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The United States Federal Government should substantially reform the provision of mental health services to the chronically mentally ill.

Contention 1 is the Harm: Polypharmacy

1. Bipolar disorder is massively on the rise.

CNN, 03/07/2011

"U.S. has highest bipolar rate in 11-nation study" <http://www.cnn.com/2011/HEALTH/03/07/US.highest.bipolar.rates/?hpt=Sbin>

About 2.4% of people around the world have had a diagnosis of bipolar disorder at some point in their lifetime, according to the first comprehensive international figures on the topic. The United States has the highest lifetime rate of bipolar disorder at 4.4%, and India the lowest, with 0.1%. Bipolar disorder is characterized by cycles of depression and mania, a euphoric, high-energy state that can result in heightened levels of creativity or output as well as erratic or risky behavior.

2. Polypharmacy, the practice of prescribing more than one atypical antipsychotic, is rapidly on the rise for bipolar patients.

Betsy Bates, Clinical Psychiatry News, 05/10/2009

"Polypharmacy for Bipolar Ever More Complex" <http://www.clinicalpsychiatrynews.com/views/commentaries/single-article/polypharmacy-for-bipolar-ever-more-complex/3ae4c4683f.html>

Recent findings from the STEP-BD trial may confirm what many psychiatrists already suspect: Polypharmacy is exceedingly common in the treatment of bipolar disorder (J. Clin. Psychiatry 2009;70:155-62). But just how complex that polypharmacy becomes—with nearly 20% of the 4,035 patients in the trial receiving four or more concurrent medications—might come as a surprise to some practitioners. The Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) was the largest-ever study of bipolar disorder. Sponsored by the National Institute of Mental Health, it ran for 5 years and concluded enrollment in 2005.

3. The practice of polypharmacy cripples patients with tardive dyskinesia.

Stephen M. Stahl, MD PhD and professor of psychiatry at UCSD, February 2002

"Antipsychotic Polypharmacy: Squandering Precious Resources?" <http://altcancerweb.com/bipolar/pharmacology/stahl/antipsychotic-polypharmacy-squandering-precious-resources.pdf>

One barrier to long term antipsychotic polypharmacy for such patients is the possibility that it will sabotage the best proven advantages of atypical antipsychotic monotherapy, namely, to reduce motor side effects and potentially prevent tardive dyskinesia. Theoretically, all antipsychotics act to control positive symptoms of psychosis by blocking dopamine D2 receptors. Atypical antipsychotics supposedly do this without causing motor side effects because they completely block D2 receptors in limbic areas controlling psychosis while incompletely blocking the D2 receptors in extrapyramidal areas controlling motor side effects. Incomplete blockade of the extrapyramidal receptors can become complete by giving 2 atypical antipsychotics, a conventional antipsychotic with an atypical antipsychotic or high doses of 1 atypical antipsychotic. Since it's impossible to block more than 100% of the D2 receptors controlling psychosis, further drug addition might only lead to more blockade of the wrong D2 receptors, with a net clinical effect not much different from treatment with conventional antipsychotic monotherapy, but with a net economic effect that can be more than 20 times the cost of conventional antipsychotic monotherapy.

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4. Tardive dyskinesia reduces the quality of life of the individual.

William M. Glazer, MD, and Bruce L. Saltz, MD, December 2006

"Managing the Risk of Tardive Dyskinesia" http://www.behavioral.net/Media/DocumentLibrary/Lilly_0612.pdf

TD is a neurologic condition caused by prolonged use of neuroleptic drugs, such as antipsychotics. TD is characterized by repetitive, involuntary, purposeless movements of different parts of the body. The most common symptoms are orofacial and may include grimacing; tongue thrusting; jaw rolling; lip smacking, puckering, and pursing; and forced eye blinking. TD also may involve dancing or writhing movements of the arms, legs, and trunk or involuntary finger movements, in which patients may appear to be playing a piano or guitar. ¹ While some symptoms are mild and visible only to trained providers, others are far more severe and easily recognized by nonmedical personnel. The involuntary movements can be embarrassing and affect basic life functions, such as eating, breathing, and walking. In addition to physical challenges, persons with TD may be faced with not only the stigma associated with mental illness, but also the stigma of having a very visible movement disorder, all of which may lead to reduced quality of life.

5. Tardive dyskinesia causes death.

Charles E. Dean and Paul D. Thuras, The British Journal of Psychiatry 2009

"Mortality and tardive dyskinesia: long-term study using the US National Death Index" <http://bjp.rcpsych.org/cgi/reprint/194/4/360.pdf>

On the initial analysis, without covariates, the presence of tardive dyskinesia, either current or remitted, was significantly associated with an increase in mortality, with a risk ratio (RR) of 1.57 (95% CI 1.23–1.99, P50.001). A parallel analysis was conducted in which the maximum DIS-CO score was used, rather than the tardive dyskinesia diagnosis. We found that for every point increase in the DIS-CO score, there was a 5% increase in the likelihood of death (RR=1.05, 95% CI 1.03–1.07, P50.001).

Dilip V. Jeste, M. D., 2004

"Tardive Dyskinesia Rates With Atypical Antipsychotics in Older Adults" <http://altcancerweb.com/bipolar/Tardive-Dyskinesia/td-rates-atypical-antipsychotics-older-adults.pdf>

Older patients are often at risk for developing serious side effects as a result of antipsychotic treatment. Drug induced movement disorders, such as tardive dyskinesia are more persistent in older than in younger patients. The risk of tardive dyskinesia from conventional antipsychotic treatment is 5 to 6 times higher in older than in younger adults. In the majority of patients who develop tardive dyskinesia, symptoms persist for months or even years. Tardive dyskinesia can lead to a number of physical and psychological complications such as difficulty eating and swallowing, weight loss, falls and difficulty keeping balance, feelings of depression and potentially suicide.

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Contention 2 is Inherency:

Marketing and general ignorance about atypical antipsychotics is directly promoting polypharmacy in the status quo.

Medical News Today, 01/07/2011

"Researcher Finds Evidence Lacking For Widespread Use Of Costly Antipsychotic Drugs" <http://www.medicalnewstoday.com/articles/213077.php>

The upswing in prescriptions for antipsychotics despite the absence of good evidence for their value in many instances is the result of marketing - whether legal or illegal - and ingrained cultural tendencies. "Physicians want to prescribe and use the latest therapies - and even when those latest therapies doesn't necessarily offer a big advantage, there's still a tendency to think that the newest drugs must be better," he said. Physicians could benefit from more feedback on what percentage of their prescriptions is for off-label uses, said Stafford. "In many cases, physicians don't realize they're prescribing off-label," he said. In fact, in a previous survey of physicians, Alexander found that the average respondent accurately identified the FDA-approval status of drugs for a given condition just over half the time.

Thus we present the following plan:

The United States Federal Government should ban the prescription of multiple atypical antipsychotics and the prescription of atypical antipsychotics beyond the FDA recommended dosage for the treatment of bipolar disorder.

FYI: Off-label use is the practice of prescribing pharmaceuticals for an unapproved indication or in an unapproved age group, unapproved dose or unapproved form of administration.[1] In the United States, the Food and Drug Administration Center for Drug Evaluation and Research (CDER) reviews a company's New Drug Application (NDA) for data from clinical trials to see if the results support the drug for a specific use or indication.[2] If satisfied that the drug is safe and effective, the drug's manufacturer and the FDA agree on specific language describing dosage, route of administration, and other information to be included on the drug's label. More detail is included in the drug's package insert.

FYI: The currently accepted therapeutic range for risperidone is 4-8 mg/day, for olanzapine is 10-20 mg/day, for quetiapine is 200-800 mg/day, and for ziprasidone is 40-160 mg/day [13]. (S.M. Stahl and M.M. Grady, Current Medical Chemistry, "A Critical Review of Atypical Antipsychotic Utilization: Comparing Monotherapy with Polypharmacy and Augmentation," 2004)

Funding and enforcement would be through normal means.

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Contention 3 is Solvency:

1. Plan would ban the use of polytherapy, effectively solving for the harms.
2. Monotherapy, the prescription of only one drug within recommended doses, provides a safe and effective alternative to polytherapy.

Reuters Health, 10/12/2010

"Antipsychotic polytherapy no better than monotherapy for bipolar disorder" <http://www.thedoctorschannel.com/video/3722.html?order=date&specialty=25&page=41>

To evaluate the safety and tolerability of SGA polytherapy compared to monotherapy, the researchers analyzed data on 1958 patients in the Systemic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) trial who received at least one SGA. Almost 10% (162) of the patients were prescribed more than one antipsychotic. "Monotherapy and polytherapy recipients were remarkably similar with respect to age, sex, age at onset, number of past affective episodes, and body mass index (BMI)," the authors found. [that] Global functioning scores were similar with monotherapy (62.3) and polytherapy (60.4), and likewise for the percentage of well days (66.9% vs. 59.3%). Moreover, rates of most adverse effects such as dry mouth, constipation, sexual dysfunction and tremor were all worse with polytherapy compared to monotherapy, even after controlling for severity of illness and medication load. Recipients of more than one SGA [Second Generation Antipsychotics] used nearly three times as much additional psychiatric treatment as patients receiving only one SGA [Second Generation Antipsychotic], Dr. Brooks and colleagues report. They conclude, "SGA [Second Generation Antipsychotic] polytherapy is associated with substantial disadvantages, ranging from increased adverse events to increased health service usage to decreased functioning."

Contention 4 is the advantage: Think of the children.

1. Children are especially vulnerable to the side effects of polypharmacy such as tardive dyskinesia.

Alexis Foster, J.D., LL.M, December 2010

"Atypical Antipsychotics for a Case of the Terrible Two" http://www.law.uh.edu/healthlaw/perspectives/2010/foster_medications.pdf

Children are especially sensitive to the effects of antipsychotic drugs. This sensitivity may increase the chance of side effects, especially muscle spasms and involuntary movements. ³¹ In one study, neuroleptic malignant syndrome showed up in 41 children, and was the most troubling side effect, according to child psychiatrist Joseph Penn, of Bradley Hospital and Brown University School of Medicine, because it can kill within 24 hours. ³² There are also severe long-term side effects of antipsychotic medications—some of which may be permanent. Tardive Dyskinesia is one of the most disturbing permanent side effects, leading to facial grimaces, tics, writhing of tongue, abnormal movements of lips, neck, trunks, and limbs. ³³ There is no treatment for TD and it is irreversible. Also especially troubling among children is excessive weight gain, and the inevitable diabetes diagnosis that follows. ³⁴

2. By prohibiting polypharmacy, the plan would reduce the long term risks of atypical antipsychotics on children by reducing the blockage of dopamine D2 receptors.