



## The Need to Preserve Access: Depakote® and Mood Stabilizer Medications

*Bipolar disorder costs twice as much in lost productivity as major depressive disorder in the U.S. workplace—a disproportionately high \$14.1 billion annually.*

*The National Institute of Mental Health, Sept 2006<sup>1</sup>*

### Bipolar Disorder

Bipolar disorder is a common psychiatric disorder that is expressed through changes in mood, energy, and thinking. These changes are different from normal ups and downs; the symptoms of bipolar disorder are often severe.

Bipolar disorder is characterized by one or more episodes of extremely elevated mood (known as mania or, if milder, hypomania). Most people with bipolar disorder also experience periods of depression or mixed episodes (symptoms of depression and mania at the same time), usually separated by periods of relative stability.

People living with bipolar disorder frequently experience other co-occurring disorders. The most common problems are anxiety disorders, substance misuse, attention deficit disorders, and medical problems like asthma and obesity. The complexity and variability of symptoms can be challenging, yet many people with bipolar disorder experience recovery with the right treatment and supports.

### Mood Stabilizer Medications

Because bipolar disorder is usually a chronic, recurring illness, long-term continuous treatment is typically recommended. While psychosocial treatments and other strategies are important, many people with bipolar disorder also find medications useful in managing symptoms.

Bipolar disorder is often treated with mood stabilizer medications to help prevent and treat manic or depressive episodes. This group of medications includes lithium and several other medications. Mood stabilizing medications differ in their side effects, drug interactions, and effectiveness in individuals and with different forms of bipolar disorder.

### Depakote® and Depakote® ER

Depakote® (divalproex sodium) and Depakote® ER (extended release) are FDA-approved for treatment of mania in bipolar disorder and appear to have advantages in treating rapid cycling episodes, mixed episodes (symptoms of depression and mania at the same time), as well as mania with co-morbid substance abuse. Depakote® (divalproex sodium) became available in generic form in July 2008 and Depakote® ER is expected to be available in generic form in 2009.

With pressures to contain costs, state Medicaid agencies and other payers may attempt to encourage or require individuals who are on Depakote® or Depakote® ER to switch to a generic form. For some individuals, generics may offer an acceptable and less costly alternative. For others, a generic may result in different or increased side effects or different effectiveness.

For example, valproic acid has the same active ingredient as divalproex sodium and is often dispensed as a generic substitute for Depakote®. However, valproic acid acts more quickly and is associated with greater gastrointestinal problems.

Generic substitution has caused problems with other types of medications. For example, in the case of a generic form of Wellbutrin XL®, a rapid rate of release resulted in serious adverse reactions for many individuals and prompted an FDA news bulletin.<sup>1</sup>

While generics contain the same active ingredient(s) in the same dosage as a brand name drug, they may differ in fillers and in other aspects, such as the rate of release.

◆ **NAMI believes that the decision to switch from a brand to a generic should be made by an individual and his or her doctor.**

<sup>1</sup> FDA News Drug Daily Bulletin, "Generic Wellbutrin Called into Question," October 22, 2007, Vol. 4 No. 207.

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Many individuals may do well on a generic form of Depakote®, but others may not. Finding the right medication to manage symptoms is critical because the failure to respond to or tolerate a medication may lead to devastating episodes of mania or depression.

During mania, mood is typically elevated and judgment impaired. During depression, despair and lack of energy may be profound. People with bipolar disorder have lost careers, relationships, and financial stability during episodes of depression, recklessness, irrational behavior or substance abuse.

Policies that encourage switching or therapeutic substitution or that impose fail-first and step therapy requirements for mood stabilizers raise serious health concerns.

### Switching

Switching individuals who are doing well on a mood stabilizer to divalproex sodium threatens continuity of care and may result in high health risks and costs.

Unlike many medications, the side effects of mood stabilizer medications can be serious.

Divalproex sodium requires regular blood tests to ensure a therapeutic level has been reached or maintained and to monitor liver functioning and other possible side effects. In addition, divalproex sodium may interact with common medications, like aspirin.

- ◆ **NAMI opposes switching persons who are stable on a mood stabilizer to a generic.**

### Fail-First or Step Therapy

Fail-first and step therapy policies require individuals to try, and even fail, on a preferred medication before they are allowed to take a non-preferred medication that may work better for them.

Unlike many illnesses, though, a medication failure in the treatment of bipolar disorder can result in emergency department visits, hospitalization—or even homelessness, incarceration or suicide. People with bipolar disorder die by suicide at a very high rate (about 10%), making it imperative to find the right medication for an individual.

- ◆ **NAMI opposes policies that require people to fail on a preferred medication before allowing another medication.**

### Therapeutic Substitution

Therapeutic substitution programs are designed to encourage pharmacists to switch a consumer from one drug to a *completely different drug* in the same general class, typically a less expensive medication.

Therapeutic substitution places consumers at considerable health and safety risk and jeopardizes appropriate medication decisions made between an individual and his or her doctor.

- ◆ **NAMI opposes therapeutic substitution of mood stabilizer medications.**

### Unique Characteristics Indicate Need for Shared Physician-Patient Decision Making

- ✓ **Person is unable to have regular blood tests.**  
Regular blood tests are needed when taking divalproex sodium or valproic acid to ensure a therapeutic blood level has been reached or maintained and to monitor for liver, pancreas and platelet abnormalities.
- ✓ **Person has difficulty with side effects.**  
Valproic acid and divalproex sodium may cause side effects that are intolerable for some, including nausea and gastrointestinal problems, weight gain, drowsiness, and rashes or hair loss.
- ✓ **Person has a history of responsiveness to Depakote® or Depakote® ER or another mood stabilizer.**  
Prescribing a generic may be appropriate in a newly-diagnosed patient or where symptoms are not fully controlled; however, generic substitution should be avoided in individuals whose symptoms have stabilized with the name brand drug or on another mood stabilizer.
- ✓ **Person is reluctant or unwilling to take divalproex sodium or valproic acid.**  
A medication cannot be effective if the consumer does not take it. During mania, people are often unaware their mood and behaviors are symptoms of illness. During depression, seeking help may seem useless or impossible. Therefore, if a person is willing to take a particular medication in a class, it is critical that it is available to them and to their doctor without restrictions.