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The Archives of Medical Psychology is a peer-reviewed journal published electronically that is dedicated to the practice of Medical Psychology. The rapidly emerging field of Medical Psychology in the evolving new healthcare delivery system requires prompt dissemination and documentation of these developments. Therefore, The Archives is using this electronic format to deliver this information to practitioners for the well being of their patients. Articles are published when they have met the standards of the review process and are determined to have potential merit for practitioners when providing healthcare services to their patients. Subscribers will be notified electronically as articles are posted on the Archives of Medical Psychology web site for their viewing. Articles submitted to the Archives for publication will be considered for review as long as they are pertinent to the practice of Medical Psychology as defined below.
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Author and reader information about the Archives of Medical Psychology, the Academy of Medical Psychology (AMP) and the American Board of Medical Psychology (ABMP) appear at the beginning of Issue I of Volume I. The Masthead, Table of Contents of Issue I, Editorial Statement, Definition of Medical Psychology, Introduction to the Archives of Medical and Editorial Policy are listed in the section on pages with roman numerals.
Emerging Concepts in Alcoholism Treatment

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Abstract
The American healthcare system will be modified in ways that recognize the importance of making substance abuse diagnoses and treatment a required component of healthcare systems. Recent advice from Governmental agencies is recommending medications to control cravings for all alcoholics and some drug addicted individuals. This recommendation continues the tendency to overestimate the efficacy of medication treatments for serious mental disorders such as the addictions, and perpetuates the fallacy of viewing “medication only interventions” as adequate treatment. Further, there are no standards requiring that Primary Care Centers and Community Hospitals have psychologists. Therefore, these centers are being given increased responsibility for screening and access to specialty care without adequate staffing to realistically treat these patients.

Introduction
The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (referred to together as the Affordable Care Act; ACAs) was signed into law by President Obama in March 2011. This law seeks to make health insurance coverage more affordable to individuals, families and the owners of small businesses. Though controversial, and drawing expected opposition from some hospital corporations, pharmaceutical houses, organized professional associations, and others with vested interests in the current health care system, the act is predicted to save billions of dollars that can be poured back into healthcare services, lower insurance premiums, and increased efficiency. The new law is built upon moving healthcare toward a more scientific, rational, integrated, and multi-disciplinary system and recognizes that early and effective treatment of substance abuse disorders must be included in order to curtail related catastrophic healthcare and societal costs. Alcohol use disorders (AUDs), including alcohol abuse and dependence, occur with an estimated 12-month prevalence of 8.46%.1 Alcohol abuse and dependence are associated with a range of adverse medical, psychiatric, family, legal, and work-related problems. Although alcoholism is a leading cause of preventable death in the United States evidence-based treatment of AUDs is not commonly used by practitioners.2,3 Thus, no rationally designed Primary Care Center or Community Hospital can be effective and responsive to the public need without inclusion of leadership psychologists with addiction and mental health specialty training and skills and substance abuse and co-occurring disorders programs.

Since 2005, the National Institute on Alcohol Abuse and Alcoholism has recommended that medication should be considered for every patient with alcohol dependence.4 In practice, few patients with alcohol dependence are prescribed medications approved by the US Food and Drug Administration (FDA) to treat the disorder. This may be because the medications are not a treatment for the syndrome of addiction, but rather are techniques designed to deal with cravings and relapse, a small portion of the addictive

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syndrome. Medications used for alcohol treatment are more specifically effective for a partial redress of that minority of alcoholics that have strong cravings and difficulty establishing initial and protracted sobriety. However, many behavioral and psychological and psychosocial techniques are available for the management of cravings and relapse and they have far less risk of organ damage and other side effects and the use of these interventions have proven to be more effective than a combination of medications and psychological treatments when applied in unitary fashion when the long time horizon is utilized in the research. Unlike so many of the psychoactive medications, which have been over-sold and real side effects minimized, the push to prescribe a pharmaceutical cravings blocker for every alcoholic are neither scientifically indicated nor likely to be well accepted.

The Concept of Pharmacological Control of Urges and the Relationship to Alcoholism Treatment

There are patients that have not developed sufficient frontal lobe development or dominance (equivalent to anatomical ego strength or Adult processing) to self-regulate. Consequently, these patients are often diagnosed as one of the mental disorders related to dysregulation as a descriptor. It is interesting that lack of parental teaching and skill development, excessive stress and hostility, and unpredictable and chaotic environments in children results in a lack of neurons or neural activity potential in sectors of the brain. Yet, when medically trained researchers find deficits in this regard, they mistakenly focus on “brain damage/deficits” or “genetic dysfunction” interpretations without adequately taking into account the nature of the development. They ignore more realistic and research adherent interpretations such as the lack of profusion of controlling and inhibiting cell assemblies. They forget to adequately discuss the need to establish reparative neurogenesis and the opportunity to capitalize on the brain’s plasticity through psychotherapy and training. Parents are experts, teachers, or negligent at proffering brain cell, neuronal connection, or lack of same and grow adaptive personalities in every generation. Simply put, parents grow brain cells and personalities they are based upon (for better or worse) all the time. Parents historically sire and raise children that are in the vast majority psychologically and physically healthy and reasonably normal. They program healthy limbic systems by being emotionally attuned to the child and empathetic while assisting the child in the development of self and other understanding (insight), all resulting in neuronal growth similar to that accomplished in psychotherapy.

When very debilitated families of origin, with very dysfunctional parenting techniques occur, we find a very high incidence of multigenerational psychological and Substance Use Disorders (SUDs). We should not be surprised when these families generate children with brains that show very different electroencephalograms, or other neurological measures. We know that the mind arises from the brain, which is compartmentalized into functional components (mini-brains) that require coordination and suppression of many components.

While autoplasticity of the brain is scientifically proven and the brain’s growth proceeds during most eras of life, the reality is that it takes a long time to grow new cell assemblies and connections that can inhibit acting out or inappropriate and non-purposeful behaviors. For example, it takes along time to learn advanced algebra (neurogenesis) and attain its attendant neuronal growth and differentiation. However,
once the cell assemblies and neuronal connections are solidified, advanced mathematics skills and insights remain for life.

In a similar way, many patients without the preparation necessary to grow brain systems that afford personalities with adequate self-regulation, need a comprehensive treatment plan. The treatment has to regulate and evolve pharmacological, structural aspects of the brain and brain based personality. The treatment must propagate cells and connections that afford supervisory inhibition of impulses and feelings. When poor training results in neural networks that produce impulsive, excessively emotional, or maladaptive behavior, autoreceptor (braking) neurons and cell assemblies must be developed. These patients must experience autoreceptor growth and learn through neuronal cell braking (external inhibition) before they can add cell assemblies and specific self-regulatory neuronal connections. The erudite clinician explains this pharmaceutical technique or techniques as a temporary, stopgap, and a "least preferred" approach and instead outlines the more permanent and effective approach of growing the neural connections and refinement necessary to achieve effective self-regulation (mental health). Thus, the frame for both allopathic (short-term) brain control and long-term brain control (brain growth and change) is set in the patient's vision of treatment. These clinicians appreciate the rapid containment of behavior achieved with medications, but seek to create more lasting brain and personality change that can mediate behavior and increase self-regulation without medicines in the long term horizon.

Erudite clinicians (be they medical psychologists, psychological physicians or psychiatrists) explain medications as a temporary and palliative stopgap infusion of medications that cause interference with normal brain function so that the patient is partially disabled and unable to react in their normal way. Psychoactive drugs that interfere with membrane action potential, neurohormonal loading and reprocessing, or second messenger signaling normal systems in ways that slow the patient's brain and nervous system, create a time lag, or accentuate neuronal firings so that we may reach, teach, and reinforce patients without their regular reactive tendencies getting in the way. This medication approach is a short-term advantage, but could debilitate the patient in the long run.

Medication approaches to the treatment of mental disorders can be conceptualized as short-term, less than elite, and ultimately inadequate treatment plans that attenuate long-range human potential. They should not be trusted solely to the hands of practitioners who are not trained and proficient in psychological diagnosis, psychotherapy, and integration of the complex concepts of brain-personality interaction, or to mid-level behavioral health providers who are not privy to the guidance and direction of a psychologist or psychologist capable of integrating the complexity of psychological (brain/personality) disease and its amelioration. Such assignment of these patients to primary care physicians with a 30 day rotation with a psychiatrist several hours a day in their medical education and a cursory understanding of the limits and efficacy of psychopharmacological techniques, or a professional counselor or social worker with a handful of counseling and case management courses is potentially dangerous and may be abusive in some cases.

The clinician using a science-based utilitarian framework has a scientific and moral responsibility establish a block to the moral hazard of reinforcing the "inferiority complex" that is extant in most seriously addicted individuals. There is a deluding belief, widely
held in our society, that one can successfully manage feelings and impulses, and even energy levels with “mind/mood altering drugs”! That delusional system is the very core philosophy of every addict. The clinician cannot, simply implicitly or explicitly, align with either the addicted patient or the modern medical system in this deluding system. To do so popularizes a distortion of reality and scientific knowledge. At this stage of the science, it would be irresponsible (and tantamount to unethical or scientific ignorance or even malpractice) to indicate or imply that “you will have to manage your moods and urges with chemicals for the rest of your life. Many pharmaceutical houses and some prescribers have followed the shrill repetitious urgings of Madison Avenue to sell the volumes of drugs that create the drug delivery system.

Primary care physicians, prescribing psychologists must offer much more than a drug delivery system and stopgap psychopharmaceutical control of behavior! Addicted people need doctors supervising the treatment plan and team with significantly more expertise and training than in medicine. The doctor supervising the treatment of the seriously addicted patient needs depth training in neuro-linguistics, behavioral, and self and developmental psychology to achieve the ultimate positive outcome. In fact, all general physicians and many psychologists, psychiatrists, social workers and professional counselors lack specialty training as addiction psychotherapists to understand and implement this mental frame setting required in the treatment of addictions. Such clinicians can provide valuable input to SUD treatment teams, but they are really marginally qualified to act as the attending doctor and to determine the treatment needs of these patients. We must recognize the deficits in our training and seek education and residencies that will prepare us to fill society’s needs for addiction services in all health care facilities. Most health care facilities will need a qualified doctor of psychology or psychiatry with specialty training in the treatment of addictions in order to do an adequate job of assessment, identification of co-occurring mental disorders, and to devise comprehensive treatment teams. The tendency for these facilities to try to overcome their needs for adequate staffing by delivering medication only approaches, or medications and health education will demonstrate the facilities lack of adequate knowledge of SUDs.

**Adherence Issues**

Adherence has been identified as a major determinant of outcome in substance abuse treatment. The problem of adherence to a treatment program is highly variable in intensity depending on the nature, experience, and staffing in programs. Many programs with highly trained senior clinicians do not rate problems of patient adherence as the great problem that they face. Therapeutically conceived centers using highly skilled and well-trained staff have programs to engage and retain their patients. Thus, they rate their significant problems as:

1. Low reimbursement rates relative to less complicated medical and medication interventions.
2. Difficulty recruiting and retaining senior and highly trained clinical staff members.
3. Limited resources to bring facilities and equipment up to competitive and desirable levels, which patients learn to expect at hospitals and primary care centers.

Primary care centers are permitted by law to hire family practice physicians with 30-day psychiatry rotations to diagnose, treat, and order treatment and supervise treatment
plans for patients with addictions. This is a deficiency in the addiction treatment system that is perpetuated by the “halo effect” relative to general physicians and well-established marketing by the primary care center. This “halo effect” practice rather than science-base practice is related to the belief that general physicians are the most knowledgeable and scientifically informed and trained clinicians in America. Ignoring science-based care require requirement for addictions has crippled patients and healthcare systems for generations. This is not an anti-physician bias, but rather a realistic recognition that the science and knowledge base is so large, deep, and complex, that no discipline can be competent in all areas of health care. It would be unfair to blame general physicians who are responsible for more than 3,000 diagnoses and treatment protocols. Additionally, many psychologists are not adequately trained to treat serious substance abuse and co-occurring disorders. This is why the tradition (in Medicine and Psychology) has developed of referring complex cases to specialists. The public doesn’t realize that this deep seated tradition of referring complex cases to specialists is a cornerstone of quality assurance in the medical system, but that without psychologists and psychiatrists in adequate staffing (or even required staffing) in America’s Primary Care Centers and Community Hospitals renders this essential component of the health care system unavailable.

Thus the tradition of general practitioners is to “screen” rather than treat complex illnesses. Doctors trained in medicine must accept one’s professional boundaries to treat by referring patients with addictions and other serious psychological disease to a specialist. It is the healthcare culture that is broken. It is faulty thinking to assume that patients with addictions have a moral deficiency and society has met its responsibility by providing access to primary care physicians with minimal mental health training but not requiring specialty care. Societal denial and unspoken contempt for these diseases of addiction and patients with these conditions are further manifested by Primary Care Centers and General Hospitals that are able to maintain their state license without enacting staffing rules and regulations that require trained psychologists or psychiatrists to meet the needs of their patients.

In the field of substance abuse treatment the knowledgeable experts highlight poor treatment of cravings. Required resources can be evaluated by staffing patterns, readily available and accurate diagnostics, co-occurring disorder treatment, and neuropsychological and medical assessment treatment and rehabilitation. These core issues have more profound impact on patient recruitment, adherence, and outcomes than the need for “a medication to control cravings.” Psychologists and other specialists in addictions understand how to apply the techniques that enhance patient recruitment and adherence in addicted patients and patients with co-occurring conditions. These skills and techniques relate to family involvement, highly structured treatment and frequent and intensive interventions during the first 90 days of treatment. High structure for the most severe patients may include, daycare treatment, parallel treatment of co-occurring disorders, and available program reinforcers. Program reinforcers may include: housing, token rewards, medical care, entertainment and recreation, attractive and comfortable facilities, biofeedback labs, cognitive rehabilitation laboratories, etc.

Seasoned substance abuse professionals realize access to appropriate resources as a more pressing problem than the pharmacological that control of cravings and urges to use alcohol wane rapidly with effective treatment in 80-90 percent or more of alcoholics and addicted individuals. Exposing them to side effects such as sedation, liver damage,
or drug interactions is not perceived as a reasonable course in a vast majority of addicted individuals. Recommending pharmaceutical interventions related to cravings for "all" SUDs is simply an over zealous interest in pharmaceutical techniques.

Most seasoned substance abuse practitioners see “thought stopping” and shifting out of the attitude that life, feelings, and behavior can be managed with medications/drugs is a core treatment focus. They believe that uncomfortable impulses and mental states can be managed with the brain as an evolvable tool. This attitude shift is a cornerstone of the brain/personality change. These practitioners believe in neurogenesis, autoplasticity, and the scientifically validated circumstance of learning/neuronal development. They are committed to an optimistic view about the idea that “one can learn to manage internal states without drugs or other temporary shortcuts with harmful long-term side effects (gambling highs, sex highs, mammon highs, food highs, nicotine highs, power and dominance highs, etc.). Seasoned addiction professionals believe that the philosophical shift from mind and mood management with “drugs” must occur in order to establish and maintain long-term sobriety and personality change.

Senior doctors in addictionology, psychologists and psychiatrists alike, believe that the effectiveness of psychological interventions has been well established in the scientific literature and in clinical experience. In this sense, and like medication plus psychotherapy for mental disorders, reinforcing the concept “you need a drug to control urgings and treatment adherence” actually evades and fails to deal with one of the core issues in drug abuse treatment… that of establishing an identity of adequacy at brain and related mood and impulse management without chemicals. Those holding this position point to the evidence that has indicated that combined pharmaceutical and psychological therapies actually decrease chances for long-term recovery.\textsuperscript{6,7}

Many specialists believe that drugs, like Vivatrol, will be found to have secondary deficiencies with regard to long-term outcomes. Many addictionologists believe that the use of drugs alone undermines this fundamental core philosophical attitudinal change by colluding with a wide spread unproven societal belief that “drugs are healthy and effective ways of managing internal states.” There is a growing and justified skepticism about the repeated and obsessive, yet, false efficacy claims fostered by the pharmaceutical industry and collaborating Governmental agencies regarding the effect of psychoactive medications.

Use of questionable research for pharmaceutical advertising creates rational and pervasive barriers to implementation of an extreme recommendation by SAMHSA of “Vivatrol for All”! Additionally, among patients who are prescribed such medication, adherence is low, which significantly reduces outcome efficacy.\textsuperscript{16} Low adherence by patients communicates at least heuristic information about possible noxious side effects and questionable efficacy profiles recognized by patients. These findings reduce the possibility of the medications use as a main intervention in a rational and professional treatment plan.

Many suspect that the “push to universal Vivatrol prescription for alcoholics” is actually a financially driven dynamic to reorganize the proven effective and research substantiated long-term treatment of SUDs into a short-term and palliative rather than curative framework. For example, self-serving letters recently distributed by managed care communities encourage doctors with mental health specialty to remember that the
A company has set a target of 8-session treatment for mental disorders without regard to the diagnosis. These letters warn of extensive reviews will be implemented past 8 sessions. Such warnings illustrate the rush to find brief psychological interventions transferred to psychopharmacological maintenance. There is no scientific evidence for this approach and assumption and those advocating such approaches in the treatment of addictions reveal their lack of scientific training or philosophical base.

This flawed treatment model conceptualization was applied to one of my recent patients who was suicidal, Alcoholic, Sedative-Hypnotic Dependent, Opiate Dependent, Bipolar Disorder: Mixed Type. Such treatment models belie a basic lack of education and/or comprehension of the nature and course of these serious mental disorders. Such naiveté contributes to the notion of “medications to manage your impulses and feelings” philosophy to addiction in America. America needs to wake up and discard the “halo effect” that predisposes the public to the illusion that every physician or psychologist is an expert or understands the scientific research and is trained in the treatment of the addictions! The core philosophical error is further exemplified by state agencies that have recently required contractors to apply a pharmaceutical technique represented by these medications to contract patients. The author is in possession of a letter and bulletin indicating the necessity to apply these pharmaceutical techniques to chronic addicts in contracted programs. These trends, along with the manualized treatment (12 sessions, complete the workbook, and out with pharmaceutical maintenance) appear to be focused on a financial decision to “spend in a relatively set package” rather than treat patients in individualized treatment plans.

Government accountants and clinical reviews by managed care committees run the risk of putting price before patients well being when treating individuals with a specific illnesses and clinical needs with medication only approaches. When they imply that pharmacological approaches are adequate to treat addiction they do not consider or understand brain autoplasticity and the difficulty of effecting enduring brain/personality change. Government manuals make it quite clear that naltrexone should not be considered as a stand-alone treatment for addiction and that specialists in addiction and mental health care should assess and treat these cases, but this standard is not well articulated in practice or clarifications to patients. While scientists proclaim research that defines addiction and mental illness as a “brain disorder,” the Governmental agencies and insurers treat these disorders as “financial interventions” and insist on palliative and short-term interventions. It is as illogical and tantamount to saying to a Spanish Major in College, you will have 6 weeks of coursework and practice and then be dropped out of colleague and will be expected to have experienced the brain change and neuronal growth to be fluent in the Spanish language. Still, many highly educated people cannot conceptualize this situation.

The control of life and behavior through drugs is a deeply seated and culturally supported core dynamic in America. However, seasoned specialty practitioners are simply too conservative, and skeptical about pharmaceutical and often debunked guideline claims to fall into line on such a major change in the proven effective approaches to alcoholism treatment. If you ask senior clinicians what they need to improve adherence during the early stage of treatment in substance abuse programs, they probably won’t say “a medication!” Most senior specialty doctors will say; “We need more senior diagnosticians and highly trained clinicians capable of accurate assessment, multidisciplinary treatment delivery, with advanced skills to improve
treatment adherence and outcomes. The American Psychological Association has developed a proficiency in addiction treatment that requires training beyond the doctorate level and successful passage of a national examination\textsuperscript{15}. Senior clinicians and psychologist experts in addiction and Medical Psychology will say, diagnoses and adequate treatment plans matter.\textsuperscript{20} They will advocate for adequate staffing of poorly staffed substance abuse treatment centers\textsuperscript{21}. They will advocate for adequate funding at the level per patient and episode that is equal with CHD, Diabetes, and Cancer that kill and disable similar numbers of individuals per year.\textsuperscript{22} Many general physicians understand these things and would advocate the same thing. They realize that they can contribute many things to a SUD treatment team, but that they cannot provide the global team and treatment plan leadership necessitated by these complex disorders when the patient is above the mild disorder level of the disease.

However, the trend in the field, and related substance abuse treatment centers is to staff them with minimally trained and qualified clinicians with poor supervision and no real standards requiring specialty doctors are actively diagnosing and involved in the treatment of these patients.\textsuperscript{23} The driving idea is find brief and cheap interventions using early career and minimally trained clinicians supervised by general physicians and with heavy reliance on manuals, pharmaceutical controls, and brief and minimal services will suffice. It is no wonder or surprise that “adherence” is a core problem in America’s substance abuse treatment centers.\textsuperscript{24,25}

In contrast to data from randomized controlled trials (RCTs), observational studies can reflect the experiences of a broad sample of patients with alcoholism who receive care in naturalistic settings. In particular, retrospective analysis of large data sets, such as those composed of insurance claims, does not impose artificially constrained treatment frequencies, fixed duration of treatment, visits with non-provider research assistants, or incentives for participation as in the manualized treatment studies. In addition, providers of services detailed in these data sets represent the full spectrum of disciplines and settings that exist in the real world. These features favor generalizability and fidelity to the real world of treatment centers. The main drawback of observational data is the potential for selection bias, which may be addressed with statistical controls.

In part, the reluctance of practitioners (physicians, nurse practitioners, and prescribing psychologists and medical psychologists) to recommend or prescribe alcoholism medications and of patients to take the medications stems from skepticism about their efficacy is mature and informed. Comparative effectiveness investigations, particularly comparing alcoholism medication treatment with standard care, are needed to address this information gap. These studies must evaluate more than short-term relapse and retention patterns. While this may be important, there are many psychological techniques that have been documented that have less physical risk. These studies, to be believable, must operationally define the target of these medications, e.g., cravings, replacement for long-term treatment, effects on the entire alcoholism syndrome rather than just sobriety and urges. Short-term, intermediate, and long-term effect of using the technique, as well as, long-term side effects must be considered. That makes comparing long-term treatment combinations, such as, medication only, medication with short-term therapy, medication with long-term therapy, combined vs. one treatment only groups, extremely complicated, expensive, and the results won’t be available for years. Even though some physicians and managed care companies are actively pressing for physicians to prescribe Vivatrol, the data show that the drug is useful in curtailing
cravings and decreasing relapse, but should be used with a combination of growth oriented therapy.

Efficacy studies using RCT designs have found that pharmacotherapy is superior to psychosocial treatment alone. However, these are short-term studies and they are not focused on the obvious general self-regulation, self-management, relational management, occupational management, and health management spheres characteristic of the disorder and the high mental disorder co-morbidity. Additionally, even the FDA approved packaging for Vivatrol indicates that the research has not substantiated the drug as a “stand-alone treatment” and cautions that the drug should be used in combination with traditional substance abuse treatment. However, it is common to see cases in which general physicians, not having psychotherapeutic techniques are prescribing Vivatrol without referring for psychotherapy of psychological treatments on a routine basis. They simply do what they know how to do rather than treat the disease in an adequate or comprehensive treatment plan. How is this going to be realistically articulated in Primary Care Centers without psychologists available or standards for multispecialty staffing or consultation! Thus, the FDA science committee recognizes the limitations of this approach, but certification and licensure standards for the centers where the techniques will be delivered do not require adequate staffing to deliver the Vivatrol technique as a component of realistic treatment approaches.

There are also inconsistencies in results across studies, with large multi-site RCTs failing to meet their specified end points for disulfram, oral naltrexone hydrochloride, and Acamprosate calcium. The high dropout rate and failure to add these and the base rate of spontaneous recovery to evaluate the drug outcomes loom as major methodological flaws. This is particularly true for alcoholism, where the “base rate” established for spontaneous recovery (growing out of the disorder with no intervention) can be over 30 percent. Without subtracting this base rate from any “effect rate” the efficacy of any intervention is over estimated. Further, the studies relative to this group of “adherence drugs” have usually used volunteer patients skewing the results due to sequestering the research to motivated and committed patients. Interestingly, even though the research is clear that where efficacy trials have shown positive findings, results have demonstrated only modest effects. Certainly, there is too little effect to advocate billions of dollars of scarce resource investment in a technique that is demanded of contracted agencies. Government information usually leads with “these drugs are effective” banners or early article conclusions and then hide the very small effect and high-risk scientific profile of these drugs later in the publication.

The National Alliance of Professional Psychology Providers, among other groups, has illuminated the limitations of medications in modifying brain/personality and mental and psychological disorders. In such a research context the existing skepticism earned by repeated pharmaceutical house, FDA, and other Government agency and guideline failures and errant conclusions makes the “Vivatrol for all” prescription a hard sell to seasoned addiction specialists and programs. Still, one can imagine the profitability of such approaches and the attraction to investors. Clearly, it would not be the approach with regard to scarce resource management recommended by most doctorate level addiction specialist clinical directors, but it makes perfect economic and political sense given the power and resources of the pharmaceutical industry. This nation has already had to live through the ill conceived and costly medications mantras of the drug industry with the “Valium is safe and effective,” “Amphetamines are safe and effective for obesity,” “Amphetamines are safe and effective for children with attentional and impulse
management disorders,” “Antidepressants are a safe and effective stand alone treatment for depression,” etc. approach to healthcare.\textsuperscript{8}

Top scientists agree that more information is also needed to compare the relative efficacy of existing alcoholism medications. We need to know about their ability to address the problem of poor adherence past the phase of cravings, and the cost-benefit and risk analysis related to some of the severe side effect profiles. For instance, Vivitrol or ReVia (naltrexone) is recommended for prevention of relapse following opioid detoxification but carries a Black Box Warning related to hepatotoxicity. This condition can cause liver damage and is contraindicated in hepatitis or hepatic failure and requires warning patients of potential for hepatic injury. Since many of the most severe patients have or have been exposed to hepatitis or have the disease, or other compromising liver disease, the routine use of this drug is somewhat suspect. Further, the drug is metabolized by the CYP45 enzyme system that is the same metabolism system as many psychoactive drugs that the patient requires. Thus, “onboard” drug concentrations and useful doses and toxic risks and side effects need to be considered. The exceedingly long half-life of 5-10 days may also be of concern to clinicians. The idea that an opioid receptor antagonist addresses the full syndrome of opiate addiction and the myriad of psychological, pain, and psychosocial factors and attitude and habit patterns of the disease would be an absurd stretch beyond belief. These potential hazards should be clearly pointed out to patients and professionals.

The Food and Drug Agency (FDA) has approved four medications for the treatment of alcohol dependence. Disulfram, an aversive agent, acts as a deterrent to drinking but fell out of favor believed to reduce the risk of relapse by stabilizing glutamatergic pathways in individuals during the post-withdrawal phase and holds concern for use with depressed patients like most chronic alcoholics. Naltrexone first approved as an oral treatment and naltrexone XR was subsequently approved also as an extended-release injectable suspension as the fourth approved medication in this class. In contrast to oral naltrexone, disulfram, and Acamprosate, which require daily dosing, naltrexone XR is administered as a monthly injection. Imagine the adherence problems encountered by giving access to weekly dose of drugs with recommended daily doses to the most impulsive, judgment compromised, manipulative patients with well known antics like doubling or trebling doses in an attempt to overcome the drug antagonism of these long-acting compounds. This is in addition to cautions against possible negative effects on patients taking prescribed CNS depressants. A favorite substance-abuse treatment avoidance of the addict is getting benzodiazepines on the street, and to ask prescribers for help with “anxiety” with benzodiazepines, sedatives for depression, opiates used by many addicts due to addiction-related trauma and pain, as well as, the use of aspirin and ibuprofen.

Naltrexone XR was designed to enhance patient adherence using infrequent dosing that is more easily controlled and monitored. Comparison of the effects of long-acting formulations vs. oral medications on treatment outcomes is of considerable interest. Although RCTs are an important source of information on comparative effectiveness, they pose obstacles to external validity that limit their applicability to clinical practice. Research complications include enrollment that favors highly motivated patients, compliance-inducing pill accounting procedures, unblinding of patient groups because of adverse events, and assessment reactivity in research subjects.\textsuperscript{30}
In contrast to data from RCTs, observational studies can reflect the experiences of a broad sample of patients with alcoholism who receive care in naturalistic settings. In particular, retrospective analysis of large data sets, such as those composed of insurance claims, does not impose artificially constrained treatment frequencies, fixed duration of treatment, visits with non-provider research assistants, or incentives for participation. In addition, providers of services detailed in these data sets represent the full spectrum of disciplines and settings that exist in the real world. These features favor generalizability. The main drawback of observational data is the potential for selection bias, which may be addressed with statistical controls.

Rational Guidelines:

1. Pharmacological techniques involving the four medications addressed in this article do not rise to the level of “a treatment” or “treatment plan” for individuals suffering from chemical dependency.\(^{31}\) [A distinction is made between a “technique” defined as an adjunctive intervention which has potential to enhance a comprehensive or adequate treatment plan, but which is not a stand-alone or sui generis treatment for a disease. “Treatment” is thought of as a set of scientifically validated techniques that, in the aggregate, address the majority and core elements of the disease and disease etiology and course.]

2. Since seriously chemically dependent individuals have been found to have a high incidence of co-morbid psychological disorders, none of these four medications should be prescribed before a careful and comprehensive psychological or psychiatric evaluation by a psychologist or psychiatrist is performed. Psychoactive medications selected and their compatibility or interactions with these four medications are defined and considered. The patient’s suicide and depressive potential and probability of medication abuse and adherence with the treatment plan compliance must be part of this evaluation.

3. Commensurate with the principle above, no chemically dependent individual should be treated with one of the four medications described in this article without ongoing substance abuse treatment supervised by a psychologist or psychiatrist with addiction treatment training and experience and full and appropriate substance abuse treatment and case management services in place. While techniques are very valuable team members, they are not necessarily the most desirable “director” to lead a substance abusing or dependent patients treatment team. The provision of accurate diagnoses and comprehensive treatment is required. Multi-disciplinary treatment teams for seriously chemically dependent, or co-occurring disorder (SUD and mental disorder) patients are essential. Psychologists with postdoctoral psychopharmacological expertise are now allowed to prescribe psychoactive medications in some states, all branches of the military in the U.S.A. and world bases, and in the Indian Health Services, and able to evaluate and recommend psychopharmacological techniques and prescriptions in other states. Clearly, in the emerging integrated care system focusing delivery upon primary care centers, these centers will need adequate staffing of either psychologists or psychiatrists or both in order to adequately address these patients clinical needs.
References
22. Institute of Medicine, National Academies of Science, Advising the Nation Improving Health. Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series. (Access 2006 http://www.nap.edu/catalog/11470.html. Pages 1-504)

Dr. Jerry Morris has a postgraduate master’s degree in business administration, another in psychopharmacology, and is a diplomate in Medical Psychology, Family Psychology, and Behavioral Health Care. He holds the APA Proficiency in the Treatment of Alcohol and Other Substance Abuse, and is an AAMFT Certified Marital and Family Therapist and Clinical Supervisor. He is board certified in School Psychology, and board certified in Case Management. He is the Director of Behavioral Health Care for Bates County Memorial Hospital and Primary Care Centers and the Clinical Director of CMHC, Inc., a comprehensive community mental health center, and the President of Morris & Morris, Inc., a health care consulting firm.
Medication Adherence:  
An Important Uncontrolled Variable in Clinical Trials  

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Over the last decade, there have been thousands of controlled clinical trials assessing the efficacy and safety of various drugs used to treat a range of illnesses. The purpose of this review is to document how adherence is controlled in pharmaceutical drug research. A review of drug studies published over the last 12 years was conducted by automated searches and manual searches. The automated searches included the use of search engines designed to scan documents for key words, while the manual searches consisted of obtaining hard copies of articles and reviews of the methods section in search of “medication adherence,” “medication compliance” and “measures.” The results revealed that the majority of clinical drug trials (range = 85% to 97%), either did not control or inadequately controlled for medication adherence.  

Background and Introduction  
Failure to adhere to treatment is a significant problem that has been well recognized in the healthcare field. Non-adherence to treatment recommendations was estimated at 40% among patients, with some studies showing that it may be as high as 75% and an average non-adherence rate estimated at about 50%.\(^1\)\(^2\)\(^3\) Turk concluded that approximately 67% of patients receiving new written prescriptions each year will show either partial or complete non-compliance.\(^4\) A more recent analysis by the World Health Organization revealed only 50% of patients diagnosed with chronic disease adhered to recommended treatment.\(^5\) A review of the literature confirmed an inverse relationship between the number of daily dose frequency and medication compliance.\(^4\) These findings suggest that more frequent dosing corresponds to less patient adherence.  

Assessment of adherence and treatment compliance is a critical component of the successful evaluation of therapeutic outcomes; however, the quantity of research on patient adherence in clinical drug trials is limited, and few investigations have evaluated strategies for enhancing patient participation.\(^6\) In clinical drug studies, in which adherence is unaccounted for, the interpretation of study results and the evaluation of drugs may be compromised.\(^7\) This review will address the importance and regularity of controlling for medication adherence in clinical drug trials. The terms adherence and compliance, although sometimes defined in different ways, are used interchangeably in the literature reviewed. Treatment adherence has been defined as the extent to which a person’s behavior coincides with medical or health advice. Adherence suggests an active patient role. Adherence also implies the act or state of staying consistent with a prescribed regimen and is likened to joining or attaching oneself to something. In  

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contrast, the term “compliance” implies a more passive role on the part of the patient, with the prescriber holding authority. Compliance denotes that a patient acquiesces, resigns or relinquishes authority over onto another, and is a willing participant in the treatment regimen.

Two specific domains regarding non-adherence have been identified. One domain focuses the locus of control with the patient. The other domain focuses the locus of control with the prescribed drug(s). From a patient perspective, non-adherence could be a result of factors such as a perceived loss of control, apathy, memory impairments, lack of financial support, denial of the illness, or the perceived or actual reduction of symptoms. From a pharmacotherapeutic perspective, non-adherence could result from the complexities of dosing, frequency of dosing, and actual or perceived negative side effects. Past studies provided evidence that the actual prescribed dosage frequency had an impact on drug compliance by patients.

Research into non-adherence to medication provided extensive details regarding the motivational factors associated with patient non-compliance. Patients have been known to adjust their medication intake rates based on the “wisdom of the body” or a “feel good”—based decision rule. That is, patients may stop taking their medication because of uncomfortable side effects.

Patients may also alter medication intake patterns, believing that their method of intake provides better clinical benefit. Furthermore, patients have often been known to stop their medication intake altogether because they do not believe they are experiencing symptomatic relief.

Factors beyond discomforting physical symptoms may also lead to non-compliance of medication regimen. Psychological reactance, a phenomenon that refers to patients’ reactions toward the restriction of their freedom to make decisions regarding their own medical care, has empirically demonstrated an important difference between a patient being a collaborative participant or a passive spectator in one’s own medical care. When the physician usurps patient participation in medical care, the patient’s commitment to treatment adherence may weaken. Patients who are not given the opportunity to participate in decisions related to their medical care are less likely to adhere to their medical regimen. A procedure known as Patient Controlled Anesthesia illustrates the phenomenon, when patients are allowed to have control over their medication (in this case, pain medication). Patients are more likely to use less medication when self-administering than when it is given and regulated by the physician or nurse. In general, it has been well established that when patients are not given a collaborative role or decision input regarding their medical care, patients are less likely to conform to a medical recommendation.

Measuring adherence
Many drug studies have not addressed the issues of medication adherence. In the few studies that have addressed this important area, the methods used to assess adherence often lacked rigor. Common methods among studies that attempted to measure adherence included clinical judgment, self-report measures (diaries, questionnaires, and interviews), pill-count data (direct observation, electronically), and pharmacy records. The drawback to these methods is that they are indirect measures of adherence and failed to record whether or not the patient ingested the medication or the correct dose(s). There are more current studies in which researchers utilized physiological
measurements such as urine toxicology screening and blood assays (Personal Communication, June 2011). Studies have shown that the most accurate and cost effective measure of medication adherence is electronic monitoring (EM). EM is capable of recording and stamping the time of opening the bottle, dispensing drugs or activating a canister. However, EM does not permit confirmation that the patient actually consumed the pill that was removed (Personal Communication, June 2011). Rather than providing monthly or weekly averages, these devices provide precise and detailed insight into a patient’s behavior when taking medications. Some studies using EM found that EM was more sensitive to detecting drug non-adherence than other methods. In addition to the accuracy of reporting medication adherence, EM has also proven helpful in providing detailed information about the patterns of medication-taking behaviors, including patterns of non-compliant behavior (e.g., missing evening doses). It appears that most deviations in medication consumption occur as omissions of doses rather than additional or modified doses, or delays in timing of doses.

*Clinical Trials*

The integrity of pharmaceutical research depends on researchers’ controlling for patient adherence to treatment regimens. The United States Food and Drug Administration’s (FDA) regulations for clinical trials require that the protocols for such studies state clearly: (1) how treatment compliance is to be monitored, and (2) the degree of compliance acceptable for continuation of the study; although the FDA requirements are only relevant for trials of medications that are going to be used to obtain an approved indication (pivotal trials). With clear guidelines set forth by the FDA regarding clinical pharmaceutical trials, it is expected that the majority of clinical drug trials should identify the issue of adherence when interpreting the results. The overall purpose of this study is to determine whether clinical trials are, in fact, measuring and reporting adherence to the medication treatment(s).

A review of literature published in the last 12 years will be undertaken to identify: (1) the extent to which drug trial research studies considered and/or attempted to control for patient adherence to their prescribed medication regimens, and (2) the extent to which studies that assessed adherence, relied on state of the art scientific methodology (i.e., EM, blood plasma) of patient monitoring.

*Methods*

*Procedures*

This study incorporated the use of electronic database searches to locate specific citations as identified by keywords found in the titles, abstracts, and full text files of published works.

*Databases selected:*

We selected three major databases for this study. The databases are listed as: (1) Science Direct, (2) PsychINFO, and (3) Medline which includes PubMed (see Table 1). These are some of the most commonly used databases and electronic search engines among college students. Students in the health and behavioral sciences utilize libraries and e-databases with which they are familiar. In a survey of college students ranging from undergraduates to doctoral researchers, Tenopir and Read discovered that 75% of undergraduates, 90.5% of Master’s level students, and 83.3% of doctoral candidates used databases upon which they were specifically trained. Although there are far more commonly used databases than could be mentioned, these three are very popular across multiple disciplines including medicine, chemistry, psychology, and
pharmacology. In one study, Medline searches yielded a sensitivity rate of 72% and a specificity rate of 75% on articles focused on economic analysis within a three month period. Medline yielded higher hit rates when compared to EMBASE, BIOSIS, LILACS and yielded 20% of non-replicated studies when reviewers searched the “prevalence of maternal mortality and morbidity from 1997 to 2002.” In health science related academic studies, authors suggest that pilot database searches begin with Medline and then extend into other databases.

Keyword Searches and Limiters:
The authors set the final search parameters for the automated search and they limited the electronic database search to peer-reviewed journal articles related to controlled clinical drug trials conducted between 1997 and 2009. We limited the electronic database searches with regard to four specific drug classes: (1) analgesics, (2) antihypertensives, (3) antidepressants, and (4) antivirals. These particular drugs represent four of the largest classes of drugs studied in clinical-trials. They are some of the most popular and most commonly prescribed categories of drugs (Personal Communication, August, 2010). We specified key words such as “non-adherence,” “adherence,” “compliance,” and “non-compliance” and “medications.” Keywords remained uniform and consistent across automated searches on all four drug class categories. Authors are not extrapolating the results to all drug trials.

We set limiters to identify the keywords, “medication,” non-adherence,” “compliance,” and “clinical drug trials” within the methods section of articles and for each drug category. Authors used the following types of key phrases:

- “adherence + clinical trials”
- “measuring adherence + clinical trials”
- “measuring adherence + clinical trials + analgesics”
- “measuring adherence + clinical trials + antihypertensive”
- “measuring adherence + clinical trials + antidepressants”
- “measuring adherence + clinical trials + antivirals”

Additional searches used the same key words and Boolean phrases with the addition of the keywords "Treatment Compliance" or "Compliance."

Manual Searches:
A second method for identifying articles was used in the study to increase the number of medication articles reviewed. The manual search consisted of obtaining hard copy or PDF versions of articles and reading the abstract, introduction, and methodology sections to determine whether the variable of adherence was controlled. One thousand thirty-eight journal articles were reviewed. Hard-copy articles were selected by manually identifying common journals found during the automated search. These journals were then obtained and reviewed for clinical drug trials.

Two trained and supervised graduate students reviewed articles manually and randomly. Specifically, student researchers used the coin toss method, which left each article with having a 50% probability of being selected. Only articles from peer-reviewed journals were selected. The graduate students read the abstracts and the methods sections to determine if adherence was addressed in the studies. A study was deemed to control for adherence if it clearly specified how it operationalized the term adherence and what method and procedures it used to control for adherence. This means there had to be
evidence of random assignment, one or more independent variable(s), and one or more defendant variable(s). In order for a study to be deemed assessing or not assessing adherence, the two graduate students had to be in complete agreement. In other words, both graduate assistants had to agree that a study addressed or failed to address adherence. Articles that were not found to have mentioned the control of adherence were excluded.

**Results**

When the key words “clinical trials” and “medications” were used, the Science Direct database yielded a total of 134,927 publications (journals and books). In a corollary search, results from the Science Direct databases produced 135,000 articles when the search word “adherence” was executed. When the search phrases, “adherence + clinical trials” were keyed in, Science Direct produced 35,546 journal articles that contained that combination of those Boolean key words. When “measuring adherence + clinical trials” were combined, a total of 9242 articles were identified. In another search attempt, when using the terms “clinical trials” + “medication adherence,” 16,217 publications, a far greater yield than when the phrase was set in reverse: “measuring adherence” + “clinical trials.” Depending on the combination of keywords or phrase, between 8.6%, and 12% of clinical trials addressed medication adherence, as evidenced in their methods sections.

A more narrow search was conducted by keying in the “measuring + medication adherence + clinical trials.” A total of 3,676 journal articles published with the same keywords, were identified somewhere in the body of those articles. Of these, 3,408 mentioned the key words “measuring medication adherence + clinical trials,” within the methods’ sections of the articles.

We targeted separate categories of medications, with a narrowed search limited to clinical trials on four classes of drugs. The medication classes examined included analgesics, anti-hypertensive drugs, antidepressants, and antivirals.

When we searched for clinical trials on analgesics, we retrieved 30,261 articles. When the search was narrowed further to include the key phrase “measuring adherence,” only 649 articles were found; translating to approximately 2% of articles. This would suggest that only 2% of the clinical trials involving analgesics controlled for adherence. By removing the key word “measuring” but leaving “adherence,” the search identified 2066 articles, approximately 7%.

When searching clinical trials on antihypertensives, Science Direct yielded 18,405 articles. When the search was narrowed to include the key phrase “adherence,” 2,349 articles were found. This translated to .1276 or approximately 13% of articles on clinical trials involving antihypertensive drugs, had mentioned adherence in their methods section. When the search included the words “measuring + adherence,” the number of articles were reduced to 734 or .0398 (approximately 4%).

When searching clinical trials on antidepressant, Science Direct showed 26,857 articles. When the search was narrowed to include the key phrase “adherence,” 2,903 articles were found. This figure translated to .1080 or approximately 10% of articles on clinical trials involving antidepressant drugs, having mentioned adherence in their methods section. When including the key phrase “measuring adherence” to the search, Science Direct found 931 articles or .0346 (approximately 3%).
Authors searched the key words “clinical trials” + “antivirals,” which resulted in 1,992 articles. When the term “adherence” was included in the search, Science Direct yielded 229 articles. When the limiter was narrowed to target the phrase, “measuring adherence + clinical trials + antivirals,” Science Direct yielded 58 articles. This translated to .0291 or approximately 3% of articles having mentioned, within their methods’ sections, a focused examination and measurement of adherence in clinical trials, as pertaining to antiviral medications.

To summate the previous findings, authors compared the four different drug classes (analgesics, antihypertensive, antidepressants, and antivirals), as pertaining to the frequency with which the measurement of adherence appeared within the methodology sections of journal articles. The antihypertensive category yielded the highest frequency of articles cited, at 13%; the analgesics came in second with 7%, and both antidepressants and antivirals yielded an equivalent, 3%.

Our original search in Science Direct targeted the key terms “clinical trials” and “medications” and resulted in the retrieval of 134,927 articles. In another, more narrowed search in Science Direct, which included the Boolean words and phrases, “clinical trials” + “measuring” + “medication adherence,” and which limited the searches to the method’s section of the articles, 3,408 articles were identified. The results of this database search shows that .0252 of the articles that contain the words “clinical trials” and “medications,” included measurements of medication adherence within their methods section. That is, approximately 3% of the clinical studies dealing with various medications purported to examine measurements of medication adherence as part of their research design. This statistic is comparable with the proportion of articles having examined medication adherence for specific drug classes; analgesics (7%), antihypertensive (13%), antidepressants, and (3%), antivirals (3%), respectively.

The results of the PsychINFO automated search revealed that of the 4,081 identified controlled drug studies, 88 studies addressed the issues of adherence or attempted to control for adherence (2.2%). There were 1,396 studies on anti-depressant medications, with 18 studies addressing the issues of adherence (1.3 %). Search results indicated that there were 89 studies on anti-hypertension medications, with 3 of those studies addressing adherence (3.4%). There were 27 studies on anti-viral drugs, nine of which addressed adherence (30.0 %). Finally, there were 150 studies on opiate analgesics, with 2 studies specifically having addressed adherence (1.3%).

The results of the Medline-PubMed automated search revealed that of the 72,994 controlled drug studies identified after the initial search, 2,084 addressed the variable of adherence or attempted to control for adherence (3.8%). To limit the material being studied, this number was reduced to 9,005 by using only articles that included anti-depressant medications, anti-hypertensive medications, antiviral medications, and opiate analgesic medications. The modified search identified 321 studies of the 9,005 studies reviewed that specifically addressed adherence to medication treatment (3.6%). There were 2,718 of those studies on anti-depressant medications, with 128 of those studies specifically addressing the issues of adherence (4.7 %). Search results indicated that there were 1,862 studies on anti-hypertension medications, with 65 of those studies addressing adherence (3.5%). In studies of opiate analgesics, 73 of the 3,829 studies addressed adherence (1.9%). Finally, there were 596 studies on anti-viral drugs and 55 of those studies addressed adherence (9.0 %).
The results of the automated search demonstrated that studies assessing antiviral medications attempted to control for adherence more than other drug studies (see table 2). Lastly, of the small percentage of studies addressing adherence, few studies in our search controlled for adherence by using the most robust measures of adherence, either EM or measures of blood plasma levels.

The combined results of the automated searches from both search engines indicate that specific medication-type studies involve addressing the issue of adherence at the following rates: Anti-depressant medication studies address adherence approximately 3.5% of the time, anti-hypertension medication studies address adherence approximately 3.5% of the time, anti-viral medication studies approximately 10.3% of the time, and opiate analgesics approximately 1.9% of the time. These results indicate that studies assessing antiviral medications, as accessed through Medline databases, attempted to control for adherence more than studies using one of the other medication-types reviewed.

The manual search for articles yielded percentage values that were relatively higher than ones obtained in the automated search. This search revealed that out of the 1,019 studies identified using search criteria, 157 studies controlled for adherence (15.41%).

The second issue to be determined by the study was the method of assessing adherence used in the studies that did address the variable. The manual search of studies found that of the studies that assessed adherence, 38.2% used pill counts (count of residual medication, pharmacy records etc.), 31.2% used self-report measures (diaries, questionnaires), 11.4% used biological measures (blood plasma levels, urine test, saliva test), and 1.2% used electronic monitoring. Additionally, 17.8% of studies identified that mentioned adherence did not specify whether or not they controlled for it and/or what method was used. Nonetheless, these studies were documented as having controlled for adherence.

Based on the combined results of automated and manual searches for articles, 11,686 articles were identified to fit the criteria for this study and of those, 510 articles addressed adherence (4.4%). The data also suggests that only a small percentage of the studies addressing adherence controlled the variable by using the most robust measures of adherence, the electronic monitoring method.

The results of both the automated and manual searches indicate that of the four classes of drug studies sampled, only a small percentage of studies controlled for medication adherence. There is a difference between the manual searches and the automated searches with the manual searches yielding higher percentages for studies controlling for adherence (15.2 %). Nevertheless, these numbers from the manual searches are still quite low and consistent with the findings from the automated searches that the majority of clinical drug trials sampled failed to control for medication adherence.

Studies that assessed adherence often used weak assessment measures such as patient self-report, prescription refill data, or basic pill counts. Despite previous research recommending the use of more reliable assessment measures such as electronic monitory or biological measures, none of the drug studies reviewed for this study used either of these methods.
Discussion

The purpose of this study was to survey clinical drug trial data and determine the levels at which research in this area addressed the variable, adherence to medication. Although, the automated and manual search of studies yielded results that were relatively different (3%-9% vs. 15.2%, respectively), the overall levels of addressing adherence in medical studies are still relatively low.

Our analysis revealed that in the past twelve years, the majority of published drug studies have failed to control for medication adherence. Despite the current FDA regulations (1997) on clinical drug trials, which mandate the investigator to monitor patient adherence to the treatment regimen, there is a low percentage of studies that even attempted to address the issue of adherence. It is important to note that not all drug studies are going to be submitted to the FDA. The importance of adherence is not just to meet the FDA standards but to interpret the results of studies accurately. Among the studies that addressed the issue, their inclusion of the assessment of adherence was problematic. Some studies merely mentioned adherence without attempting to control for the variable.

The failure to assess adherence in medical research constitutes a significant threat to the causal relationship that is crucial in the study of the efficacy of medication. The results of this review raises a number of fundamental concerns: 1) the extent to which participants adhere to their medication regimens in clinical drug trials, 2) the reliability and validity of the methods used to monitor adherence, and 3) the reliability and validity of the conclusions drawn from drug studies that failed to demonstrate adequate levels of patient adherence to medication(s) is suspect.

Limitations

There are several limitations to this study. The first of which is that there may be some measurement error in both the automated and manual searches. Furthermore, searches may have failed to identify studies that actually controlled for adherence using words not specified by the authors. Another consideration is that this study only examined the hit rates of three databases. Additionally, studies that controlled for adherence may not have been detected by the automated searches; a problem with trying to be exhaustive for such large sets of studies. This may be due to the fact that the search words or key words may not have been all inclusive. Finally, results of the manual searches indicated higher rates for controlling adherence when compared to the results from the automated searches. This may be due to a lack of sensitivity in the automated searches.

It is important to note that the automated search relied on the assumption that if a researcher included a measure of adherence in their study design, there would be specific mention of adherence and/or compliance in the title, abstract, body, or methods section of the published article. Once the identification of relevant articles was ascertained, we conducted a manual search in order to validate the results of the automated search. Since it is possible that a past researcher may have included a measure of adherence in such a way that the search engine may not have identified the “adherence” key term, the researchers also conducted manual searches in order to validate the results of the automated searches.

As mentioned in a previous section, another limitation on the study in the fact that we only searched three electronic databases, ScienceDirect, PsychINFO and Medline, which includes PubMed. In our defense, there are very popular databases among
college and post-doctoral researchers but it is prudent to note that our results may not generalize to all electronic databases or search engines.

A final limitation is evidenced by the fact that we only examined four major classes of prescribed drugs. Our results may not generalize to the adherence rates mentioned in scholarly articles focused on other drug categories. These limitations serve as focal points for future research.

Conclusion

With evidence suggesting that medication adherence in medical research is a variable not formally assessed, it is important to address the implications of these findings. Given that the precise level of drug intake during the research study period may be unknown, several major factors crucial to the research may be compromised. Conclusions about the effectiveness of the drug, as well as the long-term effects of the drug may have questionable reliability without proper assurance of adherence during the study. It is also difficult to determine whether the drug under investigation is safe for use or when it should be continued or discontinued.

The data from this study sheds new light on a variable, which has received inadequate attention in clinical drug trials. To make valid conclusions as to the efficacy of any drug requires that at least two factors be present; that the medication contains a component that should affect a disease or symptoms beyond what would be demonstrated by a placebo and the patient must consume the medication in an adequate dosage. In order to evaluate the efficacy of the active drug, all drug research protocols must include provisions for measuring adherence to the treatment regimens. Efforts to monitor medication adherence can enhance the conclusions concerning the clinical efficacy of the drug under investigation.

The results of the present analysis indicate that one essential criteria, that the patient consumes the drug as prescribed rarely occurs, and adherence is not properly accounted for and therefore the conclusions from these studies may be invalid.

References


Table 1
Databases Selected and Access Portals:

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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

John Caccavale
National Alliance of Professional Psychology Providers

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 of 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 fastest 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.

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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, they 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 known 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 is: Is it worth experiencing Extra Pyramidal Symptoms, such as pseudoparkinsonism, tardive dyskinesia 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**

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Total Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIPSYCHOTICS, OTHER</td>
<td>14.6 Billion</td>
</tr>
<tr>
<td>ANTIDEPRESSANTS</td>
<td>9.9 Billion</td>
</tr>
<tr>
<td>ANXIOLYICS</td>
<td>8.9 Billion</td>
</tr>
<tr>
<td>ANTI-CONVULSANTS</td>
<td>5.3 Billion</td>
</tr>
</tbody>
</table>

*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. 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, antidepressants, 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. The average brand name prescription price in 2008 was almost 4 times the average generic price $137.90. 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. 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 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. 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. 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 nonpsychiatric physicians and physician extenders with close monitoring of psychotropic medications they 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 “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 as 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 available data 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, and 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.

References
A Model Prescribing Act For Psychologists Seeking Prescriptive Authority

National alliance of Professional Psychology Providers

The Patient Safety Evidence Based Prescribing Act

The following is model legislation for prescriptive authority and is an evidence based model derived from the best available science related to the prescribing of psychotropic medications. Its aim is to demonstrate the differences between psychologists who utilize medications as a proficiency in providing medications related services and those prescribers in other disciplines. It is our belief that psychologists who seek prescriptive authority must demonstrate a significant difference in the ways we would provide these services because simply adding another class of prescribers to the existing list is unacceptable and not in the best interests of patients who require treatment for mental, emotional, and behavioral problems. This model is science based. The elements of the legislation are consistent with our training as psychologists and our training in the relevant medical and pharmacological issues. NIBHP believes that patient safety is foremost and medications are not and should not be first line treatments for mental, emotional and behavioral disorders. It is clear that there will always be a place for psychiatric drugs to control psychiatric disorders. However, we advocate that this intervention must only be used when other less intrusive and safe methods have been exhausted first, and only when the medications show overwhelming support to be effective for the specific patient.

We look towards the research on neurogenesis and autoplasticity of the brain, learning theory and science, psychotherapy in its broad array of techniques, psychological rehabilitation, nutrition, exercise, pharmacology and psychopharmacology for the development of prescribing standards. The management of relational quality and social support systems indicate to us that the brain, and personality can and does change through experience. Therefore, to treat mental disorders and the behavioral aspects of many physical disorders with a medication only approach is inappropriate, not supported by science or reasonably optimistic. Such an approach departs from the reality that change can and does occur and that long-term health and optimal treatment can be achieved solely through chemistry.

We understand that one of the barriers to optimal treatment is the design of the current Primary Care and Medical/Surgical Hospital System, which does not have requirements for staffing of adequate doctoral level mental health specialists and midlevel providers. Certainly, the type of complex skills required by at least one third of patients seen in these settings cannot be learned and mastered in simple workshops or a single class or set of seminars. Therefore, it is unrealistic to expect general medical staff to master or accumulate the years of knowledge, experience, supervision and training that is required to fulfill these roles. Neither will such general medical personnel have the time, interest, or inclination to re-specialize in a way that would allow them to deliver these services. Moreover, because of these deficits, medications are their primary and, most times, only treatment option.

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Since there is not an extant adequate workforce of behaviorally trained medical specialists and whereas medical psychologists are more adequately trained to encompass both the behavioral and psychopharmacological approaches, and because medical psychologists and psychiatrists will be required to supervise and direct mid-level behavioral specialists and nurses, medical psychologists who are appropriately trained should be allowed to prescribe psychoactive medications.

Failure to amend licensure laws allowing psychologists to practice to the fullest extent of their training and experience and to prescribe medications based on the prescribing standards derived from peer reviewed research and the best available science denies the public quality healthcare while increasing the costs associated with treatment.

Historically, psychologists have made meaningful contributions to hospital and healthcare facility staffs with admitting and attending privileges in many states and settings. Laws preventing medical psychologists who have acquired a proficiency in prescribing psychotropic medications are archaic and counter productive to the needs of the public, healthcare facilities, and healthcare teams in the American healthcare system. Without meaningful modifications to statutory barriers, rules, and facility staffing requirements, sufficient adaptation and rapid movement to efficient multi-disciplinary and Integrated Care Models will not be possible.

THE PEOPLE OF THE STATE OF ___________ DO ENACT AS FOLLOWS:

This Act shall be known, and may be cited as, The Patient Safety Evidence Based Prescribing Act.

SEC. 1. As used in this chapter, unless the context clearly requires otherwise and except as in this chapter expressly otherwise provided:

(a) "Licensed psychologist" means an individual to whom a license has been issued pursuant to the provisions of this chapter, which license is in force and has not been suspended or revoked.

(b) "Board" means a state Board of Psychology.

(c) A person represents himself or herself to be a psychologist when the person holds himself or herself out to the public by any title or description of services incorporating the words "psychology," "psychological," "psychologist," "psychology consultation," "psychology consultant," "psychometry," "psychometrics" or "psychometrist," "psychotherapy," "psychotherapist," "psychoanalysis," or "psychoanalyst," or when the person holds himself or herself out to be trained, experienced, or an expert in the field of psychology.

(d) "Prescriptive authority" means the authority to prescribe, discontinue, order, administer, and/or dispense without charge, drugs or controlled substances recognized for or customarily used in the inpatient or outpatient diagnosis, treatment, and the evaluation and management of individuals with psychiatric, mental, cognitive, nervous, emotional, addictive, developmental or behavioral disorders, excluding narcotics and order or utilize other procedures, consultations, devices and tests related thereto.

(e) "Health service provider" means a licensed psychologist who is duly trained and experienced in the delivery of preventive, assessment, diagnostic, and therapeutic intervention services relative to the psychological and physical health of consumers and who has done all of the following:

(1) Completed an internship and supervised experience in health care settings.
(2) Been licensed as a psychologist at the independent practice level.
(f) "Medical psychologist" means a health service provider who has received from the board, pursuant to this act, a valid certificate granting prescriptive authority, and the certificate has not been revoked or suspended. The title "medical psychologist" shall not be restricted only to those psychologists who have been certified by the board to prescribe psychotropic medications and may be used by other licensed psychologists who demonstrate training and experience in the specialty.

(g) "Drug" has the same meaning as provided in other sections of state law where the term "drug" is used.

(h) "Device" has the same meaning as provided in other sections of state law where the term "device" is used.

(i) "Prescription" has the same meaning provided and used in other sections of state law where the term "prescription" is used.

(j) "Narcotics" mean natural and synthetic opioid analgesics, and their derivatives used to relieve pain.

(k) "Evidence based" means studies that have been reviewed and reported by the Cochrane Collaborative and published in the Cochrane Review.

(l) "Primary care provider" means a licensed physician, nurse practitioner or any other healthcare provider licensed by a state to legally act as a primary care provider of physical health.

SEC. 2. The Practice of Psychology
The practice of psychology shall not include any of the following:
(a) Prescribing drugs or devices, except by medical psychologists who have received a certificate to prescribe medications.
(b) Performing surgery.
(c) Administering electroconvulsive therapy.

SEC. 3. Preparation For Prescriptive Authority And Certification
(a) Each state board shall establish and administer a certification process to grant psychologists prescriptive authority. Each medical psychologist-in-training shall be registered with the Board during the supervised clinical training and shall prescribe under the supervision and license of a qualified prescriber.

(b) The board shall develop procedures for the administration of an appropriate, valid and recognized examination and approved by the Board. The board shall charge applicants reasonable fees for the issuance of, and renewal of, a certificate to cover the costs of administering the certification process and the examination. These fees shall be deposited in a Psychology Fund.

(c) Each applicant for certification as a "medical psychologist shall show by official transcript or other official evidence satisfactory to the board that he or she has successfully completed the following through an organized Sequence of Basic Training in Human Systems and psychopharmacological courses.

Coursework shall be consistent with the following:
1. Coursework in basic anatomy and physiology
2. Coursework in Biochemistry
3. Coursework in Basic Pharmacology
4. Coursework in Clinical Medicine
5. Coursework in Diseases of the Cardiac System
6. Coursework in Diseases of the Hepatic and Renal Systems
7. Coursework in Diseases of the Respiratory System
8. Coursework Interpreting Laboratory Studies and Physical Assessment
9. Coursework in Psychotropic Pharmacotherapy
10. Coursework Interpreting Pharmacological Research and Prescribing ethics

At its discretion, the Board may certify a psychologist from a federal or other state jurisdiction that has authorized the psychologist to prescribe if the board determines that the psychologist has practiced with competence. Also, the board may, in its discretion, certify a psychologist to practice as a medical psychologist if the psychologist has lawfully prescribed in any branch of the military or under another professional license which authorizes prescribing and the training and experience under the other license is consistent with the training standards required for a medical psychologist. At the discretion of the board, approved programs may give credit for required didactic science courses taken in other educational institutions that would meet the educational requirements of the program.

2. A licensed psychologist who possesses an unrestricted board certification issued by the American Board of Medical Psychology shall be deemed to have met all of the requirements for a certificate authorizing prescriptive authority under this law.

3. A licensed psychologist who presents the board with either a post doctoral master of science degree in clinical psychopharmacology or a professional certificate in clinical psychopharmacology that was issued prior to the start date of this legislation shall be deemed to have met the educational requirements of this section.

4. Relevant supervised clinical experience to be determined by each state and consistent with obtaining skills and applied knowledge that relates to prescribing psychotropic medications. The following clinical competencies of the supervisory experience are recommended:

1. **PHYSICAL EXAM AND MENTAL STATUS**
   Possess knowledge of a comprehensive physical examination and mental status evaluation.

2. **REVIEW OF SYSTEMS**
   Possess knowledge and ability to systematically evaluate and document each of the major body systems

3. **MEDICAL HISTORY INTERVIEW AND DOCUMENTATION**
   Ability to systematically conduct a patient and family medical history and to communicate the findings in written and verbal form

4. **ASSESSMENT: INDICATIONS AND INTERPRETATION**
   Ability to order and interpret appropriate tests (e.g., psychometric, laboratory and radiological) to aid in the prescribing of a medication.

5. **DIFFERENTIAL DIAGNOSIS**
   Use of appropriate processes, including established diagnostic criteria (e.g., ICD-9, to determine primary and alternate diagnoses

6. **INTEGRATED TREATMENT PLANNING**
   Ability to utilize all available data to select the most appropriate treatment alternatives.
7. CONSULTATION AND COLLABORATION
Developing and understanding how a medical psychologist works with other professionals in an advisory or collaborative manner to effect treatment of a patient.

8. TREATMENT MANAGEMENT
Application, monitoring and modification, as needed, of treatments

9. REVIEW OF RELEVANT RESEARCH
The ability to evaluate and utilize unbiased pharmacological and psychopharmacological research studies resulting in safer and better care for patients.

SEC. 4. Renewal of Certification
(a) Each state board shall set forth the requirements for renewal of a certificate of a medical psychologist for each license renewal period.

(b) Each applicant for renewal of a certificate for prescriptive authority shall present evidence of having completed approved mandatory continuing education in the areas of medical psychology, psychopharmacology, and related prescribing practice as set forth by the board. Twenty (20) CE units per certification period are recommended.

SEC. 5. Complying With Federal and State Statutes
(a) Each medical psychologist shall hold an unrestricted license to practice psychology and shall comply with all state and federal rules and regulations relating to the prescribing, dispensing, and recordkeeping for drugs or devices. If the board determines that it facilitates administration of this act to identify a medical psychologist by another name that is consistent with other jurisdictions, it may do so.

(b) A written order of a "medical psychologist" shall include his or her identification number assigned by the board indicating certification to prescribe.

(c) A "medical psychologist" shall not delegate the prescribing of medication to any other person except for a supervised trainee in a recognized clinical training program that is preparing a medical psychologist to prescribe medications.

(d) Records of all prescriptions shall be maintained in client records.

SEC. 6. Board of Pharmacy Notification
(a) Each state board shall routinely transmit to the Board of Pharmacy a list of medical psychologists containing, at a minimum, all of the following information:

(1) The name of the psychologist.

(2) The unique identification number indicating certification to prescribe.

(3) The effective date of prescriptive authority.

(b) The board shall promptly forward to the Board of Pharmacy within 30 days of acquiring the names and identification numbers of psychologists added to or deleted from the annual list of psychologists certified to prescribe.

(c) The board shall notify the Board of Pharmacy within 30 days upon termination, suspension, or reinstatement of a psychologist's authority to prescribe.

SEC. 7. Suspension and Revocation of Prescriptive Authority
The board may refuse to issue any registration, certification or license, or may issue a registration or license with terms and conditions, or may suspend or revoke the
registration or license of any registrant or licensee if the applicant, registrant, or licensee has been guilty of unprofessional conduct. Unprofessional conduct shall include, but not be limited to:

(a) Conviction of a crime substantially related to the qualifications, functions or duties of a psychologist or psychological assistant.
(b) Use of any controlled substance of the state's Health and Safety Code, or dangerous drug, or any alcoholic beverage to an extent or in a manner dangerous to himself or herself, any other person, or the public, or to an extent that this use impairs his or her ability to perform the work of a psychologist with safety to the public.
(c) Fraudulently or neglectfully misrepresenting the type or status of license or registration actually held.
(d) Impersonating another person holding a psychology license or allowing another person to use his or her license or registration.
(e) Using fraud or deception in applying for a license or registration or in passing the examination provided for in this chapter.
(f) Paying, or offering to pay, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of patients.
(g) Willful, unauthorized communication of information received in professional confidence.
(h) Violating any rule of professional conduct promulgated by the board and set forth in regulations duly adopted under this chapter.
(i) Being grossly negligent in the practice of his or her profession.
(j) Violating any of the provisions of this chapter or regulations duly adopted thereunder.
(k) The aiding or abetting of any person to engage in the unlawful practice of psychology.
(l) The suspension, revocation or imposition of probationary conditions by another state or country of a license or certificate to practice psychology or as a psychological assistant issued by that state or country to a person also holding a license or registration issued under this chapter if the act for which the disciplinary action was taken constitutes a violation of this section.
(m) The commission of any dishonest, corrupt, or fraudulent act.
(n) Prescribing outside the parameters required in this statute.
(o) Any act of sexual abuse, or sexual relations with a patient, or sexual misconduct which is substantially related to the qualifications, functions or duties of a psychologist or psychological assistant.
(p) Functioning outside of his or her particular field or fields of competence as established by his or her education, training, and experience.
(q) Willful failure to submit, on behalf of an applicant for licensure, verification of supervised experience to the board.
(r) Repeated acts of negligence.
(s) Violating any law or statute relating to prescribing or dispensing drugs.

SEC. 8. Prescribing Method and Requirements
(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

1) Given individually for the person or persons for whom ordered that includes all of the following:
(A) The name or names and address of the patient or patients.
(B) The name and quantity of the drug or device prescribed and the directions for use.
(C) The date of issue.
(D) Either rubber-stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.
(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.
(F) If in writing, signed by the prescriber issuing the order.

(2) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(3) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

SEC. 9. PRESCRIBING STANDARDS
Medical psychologists who are authorized to prescribe medications shall adhere to the following prescribing standards:

1. Medical psychologists shall consider prescribing a medication only after a patient has been provided with information about the potential side effects and potential harm associated with the specific medication recommended for that patient. Such information shall also include information stating that the patient has the right to refuse any treatment recommended in the treatment plan.

2. A medical psychologist shall not prescribe a medication as a first line treatment for mild to moderate mood disorders, sleep disorders, anxiety disorders and attentional deficit disorders. Medications may be considered only after a suitable course of psychotherapy or behavioral intervention has been completed and where little or no progress has occurred. If a medication subsequently is prescribed, the patient shall also be provided with psychotherapy, counseling or other suitable behavioral intervention while remaining on the medication.

3. Should a medication become part of a patient's treatment regimen, the medical psychologist shall not:
   (a) Prescribe any medication that has not been evaluated and assessed to be effective as reported in at least one study by the Cochrane Review.
   (b) A medical psychologist shall not prescribe any medication that is considered "off label". Off label is defined as any medication that has not specifically been approved by the Federal Drug Administration for the specific condition being experienced by the patient.
   (c) A medical psychologist shall not prescribe any active medication as a placebo.
(d) A medical psychologist shall not prescribe more than two drugs for a patient's presenting disorder or symptoms.

(e) A medical psychologist shall not prescribe a medication for the lifetime of the patient. Medications regimens must be routinely evaluated and should be terminated if the patient's condition and symptoms are not significantly improved within 2 months of treatment.

(f) A medical psychologist shall not prescribe a medication above the upper limit of a dosage for which the medication has been approved.

(g) A medical psychologist shall not prescribe a medication that has not out performed a placebo or other medication in its class. When assessing the performance of a medication, a medical psychologist shall utilize the findings, if any, reported and published by the Cochrane Collaboration and if any other two articles in peer reviewed professional journals have demonstrated a placebo is performing as well or outperforming the medication.

(h) Prescribing medications is an acquired proficiency and is not a practice specialty. A medical psychologist's practice shall not comprise medication only services or comprise more than 50% of an out-patient practice. Except in an emergency, a medical psychologist shall not prescribe a medication for any patient that is not a regular patient of the medical psychologist. A medical psychologist employed in an inpatient, emergency department or on-call setting shall be exempted from this provision.

(i) A medical psychologist shall not accept any reward, perk or incentive from any pharmaceutical manufacturer, distributor, or drug industry representative or third party connected with the manufacture, promotion or sale of a medication.

(k) A medical psychologist shall not accept any sample medications from any pharmaceutical manufacturer, distributor, or drug industry representative or third party connected with the manufacture or sale of a medication.

SEC 10. Collaboration With Primary Care Providers
Medical psychologists who are authorized to prescribe psychotropic medications shall adhere to the following:

(a) Any patient considered for medication shall first be evaluated and cleared by the patient's primary care provider as to the patient's physical health and any contraindication for a psychotropic medication under consideration. Should the patient not have a designated primary care provider, the medical psychologist shall make every attempt to arrange a suitable referral.

(b) Routinely, medical psychologists shall provide the patient's designated primary care provider with a report of the patient's condition and medication regimen no less than once per year while under the psychologist's care.

SEC. 11. Amending Other Related Statutes

(a) All statutes in the state's Health & Safety that define who can prescribe medications must be amended to include "medical Psychologists."

(b) All statutes in the state's Health & Safety that define who may take orders for a prescription must be amended to include "medical Psychologists" and should read: "Healthcare providers(nurses, psychiatric technicians etc) shall carry out oral and written orders for medications, patient monitoring, behavioral interventions, and diagnostic sampling from a "medical psychologist" and shall
implement these orders when the orders are within the facility and psychology practice act defined role of the “medical psychologist.”
A Review of
Handbook of Clinical Psychopharmacology for Psychologists: Preparation for the Psychopharmacology Examination for Psychologists (PEP).
By Mark Muse & Bret Moore (Eds.)

Julie Myers

Receipt of the Handbook of Clinical Psychopharmacology for Psychologists for review was a special privilege. Mark Muse and Bret Moore (Eds.) have assembled a book rich with the essentials of medical psychology. This book brings together in a single volume a vast amount of information normally contained in a dozens or more volumes. It is well written, concise yet comprehensive, well organized, and densely packed with lists, tables, vocabulary, and references. For those of you awaiting the release this book, you will not be disappointed. It is essential reading for anyone interested in the practice of medical psychology and to update or review their skills of prescribing psychotropics. For those studying for the Psychopharmacology Examination for Psychologists (PEP) this book is pure gold.

This is not a book about psychotropic medications. Rather, it is a book written for those who want or need to know how to safely prescribe or consult about psychotrophic medications. For those looking for a comprehensive text about the tasks of prescribing as a medical psychologist, this book uniquely serves that role.

From the preface by DeLeon & Wiggins, “Training for RxP is extensive, as reflected in the content of this book. Psychologists who undergo such training are well versed in the psychobiosocial model, and are proficient enough to write their own training manual. …. RxP is not a mere replication of the medical curriculum; rather, it fulfills the medical curriculum and surpasses it with its own unique emphasis on the integration of biological components within psychosocial aspects of mental health.”

For the medical psychology novice, some of this book may be difficult to comprehend with a casual reading, while those well versed in prescribing practice should be comfortable with a more casual review of familiar material. As a reference, this book is accessible to anyone, especially its easily understood and comprehensive tables and figures. Individual chapters may be particularly useful for certain audiences, for example those who formulate public policy about prescriptive authority or those designing an integrated primary care model.

The subtitle of this book is Preparation for the Psychopharmacology Examination for Psychologists (PEP). The PEP examination covers ten content areas and tests the knowledge necessary for the practice of the prescribing medical psychologist. As anyone who has studied for the PEP knows, the sheer volume of material is substantial. Most challenging is this essential material is scattered in many books ranging from basic medicine, to psychiatry, neurology, pharmacology, lab testing, and psychology. I amassed nearly 20 books in preparation for the PEP examination, only to find, many of them contained only minimally relevant material. To date, there has been no definitive

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text or test preparation material. The Handbook of Clinical Psychopharmacology for Psychologists fills this void and is a welcome relief for test preparation. It will serve to organize the course of study, replace many books, and help assure that potentially critical information is not skipped.

Most of the material in this book is familiar for those having completed the postdoctoral training in psychopharmacology. However, when studying for the PEP, one could easily get bogged-down by the details in some of the denser chapters. Instead of trying to memorize everything, the questions at the end of each chapter are a useful way to identify where additional review is needed. Also, one can then use the accompanying CD-ROM to take a sample PEP examination, which simulates the examination with 150 questions. The test can be taken repeatedly to improve the score, which is broken down into a score for each content domain. This categorization of domains is helpful in identifying where one should concentrate additional review.

Chapters of the book include definitions, neuroscience, physiology, pathophysiology, assessment and monitoring, differential diagnosis, pharmacology and psychopharmacology, research, and ethical issues. The text is easily understood and is supported by 64 tables and figures. The tables are exceptional and make for handy references that summarize much of the important information of the text. Each chapter has extensive references, questions for review, and over 1000 vocabulary definitions. Subheadings would have been a useful addition to the Table of Contents to make the book easier to use as a reference text.

The preface is written by two long-time champions of prescriptive authority (and former APA presidents), Patrick DeLeon & Jack Wiggins. They present the compelling reasons behind the prescriptive authority movement in psychology (RxP), including the need for adaptation in a changing health care environment. The authors emphasis the unique role that psychologist trained in psychopharmacology can play in addressing the psychobiosocial model.

In Chapter 1, Moore and Muse clarify some of the terms used in the RxP movement, including the often confused term of medical psychologist. Within the profession of psychology, the term medical psychologist is an inclusive one, encompassing health psychology, neuropsychology, primary care psychology, and others. This is consistent with APA Division 55 (Psychopharmacology), APA Division 38 (Health Psychology), and the Academy of Medical Psychology. In Louisiana, the title “medical psychologist” is reserved only for medical psychologists with prescriptive authority under the aegis of the state medical board, which has lead to some confusion about the term. For the purposes of this book, “Medical Psychology is a post-doctoral specialty within applied psychology which integrates evidence-based psychological principles with medical science for the purpose of diagnosing and treating emotional, cognitive, behavioral, and psychosomatic disorders. Pharmacologically-trained medical psychologists prescribe, in concert with psychobiosocial interventions, psychotropic medications or advise patients and professionals on the use of such medication.” The authors use the term “prescribing medical psychologist” exclusively for those medical psychologists who prescribe medications, which will be referred to as PMP in this review.

In at times strong terms, the authors make a compelling argument for prescriptive authority. Although an exhaustive history of the RxP movement is not included, the core issues of the RxP are discussed. These issues fall into three broad categories: 1)
Prescribing medical psychologists are in a unique position to offer improved care due to their extensive training in the psychobiosocial model, 2) there is a shortage of psychiatrists practicing in underserved communities, leaving the task of writing prescriptions for psychotropics to other, poorly trained in the biopsychosocial model, and 3) psychologists need to adapt to changing a health care environment or risk becoming obsolete.

As neither the purely medical nor the purely psychological model is sufficient to understand and treat many mental health issues, PMP training must be extensive and rigorous. Although the motivation for improved patient care may be sufficient for many to endure the long hours of study, the authors do not shy away from two factors that may serve PMP further. First, RxP training may allow PMP to carve out a distinct niche for themselves because the business of psychotherapy is becoming increasingly crowded by shorter career-path professionals. And second, as with any professional, who invests both time and money in advanced training, financial rewards need not be unexpected nor be apologized for.

Muse and Moore discuss the integration of clinical psychopharmacology within the practice of medical psychology in Chapter 2. Medical psychologists must be able to integrate the psychological, biological and social factors when formulating treatment and must possess the ability to think and act holistically integrating psychopharmacological and psychological approaches.

Although current wisdom is that psychotherapy and medication are best used together, the authors argue that monotherapy may in fact be preferred for some disorders. The works of several authors—notably Morgan Sammons and Robert Julien—are reviewed for their conclusions concerning the preferred treatment for different disorders. The information is neatly summarized in a table entitled “Monotherapy vs. Combined Therapy in Psychobiosocial Treatment.” Although not meant as an algorithm for care, many professionals may view it as such. This table summarizes the conclusions into: a) when medication may be superior to psychotherapy as monotherapy (e.g. MDD with psychosis), b) equal to psychotherapy (e.g., Tourettes), c) less efficacious than psychotherapy (e.g., eating disorders), and d) contraindicated (e.g. phobias). For a few disorders—schizophrenia, bipolar mania, ADHD, panic, OCD with obsessions and MDD—combined therapy is superior. Although anxiety is the most common disorder seen in treatment, GAD it is notably absent in the table. Also not included is a substantive discussion about the cost of therapy. If viewed from a population perspective in which health care dollars are a finite resource, medication monotherapy might rank higher than psychotherapy in some cases if costs were included, particularly for those disorders that require extended sessions of psychotherapy vs. generic medication.

The authors discuss the difficulties in reaching conclusions as presented in the aforementioned table, as research results are often clouded by factors such as placebo effects, etc. Too, although the biological paradigm assumes specific underlying mechanisms, patient’s expectation for change may drive improvement, as meaning is derived from subjective emotional arousal according to the context. Thus, psychotropics may be merely nonspecific agents. The authors argue that distress may be necessary for therapeutic change, and as medications are meant to reduce symptoms, early administration in the course of psychotherapy may suppress change. Psychologists, physicians, administrators, and patients would likely have different views on the length
and limits of suffering to promote change. With more research, the table will likely evolve. Given the large number of clinical trials conducted each year and the massive amount of information that requires review. The PMP must be familiar with certain landmark studies such as the STAR*D, STEP-BD, TADS, CATIE, and others, which are reviewed by the authors.

Chapter 3 on neuroscience by Fogel & Kapalka has little that seems controversial. It is a succinct and straightforward review of the essentials of neuroscience including neurons, neurotransmitters, the nervous system, and brain structure and function. The authors’ use of enumerations, e.g., listing the four things needed to classify a substance as a neurotransmitter, helps to sort-out key concepts. Although the content is familiar to anyone who has completed RxP training, additional diagrams of the brain and/or study materials would help support the learning or relearning of this material.

Nervous system pathology is reviewed in Chapter 4 by Muse, Borkum, & Wyatt. It covers dementias, mental retardation, chronic pain, and traumatic brain injuries (TBI). Also covered are neurodevelopmental, vascular, seizure, sleep, movement, and neuropathologic disorders. One table nicely summarizes extrapyramidal side effects. There are nearly 250 vocabulary terms defined in this chapter, reminding one of the depth of knowledge required of the PMP. This chapter provides an excellent source for anyone needing to review the array of neurological disorders that can masquerade as or complicate mental health diagnoses.

Chapter 5 by Kotkin covers physiology and pathophysiology. PMP must be intimately familiar with and review often the different physical systems of the body and be aware of the things that can go awry. Reviewed are the cell, immunology and the endocrine, hematological, cardiovascular, lymphatic, musculoskeletal, integument systems and their pathologies. This chapter reminds one of why PMPs cannot operate in a vacuum; they must consult and refer out to specialized medical personnel with regularity (thus why the integrated primary care model makes sense to many trained in RxP.) Perhaps useful would be an expanded discussion of the liver, since hepatic function is so important in drug pharmakinetics.

Robert Younger writes about biopsychosocial and pharmacological assessment and monitoring in Chapter 6. The emphasis here is how to prescribe safely for a particular individual. Knowing what a drug does in general does not directly translate to knowing how the drug will act in any particular person. That is why PMPs must continually monitor both medical and psychological conditions, assessing the whole person. They should understand the basics of physical examinations, even if they are not required to show competency at performing them. The tables in this chapter are particularly useful for reference and for studying for the PEP exam. Tables include review of systems, cranial nerve examination, normal basic metabolic panel results, CYP450 common interactions, comprehensive metabolic panel, critical drug values, and therapeutic drug monitoring.

Differential Diagnosis in Medical Psychology (Chapter 7) is authored by McGuinness, Tilus, McGuinness, & Sa. It covers medical disorders that present as mental disorders, mental disorders that present as medical disorders, overlapping symptomatology, dual diagnosis, co-morbid conditions, iatrogenic effects, substances of abuse, population variations, and responses that clarify diagnosis. Prescribers must be keenly aware that diagnoses are not static and must be non-rigid in their thinking to avoid becoming locked
into a diagnosis. This chapter is essential for studying for the PEP that contains case presentations requiring flexible thinking for differential diagnoses.

Chapter 8 is on pharmacology (by Tackett). Subjects covered are pharmodynamics, pharmakinetics, pharmacogenetics, drug development, phase trials for drugs, and generic drugs. Useful tables include CYP450 and substrates, as well as, the Drug Enforcement Agency (DEA) schedule of drugs. One must understand the basics of pharmacology to understanding psychopharmacology. Drugs change, but the underlying science of pharmacology does not. This chapter makes psychologists who have a good knowledge of psychopharmacology more aware of this basic science.

The Practice of Clinical Psychopharmacology by Burns, Walker, & Rey (Chapter 9) covers evaluation, treatment initiation, treatment monitoring, and special populations. It covers the practical side of medication prescribing, step by step and can serve as a practice guide for PMPs. This is valuable reading for those interested in setting up integrated primary care programs. The chapter addresses basic psychotherapeutic drug classes, briefly. It has a comprehensive table that summarizes psychotherapeutics as a handy reference.

In Chapter 10, McGrath gives us an excellent review of the basics of research design and analysis. Concepts will be familiar to psychologists, but the review is designed to be particularly relevant to drug research. The drug review process is also summarized. It would have been interesting to see the large-scale drug studies discussed in Chapter One analyzed in this chapter.

Psychologists are keenly aware of their code of ethics regarding their professional status as psychologists. Chapter 11 (Cosgrove & Moore) summarizes the professional, legal, ethical, and inter-professional issues of clinical psychopharmacology. Practicing as a PMP requires a high standard of professional practice. This final chapter discusses the need for better patient education, documentation, compliance with state statues, and awareness of patient rights as a practicing PMP. It also discusses the balance that prescribers must find between their ethical codes and business interests of large pharmaceutical companies.

The last information in the book is about the procedures of writing a prescription and includes a reproduction of a prescription written by Mark Muse. This simple piece of paper represents the culminations of years of study and is a reminder of the awesome responsibility and privilege of being a prescribing medical psychologist.

The Handbook of Clinical Psychopharmacology for Psychologists is edited by Mark Muse (prescribing medical psychologist in Louisiana) and Bret Moore, (conditional prescribing psychologist in the New Mexico). Gloria Frigola illustrates it. The authors include some of the most well-known names of the RxP movement and specialists in their fields: Patrick DeLeon, Jack Wiggins, Mark Muse, Bret Moore, Ken Fogel, George Kapalka, Jonathan Borkum, Massi Wyatt, Lawrence Kotkin, Robert Younger, Kevin McGuinness, Michael Borkum, Erin McGuinness, Mary Sa, Randall Tackett, William Burns, Lenore Walker, Jose Rey, Robert McGrath, and Lisa Cosgrove.

Julie Myers, PsyD, MSCP is a Licensed Clinical Psychologist in San Diego. Dr. Myers is also Board Certified in Biofeedback and Certified as a Master Addiction Counselor. She specializes in teaching self-regulatory strategies for coping with addictive behaviors and substance use, depression, anxiety, bipolar disorder, panic, phobia, inattention, impulsivity, and sleep problems in adults and adolescents. As an experienced psychologist, she is dedicated to empowering individuals and families to regain control over their lives. Dr. Myers uses a cognitive-behavioral and positive psychology approach, adding biofeedback, neurofeedback, EMDR, exposure therapy, and medication consultation if indicated.
The Graduate Course You Never Had:
A Review of a Book by Dr. Larry Waldman

Elle C. Walker

Dr. Waldman’s book reminded me once more of what I did not get in graduate school? It takes a savvy person to capitalize on where to go to meet a need in business. Even a psychologist can be inspired to look beyond the boundaries of the office and grow into areas where one can really flourish and create additional income streams in business. This is precisely the view Dr. Waldman wants us to take and be creative and insightful.

Dr. Waldman’s motivation for writing this book stems from the fact that he has witnessed so many of his colleagues struggle with the business side of practice. This book can be a compass to guide you on a journey and help decode some of the mystery of business! With great respect for the busy professional’s time, it is organized and punctuated with witty quotes, important highlighted points, summaries and action steps to take in each chapter. Dr. Waldman makes sure we are able to quickly process and take away great ideas and a structural business framework in which to grow our practice.

Whether one is a “newbie” like me, or a seasoned professional, there is something for everyone here. A few of my favorite chapters in the book was Chapter 2: Private Practice as a Business and of course Chapter 7: Developing a Cash-Pay, Fee-For-Service Practice. Then, Chapter 8: Soliciting Physicians and other Professionals offers useful ideas for medical psychologists.

I definitely gleaned some valuable lessons from a practitioner who has been in the trenches for over 30 years on how to value your time and services. There is great value in sharing experience and information that can take one’s business to another level especially if it keeps us from feeling alienated in the business world. Dr. Waldman succinctly tackles almost every conceivable subject you may have pondered as a modern clinician. Everything involving the bare bones of private practice to the inevitability of practice in the digital age is covered in the 154 pages of Dr. Waldman’s book.

When it comes to thinking “out of the office” Dr. Waldman has taken some of the anxiety out of developing an action plan and providing a road map by which to proceed. For that I am grateful.

Dr. Waldman’s diverse practice of clinical and forensic psychology is located in Phoenix, Arizona. Clinically, he sees children, teens, parents, adults, and couples. His forensic work involves custody evaluations, parenting coordinating, court-ordered evaluations, and consultations with immigration, personal injury, and estate planning attorneys. Additionally, he consults to Social Security and teaches at Northern Arizona University.

Dr. Waldman has written other books of interest that include the titles, “Who’s Raising Whom? A Parent’s Guide to Effective Child Discipline,” “Coping With Your Adolescent,”

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“How Come I Love Him But Can’t Live With Him?” and “Making Your Marriage Work Better.” He just completed another invited workshop co-sponsored by the Academy of Medical Psychology based on his current book. “The Graduate Course You Never Had” ISBN 978-0-943247-97-7 is available through Amazon for $18.95, or by emailing Dr. Waldman at LarryWaldmanPhD@cox.net.

Dr. Elle C. Walker received her PsyD degree from the California Graduate Institute. She is a licensed psychologist in CA who practices clinical psychology and family counseling with adults and children. She has a special interest in autism. She is Board Certified by the American Board of Behavioral Healthcare Practice and serves on the Board of Directors of ABBHP.