

**FACTS ON ACCESS TO MEDICATIONS FOR PEOPLE WITH DEPRESSIVE,  
BIPOLAR AND ANXIETY ILLNESSES:**

**THE POLICYMAKER'S RESOURCE**

*"The past decade has seen an outpouring of new drugs introduced for the treatment of mental illness. New medications for the treatment of depression ... are among the achievements stoked by research advances in both neuroscience and molecular biology."*

U.S. Surgeon General Report on Mental Health, 1999

**MEDICATIONS FOR PEOPLE WITH DEPRESSIVE, BIPOLAR AND ANXIETY  
DISORDERS SHOULD BE EXEMPT FROM RESTRICTIVE PUBLIC POLICIES**

- Unlike many medications that treat other illnesses, medications that treat depressive, bipolar and anxiety disorders cannot be used interchangeably.
- Because of the biologic differences among patients, medications that treat these disorders work differently for each person.
- Also, because the brain is such a complex organ and these disorders are so complex, medications affect each person's brain in a very different way.
- The side effects of these medications can be extremely serious, and vary with each patient. The worse the side effects, the less likely a patient will be able to stay on treatment.
- Forcing physicians to change medications that treat depressive, bipolar and anxiety disorders interferes with clinical decision making. It can weeks or months to determine if a medication works, and if not, additional weeks with no medication is required before a new one is tried. Each failed episode results in suffering and possible worsening of a patient's condition.
- Access to medications for people with these disorders is essential for achieving the best possible clinical outcome as quickly as possible, which leads to the most cost-effective policy for policymakers and states.
- These disorders are three of the leading disabilities in the U.S. Access to medications for these disorders ensures effective and faster treatment, thereby returning people to work earlier.
- No real cost savings, even in the short term, will result from Medicaid policies that restrict medication choices for people with these disorders.
- Access to medications is critically important based on the unique nature of the medications and the individual characteristics of people with these disorders. State legislators should preserve and/or restore state funding for medications for people living with these illnesses.

## Introduction

- **The treatment of persons with depressive, bipolar and anxiety disorders has been transformed in recent years with the introduction of ground-breaking medications that can relieve many of the symptoms. The result has been improved quality of life and improved productivity for many Americans.**
- For example, between 80-90% of those living with serious depression can be effectively treated and return to their normal daily activities and feelings.
- However, finding the medications and dosages that work best for different patients requires many considerations – the diagnosis, medication factors and individual patient factors.
- Failure to take these factors and others into account, can prove catastrophic for people with these disorders – creating serious consequences for the individual, family, and potentially the entire community.

Between 80-90% of those living with serious depression can be effectively treated and return to their normal daily activities and feelings.

- External barriers such as "fail-first" strategies may impair the ability of people with these disorders to adhere to treatment. This is important because the first

few episodes need effective treatment to improve the trajectory of response in the future.

- Cost-containment policies such as restrictive formularies and "fail-first" policies are inappropriate and counter-productive. Any policy that restricts access to medications for depressive, bipolar and anxiety disorders interferes with the practice of medicine and denies patients appropriate clinical treatment.
- These factors are the reasons that the independent Kaiser Family Foundation -- in their recent report on prior authorization for medications -- specifically recommended that psychiatric medications be exempt from any public policies that restrict access to medications.

## What is Non-Interchangeability?

- **"Non-interchangeability" means each medication within the given classes of medications that treat depressive, bipolar and anxiety disorders are unique and cannot be therapeutically substituted for another medication.**
- Psychotropic medications are different from other medicines. It takes time to judge their effectiveness and measure patient reactions.
- Because the drugs vary greatly, corresponding public policies must provide room for flexibility.
- For example, a major class of psychiatric medications is anti-depressants. Within this group of drugs, each medication affects the brain differently leading to highly individualized responses and side-effect profiles from one patient to the next.

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- No medication works for all patients, all forms of depression or anxiety disorders, all situations, or is superior in effectiveness over all others within or between classes.
- There is significant evidence that between 40 to 60 percent of patients fail to respond adequately to the first anti-depressant they are prescribed by a physician, yet when

switched to another medication within the same class (e.g. from one SSRI to another) their responses improve. This evidence directly supports the concept of non-interchangeability.

### The Patient's Individuality

- Most medication choices to treat depressive, bipolar and anxiety disorders require both knowledge about the specific patient and professional judgment.
- Proper medications and dosages for these disorders depend on the age of the patient, gender, family history, the chronic nature of the illness and the general health status of the individual.

Figure 1.

#### Denying Medications to People with Mental Illness Shifts Costs to Other Systems

- 20% of the Prison Population Has a Mental Illness
- 46% of the Homeless Population Has a Mental Illness
- 25% of all Admissions for Emergency Medical Services and Hospitalizations are People with Mental Illnesses
- 80% of Children Entering the Juvenile Justice System Have a Mental Illness
- 26% of Social Security Insurance Beneficiaries Have a Mental Illness, Reflecting a 90% Unemployment Rate Among People with Mental Illnesses

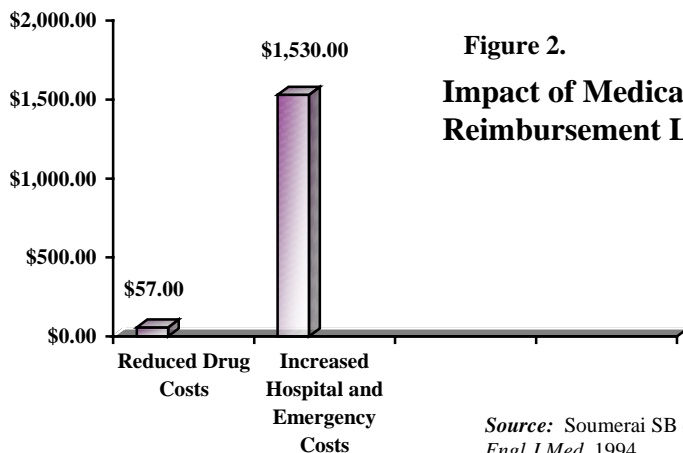


Figure 2.  
**Impact of Medicaid Drug Reimbursement Limits**

Source: Soumerai SB et al. *N Engl J Med.* 1994.

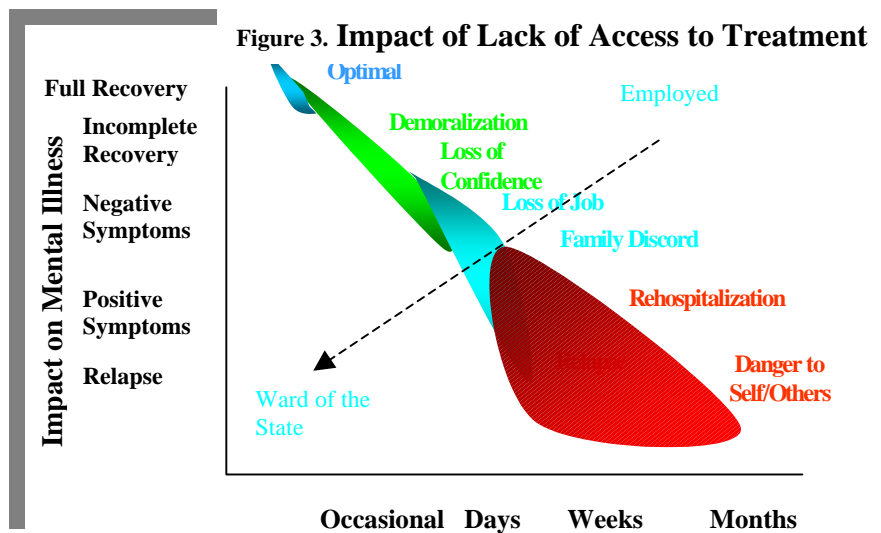
- The choice of medication by the physician should be evidence-based and consistent with practice guidelines and take into account unique patient characteristics.
- Differences in drug metabolism related to ethnicity, as well as cultural influences on patient and caregiver attitudes are also

important factors in the successful treatment of many illnesses, including depressive, bipolar and anxiety disorders.

- Restrictive formularies may discriminate against those patients who need alternate medication choices because of genetic factors.
- It is critically important to maintain physician and patient choice in order to find an effective treatment, as quickly as possible, thus achieving the best possible clinical outcome and avoid much higher costs downstream in the form of emergency department visits, hospital stays and crisis management, **(Figure 1)**.
- Patients are less likely to adhere to treatment on medications that are not best for them and without supporting services, and are more likely to suffer a serious episode.
- Financial or procedural barriers to medication access should be avoided for the most vulnerable populations such as people with major depression, bipolar disorder, and anxiety disorders. Careful selection of medications can prevent severe illness, hospitalization or death.
- People with these disorders often do not respond to the first or second medication regimen because of idiosyncratic differences between patients. It is often impossible to predict which medications will ultimately will be effective.
- Such patients have notoriously poor compliance with medication regimens so any changes in medications are likely to disturb fragile and biologic equilibriums, resulting in an expensive exacerbation of the illness, **(Figure 2)**.

### Restrictive Formularies are Bad Economics for States

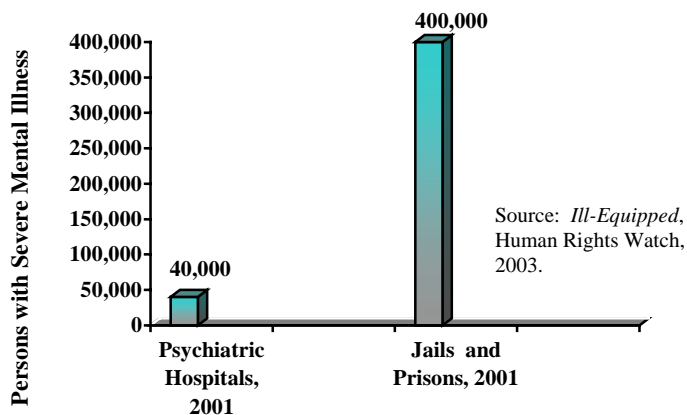
- Because of the characteristics of depressive, bipolar and anxiety disorders, and the uniqueness of medications that treat these illnesses, restrictive formularies are not likely to control costs as effectively as they control the costs for other chronic diseases, and could



negatively affect the treatment-matching process, depending on formularies' structures, (Soumerai, 2003 and 2004; Towse, 2003; Hensley, 2001; Horn, 2003).

- Failure to treat moderate to severe forms of depressive, bipolar and anxiety disorders with the most effective and appropriate medications available results not only in incomplete recovery and potential relapse, but potentially in increasingly severe symptoms, leading to a patient's death by suicide, **(Figure 3)**.

**Figure 4.**  
**Jails and Prisons: The New “Psychiatric Hospitals”**



- People with depressive, bipolar and anxiety disorders are at high risk of attempted and completed suicide; however, they frequently return to work if they are adequately treated.
- Denying access to needed medications ultimately increases costs to the state’s Medicaid system.
- For example, if limits to one anti-depressant are imposed, about 25% of patients will not respond to that agent and will need to switch, resulting in a

referral to a more costly psychiatry specialty sector or patient drop out. Patients who switch anti-depressants are in treatment 50% longer and cost approximately 50% more to treat in more costly treatment settings.

- Denying access also increases costs in other areas through increased homelessness and incarceration. Jails and prisons have become the “de facto” psychiatric hospitals in the U.S., (**Figure 4**).
- A study conducted by the University of Southern California found that “fail first” policies for psychiatric medications cost the state more than \$2,500 per consumer in just a 6-month period.
- A federally funded study conducted by The Lewin Group found that reductions in pharmaceutical budgets gained by excluding effective medications from coverage is more than offset by increases elsewhere in the system such as increased hospitalization and emergency room use.

## **Positive Effects of Open Access to Medications are Enormous**

- **Enhanced productivity** – With appropriate treatment, most people with depression, bipolar and anxiety disorders are capable of working and contributing to the American tax base. In fact, a recent survey found that the majority of the costs of treating depression are offset by the increased productivity of the individuals who receive treatment.
- **Decreased public expenditures for hospital based services** – The provision of appropriate treatment for these disorders decreases the necessity of crisis-oriented psychiatric services in inpatient treatment settings, the costs of which are frequently financed by publicly funded programs such as Medicare, Medicaid, or state mental health funds.
- **Lower burdens on law enforcement, courts and corrections** – Police have become front line responders to people experiencing psychiatric crises in the U.S. Correctional facilities have become the largest de-facto psychiatric treatment facilities

(10). The availability of timely and appropriate treatment for people with mental disorders will lessen significantly the considerable financial and human resource burdens that these roles entail. While people with serious mental illnesses are generally no more violent than the rest of society, the availability of appropriate treatment will also have a positive impact on public safety.

- **Healthier and more productive families** – The availability of appropriate treatment for people with these disorders decreases burdens on family members to provide constant care, and thereby allows these family members to work and contribute more to society.

## **The Physical Health-Mental Health Connection**

- Research demonstrates that mental health is key to overall physical health. Mental illnesses frequently co-exist with medical disorders.
- Improving services for individuals with mental illnesses requires paying close attention to how mental health care and general medical care interact.
- While mental health and physical health care are clearly linked, a major gap exists between the mental health care and general health systems in practice.
- A number of studies have shown that adults with common medical disorders have high rates of depression and anxiety. Depression is common in people with coronary heart disease and other cardiac illnesses. This situation is especially dangerous because depression increases the risk of dying from heart disease by as much as three-fold.
- When considering older adults who have physical illnesses – such as heart disease, stroke, cancer, and arthritis – roughly 25% also have depression.
- Depression impairs self-care and adherence to treatments for chronic medical illnesses.
- People with both diabetes and depression have an increased likelihood of experiencing a greater number of diabetes complications compared to those without depression.
- Evidence suggests that improved treatments and outcomes of the physical problems of those suffering from mental illness result from improved access to medications. Also mental illnesses may improve by appropriately treating those with medical complications was well.

## **The Evidence Base for Newer Anti-Depressant Medications**

*“Over the past decade, the selective serotonin reuptake inhibitor (SSRI) class of anti-depressants has largely replaced the older and more problematic tricyclic anti-depressants, based in large part on the safety and side effect considerations.”*

Steven E. Hyman, M.D., Former Director, National Institute of Mental Health

- **The newer class of anti-depressants, called SSRIs, has been hailed as a breakthrough in the treatment of depression by scientists and physicians.**

- A very large body of research has been conducted on individual anti-depressant medications, and on comparisons between classes of anti-depressant medications as well as between different drugs within the same class of anti-depressant medication.
- The evidence base is moderately strong that the newer, and consequently more costly, anti-depressants (SSRIs, selective norepinephrine reuptake inhibitors (SNRI), and atypicals) are generally more effective than older anti-depressants (tricyclics). Newer medications are also safer and have both fewer side effects and less severe side effects.
- The introduction of SSRIs significantly reduced the number of patients who had stopped taking their medication compared to those who were given older medications, according to a study of 2,600 patients with depression who received prescriptions for anti-depressant drugs.
- The cost of treating major depression in the U.S. decreased by 25 percent from 1991 to 1995, a trend that was driven largely by the development of increasingly effective anti-depressant medications.
- Anti-depressant medications represent less than 10% of total direct costs of depression.

Newer medications are also safer and have both fewer side effects, and less severe side effects.

- A recent landmark government-financed study has found that anti-depressants are effective in treating depression

in children and adolescents. The study, called the Treatment for Adolescents with Depression Study (TADS), involved youths between the ages of 12 and 17. Researchers said that benefits of taking anti-depressants for depressed children far outweighed the risks and that adverse events are extremely rare. The study also found that the combination of medications and talk therapy offer the best results for children with moderate and severe depression.

## **The FDA and Anti-depressants**

- Recently, the FDA has required additional warnings that alert consumers of the increased risk of suicide to patients when they are started on SSRI therapy and/or when their dose is titrated. Although the risk is small, additional monitoring by the physician is suggested.
- Providing both doctors and parents with complete information represents sound clinical practice. Discussion of benefits and risks in prescribing any medication or course of treatment is essential.
- Close monitoring is appropriate. There is also a need for a clear warning that depression can have significant consequences, including suicidality, if not appropriately treated.
- Fail first policies will increase the number of medication changes and will change the dose concentration required to stabilize patients. Forcing economically deprived people to go through this process is the de facto equivalent of trading of risk for cost.

- Given this new warning, it is more important than ever to allow physicians the flexibility of selecting an agent that will increase the likelihood of a quick positive outcome.
- Only the doctor can know what is best for each individual patient because of the unique actions of each medication, the unique manifestation of the disease in each individual, the mental health history of patients and their families, and the use of other medications for other medical problems.

## Clinical Improvements in the Real World

- **The concept of interchangeability for anti-depressants and anti-anxiety drugs is based on analyses of clinical trial results collected for approval of medications by the Food and Drug Administration (FDA). However, these studies are faulty.**

Researchers have found that up to 86 percent of patients in treatment in clinical situations for depression, would have been excluded from a randomized clinical trial for an anti-depressant, mostly because of the presence of another chronic illness.

- Studies designed to meet FDA requirements for approval are based on narrowly defined efficacy. Evidence now shows these studies do not equate to the effectiveness of medications in the general population.

- Researchers have found that up to 86 percent of patients in treatment in clinical situations for depression, would have been excluded from a randomized clinical trial for an anti-depressant, mostly because of the presence of another chronic illness.
- The bottom line is that research has shown that there is significant variation in individual responses to psychiatric medications and that there are dramatic health and financial costs resulting from limiting access to appropriate medications.

## Conclusion

- **Access to anti-depressant, anti-anxiety and anti-convulsant medications versus barriers to treatment can mean the difference between hope and despair, recovery and struggle, life and death.**
- The stream of new medications that has reached millions of people with depressive, bipolar and anxiety disorders holds enormous potential.
- Yet, barriers are being imposed by state policymakers that restrict access to needed medications for people with these disorders.
- Given many states' budget crises, some may be tempted to limit access to medication and cut funding for services for those with mental illness. However, this is not the

Based on the uniqueness of the medications and the individual patient characteristics of depressive, bipolar and anxiety disorders, it is critically important for state legislators to preserve and/or restore state funding for medications for people with depressive, bipolar and anxiety disorders.

way to create an effective, efficient mental health system for those served by Medicaid and other public programs.

- Access to medications for people with depressive,

bipolar and anxiety disorders is essential for achieving the best possible clinical outcome as quickly as possible, which leads to the most cost-effective policy for legislators and physicians.

- Based on the uniqueness of the medications and the individual patient characteristics of depressive, bipolar and anxiety disorders, it is critically important for state legislators to preserve and/or restore state funding for medications for people with depressive, bipolar and anxiety disorders.

## References

- American Society of Clinical Psychopharmacology: Anti-depressant Basics: Part 2. Treatment Considerations, in *ASCP Model Psychopharmacology Curriculum*, New York, ASCP. 2001.
- Boland, R.J., and M.B. Keller. *Treatment of Depression. The American Psychiatric Publishing Textbook of Psychopharmacology, 3<sup>rd</sup> edition*, Edited by Schatzberg, A.F. and C.B. Nemeroff. Washington, DC, American Psychiatric Press, 850, 2003.
- Chochinov, H.M. Depression in Cancer Patients. *Lancet Oncology*, 2, 2001, pp. 499-505.
- DeGrott, M., et al. Association of Depression and Diabetes Complications: A Meta-Analysis. *Psychosomatic Medicine*, 63, 2001, pp. 619-630.
- Ford, D.E. Depression is a Risk factor for Coronary Artery Disease in Men: The Precursors Study. *Archives of Internal Medicine*, 158, 1998, pp. 1422-1426.
- Frances, A., et al. Treatment of Schizophrenia. *Journal of Clinical Psychiatry*, 57, 1996, pp. 1-59.
- Gupta, A., et al. Post-stroke Depression. *International Journal of Clinical Practice*, 56, 2002, 531-537.
- Hensley, P.L., and H.G. Nurberg. Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls. *Pharmacoeconomics*, 19:10, 2001, pp. 973-982.
- Horn, S.D. Limiting Access to Psychiatric Services Can Increase Total Health Care Costs in Managing Mental Illness: The Hidden Costs of Restricting Access to Medications. *Drug Benefit Trends*, Vol. 15, Supplement 1, December 2003, pp. 12-18.
- Kessler, R.C., et al. Depression in the Workplace: Effects on Short-Term Disability. *Health Affairs*, Vol. 18, No. 5, 1999, pp. 163-171.
- Kent, J.M., Coplan, J.D., and J.M. Gorman. Clinical Utility of the Selective Serotonin Reuptake Inhibitors in the Spectrum of Anxiety. *Biological Psychiatry*, 44, 1998, pp. 812-824.
- Klein, D.F., et al. Improving Clinical Trials: American Society of Clinical Psychopharmacology Recommendations. *Archives of General Psychiatry*, 59, 2002, pp. 272-278.
- Managing Mental Illness: The Hidden Costs of Restricting Access to Medications. *Drug Benefit Trends*, Volume 15, Supplement 1, December 2003.
- Maximizing Pharmacotherapy in the Treatment of Major Depression: The Case for Maintaining Open Access to Medically Indicated Medications*. American Psychiatric Association, Office of Healthcare Systems and Financing, March 2004.
- NAMI. *Refining Messages and Strategies to Preserve Access to Mental Health Medications – Conference Proceedings*. National Mental Health Association and the American Psychiatric Association, January 25-26, 2004.
- New Freedom Commission on Mental Health. *Achieving the Promise: Transforming Mental Health Care in America. Final Report*. DHHS Pub. No. SMA-03-3832. Rockville, MD: 2003, pp. 29-33.
- Peet, M. Induction of Mania with SSRIs and Tricyclic Anti-depressants. *British Journal of Psychiatry*, 164, 1994, pp. 549-550.
- Preskorn, S.H. Classification of Neuropsychiatric Medications by Principle Mechanism of Action: A Meaningful Way to Anticipate Pharmacodynamically Medicated Drug Interactions. *Journal of Psychiatric Practice*, 9, 2003; 9:376-384.
- Solomon, D.A., Keller, M.B., and A.C. Leon. Recovery from Major Depression: A 10-Year Follow-up Across Multiple Episodes. *Archives of General Psychiatry*, 54, 1997, pp. 1001-1006.
- Soumerai, S.B. Benefits and Risks of Increasing Restrictions on Access to Costly Drugs in Medicaid. *Health Affairs*, 23:1, January-February, 2004, pp. 135-146.
- Soumerai, S.B. Unintended Outcomes of Medicaid Drug Cost-Containment Policies on the Chronically Ill, *Journal of Clinical Psychiatry*, 64 (suppl 17), 2003, pp. 19-22.

Stark, D.P., et al. Anxiety in Cancer Patients. *British Journal of Cancer*, 83, 2000, pp. 1261-1267.

Towse, A., The Efficient Use of Pharmaceuticals: Does Europe Have Any Lessons for a Medicare Drug Benefit? *Health Affairs*, 22:3, May-June 2003, pp. 42-45.

Turner-Cobb, J.M., et al. Social Support and Salivary Cortisol in Women with Metastatic Breast Cancer. *Psychosomatic Medicine*, 62, 2000, pp. 337-345.

Westenberg, H.G. Developments in the Drug Treatment of Panic Disorder: What is the Pace of SSRIs? *Journal of Affective Disorders*, 1996, 40, 85-93.

World Health Organization. *The World Health Report. Mental Health: New Understanding, New Hope*, 2001, p. 90.

U.S. Department of Health and Human Services. *Mental Health: A Report of the Surgeon General*. Rockville, MD: U.S Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services, National Institutes of Health, National Institute of Mental Health, 1999.

Zornberg, G.L. and H.G. Pope. Treatment of Depression in Bipolar Disorder: New Directions for Research. *Journal of Clinical Psychotherapy*, 1993, 13, 397-408.