

# **Saving Lives, *Saving Money***

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*The Case for Open And Unrestricted  
Access to Mental Health Medications*

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**Texas Society of Psychiatric Physicians  
2003**

## **Texas Society of Psychiatric Physicians**

### *A District Branch of the American Psychiatric Association*

The Texas Society of Psychiatric Physicians was created in 1956 as the Texas Neuropsychiatric Association, a state branch of the American Psychiatric Association. It was first designated as the Texas District Branch of the American Psychiatric Association and incorporated in that name as a non-profit scientific organization in 1963. Following a membership vote in May 1986, the Constitution and Bylaws were amended to reflect the new name, Texas Society of Psychiatric Physicians. The name was changed to emphasize that psychiatry is the only branch of medicine which specializes in and deals with the delivery of care and treatment of persons with mental illness, and that it is the only mental health provider whose members are trained and licensed as physicians. By adopting the name change to the Texas Society of Psychiatric Physicians, the Society underscored psychiatry's special, unduplicated role in the care and treatment of mental illness.

- TSPPs purpose is summarized in its Mission Statement: The Texas Society of Psychiatric Physicians is dedicated to developing the highest quality of comprehensive psychiatric care for patients, families, and communities.

- TSPPs objectives are to function in cooperation with, and as a component part of, the American Psychiatric Association:

- To promote the best interests of patients and those actively or potentially making use of mental health services;
- To advance the standards of all psychiatric services and facilities;
- To foster the cooperation of all who are concerned with the medical, psychological, social, and legal aspects of mental health and illness;
- To make psychiatric knowledge available to other practitioners of medicine, to scientists in other fields of knowledge, and to the public; and,
- To assist the American Psychiatric Association in the promotion of its aims and objectives.

TSPP has 1400 members and 17 local affiliated chapters located throughout Texas: Austin, Bexar County, Brazos Valley, Corpus Christi, East Texas, El Paso, Galveston-Brzaoria, Heart of Texas, Houston, Lone Star, North Texas, Red River, South Texas, South-east Texas, Tarrant, Victoria, and West Texas.

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Mental illness affects an estimated 550,000 adults and children in Texas, but its consequences and costs are felt by many more, including family members, law enforcement officers, members of the judicial system, health care workers and the general public.

In recent years, powerful new medications have revolutionized the treatment of mental illnesses, allowing people with even the most serious disorders, such as schizophrenia, to live successfully in the community, hold jobs, maintain healthy relationships and pursue productive lives. But budget pressures and rising Medicaid costs could well threaten the availability of some of these life-changing medications.

As the State weighs strategies to reign in Medicaid costs, it will be tempting for policymakers to consider restricting access to mental health medications to achieve the appearance of short-term savings. However, as this report documents, such restrictions would have a serious detrimental impact on other budget categories, costing the State and local governments much more than they would save.

Any immediate savings created by limiting medications is quickly eclipsed by other costs, because untreated or inadequately treated mental illness often results in expensive community consequences: including law enforcement and judicial involvement, emergency room treatment and hospitalization.

And the cost in human suffering is incalculable.

In an effort to help policymakers avoid policy choices with expensive results – in human and financial terms – we offer this review of research findings related to mental health treatment and experiments to restrict mental health medications. As mental health treatment professionals, we well know that the treatment of people with mental illnesses is highly individualized. A one-size-fits-all approach will not work in this area; it will seriously backfire. The bottom line is clear: as documented in study after study, open access to mental health medications saves lives and saves money.

# *Key Findings*

- Patient response to psychiatric medicines is highly individualized. Reaction to medications is influenced by factors such as physiology, gender, age, ethnicity and severity of illness.
- Restriction-based programs put the government – not trained physicians – in charge of deciding which pharmaceuticals are best for patients.
- Atypical antipsychotic medications are not therapeutically interchangeable. They vary in molecular structure, dosing, tolerability, efficacy and safety, metabolism and effect on cognition.
- Restricting access to mental health medications leads to increased costs to the state and society and discourages appropriate physician prescribing patterns.
- Requiring drug failure in mental health may reduce the chances for recovery because response to an antipsychotic drug can take weeks and the side effects and personal, medical and social costs can be substantial.
- Studies have shown that with the maintenance of appropriate drug therapy some persons with schizophrenia recover completely, while others may improve to the point where they can live independently.
- Price controls are not based on sound clinical evidence because their long-term impact has not been adequately evaluated.
- Studies show that restrictive formularies do decrease drug spending, but they significantly increase physician spending and mental hospital spending, which more than offset any drug cost savings.
- There is no guarantee that a person suffering from severe mental illness will return to their previous level of functioning following a treatment failure.
- Research suggests that for every one dollar saved by restricting access to mental health medications, up to 17 dollars will be lost due to inadequate control of the disease state.

# *Recommendations*

- The state should support open access to all mental health medications within the Medicaid program.
- Atypical antipsychotics should be offered as a first-line treatment for schizophrenia and other mental illnesses involving psychosis.
- Decisions regarding appropriate treatment for an individual with a mental illness should be left to the discretion of the treating physician, not a third party.
- Unrestricted access to mental health medications for Medicaid patients should include people with mental illnesses who are incarcerated in state prisons or committed to state mental hospitals.
- The state should mandate that people with mental illnesses who are incarcerated in local jails have access to the psychiatric medications prescribed by their doctors.
- The state should continue efforts to expand community/evidence-based care, such as Program for Assertive Community Treatment (PACT) and new generation antipsychotic medications for people with mental illnesses.
- The state should have diversion programs, which allow a person's mental condition to be considered prior to arrest or sentencing, to ensure that non-violent offenders receive appropriate treatment instead of punishment.
- The state should work to promote eligibility for Medicaid, either by broadening access to the program by altering the eligibility criteria or by working to qualify already eligible persons.

State policies should recognize and reflect that serious mental illnesses, such as schizophrenia and bipolar disorder are biologically based illnesses that deserve the same consideration and protection as other chronic diseases.

# *The Prevalence and Costs of Mental Illness*

The outlook for the successful treatment of mental illness has never been better, yet too many people are going untreated. Of the estimated 550,000 Texans with mental illnesses, only 150,000 adults and children with severe and persistent mental illnesses such as bipolar disorder or schizophrenia are seen in our public health system. Another 150,000 adults and juveniles, who were former patients in our public mental health system, are now in our prisons, jails, or on probation or parole. <sup>(1)</sup>

- Roughly 1% of the U.S. adult population is diagnosed with schizophrenia and according to the U.S. Dept. of Health and Human Services, approximately 90% of those patients are Medicaid recipients. <sup>(2)</sup> Schizophrenia is one of the most common and most debilitating mental illnesses.
- Bipolar disorder affects 1.5% of the population, <sup>(3)</sup> but only 27% of those suffering are undergoing treatment. One of every 4-5 untreated patients commits suicide. <sup>(4)</sup>
- Almost half of the adults with serious and persistent mental illnesses are between the ages of 25 and 44. <sup>(5)</sup>

Recent research suggests that schizophrenia is associated with abnormalities of the brain chemistry and brain structure, along with abnormalities of neurotransmitters (e.g., dopamine, serotonin). Brain-imaging technology has demonstrated that schizophrenia is as much an organic brain disorder as is multiple sclerosis, Parkinson's or Alzheimer's disease. To be diagnosed with schizophrenia, a patient must have psychotic, "loss of reality" symptoms for at least six months and show increasing difficulty in functioning normally. <sup>(6)</sup>

Bipolar disorder, also known as manic-depression, is a brain disorder that results in recurring or cycling episodes of mania and depression. Although it often is described as a "mood disorder," episodes can affect speech, appetite, sleep, thinking, and judgment. And since it is a chronic disease, it requires ongoing treatment. Bipolar disorder can be controlled if it is properly treated. However, left untreated it can only get worse with the symptoms more pronounced, potentially resulting in job loss, failed marriage, and drug and alcohol abuse. <sup>(7)(8)</sup>

Most people with bipolar disorder who are receiving treatment are able to lead productive and satisfying lives. But early and continued intervention and proper medication are essential parts of successful treatment. The type and amount of medication administered depends on individual episodes and severity of the disease. <sup>(7)</sup>

While there is no cure for severe mental illnesses, such as schizophrenia and bipolar disease, they are highly treatable disorders. According to the National Advisory Mental Health Council, the treatment success rate for schizophrenia is comparable to the treatment success for heart disease. <sup>(9)</sup> Studies have shown that with the maintenance of

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## The Prevalence and Costs of Mental Illness

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appropriate drug therapy, some persons with schizophrenia recover completely, while others may improve to the point where they can live independently.<sup>(10 - 13)</sup> However, in order to help patients avoid or reduce frequent relapses and rehospitalizations, schizophrenia should be diagnosed and treated as early as possible.

- About 80% of those with schizophrenia who stop taking their medications after an acute episode will have a relapse within one year, whereas only 30% of those who continue their medications will experience a relapse in the same time period.<sup>(14)(15)</sup>
- The treatment success rate for a first episode of schizophrenia is 60%,<sup>(97)</sup> and medication appears to improve the long-term prognosis for many people with the disease.<sup>(11)(12)(16)</sup> The success rate for the first episode of bipolar disorder is 80%.<sup>(97)</sup>

Texas is the 2<sup>nd</sup> largest state and 2<sup>nd</sup> in rate of population growth, yet it spends fewer dollars per person on the public mental health system than 42 other states. State funding, when adjusted for inflation, has declined 6 percent from 1981. This has translated into a public mental health system that is expected to do more with less and is doing less with less.<sup>(1)</sup>

Due to inadequate funds caused by failure to adjust for population increases and the higher cost of new medications, many Texans with mental illnesses who are not already Medicaid enrolled or eligible, are likely to be denied access to care. Prolonging the wait for treatment by restricting access to necessary medications can lead to devastating results for those who suffer severe mental illnesses, including rehospitalization, criminal behavior, and even suicide.<sup>(2)</sup>

The estimated cost to society for treating mental illness is \$69 billion per year nationally.<sup>(8)</sup> Schizophrenia treatment is responsible for 22% of total mental illness costs and 2.5% of all health care costs throughout the nation.<sup>(17)</sup> Studies of the direct costs of schizophrenia show that drug therapy represents a relatively small (12%) portion of the total direct cost of schizophrenia while hospitalization and other institutional expenses result in the largest percent of costs.<sup>(18)</sup>

Costs related to homelessness, hospitalization, incarceration and suicide are significant:

- A New York City study found that more than 80% of homeless people admitted to the hospital were there as a result of symptoms of mental illness or substance abuse. Ten thousand homeless people with mental illness were determined to cost taxpayers \$40,500 per person per year in hospital and law enforcement costs.<sup>(19)</sup>
- State prisons have become defacto state mental institutions with as many as 23% of inmates suffering from a mental illness, at significant cost to states. A 1994 study



estimated that cases involving persons with serious mental illnesses cost the state of California \$1.8 billion in corrections, law enforcement, prosecution, public defense, and court costs. <sup>(20)</sup>

- Up to 65% of patients with schizophrenia suffer from associated depressive symptoms and 15% of schizophrenics commit suicide. <sup>(21)</sup> <sup>(22)</sup> The direct and indirect costs of each suicide are estimated at \$397,000. <sup>(23)</sup>

*400,000 adults and  
150,000 children in  
Texas need mental  
health treatment. <sup>(97)</sup>*

# Restrictions Drive Up Costs

There are a number of ways states restrict access to medications. These include:

- **Co-payments:** Requires or increases out of pocket expense for the consumer.
- **Dispensing limits:** Limits the number of prescriptions a patient in a government-sponsored program can have. For patients with co-occurring illnesses, this can force a difficult decision of deciding which illness to treat.
- **Prior authorization:** Doctor must seek approval from a third party to prescribe a drug not included in the government formulary. Often requires written paperwork and delays for approval.
- **Requiring generics:** Just as it sounds, this policy requires patients to take generic medicines. Generics, however, are not always therapeutically equivalent to brand names, and sometime the most effective drug is not available in a generic.
- **Step therapy/"fail-first" policies:** With these policies, a patient must start on a less expensive drug and then fail on that drug, and then fail on a second drug, before he or she is put on the most effective drug. These policies are based on cost – not science – and put doctors in a position of having to prescribe a certain drug when they know another would be more effective.

Many studies have documented that restricting access to mental health medications leads to increased costs to the state and society. <sup>(25 - 28)</sup> Furthermore, formulary restriction programs inhibit research and development into new mental health treatments simply because there is less money to invest.

Some states that have implemented formulary restriction programs to cut short-term costs in mental health medication spending have discovered that these strategies often lead to significant increased costs in other areas.

- A 1994 study that compared New Hampshire, which limits prescriptions to three a month, and New Jersey, which has a no-limits policy, found that the prescription cap was linked to a substantial reduction in the number of drugs to treat schizophrenia with a concomitant increase in the use of community mental health centers, emergency mental health services and partial hospitalization. The increase in mental health services costs was 17 times higher than the savings in drug costs. <sup>(28)</sup>
- A 1998 MediCal study demonstrated that switching antipsychotics cost the state between \$6,000-\$8,000/patient due to an increase in hospitalizations. Lack of antipsychotic efficacy accounted for 63% of rehospitalization costs, while lack of compliance to medication accounted for 37% of the costs. <sup>(29)</sup>

*Texas Ranks  
43<sup>rd</sup> in per capita  
spending for public  
mental health and  
mental retardation  
services. <sup>(24)</sup>*

*29,000 prison inmates; 106,000 adults and juveniles on probation or parole; and in excess of 15,000 adults in county and city jails in Texas had contact with the public mental health system in the previous 5 years before entering the criminal justice system.* <sup>(34)</sup>

There are several documented reasons why formulary restriction strategies are detrimental not only to people with serious mental illnesses, but also to the law enforcement, judicial and health care communities, and to the state as a whole.

Prior authorization causes wasteful and inappropriate physician prescribing patterns.

- Data from a call center established to evaluate a prior authorization program put into place in Michigan found that 2/3 of calls were to report preventable adverse problems stemming from restricted access to medications. <sup>(30)</sup>
- A survey in Ontario, Canada, revealed that 66% of the physicians who responded felt that a limited-use listing for medications did not help them prescribe drugs more appropriately, but rather that it inhibited them from prescribing medications that they believed were in the best interests of the patient. <sup>(31)</sup>
- A 1996 survey of 200 physicians participating in the TennCare Medicaid program found that two-thirds of the physicians who were forced to switch prescriptions reported serious consequences in their patients, including deaths, strokes, and adverse drug interactions. <sup>(32)</sup>

Establishing a restriction-based system also requires additional funding from the state to hire staff to make and track prior approvals. <sup>(2)</sup>

- A comparison by Sudovar and Rein found that California could have saved \$14 million in the late 1970s by replacing its restrictive prescription policies with a less restrictive model. Of those savings, \$5 million would have come from reduced administrative costs. <sup>(2)</sup>

Fail-first policies require patients to first try and fail on the formulary drug, which means that weeks or months may go by before the patient receives appropriate medication. <sup>(2)</sup> The time lost forcing patients to fail on the less-expensive and effective medications can lead to devastating results, such as suicides, harm to the consumer or others, increased hospital/ER visits, family/societal burden, homelessness, and incarcerations. Recent research has shown that fail-first policies may reduce chances for recovery. <sup>(2)</sup> The American Psychiatric Association, a national medical specialty society representing more than 38,000 psychiatric physicians, opposes any restriction policy as contrary to the best interests of patients since patient response to psychotropic medications can be highly idiosyncratic. <sup>(2)</sup>

A 1999 Kentucky Legislative Research Commission report states, "In the case of schizophrenia, the side effects, and the personal, medical, and social costs (of therapeutic

failure).can be very substantial. In such cases of therapeutic failure, ‘medication delayed is tantamount to medication denied.’”<sup>(33)</sup>

Medication substitution and prescription cap policies also may reduce chances for a patient with a mental illness to recover. This is especially true for older Americans, who are less likely to respond favorably to a substitution drug.

- A 2002 Harris Interactive Survey by Patient Project Care found that 19% (11 million) of Americans aged 50 and older have had their medication switched due to formulary restrictions. Of those, 12% were switched from a drug on which they were stabilized to one that was less expensive; 13% reported the new drug was ineffective; 22% reported experiencing side effects from the substitution. Of the 58%, who had more than mild side effects or found the substitute drug to be ineffective, one-third required a separate medication to treat the side effects.<sup>(35)</sup>
- A 1991 study found that medication use decreased but nursing home admissions increased after a three-prescription limit per patient per month was implemented in the New Hampshire Medicaid program.<sup>(27)</sup>

These cases illustrate that price controls are not based on sound clinical evidence because their long-term impact has not been adequately evaluated. These restriction-based programs ultimately allow the government – not trained physicians, researchers or pharmacists – to decide which pharmaceuticals millions of patients can use.<sup>(36)</sup>

*In one state, restricting access to medications resulted in costs that were 17 times higher than the savings.<sup>(28)</sup>*

# *The Value of New Atypicals vs. Older Medications*

The leading atypical antipsychotic drugs (e.g. clozapine [Clozaril], risperidone [Risperdal], olanzapine [Zyprexa], aripiprazole [Abilify], quetiapine [Seroquel], and ziprasidone [Geodon]) were introduced within the last 10 years and have improved the treatment of serious and chronic mental illnesses ever since. These medications are effective in improving the symptoms of mental illness, reducing troublesome side effects, decreasing the use of inpatient hospitalization as a primary intervention, enhancing the effectiveness of community mental health systems as the provider of primary treatment, and improving interpersonal skills and motivation. <sup>(37)</sup>

A growing number of studies are finding favorable patient outcomes and reduced costs for this new class of drug treatment. <sup>(38)</sup> The mental health community, including the National Mental Health Association, the National Alliance for the Mentally Ill (NAMI), and the National Institute of Mental Health, as well as health care providers, including the American Psychiatric Association, support the use of atypical antipsychotics and believe that these new drugs should be readily available for those with serious mental illnesses, if not a first-line treatment option.

- “The Expert Consensus Guideline Series: Treatment of Schizophrenia 1999” recommends atypical antipsychotic agents as a first-line option for the treatment of patients with a first episode of schizophrenia with predominately positive or both negative and positive symptoms. <sup>(95)</sup>

While the conventional antipsychotic agents (e.g. haloperidol [Haldol], chlorpromazine [Thorazine] and thioridazine [Mellaril]) were primarily dopamine antagonists, the newer line of atypicals target other neurotransmitter receptors, most notably serotonin receptors, as well as dopamine receptors. <sup>(39)</sup> As a result, unlike the newer atypicals, which are effective in treating both positive and negative symptoms and cognitive functioning, the first generation typical antipsychotic agents are only effective in treating positive symptoms (e.g., hallucinations and delusions), <sup>(40-43)</sup> while ineffective in treating negative symptoms (e.g., apathy, social and emotional withdrawal).

Furthermore, traditional medications are not effective in the treatment of cognitive symptoms beyond occasional improvement in attention. <sup>(40) (44-46)</sup> Cognitive impairment, such as depression, is independent of positive and negative symptoms, but is a core feature of schizophrenia which deals with many areas of function, such as information control and processing or executive functioning (the most commonly reported deficit), attention, verbal recall, visuospatial abilities, and fine motor skills. <sup>(47-50)</sup> Under treatment with traditional antipsychotics there was a presumption that lack of efficacy to cognitive functioning was secondary to cerebral damage. That notion was challenged with the introduction of the newer atypicals. <sup>(51) (52)</sup>

*Suicide took the lives of at least 2,093 Texans in 2000. Over 90 percent suicide victims have a significant mental illness at the time of their death.* <sup>(53)</sup>

## *The Value of New Atypicals vs. Older Medications*

*A study of Texas state psychiatric patients found hospital inpatient cost savings of \$27,850 per patient per year with treatment with atypical antipsychotic medication.<sup>(69)</sup>*

- Preliminary demonstrations with clozapine treatment resulted in benefits to verbal production, visuomotor tracking, and immediate verbal recall. Risperidone treatment showed improved attention and verbal working memory.<sup>(54-60)</sup>
- Another recent study showed an improvement of 10 IQ points in patients treated with olanzapine as a first line treatment. In general, atypical antipsychotics improve cognitive status by about 5 IQ points. This translates into significant positive change in rehabilitation rates and recovery of lost productivity.<sup>(61)</sup>
- Findings from 31 published studies on more than 12,000 individuals generally showed that atypicals led to significant improvements in negative symptoms compared to conventional antipsychotics, including improvements in psychosocial functioning.<sup>(62)</sup>

The newer atypicals, when compared to these first generation drugs, are also superior for treating depressive and psychotic symptoms, hostility, and suicidal tendencies in schizophrenic patients.<sup>(63)</sup> Furthermore, these medications have a lower incidence of life-threatening side effects, such as extrapyramidal symptoms (EPS) including: tardive dyskinesia (muscular contractions that may lead to respiratory distress or become permanent), dystonia (movement disorders that may lead to noncompliance with treatment and require hospitalization and sometimes liver function changes) and Neuroleptic Malignant Syndrome.<sup>(64)</sup>

- The side effects of older typicals are so severe and common that, according to one estimate, up to 50—90% of patients using the drugs on a long-term basis will experience motor problems. Some researchers believe they do more harm than good.<sup>(65)</sup>
- At least 30% of patients taking first generation agents relapse in the first year of treatment, as many as 60% experience relapse after one-year of therapy,<sup>(66)</sup> and between 30% and 60% develop extrapyramidal symptoms (EPS) and are at risk for developing tardive dyskinesia.<sup>(65) (67)</sup>

Patients have had difficulty continuing the use of these older medications because they also cause other severe side effects, such as weight gain, fatigue, stiff body movement, and blurred vision.<sup>(67)</sup> Because there are fewer side effects, atypicals appear to improve overall patient compliance and thus facilitate effective early treatment.<sup>(67)</sup>

- Early and effective treatment may ameliorate the long-term management requirements of schizophrenia and reduce morbidity and mortality, whereas prolonged psychosis prior to treatment initiation may result in diminished response and poorer outcomes.<sup>(68)</sup>

## *The Value of New Atypicals vs. Older Medications*

- 41%-55% of patients with schizophrenia are noncompliant with typical antipsychotics, which increases the risks of relapse and rehospitalization. <sup>(70)</sup>
- 63% of direct costs related to first hospitalization within two years of initial discharge result from a lack of antipsychotic medication response and 37% result from medication noncompliance. <sup>(71)</sup>

Research concludes that while the newer atypical antipsychotic medications may initially cost more than older treatments, the long-term savings and benefits, including demonstrated superior efficacy <sup>(76)</sup> and improved quality of life <sup>(72)</sup> <sup>(73)</sup> for patients taking the newer drugs far outweigh any original prescription costs. <sup>(74)</sup>

- A study of Texas state psychiatric patients found hospital inpatient cost savings of \$27,850 per patient per year with atypical treatment. <sup>(69)</sup>
- A study examining the costs of schizophrenia to a state Medicaid program, including pharmacy, medical, hospital, and outpatient services over a five-year period showed that the total cost per patient was \$2,458 lower for the group treated with the new antipsychotic drug. Another study showed that employment rates doubled with the use of the new medicines. <sup>(75)</sup>
- A measurement by the Brief Psychiatric Rating Scale (BPRS) showed that olanzapine demonstrated superior overall efficacy as compared with haloperidol (an older antipsychotic). For example, patients treated with olanzapine were twice as likely over a one-year period to return to work part- or full-time. <sup>(76)</sup>

*The priority population in Texas for public mental health and mental retardation services grows by 11,500 new people each year. <sup>(77)</sup>*

# *Atypicals Are Not Interchangeable*

Atypicals are a heterogeneous group of medications, and therefore, cannot be said to constitute a therapeutic class. <sup>(78)</sup> Each has a different molecular structure, dosing levels, side effects, effectiveness, and safety. Patient response to each can vary due to such factors as the severity of the disease and individual metabolism. <sup>(79)(80)</sup>

Population variables such as gender, age, smoking, and ethnicity can impact the way a person with a serious mental illness should be treated. For example, relative to their Caucasian counterparts, African-Americans may metabolize antipsychotic drugs slower, putting them at a higher risk for overdosage and greater side effects. <sup>(81)</sup> And older patients with schizophrenia in relation to their younger counterparts tend to display more negative symptoms, including hallucinations, delusions, and thought disorders. <sup>(82)</sup>

Studies confirm that atypicals should not be “lumped” together. Findings from a study comparing olanzapine and risperidone indicated that when schizophrenia treatment choices are made, olanzapine and risperidone should not be lumped into a single atypical category, but instead should be considered separately based on their distinct clinical profiles. <sup>(83)</sup>

Since all antipsychotic medications do not work immediately and many drug-to-drug interactions can occur between and among atypicals, experts recommend that doctors give the antipsychotic time to take effect before switching to another antipsychotic, adjusting the dose, or adding another medication. <sup>(14)</sup>

Some drug-specific indications and side effects include:

- Olanzapine is the only agent indicated for treatment of both schizophrenia and mania in bipolar-1 disorder and has a low potential for drug-to-drug interactions. <sup>(65)</sup>
- Clozapine was recently approved by the FDA for the treatment of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are at chronic risk. <sup>(84)</sup>
- Clozapine has been preferred for those experiencing compulsive water drinking and/or aggression or violence as side effects. <sup>(85)</sup>
- Risperidone and ziprasidone are the least likely to cause weight gain and sedation. <sup>(85)</sup>
- Quetiapine, Clozapine, and olanzapine are the least likely to cause movement disorders. <sup>(85)</sup>
- Aripiprazole, with a slightly different mechanism of action, was approved in November of 2002 by the FDA for the treatment of schizophrenia. <sup>(86)</sup>

*Forty-four percent of youths sent to the Texas Youth Commission have a serious emotional disturbance.* <sup>(34)</sup>



## *Atypicals Are Not Interchangeable*

- Clozapine is the preferred drug for patients with severe refractory symptoms.<sup>(87)</sup>

Treatment of mental illness is highly individualized. Patient response to psychiatric medicines can vary greatly, often taking weeks or months to determine whether the drugs are having the intended effect. Restricting access to appropriate medicines for these individuals may leave them without effective treatment, unnecessarily expose them to side effects, and confound a health care provider's ability to make the right choice based on a patient's unique needs. And since virtually all antipsychotic prescriptions are associated with some level of side effect where risk is involved, a physician needs to determine which treatment favors individual patients according to health concerns, predisposing factors, and other considerations.

This is especially apparent within the elder population, where physiologic changes can affect the absorption, distribution, metabolism, and elimination of medications. Because of greater physiologic variability, the elderly often respond to drugs less predictably. Since this group often takes several drugs simultaneously, they are at greater risk for adverse reactions and significant drug to drug interactions. The opportunity for these events increases as the prescription count increases.<sup>(88)</sup>

*Patient response to psychiatric medicines can vary greatly, often taking weeks or months to determine whether the drugs are having the intended effect.*

For example, in a real-world analysis of prescription data for more than 74,000 patients, olanzapine proved to be used more in younger and more moderate to severely ill patients who usually require higher antipsychotic dosages. Risperidone is used more frequently in the elderly and adolescent populations (older than 65 and younger than 18).<sup>(68) (79) (89)(90)</sup>

# *Providing Open Access To All Medications Saves Money*

The higher costs associated with new pharmaceuticals often are offset by reductions in other direct costs (e.g., hospitalization) and indirect costs (e.g., improved worker productivity).<sup>(36)</sup> Some benefits of new pharmaceuticals include reduced hospitalizations, improved side-effect profiles, reduced patient visits, broadened formulary choices, reduced injuries, enhanced patient adherence, reduced absenteeism, enhanced longevity, less expensive treatments, enhanced quality of life, reduced invasive treatments, and enhanced workplace performance.<sup>(36)</sup>

Research repeatedly shows that providing open access to medications saves more money than it costs.

- In a 1993 study by W.J. Moore and R. J Newman that focused on the effects of formulary restrictions in 47 Medicaid programs over four years, researchers concluded that while restrictive formularies decreased drug spending by 13.4%, they increased physician spending by 28.7% and mental hospital spending by 39.1%, which more than offset any drug cost savings.<sup>(91)</sup>
- For every dollar spent on prescription drugs, there is a \$4 decline in hospital spending.<sup>(92)</sup>
- A study conducted by the American Medical Association showed that increased cost-sharing for prescription drugs in seniors and welfare recipients was followed by reductions in use of essential drugs and a higher rate of serious adverse events and emergency room visits associated with these reductions.<sup>(93)</sup>

If drugs are put on a preferred drug list solely on the basis of economic consideration without regard for medical consequences, then it is likely that more expensive services will replace those “expensive” drugs that are removed from the formulary.<sup>(94)</sup>

*Researchers concluded that while restrictive formularies decreased drug spending by 13.4%, they increased physician spending by 28.7% and mental hospital spending by 39.1%, which more than offset any drug cost savings.<sup>(91)</sup>*

# Medical Term Glossary

**Alzheimer's Disease:** A neurodegenerative disease, which is characterized by loss of nerve cells in the hippocampus and polymodal areas of the brain. The result is impaired memory, thinking and behavior. At the end of the disease, much of the cortical and subcortical brain area is filled with two different types of lesions, amyloid plaques and neurofibrillary tangles. Alzheimer's is the most common form of dementia and the fourth leading cause of death after heart disease, cancer and stroke. Over 4 million Americans are afflicted with the disease.

**Atypical Antipsychotics:** The "newer" medications used to treat psychosis (hallucinations, paranoia, etc.). This line of drugs blocks various dopamine receptors in the brain as well as other neurotransmitter receptors, most notably serotonin receptors. Atypicals are able to address the negative symptoms associated with schizophrenia, as well as positive symptoms, depression and cognitive impairment. These new medications have fewer muscle-related side effects, EPS, and may be less sedating.

**Bipolar Disorder:** (also known as manic-depression) is a serious but treatable brain disease, which currently affects 2.3 million Americans or about 1.5 percent of the population. It results in recurring episodes from mania (severe highs) to depression (extreme lows), which affects judgement, speech, thinking, appetite, sleeping patterns, etc. Symptoms may be present since infancy or early childhood, or may suddenly emerge in adolescence or adulthood.

**Cognitive Functioning:** Includes information control and functioning, attention, verbal recall, visuospatial abilities and fine motor skills.

**Conventional Antipsychotics:** The "older" medications used to treat psychosis (hallucinations, paranoia, etc.). They block various dopamine receptors in the brain. In addition to limiting psychosis, lower dopamine levels also affect the motor system. This line of antipsychotics is effective in treating the positive symptoms of schizophrenia. Side effects that are common to these medications are called Extra-Pyramidal Side effects, or EPS, which are muscle-related.

**Delusions:** Bizarre, false beliefs that seem real to the person with schizophrenia, but are not real. Sometimes these delusions can be paranoid in nature.

**Dementia:** A loss of intellectual functioning (thinking, remembering and reasoning). So severe that it interferes with daily functioning and eventually results in death.

**Dystonia:** Contraction of muscles.

**Efficacy:** Effectiveness.

**Extrapyramidal Symptoms (EPS):** Muscle-related side effects associated mainly with older typical antipsychotics. They include tardive dyskinesia (muscular contractions that may lead to respiratory distress or become permanent), dystonia (movement disorders which may lead to noncompliance with treatment and require

## *Medical Term Glossary*

hospitalization and sometimes liver function changes) and Neuroleptic Malignant Syndrome. These side effects can be life threatening.

**Hallucinations:** Unusual, unreal perceptions of the environment. May include hearing voices, seeing objects, lights or faces, smelling things and feeling things.

**Multiple Sclerosis:** A disorder of the central nervous system (brain and spinal cord) caused by the gradual damage to nerve cells' outer covering (myelin). The result is decreased nerve functioning, which leads to many symptoms. Episodes can last for days, weeks or months. Symptoms vary but may include weakness, paralysis, tremor, muscle spasticity, dysfunctional movement, numbness, facial pain, loss of vision, etc. Approximately 1 out of every 1,000 people are affected.

**Negative Symptoms:** These symptoms are less apparent than positive symptoms in schizophrenia, but just as common. They include lack of emotional expression, apathy and social withdrawal.

**Positive Symptoms:** The symptoms most commonly associated with schizophrenia. Otherwise known as "psychotic" symptoms, which include thought disorder, hallucinations and delusions. Hallucinations can be heard, seen or felt. Delusions are usually in the form of paranoia.

**Parkinson's Disease:** The first neurologic disease to be associated with a loss of a neurotransmitter in the brain, called dopamine. An age-related disease that affects a region of the brain known as the basal ganglia. This disease affects movement, balance, speech, swallowing, walking, and muscle tone. Up to 1.5 million persons in the U.S. are afflicted with this chronic disease. The manifestations that are commonly associated with Parkinson's are bradykinesia, or slowness of movement, akinesia, or absence of movement, and increased muscle tone.

**Schizophrenia:** A biologically based disease of the brain, which currently affects 2.2 million Americans, or approximately one percent of the population. To be diagnosed with schizophrenia, a patient must have psychotic, "loss of reality" symptoms for at least six months and show increasing difficulty in functioning normally. The symptoms most commonly associated with the disorder are positive and negative symptoms. Other frequent symptoms connected to the disease are depression and cognitive impairment. Schizophrenia can affect anyone at any age, but most cases develop between ages 16 and 30.

**Tardive Dyskinesia:** The most serious side effect of antipsychotic drugs, which causes involuntary and abnormal movements of the face, mouth, and/or body. This condition usually develops in older patients, affecting 15 to 20 percent of those who have taken older antipsychotic drugs for years.

**Thought Disorder:** A symptom of schizophrenia. An increased difficulty in thinking and speaking clearly.

**Withdrawal:** Retracting from society and relationships with others. Indicated by a lack of interest in social activities and difficulty in communicating with others.

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