

Groups Join to Fight for Mental Health Reform

BY NELLIE BRISTOL
Contributing Writer

WASHINGTON — A coalition of national mental health organizations—including the American Psychiatric Association and the National Alliance for the Mentally Ill—has launched a campaign aimed at implementing some of the goals set 2 years ago by the New Freedom Commission on Mental Health.

A top priority of the effort, called the

Campaign for Mental Health Reform, is the enactment of mental health-parity legislation. Other priorities include using Medicaid funds for home- and community-based care instead of institutional services and allowing states to fund comprehensive treatment plans. The campaign also will work for legislation aimed at allowing families to buy into Medicaid services for children with disabilities.

Ending discrimination in the treatment of mental illness is “the next frontier,” according to Sen. Edward M. Kennedy (D-Mass.), who attended the press event in late July outlining the campaign’s agenda.

“It is something that this country has to come to grips with. [We] should and will be the better country, be a fairer, more just country, when we deal with this in the way that we have with physical illness,” said Sen. Kennedy, who was joined by several other members of Congress, including Sen. Mike DeWine (R-Ohio), Rep. Patrick Kennedy (D-R.I.), Rep. Sue Myrick (R-N.C.), and Rep. Jim Ramstad (R-Minn).

The coalition’s steering committee members are from the Bazelon Center for Mental Health Law, the National Association of State Mental Health Program Directors, the National Mental Health Association, and NAMI. The group developed “Emergency Response: A Roadmap for Federal Action on America’s Mental Health Crisis,” which lists 28 “action steps” aimed at improving provision of mental health services in the United States.

In 2003, President Bush’s New Freedom Commission on Mental Health report called for “fundamental transformation of the nation’s approach to mental health care.” However, the Campaign for Mental

Health Reform noted in its executive summary that “there has been little progress in realizing the commission’s goals or implementing its recommendations.”

In fact, since the commission released its report, the campaign noted, 63,000 Americans have died from suicide; more than 200,000 Americans with mental illness have been incarcerated; more than 25,000 families have given up custody of their children to get them mental health services; and juvenile detention centers have spent \$200 million “‘warehousing’ youth instead of providing treatment.”

The campaign estimates that the U.S. economy has lost more than \$150 billion in productivity because of unaddressed mental health needs. Other priorities for the group include reforming copayments for mental health treatment under Medicare and providing early identification and effective treatment both for returning veterans at risk of posttraumatic stress disorder and to mothers and children who receive health care at federally funded maternal- and child-health clinics.

The coalition also advocates presumptive eligibility for Social Security benefits and Medicaid for mentally ill homeless people and diverting mentally ill individuals who have committed nonviolent crimes into treatment instead of jail or prison.

Some of the group’s priority proposals are included in legislation pending in the House or Senate, campaign director Charles Konigsberg said. For example,

mental health parity is outlined in the Paul Wellstone Mental Health Equitable Treatment Act of 2005, sponsored in the House by Rep. Kennedy. Attempts to pass mental health-parity legislation have failed for the last several years.

Legislation to encourage states to let parents keep custody of their mentally ill children and still receive services is sponsored in the House by Rep. Ramstad and in the Senate by Sen. Susan Collins (R-Maine).

Mr. Konigsberg said the campaign considers its effort complementary to that of a federal agency agenda for mental health services improvement announced a few days earlier by six federal departments. The “multiyear effort to alter the form and function of the mental health system,” includes a federal executive steering committee that would oversee the “mental health system transformation,” according to press materials.

The 70-item Mental Health Action Agenda includes reinforcing the message that mental illness and emotional disturbances are treatable and that “recovery is the expectation,” through a national public education program sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA).

The agenda also proposes working to reduce the number of suicides through implementation of the National Strategy for Suicide Prevention and helping states formulate and implement comprehensive state mental health plans that would be able to create individualized plans of care. ■

A top priority of the effort, called the Campaign for Mental Health Reform, is the enactment of mental health-parity legislation.

‘Parity Plus’ Urged for Mental Health Benefits

BY JOYCE FRIEDEN
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Sometimes, being equal is just not enough—at least, that’s what the Progressive Policy Institute says.

A paper from the a liberal Washington think tank suggests that rather than aiming for simple dollar-for-dollar parity with physical health benefits, advocates for mental health parity should insist that providers be held accountable for delivering high-quality, cost-effective services.

The business community is intrigued by this idea, said David Kendall, senior fellow for health policy at the institute. “Employers see themselves as leaders in the outcomes disclosure field, and their argument has been all along that parity shouldn’t mean unlimited entitlement to [mental health] services,” he said. “So if we can find ways to discipline the demand side with outcomes [data], I think that may help break the deadlock on parity.”

One reason the Progressive Policy Institute (PPI) published the paper is that President Bush has “dropped the ball” on reforming the mental health system, even though he himself called for such reforms about 4 years ago, Mr. Kendall said.

In the report, PPI notes that enhanced parity “would bring together a wave of cutting-edge reforms—some proposed, some already proven—that aim to promote effective treatments and tangible results, often reinforced by pay for performance or other incentives.” One example would be Assertive Community Treatment (ACT), in which mobile interdisciplinary teams give 24-hour assistance to hard-to-reach mentally ill patients. “When states fail to adopt such practices, the cost of preventable hospitalization soars.” Parity legislation should “require the disclosure of performance results, not just reimbursement for any service provided,” the report said. “Without some form of accountability, mental health parity risks turning into a blank check for mediocre treatment-as-usual. Legislation should include a requirement to use at least some of the measurements developed by the Substance Abuse and Mental Health Services Administration,” such as its Mental Health Consumer-Oriented Report Card.

Rep. Patrick Kennedy (D-R.I.), chief sponsor of a parity bill in the House of Representatives, said that although accountable mental health care is a laudable goal, Parity Plus is not the way to go

about achieving it. “If we are to ever rid the prejudice associated with this country’s mental health policy, we cannot at the same time require some kind of higher standard of accountability for mental health care,” he said at a PPI forum on Parity Plus.

Nicholas Meyers, director of government relations at the American Psychiatric Association, in Arlington, Va., agreed. “We appreciate the interest of PPI in the parity issue, but framing and conditioning approval of parity on a range of performance initiatives is both a very dubious political strategy and perpetuates the stigma,” he said. Furthermore, performance measures are still in the early stages of development, especially in the area of pay for performance, Mr. Meyers said. For example, “There are a whole host of technical issues: Who owns the information that’s being reported? What protections are provided for confidentiality? How and by whom are measures developed and validated?”

Despite this opposition, PPI’s Mr. Kendall thinks that there is one other way a Parity Plus proposal helps to advance the mental health care debate: It puts some of the onus for improvement squarely on the managed care plans. ■

VYTORIN® (ezetimibe/simvastatin)

VYTORIN: There are insufficient data for the safe and effective use of VYTORIN in pediatric patients. (See Ezetimibe and Simvastatin below.)

Ezetimibe: The pharmacokinetics of ezetimibe in adolescents (10 to 18 years) have been shown to be similar to that in adults. Treatment experience with ezetimibe in the pediatric population is limited to 4 patients (9 to 17 years) with homozygous sitosterolemia and 5 patients (11 to 17 years) with HoFH. Treatment with ezetimibe in children (<10 years) is not recommended.

Simvastatin: Safety and effectiveness of simvastatin in patients 10-17 years of age with heterozygous familial hypercholesterolemia have been evaluated in a controlled clinical trial in adolescent boys and in girls who were at least 1 year post-menarche. Patients treated with simvastatin had an adverse experience profile generally similar to that of patients treated with placebo. **Doses >40 mg have not been studied in this population.** In this limited controlled study, there was no detectable effect on growth or sexual maturation in the adolescent boys or girls, or any effect on menstrual cycle length in girls. Adolescent females should be counseled on appropriate contraceptive methods while on therapy with simvastatin (see CONTRAINDICATIONS and PRECAUTIONS, Pregnancy). Simvastatin has not been studied in patients younger than 10 years of age, nor in pre-menarchal girls.

Geriatric Use

Of the patients who received VYTORIN in clinical studies, 792 were 65 and older (this included 176 who were 75 and older). The safety of VYTORIN was similar between these patients and younger patients. Greater sensitivity of some older individuals cannot be ruled out. (See CLINICAL PHARMACOLOGY, Special Populations and ADVERSE REACTIONS.)

ADVERSE REACTIONS

VYTORIN has been evaluated for safety in more than 3800 patients in clinical trials. VYTORIN was generally well tolerated.

Table 1 summarizes the frequency of clinical adverse experiences reported in ≥2% of patients treated with VYTORIN (n=1236) and at an incidence greater than placebo regardless of causality assessment from 3 similarly designed, placebo-controlled trials.

Table 1
Clinical Adverse Events Occurring in ≥2% of Patients Treated with VYTORIN and at an Incidence Greater than Placebo, Regardless of Causality

Body System/ Organ Class	Placebo (%)	Ezetimibe 10 mg (%)	Simvastatin** (%)	VYTORIN** (%)
Adverse Event				
	n=311	n=302	n=1234	n=1236
Body as a whole – general disorders				
Headache	6.4	6.0	5.9	6.8
Infection and infestations				
Influenza	1.0	1.0	1.9	2.6
Upper respiratory tract infection	2.6	5.0	5.0	3.9
Musculoskeletal and connective tissue disorders				
Myalgia	2.9	2.3	2.6	3.5
Pain in extremity	1.3	3.0	2.0	2.3

* Includes 2 placebo-controlled combination studies in which the active ingredients equivalent to VYTORIN were coadministered and 1 placebo-controlled study in which VYTORIN was administered.

** All doses.

Post-marketing Experience: The adverse reactions reported for VYTORIN are consistent with those previously reported with ezetimibe and/or simvastatin.

Ezetimibe: Other adverse experiences reported with ezetimibe in placebo-controlled studies, regardless of causality assessment: *Body as a whole – general disorders:* fatigue; *Gastrointestinal system disorders:* abdominal pain, diarrhea; *Infection and infestations:* infection viral, pharyngitis, sinusitis; *Musculoskeletal system disorders:* arthralgia, back pain; *Respiratory system disorders:* coughing.

Post-marketing Experience: The following adverse reactions have been reported in post-marketing experience, regardless of causality assessment: Hypersensitivity reactions, including angioedema and rash; elevated creatine phosphokinase; elevations in liver transaminases; hepatitis; thrombocytopenia; pancreatitis; nausea; cholelithiasis; cholecystitis; and, very rarely, myopathy/rhabdomyolysis (see WARNINGS, Myopathy/Rhabdomyolysis).

Simvastatin: Other adverse experiences reported with simvastatin in placebo-controlled clinical studies, regardless of causality assessment: *Body as a whole – general disorders:* asthenia; *Eye disorders:* cataract; *Gastrointestinal system disorders:* abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea; *Skin and subcutaneous tissue disorders:* eczema, pruritus, rash.

The following effects have been reported with other HMG-CoA reductase inhibitors. Not all the effects listed below have necessarily been associated with simvastatin therapy. *Musculoskeletal system disorders:* muscle cramps, myalgia, myopathy, rhabdomyolysis, arthralgias.

Nervous system disorders: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, dizziness, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy, psychic disturbances.

Ear and labyrinth disorders: vertigo.

Psychiatric disorders: anxiety, insomnia, depression, loss of libido.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included 1 or more of the following features: anaphylaxis, angioedema, lupus erythematosus-like syndrome, polymyalgia rheumatica, dermatomyositis, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, eosinophilia, arthritis, arthralgia, urticaria, asthma, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal system disorders: pancreatitis, vomiting.

Hepatobiliary system disorders: hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma.

Metabolism and nutrition disorders: anorexia.

Skin and subcutaneous tissue disorders: alopecia, pruritus. A variety of skin changes (eg, nodules, discoloration, dryness of skin/mucous membranes, changes to hair/nails) have been reported.

Reproductive system and breast disorders: gynecostasia, erectile dysfunction.

Eye disorders: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Abnormalities: elevated transaminases, alkaline phosphatase, γ -glutamyl transpeptidase, and bilirubin; thyroid function abnormalities.

Laboratory Tests

Marked persistent increases of serum transaminases have been noted (see WARNINGS, Liver Enzymes). About 5% of patients taking simvastatin had elevations of CK levels of 3 or more times the normal value on 1 or more occasions. This was attributable to the noncardiac fraction of CK. Muscle pain or dysfunction usually was not reported (see WARNINGS, Myopathy/Rhabdomyolysis).

Concomitant Lipid-Lowering Therapy

In controlled clinical studies in which simvastatin was administered concomitantly with cholestyramine, no adverse reactions peculiar to this concomitant treatment were observed. The adverse reactions that occurred were limited to those reported previously with simvastatin or cholestyramine.

Adolescent Patients (ages 10-17 years)

In a 48-week controlled study in adolescent boys and girls who were at least 1 year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia (n=175), the safety and tolerability profile of the group treated with simvastatin (10-40 mg daily) was generally similar to that of the group treated with placebo, with the most common adverse experiences observed in both groups being upper respiratory infection, headache, abdominal pain, and nausea (see CLINICAL PHARMACOLOGY, Special Populations and PRECAUTIONS, Pediatric Use).

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