The Need For Science-based Prescribing Standards In Mental Health Treatment

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Introduction

Psychotropic medications have now surpassed behavioral interventions as first line treatments as mental health care has shifted to primary care venues. Between the years 2006-2010, expenditures for these medications have increased while the overall budget for mental health has decreased by almost half. Over 80% of the prescriptions for psychotropics are written by primary care physicians. Yet, there is a growing and justified recognition that the public no longer believes that primary care physicians have the time, training and experience to properly diagnose and treat mental, emotional, and behavior disorders. Despite the increased use of psychotropic medications, numbers of studies continue to show that their effectiveness is questionable in as much of the supporting data used to justify the use of these medications may be tainted, missing, or wrongly reported. Moreover, prescribing practices remain influenced not by the available science but by drug company recommendations and ill-advised physician prescribing behaviors. Prescribing standards that are based on unbiased reporting of clinical trials and validated research and restoring psychotherapy as a first line treatment can provide patients with a higher quality of care that now is lacking under present practices. Moreover, these changes have the potential to significantly lower the cost of providing care for patients suffering from mental, emotional, and behavior disorders.

The medicalization of mental and behavioral health and the shift of treatment from psychiatry to primary care have resulted in a number of unforeseen consequences that is impacting both the access and provision of quality care. This shift to primary care providers has been accompanied by a general decrease in an appropriate evaluation and diagnosis from doctoral level mental health professionals (psychiatrists and psychologists) as medications has been typically accepted as a first line treatment for these disorders. Further, the result of this shift has led to poor health outcomes, increased health care costs and a lower standard of care for patients. Moreover, the poor outcomes associated with inappropriate psychotropic prescribing regimens are based on compromised science generated by drug manufacturers. On the whole, patients are not benefiting from these treatments while drug maker marketing expenses and the proliferation of non-performing medications have become a significant factor in rising healthcare costs. Two recent studies underscore the importance of addressing both the appropriateness of providing mental health care in a primary care setting by non doctoral level behavioral health specialists, and the need to develop prescribing standards that are based on the best available science that can justify the use of any particular psychotropic medication.

A survey conducted by the National Alliance on Mental Illness (NAMI) of families who are seen in primary care emphasizes the insufficient and inadequate mental health care that patients routinely are receiving in primary care venues. Among other important findings, patients related their concern that their primary care providers frequently lack a comprehensive referral
system to mental health specialists. They cited a need for information on behavioral interventions and strategies and a need for mental health professionals who accept private and public insurance. A majority cited a need for primary care physicians to be honest about the shortage of mental health care doctors.

Those surveyed demonstrated that they had an above average knowledge about the lack of access and quality care that is available to patients with mental, emotional, and behavior disorders who are treated in a primary care setting. Fifty-nine percent (58%) of those surveyed said their primary care doctors were not knowledgeable about mental health treatment. Sixty-four percent (64%) related that their primary care doctors were not knowledgeable about local resources for patients with mental disorders. Little more than one third of the respondents, 34 percent (34%) stated their primary care doctors were "knowledgeable" about mental illness – 17 percent (17%) stated that they believed their primary care doctor were “somewhat knowledgeable” about mental illness. Given that primary care physicians are the first to see patients with mental, emotional, or behavior issues, these results are cause for alarm. Patients clearly are aware that they require the services of mental health professionals because primary care physicians are simply not trained or skilled to deliver the services they require. While the patients in this study were not asked directly about medications, the fact that a majority of respondents cited a need for traditional mental and behavioral health care implies that patients are not convinced or satisfied with medication only treatments.

**Using Active Medications as Placebos Is Not Good Patient Care**

A second and alarming survey of primary care physicians was reported by Brody and Light\(^8\). In their survey of 1000 randomly selected primary care physicians a wide array of questionable prescribing practices by PCPs are reported. The authors cite prescribing practices where antibiotics and psychotropic medications, for example, are routinely used by PCPs as placebos to quiet the reported, but believed to be insignificant, symptoms of their patients. The large number of PCPs who report this practice is significant and alarming. Fifty-six percent (56%) of the physicians surveyed reported that they had used a placebo in clinical practice. Forty percent (40%) reported that they had used an antibiotic as a placebo, while only 11% had used traditional, inert substances as placebos. The most frequently reported reason for prescribing active medications as placebos was “the unjustified demand by patients for medications.” resulting from television and print media pharmaceutical company advertising. Eighty-five percent (85%) of the surveyed physicians stated that they believed placebos can have psychological and physical benefits. The majority of respondents, 61%, recommended prescribing a "placebo" as an alternative to providing no treatment at all. A small 8% of the respondents reported that clinical placebo use should be categorically prohibited.

Clearly, there can be little, if any, medical justification for using an active drug as a placebo. A very large percentage of the public and healthcare professionals are aware that resistance to antibiotics, for example, has been steadily increasing. All have been warned to
reduce the unnecessary use of antibiotics. It is incredulous and disturbing to find that physicians are disregarding such an important warning and thereby contributing to a major health problem.

Moreover, active drugs pose real and potentially harmful risks to patients which cannot and should not be minimized. While it is difficult to predict an actual epidemiological consequence related to using active drugs as placebos, it is clear that there will be patients who will experience side effects, which will lead to additional harm, treatment and cost. All of which, should never be part of medical practice. Using active medications as placebos should be viewed as an unethical and unacceptable prescribing practice. When the findings of these two important studies are taken together, there are clear health care policy implications that cannot be ignored. With respect to the provision and treatment of mental health in primary care there must be significant changes if primary care physicians are to remain part of the solution.

**Providing Mental and Behavioral Healthcare in Primary Care**

Providing care to patients suffering from mental, emotional, and behavior disorders in a primary care setting by non-behavioral health specialists is a major healthcare issue that impacts patient care, healthcare costs, healthcare policy, and practice economics. It is imperative that the primary care physician's response to a patient expressing symptoms of anxiety, depression, hypomania, and a variety of additional signs of emotional distress, must be a complete diagnostic work up by a doctoral level behavioral health specialist and not an immediate prescription for psychotropic medication or an active medication as a placebo. Should medication ultimately be included in a treatment regimen, pharmacotherapy should be a collaborative effort between physicians and a qualified doctoral behavioral health specialist, preferably by a psychologist trained in psychopharmacology and medical psychology, or psychiatrist when available. In a non-emergency context, time must be taken to understand the complete nature of the patient’s psychopathology if, in fact, it does exist. Treatment resulting from this understanding should be based on the best available evidence that the treatment will help the patient resolve their presenting complaint. Moreover, medications should never be prescribed for a patient simply because they demand medications. This best practice approach is the standard of care all of our patients require and deserve.

The pharmaceutical industry has made it very difficult to trust the current “best” psychiatric approach to health care. 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. The studies by Kirsch and Turner clearly demonstrate that evidence-based medicine is valuable and necessary but the evidence must be complete and unbiased. Selective publication of clinical trials and their outcomes lead to inaccuracies about a drug's effectiveness and distort the risk–benefit ratio that prescribers rely upon when recommending and selecting a medication for a patient.
The medicalization of mental, emotional, and behavior disorders has resulted in a medication prescription for every presenting symptom and with questionable benefits.\textsuperscript{13-17} According to the industry leading IMS National Sales Perspective for 2010, the retail sales for several classes of psychotropic drugs sheds light on how ubiquitous psychotropic drugs have become first line treatments. It should be noted, however, that the retail costs of these drugs show the amount of over-prescribing that is taking place in primary care and represent the least cost associated with over prescribing. Additional costs of over-prescribing these drugs are related to side effects and their relationship to permanent disability associated with their long term use.\textsuperscript{18,16} The sales of antipsychotic medications, for example, have become the number one class of prescription drugs with 16.1 billion in sales spread over 58 million prescriptions. They now out sell statins. What these sales figures also demonstrate is that the number of prescriptions for antipsychotics is far greater than the total universe of patients that these drugs are designed to treat. In a recent analysis of prescribing trends for antipsychotics, Verdoux, Tournier and Bégaud\textsuperscript{19} looked at 17 studies that reported on the use of antipsychotics. The analysis showed a steady yearly increase in anti psychotic prescriptions, which the authors ascribed to the dramatic rise in prescriptions of atypical neuroleptics. They concluded that antipsychotics are often prescribed for non-psychotic disorders in adults as well as in children and adolescents.

If every individual diagnosed with a psychotic disorder in the U.S.A. were given a prescription for these drugs for an entire year, however unlikely an occurrence, this would account for about 30 million prescriptions. This is based on a 1\% prevalence rate for schizophrenia in the USA.\textsuperscript{20} As one can see, prescriptions for antipsychotics were in excess of 52 million prescriptions for both time periods. Sales of antidepressants continue to climb and imply significant over-prescribing as well.

These issues are important to all prescribers of psychotropic medications because patients rely on receiving the best treatment options available. There is no expectation that they will receive a medication that has little, if any, relationship to their symptoms or condition but can be damaging to their health. Worse, there is no expectation that they will receive a risky and ineffective treatment when a safe and effective treatment is available. The research conducted and reported by drug manufacturers and marketed to the public is simply not trustworthy. Therefore, the more salient issue is that all prescribers of psychotropic medications should strictly adhere to an evidenced based standard of care for patients requiring pharmacotherapy. The “evidence” must be independent research not tainted by pharmaceutical industry marketing efforts or physicians on drug company payrolls extolling 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 care, by the right people, at the right time.”

Public awareness, public policy regarding best practices, and the standard of care for patients treated with psychotropic medications are essential to effect positive change in how patients with mental, emotional, and behavior issues are cared for. While quality and effective care must be the primary concern for providers, when behavioral healthcare is delivered by the appropriate mental health professional, healthcare costs are significantly reduced.\textsuperscript{21-23} Based on this research, it is our contention that doctoral behavioral health specialists offer a better model,
essentially free of these conflicts, for providing full service mental health treatment. Preferably, these mental health professionals will be integrated and co-located into the primary care setting. However, up to now, primary care physicians have resisted this integration preferring to take the mantle of primary providers of mental and behavioral health. The two studies cited overwhelmingly demonstrate that PCPs should not be the primary providers of mental health care.

It is important to look at the relationships between drug makers, health care providers, and the United States Food and Drug Administration, in understanding the potential for these patients to thrive. It is our contention that presently, conflicts of interest, unchecked prescribing practices, and shoddy research negates the best practice approach and makes it impossible for patients to receive the appropriate standard of care. Moreover, the real potential for change will come from providers who have the ability to change the way they prescribe and from patients who understand practice standards that places the prescribing of psychotropic medications within a framework derived from unbiased evidence-based studies. This goal may be more easily said than done due to the many reported instances where the credibility of drug research has become highly suspect. Marcia Angell, former editor of the New England Journal of Medicine and a leading critic of Big Pharma, puts it more bluntly: "Psychiatrists are in the pocket of industry." She particularly stated that most of the Diagnostic and Statistical Manual of Mental Disorders (DSM) have ties to the drug industry.

A New Prescribing Model Is Needed

Prescribing models and practices generally are based on recommended doses and applications derived from short term clinical trials supported by drug manufacturers. Other influences in how and when a drug is prescribed include drug company seminars, published papers, and the personal or supervised experiences of the prescriber. The Ioannidis and associates meta analyses and replication of drug maker studies charges that 90% of the published medical information doctors rely on is flawed. These flaws include manipulation of data, excluding data in clinical trials, and ensuring positive results by comparing “new drugs” with known inferior drugs all ready in the market place.

Findings from Ioannides’ meta analysis revealed that SSRIs were no more effective than placebo for most cases of depression which raised the question of trusting and relying on information generated by drug company sponsored research, drug company findings of off label use, and FDA marketing approval. These finding are consistent with those reported in the Kirsch and Turner studies. All of these studies are published in mainstream medical journals. Many, if not all, have been discussed in medical conferences and have received write-ups in newspapers and other print outlets. All can be searched and read on the internet. Providers, therefore, have little excuse, if any, not to have read or heard about studies. Moreover, they all come to the same conclusions: Drug–placebo differences with respect to the effectiveness of antidepressants increase as a function of baseline severity, but are relatively small even for severely depressed patients. Any relationship between initial severity and antidepressant
effectiveness is likely to be attributable to decreased responsiveness to placebo among very severely depressed patients, rather than to a response to the medication.

In behavioral health practice, algorithms, essentially flow charts, have been developed to aid a prescriber. The extent to which any of these algorithms are credible and are followed is unknown. The lack of systematic prescribing principles contributes to practices that do not utilize the most current scientific findings about the use and benefit of a medication. Use, for the most part, is left to the prescriber. Patients are placed in the position of having to trust that their providers, who rely on flawed information, to be knowledgeable and certain their prescription will result in significant benefit. The available evidence suggests that a significant amount of medical treatment is ineffective and contributes to increased risks to patients. The standard of care provided to patients, therefore, is judged to be poor and mostly ineffective.

An approach to prescribing that is derived from a set of "prescribing principles" based on the available independent science could provide a model that would benefit patients, reduce risks associated with side effects, reduce medication errors, and reduce costs associated with misdiagnosis and treatments. The purpose of this paper is to propose a model for the prescribing of psychotropic medications but can also be extended to other classes of medications.

**Practice Standards for Prescribing Psychotropic Medication**

Primarily, the prescribing standards that follow are directed to all health care providers who have been authorized to prescribe psychotropic medications. These standards and prescribing practices 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 standards. Two of the authors are clinical psychopharmacologists. The third author is a national leader of integrated healthcare and has a long history of integrating and promoting behavioral health services into primary care. Hopefully, these prescribing standards will be adopted by all prescribers of psychotropic medications that practice in an out-patient setting. Patients seen in an emergency and who may be hospitalized clearly need treatments that differ from those seen in out-patient settings. Thus, while some, or many, of the proposed standards may also apply to these patients, we acknowledge that different conditions apply and distinct standards should be developed for emergencies and patients requiring hospitalization or incarceration who present a danger to self or others.

**Psychotropic Medications Are Not Effective 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. This 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 behavior disorders.\textsuperscript{32,33} Primary Care Physicians and physician extenders typically rely on the superficial menus of symptoms listed in Diagnostic and Statistical Manual of Mental Disorders (DSM) and the International Classification of Diseases (ICD) or brief and simplistic survey instruments to determine which psychotropic to prescribe. 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.\textsuperscript{34-36}

Psychotropic medications should only be considered after a patient has been fully evaluated and diagnosed by a doctoral level behavioral/mental health specialist and has failed to significantly improve from non medication intervention. 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.\textsuperscript{38,1}

\textbf{Off-Label Prescribing}

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.\textsuperscript{26,38} 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 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. A survey of more than one thousand patients receiving antidepressants, for example, found that a majority of usage (56\%) was for conditions other than those for which the FDA had approved the medication.\textsuperscript{39} It is estimated that off-label prescriptions account for at least 21 percent of pharmaceutical sales, amounting to at least 150 million prescriptions annually.\textsuperscript{38}

If off-label prescribing is not seen as a real risk to patients then why have clinical trials at all? 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. In fact, atypical anti-psychotics had been routinely prescribed off label for dementia patients until the FDA ordered a halt to the practice due to the high number of deaths associated with this drug among patients with this condition. A 2008 study\textsuperscript{40} published in Pharmacotherapy identified a high volume of off-label prescribing in the absence of good evidence for a substantial number of drugs, particularly antidepressants, anti-psychotics, and anxiolytic-sedatives.
Limiting 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. Some have recommended 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. 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. As long as existing drugs with known profiles are available, the rush to prescribe a newer one that is relatively untested and who’s testing may be flawed is unwarranted. Presently, the Cochrane Databases and Reviews (Cochrane Collaboration) is one place where reporting unbiased studies can be trusted. Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognized as the highest standard in evidence-based health care. We recommend that only studies reported in the Cochrane Review be accepted when determining the effectiveness of a psychotropic medication.

Prescribing Medications That Have Not Been Proven To Be More Effective Than Placebo or An Existing Medication Currently Approved in its Class

We recommend that a psychotropic medication must out perform a placebo or a proven existing medication before being prescribed. Again, we look to studies reported in the Cochrane Reviews to determine effectiveness. 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. Many times, competing psychotropic drugs in a similar class are slightly altered simply to gain market share. 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.

Prescribing Active Medications as Placebo

The potential harm and additional risk to patients when an active medication is used as a placebo is not justified and must be stopped. This practice is a misuse of prescribing and
unethical in the most favorable of light. This practice must be abandoned and halted as there is absolutely no positive rationale for its existence in a treatment regimen.

**Polypharmacy Should Be Minimized and Restricted**

The practice of polypharmacy is in itself an admission that the drug being augmented is ineffective for the condition it was prescribed for. With respect to psychotropic medications there are no reliable studies that show more than two drugs of the same class (e.g. antidepressants) more beneficial to the patient.\(^4\)\(^4\)\(^6\) 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 is a dopamine D2 receptor partial agonist with partial agonist activity at serotonin 5HT1A receptors and antagonist activity at 5HT2A receptors. Essentially, when added to other serotonergic medications (SSRIs), as recommended by the manufacturer, it may not only defeat the action of the SSRI, but most probably acts as a mere anxiolytic, which can easily be addressed with non-drug treatment that 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), and metabolic_disease are increased risks for patients taking Aripiprazole. There are many more examples of inadvisable polypharmacy that support a prescribing standard limiting its use.

**Lifetime Medication Regimens**

Many patients are kept on long term regimens with no scientific basis supporting long term use. Patients who are being treated with psychotropic medications should be placed on a short term trial lasting no longer than the time period reported in the clinical trial for that drug. Typically, clinical trials with 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. For all classes of psychotropic drugs, if a patient shows no significant improvement during a reasonable trial period then the medication should be
discontinued. There is sufficient evidence that the continued use of both antidepressants and antipsychotics lead to lifetime disabilities.\textsuperscript{14,16,18}

**Prescribing 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.\textsuperscript{55,56} Therefore, psychotropic medications, when prescribed at all, should never exceed the upper range of the recommended dosage.

**Financial Incentives and Perks from Drug Industry**

Patients rarely benefit, if at all, from prescribers who accept gifts and perks from drug industry sources.\textsuperscript{47} Whether these perks include free continuing education, consultant fees, free pens or pencils, these perks come with the cost of abandoning the unbiased selection of a medication. Free samples of medications should be banned from practice. Free samples are designed to “hook” the patient and prescriber on the brand. Providers can easily write a prescription for a few pills to determine if the medication works for the patient. Balancing the economics of “free” sample medications and prescriber independence is an easy call.

**Discussion**

This article highlights many of the problems presently seen in prescribing psychotropic medications. The authors propose a higher standard of care for all prescribers of psychotropic medication. While the standards presented are not finite and can be expanded, they are science based, safety-focused, and directed to providing patients with more effective and efficient behavioral health services.\textsuperscript{1,48-50} They are a good start that will protect patients and, at the same time, lower the long term costs associated with providing behavioral healthcare.

Prior to the introduction of SSRIs, psychotherapy was the most utilized treatment for mental, emotional, and behavior disorders. It was the first line treatment for the varied disorders seen in practice. The time period, from the 1950's through the latter 1990s, saw the greatest growth in the budget for mental health. However, as psychotropic medications were introduced into medical practice, the use of psychotherapy has been in a continual decline\textsuperscript{51} even though the effectiveness of many psychotropic drugs do no better than first generation medications.\textsuperscript{52-53} Although these medications present physicians with the opportunity to become behavioral health providers, one cannot be expected to be a skilled behavioral health specialist with the little training that most non psychiatric physicians rely upon to assess, diagnose and treat patients presenting with behavioral health issues.

The reason for this is simple: Mental, Emotional, and Behavior Disorders are complex and can lead to serious consequences when not properly identified and effectively treated when
relying upon drugs whose effectiveness and use is highly suspect due to biased and rigged clinical trials and misrepresentations by drug manufacturers. Assessment and diagnosis by a skilled professional must be the first step before even considering a medication. This is not likely to occur in a primary care setting without collaboration with a doctoral level behavioral health specialist.

Between the years 1996 and 2006, expenditures for behavioral health treatment rose from $35.2 billion in 1996 to 57.5 billion in 2006. In 2009, psychiatric drug manufacturers had overall sales in the US in excess of $15 billion from antipsychotics, $9.6 billion off antidepressants, $11.3 billion from antiseizure drugs and $4.8 billion in sales of ADHD drugs, for a total of over $40 billion dollars.54

By 2010, the insufficient expenditure for mental healthcare amounted to nearly 4% of total healthcare expenditures of $2.2 trillion dollars. However, expenditures for mental healthcare is directly related to the expanded use of psychotropic medications and the concomitant shift of health care delivery for mental, emotional, and behavioral disorders into the realm of primary care resulting from a critical shortage of psychiatrists in the United States.57,58 Yet overall positive outcomes have been low and there is greater disability among those persons who are maintained on psychotropic medications. This is extremely problematic in that most general practice physicians, family practice physicians, internal medicine physicians, OB/GYNs, and other primary care doctors do not have the necessary time, formal education, and training to meet the required standard of care for these patients.48 The public recognizes this and is looking for access to well trained traditional mental health practitioners. Meanwhile, many primary care physicians remain committed to ineffective treatment with psychotropic medications as first line care.

The Ability to Prescribe Does Not Mean One Must Prescribe

Prescriptive authority does not mean that behavioral health should be medicalized. In mental health practice the authority to prescribe does not mean that a drug is the most effective treatment for mental, emotional, and behavior disorders. As behavioral health specialists we know and understand that psychotherapy is the scientifically validated treatment for most behavioral disorders. However, because behavioral health specialists are not the primary behavioral health provider, and because there is a critical shortage of psychiatrists in the United States, that decision has been transferred to primary care physicians. This does not suggest that should the number of psychiatrists magically increase, the problems outlined in this paper would be resolved. Psychiatry, itself, with its almost total reliance on medications and its inability to divest itself from drug manufacturers, actually is a major part of the problem and not likely to be part of the solution.

Physicians generally accept medications as the first line treatment for mental, emotional, and behavior problems. Consequently, psychotherapy has been in decline year-over-year since these medications have become the dominant treatment option.25 Thus, the use of ineffective medications used in the treatment of behavioral health has greatly contributed to the decline of psychotherapy and as a first line treatment for behavioral disorders despite the potential risk,
harm, and ineffectiveness of many psychotropic medications. The adoption of the standards presented herein will provide a model for prescribing that clearly separates effective prescribers, who utilize the best available science, from other prescribers, who may continue to prescribe medications without a careful analysis of whether they should be prescribed, at all.

**The Problems of Medicalization Must Be Addressed**

Prescribing standards and a new model for prescribing are imperative because they represent a viable alternative to the medicalization of mental health. If medications are to be part of a treatment regimen, then doctoral level behavioral health specialists need to be part of the assessment, treatment, and monitoring of these patients. We acknowledge that the recommended standards are consistent with being behavioral health specialists. However, these standards are not created in a vacuum. They stem from a systemic failure to address the effective treatment of mental, emotional, and behavior disorders since psychotropic drugs became the popular and first line treatment for depression and other psychiatric maladies.

Primary care is not the best venue for the evaluation, diagnosis, and treatment of mental disorders absent collaboration with a doctoral level behavioral health specialist. Preferably, that collaborator would be onsite and integrated into the primary care setting. Studies, over the past two decades, have reported that many primary care physicians do not provide patients suffering from mental, emotional, and behavior disorders the requisite minimal standard of care.\(^{59-61}\) In fact, one of the largest studies looking at the standard of care provided in primary care settings shows that patients who are depressed or experiencing problems from substance abuse receive care significantly below the minimal standard of care with only 53% of the standard designated for depression and 10% of the standard for substance abuse issues being met.\(^{30}\) These failures can be ascribed to the challenges inherent in evaluating psychiatric disorders and finding an appropriate medication regimen, if even necessary, that will help these patients. Recognition of major depressive disorder in primary care remains a challenge\(^{62}\) and several studies show that primary care physicians missed the diagnosis of major depression in a very high percentage of patients with the disorder even committing fraud when coding for depression.\(^{63-65}\) Adding to the problem, psychiatric clerkships and rotations are not popular choices in medical school further adding to the primary care physician's inability to correctly diagnose and treat the broad range of mental health concerns that present in their offices.\(^{58}\)

The inherent problems of providing mental health care in primary care settings directly impacts access to care. If the care received is not adequate in meeting the needs of the patient and the standard of care to treat mental disorders is not met, then those patients do not have access to appropriate care. The inability to see a physician is of little value if a patient cannot receive care appropriate to their condition. This means that patients presenting with symptoms of mental, emotional, and behavior disorders must receive an appropriate evaluation and diagnosis by a doctoral level behavioral health specialist before even considering a psychotropic medication.
The failure to address the medicalization issue will continue to be problematic to primary care providers and other physicians. This failure will invite lawsuits and regulation by patients, legislators or regulators. Despite all the marketing by drug companies, with the unwavering support of psychiatry and some physicians, the public remains leary of psychotropic medications. There also is reliable research that clearly casts doubts on the effectiveness of many of these drugs.\textsuperscript{3,6,12,17,18,43,66} As healthcare professionals, we cannot continue to support the present prescribing practices without being the primary critics of ineffective medications and their use over or along with psychotherapy. We must adopt an affirmative stance and positions that place the use of psychotropic medications in their proper perspective based on the best research available. Research that has become increasingly more difficult to rely upon due to the outright suppression of negative results by drug companies, which includes deceptive reports citing positive results, is unacceptable. Evidence based practice must begin with evidence base prescribing.

**Focus On Being Healthcare Providers Who Can Also Prescribe**

Looking at all the available data, suspect or not, there are some patients with mental, emotional, and behavior disorders who are helped by medication alone or in combination with psychotherapy. This leaves a significant number of patients that can benefit from psychotherapy alone. Depression and other mood disorders, anxiety disorders, sleep disorders, and a host of other behavior and life style problems respond better to psychotherapy and behavioral intervention than to medications and without the risks and side effects of medications.\textsuperscript{1,67,68} These are issues that the general public, policy makers, and law makers must be made aware of.

The medicalization of mental, emotional, and behavior disorders with psychotropic medication as the first line treatment does not work for a significant majority of patients. It is inefficient and ineffective. Moreover, it adds to the out of control, high costs of health care. More specifically, patients are being denied effective treatment from behavioral health providers. Adopting, promoting, and adhering to prescribing standards that derive from unbiased research and sound science is one way that we can provide the best benefit to patients suffering from mental, emotional and behavioral disorders. To repeat, the overriding message must be: “Provide the right care, by the right people, at the right time.”

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