacy protections mandated by the HIPAA regulations into the new electronic health care system, APA's immediate past president, Paul Appelbaum, M.D., expressed concern about breaches of confidentiality and the HIPAA regulations themselves.

"Greater ease of access to electronic medical records is a double-edged sword," he told *Psychiatric News*. "Although patient care can be improved by accurate data, if information ends up in the wrong hands, jobs can be lost, insurance denied, mortgages refused, and personal relationships altered."

Appelbaum continued, "Perhaps news of the government's plans for what essentially will be a national data bank of personal medical information will stimulate a closer look at the misguided HIPAA privacy regulations. As currently framed, they would allow—indeed facilitate—the uncontrolled sharing of large amounts of electronic patient data, a frightening prospect to anyone who recognizes that privacy is critical to high-quality medical care."

In a complementary initiative, Thompson commissioned the Institute of Medicine (IOM) to develop a standard model electronic medical record (EMR) to be ready some time next year. Ultimately, the goal is to integrate the EMR with SNOMED-CT, according to the press release.

HHS is encouraging and facilitating the widespread use of modern information technology to improve the nation's health care system, said Thompson in the press release.

"Adopting a common clinical terminology and codes will simplify health care communication with the government and ultimately benefit the public," John Goethe, M.D., told *Psychiatric News*. He is the director of the Burlingame Center for Psychiatric Research and Education of the Institute of Living in Hartford, Conn.

Thompson said, "This unified EMR system will prove invaluable in facilitating the automated exchange of clinical information needed to protect patient safety, detect emerging public health threats, better coordinate patient care, and compile research data for patients participating in clinical trials."

Diane Aschman, chief operating officer for SNOMED International, told *Psychiatric News*, "The beauty of SNOMED-CT is that it is designed to index medical record information across medical specialties and sites including signs and symptoms, diagnoses, and procedures. The clinical terms are encoded in a computerized format, which facilitates data gathering for many purposes including public health surveillance and research."

NLM chose SNOMED-CT for use by both the federal and private sectors because studies have shown that it is the most comprehensive and widely used medical vocabulary in the world, said Aschman. At least 40 countries including the United Kingdom and small health care businesses in the United States have adopted SNOMED-CT, according to Aschman.

SNOMED evolved from a reference terminology for pathologists in the 1960s into a comprehensive clinical terminology through CAP's collaborative efforts with primary care physicians, nurses, and other allied health care professionals. Several medical specialty vocabularies, including ones for mental health, have been incorporated into SNOMED-CT, explained Aschman.

Several groups including the IOM and

the National Committee on Vital and Health Statistics (NCVHS) have recommended in reports and studies that the federal government adopt a common health care language and subsidize the maintenance and distribution costs.

Agencies within HHS that helped fund the NLM license to use SNOMED-CT include the Centers for Disease Control and Prevention, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, according to the NLM statement. HHS is also coordinating its efforts to standardize health information with other health agencies as part of the Consolidated Health Informatics Initiative, a health care component of President Bush's eGov Initiatives, according to a SNOMED International press release.

To protect confidential patient information, SNOMED-CT uses codes rather than text to represent clinical terms, said Aschman. HHS spokesperson Bill Hall said the unified electronic medical records system will be developed in compliance with HIPAA requirements.

HHS also announced last month that it will establish a new health care technology council. Its initial focus will be on creating incentives for health care organizations to adopt a standard medical terminology such as SNOMED-CT, electronic medical records, and other government standards, according to the July 2 *iHealth Beat*.

**Fact sheets on UMLS/SNOMED are posted on the Web at <[www.nlm.nih.gov/research/umls/Snomed/snomed\\_faq.html](http://www.nlm.nih.gov/research/umls/Snomed/snomed_faq.html)>. ■**

## SCULLY MEETS WITH FRIEND OF PSYCHIATRY ON CAPITOL HILL

APA Medical Director **James H. Scully Jr., M.D.** (left), chats with **Rep. Gary Miller** (R-Calif.) recently on Capitol Hill. Miller is a longtime supporter of initiatives to benefit mentally ill Americans, including the quest for parity in insurance coverage and increases in the budgets of the mental health and substance abuse institutes at the National Institutes of Health.

Scully's visit is part of an ongoing program at APA—through its political action committee, *APAPAC*—in which APA members educate federal and state legislators and policymakers about mental health issues.



# APA Urges Bigger Increase In MH Research Budget

The next NIH budget may end up billions of dollars short of APA's advocacy goal. APA hopes its Senate allies will direct additional funds to the premiere health research agency.

BY CHRISTINE LEHMANN

APA is holding out hope that its Senate allies will prevail in increasing the Fiscal 2004 budget for the National Institutes of Health (NIH) when the full Senate votes on the next year's spending bill for the departments of Labor, Health and Human Services, and Education.

It was uncertain as of July 21 whether

the Senate vote would occur before or after this month's congressional recess.

Once the Senate votes on the labor and health and human services appropriations bill, conferees from the House and Senate will meet to reconcile differences between their versions of the appropriations bill.

The Senate Appropriations Committee passed its appropriations bill (S 1356) in June with a 3.7 percent increase for NIH.

The House of Representatives passed its spending bill (HR 2660) with a 2.5 percent increase for NIH.

The increase of \$1 billion in the Senate bill resulted from a vote approving an amendment to the Fiscal 2004 budget resolution by Sens. Tom Harkin (D-Iowa) and Arlen Specter (R-Pa.) that provided an additional \$2.8 million for discretionary health research and services programs, including \$1.8 million for NIH.

"While APA fully appreciates that the Senate Appropriations Committee is recommending a 3.7 percent increase in the NIH budget from Fiscal 2003, we are still hopeful that when the legislation goes to the Senate floor, additional funds will be directed to NIH," said Eugene Cassel, J.D., acting director of government relations at APA.

APA and other members of the Mental Health Liaison Group and Ad Hoc Group

for Research Funding lobbied for a 10 percent increase above the current level for NIH and the three mental health and addictions institutes. That would raise the total NIH budget to \$30 billion in Fiscal 2004, \$2.1 billion more than the amount proposed by President Bush and passed by the House.

**"We are still hopeful that when the legislation goes to the Senate floor, additional funds will be directed to NIH."**

The Senate traditionally appropriates more generous increases for NIH than does the House. This pattern is also seen in the following Fiscal 2004 budget increases for the national institutes devoted to mental health, drug abuse, and alcoholism:

- **National Institute of Mental Health:** The Senate proposed an increase of \$58.9 million for a total of \$1.4 billion, compared with the House's proposed increase of \$41.1 million for a total of \$1.38 billion.
- **National Institute on Drug Abuse:** The Senate proposed an increase of \$35.9 million for a total of \$997.6 million, compared with the House's proposed increase of \$33.9 million for a total of \$995.6 million.
- **National Institute on Alcohol Abuse and Alcoholism:** The Senate proposed an increase of \$15.4 million for a total of \$431.5 million, compared with the House's proposed increase of \$14 million for a total of \$430.1 million.

The proposed increases in Fiscal 2004 for NIH and the mental health and addictions institutes, however, are nearly two-thirds lower than the previous increases passed by Congress annually since Fiscal 1998. Congress passed a 15 percent increase for NIH in Fiscal 2003, for example, that led to the doubling of its budget between 1998 and 2003.

Members of APA's Academic Consortium, Mental Health Liaison Group, and Ad Hoc Group on Research Funding have voiced concerns that smaller increases in Fiscal 2004 will curtail crucial ongoing research projects and impede future advances in understanding the causes of mental illnesses and developing effective treatments for those illnesses.

Meanwhile, the House passed larger funding increases than the president's budget recommendation for certain programs within the Substance Abuse and Mental Health Services Administration (SAMHSA).

The Center for Mental Health Services' mental health demonstration grant program for children was increased by \$6.7 million over the president's recommendation, for example, and the Program for Alternatives to Homelessness (PATH) was increased by \$9 million over the president's recommendation, according to Lizbet Boroughs, an associate director in APA's Division of Government Relations.

*An update on the status of Fiscal 2004 appropriations relevant to mental health can be accessed on the Thomas Web site at <<http://thomas.loc.gov/home/approp/app04.html>> by going to "Labor/HHS/Education." The House and Senate bills (HR 2660, S 1356) and their respective appropriations committee reports are posted there. ■*



# JANSSEN RISPERDAL P4C

# JANSSEN RISPERDAL P4C



# JANSSEN RISPERDAL P4C

## MH Advocates Hope Outreach Benefits Youth on Probation

**Group therapy sessions on anger management and substance abuse are offered to youth on probation in one New Jersey county in an effort to promote better mental health and reduce recidivism rates.**

BY EVE BENDER

**I**n New Jersey, the underlying mental health problems that have led many youth to the doors of the juvenile justice system have gone unaddressed for too long, say leaders of that state's Mental Health Association. These problems are finally being addressed through a program of screening and group therapy.

Staff at the National Mental Health As-

sociation (NMHA) and its New Jersey affiliate appeared at the 2003 NMHA Annual Conference in Washington, D.C., in June to discuss the steps they have taken to address the problem of youth who are on probation and have untreated substance abuse and mental health problems.

New Jersey was the focus of the NMHA's first effort to address the problem in its 1999 report, "The Community Assessment

Project: A Look at Mental Health and Substance Abuse Treatment Needs," according to Hazel Moran, the NMHA's associate director of juvenile justice.

The report, which summarized the concerns of various stakeholders in the juvenile justice and mental health systems, concluded that there was a lack of coordination among state-run services provided to youth in the juvenile justice system. It pointed out as well that there was no systematic mental health screening of youth who entered the system, despite the fact that, according to Moran, "as many as 80 per-



**Discussing how to help New Jersey youth who are on probation and have untreated substance abuse and mental health problems in New Jersey are (from left) Mary Lynne Reynolds, executive director of the MHA in Southwestern New Jersey; Hazel Moran, associate director of juvenile justice at NMHA; and Jennifer Miller, director of training and marketing for the MHA of New Jersey.**

cent of youth in the juvenile justice system have a diagnosable mental health disorder."

After the NMHA issued the report, the MHA of New Jersey launched the Juvenile Justice Probation Project to determine the rate of mental health problems among youth on probation in New Jersey.

With the cooperation of the Probation Services Division of the Superior Court of New Jersey, counselors screened 296 juvenile probationers for mental health problems between fall 2001 and summer 2002 as part of the project.

Probationers in three counties—Camden, Bergen, and Mercer—completed the Massachusetts Youth Screening Instrument (MAYSI) upon entering the juvenile justice system, according to Jennifer Miller, director of training and marketing for the MHA of New Jersey. All screenings were voluntary.

Miller informed attendees that scores falling within the "caution" range on the MAYSI indicate possible clinical significance, and scores within the "warning" range indicate the heightened need for clinical attention.

These were among the findings:

- 1.5 percent of the youth scored within the warning range for suicidal ideation.
- 20 percent fell within the caution range on the drug and alcohol scale.
- 30 percent scored within the caution range and 13 percent within the warning range on the anger and irritability scale.

When project leaders compared scores between boys and girls in the sample, they found that more girls (20 percent) than boys (4 percent) scored in the warning range on the depression and anxiety scale; more girls (17.5 percent) than boys (4.5 percent) experienced four or more traumatic experiences in their lives; and more girls (27.5 percent) than boys (9 percent) scored in the warning range on the suicidal ideation scale.

Once the state MHA more clearly understood the extent of mental health problems in juveniles on probation, staff from the the Southwestern New Jersey MHA in Camden County decided to take action.

"We identified the youth who had problems, but realized that our community mental health services were overloaded," said Mary Lynne Reynolds, M.P.A., who is executive director of the MHA in Southwestern New Jersey. "We wondered what we could offer that would be accessible and would help kids."

In summer 2002, Reynolds and her staff in Camden County began offering group

*please see **Youth** on page 37*

# U.S. Not Ready to Respond To Disasters' MH Fallout

This is the first of a two-part series focusing on public health strategies addressing psychological aspects of terrorism. This article examines an Institute of Medicine report released this summer on a public health response to terrorism. The concluding article will report on a document by the National Advisory Committee on Children and Terrorism.

BY CHRISTINE LEHMANN

A report from the Institute of Medicine (IOM) provides a public health blueprint that federal and local agencies can use to address the psychological, social, and medical aspects of terrorist and hazardous events.

The report, titled "Preparing for the Psychological Consequences of Terrorism," states that the nation's mental health, public health, medical, and emergency response systems are not prepared to meet a range of emotional, behavioral, and cognitive reactions that are expected to result from a terrorist or hazardous event or threat of such an event.

Among the terrorist or hazardous events defined in the report are detonations of conventional explosives and biological, radiological, chemical, and nuclear attacks.

IOM committee member and psychiatrist Robert Ursano, M.D., explained to *Psychiatric News*, "People tend to react to traumatic events such as terrorism in one of three ways: Some people may experience symptoms of insomnia, fear, anxiety, vulnerability, and anger. Another group of people respond by increasing their intake of alcohol or tobacco and may avoid air travel. A third, small number of individuals develop psychiatric illnesses such as posttraumatic stress disorder [PTSD] or depression."

Ursano is a professor of psychiatry and neuroscience and chair of the department of psychiatry at the Uniformed Services University of the Health Sciences in Bethesda, Md., and a past chair of APA's Committee on Psychiatric Dimensions of Disasters.

Another committee member and psychiatrist, Carol North, M.D., commented to *Psychiatric News*, "Addressing and managing the psychological aspects of terrorism is an important public health issue. The report lays out a comprehensive roadmap to strengthening Americans psychologically before, during, and after a terrorist or hazardous event."

North is a professor of psychiatry at Washington University School of Medicine in St. Louis.

The report states that addressing "different terrorist scenarios and different effects on various groups of people will require universal preparedness by all systems responsible for the public's health."

## Infrastructure Gaps Found

The committee found gaps in five general areas: coordination of agencies and services, training and supervision, public communication and dissemination of information, financing, and knowledge of evidence-based services.

The report explains that coordination of agencies and services includes these activities:

- Organization and management of different services to individuals with different

needs and to the same individuals over time as their needs change.

- Licensing and credentialing of professionals providing care, and clarifying the role of various service professionals.
- Communication between different levels of government and the integration of various sources of funding.

A training and supervision issue cited in the report is the shortage of psychiatrists and



Robert Ursano, M.D., believes that comprehensive disaster planning entails being able to respond to a wide range of mental health consequences.

mental health professionals with disaster training and experience. "Historically psychiatrists have been less active in this arena than mental health professionals, and they are still figuring out what their role should be in settings related to disasters," said North.

## Public Education Critical

"Public communication and dissemina-

tion of information are critical following a terrorism event, particularly in the case of chemical, biological, radiological, or nuclear terrorism when instruction is critical for effective management," states the report.

The issues to be resolved include identifying who will deliver this information to the public, the media, political leaders, and service providers and how it will be communicated, according to the report.

Lt. Col. Cameron Ritchie, public affairs representative for the Society of Uniformed Services Psychiatrists, has an interest in the psychiatric aspects of biochemical and conventional warfare. She told *Psychiatric News*, "We have enough information from environmental disasters, including Chernobyl, and exposure to biochemical agents, including anthrax, and SARS to know that people generally don't panic. The exception is when a disaster occurs in a crowded place such as a fire in a nightclub with limited access to exits."

Ritchie continued, "When people are given consistent messages about appropriate see *Disaster* on page 38

# Clinicians, Case Managers Can Influence Decisions About Advance Directives

Psychiatric advance directives provide a way for patients to indicate treatment preferences in the event they are incompetent, but experts say their implementation has raised questions.

BY MARK MORAN

Psychiatric "advance directives"—documents composed in advance of a psychiatric relapse to outline treatment preferences in the event that a patient becomes incompetent—are favored by patients with severe psychiatric illness when they have a case manager or clinician who actively supports use of the documents.

That was the conclusion from a survey of 303 adults with serious mental illness who were receiving community mental health services and who had experienced at least two psychiatric crises in the preceding two years. The survey was published in the July *Psychiatric Services*.

"The majority of consumers, when approached systematically and asked if they are interested in advance directives, say they are interested in creating the document," study author Debra Srebnik, Ph.D., told *Psychiatric News*.

She is an assistant professor of psychiatry in the department of psychiatry and behavioral sciences at the University of Washington School of Medicine.

In the study, associations were examined between level of interest in creating the document and a variety of variables: demographic characteristics, psychiatric symptoms, level of functioning, diagnosis, history of hospitalization, history of outpatient commitment orders, support for the directives by case managers, and site differences.

Of the survey participants, 161 (53 percent) expressed an interest in the directives. Variables significantly associated with interest were the support of the case manager for the document and no history of outpatient commitment.

Before introducing information about the directives to the participants, case managers rated themselves, using a Likert scale, on four questions assessing support for the concepts of psychiatric advance directives:

- How useful do you think psychiatric advance directives would be for consumers during mental health crises?
- How useful do you think psychiatric advance directives would be for service providers during mental health crises?
- How do you feel, personally, about psychiatric advance directives?
- How useful would it be for consumers to have service providers help them complete psychiatric advance directives?

Srebnik told *Psychiatric News* that the idea that patients with no history of outpatient commitment orders were more likely to be interested in advance directives ran counter to a research hypothesis: The researchers had assumed that those with such a history might prefer to have a written advance directive as a substitute for commitment.

Srebnik explained, however, that the theoretical foundation of that assumption overlooks the real preferences and tendencies among such patients. Having an outpatient commitment order may serve as a proxy for unmeasured variables, such as treatment engagement, adherence, or appreciation that one has a mental illness requiring treatment.

"For those who discount the need for treatment, psychiatric advance directives will predictably be of little interest, except possibly as a vehicle for refusing future treatment," Srebnik and colleagues wrote in the article. "The directives may be valuable only to individuals who perceive value in the treatment that the documents direct."

In the article "Implementing Psychiatric Advance Directives: Service Provider Issues and Answers" in the May 13 *Journal of Behavioral Health Services and Research*, Srebnik and Lisa Brodoff, J.D., of the School of Law at Seattle University outlined questions raised by service providers about psychiatric advance directives.

Among these issues are access to direc-

tives, competency to execute directives, the relationship of directives to standards of care, and liability for honoring and not honoring directives.

Srebnik said that anecdotally "there are very few of these documents in circulation." And even when they exist, it may be difficult or impossible to access them in an emergency situation.

"Imagine the situation where a patient is having a crisis and has to go to the emergency room," she said. "The staff has never seen the patient before, and the patient may or may not even remember that a directive exists. That's the end of the discussion. The service provider may never know the directive exists, and in some systems it may be difficult to get their hands on the documents."

Jeffrey Metzner, M.D., chair of APA's Council on Psychiatry and Law, said that among the problems with psychiatric advance directives is that they might be used to indicate a preference for no treatment.

"Under ordinary circumstances, if a patient were incompetent, that patient would meet civil commitment criteria," he said. "If a directive indicates no treatment, I don't think anyone is going to follow that directive."

Metzner said that advance directives might be most useful to clinicians when they indicate a preference for or against a particular treatment over a range of options.

"If there is a choice of treatments, and you've expressed a preference for one, the psychiatrist will be more likely to use that one than another," he said.

"The study was not about the pros and cons of using advance directives, though it implies that they are good and that they are underutilized," said Metzner, a clinical professor of psychiatry at the University of Colorado Health Sciences Center. "The real conclusion is that patients are more likely to use advance directives if the case manager or clinician thinks it is a good idea and conveys it to the patient. The message is that people working with severely mentally ill people ought to educate themselves about psychiatric advance directives and talk with patients about them."

The study, "Interest in Psychiatric Advance Directives Among High Users of Crisis Services and Hospitalization," is posted on the Web at <<http://ps.psychiatryonline.org/cgi/content/full/54/7/981?>>. ■

**HOUSE--  
1/4**

**SILVER HILL HOSP  
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**HSE  
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# Psychiatry Choice Sometimes A Delayed Reaction

Some psychiatrists have taken a circuitous route to their profession, training first in another area of medicine. They bring to their practice and their patients a dual or even triple medical perspective.

BY MARK MORAN

Many psychiatrists practicing today made a decision while still in medical school—based on personal inclination, exposure to mentors, or happenstance—about the kind of training they would pursue in residency.

After that, the course of their professional future was set early in their medical career.

But some have taken a more circuitous route to the profession, training first in another area of medicine before entering psychiatry—because of a natural evolution, a change of heart and mind, or perhaps for reasons that are not entirely voluntary. These jacks of more than one trade bring to their practice and their patients the special perspective of the double- or even triple-boarded physician.

And they are liable, of course, to come to the profession with a little more mileage than their counterparts who proceeded directly from medical school into psychiatry—a feature that can be an asset.

“The residency is not so demanding that someone who is 40 or 45 can’t stand it,” said Deborah Hales, M.D., director of APA’s Division of Education, National, and Minority Programs, who began her career as a pediatrician.

“You come with an advantage over the younger residents,” she observed. “When I was beginning psychiatry training, it was mildly uncomfortable to be a lower-level resident again after having been the director of an adolescent clinic. But even though I knew nothing about psychiatry, I already knew how to be a doctor. That counts for something and makes the transition easier.”

## Psychology of Patients

The number of physicians who come to the field after training in another medical specialty is difficult to ascertain, but experts knowledgeable about workforce issues suggest it is not insubstantial.

Sydney Weissman, M.D., said that physicians enter into psychiatry at every stage in a career, and that they are invariably drawn by an interest in the psychology of their patients—not by salary.

“I’ve seen people with very successful medical practices drop it all to go into psychiatry residencies,” he told *Psychiatric News*. “The entry of people into psychiatry occurs throughout the practice life of a physician. It is not uncommon to have people in their 50s in a psychiatry residency.”

For many, a natural evolution can be seen—at least retrospectively—in the professional and personal choices that led them to psychiatry.

Heather Walter, M.D., M.P.H., director of children’s outpatient psychiatric services at Children’s Memorial Hospital of Northwestern University, began her career in emergency medicine, later switched to preventive medicine, and then trained in psychiatry and child psychiatry.

She chose emergency medicine “because

ter’s degree in public health.

Her initial interest was the prevention of cardiovascular disease through the reduction of known risk factors among adults. But in the early 1980s, autopsy studies began to appear with a remarkable finding: Some children had atherosclerotic plaques in their blood vessels.

“I devoted the next six years to developing, implementing, and evaluating cardiovascular risk-reduction programs for children,” Walter said.

“These programs were school based and delivered by teachers focusing on nutrition, physical fitness, and smoking prevention.



Deborah Hales, M.D., became a psychiatrist after she had been a pediatrician. Being an experienced physician before the switch made the transition easier.

In these kinds of programs, as in much of preventive medicine, the primary intervention is behavior modification.”

But the complexity of behavior change, and the extreme difficulty people experience in altering their behavior—even when the benefits of doing so are obvious—soon became impossible to ignore.

## The Puzzle of Behavior

A growing fascination with the multiple determinants of behavior change and resistance to change—both conscious and unconscious—and her own experience with psychiatry

please see *Career Choice* on page 38

# education & training

## Surprising Attitudes Found Among Some Medical Students

While a majority of future physicians at one medical school have a positive attitude toward psychiatric patients, a sizable minority view them negatively and would just as soon avoid them.

BY KEN HAUSMAN

Psychiatrists and advocates for the mentally ill have their radar finely tuned to pick up stigmatizing messages in print, on the airways, and on the big screen. But a recent study at one medical school found another venue where negative views of psychiatry and people with mental illness are common.

Unfortunately, that place is in the class-

rooms and hospitals that are training the next generation of physicians, according to data presented at the June meeting of the Association of Directors of Medical Student Education in Psychiatry (ADMSEP) in Jackson Hole, Wyo.

Nutan Vaidya, M.D., interim chair of the psychiatry department at Chicago Medical School and director of medical student education in psychiatry, said she found the

results of her survey of the attitudes of second-year medical students toward patients with psychiatric and neurological disorders “pretty depressing.”

Vaidya expected that once medical students were exposed to psychiatric and neurological illnesses and patients in their preclinical didactic classes (and then in their third-year clerkships), they would exhibit positive changes in their attitudes toward patients in these two medical areas.

“When students are more confident” in their ability to recognize psychopathology and have learned that these illnesses are treatable, they would be ex-

pected to develop a more positive attitude toward psychiatric patients and their illnesses, Vaidya said.

What she found, however, was that the students’ attitudes did not turn out to be as positive after exposure to extensive course work in psychiatry and neurology as she had hypothesized.

Vaidya used a survey instrument called the Medical Condition Regard Scale (MCRS), which was developed by psychiatrist George Christison, M.D., and colleagues at Loma

Linda University medical school. Subjects taking the MCRS indicate their attitudes toward particular illnesses on a six-point scale that ranges from “strongly disagree” to “strongly agree.” Eighty students responded.

She found that not only were attitudes of some of the sophomore medical students negative, but 28 percent said they did not find working with anxiety disorder or schizophrenia patients satisfying. In addition, 17 percent said they prefer not even to work with anxiety disorder patients, and more than 1 out of 3—35 percent—did not want to work with patients who have schizophrenia.

Also troubling, Vaidya noted, was that 25 percent of the students said they did not feel compassionate toward anxiety disorder or schizophrenia patients, while about 15 percent labeled both groups of patients “irritating.” In addition, 10 percent said there should not be insurance parity for anxiety disorder treatment, and 2 percent said the same for schizophrenia.

The attitudes of the students she surveyed may also bode poorly for future care of Alzheimer’s patients. Twenty-nine percent of the students said that they find working with these patients unsatisfactory. Thirty-one percent said that they would prefer to avoid working with such patients. Fourteen percent indicated they did not feel compassionate toward Alzheimer’s patients, and 4 percent did not think there should be insurance parity for Alzheimer’s disease care.

“In general, we found that the more chronic the disorder, the more negative the attitudes,” Vaidya noted.

While she found the survey results discouraging—and pointed out that they were only for one medical school—she said psychiatric educators could take heart from the fact that a majority of the medical students did indicate positive attitudes toward patients with anxiety disorders, schizophrenia, and Alzheimer’s disease and toward their ability to treat them compassionately.

Looking at the bright side, she said that her survey of students’ attitudes indicates “that the majority come in with positive attitudes, so the change is not significant.” In addition, these second-year students have not yet had the opportunity to see how medical interventions can actually improve the condition of psychiatric patients with chronic disorders, she suggested.

“The average physician should have a positive attitude toward psychiatric patients,” Vaidya said. “We [educators] want to make sure that our students don’t exhibit the same prejudice toward the mentally ill” as a large portion of the general public does. ■



**Nutan Vaidya, M.D.:** “In general, we found that the more chronic the disorder, the more negative the [students’] attitudes.”

**OSLER INST (2)**  
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**HSE--OFFICE RESEARCH**  
**AWARD “PRIORITY”**  
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# education & training

## Do Medical Students Benefit From Psychotherapy Training?

Almost every physician can benefit from learning key concepts underlying psychotherapy, but experts disagree over whether teaching psychotherapy is an efficient use of medical students' brief psychiatry clerkships.

BY KEN HAUSMAN

**I**t would be nearly impossible to find a psychiatric educator to disagree with the notion that all psychiatrists in training have to learn the theory and skills needed to conduct psychotherapy. But what about medical students fulfilling their psychiatry clerkship requirement?

Since most of those third-year students will enter medical fields other than psychiatry, are there far more important knowledge and skills that these students need to master in their four- to eight-week exposure to psychiatry?

A panel of medical educators at the June meeting of the Association of Directors of Medical Student Education in Psychiatry (ADMSEP) in Jackson Hole, Wyo., showed that there are different views on the issue among the people who design and oversee these psychiatry clerkships.

### Psychotherapy Training Premature

G. Scott Waterman, M.D., is among those who believe that teaching psychotherapy to medical students is largely a waste of valuable time, considering the amount of material that has to be crammed into a few weeks of a psychiatry clerkship. Waterman, an associate professor of psychiatry at the University of Vermont, suggested that if psychiatry clerkship directors asked themselves several questions, the conclusion about whether to teach psychotherapy would become clear.

First, he asked, "How can we best use the limited time clerkships offer for teaching our ever-growing discipline?" Is teaching psychotherapy techniques and knowledge something all physicians need to know? Will it prepare students to assimilate new data in treating and understanding psychiatric disorders?

Furthermore, during what part of the training and education sequence is it logical to teach psychotherapy? Should it come this early in training, when students have had minimal exposure to actual patients?

He indicated that the answers point to clerkships' being an inappropriate venue in which to instruct future physicians in psychotherapy, particularly since psychotherapy is a "longitudinal treatment, and clerkships are cross-sectional," Waterman said. He noted as well that medical students are rarely receptive to a treatment or theory that lacks a readily evident scientific basis, as is the case with psychodynamic psychotherapy, he said. Trying to cram a psychotherapy teaching module into a short clerkship may have the unintended consequence of reinforcing misunderstandings about it.

Waterman urged psychiatrists who educate medical students to focus instead on teaching clinical evaluation, differential diagnosis, and differential therapeutics. The best way to at least introduce medical students to psychotherapy is to teach its history and the philosophy behind it, he said, and indicate how its principles are "widely

agreed upon" by psychiatrists and mental health professionals.

### Continuous Training Needed

Taking the opposite position on the issue, Theodore Feldmann, M.D., an associate professor of psychiatry at the University of Louisville, maintained that psychotherapy is such an "essential compo-

nent" of psychiatric practice that it should indeed be a component of medical school psychiatry clerkships.

All patient encounters involve, or should involve, understanding and skills that are in the broadest sense part of the psychotherapeutic framework, he continued. Key concepts such as the unconscious, transference, and countertransference come into play in routine doctor-patient relationships.

While he acknowledged that psychiatry clerkships are far too time limited to instill

a comprehensive understanding of psychotherapy, Feldmann emphasized that psychiatric educators should "infiltrate the curriculum" by explaining psychotherapeutic



**Scott Waterman, M.D., believes clerkships are an inappropriate venue in which to instruct future physicians in psychotherapy.**

concepts at every opportunity. Doing so, he noted, will make them relevant to the practice of primary care and specialties other than psychiatry.

Of course, selling his idea to medical school course directors can be a challenge, he admitted.

His suggestions for spreading out the teaching of psychotherapy—curriculum content he has helped implement at

his institution—included, in the first medical school year, teaching basic interviewing skills, how to conduct a brief mental status exam, and basic counseling and cri-



sis-intervention techniques.

In year two, Feldmann advised teaching theories of personality development, more complex interviewing skills, how transference and countertransference enter the doctor-patient relationship, and theories and techniques of psychotherapy.

Third-year psychiatry clerkships can further expose medical students to psychotherapy by teaching elements of a psychiatric diagnostic formulation, providing supervised psychotherapy experience, having students write up a patient assessment, and writing a paper on psychotherapy. The clerkship at Louisville also provides a computerized cognitive-behavioral therapy experience, which was developed by a faculty member there, he said.

Janis Cutler, M.D., associate professor and co-director of medical student education in psychiatry at Columbia University, *please see **Psychotherapy** on page 37*

ADMSEP’s Ambitious Agenda

In 1974 a small group of psychiatrists who educate medical students about psychiatry decided they and their colleagues needed an official forum for exchanging curriculum ideas and keeping abreast of developments in this corner of medical education. By the next year, as a result of their initiative, a new organization was born—the Association of Directors of Medical Student Education in Psychiatry (ADMSEP).

Now with a membership of more than 130 educators representing medical schools throughout the United States and Canada, ADMSEP puts on a popular annual meeting and has an active list serve. Questions raised by members on the list serve have, in fact, generated several research projects in the field.

ADMSEP declares its mission to be

- Championing excellence in medical student psychiatric education.
- Supporting, developing, and disseminating research and innovation in teaching methods, content, and evaluation.

- Developing goals and objectives for medical student psychiatric education.
- Fostering the professional development and career satisfaction of medical student psychiatric educators.
- Providing support, guidance, and resources to medical students considering a career in psychiatry.
- Collaborating with other psychiatric and medical education organizations to pursue common interests.

ADMSEP leaders made a concerted effort to enhance the group’s collaborations with other psychiatric organizations focused on education and training in the early 1990s, when there was a dramatic drop in the number of medical graduates opting for careers in psychiatry. These liaisons were with organizations such as the American Association of Directors of Psychiatric Residency Training, Association for Academic Psychiatry, and APA.

Over its nearly three decades, ADMSEP’s “most valuable product,” according to former president Irwin Hassenfeld, M.D., “has been the informal relationships and friendships formed among members.”

## state watch

State officials honor the Massachusetts Psychiatric Society, and the GAO criticizes federal and state bureaucrats for failing to monitor Medicaid waivers.

BY KATE MULLIGAN

### MPS Increases Influence on Massachusetts Health Policies

No one wants to think about where to cut state budgets. For months, however, members of the Massachusetts Psychiatric Society (MPS) helped state officials consider how to curtail Medicaid prescription drug costs with minimal pain and disruption to patients and psychiatrists.

On June 24, Kenneth Duckworth, M.D., acting state commissioner of mental health, presented MPS President James Ellison, M.D., M.P.H., with the Clinical Excellence Distinguished Service Award for the society's advisory work in the development of the Massachusetts Health

Drug List, a preferred drug list using principles for drug formularies developed by MPS.

Ellison was one of four MPS representatives on the state's Psychopharmacology Work Group, which developed a program to educate physicians about costly prescribing habits that are not evidence based. As a result of the program, the number of patients taking five or more psychotropic medications went from 559 in January 2002 to 25 in January 2003. The cost went from \$305,000 a month for the first group to \$20,000 a month for the second (*Psychiatric News*, May 16).

In related news, MPS's immediate past president, Elizabeth Childs, M.D., has been

appointed state commissioner of mental health. Childs was director and chief of psychiatry at Carney Hospital in Dorchester.

Immediate APA past president Paul Appelbaum, M.D., who is from Massachusetts, told *Psychiatric News*, "This is the first time in more than two decades that Massachusetts has had a psychiatrist as commissioner of mental health. Dr. Childs's appointment is a wonderful and welcome example of psychiatrists moving back into positions of responsibility in the public sector. I'm sure she will do a great job."



**James Ellison, M.D., received the Clinical Excellence Distinguished Service Award on behalf of the Massachusetts Psychiatric Society.**

### CMS Faulted For Implementation Of Medicaid Waivers

The government's General Accounting Office (GAO) found that the Centers for Medicare and Medicaid Services (CMS) is not "fully complying with statutory and regulatory requirements when it renews [Medicaid] waivers."

Medicaid home and community-based services (HCBS) waivers are the primary means by which states provide non-institutional long-term care. CMS has the right

of approval for waivers and the legal obligation to monitor their impact through regional offices of the Department of Health and Human Services (HHS).

HCBS waivers can enable states to receive funding for transportation, nursing and personal-care services, respite care, and training of caregivers for the Medicaid population who is eligible for institutional care.

From 1991 through 2001, the HCBS waivers grew from 5 percent to 19 percent of Medicaid expenditures, representing \$1.6 billion to \$14.4 billion. From 1992 to 1999, the number of beneficiaries covered by waivers nearly tripled.

More than 70 percent of the waivers that the GAO reviewed documented one or more quality-of-care problems. The most common problems were "failure to provide necessary services, weaknesses in plans of care, and inadequate case management."

The HHS regional office in Dallas, for example, found that in Oklahoma 27 percent (4,303 beneficiaries) received none of their authorized personal-care services, and 49 percent received only half of their authorized services.

As of June 2002, almost one-fifth of the waivers in place for three years or more had either never been reviewed or were renewed without a review. For an additional 16 percent of the waivers, reports were never finalized.

States' waiver applications and annual reports for waivers often contained little or no information on state mechanisms for assuring quality in waivers, thus limiting information available to CMS when considering renewals.

In a written response to the report, CMS administrator Thomas Scully said that states are responsible for "quality assurance."

Sen. Charles Grassley (R-Iowa), one of two senators to request the GAO report, said, "These waivers should be put on hold until the department gets a handle on the quality of care going to older and disabled Americans."

In a letter to HHS Secretary Tommy Thompson, Grassley and Sen. John Breaux (D-La.) asked the Bush administration to submit a corrective plan by July 28.

Selby Jacobs, M.D., a member of the APA Committee on Public Financing of Psychiatric Care and a professor of psychiatry at Yale University, told *Psychiatric News*, "As the Bush administration attempts to shift greater control and management of Medicaid from the federal government to the states, we ought to fear not only for the quality, but also the adequacy of services. The GAO report contains alarming information that suggests what might happen if federal oversight over Medicaid continues to diminish. In my

## Resources Make Sex Talks Less Stressful

Parents no longer have to dread the “birds and bees” talk. Planned Parenthood is offering several resources to help families have informed discussions about sexuality.

BY EVE BENDER

To encourage parents to communicate with their children about sexuality and to educate the public about healthy and responsible sexual behavior, the Planned Parenthood Federation of America is promoting October as National Family Sexuality Education Month (NFSEM).

APA is one of a 57-member coalition supporting NFSEM, during which workshops, health fairs, and other forums for fostering family discussions about sexuality take place across the nation.

According to an NFSEM brochure, “age-appropriate information on sexuality leads to responsible sexual behavior in young people as they make the transition into adulthood. Lack of information, on the other hand, leads to misinformation and poses health and life-threatening risks in young people’s lives. . . .”

Mike McGee, vice president of education and social marketing at the Planned Parenthood Federation of America told *Psychiatric News* that young people are the targets of billions of dollars of advertising in which “sex is the star.” However, these messages are rarely accurate or realistic, he acknowledged.

“Parents are concerned about the messages their children are getting in regards to sexuality. They want to ensure that their children get accurate information so they can lead healthy and safe lives,” McGee said.

Planned Parenthood is distributing brochures aimed at helping parents speak more comfortably with their children about sexuality.

There are also guides tailored to young people, health professionals, educators, and others addressing many aspects of sexuality.

***More information about National Sexuality Education Month and resources for teens and parents is available on the Web at <[www.plannedparenthood.org](http://www.plannedparenthood.org)> or by calling (800) 669-0156.*** ■

opinion, leaving the standards for quality and adequacy to be worked out on a state-by-state basis—usually by behavioral managed care organizations that have contracted with the state Medicaid agency—would be a mistake. The federal government should not shirk its responsibility to set expectations for quality and adequacy that build greater accountability into the waiver process.”

“Long-Term Care: Federal Oversight of Growing Medicaid Home and Community-Based Waivers Should Be Strengthened” (GAO-03-576) is available on the Web at <[www.gao.gov](http://www.gao.gov)>.

### Oregon Rethinks Health Plan

Gov. Ted Kulongoski (D) and state legislative leaders sent a letter to President Bush committing the state to legislation that would overhaul the Oregon Health Plan (OHP) by rationing health care based on a resident’s income and medical need.

The state legislature is prioritizing populations of OHP enrollees based on income and ranking medical benefits within each income group. At the top of the benefit list

is mental health care, along with prescription drugs, laboratory and X-ray work, and doctor visits, according to <[www.kaisernetwork.org](http://www.kaisernetwork.org)> on June 13.

The OHP gained national attention as an early effort to expand Medicaid coverage to more low-income people by prioritizing and limiting medical services (*Psychiatric News*, April 19 and October 18, 1991).

John McCulley, Oregon Psychiatric Society executive secretary, said that the state legislature’s Joint Ways and Means Committee is considering appropriations for the legislation. “We’re pleased that mental health has been regarded as a high priority. Mental health advocates were also able to keep psychotropic medications out of the group of medications that is to be subject to capitation.”

As of July 1, Kulongoski had signed a stop-gap budget bill that would stave off for one month new cuts in health benefits. Cuts are still in effect for coverage of outpatient mental health care for 100,000 OHP members who lost those benefits on March 1 (*Psychiatric News*, April 4).

### Federal Tax Cut Impact Could Reverberate At State Level

States had good news in the legislation (HR 2) that authorized a \$350 billion package of tax cuts.

The law, signed by Bush on May 28, included \$10 billion to increase the federal matching rate for Medicaid by 2.95 percent until October 24, 2004, and \$10 billion in direct aid to state governments.

State officials, however, are finding that the impact of the short-term increased support from the federal government could be tempered by the loss of state tax revenue.

State and federal tax laws frequently are “coupled” so that cuts at the federal level trigger cuts at the state level.

### House Passes Bill Threatening State Parity Laws

The Small Business Health Fairness Act (HR 660) passed the House of Representatives in late June by a vote of 262-162 and has been referred to the Senate Committee on Health, Education, Labor, and Pensions.

The bill, which addresses the problem

of the growing number of Americans without health insurance, would allow businesses in the same trade groups to form association health plans (AHPs).

Those plans would be exempt, however, from state laws that mandate parity and provide consumer protections.

In fact, in September 2002 the Department of Labor released a report that praised AHPs because “by operating under federal law, [they] can avoid the cost of state benefit mandates” (*Psychiatric News*, May 2).

In January APA joined other members of the Mental Health Liaison Group in a letter to Rep. Dennis Hastert (R-Ill.), speaker of the House, and Sen. William Frist (R-Tenn.), Senate majority leader and a physician, opposing legislation that “would exempt association health plans from state regulation and thereby undermine state mental health parity laws and other critical consumer protections.” ■

# HSE-ANN MTG TAPES

## PBW



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# Most NAMI Chapters Dodge State Budget Ax

**Although public mental health is being hit hard by state budget crises, state affiliates of the National Alliance for the Mentally Ill are faring, on the whole, fairly well as far as state funding is concerned.**

BY JOAN AREHART-TREICHEL

In late June, three of the four employees of the National Alliance for the Mentally Ill in Alaska “packed it in,” as the saying goes. The reason? NAMI Alaska—which was dependent almost entirely on state funds for its existence—had been advised that it would lose all of its funding from the state once the state’s new fiscal year started on July 1.

“NAMI Alaska is not going to go away,” Beth LaCrosse, president of NAMI Alaska, told *Psychiatric News*. “They may take our money, they may take our building, but they can’t stop the grass roots from continuing to speak out and provide support, education, leadership, and advocacy. We have basically an all-volunteer staff now until we can find other sources of funding.”

The predicament of NAMI Alaska raises the issue of how other NAMI affiliates are faring. After all, numerous states are experiencing budget crises, with devastating effects on public mental health care.

NAMI California will probably be receiving less state money during Fiscal 2003-04 than before, Grace McAndrews, executive director of NAMI California, told *Psychiatric News*. And if that is the case, then NAMI California will have to do away with its Family-to-Family Education Program. The program is a 12-week course offered by family members of persons with a serious mental illness for other family members who also have a loved one with a serious mental illness. Forty-five other state chapters of NAMIs have also been offering the program (*Psychiatric News*, July 4).

Although NAMI Maine will not be receiving any cuts in state funds during the

current fiscal year, it *will* be taking a 19 percent hit during Fiscal 2004-05 on top of a 20 percent reduction between Fiscal 2001 and 2003, Carol Carothers, executive director of NAMI Maine, said. This reduction, she said, means that NAMI Maine will have to lay off staff and reduce a number of programs—for instance, helping persons with mental illness and their families on a one-to-one basis, keeping a hot line/warm line open five days a week, and participating in policy making.

In contrast, “most state NAMIs did not receive a significant cut in state funding” for Fiscal 2003-04, Katrina Gay, chief of field operations for NAMI’s national office, headquartered in Arlington, Va., told *Psychiatric News*. For instance, NAMI Kansas got \$3,500 less, which is about 5 percent less than last fiscal year. In other words, as far as state funding for state NAMIs during Fiscal 2003-04 was concerned, “it was not as devastating as we had expected,” Gay acknowledged.

In fact, some state NAMIs will continue to receive about the same amount of state funds during Fiscal 2003-04 as during the last one. One example is NAMI New Jersey, Phil Lubitz, its director of advocacy programs, told *Psychiatric News*. Another example is NAMI Ohio, said Stacy Smith, director of operations there.

Moreover, some state NAMIs have even gotten modest increases in state funding, Gay pointed out. Thus overall, the state NAMI budget for Fiscal 2003-04 has increased, not decreased.

“Yes, it’s very interesting,” Gay said, “and while I don’t know why, I can speculate. Some of the core services that NAMI provides are doing a good job. Yes, we are an advocacy organization, and that is the heart of what we do. But in addition to advocacy, we provide support and education, which are vital to the community. So I’d like to think that NAMIs are seen as a valuable asset; otherwise, they wouldn’t continue to be funded in times of budget cuts.”

What makes NAMI Alaska’s situation so unusual and so critical, Gay explained, is not just that it lost all of its state funding, but that it depended almost entirely on this funding. And the same can be said about NAMI Maine. It is 98 percent dependent on the state for money, Carothers said, so that a reduction in state funding of 39 percent between Fiscal 2001 and 2005 translates into a similar reduction in its entire budget during those four years.

Thus, national NAMI encourages its state affiliates to seek funding from many sources, so that if one source dries up, it has others to fall back upon, Gay stressed. Indeed, that is what NAMI California has been doing, McAndrews pointed out. Even if it has to eliminate its Family-to-Family Education Program, “in the scheme of our budget, it’s not that much,” she said.

Besides the states, Gay said, other money sources for state NAMIs include the federal government, corporations, private foundations, membership dues, and donations from individuals. Individual donations are probably the largest source of revenue.

When state NAMIs get money from the federal government, Gay explained, it often comes through a block grant from the federal Center for Mental Health Services, and when they get money from the state, it is usually in the form of a grant, but sometimes in the form of a contract. ■



# Psychiatry Fellows to Be Integral Part of Institute

Psychiatry residents who are APA/Bristol-Myers Squibb fellows will get valuable experience as faculty at this fall's institute.

BY BEATRICE EDNER

A highlight of every Institute on Psychiatric Services is a series of sessions featuring APA/Bristol-Myers Squibb fellows as faculty. These third- and fourth-year residents were selected for the fellowship based on their record of academic and professional achievement and their commitment to the field of public psychiatry. Since the fellowship's founding, approximately 300 APA/Bristol-Myers Squibb fellows have participated in the institute and presented highly acclaimed and well-attended workshops.

This year's institute features the following sessions to be presented by 2002-04 APA/Bristol-Myers Squibb Fellows:

- "Criminals or Patients? Attitudes of Psychiatrists to Emotionally Disturbed Persons"
- "Media and Psychiatry: Friend or Foe?"
- "Perception Becomes Reality: Patients' Views on Physician and Pharmaceutical Industry Relations"

The 2002-04 fellows are Claire Monica Belgrave, M.D., of SUNY Downstate Medical Center; Leslie L. Buckley, M.D., M.P.H., of the University of Toronto; Grace Monica Cotelingam, M.D., of the University of Maryland School of Medicine; Caroline E. Fisher, M.D., Ph.D., of the University of Massachusetts Medical School; Elizabeth B. Ford, M.D., of New York University School of Medicine; Elizabeth R. LeQuesne, M.D., of Columbia University College of Physicians And Surgeons; Joelle Pauporte, M.D., of Cornell University, Payne Whitney Clinic; Bruce E. Rudisch, M.D., of Emory University School of Medicine; Allison Mary Wehr, M.D., of Harvard Longwood; and Karen S. Wiviott, M.D., J.D., of Northwestern University Medical School.

Bea Edner is manager of the APA/Bristol-Myers Squibb Fellowship in Public Psychiatry.

## Register Now!

A copy of the preliminary program booklet, which includes registration, housing, and air travel information, can be obtained by calling the APA Answer Center at (888) 357-7924 or by clicking on the IPS logo on APA's Web site at <www.psych.org>.

### Register in one of three ways:

- Register online by going to the Web site <www.psych.org/sched\_events/ips03/registration/regindex.cfm> and click on "Register Online."
- Download a registration form at <www.psych.org/sched\_events/ips03/registration/regindex.cfm> and mail or fax the completed form to APA.
- Use the registration form found in the preliminary program booklet and mail or fax the completed form to APA.

Save on fees by registering before September 29.

In addition to the 10 fellows serving as faculty, the institute will welcome the recently selected 2003-05 APA/Bristol-Myers Squibb Fellows. They are Kathleen D. Asklund, M.D., of Dartmouth Medical School; Peter C. Iversen, M.D., of Wright State University School of Medicine; Angela L. Leon-Guerrero, M.D., of the University of Texas Southwestern Medical Center at Dallas; Holly V. MacKenna, M.D., of Louisiana State University Health Sciences Center; Edward J. Maxwell, M.D., of Brown University; Jennifer M. Rosenberg, M.D., of

Harvard Longwood; Bobby Singh, M.D., of the University Hospitals of Cleveland; David Lucas Smith, M.D., of the University of North Carolina School of Medicine; Peter B. Stanbro, M.D., of Boston University School of Medicine; and Stephen M. Thielke, M.D., of the University of Washington School of Medicine.

Both fellowship classes will participate in a number of activities designed to augment the institute's program and provide opportunities to become acquainted with leaders in the field. Additionally, they will join other residents in the sessions that the program committee has arranged specifically for resident attendees.

The APA/Bristol-Myers Squibb Fellowship is funded through a grant to APA by Bristol-Myers Squibb Company. ■



Dating back to 1634, the Boston Common and Public Gardens provide 75 acres of green space in the heart of Boston's densely packed downtown core.

## Drug-Company Marketing Tactics Grist for Institute Debate on Ethics

Does pharmaceutical marketing influence physicians' clinical decisions? Or are physicians informed practitioners quite capable of making objective decisions?

BY CHARLES HUFFINE, M.D.

The role of pharmaceutical companies in psychiatry is being hotly debated within our profession. No issue raises more passion than that of the propriety of these companies attempting to influence our clinical decision making. Also of concern is the perception of those outside the profession of psychiatry that drug companies can influence psychiatrists with presents, dinners, and free samples.

This issue appears frequently on the American Association of Community Psychiatrists (AACP) list serve. Lately, the discussions have had a degree of intensity that seems to mirror the growing ambivalence regarding pharmaceutical companies.

In an effort to bring some depth and wisdom to that discussion, the Scientific Program Committee of APA's Institute on Psy-

chiatric Services offers the debate "Resolved: It Is Unethical for Psychiatrists to Invite Sales Representatives to Market Products Through Such Methods as Educational Materials, Samples, and Gifts in Clinical Settings."

The participants in this debate are, on the affirmative, Charles Goldman, M.D., director of public psychiatry training in the department of neuropsychiatry and behavioral sciences at the University of South Carolina; and, on the negative, Michael Silver, M.D., of the Providence Center and a member of the clinical faculty at Brown University in Rhode Island and a former AACP president. David Moltz, M.D., co-chair of the AACP's Ethics Committee, will be the moderator.

Both Drs. Goldman and Silver are thoughtful leaders in community psychiatry and are passionate about ethical issues in our profession. It will be a treat hearing this affect-filled subject dealt with by two such wise and gracious colleagues. ■

Dr. Huffine is a member of the Scientific Program Committee of the 2003 Institute on Psychiatric Services.

AMERICAN PSYCHIATRIC ASSOCIATION  
55th INSTITUTE ON PSYCHIATRIC SERVICES



Access to Integrated  
Mental Health Care

October 29-November 2, 2003



The Massachusetts State House, across the street from Boston Common, was designed by Charles Bulfinch and completed in 1798.

## Time to Register For Institute's CME Courses

Register now for any of the 16 CME courses to be offered at APA's Institute on Psychiatric Services. They offer interactive learning in a small-group format.

There will be 16 CME courses offered at APA's 55th Institute on Psychiatric Services. The CME courses provide an in-depth, interactive learning experience taught by master instructors on various subjects in the field of psychiatry.

The courses will cover a wide range of topics, including clinical techniques and advances in theoretical models. The courses are taught at a basic level, requiring no previous experience or knowledge unless specifically noted otherwise.

The fees for courses are as follows:

- **Half day** (four credit hours): advance, \$100; on-site, \$130
- **Full day** (six credit hours): advance, \$160; on site, \$185

To maintain the small-group learning environment and facilitate discussion, enrollment is limited. The number of participants for each course is predetermined on the basis of the topic and specific format of the course. This allows the faculty to preserve the interactive atmosphere that has made the courses so consistently popular, yet makes it extremely important to enroll early. The deadline for course enrollment and advance registration is September 29.

Additional information about the courses is available by contacting Liz Rumsey by phone at (703) 907-7813 or by e-mail at [erumsey@psych.org](mailto:erumsey@psych.org). See box at left for registration information. ■



## Universal Health Insurance Won't Break Bank

**The cost of providing care to the 41 million uninsured people in the U.S. would be less than annual inflation in health spending, but still would require a commitment of new resources in a time of fiscal deficits.**

BY MARK MORAN

**A**dditional medical care provided to newly insured people under a system of universal health insurance coverage would increase total health care spending about 3 to 6 percent.

That translates into an increase in the health care portion of the gross national product of less than 1 percent, according to a report prepared for the Kaiser Commission on Medicaid and the Uninsured and published on the *Health Affairs* Web site on June 4.

Jack Hadley, PhD., a principal research associate at the Urban Institute, told *Psychiatric News* that the finding suggests the cost of universal health coverage is not as insurmountable as sometimes thought.

"The most important finding is that if you think of the cost of providing insurance as a cost of providing additional medical care for people who are currently uninsured, it is a relatively small amount of money," Hadley said. "We should not think of universal coverage as an unaffordable or unattainable objective."

In the study, Hadley and co-author John Holahan, also of the Urban Institute, based their estimates on two scenarios: the first assumed that medical spending by the newly insured would be similar to that of either low- or middle-income people covered by the "average" private insurance policy; the second assumed that spending would resemble that of people covered by the "average" public insurance policy (usually Medicaid or State Children's Health Insurance Program).

The analysis suggests that the uninsured would use \$33.9 billion to \$68.7 billion (in 2001 dollars) in additional medical care if they were fully insured, depending on which scenario is used.

Hadley acknowledged that there has been debate about the actual numbers of uninsured, since many Americans are uninsured for only a portion of a year (*Psychiatric News*, June 20). But he said the analysis includes cost estimates of full-year coverage for those among the uninsured who have part-year coverage.

"This study shows that the direct cost of providing care to the 41 million uninsured would be less than annual inflation in health spending—which was 8.7 percent in 2001—but still would require a commitment of new resources in a time of fiscal deficits," said Diane Rowland, executive director of the Kaiser Commission on Medicaid and the Uninsured.

Data for the analysis are from the Medical Expenditure Panel Surveys conducted in 1996, 1997, and 1998. The survey is a nationally representative sample of the noninstitutionalized population and contains detailed information on annual total charges and payments for health care used, monthly information on insurance coverage, and demographic and health characteristics.

In the estimates for additional medical spending based on average private insurance, people making more than 400 percent of the poverty level were excluded from the

analysis. This was to avoid possible differences in care-seeking behavior resulting from differences in socioeconomic status between the uninsured and higher-income people with full-year coverage. The latter might be more likely to use costly, out-of-network providers than would lower-income people with the same insurance coverage, and would be generally less deterred by cost sharing, according to the study authors.

Under an "average" public health plan, estimated per person spending by people previously uninsured for any part of the year would rise by a little over 50 percent, increasing from \$1,383 to \$2,121, according to the study.

Under an "average" private health plan, per person spending would rise to \$2,676. Hadley cautioned, however, against drawing an assumption that publicly funded universal health care would necessarily be "better" than privately funded care.

"We do estimate public insurance to be less costly than private insurance, mainly because it is stingy to the extent that Medicaid can cover people at lower payment rates," Hadley said. "If public programs were to expand, and all people were in a public program, my guess is that political pressure would mount to increase payment rates."

By looking strictly at the additional cost of medical care for newly insured people,

the analysis assumes a "perfectly targeted" reform strategy. Plans to expand coverage typically entail larger cost increases for government because some privately insured people will inevitably switch to the government-subsidized plan, he said.

Further, by looking at "average" health plan characteristics, the analysis does not take into account assumptions about specific features of potential plans, such as mental health benefits.

Nonetheless, Hadley said, "there is pretty good evidence that when people are uninsured, they tend to show up for care at a more advanced stage. The process of care with insurance would be more effective and efficient with benefits that would potentially offset some of these costs."

***The article, "Covering the Uninsured: How Much Would It Cost?," is posted on the Web at <[\*\*24\*\* PSYCHIATRIC NEWS / August 1, 2003](http://www.kff.org/content/2003/20030604/>. ■</a></i></b></p>
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# Cost of Bringing New Drugs To Market Rising Rapidly

Rising costs for clinical testing of new drugs, among other factors, appear to have contributed to a steep increase in total research and development costs for drug manufacturers.

BY MARK MORAN

**T**he average total research and development cost for new drugs in the late 1990s was \$897 million, according to a report by the Tufts Center for the Study of Drug Development.

That total was more than double the average total cost of bringing a new drug to market in the 1980s, and more than five times the cost in the 1970s.

This rapid rise in research and development (R&D) costs has been driven largely by steep increases in the costs of clinical testing, which have grown five times as fast as preclinical testing costs, the center states.

The Tufts Center for the Study of Drug Development, affiliated with Tufts University, provides strategic information to help drug developers, regulators, and policymakers improve the quality and efficiency

of pharmaceutical development, review, and utilization.

"The overall increase in costs was largely driven by increases in development costs during the clinical studies period, as opposed to basic research," Joseph DiMasi, Ph.D., director of economics for the center, told *Psychiatric News*. "The number of subjects has increased substantially over the period, and the complexity of clinical trials has increased, with more procedures being applied and more tests than in the past."

A particularly noteworthy component of the increase in costs of clinical testing is the rise in "postapproval" research and development. This refers to clinical studies performed after FDA approval—known as Phase IV studies—which are often mandated in the case of drugs that are put on a fast track for approval. Fast-track approval status requires manufacturers to commit to continuing clinical testing after marketing approval.

Most of the drugs on fast-track approval are developed for cancer or AIDS, DiMasi said. While fast-track approval was originally designed for drugs to treat life-threatening conditions, he continued, it is increasingly being used for drugs to treat serious conditions, but not immediately life threatening.

"The FDA is opening more drugs to postapproval commitments, thereby shifting the R&D costs to the postapproval period," DiMasi said.

## Other Reasons at Work

Also contributing to the rise in clinical testing costs is the fact that more companies are testing their products against competitors' drugs, as opposed to testing them against a placebo. Those tests are longer and require larger sample sizes, DiMasi said.

Alan Gelenberg, M.D., chair of APA's Committee on Research on Psychiatric Treatments, acknowledged the validity of the study's findings, but said there may be many factors involved in the increase in R&D costs that are unrelated to the development of drugs, including the costs of mergers within the pharmaceutical industry.

Gelenberg also said that while the pharmaceutical industry is spending more money on research and development, researchers at academic medical centers—which have traditionally relied on pharmaceutical funding of clinical studies to finance research projects—have actually found their resources shrinking as companies have turned to contract research organizations to conduct clinical studies.

Gelenberg is professor and chair of psychiatry at the University of Arizona.

## Three Decades of Studies

The Tufts Center study is the third in a series of studies on the costs of drug development. The first, published in 1979, looked at the costs of drugs brought to market approval during the 1970s; the second looked at costs in the 1980s; the recent study looks at costs of research and development for drugs brought to market in the late 1990s.

Data for the present study were obtained from 10 multinational, foreign, and U.S. pharmaceutical firms through a confidential survey. Data were collected on clinical phase costs for a randomly selected sample of investigational drugs in development by firms participating in the study. Sixty-eight drugs were studied, including those that made it to market, drugs that were not brought to market, and some that were still in development.

DiMasi told *Psychiatric News* that a new study not yet published will be looking at costs of drug development by therapeutic category. That report will look at drugs in four categories: analgesic drugs, anti-infection drugs, central nervous system drugs, and cardiovascular drugs.

Another noteworthy finding, DiMasi said, was that drug companies appear to have become better at weeding out drug failures early in the development process. The rate of drugs that failed Phase I testing was 37 percent in the 1990s, compared with 32.5 percent in the 1980s.

Yet even with this increasing success at weeding out failures before they proceed to more expensive testing and development, only 21.5 percent of the drugs that begin Phase I clinical trials ever get to market, according to the center.

"Making the process more efficient involves making earlier decisions and attempts to shorten the development process," DiMasi said. ■



COMPILED BY JIM ROSACK

### Regulatory and Legal Briefs

• **Lamictal** was approved June 23 by the FDA for the maintenance treatment of adults with bipolar I disorder. The drug delays the onset of mood episodes (depression, mania, hypomania, mixed episodes). Lamictal is only the second medication (lithium was the first) to be approved for the long-term maintenance of patients with bipolar disorder. While Lamictal delays the onset of mood episodes, it has not been found to be an effective treatment for ending an acute mood episode. Common adverse events include nausea, insomnia, somnolence, back pain, and rash. Complete prescribing information is available on the Web at <www.lamictal.com>.

### Research Briefs

• Monitoring **lithium** levels is routine; however, new research indicates that the utility of lithium blood levels in women who are breast-feeding may not be a good estimate of how much of the medication may be passing to the infant. In a study from the Motherisk Program in Toronto, lithium levels present in breast milk were found to be widely variable, ranging from zero to 30 percent of the maternal dose. *Therapeutic Drug Monitoring* 2003; 25(3):364-366

• **Antipsychotic prescribing** has been shown in the past to be subject to cultural and racial bias. A new analysis of data from January 1996 through August 1998 indicates the bias was still present. When other demographics were controlled for in a sample of 2,600 patients receiving medication through the Texas Medicaid system, African Americans were found to be significantly less likely to receive a newer, atypical medication, such as olanzapine, than haloperidol. *J Clin Psychiatry* 2003; 64:635-639

• **NSAIDs** may not be of any benefit to patients with Alzheimer's disease. Non-steroidal anti-inflammatory drugs have been linked in previous research to a slowing of the rate of decline of patients with mild to moderate Alzheimer's. Laboratory data have also indicated that these drugs may decrease the formation of pathological amyloid plaques. However, in a report from the Alzheimer's Disease Cooperative Study consortium, two NSAIDs, rofecoxib and naproxen, were found to have no signifi-

cant effect on patients' ADAS-Cog scale scores compared with placebo over one year. *JAMA* 2003; 289(21):2819-2826

• Long-term **benzodiazepine** use does not appear to lead to notable escalation in doses. A review of more than 2,400 patients in the New Jersey Medicaid system looked for patients who had received prescriptions for benzodiazepines indicating at least two years of continuous use. No clinically or statistically significant changes in dosage were observed over time. The overall incidence of escalation of dose was 1.6 percent. Those at higher risk of dose escalation were patients who also were prescribed antidepressants and those who filled duplicate prescriptions at multiple pharmacies over short periods of time. Elderly and disabled patients had lower risk of dose escalation than did younger patients. *Psychiatric Services* 2003;54:1006-1011

• Discontinuation of **antidepressants** in patients with bipolar disorder significantly increases patients' risk of depressive relapse. A total of 84 patients who had achieved remission from a depressive episode with an antidepressant added to a mood stabilizer were followed for at least one year. One year after successful antidepressant response, 70 percent of the 43 patients who had stopped the antidepressant within the first six months had expe-

rienced a depressive relapse, compared with 36 percent of the 41 patients who had continued their antidepressant medication beyond six months. No apparent effect was seen in incidence of manic episodes between the two groups. *Am J Psychiatry* 2003; 160:1252-1262

• **Escitalopram** appears to be effective and is well tolerated by patients with depression treated in the primary care setting. An eight-week, double-blind, placebo trial compared escitalopram with citalopram and placebo. Escitalopram was statistically significantly better than placebo, based on scores from the Montgomery-Asberg Depression Rating Scale. In addition, both medications were well tolerated, with adverse effect rates equivalent to those of placebo. Patients taking escitalopram had a significantly higher rate of response than those taking both placebo and citalopram. *Int Clin Psychopharmacology* 2003; 18(4):211-217

• **Sertraline** may be more effective than **fluoxetine** for treatment of anxious depression. In an analysis of five double-blind comparator studies with a total of 650 patients, both drugs were found to have a comparable antidepressant effect in general in patients with major depression. However, when data were analyzed according to subgroups of patients with anxious depression compared with those with severe depression, sertraline was linked to significantly greater im-

provement on the Hamilton Depression Rating Scale in those with anxious depression. *Int Clin Psychopharmacology* 2003; 18(4):203-210

• **Sertraline** appears to be effective and well tolerated in elderly patients with depression. In a study of more than 550 patients randomly assigned to receive either sertraline or placebo, the patients taking sertraline had significantly more improvement in their scores on the Hamilton Depression Rating Scale and the Clinical Global Impression severity and improvement subscores. *Am J Psychiatry* 2003; 160:1277-1285

### Industry Briefs

• Forest Laboratories announced June 19 that a preliminary analysis of data showed that there was no significant difference between patients who had mild to moderate Alzheimer's disease and were given **memantine** in combination with a cholinesterase inhibitor compared with patients who received placebo and the same cholinesterase inhibitor.

Previous research had shown both reductions in the rate of decline as well as improvement in scores on cognitive exams in patients with severe Alzheimer's disease taking memantine alone. Researchers had hoped that the combination of memantine, added to standard cholinesterase therapy would produce more improvement than memantine alone. ■

## health care economics

# Slashing Methadone Programs Carries Hidden Costs

Evidence that methadone treatment saves money comes from the streets of Portland and from a think tank in North Carolina.

BY KATE MULLIGAN

**R**eal-world experience and a speculative cost-simulation model both lead to a similar conclusion.

Methadone treatment saves money when its price tag is offset by the costs to the criminal justice system of persons who are addicted to heroin.

Oregon Public Radio (OPR) examined the impact of the forced weaning of an estimated 1,500 addicts off methadone when that treatment was phased out beginning March 1.

The reduction in services came about when Oregon state officials eliminated prescription drug benefits, outpatient mental health benefits, and substance abuse treatment for 100,000 persons who are eligible for the Oregon Health Plan but do not meet income-eligibility criteria to be part of the "mandatory" population guaranteed coverage through the Medicaid program.

Typically, they are adults whose incomes are below the federal poverty level but who do not otherwise qualify for Medicaid by fitting into a category of eligibility defined in Medicaid legislation (*Psychiatric News*, April 4).

At the time, David Pollack, M.D., medical director of the Office of Mental Health and Addiction Services in the Oregon Department of Human Services, told *Psychi-*

*atric News* that the elimination of reimbursement for methadone is a good example of how many of the cuts are "penny wise, but pound foolish."

OPR reporter Kristian Foden-Vencil reported on April 4 that Cliff Jensen, commander of Portland's East Precinct, said that crimes like burglary and shoplifting were up more than 40 percent since January. Jensen said that the "addictive lure" of drugs like methamphetamine and heroin is so strong that people who are no longer getting help at social-service agencies are reverting to their previous lifestyles.

She also quoted Gerald Parker, a recovering addict who was losing his methadone treatment. He warned the public of the effect of the cuts. "There's going to be a lot more stealing; the stores are going to start raising their prices again. If you get caught, you'll have to go to the judicial system, where it costs them to take you to court. Housing in the jails [costs money as well], so it's going to cost more in the long run than to pay for the methadone program."

In a presentation at the AcademyHealth meeting in Nashville in June, Gary Zarkin, Ph.D., offered a different kind of testimony to the economic costs of addiction. He said that the mean figure was \$1,061,639 for

lifetime crime and criminal justice costs for an individual who had ever used heroin.

That finding came from a speculative analysis in which the benefit-cost ratio for outpatient methadone treatment was calculated over the lifetime of an individual through use of a simulation model.

Zarkin is director of the Center for Interdisciplinary Substance Abuse Research at RTI International in North Carolina.

He said that previous studies had examined the costs and benefits of a single-treatment episode. Those studies typically have yielded a cost-benefit ratio of 4.9. Drug abuse, however, is a chronic condition and usually is not treated successfully in one treatment episode. So, according to Zarkin, a simulation model is helpful because it can predict benefits and costs over a lifetime. With the model, the lifetime cost-benefit ratio rose nearly 10-fold to 40.

A simulation model is an analytical method meant to imitate a real-life system. It calculates multiple scenarios of a model by repeatedly sampling values from probability distributions for the uncertain variables and using those values for the cell.

Researchers have used simulation models to evaluate costs and benefits of treatment for other chronic conditions, such as coronary heart disease and diabetes.

Zarkin and his colleagues used age, gender, current heroin use, heroin use history, methadone treatment history, and employment status to establish probability distributions. They considered six outcome factors that are central to determining the cost-benefit ratio: heroin use, methadone treatment, criminal behavior/criminal justice, time spent incarcerated, employment, and health care costs. ■

## Medication Names and Manufacturers

The following medications appear in this edition of Med Check.

- **Citalopram:** Celexa (Forest)
- **Escitalopram:** Lexapro (Forest)
- **Fluoxetine:** Prozac (Lilly), generic
- **Haloperidol:** Haldol (McNeil)
- **Lamotrigine:** Lamictal (GlaxoSmithKline)
- **Lithium:** Lithobid (Solway), Eskalith (GSK), numerous generics
- **Memantine:** brand name pending FDA review (Forest)
- **Naproxen:** Anaprox (Roche)
- **Olanzapine:** Zyprexa (Lilly)
- **Rofecoxib:** Vioxx (Merck)
- **Sertraline:** Zoloft (Pfizer)

# PFIZER XANAX XR P4C

# PFIZER XANAX XR P4C



# PFIZER XANAX XR P4C

# Intimate-Partner Murders Tied to Several Factors

**What factors increase a woman's chances of being murdered by her partner? Having a physically abusing, unemployed, gun-possessing, or threatening partner are four of them, a new study suggests.**

BY JOAN AREHART-TREICHEL

**E**ven though American women may fear being murdered by a stranger on the streets, they are more likely to be killed by a spouse, lover, ex-spouse, or ex-lover.

But which intimate partners pose the greatest dangers to American women? Jacquelyn Campbell, Ph.D., a professor of nursing at Johns Hopkins University, and

colleagues, conducted a study to answer that question.

The focus of their study was 220 women who had been killed by intimate male partners, the intimate partners themselves, 343 women who had been physically abused or threatened with a weapon by a current or former intimate partner within the past two years, and the current intimate partners of these 343 women. In other words, the 343

women and their current partners served as control subjects.

The researchers compared certain characteristics of the partners who had killed with those of the current partners of the 343 control subjects to identify factors that increase a woman's chances of being murdered by her intimate partner.

The researchers found that 70 percent of the partners who had killed had been physically abusive, whereas only 10 percent of the current partners of the control subjects were physically abusive. Thus, physical abuse appears to be a major risk factor for intimate partner femicide, as other studies have found.

What's more, having a partner who is unemployed, has a gun, and threatens to kill his partner were found to be risk factors. So was a partner's use of illicit substances. However, a partner's use of alcohol was not, nor were a partner's prior arrests for intimate-partner violence. In fact,

arrests for domestic violence actually decreased the risk of murder.

Campbell and her team also used the data they had collected about their subjects to pinpoint circumstances that increase a woman's chances of being slain by an intimate partner. One, they found, is living with an intimate partner while also living with a child from a previous relationship.

Another is living with a physically abusive partner, then separating from him, especially if he is highly controlling. Still another is leaving a physically abusive partner for another partner.

The results of the study by Campbell and her colleagues appear in the July *American Journal of Public Health*.

The study was funded by the National Institutes of Health, Centers for Disease Control and Prevention, and National Institute of Justice.

*An abstract of the study, "Risk Factors for Femicide in Abusive Relationships: Results From a Multisite Case Control Study," is posted on the Web at <[www.ajph.org/cgi/content/abstract/93/7/1089?](http://www.ajph.org/cgi/content/abstract/93/7/1089?)>.* ■

## Autism Research Focus of Major NIMH Initiative

**Autism researchers at academic centers across the U.S. are benefiting from a five-year grant from the National Institutes of Health.**

**T**he National Institutes of Health (NIH) has awarded almost \$10 million in grants to six new research centers to study the biological basis of autism and advance treatments for those with autism.

The funding is part of a larger initiative of NIH called the Studies to Advance Autism Research and Treatment Centers Program (STAART), which is funded by the NIH Autism Coordinating Committee.

"This major network of centers will accelerate advances in our knowledge about autism causes and treatments and help us to achieve our mission of reducing the burden associated with autism spectrum disorders," said Thomas Insel, M.D., in an NIH press release last month.

Insel is director of the National Institute of Mental Health and chair of the NIH Interagency Autism Coordinating Committee.

The STAART centers that received funding are located at the University of Washington in Seattle, which received \$1.6 million to research autism; University of California, Los Angeles, \$1.4 million; Boston University, \$1.7 million; University of Rochester, \$1.5 million; Kennedy Krieger Institute in Baltimore, \$1.5 million; and Mt. Sinai Medical School, \$1.6 million.

Last year NIH funded two STAART autism researchers at the University of North Carolina-Chapel Hill and at Yale University.

Investigators at each STAART center will use the grant money to conduct research on autism's causes, diagnosis, early detection, prevention, and treatments.

This year's grants are just the beginning—NIH is expected to spend \$65 million over the next five years on the eight autism research centers, according to the press release. ■

**ASTRA ZENECA SERO-  
QUEL (AKATHISIA)  
P4C**

# Skepticism Greets Report Of Schizophrenia Recovery

Schizophrenia has long been considered a chronic, neurodegenerative disease. Yet some people do improve considerably over time, raising questions about both the definition of the disease and the meaning of the word “recovery.”

BY MARK MORAN

**T**he unblighted landscape of lucidity and mental health and the delusional regions of schizophrenia are believed to be separated by a chasm no one traverses.

Yet Frederick Frese, Ph.D., has by his own account crossed the terrain more than once, as if the two places were a contiguous territory with an uncertain boundary.

A psychology faculty member in the departments of psychiatry at two medical schools, a frequent speaker, a former board member and vice president of the National Alliance for the Mentally Ill, and a long-time clinician at a major psychiatric hospital, Frese would seem to have covered, and recovered, much ground since the days when he was first diagnosed with paranoid schizophrenia in 1966.

But whether Frese has “recovered” from schizophrenia—or, to put the matter another way, if what he has recovered from was schizophrenia or something else—is a matter of debate for some.

Not for Frese. He recounts with candor his years in and out of state, county, military, VA, and private hospitals and—with a degree of humor—his time as a serviceman at a Marine Corps barracks when he became convinced that he had discovered a plot by the enemy to hypnotize high-ranking military officials. Or the day he was carried off in an ambulance from a cathedral following a breakdown when he believed he had “cracked the code of the universe,” uniting the wisdom of the East and the West.

“I have been diagnosed and treated for schizophrenia for 35 years,” he told *Psychiatric News*. “In light of my history, it is difficult for me to understand how one can argue that I have been misdiagnosed. But the mental health professions have been wedded to the belief that you can’t possibly recover, and I have been told—some what tautologically—that if I have recovered, I must have had something else.”

Throughout those 35 years, Frese has been treated with drugs, gotten better, and relapsed from time to time. To this day, he said, he continues to experience symptoms. Yet he has also compiled a record of professional and personal achievement that many would envy.

So it would seem that “recovery” from schizophrenia—or from many mental illnesses—is a tricky concept. “It is not accurate to characterize anyone who is subject to symptoms as fully recovered,” Frese said. “I don’t characterize myself as recovered, but recovering.”

## Neurodegenerative Disease?

The prospect of recovery does, in fact, fly in the face of orthodox psychiatric belief, which has held to the definition of schizophrenia—put forward more than a century ago by the German neurologist Emil Kraepelin—as a chronic, neurodegenerative brain disease.

But some researchers today cite a body

of 10 longitudinal studies of two-to-three decades in length showing that many people with schizophrenia do in fact recover to some degree and that some go on to live lives that may be indistinguishable from the healthy.

In 1987 Courtenay Harding, Ph.D., published findings from a 32-year longitudinal study of 269 back-ward patients from Vermont State Hospital. This intact cohort participated in a comprehensive rehabilitation program and was released to the community in a planned deinstitutionalization effort during the mid-1950s. At their 10-year follow-up mark, 70 percent of these patients remained out of the hospital, though social isolation and recidivism were common.

Twenty to 25 years after their index release, 262 of these subjects were blindly assessed and rediagnosed using modern criteria with structured and reliable protocols. One-half to two-thirds of them had achieved considerable improvement or recovery, corroborating findings from Europe and elsewhere.

But Harding said that her findings, and the notion that people with schizophrenia recover, is greeted generally with skepticism. “People look at me like I am from another planet,” she told *Psychiatric News*.

Harding is director of the Institute for the Study of Human Resilience and senior director of the Center for Psychiatric Rehabilitation at Boston University.

She added that the skepticism is not difficult to understand given that few studies on the course of schizophrenia have taken a longitudinal approach. “What happens in most research strategies is that the investigators follow a cohort of convenience for a short time while they are still in treatment,” Harding said.

Consequently, the literature tends to corroborate what psychiatrists see on a day-to-day basis: chronic disease and recidivism. But Harding said that impression is a classic example of the “clinician’s illusion”—a misapprehension about the nature of disease, common to any number of chronic conditions, that is an artifact of a physician’s practice: The physician tends to see only those patients who are sickest and who do not respond to treatment, while those who are less infirm and respond are—naturally enough—seen less frequently or not at all. In time, the physician cannot help but form an impression of nearly incurable chronicity.

“Any clinician worth his salt will tell you it happens,” Harding said. “You get inured to what the range is because you keep seeing these [chronic] people right in front of your nose.”

And the short-term clinical reality of schizophrenia is frequently dismal. “The day-to-day experience is heavily crowded caseloads and shelters where it doesn’t look like anyone is getting better,” she said. “The expectation is that you do stabilization and maintenance with medication and entitlements, and that’s the best you can do.”

Yet Harding said that outside the range of the “clinician’s illusion” are uncounted

patients who have passed through and out of systems of care, gotten married, and are holding jobs. “Most of them are not even known in the community as having mental illness,” she said. “They have gone about their lives and are embedded in society.”

## Influenced by Kraepelin

The concept of schizophrenia as a disease from which no one recovers is itself embedded in history. Robert Spitzer, M.D., who was editor of *DSM-III*, said that the criteria for schizophrenia in that edition—and succeeding editions—were heavily influenced by researchers who took as their guide the definition proposed by Kraepelin.

Moreover, Spitzer said that Harding’s statistics about recovery “seem very dubious” to many clinicians—though he acknowledges that the “clinician’s illusion” is a phenomenon to be reckoned with.

While claiming to hold no doctrinaire position himself, he added, “As a clinician, if I saw someone who had schizophrenia and who had fully recovered, I would personally be very puzzled.”

Harding believes that schizophrenia is not one disease, but comprises a “group of schizophrenias,” and that heterogeneity of outcome is the true hallmark of the disorder. She said that research has shown a range of prognoses, with affective disorders having the best, followed by schizoaffective disorders, paranoid schizophrenia, and then those with disorganized thinking.

“The course of schizophrenia is a much more complex and heterogeneous process than has been appreciated,” she said. “The narrow medical model targets pathology, whereas a recovery model targets strengths of the individual, the family, the clinician, the social network, and systems of care upon which to build the rehabilitation process.”

## Long-Lasting Implications

William Carpenter, M.D., director of the Maryland Psychiatric Research Center (MPRC), agrees that schizophrenia is much more likely a cluster of syndromes than a single disease. “There may be forms of the illness that meet current criteria from which recovery does take place,” he told *Psychiatric News*.

But Carpenter holds a somewhat more

circumspect view of the prospects for recovery. “In the main, the people who meet the criteria are likely to have long-lasting adverse implications,” he said. “The question of recovery then becomes entirely a matter of how you define recovery. If you define it as living and functioning as if one never had the disease, that rarely happens. If you define it as being clinically stable and making a good adaptation, that probably happens with some frequency, but it would still be a minority of patients.”

He added, “You can have a favorable course without it being as though you never had the disease.”

Further, the measures of “recovery” are likewise relative: a patient may be working full time but in a very diminished capacity compared with what he or she might have been capable of without the disease.

Carpenter said he was at one time distrustful of his own possibly illusory understanding of schizophrenia, derived from the patients he saw at the MPRC—they are largely very sick and have not responded to treatment. “For a long time I thought our view of the disease was heavily tainted by Kraepelin, and that we needed a more epidemiologically based understanding,” he said.

In the late 1980s he participated in a study of “first episode” schizophrenia in the Suffolk County area of Long Island, N.Y. The study, published in the January 1998 *American Journal of Psychiatry*, looked at the course of disease in a community sample of young patients who were being treated very early.

“Arguably, we would be seeing a population that was much more representative of the illness,” Carpenter recalled.

The preliminary results were sobering. “The impression was that every story is a sad story,” he said. “It reawakened in me the view that even if you start with a representative community sample of people getting their first diagnosis, the illness takes a really bad toll on almost all the people almost all the time.”

Carpenter agreed, however, that the orthodox view of schizophrenia as a disease that always has an inexorably downward course is simply wrong. Moreover, even in the case of the sickest patients there appears to be some natural improvement with aging.

*please see Recovery on page 37*

## Comprehensive Care Not the Norm

Recovery from schizophrenia may be a matter of debate, but researchers agree that the prospects for any degree of recovery improve greatly when patients receive the best treatments available—something that happens far less frequently than it should.

Those best treatments include not only medication, but also proven psychosocial strategies aimed at involving the family, caregivers, and social network to build on strengths rather than focus on pathology.

Courtenay Harding, Ph.D., notes, for instance, that in her long-term follow-up study of deinstitutionalized patients in Vermont (see story above), those patients benefited from a comprehensive, coordinated biopsychosocial rehabilitation program. “The program became so well known that people came from all over the world to see it,” she said.

But such comprehensive treatment is the exception rather than the rule. Today the rule is “low expectations, reduced collaboration, and system disarray.”

In 1989 the Schizophrenia Patient Outcome Research Team (PORT)—a project of the federal Agency for Healthcare Policy and Research to look at the availability of best practices for a host of common conditions—found that the rates at which patients were offered both medication and proven psychosocial treatment strategies were well below 50 percent.

The PORT found that psychosocial treatments are often prescribed at the point of hospital discharge but that follow-through in the community is low. Moreover, psychosocial treatment varied in conformance rates based on location: Patients in some states are more likely than those of another to be prescribed a vocational intervention and less likely to be prescribed a family intervention or psychotherapy.

“There is a huge shortfall in the intellectual preparedness of the field,” said William Carpenter, M.D., director of the Maryland Psychiatric Research Center. “Patients are very unlikely to get the treatments that we know work.”



# **ASTRA ZENECA SERO- QUEL (EPS) P4C**

# Tardive Dyskinesia Improves With Amino Acid Cocktail

Branched-chain amino acids appear to improve significantly the abnormal movements of tardive dyskinesia, at least in men.

BY JIM ROSACK

**B**ranched-chain amino acids (BCAA) may reduce symptoms of tardive dyskinesia in patients taking antipsychotic medications by an average of 36.5 percent, compared with placebo.

In a double-blind, placebo-controlled trial reported in the June issue of the *American Journal of Psychiatry*, the improvements seen in patients treated with BCAA were noted after the first week of treatment, sustained throughout the three-week duration of the trial, and highly statistically significant. Patients who received placebo experienced a nonstatistically significant worsening of the abnormal-movement patterns associated with tardive dyskinesia (TD).

"Patients using the product experienced significant improvement with minimal side effects," said Mary Ann Richardson, Ph.D., principal investigator of the study and director of the Movement Disorders and Molecular Psychiatry Division of the Nathan S. Kline Institute for Psychiatric Research. Richardson is also a professor of psychiatry at New York University Medical School.

BCAA, sold under the brand name Tarvil in the United States, is classified as a medical food by the FDA. A medical food is defined as any food that is "formulated to be consumed orally or administered enterally under the supervision of a physician and [is] intended for the dietary management of a specific disease or condition that has nutritional requirements."

The FDA does not regulate medical foods, but is in the process of proposing rules to do so. The only regulations currently in force are a ban on the sale of medical foods in general stores and supermarkets and a requirement that the label must clearly state "that the product is intended to be used to manage a specific medical disorder or condition."

Tarvil is indicated "for the dietary management of tardive dyskinesia (TD) in males." The indication also notes that TD is "an abnormal movement disorder that is secondary to the treatment of psychiatric disorders with antipsychotic medication."

The product is formulated as a powder that when mixed with water forms a pineapple-flavored drink. It is usually given three times a day, with the dose titrated to patients' body weight and specific medical condition.

Richardson and her colleagues observed TD movement patterns and frequency in patients through videotaped sessions at baseline, one week, two weeks, and the end point of three weeks. All videos were then reviewed by Richardson, who was blinded to which patient had been assigned BCAA or placebo, as well as which of the four recorded videos of each patient represented which timepoint within the study.

The total number of patients assigned to the two groups was 48. Of those, 36 (75 percent) completed the three-week trial. On an intention-to-treat analysis with last observation carried forward, 41 patients who completed at least the first week of the trial were included in the final data analysis.

For the primary outcome measure—the percent of change in tardive dyskinesia movements—a significant decrease was found at three weeks between patients taking BCAA (a 36.5 percent reduction in TD movements) and those receiving placebo (3.4 percent increase in TD movements). No changes were noted in blood levels of the antipsychotic medications, nor were any significant changes seen in levels of blood glucose. No significant differences appeared between patients receiving BCAA and placebo for overall physical examination, complete blood count, blood chemistry profiles, or urinalysis screens.

The only side effects noted were transient gastrointestinal distress following dosing.

Blood levels of BCAA directly correlated with dosing, and in patients receiving BCAA, improvements noted at week one predicted improvement at both week two and week three.

The range of response within the group taking BCAA varied significantly, from a 60 percent or greater reduction in TD movements in more than one-third of the group to little or no change in TD movements. However, only one patient taking BCAA experienced an increase in TD movements on the medical food.

"The magnitude of the clinical response on a subject-by-subject basis in the [BCAA] group... demonstrates the strong clinical efficacy of the amino acids in treatment in a majority of patients," Richardson and her colleagues pointed out. "These findings also reflect the heterogeneity of tardive dyskinesia and serve as a reminder that no one treatment is appropriate for all patients."

The report stressed that the results apply only to the use of BCAA in men. There is limited evidence to suggest that the mechanism of antipsychotic-induced TD may be different in women.

**The study, "Efficacy of the Branched-Chain Amino Acids in the Treatment of Tardive Dyskinesia in Men," is posted on the Web at <<http://ajp.psychiatryonline.org/cgi/content/full/160/6/1117>>. ■**

## letters to the editor

### Off the Mark

**T**he letter in the June 6 issue titled "Off the Couch" in which Drs. David Brody and Michael Serby refer to psychoanalysis as a "marginalized treatment" no more relevant to psychiatry than "musicology" requires a brief reply.

Readers need refer only to the article on the very same page to find compelling reasons for valuing psychoanalysis both as a technique for treatment and for its concepts, which are so widely used in psychodynamic psychotherapy. In his article "Uses of Self in Psychiatric Training," Dinu Gangure, M.D., stated, "What I found helped me understand and participate more effectively in the psychotherapeutic process was undergoing a personal psychotherapy myself." Even if the juxtaposition of that article and letter was simply fortuitous, *Psychiatric News* is to be congratulated on it.

The letter by Drs. Brody and Serby is simply not reflective of residency programs or of current thinking in psychiatry.

ANN R. TURKEL, M.D.  
New York, N.Y.

*Dr. Turkel is president of the American Academy of Psychoanalysis and Psychodynamic Psychotherapy.*

**D**rs. David Brody and Michael Serby mock psychoanalysis in their letter in the June 6 issue. Trying to explain the relevance of psychoanalysis to most psychiatrists is as difficult as explaining the relevance of Einstein's theories to one schooled in Newtonian physics. The easy

success of modern psychotropics and the facile yet unproven theories of neurochemistry lull many into the belief that there is no unconscious mental life. My personal analysis a quarter of a century ago not only inspired my interest in psychiatry at a time when the only antidepressants were the tricyclics, but also demonstrated that there was a subterranean mental world.

Today I would not recommend psychoanalysis to 99 percent of my patients in either the office or psychiatric hospital. Yet the tool of psychoanalytic thinking and the self-understanding it provides are as relevant as the prescription pad I carry. The fault is not with the patients or with the method because of the difficulty of submitting psychoanalysis to research scrutiny or validation. Many theories of modern physics were at first untestable because of limitations of technology. Therefore, regrettably, we fall back on "anecdotal reports," which are perhaps the only scientific instrument so far with any power in psychoanalysis. Yet, this mode of testing is not recognized as useful in contrast to current double-blind, controlled methods that are used when we deal with limited variables in clinical trials.

Yet, even the seemingly rosy success of cognitive therapy confirmed by these current instruments is recently questioned because of ascertainment bias, not to mention other weaknesses in methodology. The closer we look at many psychiatric questions, the more confusing the issues become.

MARKHAM KIRSTEN, M.D.  
Fresno, Calif.

### Army Psychiatry

**H**aving served in the U.S. Army from 1968 to 1973 during the height of the Vietnam War, I read with interest the History Notes column in the May 2 issue by Lucy Ozarin, M.D., titled "Psychiatry in War." Dr. Ozarin described the psychiatric input into World Wars I and II, but much less after that period.

As a young community psychiatrist with a master's degree in public health, I spent three years of my psychiatry residency at Walter Reed Army Hospital and then two years as the assistant psychiatry consultant in the Office of the Surgeon General of the Army.

Community psychiatry was growing rapidly in the U.S. Army during this time. The first community psychiatrist in the Army was the chief psychiatric consultant to the Surgeon General of the Army, Mathew Parrish, M.D., who was assisted by Billy E. Jones, M.D. I replaced Jones as the assistant psychiatry consultant. These are names known to many APA members.

During my residency, as an experiment in community psychiatry run by the Walter Reed Army Institute of Research, I was placed with the 75th Engineering Battalion at Fort Meade, Md., to see what community psychiatry had to offer to returning Vietnam veterans.

During my time in the Army surgeon general's office, I had exceedingly interesting consultative assignments. I served on the Army Board for the Correction of Medical Records for those who were inappropriately discharged from the Army without a medical discharge. I was the only non-general officer on the Morale and Discipline Committee, a group of general officers who deliber-

**Readers are invited** to submit letters not more than 500 words long for possible publication. Submission of a letter implies consent for publication unless otherwise indicated. All letters are subject to editing to meet style, clarity, and space requirements. Receipt of letters is not acknowledged. Send submissions to Letters to the Editor, *Psychiatric News*, APA, Suite 1825, 1000 Wilson Boulevard, Arlington, Va. 22209; fax: (703) 907-1094; e-mail: [pnews@psych.org](mailto:pnews@psych.org).

Opinions expressed in letters do not necessarily reflect the views of APA or the editors. Clinical opinions are not peer reviewed and thus should be independently verified.

ated on how to improve morale and discipline. I was able to be present because I was a psychiatrist representing the surgeon general, not as a major. I also served on the Nuclear Surety Review Board to help determine who should be allowed to handle nuclear weapons and on the Conscientious Objector Review Board to determine who was a true conscientious objector.

During the Vietnam War, many of our psychiatric colleagues were serving throughout the world, bringing psychiatric expertise to our troops, to command, and to military dependents.

During 1971 to 1973, when many substance-abusing troops were returning from Vietnam, I traveled around the U.S. helping to set up alcohol and drug abuse programs. It was my experience that we in psychiatry were greatly appreciated and most welcome. I had the unusual experience of writing the first Army regulation on the Confidentiality of Medical Records (AR 40-42). According to AR 40-42, commanders were given only as much information as was necessary for them to deal with soldiers so that psychiatrists were able to treat these indi-

*please see Letters on page 37*

# ASTRA ZENECA SEROQUEL P4C

## history notes

# Group Therapy Passes Centennial

BY LUCY D. OZARIN, M.D., M.P.H.

The field of group psychotherapies has produced a rich literature, since it encompasses a large variety of theories and practices.

The field includes psychoanalytic, interpersonal, gestalt, transactional, crisis, supportive, cognitive-behavior, family, and other types of group psychotherapy. In addition, a large number of self-help and recovery groups, such as Alcoholics Anonymous, that are operated by people who are not psychiatrists or mental health professionals have similar goals.

The common goals of group psychotherapies are to alleviate symptoms, correct faulty perceptions, improve commu-

nication, modify behavior, and/or alter family dynamics.

Irvin Yalom, M.D., lists 11 basic factors that help to bring change through group psychotherapeutic methods: instillation of hope, universality, information exchange, altruism, correction of family dynamics, development of socialization techniques, imitative behavior, interpersonal learning, group cohesiveness, catharsis, and existential factors.

Group methods to alleviate symptoms have existed for ages, often through group rituals of a religious nature. At the turn of the 20th century, psychologists in Germany, especially Kurt Lewin, began to explore be-

havior in relation to environmental influences, an approach that moved the locus of behavior from within the individual to the result of forces in the interaction of the individual with outside influences.

In 1906 Joseph Pratt, M.D., an internist in Boston, was faced with treating home-bound poor patients with tuberculosis and began to hold structure classes to help them learn to better manage their disease. It became evident to him that the added influence of the patients upon each other was quite helpful. Similar classes for psychiatric patients were started under the same church sponsorship.

The term group psychotherapy, coined around 1931, is usually credited to J.L. Moreno, M.D., who brought his psychodrama technique from Vienna to New York in 1925 and began to hold group sessions that became increasingly geared to therapeutic goals (*Psychiatric News*, May 16).

Throughout this period, other psychiatrists, mainly those with psychoanalytic backgrounds, also began to use group methods. These psychiatrists included Burrows, Marsh, Zazell, Wender, and Schilder. S.R. Slavson, a psychiatrist who worked with the Jewish Board of Guardians in New York, developed group methods to treat children and adolescents. Slavson was the first president of the American Group Therapy Association, serving from 1943 to 1946. The organization's *International Journal of Group Psychotherapy* began publication in 1951 and is still being published.

World War II provided a major impetus for the study and application of group methods to treat psychiatric disorders. Great Britain, which had entered the war in 1939, was faced with large numbers of psychiatric casualties, and group methods became necessary to be able to treat such a large population. The psychiatrist leaders in this movement—which was largely psychoanalytic in nature, with a Kleinian basis—included S.H. Foulkes and W. Bion. The social clubs of J. Brier came into being at this time, as did the therapeutic communities advocated by Maxwell Jones.

The American military in World War II also used group methods to treat the large numbers of psychiatric casualties. After the war, the Veterans Administration (VA) sponsored a major research project on group psychotherapy at several VA hospitals. The study, carried out by psychiatrists F. Powdermaker, M.D., and J. Frank, M.D., was published in 1953.

The literature attests to the growth and spread of group psychotherapy. It appears to be here to stay. ■



## Psychotherapy

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agreed that teaching psychodynamic psychotherapy should be done and is in fact quite doable.

During Columbia's psychiatry clerkships, faculty demonstrate this type of psychotherapy and teach major concepts such as the unconscious, transference, and countertransference, which, she said, are "vital to understanding the powerful relationship between doctor and patient."

"The best way to bring those concepts to life is to demonstrate them in a clinical application of psychodynamic psychotherapy," Cutler said.

Students attend three 90-minute seminars taught by a psychodynamically trained psychiatrist during which one or two patients are presented through detailed process notes and vignettes. The teacher challenges the students to respond as if they were the therapist or the therapist's supervisor.

This is a "good compromise," Cutler noted, because students "feel as if they're doing therapy" without actually conducting a rudimentary form of therapy with a patient.

The Columbia program has elicited "extremely positive responses" from students, she said, adding that this degree of exposure to psychotherapy "is a draw for students into the field," particularly those attracted to the idea of developing a stronger relationship with patients than other medical fields allow.

Myrl Manley, M.D., ADMSEP's president-elect and associate professor of psychiatry at NYU Medical School, joined Waterman in giving a thumbs down—though

a "qualified" one—to teaching psychotherapy in medical school clerkships.

One of Manley's primary concerns is that there is "a danger of devaluing" psychotherapy if students come away with the idea that any type of talking they do with patients qualifies as psychotherapy. "It is an incredibly complex set of skills honed by years of experience," he stressed, and providing a few days' worth of exposure to the modality shows students "a grotesque caricature of the real thing." In addition, the "mere presence" of medical students, he said, "distorts the process of psychotherapy."

The solution, Manley maintained, is to "teach students *about* psychotherapy even if we can't teach them to *do* it." For example, it is important to teach clerkship students that "all psychotherapies are not the same; there are different theoretical schools that use very different interventions."

Students also need to know that "the choice of a particular psychotherapy for a particular patient is not arbitrary," but are guided by psychiatrists' "understanding of the indications for particular modalities," he said.

Regardless of whether clerkship directors decide to teach psychotherapy to medical students, Julia Frank, M.D., who directs the psychiatry clerkship at George Washington University's medical school, insisted that it is critical for students to learn psychodynamic concepts.

A thorough grounding in these ideas will help all physicians better understand what motivates a patient to adhere to or ignore treatment regimens and "forge an alliance" with their patients. It will also show future physicians that "what you see is *not* what you get." That is, that all patients' behaviors are molded by life experiences that are "hidden from the observer, unless that observer makes an effort to learn about them," Frank said. ■

## letters to the editor

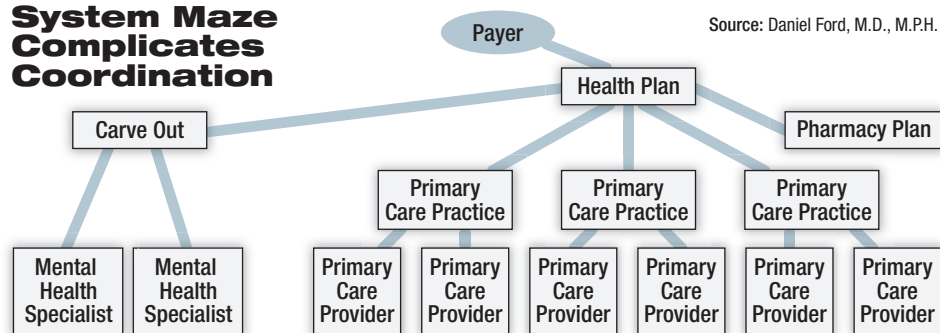
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viduals. As an experiment, I was even given the opportunity of personally transporting soldiers from Ft. Meade to a methadone-maintenance program in Washington, D.C., so that they could be withdrawn from heroin while remaining on active duty.

I am sure our colleagues in the Gulf War and Iraq War will have similar stories to tell, but to my knowledge no one has written about the things I experienced during the Vietnam War, and I thought this would be of interest to colleagues.

HARVEY L. RUBEN, M.D., M.P.H.  
New Haven, Conn.

## The Health Care System Maze Complicates Coordination



## Depression

continued from page 1

ing from the National Institute of Mental Health and the MacArthur Foundation, the intervention trained care managers to assess depression, educate patients about effective treatment, and monitor their responses over two years.

All patients met *DSM-IV* criteria for major depression.

Rost said, "Depressed patients who recognized and acknowledged that they had psychological problems in the initial consultation were much more likely to improve as a result of treatment than those who only complained of physical symptoms."

There were no statistically significant differences between the two groups in terms of severity of symptoms of depression or socioeconomic factors such as level of education.

Rost said, "Of course, we want to be able to help everyone who has been diagnosed with depression, but it is also important to be able to identify groups who offer good potential for cost savings, so that we can make a strong case that treatment for depression can save health plans money. Our findings also suggest that we may need different kinds of interventions to be successful with patients who do not initially acknowledge symptoms associated with depression." The study is under journal review.

### Substantial Treatment Barriers

Daniel E. Ford, M.D., M.P.H., took the opposite approach to the problem when he told the audience about barriers to effective treatment. He said that primary care physicians perceive that there is less access to "high-quality" specialty mental health services than to other high-quality medical services and that access to mental health services is negatively affected by the number of managed care contracts held by the primary care physician.

Ford is a professor of medicine, psychiatry, and health policy and management at Johns Hopkins University School of Medicine. His initial comments were based on a study he helped write, "Managed Care Organizational Complexity and Access to High-Quality Mental Health Services: Perspective of U.S. Primary Care Physicians," published in the May-June *General Hospital Psychiatry*.

The authors speculated that for primary care physicians, the impact of organizational complexity, such as multiple contracts, mental health carvein and carveout clauses, and gatekeeper requirements, would impact access to mental health specialty providers.

They used data from the Community Tracking Study Physician Survey, conducted by the Center for Studying Health System Change, collected between 1996 and 1997.

Ford said primary care physicians ranked access to high-quality mental health services much lower than access to other specialty medical services (28 percent; 95 percent confidence interval [CI] versus 81 percent, 95 percent CI).

Perceived access to high-quality mental health services was inversely related to the

number of managed care contracts held by the physician. The highest perceived access was for physicians with no managed care contracts (38 percent access, 95 percent CI). The lowest was for practices with 25 or more contracts (24 percent access, 95 percent CI).

### Gatekeepers Affect Perceptions

The effect of gatekeeper requirements on the perceived availability of high-quality mental health services was more complicated. Gatekeeping requirement was defined as the percentage of patients within a practice subject to managed care gatekeeping requirements.

Physicians with practices in which 41 percent to 60 percent of patients had gatekeeper requirements reported the lowest perceived access. Physicians who had no patients subject to gatekeeper requirements and physicians with practices in which all patients were subject to gatekeeper requirements reported the highest perceived access.

Ford speculated that the reason for this surprising finding might be that if a high percentage of the patients within a practice had gatekeeper requirements, the physician would be more likely to learn how to deal with those requirements than if the practice had a mixture of patients.

He told the audience that barriers also result from the number of stakeholders involved in health care delivery and their different expectations and needs from the system (see diagram).

Coordination of mental health care or of mental health with primary care will not become a high priority for payers until it can be shown to reduce costs and result in fewer complaints from health plan enrollees. The result is that family members, particularly in cases of serious mental illness, frequently become de facto care coordinators. ■

## Recovery

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"Clinicians should assume that most patients have a chance for substantial stability and have a chance to regain much of their lost niche in society," Carpenter said. "Individuals will vary in how far they can go in accomplishing that."

Recovery in any one patient would seem also to hinge on the largely unquantifiable variable of human individuality and resilience.

Frederick Frese joined Carpenter and Harding in urging clinicians to shed illusions of a hopeless prognosis and to partner with the recovery movement and "live with ambiguity." The latter may be another way of phrasing Harding's advice to "seek out the person behind the disease"—a person who may just possibly defy the odds.

"Increasingly, patients and clinicians need to work together," Frese said. "The voice of those of us in recovery should be given maximal dignity and respect. That will be to the clinician's advantage." ■

## Youth

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therapy to youth on probation. The groups, which have focused on issues such as anger management, substance abuse, and young women's issues, are facilitated by bilingual social workers and are held in the office of the MHA of Southwestern New Jersey, located just two blocks from the probation office.

In addition to being held in a non-threatening environment, Reynolds said, pizza and hoagies are offered to those attending the sessions, which have attracted 60 probationers over the past year.

Reynolds noted that excessive anger and substance abuse are frequently indicators of other underlying mental health problems such as depression or traumatic loss.

Reynolds added that given the "horrific" environments in which some of the youth have been raised—environments that include poverty, sexual and physical abuse, and neglect—"it would take an exceptional person not to develop mental health problems."

Establishing mental health screening for every youth who comes through the Camden County Probation Department—and providing treatment to those who need it—is a primary goal of the MHA of Southwestern New Jersey, Reynolds said.

"The positive attention, nurturing, and self-esteem building in groups is the first step to helping these kids to lead healthier lives," she said, noting that many youth in the juvenile justice system have a mistrust of mental health professionals. "It is our hope that the trust built between youth and mental health professionals established in these groups carries over into future mental health care." ■

## Career Choice

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choanalytically oriented treatment converged to propel Walter into a psychiatry residency at New York University, and then into child psychiatry training at Columbia University College of Physicians and Surgeons.

Walter said that her prior training has a substantial influence on her practice of psychiatry. "Child psychiatry is unique in that it has a strongly preventive orientation," she said. "To prevent disruptive behavior disorders, we work extensively with parents around effective parenting techniques and with teachers around effective classroom management techniques. We deliver interpersonal skills training to children to prevent aggressive conflict resolution and social withdrawal from extreme shyness. We teach coping skills to prevent the development of anxiety and mood disorders, and we work with psychologists to identify learning and language problems to prevent academic failure."

### Psychiatry and Reproductive Health

Others who made a career switch look back on their earlier choices and see that, in a sense, they had been practicing some psychiatry all along.

Diana Dell, M.D., trained as an obstetrician-gynecologist at Charity Hospital of New Orleans and later practiced in Baton Rouge. "It was the proper combination of surgery and psychiatry for me," she said of her choice. "I saw a lot of people with de-

pressive disorders, and I was the only person in town that really liked treating premenstrual symptoms. I welcomed those patients, so right from the start my practice was on the psychological side."

And it exposed her to the psychiatric components of reproductive health that has informed her practice today. "We need to be aware of the fact that 1 in 5 women who have a baby will have a major depression within a year," she said. "So the ob-gyn is seeing a lot of these patients."

Dell said that when she moved in 1993 to Durham, N.C., to practice at Duke University Medical Center, she considered the idea of getting some additional training in psychiatry. "I knew there were things I was missing," she said. "At the time, I was treating a lot of patients with chronic pelvic pain, and I needed to know more."

In time, though, a medical condition of her own would force that decision. During her first winter in Durham, she began to experience a severe and persistent pain from a lumbrical abnormality in her dominant hand that made surgical work increasingly difficult. She found herself relying more and more on residents to assist in surgical and delivery situations she would have routinely handled herself.

A turning point came in the middle of a



**Diana Dell, M.D.:** "There are times when I miss my ob-gyn patients. They would meet me in the shopping mall and rush up to show me their baby pictures."

night while she was icing her hand for control of the pain when she received a call for one of the most difficult obstetrical emergencies, a shoulder dystocia. When the fourth-year resident had trouble disimpacting the baby's shoulder, Dell hesitated to intervene, knowing that the resident needed to learn how to perform the maneuver—but also worrying that she might not have the hand control to do it herself.

She was successful in delivering the infant, but was later haunted by the incident. "I was awake for a very long time," she recalled, "thinking to myself that 'the time has come.'"

She started a psychiatry residency with the next class at the University of North Carolina, a choice that was not without reservations. "There was so much overwork in obstetrics," she said. "Even when I started my psychiatry training, I still had the hope that if I rested it enough, my hand would get better."

It never did, and though surgery corrected the problem, it left her with a loss of sensation. "I was rapidly realizing that returning to ob-gyn was not really an option."

Today she is an assistant professor in the department of psychiatry and director of the maternal wellness program at Duke, where she manages pregnant and lactating patients who have psychiatric disorders.

She is not without a sense of loss. "There are times when I miss my ob-gyn patients," she said. "They would meet me in the shopping mall and rush up to show me their baby pictures."

Now, she said, her psychiatric patients feel the stigma of mental illness and are much less likely to greet her in public. "It's a different population, and I miss the wellness."

John Wynn, M.D., of Seattle, Wash., completed a residency in internal medicine in 1986 at Michael Reese Hospital in Chicago and completed a psychiatry residency at UCLA in 1989. Today, he is in private practice in Seattle and is also medical director of psycho-oncology at the Swedish Cancer Institute.

His interest in psychiatry actually predates his training in internal medicine, when he was a "James Scholar" at the University of Illinois School of Medicine. An innovative program allowing medical students to design their own medical curriculum, the scholarship allowed Wynn to design a curriculum in pursuit of his interests in internal medicine, pathology, neurology, and psychiatry.

Wynn opted to train in internal medicine first, hoping to complete his medical education before "moving on" to psychiatry. Although he enjoyed his internal medicine residency, his interest in psychiatry endured, and he gratefully recalls a mentor at Michael Reese who, informed of his decision to enter a psychiatry residency at UCLA, told Wynn: "I can't think of a more fascinating, wide-open field to enter. You're going to have a great time."

Like Dell, Wynn said that his initial training has sharpened his eye for the physical and medical conditions of patients he is treating for mental illness. "The volume of suffering I saw as an internal medicine resident was powerful for me," he told *Psychiatric News*. "I connect very quickly with

physicians in other fields, I'm less intimidated by them, and they feel I speak their language."

### Preventable Factors

Like Dell, Hales was drawn initially to a field that was heavily weighted with issues relevant to psychiatry and mental health. She trained in pediatrics at the residency program in social medicine at Montefiore Hospital in New York and finished a one-year fellowship in adolescent medicine at Columbia.

"Adolescent medicine has so much to do with psychiatry," she observed. "When you work in outpatient adolescent medicine, you function as a dermatologist, gynecologist, sports medicine specialist, and psychiatrist."

It was the psychiatric aspects of her work with adolescents that appealed to her most. "In the late 1970s and early '80s, adolescents were the only group in the population that had a rising death rate," she said. "There were all kinds of preventable factors from which teens were dying. It seemed to me that psychiatry was the most interesting way to deal with those issues."

She trained at Stanford and later went into private practice half time while serving as a residency training director at San Mateo County (Calif.) Mental Health Services before joining APA's staff in 2001.

The circuitous path may be the longer, more arduous one, but it has its advantages—particularly for those who wind up treating mentally ill people.

"It's the one field of medicine where your life experience really helps you," said Hales. "You have technical training, as in every part of medicine, but in psychiatry your maturity is an asset as opposed to a liability. For the psychotherapist especially, the wiser you are, the better job you can do for your patients."

The sentiment is echoed by Walter. "The clear disadvantage is that I am 10 years behind my same-age peers in career development," she said. "But the advantage is the richness of my experience. I have many more vantage points from which to view my work—and my life—generally." ■

## Disaster

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ate precautions to take in the event of a terrorist attack, they have a greater sense of control and less anxiety. For example, in the event of a biochemical attack, people should 'shelter in place.' This means staying put at work, school, or at home, and having enough supplies including food and water to last a few days."

The IOM committee found that the funding of services and planning for psychological consequences are generally inadequate. The amount of funding, duration of funding, services eligible for coverage, and the inclusion of mental health services in broader terrorism preparedness plans require more attention, the report states.

"There is a clear need for more resources to address the lack of empirically based knowledge and services," said North.

### Workplace Needs Included

The report is unique in that it addresses the psychological needs of workers as part of public health preparedness. "Recent terrorist events—especially September 11, 2001—occurred in the workplace. The mental health needs of certain workers, including construction, utility, and postal workers, and children and teachers in school need to be considered," said Ursano.

The committee recommended that the National Institute for Occupation Safety and Health and the Department of Labor collaborate on developing guidelines to protect workers from the psychological consequences of terrorism. Another recommendation was that the Department of Education collaborate with state and local education systems to ensure adequate preparedness, according to the report.

### NIMH Role

The committee's work, which included three two-day meetings between last October and February, was funded by the National Institute of Mental Health (NIMH) and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Farris Tuma, Sc.D., chief of the Traumatic Stress Program at NIMH, told *Psychiatric News*, "The NIMH will use the IOM report to frame and guide our research questions about which interventions are most effective in facilitating resilience and recovery in vulnerable populations."

Tuma continued, "The research community will collaborate with SAMHSA and the Centers for Disease Control and Prevention in developing effective mental health care strategies for the public."

"A major challenge is identifying the biological and/or symptom profiles of people most likely to develop long-term problems in response to traumatic events. Once we have reliable and valid diagnostic tools, we can differentiate high-risk individuals early on from the majority of victims who experience some acute reactions or symptoms but recover with support and time. Then we can provide appropriate interventions to each group."

NIMH is also working on interventions that can be applied in a variety of settings. "We have begun preliminary work on developing a Web-based primary care trauma intervention that involves some contact with a health care professional and also has Web-based exercises that can be done independently, which is not traditional cognitive behavioral therapy," said Tuma.

**The IOM report, "Preparing for the Psychological Consequences of Terrorism," is posted on the National Academy Press Web site at <<http://books.nap.edu/books/0309089530/btml/index.html>>. ■**

# FOREST LEXAPRO P4C



# FOREST LEXAPRO P4C



# FOREST LEXAPRO P4C

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# Malpractice

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contacted the AMA to get involved in the fight for medical liability reform and have generated more than 50,000 communications with members of Congress.”

Following defeat of the bill, President George Bush issued a statement urging Congress to pass liability reform.

“I am disappointed that the Senate has failed to pass medical liability reform legislation,” the president said. “The nation’s medical liability system is badly broken, and access to quality health care for Americans is endangered by frivolous and abusive lawsuits. . . . The American people want and deserve access to doctors in their own communities, yet the number of physicians has decreased in states without reasonable litigation reforms. The liability crisis, particularly the use of defensive medicine, also imposes substantial costs on the federal government and all Americans.

“For the sake of all Americans,” the pres-

ident said, “it is time for the Senate to pass meaningful medical reform liability legislation and get it to my desk.”

But Democrats, who opposed the bill, say the steep increases in liability premiums in some parts of the country have been caused by insurers who maintained premiums at artificially low levels for years to gain more customers, making up for the low prices with big gains on stock market investments. When the market declined, insurers raised premiums dramatically.

## APA Backs Reform Bills

Michael Strazzella, deputy director for congressional relations in APA’s Division of Government Relations, pointed out that APA supported this bill and other federal malpractice reform efforts, as a member of the Health Coalition on Liability and Access.

The coalition includes more than 50 organizations representing physicians, insurers, and patients.

“APA regrets that the Senate did not pass medical liability reform legislation but strongly urges senators to continue to ex-

amine the issue and find a solution to this national crisis,” Strazzella said.

## Caps Affect Physician Supply

In related news, the Agency for Healthcare Research and Quality (AHRQ) released a report showing that states that have enacted limits on noneconomic damages in medical lawsuits have about 12 percent more physicians per capita than states without such a cap.

The study looks at the growth of the physician workforce since 1970, before any state had enacted caps, and adjusts for the impact of other factors believed to affect physician supply, such as per-capita income and the presence of physician residency programs.

What the study found was that physician supply has grown more in states with caps than in states without caps.

According to the study’s authors, Fred Hellinger, Ph.D., and William Encinosa, Ph.D., “These findings demonstrate that state laws limiting noneconomic damages in medical malpractice cases increase the num-

ber of physicians who practice in the states.”

Both authors are with the AHRQ’s Center for Organization and Delivery Studies.

They found that by 2000, states that had enacted caps had a significantly higher number of doctors (135) per 100,000 county residents compared with states that didn’t enact caps (120 per 100,000). In 1970 there was no statistically significant difference between states in their per capita supply of physicians, according to the study.

The study, released on the day debate commenced in the Senate on the Ensign bill, was hailed by the administration as proof of the need for medical liability reform.

“Our broken medical litigation system is affecting patients’ ability to find a doctor,” Health and Human Services Secretary Tommy Thompson said. “This study confirms and quantifies the association between reasonable limits in medical lawsuits and the supply of physicians available to treat patients who need them. It is critical that we fix this broken litigation system now. In the current system, the fear of excessive awards stimulates wasteful defensive medicine and deters doctors and hospitals from identifying and addressing medical errors, thus increasing costs and decreasing quality.”

*The AHRQ study, “Impact of State Laws Limiting Malpractice Awards on Geographic Distribution of Physicians,” is posted on the Web at <www.abrq.gov/research/tortcaps/tortcaps.htm>. More information about the coalition, Senate bill S 11, and other liability reform efforts is posted on the Web at <www.bcla.org/>. ■*

# from the president

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have a serious budget shortfall. Where else in the budget would you suggest we make cuts to preserve the Medicaid funding for mental health? Education? Firefighters? Police? Roads? We have to cut somewhere.”

“What should I have said?,” asked my colleague.

My reply to the congressman might have been: “Yes, you do have a very real, very serious problem. I can’t tell you where to cut; however, I can tell you that if you cut the mental health/Medicaid budget, you are going to face a far worse problem. You will have a worse problem in the streets, because there will be a major increase in homelessness, and the police force will need to be reinforced and taught to handle the problems caused by the severely persistently mentally ill who are not receiving treatment. The disintegration of the failed treatment system will affect every stratum of the community.”

## Advocating Made Easy

APA’s Web site at <www.psych.org> has readily available information about who and how to reach your local, state, and federal legislators. Click on “Public Policy Advocacy,” and a sample letter, along with the names and addresses of the appropriate people to contact, will immediately appear. Use the information on the site, such as the Medicaid Tool Kit, to prepare yourself for a meeting with the legislator or staff assigned to health matters.

## Activating Future Advocates

If you are experienced in meeting with political figures, take young colleagues along when you meet with members of Congress or state legislators. Advocacy work isn’t difficult, and colleagues will be enthusiastic as they embrace the process. It happened to me. ■



celaproam HBR

Tablets/Oral Solution

### Rx only

**Brief Summary:** For complete details, please see full prescribing information for Celera. **INDICATIONS AND USAGE** Celera (citalopram HBr) is indicated for the treatment of depression. The efficacy of Celera in the treatment of depression was established in 4-6 week controlled trials of outpatients whose diagnoses corresponded most closely to the DSM-III and DSM-III-R category of major depressive disorder. A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, a suicide attempt, or suicidal ideation. The antidepressant action of Celera in hospitalized depressed patients has not been adequately studied. The efficacy of Celera in maintaining an antidepressant response for up to 24 weeks following 6 to 8 weeks of acute treatment was demonstrated in two placebo-controlled trials. Nevertheless, the physician who elects to use Celera for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. **CONTRAINDICATIONS** Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated (see WARNINGS). Celera is contraindicated in patients with a hypersensitivity to citalopram or any of the inactive ingredients in Celera. **WARNINGS** Potential for Interaction with Monoamine Oxidase Inhibitors. In patients receiving serotonin reuptake inhibitor drugs in combination with a monoamine oxidase inhibitor (MAOI), there have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma. These reactions have also been reported in patients who have recently discontinued SSRI treatment and have been started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Furthermore, limited animal data on the effects of combined use of SSRIs and MAOIs suggest that these drugs may act synergistically to elevate blood pressure and evoke behavioral excitation. Therefore, it is recommended that Celera should not be used in combination with an MAOI, or within 14 days of discontinuing treatment with an MAOI. Similarly, at least 14 days should be allowed after stopping Celera before starting an MAOI. **PRECAUTIONS** General **Hypotension** Several cases of hypotension and SIAOH (syndrome of inappropriate antidiuretic hormone secretion) have been reported in association with Celera treatment. All patients with these events have required discontinuation of Celera and/or medical intervention. **Activation of Mania/Hypomania** In placebo-controlled trials of Celera, some of which included patients with bipolar disorder, activation of mania/hypomania was reported in 0.2% of 1063 patients treated with Celera and in none of the 446 patients treated with placebo. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorders treated with other marketed antidepressants. As with all antidepressants, Celera should be used cautiously in patients with a history of mania. **Seizures** Although anticonvulsant effects of citalopram have been observed in animal studies, Celera has not been systematically evaluated in patients with a seizure disorder. These patients were excluded from clinical studies during the product’s premarketing testing. In clinical trials of Celera, seizures occurred in 0.3% of patients treated with Celera (a rate of one patient per 98 years of exposure) and 0.5% of patients treated with placebo (a rate of one patient per 50 years of exposure). Like other antidepressants, Celera should be introduced with care in patients with a history of seizure disorder. **Suicide** The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Prescriptions for Celera should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose. **Interference With Cognitive and Motor Performance** In studies in normal volunteers, Celera in doses of 40 mg/day did not produce impairment of intellectual function or psychomotor performance. Because any psychoactive drug may impair judgment, thinking, or motor skills, however, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Celera therapy does not affect their ability to engage in such activities. **Use in Patients With Concomitant Illness** Clinical experience with Celera in patients with certain concomitant systemic illnesses is limited. Caution is advisable in using Celera in patients with diseases or conditions that produce altered metabolism or hemodynamic responses. Celera has not been systematically evaluated in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were generally excluded from clinical studies during the product’s pre-marketing testing. However, the electrocardiograms of 1116 patients who received Celera in clinical trials were evaluated, and the data indicate that Celera is not associated with the development of clinically significant ECG abnormalities. In subjects with hepatic impairment, citalopram clearance was decreased and plasma concentrations were increased. The use of Celera in hepatically impaired patients should be approached with caution and a lower maximum dosage is recommended. Because citalopram is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Until adequate numbers of patients with severe renal impairment have been evaluated during chronic treatment with Celera, however, it should be used with caution in such patients. **Drug Interactions CNS Drugs** – Given the primary CNS effects of citalopram, caution should be used when it is taken in combination with other centrally acting drugs. **Alcohol** – Although citalopram did not potentiate the cognitive and motor effects of alcohol in a clinical trial, as with other psychotropic medications, the use of alcohol by depressed patients taking Celera is not recommended. **Monoamine Oxidase Inhibitors (MAOIs)** – See CONTRAINDICATIONS and WARNINGS. **Cimetidine** – In subjects who had received 21 days of 40 mg/day Celera, combined administration of 400 mg/day cimetidine for 8 days resulted in an increase in citalopram AUC and C<sub>max</sub> of 43% and 39%, respectively. The clinical significance of these findings is unknown. **Digoxin** – In subjects who had received 21 days of 40 mg/day Celera, combined administration of Celera and digoxin (single dose of 1 mg) did not significantly affect the pharmacokinetics of either citalopram or digoxin. **Lithium** – Co-administration of Celera (40 mg/day for 10 days) and lithium (300 mmol/day for 5 days) had no significant effect on the pharmacokinetics of citalopram or lithium. Nevertheless, plasma lithium levels should be monitored with appropriate adjustment to the lithium dose in accordance with standard clinical practice. Because lithium may enhance the serotonergic effects of citalopram, caution should be exercised when Celera and lithium are coadministered. **Theophylline** – Combined administration of Celera (40 mg/day for 21 days) and the CYP1A2 substrate theophylline (single dose of 300 mg) did not affect the pharmacokinetics of theophylline. The effect of theophylline on the pharmacokinetics of citalopram was not evaluated. **Sumatriptan** – There have been postmarketing reports describing patients with weakness, hyperreflexia, and incoordination following the use of a selective serotonin reuptake inhibitor (SSRI) and sumatriptan. If concomitant treatment with sumatriptan and an SSRI (eg, fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram) is clinically warranted, appropriate observation of the patient is advised. **Warfarin** – Administration of 40 mg/day Celera for 21 days did not affect the pharmacokinetics of warfarin, a CYP3A4 substrate. Prothrombin time was increased by 5%, the clinical significance of which is unknown. **Carbamazepine** – Combined administration of Celera (40 mg/day for 14 days) and carbamazepine (titrated to 400 mg/day for 35 days) did not significantly affect the pharmacokinetics of carbamazepine, a CYP3A4 substrate. Although trough citalopram plasma levels were unaffected, given the enzyme-inducing properties of carbamazepine, the possibility that carbamazepine might increase the clearance of citalopram should be considered if the two drugs are coadministered. **Triazolam** – Combined administration of Celera (titrated to 40 mg/day for 28 days) and the CYP3A4 substrate triazolam (single dose of 0.25 mg) did not significantly affect the pharmacokinetics of either citalopram or triazolam. **Ketoconazole** – Combined administration of Celera (40 mg) and ketoconazole (200 mg) decreased the C<sub>max</sub> and AUC of ketoconazole by 21% and 10%, respectively, and did not significantly affect the pharmacokinetics of citalopram. **CYP3A4 and CYP2C19 Inhibitors** – *In vitro* studies indicated that CYP3A4 and CYP2C19 are the primary enzymes involved in the metabolism of citalopram. However, coadministration of citalopram (40 mg) and ketoconazole (200 mg), a potent inhibitor of CYP3A4, did not significantly affect the pharmacokinetics of citalopram. Because citalopram is metabolized by multiple enzyme systems, inhibition of a single enzyme may not appreciably decrease citalopram clearance. **Melprolone** – Administration of 40 mg/day Celera for 22 days resulted in a two-fold increase in the plasma levels of the beta-adrenergic blocker melprolone. Increased melprolone plasma levels have been associated with decreased cardioselectivity. Coadministration of Celera and melprolone had no clinically significant effects on blood pressure or heart rate. **Imipramine and Other Tricyclic Antidepressants (TCAs)** – *In vitro* studies suggest that citalopram is a relatively weak inhibitor of CYP2D6. Coadministration of Celera (40 mg/day for 10 days) with the tricyclic antidepressant imipramine (single dose of 100 mg), a substrate for CYP2D6, did not significantly affect the plasma concentrations of imipramine or citalopram. However, the concentration of the imipramine metabolite desipramine was increased by approximately 50%. The clinical significance of the desipramine change is unknown.

**CELERA™**  
(citalopram HBr)  
Tablets/Oral Solution

Nevertheless, caution is indicated in the coadministration of TCAs with Celera. **Electroconvulsive Therapy (ECT)** – There are no clinical studies of the combined use of electroconvulsive therapy (ECT) and Celera. **Pregnancy** **Pregnancy Category C** – There are no adequate and well-controlled studies in pregnant women; therefore, citalopram should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Labor and Delivery** The effect of Celera on labor and delivery in humans is unknown. **Nursing Mothers** As has been found to occur with many other drugs, citalopram is excreted in human breast milk. The decision whether to continue or discontinue either nursing or Celera therapy should take into account the risks of citalopram exposure for the infant and the benefits of Celera treatment for the mother. **Pediatric Use** Safety and effectiveness in pediatric patients have not been established. **Geriatric Use** Of 4422 patients in clinical studies of Celera, 1357 were 60 and over, 1034 were 65 and over, and 457 were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Most elderly patients treated with Celera in clinical trials received daily doses between 20 and 40 mg. In two pharmacokinetic studies, citalopram AUC was increased by 23% and 30%, respectively, in elderly subjects as compared to younger subjects, and its half-life was increased by 30% and 50%, respectively. 20 mg/day is the recommended dose for most elderly patients. **ADVERSE REACTIONS** The premarketing development program for Celera included citalopram exposures in patients and/or normal subjects from 3 different groups of studies: 429 normal subjects in clinical pharmacology/pharmacokinetic studies; 4422 exposures from patients in controlled and uncontrolled clinical trials, corresponding to approximately 1370 patient exposure years. There were, in addition, over 19,000 exposures from mostly open-label, European postmarketing studies. The conditions and duration of treatment with Celera varied greatly and included in overlapping categories open-label and double-blind studies, inpatient and outpatient studies, fixed-dose and dose-titration studies, and short-term and long-term exposure. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, ECGs, and results of ophthalmologic examinations. Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tables and tabulations that follow, standard World Health Organization (WHO) terminology has been used to classify reported adverse events. The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. **Adverse Findings Observed in Short-Term, Placebo-Controlled Trials** **Adverse Events Associated With Discontinuation of Treatment** Among 1063 depressed patients who received Celera at doses ranging from 10 to 80 mg/day in placebo-controlled trials of up to 6 weeks in duration, 16% discontinued treatment due to an adverse event, as compared to 8% of 446 patients receiving placebo. The adverse events associated with discontinuation and considered drug-related (ie, associated with discontinuation in at least 1% of Celera-treated patients and at a rate at least twice that of placebo) are shown in TABLE 1. It should be noted that one patient can report more than one reason for discontinuation and be counted more than once in this table.

TABLE 1. Adverse Events Associated With Discontinuation of Treatment in Short-Term, Placebo-Controlled Depression Trials		
Percentage of Patients Discontinuing Due to Adverse Event		
Body System/Adverse Event	Celera (N=1063)	Placebo (N=446)
<b>General</b>		
Asthenia	1%	<1%
<b>Gastrointestinal Disorders</b>		
Nausea	4%	0%
Dry Mouth	1%	<1%
Vomiting	1%	0%
<b>Central and Peripheral Nervous System Disorders</b>		
Dizziness	2%	<1%
<b>Psychiatric Disorders</b>		
Insomnia	3%	1%
Somnolence	2%	1%
Agitation	1%	<1%

**Adverse Events Occurring at an Incidence of 2% or More Among Celera-Treated Patients** TABLE 2 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred among 1063 depressed patients who received Celera at doses ranging from 10 to 80 mg/day in placebo-controlled trials of up to 6 weeks in duration. Events included are those occurring in 2% or more of patients treated with Celera and for which the incidence in patients treated with Celera was greater than the incidence in placebo-treated patients. The prescriber should be aware that these figures cannot be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ from those which prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the basis for the assessment of the relative contribution of drug and non-drug factors to the adverse event incidence rate in the population studied. The only commonly observed adverse event that occurred in Celera patients with an incidence of 5% or greater and at least twice the incidence in placebo patients was ejaculation disorder (primarily ejaculatory delay) in male patients (see TABLE 2).

TABLE 2. Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials*		
Percentage of Patients Reporting Event		
Body System/Adverse Event	Celera (N=1063)	Placebo (N=446)
<b>Autonomic Nervous System Disorders</b>		
Dry Mouth	20%	14%
Sweating Increased	11%	9%
<b>Central &amp; Peripheral Nervous System Disorders</b>		
Tremor	8%	6%
<b>Gastrointestinal Disorders</b>		
Nausea	21%	14%
Diarrhea	8%	5%
Dyspepsia	5%	4%
Vomiting	4%	3%
Abdominal Pain	3%	2%
<b>General</b>		
Fatigue	5%	3%
Fever	2%	<1%
<b>Musculoskeletal System Disorders</b>		
Arthralgia	2%	1%
Myalgia	2%	1%
<b>Psychiatric Disorders</b>		
Somnolence	18%	10%
Insomnia	15%	14%
Anxiety	4%	3%
Anorexia	4%	2%
Agitation	3%	1%
Dysmenorrhea†	3%	2%
Lbido Decreased	2%	<1%
Yawning	2%	<1%
<b>Respiratory System Disorders</b>		
Upper Respiratory Tract Infection	5%	4%
Rhinitis	5%	3%
Sinusitis	3%	<1%
<b>Urogenital</b>		
Ejaculation Disorder*	6%	1%
Impotence†	3%	<1%

\* Events reported by at least 2% of patients treated with Celera are reported, except for the following events which had an incidence in placebo  $\geq$  Celera: headache, asthenia, dizziness,

constipation, palpitation, vision abnormal, sleep disorder, nervousness, pharyngitis, micturition disorder, back pain. † Denominator used was for females only (N=638 Celera; N=252 placebo). \* Primarily ejaculatory delay. ‡ Denominator used was for males only (N=425 Celera; N=194 placebo). **Dose Dependency of Adverse Events** The potential relationship between the dose of Celera administered and the incidence of adverse events was examined in a fixed-dose study in depressed patients receiving placebo or Celera 10, 20, 40, and 80 mg. Jonkhoefer’s trend test revealed a positive dose response (p<0.05) for the following adverse events: fatigue, impotence, insomnia, sweating increased, somnolence, and yawning. **Male and Female Sexual Dysfunction With SSRI’s** Although changes in sexual desire, sexual performance and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that selective serotonin re-uptake inhibitors (SSRIs) can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling, are likely to underestimate their actual incidence. The table below displays the incidence of sexual side effects reported by at least 2% of patients taking Celera in a pool of placebo-controlled clinical trials in patients with depression.

Treatment	Celera (425 males)	Placebo (194 males)
<b>Abnormal Ejaculation</b> (mostly ejaculatory delay)	6.1% (males only)	1% (males only)
<b>Decreased Libido</b>	3.8% (males only)	<1% (males only)
<b>Impotence</b>	2.8% (males only)	<1% (males only)

In female depressed patients receiving Celera, the reported incidence of decreased libido and anorgasmia was 1.3% (n=638 females) and 1.1% (n=252 females), respectively. There are no adequately designed studies examining sexual dysfunction with citalopram treatment. Priapism has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes** Celera and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Celera treatment. In addition, a comparison of supine and standing vital sign measures for Celera and placebo treatments indicated that Celera treatment is not associated with orthostatic changes. **Weight Changes** Patients treated with Celera in controlled trials experienced a weight loss of about 0.5 kg compared to placebo patients. **Laboratory Changes** Celera and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Celera treatment. **ECG Changes** Electrocardiograms from Celera (N=802) and placebo (N=241) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. The only statistically significant drug-placebo difference observed was a decrease in heart rate for Celera of 1.7 bpm compared to no change in heart rate for placebo. There were no observed differences in QT or other ECG intervals. **Other Events Observed During the Premarketing Evaluation of Celera (citalopram HBr)** Following is a list of WHO terms that reflect treatment-emergent adverse events, as defined in the introduction to the ADVERSE REACTIONS section, reported by patients treated with Celera at multiple doses in a range of 10 to 80 mg/day during any phase of a trial within the premarketing database of 4422 patients. All reported events are included except those already listed in TABLE 2 or elsewhere in labeling, those events for which a drug cause was remote, those event terms which were so general as to be uninformative, and those occurring in only one patient. It is important to emphasize that although the events reported occurred during treatment with Celera, they were not necessarily caused by it. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring on one or more occasions in at least 1/100 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1000 patients; rare events are those occurring in fewer than 1/1000 patients. **Cardiovascular** – Frequent: tachycardia, postural hypotension, hypotension. Infrequent: hypertension, bradycardia, edema (extremities), angina pectoris, extrasystoles, cardiac failure, flushing, myocardial infarction, cerebrovascular accident, myocardial ischemia. Rare: transient ischemic attack, shingles, atrial fibrillation, cardiac arrest, bundle branch block. **Central and Peripheral Nervous System Disorders** – Frequent: paresthesia, migraine. Infrequent: hyperkinesia, vertigo, hyper-tonia, extrapyramidal disorder, leg cramps, involuntary muscle contractions, hypokinesia, neur-algia, dystonia, abnormal gait, hypesthesia, ataxia. Rare: abnormal coordination, hypersthesia, ptosis, stupor. **Endocrine Disorders** – Rare: hypothyroidism, goiter, gynecoma-stia. **Gastrointestinal Disorders** – Frequent: saliva increased, flatulence. Infrequent: gastritis, gastroenteritis, constipation, eructation, hemorrhoids, dysphagia, teeth grinding, glossitis, esophagitis. Rare: colitis, gastric ulcer, cholelithiasis, choleliths, duodenal ulcer, gastroesophageal reflux, glossitis, jaundice, diverticulitis, rectal hemorrhage, hiccups. **General** – Infrequent: hot flushes, rigors, alcohol intolerance, syncope, influenza-like symptoms. Rare: hayfever. **Hemic and Lymphatic Disorders** – Infrequent: purpura, anemia, epistaxis, leukocytosis, leucopenia, lymphadenopathy. Rare: pulmonary embolism, granulocytopenia, lymphocytosis, lymphopenia, hypochromic anemia, coagulation disorder, granulo bleeding. **Metabolic and Nutritional Disorders** – Frequent: decreased weight, increased weight. Infrequent: increased hepatic enzymes, thirst, dry eyes, increased alkaline phosphatase, abnormal glucose tolerance. Rare: bilirubinemia, hypokalemia, obesity, hypokinesia, hepatitis, dehydration. **Musculoskeletal System Disorders** – Infrequent: arthritis, muscle weakness, skeletal pain. Rare: bursitis, osteoporosis. **Psychiatric Disorders** – Frequent: impaired concentration, amnesia, apathy, depression, increased appetite, aggravated depression, suicide attempt, confusion. Infrequent: increased libido, aggressive reaction, paranoia, drug dependence, depersonalization, hallucinations, euphoria, psychotic depression, delusion, paranoid reaction, emotional lability, panic reaction, psychosis. Rare: catatonic reaction, melancholia. **Reproductive Disorders/Female** – Frequent: amenorrhea. Infrequent: galactorrhea, breast pain, breast enlargement, vaginal hemorrhage. \*% based on female subjects only: 2955. **Respiratory System Disorders** – Frequent: coughing. Infrequent: bronchitis, dyspnea, pneumonia. Rare: asthma, laryngitis, bronchospasm, pneumonitis, sputum increased. **Skin and Appendages Disorders** – Frequent: rash, pruritus. Infrequent: photosensitivity reaction, urticaria, acne, skin discoloration, eczema, alopecia, dermatitis, skin dry, psoriasis. Rare: hypertrichosis, decreased sweating, melanos, keratitis, cellulitis, pruritus ani. **Special Senses** – Frequent: accommodation abnormal, taste perversion. Infrequent: tinnitus, conjunctivitis, eye pain. Rare: mydriasis, photophobia, diplopia, abnormal lacrimation, cataract, taste loss. **Urinary System Disorders** – Frequent: polyuria. Infrequent: micturition frequency, urinary incontinence, urinary retention, dysuria. Rare: facial edema, hematuria, oliguria, pyelonephritis, renal calculus, renal pain. **Other Events Observed During the Non-US Postmarketing Evaluation of Celera (citalopram HBr)** It is estimated that over 30 million patients have been treated with Celera since market introduction. Although no causal relationship to Celera treatment has been found, the following adverse events have been reported to be temporally associated with Celera treatment, and have not been described elsewhere in labeling: acute renal failure, akathisia, allergic reaction, anaphylaxis, angioedema, choreoathetosis, chest pain, delirium, dyskinesia, echymosis, epidermal necrosis, ery-thema multiforme, gastrointestinal hemorrhage, grand mal convulsion, hemolytic anemia, hepatic necrosis, myoclonus, neuroleptic malignant syndrome, nystagmus, pancreatitis, priapism, prolactinemia, prothrombin decreased, QT prolonged, rhabdomyolysis, serotonin syn-drome, spontaneous abortion, thrombocytopenia, thrombosis, ventricular arrhythmia, Torsades de pointes, and withdrawal syndrome. **OVERDOSAGE Human Experience** Although there were no reports of fatal citalopram overdose in clinical trials involving overdoses of up to 2000 mg, postmarketing reports of drug overdoses involving citalopram have included 12 fatalities, 10 in combination with other drugs and/or alcohol and 2 with citalopram alone (3920 mg and 2800 mg), as well as nonfatal overdoses of up to 6000 mg. Symptoms most often accompanying citalopram overdose, alone or in combination with other drugs and/or alcohol, included dizziness, sweating, nausea, vomiting, tremor, somnolence, and sinus tachycardia. In more rare cases, observed symptoms included amnesia, confusion, coma, convulsions, hyperventilation, cyanosis, rhabdomyolysis, and ECG changes (including QTc prolongation, nodal rhythm, ventricular arrhythmia, and one possible case of Torsades de pointes).

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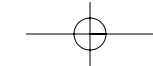
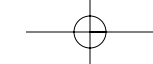
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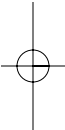
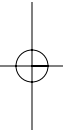


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