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Changes To Reimbursement Rules For Prescribing Psychotropic Medications: Small Changes That Can Significantly Reduce Total Healthcare Costs While Increasing The Quality of Care For Patients

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Introduction

Changes in how certain medications are authorized and reimbursed can have a significant impact on both overall healthcare costs and the standard of care provided to patients. Clearly, a topic well suited to the current economic and political environment. In a time where limited resources dictate establishing healthcare priorities, the issue comes down to which types of services should be reimbursed and which ones either restricted or paid for by the patient. However, the comparative effectiveness of one medication to another is not a uni-dimensional assessment. A simple "did Group A do better than Group B" can provide only a sliver of whether a treatment is effective. Health care providers are constantly faced with study after study touting the benefits of some new drug, a new procedure, a new therapy, or new look at something previously used. With respect to drugs, numbers are always misleading. For example, a study may show that drug A is about 40% more effective than drug B. On the surface, it would appear that drug B is less effective. However, upon further analysis, the reported effectiveness in the reduction of symptoms shows the "effectiveness" to be only 3% to 2% better. Although the treatment effect is small and really insignificant, the manufacturer can claim a whopping increase in effectiveness. This is a common and frequent occurrence in medicine. Medications account for hundreds of billions of dollars in the overall healthcare budget. Fact: For calendar year 2009, total sales of prescription medications exceeded $300 billion dollars.[1]

Outcomes without a relationship to reduced costs obscures the real and significant impact that a treatment has on healthcare policy. An analysis of what treatments work best and their costs can shed light on why the medicalization of behavioral health has proven to be more a function of the power of drug manufacturers than to the available science on medications and an economic analysis of their worth and effectiveness. The goal here is to propose a set changes to both Medicare and other federally funded healthcare programs for the reimbursement of psychotropic medications, although clearly these rule changes can be applied to other classes of medications. We start with psychotropic medications for several reasons:

1. Psychotropic medications are the fasted growing segment of the drug industry.
2. Although clearly bad policy, the mental healthcare budget politically and historically has been an easy target for cuts.
3. There are many unbiased studies that support the ineffectiveness of psychotropic medications.

4. The FDA already has issued positions and warnings that can be used to support the proposed changes.

5. The economic impact of the proposed changes can be clearly established.

Costs For Medication Treatments

Between the years 1996 and 2006, expenditures for mental and behavioral health treatment rose from $35.2 billion in 1996 to 57.5 billion in 2006. By 2009, depending upon what is counted as "mental health treatment", the total expenditure for mental healthcare amounted to about 4% of total healthcare expenditures of $2.2 trillion dollars, or about $100 billion dollars.[2] This increase in expenditures is directly related to the expanded use of psychotropic medications and to the shift of behavioral and mental healthcare to primary care physicians. While the terms "behavioral and mental" are assumed by some to be synonymous, the are not. For example, the treatment of depression would be considered "mental health" but problems with sleep would be considered "behavioral". The shift to primary care has led to misdiagnoses and non-treatment of behavioral health disorders.[3-6] The result of this shift clearly can be associated with poor health outcomes and increased health care costs. On the other side of this issue, but one that is less likely to be reported, is the impact of an appropriate diagnosis and treatment of behavioral health disorders on reducing total health care expenditures.

The net effect and clinical significance of medications is that, increasingly, fewer people are benefited from many medication interventions. For example, statin medications are the second most common class of drugs that are prescribed.[1] Yet, study after study shows that the big gainers from these drugs are people who already have experienced a heart attack.[7,8] People who are healthy with no know cardiac symptoms or significant risks, but have high cholesterol, are not helped by statins.[7] Yet, physicians and medical guidelines continue to press people to use them. Statins account for about $15 billions of dollars in sales, annually.[1] Billions of dollars expended on non-performing drugs leaving many people with side effects from these drugs as their only "benefit". Moreover, behavioral interventions to help patients adhere to better diets, exercise and other lifestyle programs, are so infrequently prescribed yet can be much more effective than these drugs and far less costly over the life of the patient.[9]

Psychotropic medications, on the other hand, year after year, continue to see big gains in overall prescriptions written and increases in sales. For example, for the 2009 calendar year, the number of prescriptions written for antipsychotic medications exceeded 52 million producing sales of $14.6

billion dollars. In fact, sales of antipsychotics were the number one medication in overall sales for 2009 replacing statin medications.[1] Clearly, antipsychotic medication are being over prescribed off label for non-psychotic conditions despite the potential dangerous side effects for these drugs. A recent study shows that there is measurable brain shrinkage as a result of taking these medications.[10]

Antipsychotics are being prescribed for sleep disorders, depression, and anxiety – all of which respond positively to psychotherapy and behavioral intervention. So the question becomes: Is it worth experiencing Extra Pyramidal Symptoms, such as pseudoparkinsonism, tardive dyskinsia and brain shrinkage when more cost effective treatments such as psychotherapy is so much more effective for these non-psychotic conditions and with little to no side effects and at less overall cost? Moreover, there are several important data driven studies showing that over the long term, antipsychotic medications produce more disability than schizophrenics who had not been medicated.[11,12] In countries where these medications are not readily available, for example, schizophrenia responds well to non-medication treatment.[12] A change in reimbursement policy can create a shift from ineffective and inappropriately prescribed medications to effective treatments with a corresponding decrease in costs. The following provides some cost comparisons for psychotropic medications for the calendar year 2009.

Table 1

Comparative Costs of Selective Psychotropic Medications
Calendar Year 2009

Total US Prescription Market: $300.3 Billion Dollars

Drug Class	Total Sales
ANTIPSYCHOTICS,OTHER	14.6 Billion
ANTIDEPRESSANTS [1]	9.9 Billion
ANXIOLYTICS	8.9 Billion
ANTI-CONVULSANTS	5.3 Billion

[1]. Sales of SSRIs and SNRIs, only. Excludes Tricyclic and MAOI classes of antidepressants.
Source: IMS National Sales Perspectives™

Let's compare these expenditures with data from the year 1997 to 2004. In 2004, total expenditures for prescribed psychotropics was at least 2.5 times as high as in 1997, increasing from $7.9 billion to $20.0 billion. In the same time span, the total number of prescriptions for these drugs increased significantly from 141.9 million prescriptions to 244.3 million prescriptions, overall. The total number

of persons reporting using a psychotropic medication increased from 21.0 million people to 32.6 million people. Moreover, from 1997 to 2004, the average per purchase price for a psychotherapeutic medication increased from $55.80 to $82.00.[13] In comparison, prescriptions for antipsychotics alone scored sales of $15 billion dollars in 2009 with 52 million total prescriptions written. Combining the total sales of antipsychotics, antidepressaants, anxiolytic and anti-convulsant medications account for total sales of $38.7 billion dollars for the calendar year 2009. The conservative estimates of the number of people using at least one psychotropic medication during 2009 is about 55 million people[13] The average brand name prescription price in 2008 was almost 4 times the average generic price $137.90.[14] Note: The majority of psychotropic drugs have no generic alternative because drug manufacturers continue to flood the market with "newer" drugs while older drugs are still under patent protection. Physicians are then lobbied to prescribe the newer drugs.

Clinical Research Data From Drug Companies Are Unreliable

The pharmaceutical industry has made it very difficult to trust the current "best" psychiatric approach to health care.[15] The best practice, evidence based approach to behavioral health is dependent upon medical and psychological research. Professions that strongly endorse and call for evidence based medicine cannot continue to ignore the lack of substantive evidence that is clearly missing when psychotropic medications comprise the foundation and basis for treatment.[16,17]

The medicalization of mental, emotional, and behavior disorders has resulted in a medication prescription for every presenting symptom. Clinical trial reliability and credibility are important issues to all prescribers of psychotropic medications because we all rely on the research conducted by drug makers, industry marketing, and the FDA in treating patients. However, the more salient issue is that all prescribers of psychotropic medication should strictly adhere to a data based standard of care for patients requiring pharmacotherapy. The data must be independently evaluated research that is not tainted by pharmaceutical industry marketing efforts, or physicians on drug company payrolls who extol the virtues of drugs that may have no benefit, or are harmful to patients. The overriding message that must be sent to patients and policymakers is, " "**Provide the right treatment by the right person, at the right time, and at the right cost."**

Changes To Reimbursement Policy

It is clear that drug companies and physicians are not likely to change the way they do business or moderate their practices to conform with the data based research with respect to any class of

medication, let alone psychotropic medications. This is why a change in how these drugs are reimbursed is the more likely approach that will bring prescribing practices inline with both the "best practice" approach that is based on unbiased research. Primarily, the changes in reimbursement policy that follow are directed to all health care providers who have been authorized to prescribe psychotropic medications. They derive from and are based upon the most reliable and consistent data about medications and on the available psychopharmacology science. While the focus is on psychotropic medications, we believe that patients prescribed other classes of medications may also benefit from the adoption of these changes. However, presently, we are addressing the need for change in the prescribing of psychotropic medications.

Psychotropic Medications Are Not First Line Treatments.

Many patients who present with anxiety, agitation, insomnia, hypomania, mania, irritability, hostility, restlessness, or signs of depression, are provided medications as the first line treatment for their condition when, in fact, many of these medications have not been proven to be more effective than placebo or psychotherapy.[18-21] The medicalization of psychiatric disorders resulting in a prescription as a first line treatment is due to primary care physicians not having the time or expertise to develop differential diagnoses for their patients presenting with signs and symptoms of mental, emotional, and behavioral disorders.

Moreover, PCPs, either do not read or understand the intricacies involved in clinical trial data. Primary Care Physicians and physician extenders typically rely on the superficial menus of symptoms listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM) or brief and simplistic survey instruments to form a diagnosis. This methodology falls significantly short of the appropriate standard of care especially when viewed with the knowledge that 100 percent of the psychiatrists who authored the mood and psychotic disorders sections of the DSM-IV had undisclosed financial ties to pharmaceutical companies[22] This is only one reason why obtaining an appropriate evaluation and diagnosis from a specialist must precede a prescription. The following are proposed rule changes to Medicare reimbursement and other federally funded healthcare programs that will promote better quality care while reducing overall costs associated with ineffective and needless medications.

Changes To Reimbursement For Psychotropic Medications

Proposed Rule Change #1: Medicare and other federally funded mental health programs should not reimburse for any psychotropic medication before a patient has been appropriately evaluated and

diagnosed by a doctoral level mental health specialist or licensed clinical social worker. Appropriate diagnosis is the most important variable when considering a treatment option. Appropriate diagnosis reduces unneeded office visits and expensive diagnostic tests that are routinely provided in primary care settings. Moreover. an appropriate evaluation and diagnosis reduces the cycle of prescribing a variety of drugs that are ineffective and costly. If pharmacotherapy is determined to be part of the treatment regimen, collaboration with a behavioral health provider can provide non psychiatric physicians and physician extenders with the close monitoring psychotropic medications require.[23,24]

Potential Cost Impact

Cost savings to the taxpayer for this rule change can be significant. When considering the cost of a medication treatment, several external factors must be considered. The actual cost of the medication is the least costly factor. Costs associated with adverse drug events can be a costly multiple of the initial cost of the medication. For example, the projected cost associated with adverse drug events was $172 billion dollars for the year 2007.[25] The projected cost of additional hospitalizations associated with adverse drug events adds about $6000 to a hospital stay.[25] Given that psychotropic medications are the fastest growing segment for the drug industry and among the most costly for Medicare and federally funded healthcare programs, there will be significant savings by not reimbursing for any medication regimen unless a patient has received an appropriate evaluation and diagnosis by a doctoral level psychologist or psychiatrist. Moreover, costs associated with inappropriate diagnosing and increased tests and office visits because of this will be significantly decreased.

Proposed Rule Change #2: No Reimbursement For Off-Label Prescribing Of Psychotropic Drugs

Off label prescribing for conditions that are not approved by the FDA, though completely legal, is an abuse of the drug approval system and inconsistent with the manifest function of why such a system exists. Off label prescribing is a marketing strategy employed by the drug makers to bolster sales of pharmaceuticals.[26,27] The government drug approval systems in all countries exist to protect the public from drugs that may be unsafe and/or inappropriate for use for conditions for which none or not enough research data exist. Off label prescribing essentially are “guinea pig” trials with no oversight or protection for consumers. Off label prescribing of drugs that have not been tested for the specific condition for which they were approved is a marketing strategy that benefits drug manufacturers in the absence of any available science to substantiate its use for the untested condition.

If off-label prescribing is not seen as a real risk to patients then why have clinical trials at all? The FDA penalizes drug companies that market drugs for off label use but have not been approved. The FDA does not penalize physicians for prescribing these same drugs off label because the FDA claims that "this would entail the regulation of medical practice." Clearly, this policy that exempts physicians from penalty for prescribing drugs off label is not credible. The FDA utilizes a drug classification system and there are many drugs that physicians are not legally able to prescribe. We see no reason why manufacturers and distributors alike are not held liable for their part in distributing unapproved drugs. We argue that just because a medication may have some known side effects reported for one condition contributes little, if any, assurance that the same medication is effective and safe for another condition. There should be no reimbursement for any psychotropic medication that is prescribed off label. Alternatively, a rule change that will not reimburse for off label drugs can still allow for patients to pay for an off label prescription. This does not, however, address the safety issues associated with the practice.

Potential Cost Impact

While it is difficult to accurately calculate the savings to taxpayers should this rule be implemented, we can still nevertheless attempt projecting a reasonable cost savings by looking at studies that present reasonable data. For example, a 2009 study reports that among the nearly 300,000 veterans who received a prescription for an antipsychotic medication in 2007, more than 60% had no record of a diagnosis for which the drug was approved. More than 40% of the patients had a diagnosis of PTSD. Other patients receiving off-label antipsychotics had diagnoses of major or minor depression, anxiety disorder, or alcohol or drug use or dependence. Quetiapine and Risperidone were the two most frequently prescribed off-label drugs. The authors estimate that this off-label use of psychiatric medications translates to $4 to $5 billion in health care expenditures for veterans.[28]

In a study on the costs for anti-convulsant medications that were prescribed off label, the state of Wisconsin found that 60% of the prescriptions for Gabapentin (Neurontin) were issued without any relationship to a diagnosis and off label at a cost of $40 million dollars to the state.[29] This expenditure is significant for a relatively small state and for only one drug. Multiplying the Wisconsin experience to other states and other psychotropic drugs is likely to yield similar findings. These are not isolated examples.

In another 2008 study published in Pharmacotherapy, the authors found and identified a high volume of off-label prescribing in the absence of good evidence for a substantial number of drugs, particularly antidepressants, antipsychotics, and anxiolytic-sedatives. Drugs that consistently rank high in both retail sales and off label prescribing were quetiapine, warfarin, escitalopram, risperidone, montelukast, bupropion, sertraline, venlafaxine, celecoxib, lisinopril, duloxetine, trazodone, olanzapine.[30] So, it is clear that restricting the reimbursement for off label prescribing is both a cost savings a well as promoting quality treatment for mental health patients.

Proposed Rule Change #3: No Reimbursement For Any Psychotropic Medications That Have Not Been Validated By Unbiased Peer Review.

Newly introduced medications should reach a standard before being prescribed to patients. Drug approval must be the floor and not the ceiling for its use. In fact, Public Citizen recommends waiting seven years before using a newly approved medication because 20% of new medications receive black box warnings or are removed from the market and only half of the serious adverse events are identified in that period of time.[31] Unbiased peer review takes time to establish the effectiveness and safety of a drug. When providers prescribe these medications without waiting to determine the real side effects and safety issues, patients become part of an experiment that has not been agreed to with true informed consent. We advocate that as long as existing drugs with known profiles are available, the rush to prescribe a newer one that is relatively untested and whose testing may be flawed is unwarranted.

Potential Cost Impact

Assuming the projections stated by Public Citizen, about $10 billion dollars can be saved by restricting the reimbursement of psychotropic medications that have not been adequately reviewed by unbiased peer review. This figure is only for the retail costs of these drugs and does not include savings that would result from decreased adverse events.

Proposed Rule Change #4: No Reimbursement Of Any Psychotropic Drug That Has Not Been Proven To Be More Effective Than Placebo Or To An Existing Medication Currently Approved In Its Class.

Clinical trials**,** for the most part, have become part of a drug company's marketing strategy. The science involved in testing these drugs are highly suspect, at best.[26,32] Many times, competing psychotropic drugs in a similar class are slightly altered simply to gain market share.[33] They offer little, if any, benefit over existing drugs or placebos. Clinical trials, which are routinely farmed out to private companies specializing in conducting short trials with paid volunteers, test these drugs against a designed placebo. Rarely, if ever, are these drugs compared to existing medications that have been

approved for a specific use. Rising healthcare costs from these unneeded and typically more expensive medications occur when these medications are prescribed. Moreover, any significant benefit to patients is rarely demonstrated from medications that are not significantly more effective than existing drugs.

Potential Cost Impact

Newly marketed medications typically replace older, more established medications and generally are more costly. The introduction of new medications into a class quickly impact the average cost of prescriptions. This is one reason why the average cost of a prescription medication increased to $137.00 from $89.00 in 2007.[14] Combining this with the incidence of adverse drug events associated with newer drugs, and the costs associated with ADEs, significant healthcare savings can be expected if the reimbursement for newer drugs is restricted.

Proposed Rule Change #5: Polypharmacy Should Be Minimized And Restricted.

With respect to psychotropic medications there are no reliable studies that show more than two drugs of the same class (e.g. antidepressants) is more beneficial to the patient.[34] There must be reliable and unbiased data to support prescribing more than two medications from the same class or from a class that essentially provides the same or similar side effects. For example, polypharmacy generally is defined as two drugs from the same class of medications. However, drug manufacturers are more frequently combining two medications into one pill and marketing that drug as a single medication. Adding additional medications in the same or similar class to these combined drugs disguises and increases the risk to patients that derive from polypharmacy.

An example of unwarranted and potentially dangerous polypharmacy is the latest recommendation by drug manufacturers that antipsychotic medications, such as Aripiprazole, be added for depression augmentation. Aripiprazole targets dopamine receptors and partially blocks serotonergic receptors. Essentially, when added to other serotonergic medications (SSRIs), as recommended by the manufacturer, they may not only defeat the action of the SSRI, but most probably act as a mere anxiolytic, which can easily be addressed with non-drug treatment and pose no risks. Given the potential and real risks associated with antipsychotics, is it worth the overall health risks to patients, which includes increased risk of stroke and ministroke; very high fever, rigid muscles, shaking, confusion, sweating, or increased heart rate and blood pressure? There is also an increased risk for neuroleptic malignant syndrome (NMS), a rare but very serious side effect which could be fatal. Moreover, tardive dyskinesia (TD), diabetes, and hyperglycemia are increased risks with Aripiprazole.

Potential Cost Impact

Sales of antipsychotic medications are now the fastest growing segment of psychotropic medications. Clearly these medications are being over-prescribed. For 2009, 52 million prescriptions for these medications accrued sales of $15 billion dollars.[1] Given that the best data available shows that the incident rate of schizophrenia in the U.S. Population is about 1%.[35] The population of people between the ages of 15 to 85 years of age was about 271 million for 2010.[36] This equates to about 2.7 million people expected to have schizophrenia. Assuming, just for argument, that each person with this disorder received a monthly prescription for the entire year, this would indicate a need for about 32 million prescriptions. Instead, we see that for 2009, 52 million prescriptions were written for antipsychotic medications. Potentially, 40% of these prescriptions were for off label use at a cost of $6 billion dollars. In an era of limited resources, can and should we continue to allow these resources to be squandered to support drug company profits? Moreover, should we allow patients to be prescribed these medications that have both serious side effects and high risks for disease unrelated to their presenting problem?

Proposed Rule Change #6: Reimbursement For Psychotropic Medication Regimens Should be Time Limited

Many patients are kept on long term regimens with no scientific basis supporting long term use. In fact, the best available data shows that the longer a patient is on these medications, the greater the likelihood that they will become more disabled.[11] Patients who are being treated with psychotropic medications should be placed on a short term trial lasting no longer that the time period reported in the clinical trial for that drug plus a reasonable additional period of one month. This would mean that a trial lasting no more than three months would be more than a reasonable time period to see if a medication is effectively impacting the patient's condition. Typically, clinical trials for psychotropic medications last no more than six weeks. For example, hypnotic medications and most anxiolytics are not designed for long term use yet many patients are prescribed these medications continuously with little concern for the safety of the patient. These classes of drugs must be time limited. They foster dependency and, in many cases, physical addiction. For other classes of drugs, such as antidepressants, if a patient shows no significant improvement during a reasonable trial period then the medication should be discontinued. Alternatively, patients could be allowed to pay for an additional period the beyond recommended trial period.

Potential Cost Impact

When one considers that psychotropic drug sales, excluding drugs used to treat substance abuse, account for almost 50% total mental health expenditures, limiting reimbursement to a reasonable, specified time period based upon the unbiased clinical trial data can significantly impact and reduce total overall healthcare costs. For example, a good assumption is that only 9% to 15% of patients may see their condition improve with a medication regimen.[21] Thus, about 85% of the prescriptions and costs for these medications are a waste of resources. The potential cost savings can be about $12.75 billion dollars on the cost for antipsychotic medications, alone. This figure only includes the retail cost of this drug and the amount that is prescribed off label for antipsychotic medications.

For antidepressants, a similar savings of $8.5 billion dollars can be achieved. Savings for the costs associated with anxiolytic medications are projected to be about $6.8 billion dollars. These numbers are based on retail sales for 2009 and do not include the expected increase in costs for these drugs over time. If a time limit were imposed on the length of time that these medications could be prescribed, the savings would even be greater as the quality of care would increase.

Proposed Rule Change #7: No Reimbursement Of Doses Above The Recommended Range.

Many patients are prescribed medications significantly above the upper range for which the drug has been recommended and approved with no scientific data supporting this practice. There is great risk to patients when a drug is prescribed in amounts greater than the upper limit.

Potential Cost Impact

Generally, the cost for higher doses of a drug results in increased costs. For example, the cost of 10 mg of a drug can be double that of the 5 mg version. To accurately calculate cost savings, one would have to know the sales of a particular medication by dosage. By obtaining industry data, policymakers will be able to credibly assess cost savings, which is projected to be significant when one understands that higher doses does not mean greater benefit or any benefit, at all. Nevertheless, in most cases, a good assumption is that a doubling of dose equates to a doubling of price.

Discussion

Generally, there are few times when good policy derives from good science and practice. A policy that equates the effectiveness of psychotropic medications with cost and quality of care with the adoption of rules for the reimbursement of these medications would appear to be one of those times when policy

follows good science and good care. A strong case can be made that the growing use of psychotropic medications is not supported by a demonstrable need for these drugs or by an unbiased review of the science that their use depends upon. The American public, and others worldwide, have become the target of drug companies and physicians whose profits and livelihood depend upon selling and prescribing these drugs for conditions that patients simply do not have. Moreover, there is growing data that suggests these medications may even be fueling the conditions that they are supposed to be treating.[16,17]

In his seminal book, *Anatomy of an Epidemic*[37], Robert Whitaker presents important data that unveils the extent of this problem. In an era when economic resources are limited, the question becomes: Should we maintain healthcare policies that promote illness at great costs so that a few corporations can reap great benefits or should we adopt policies that promote health at considerable cost savings? On the surface, it would appear that this is a "no-brainer." However, logic, reasonableness, practicality, and appropriateness have not been the hallmark of national healthcare policy. There are just too many special interests and the public appears not to be included in the mix. But, economic realities may be the catalyst for positive change because we cannot continue to stay the course with respect to rising and consuming healthcare costs.

However, while cost effectiveness is a main issue, there are more important considerations in this debate. If these medications were simply innocuous concoctions where cost was the only issue, there might be some flexibility in how we design "fixes" to the system. But they are not innocuous. These are dangerous drugs that may be promoting more illness at a level that we have not yet been able to detect because long term studies are not available. In fact, they may never be available given the propensity of drug manufacturers to hide negative results and physicians who continue to prescribe and praise these drugs even in the face of their ineffectiveness.

Economic events are not uni-dimensional. That is, the reality of economic relationships is that there are multiplier effects, perverse incentives, an unexpected results that derive from transactions. In the case of prescription drugs, and perhaps all of medical practice, the multiplier effects of bad prescribing can increase the costs of treatment through side effects and by causing greater ill health. There are perverse incentives built into the drug industry where greater profits follow illness and better health decreases profits. Of course, better health accrues a greater benefit to society but society has not been the focus of healthcare policy.

An important question to consider: How is it that healthcare professionals and policy makers, who are have achieved the highest level of education, training and experience, are probably at the top of the intellectual pyramid, have designed a healthcare system that is totally out of control? Clearly, there may be many reasons for this but one reason is either the inability or unwillingness to create a balance between promoting and protecting free market practices and the common good. Yet, failure to address these issues will lead to a situation where the rate of disability resulting from the long term use of these medications will cripple the national economy to say nothing of the misery that will accrue to those individuals who have been harmed by these drugs.

Our healthcare system is so damaged that, if thalidomide was introduced by drug companies today, it is probable that tens of thousands of infants would be born without limbs. As it were, when the drug was introduced, only 17 cases of "thalidomide" babies were born in the United States. When the drug was introduced back then, the public was reassured by physicians and the drug companies that the drug was safe for pregnant women. Recall that thalidomide was introduced as a sedative medication. In today's reality of psychotropic drug marketing, physicians would be writing prescriptions for thalidomide in the same quantity and recklessness that they now write antipsychotics for pregnant women. Does anyone really doubt that this would be the case?

In conclusion, rewriting the rules for reimbursement for these drugs would be small but significant step in bringing some control to a system that is out of control. Overall consumers would still have access to existing medications should that be their choice. Moreover, if the cost of a particular drug is not reimbursed, patients who so choose can always pay for it themselves. This is free market economics.

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