

Psychopharmacology and the Biological Heuristic: What Happens Next?

President's Column
Morgan Sammons, Ph.D., ABPP



Colleagues, for this newsletter column, I'm reproducing much of my Division 55 Presidential Address given at convention in Toronto. By way of disclaimer, I note that substantial portions of this address will also be included in my chapter in a forthcoming text edited by John Norcross, Gary Vandenberg, and Don Friedheim (*A History of Psychotherapy*, vol. 2; APA Books).

Biological psychiatry is in ascendance. Edward Shorter, in his 1997 volume "A History of Psychiatry" introduced that text with the thesis that "if there is one central intellectual reality at the end of the twentieth century, it is that the biological approach to psychiatry—treating mental illness as a genetically influenced disorder of brain chemistry—has been a smashing success" (Shorter, 1997, vii).

"One central intellectual reality." What an extraordinary statement. More a reality, then, than the untwisting of the double helix, upon which many of the foundations of "genetically influenced disorder(s)" rest? More a reality than the understanding that

many characteristics of human behavior are far more fundamentally shaped by complex interactions with the social and interpersonal environment than any sequencing of amine pairs making up the aforementioned double helix? Apparently so, for the presumption of biological causality inflects every aspect of our consideration of mental functioning and mental distress. Consider yet once again Shorter, now attempting to strike a balance between biological and non-biological causes of mental disorders: "Having a partly biological and genetic basis, psychiatric illness is as old as the human condition. Although not all mental disturbances are buried in the integuments of our nervous system, some certainly are, arising from disorders of the chemistry of the brain itself. It follows then that human society has always known psychiatric illness, and has always had ways of coping with it" (Shorter, 1997, p 1).

Pretty straightforward stuff, right? Mental disorders are a product of both brain and mind, nature and nurture, person and society. Equilibrium is achieved, dualism reigns content. It's only when we look a bit more closely at Shorter's statement that we find...

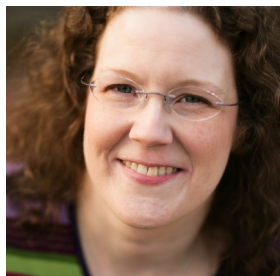
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From the Editor– What’s Therapeutic About “Forced” Drug Switching?

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Mary, a 35 year-old woman, has been experiencing moderate symptoms of depression

for the past month. Her job was cut from full-time to part-time 6 months ago, and her family has been struggling financially since then. Mary has a family history of depression but no history of mental health difficulties. She is not taking any medications, other than ibuprofen for minor aches and pains which have increased recently.

Mary’s primary care physician, Dr. Dogood, is most comfortable with prescribing the SSRI’s (Selective Serotonin Reuptake Inhibitors), sertraline (Zoloft) and fluoxetine (Prozac), having used these medications for years. But he likes to provide samples to patients, especially when they are struggling financially. He is becoming more comfortable with prescribing escitalopram (Lexapro) but gave the last samples to a patient yesterday. A pharmaceutical representative recently left samples of duloxetine (Cymbalta), an SNRI (Serotonin Norepinephrine Reuptake Inhibitor). Dr. Dogood decides that Cymbalta may be an appropriate choice for Mary, given that she has reported vague aches and pains, though she does not have fibromyalgia. So, he gives Mary samples of Cymbalta lasting 2 weeks, and a prescription to fill if she tolerates the medication.

Mary appreciates the samples, given her financial situation. She takes samples of Cymbalta, 30 mg per day for 2 weeks

which she tolerates well, so she takes the prescription to her local pharmacy. She is informed that Cymbalta is in the top tier of the formulary for her insurance plan, and the copay will be \$50. She does not want to start over with a different medication, so she pays for the prescription with money she had set aside for groceries. She feels a little better on 30 mg per day of Cymbalta, and much better about 4 weeks after Dr. Dogood titrates to 60 mg per day.

Mary’s mood has been stable for 6 months when she gets a letter indicating that Cymbalta will no longer be covered by her insurance plan. The letter encourages Mary to talk with her physician about lower cost alternatives, such as venlafaxine (Effexor), another SNRI, or a generic SSRI [i.e., fluoxetine, sertraline, paroxetine (Paxil), citalopram, (Celexa)]. Mary tells Dr. Dogood that though Cymbalta is working very well for her, she cannot afford to continue it if she has to pay out of pocket.

Mary experiences difficult withdrawal symptoms while tapering off of Cymbalta, and a relapse of depressive symptoms. She then “fails” venlafaxine, fluoxetine, and sertraline because of intolerable side effects. This process takes weeks, and Mary becomes discouraged and even more depressed. Her health plan will still not cover Cymbalta. So, Dr. Dogood then prescribes citalopram 20 mg per day, which Mary tolerates; After a gradual titration to 60 mg per day over a number of weeks, Mary feels better, though not as good as while on Cymbalta. Copays for multiple visits to see Dr. Dogood and for multiple prescriptions have increased her financial strain. Mary feels resentful, and says she feels like a “guinea pig” after being tried on so many medications.

Mary has experienced a form of “forced” drug switching, also known as “therapeutic drug switching.” Therapeutic drug switching occurs when a patient is required to switch from a medication on which they are stable to another medication, often a generic in the same class, or to pay out of pocket to continue the originally prescribed medication (Skinner, Gray & Attara, 2009).

The term, “therapeutic substitution” has been used interchangeably with “therapeutic drug switching.” But according to the American Psychiatric Association (APA), National Association of the Mentally Ill (NAMI), Mental Health America (MHA), and the National Council for Community Behavioral Healthcare (NCCBH), in their Joint Statement on Therapeutic Substitution (2008), therapeutic substitution occurs specifically when a patient tries to fill a prescription and the pharmacist must contact the prescriber for permission to substitute a “preferred” medication, or the patient must pay for the originally prescribed medication out of pocket. Therapeutic substitution may be prompted by a required step therapy protocol, where the patient has to “fail” medication(s) on the formulary in the same class prior to the plan...

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Sammons, *President's Column*, continued

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... something terribly wrong. What Shorter actually says in this brief paragraph perfectly reflects our current bias – only biology matters. Because some disorders are purely organic, says he, we must always have known about madness – that is to say, without this biological imbalance, madness would never have existed.

In fact, I believe that almost the exact opposite represents a better understanding of human's historical and current understanding of mental disease. Our conceptualizations of madness have always been both biological and social. I believe, despite the many merits of the biological heuristic, it will soon be eclipsed by a more potent and more comprehensive explanation that does not negate understanding based on biological models, but places this understanding in the proper context by which all such disorders must be understood.

So let's set history straight. Far from limiting their descriptions of madness to organically mediated forms, Western ancients, unencumbered by overwhelmingly dominant biological models, had classification systems for mental disorders that we, in our DSM driven era, would be hard pressed to say we've substantially improved on. Think of what the ancient poets sang,

and what has come down to us today, in history disguised as legend. Ancient Western societies recognized at least 4 different classes of madness – two of which were inherent and two acquired. There were those who intrinsically were mad, and probably represented a more biological quadrant of mental disorders, what today we call psychosis, mania, or severe compulsive behaviors. We find descriptions of such madness in those who were seers, oracles, and priestesses – what has been called an “ecstatic visionary shamanism”, although we must be careful not to romanticize ancient views of mental illness- rejection, squalor, exploitation, and homelessness were certainly not unknown. Another form of ancient madness is also well known - not those who were inherently mad, but those who *became* mad as a result of Bacchanalian excesses – the madness that derives from indulgence in alcohol and other intoxicants. The third major diagnostic category described by Western ancients, was, then and now, that which accounts for the most commonly occurring form of madness – those who were made, or *driven* mad – generally as a result of profound grief, loss, or perhaps transgression of societal or historical taboos. Depression, less severe anxiety and post-partum conditions might best represent this group (here it is interesting to speculate on another classical distinction

– between madness as a gift, as in prophecy, and madness as a punishment) Finally, then as now, we have a “catch-all” category of madness, multi-factorial but mostly biological in origin, represented by those with mental retardation or , structural brain defects due to birth trauma, head injury, or metabolic or systemic illness (age related dementias, syphilis and the like). These unfortunates were not classically mad, but, then and now being largely untreatable by other branches of medicine, fell into the realm of those who treated the mind.

It seems clear that the ancients recognized a biological component to mental illness, but were not, as we are today, beholden to such an explanation. The “biological fallacy,” if you will, is, I believe, largely a product of modern times and Western medicine, ultimately having roots in medieval notions that imbalances in body humors led to the production of all types of disease. There is, however, a second fallacy, also historically contained in the notion of humoral imbalances that has driven much of our thinking about madness from the end of the 19th century on – the fallacy of causality – and nowhere is the causality fallacy better illustrated than by the monoaminergic hypothesis of depression.

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Following work performed in the late 1950 and early 1960 by Julius Alexrod and colleagues on monoaminergic neurotransmission, the monoamine hypothesis of depression was introduced and since then has been the dominant heuristic in our understanding of the disorder. The evidence was clear – The production or availability of monoamine neurotransmitters in patients with depression was deficient. Depressed patients had fewer urinary excretions of the primary metabolites of serotonin norepinephrine than did not depressed patients. In a few famous but extraordinarily small studies, central serotonin levels were found to be abnormally low in patients who had committed suicide. It was therefore inescapable – low levels of serotonin (or other neurotransmitters) led to depression, improving the central availability of serotonin would therefore fix depression. Similarly, excess dopaminergic activity in certain neural pathways led to psychosis, or at least the positive symptoms of schizophrenia. Directionality was unquestioned. Although the vital question—were low levels of serotonin causal of depression or were they a consequence of the disease? was undoubtedly asked, over time, the assumption of causality became implicit – depression was caused by a dysregulation of central

monoaminergic neurotransmitters – not the obverse. Recent history suggests that when we fail to address the issue of causality we run into trouble. Consider the controversy surrounding the role of cortisol in the production of depression. In the late 1980s, observations of excess serum cortisol in depressed patients led to some rather intense speculation as to the role of corticosteroids in the production of depression. Indeed, for several years, the dexamethasone suppression test became a popular, in inaccurate and ultimately useless, tool to “diagnose” depression, the assessment of which, then and now, remains almost purely clinical. But the causality fallacy has a long history in biological psychiatry, predating the monoamine hypothesis by at least a century. One earlier example can be found in the presumed link between bloody ears (hematoma auris) and insanity. In 1870, Dr. Edward Hun, finding a high incidence of bloody ears in asylum inmates, speculated that this condition was predictive of insanity (Shorter, 1997), rather than making the obvious and correct inference – that asylum inmates were routinely physically abused by their keepers.

Failure to question these assumptions has led to both a theoretical and investigatory impasse in current conceptions of mental disorders. Biological heuris-

tics seem to be running out of steam, but since we’ve successfully convinced ourselves that only biology matters we have no ability to redirect our attention to alternatives. This fierce allegiance to one explanatory heuristic reflects the bipolar nature of modern psychiatric theory – we have transitioned from the highly theoretically elaborate but empirically baseless tenets of classical psychoanalytic thinking to the absolutist dogma of biology. This has left little room for a moderate, essentially pragmatic approach to mental disease.

Advances in the understanding of the neurobiological mechanisms associated with mental disorders have led to the development of a large number of pharmacological interventions. Since the beginning of the modern psychopharmacological era in the early 1950s, psychotropics have been among the most commonly prescribed drugs of any class. The increase in use of drugs to treat mental disorders has been particularly evident in the decades following the introduction of the first selective serotonin reuptake inhibitor in the late 1980s. It is no surprise to find, then, that pharmacotherapy is today the most common form of treatment for mental disorders and that the use of pharmacological treatments has come at the expense of



Sammons, *President's Column*, continued

psychological interventions. In 2007 antidepressants were the most commonly prescribed drug in the US and remain among the most commonly prescribed drug of any class around the globe. Antidepressant or antipsychotic drugs are almost always listed among the top 10 selling drugs both within the US and in the global market.

How did we get to this point? Again, a look at history, this time more recent, helps explain. Many current controversies in modern psychopharmacology, including questions of the utility of a drug for a particular disorder or attempts to expand or redefine a clinical condition in order to improve drug sales, are reflected in the early clinical history of modern psychopharmacology. Few clinicians are aware that one of the earliest attempts to market a psychotropic involved the amphetamine benzedrine, which was first marketed as a nasal decongestant. After observations of its stimulant properties, attempts were made to market it as an antidepressant. But it became clear rather early that stimulants were of limited efficacy in treating severe depressive conditions. The drug was accordingly marketed as a treatment for mild depression or anhedonia – a diagnosis that did not previously exist (Rasmussen, 2008).

It is tempting to ascribe the enduring

nature of such controversies to pharmaceutical manufacturers' attempts to maximize profits on patented agents, but the reality is more complex. Numerous factors influence our view of psychopharmacological treatment, among them the limitations posed by a diagnostic nosology that is acknowledged to be imprecise but yet often forces artificial distinctions between common mental disorders (e.g., consideration of anxiety and depression as separate disorders, rather than points on a continuum). Additionally, as we have said, treatment with psychotropics is almost always less than definitive. Symptoms improve, but rarely resolve with drug treatment, making the calculation of risks and benefits associated with pharmacological treatment an essential clinical as well as ethical consideration. Finally, the view by some professionals that the choice to use psychotropics is in some manner a moral decision (e.g., the belief that it is morally better to seek relief via psychotherapy than via the use of pharmacology) adds yet another factor to the complexities of modern psychopharmacological treatment.

The modern psychopharmacological era can be divided into five distinct periods of drug development and clinical practice. The first phase existed prior to the 1950s, when few effective pharma-

cological interventions were available. Nonspecific sedating compounds (opiates, bromides, barbiturates) were used to control mania or psychosis. A focus on institutional treatment and a variety of invasive interventions (insulin coma, electroconvulsive therapy, lobotomy) for these conditions or severe depression restricted treatment to the more seriously ill.

The second period started in the 1950s, a period of tremendous pharmacological innovation and one that heralded the introduction of the first effective drug treatment for several disorders. Lithium was re-introduced into clinical practice in 1949, followed in short order by chlorpromazine, reserpine, meprobamate, and imipramine and iproniazid. The modern psychopharmacological era was born.

A third period of "in-class" drug development lasting several decades then prevailed from the early 1960s to the late 1980s or early 1990s. This period was characterized by the expansion of pharmacological options, but almost always within the same class as the index agent introduced in the 1950s. It was also marked by the rapid growth of biological models of mental disorders and their treatment. With the exception of the introduction of the antidepressant...

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Use of Antidepressants in Palliative and End of Life Care

E. Alessandra Strada, Ph.D.



Palliative Medicine, recently recognized as a medical subspecialty, focuses on actively

treating physical, psychological, psychiatric, social, and spiritual distress experienced by patients with serious and advanced illness, and their caregivers. The main goal of these interventions is to allow patients to experience the best quality of life, for as long as possible. In order to create physical comfort for the patient, the palliative care team takes a very proactive approach to the treatment of pain. Additionally, other distressing physical symptoms that can limit quality of life are also actively treated. These symptoms include fatigue, weakness, nausea, constipation, anorexia, and shortness of breath.

For the patients, a diagnosis of serious illness often marks the beginning of physical and emotional losses that may end with death. As a result, psychological distress, including depressive symptoms are frequently experienced by patients with advanced illness. As the illness progresses and patients approach the end of life, the focus on quality of life shifts somewhat to an emphasis on minimizing physical and psychological distress during the dying process, for

patients and caregivers. Palliative care considers patients and caregivers as a unit of care. Therefore, the efforts of the palliative care treatment team include attention to caregivers' psycho-spiritual well-being.

Depression is not uncommon in palliative care and hospice patients. Rates are estimated between 22% to 75% (Chochinov & Breitbart, 2009; Miller & Massie, 2006; Block, 2000). Untreated depression creates significant suffering for patients and caregivers, and is associated with suicidal ideation and increased requests for hastened death in terminal patients (Wilson et al., 2007; O'Mahony et al., 2005; Brugha, 1993).

Diagnosing depression in patients with advanced illness is complicated by the fact that many of the somatic symptoms of depression, such as fatigue, sleep disturbances, loss of energy, and weight loss are common in patients with advanced illness. Additionally, the term depression is sometimes used to indicate psycho-spiritual distress where the patient feels low, sad, or demoralized due to the progression of the illness, as there is a transition from a curative to a palliative modality of care. This transition often means not only that cure cannot be achieved, but that the patient's prognosis may be poor and death is an increasingly certain and near outcome. As a result, patients and caregivers' may

experience profound disappointment, sadness, grief, and loss of existential meaning. The resulting psychological distress warrants the use of any adequate and available treatment options. Frequently, the best approach is an integrative effort which combines the judicious use of psychotropics, psychotherapeutic interventions, and spiritual care.

Antidepressant medications and psycho-stimulants may have an important role in palliative medicine because they can be used to treat a variety of symptoms, including pain and fatigue. In choosing pharmacological agents clinicians are guided by goals of treatment, side effect profile, medical co-morbidities, drug interactions, and patient's prognosis.

Selective Serotonin Reuptake Inhibitors (SSRIs)

Generally considered the first line of treatment for depressive disorders in patients with serious and advanced illness, SSRIs have shown to be effective and have a low side effect profile. However, the amount of time required for full therapeutic effect is usually on the order of weeks. This time delay can be problematic when patients have limited prognosis and the goal is to achieve a rapid onset of action. In patients with a life expectancy of several months, these medications have been



Strada, Use of Antidepressants in Palliative Care, continued

shown to be helpful and effective (Fisch et al., 2003; Holland et al., 2006).

While fluoxetine and paroxetine are potential inhibitors of cytochrome P450 enzymes, therefore increasing the likelihood of drug-drug interactions, sertraline, citalopram or escitalopram carry a lower risk of inhibition and thus lower potential drug interactions. Minimizing potential for drug to drug interaction is particularly important with palliative care patients, who usually have numerous co-morbidities and, therefore, take several medications.

Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)

Venlafaxine and duloxetine are generally found to be well tolerated and with side effect profiles similar to SSRIs. Venlafaxine acts as an SSRI at lower doses, usually only inhibiting reuptake of norepinephrine at doses above 150 to 225mg per day. The starting dose for venlafaxine is usually 37.5 mg per day, and 30 mg per day for duloxetine. Their stimulating effects, and the generally shorter period of time required to show therapeutic effect, make them a reasonable choice for patients who complain of fatigue in addition to low mood and have a limited prognosis (Chochinov & Breitbart, 2009). Both medications may contribute to hypertension and may result in nausea and dizziness, which can cause significant distress to palliative care patients, who

may already experience nausea as a result of illness.

Psychostimulants

Methylphenidate and dextroamphetamine act predominately through release of dopamine from the presynaptic terminal. Additionally they block reuptake of dopamine (Sood et al., 2006). Side effects include agitation, insomnia, tachycardia, hypertension and, as a result of the increased dopamine levels, psychotic symptoms (Lloyd-Williams et al., 1999). Methylphenidate is now available in a transdermal patch. Unless there are medical contraindications, psychostimulants are generally preferred over SSRIs when patients' prognosis is in the order of a few weeks, but they would still like to be able to engage with loved ones. Methylphenidate and dextroamphetamine have been shown in the palliative care population to be a rapid and effective treatment of depressive symptoms (Macleod, 1998). Response is anticipated within 48 hours of initiation of treatment. Fatigue is another highly distressing and prevalent symptom in patients with advanced illness who are approaching death. Fatigue should therefore be considered for treatment in palliative and end-of-life care. While the idea of "giving more energy" to a patient who is dying may sound like a paradox, it can be a reasonable goal of care when identified as desirable by the patient. Methylphenidate (Ritalin) has been

shown to be effective in the treatment of fatigue (Sarhill et al., 2001). Dosing of methylphenidate ranges from 5mg daily to 10mg BID, and as high as 30mg total daily dose. While it has been described as being generally well tolerated, some studies have described insomnia and cardiovascular toxicity as complications from treatment.

Modafinil (Provigil) is a novel agent generally used for the treatment of narcolepsy, obstructive sleep apnea and sleep problems related to shift work. It is thought to enhance the activity of the hypothalamic wakefulness center, promoting release of histamine, orexin and hypocretin. It has less potential for dependence and fewer side effects than traditional stimulants. Used at low doses (200-225mg) in chronically ill and cancer patients, modafinil has effectively improved fatigue without significant side effects. Clinical experience suggests that this effect can be achieved quite rapidly, and may not require weeks of treatment for improvement. In terminally ill patients the starting dose should be 100 mg per day and titration should be slow, carefully monitoring patients' response.

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Diagnosis of Bipolar Disorder: What is the Role of Self-Report?

Christopher Miller, MA



Bipolar disorder represents a very serious mental health problem. Its impact includes increased health care costs, lost work productivity, elevated psychiatric and medical comorbidity, hospitalization, and suicide (Andlin-Sobocki & Wittchen, 2005; Baldasserini & Tondo, 2003; Kupfer, 2005; Peele, Xu, & Kupfer, 2003). Based on these costs, bipolar disorder has been placed among the top ten disabling conditions worldwide (World Health Organization, 2004).

For some time now, researchers and clinicians alike have aimed to develop a brief, valid self-report scale to quickly and reliably detect bipolar disorder. A goal of this report is to describe existing scales for detecting bipolar disorder, as well as some practical and conceptual issues that make identification of bipolar through self-report difficult.

The Mood Disorder Questionnaire (MDQ; Hirschfeld et al., 2000) is perhaps the best-known bipolar screener. It features 13 yes/no questions covering bipolar symptoms, as well as two items to cover whether the symptoms co-occurred and caused at least moderately severe problems. A positive screen is achieved by endorsing at least 7 of the

13 symptoms, along with endorsing the items regarding co-occurrence and severity. The MDQ has demonstrated moderate sensitivity and specificity for detecting bipolar I disorder in an outpatient setting (Hirschfeld et al., 2000). Subsequent studies, however, have found limited sensitivity among outpatients, especially in detecting bipolar II disorder (Hirschfeld et al., 2005; Miller et al., 2004), and even lower sensitivity to bipolar disorders overall in the general population (Hirschfeld et al., 2003). The item regarding severity may be problematic in outpatient populations, as those with low insight or bipolar II disorder may be unlikely to recognize the consequences of the disorder. The cutoff of 7 out of thirteen symptoms may be problematic in college populations, as many of the symptoms appear normative for undergraduates (e.g. periods of high energy or bursts of activity). Indeed, some preliminary research suggests that as many as 75% of college students may endorse 7 or more of the MDQ's initial 13 items (Miller, 2008).

The General Behavior Inventory (GBI; Depue et al., 1989) was designed to identify lifetime bipolar affective disorders. In its complete 73-item form, it has been subjected to many validation studies with both clinical and non-clinical populations (Depue et al., 1989; Klein et al., 1989) and has performed

well at detecting milder portions of the bipolar spectrum. The GBI's utility as a screening instrument is limited, however, by both its length and the complexity of its items: many of the items appear to tap several symptoms simultaneously while also addressing related issues such as severity, frequency, and duration.

The Hypomanic Personality Scale (HPS; Eckblad & Chapman, 1986) is an inventory designed to identify those at risk for hypomanic or manic episodes, originally validated in undergraduates. It consists of 48 items presented in a true/false format. It has demonstrated some ability to detect hypomanic episodes in undergraduates (Eckblad & Chapman, 1986; Meyer & Hautzinger, 2003) and, more impressively, predicted the onset of hypomania and bipolar disorders in the same sample over a 13 year follow-up (Kwapil et al., 2000). Despite these successes, the HPS appears to identify a prohibitively high number of false positives at the cutoffs commonly used. This issue of false positives appears troublesome enough that even the original authors did not recommend it for routine screening. The HPS may be useful, however, in identifying those "at-risk" for bipolar disorder in research settings where further screening can be done (e.g. see Johnson, Ruggiero, &



Miller, *Diagnosis of Bipolar Disorder*, continued

Carver, 2005; Klein, Lewinsohn, & Seeley, 1996). Some authors have attempted to distill a shorter version of the HPS that may be suitable for screening in clinical settings (e.g. see Meads & Bentall, 2008).

Other screening tools have been subjected to less empirical study. The Hypomania Checklist (HCL; Angst et al., 2005) exists in both 20- and 32-item versions and was designed to detect hypomania among depressed outpatients. Like the HPS, its use appeared to result in too many false positive screens, in one study. The Bipolar Spectrum Diagnostic Scale (BSDS) uses a paragraph format and appears sensitive to bipolar II disorder, but has only been evaluated in two studies (Ghaemi et al., 2005; Phelps & Ghaemi, 2006). The Temperament Evaluation of Memphis, Pisa, Paris, and San Diego – Autoquestionnaire version (TEMPS-A) has been validated as a measure of hyperthymic temperament in several countries, and was the focus of an entire issue of the *Journal of Affective Disorders* (Akiskal & Akiskal, 2005). However, it has not been evaluated as a screening tool per se.

In addition to the screening tools reviewed briefly above, numerous other scales exist, or are currently under development, for detecting bipolar disorder. Despite the variety of scales,

self-reports for bipolar disorder have lagged behind those for other mental health conditions. Lack of insight into one's illness is an issue that likely contributes to this gap. It stands to reason that patients who do not recognize their symptoms or the consequences thereof will be unlikely to receive a positive screen on any self-report scale. Insight is likely to be lowest early in the course of disorder, when successful detection of bipolar disorder might be most helpful (Yen et al., 2004).

Difficulties with insight go beyond simply recognizing symptoms, however: the MDQ, for instance, requires that the patient endorses at least moderate problems related to their manic symptoms to receive a positive screen. Other scales do not include separate items on problems caused by symptoms, but items do incorporate certain features that require an awareness of negative consequences – hence, a positive screen is easier to achieve when insight is present. Thus, a patient's lack of insight into the functional impairment caused by his or her bipolar symptoms may result in a negative screen even if the patient acknowledges the presence of the symptoms themselves.

The issues of insight into one's symptoms and the impairment caused by them are further complicated in the context of bipolar II disorder. Hypo-

manic episodes by definition do not cause any impairment, and so patients suffering from bipolar II disorder are unlikely to be identified by existing measures that require some level of impairment to achieve a positive screen. If your clinical setting features a high prevalence of bipolar II disorder, then a self-report tool that requires patients to endorse severe problems due to hypomanic symptoms may not be appropriate.

The context in which screening typically occurs can also make detection of bipolar disorder via self-report difficult. People with bipolar disorder typically present for treatment while depressed (Mynatt, Cunningham, & Manning, 2002), and the memory biases associated with depression (e.g. Joormann, Teachman, & Gotlib, 2009) may make reporting on manic symptoms difficult. Insight tends to be lower when patients are manic as well, and therefore the use of self-report scales with patients who are acutely distressed is not recommended.

The issues described above – a lack of insight among patients with bipolar disorder and biases induced by acute symptoms – make detection of bipolar disorder through self-report difficult. Another issue to consider is that of...

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Everything You Always Wanted to Know about Oregon's Battle for Prescription Privileges But Were Told Not to Ask

Robin Henderson, Psy.D.



Sssh..... be very, very quiet..... That's been the mantra of Oregon's battle for prescription privi-

leges, and to be honest, while difficult to maintain radio silence, I think it's proved to be a pretty good strategy. That is, until we came out of the closet with a BANG and passed through Oregon's House of Representatives! We aren't done yet, but we can start to tell the story what really happened in the 2009 Legislature.

Oregon started the year with House Bill 2702, sponsored by many of Oregon's "healthcare guru" Legislators and ready to finally pass into law. We had strong bipartisan support in both the House and the Senate. We had a new lead lobbyist, Lara Smith of Smith Government Relations, and had also brought back our spot lobbyist, Gary Conkling of Conkling, Fiskum and McCormick to run the campaign. The "RxP Faithful" reconvened—me, Doug Marlow, Lynnea Lindsey, David Wade and Peter Grover, all members of the OPA dedicated to passing this legislation in our lifetime. Together, we spent months strategizing the messaging to Legislators and made the decision again to downplay this legislation in the public eye until we got our-

selves out of the House. This decision actually worked quite well for us, as it kept us out of the national debate on the issue, and kept the "fringe groups" out of the email boxes of our Legislators.

The battle in the House was pretty straightforward. We presented in the House Healthcare Committee, chaired by Representative Mitch Greenlick, and passed out, 7 – 3. The House floor debate was expertly crafted by our two psychologist Legislators—Representative Phil Barnhart and Representative Bill Kennemer. Their passionate stories, along with the support of many other Representatives, gave HB 2702 safe passage with a vote of 47 – 11 on its way to the Senate. We were finally out of the House—and thrust right into the national spotlight.

There are quite a few things that happen when you pass out of the House. You have momentum and lots of positive energy. And, you have a really BIG target on your back, because nothing energizes the opposition more than a rousing defeat. Overnight, we found ourselves right in the middle of the national debate, and opposition emails began filling the boxes of the Senate. Most of these emails came from one group—Psychologists Opposed to Prescribing Privileges for Psychologists (POPPP).

We had never heard of these people! Who were they, and why were they spreading lies and untruths about our Bill?

As always, the first calls go to Deborah Baker at APA. She is the best resource around for anything related to this issue, and she had the goods on this group. I'm sure most folks in Division 55 have heard of these people, but if you haven't, Google them. They're a trip. Over time, we watched as the same people would send variations of the same garbage day after day, creating a large influx of opposition email from a small number of people. Toward the end of Session, I found out that one of these people was actually deceased, so someone was using their name (and email alias) to send out opposition mail. It was pretty amazing.

For Legislators who were solidly in our corner, this email became a distraction, and eventually, a humorous aside during conversations. For Legislators opposed to the issue, they used the misinformation and massive number of emails to entrench their position, and some would share the misinformation with those on the fence. Our Senate campaign quickly became a battle of facts. How quickly could we produce answers to the incredible volume of misinformation that suddenly landed in



Henderson, Oregon RxP Update, Continued

our laps?

The Senate hearings took a different tone. Psychiatry knew they had not presented themselves well in the House, so they brought in different speakers for the Senate battle. Many Senators were focused on the national information they were now inundated with, and we needed to produce solid, reliable answers to their questions that would put the doubts to rest. We made the decision to invite three guest speakers from out of state to testify—Mario Marquez, Glenn Ally and Morgan Sammons. Each brought with them their experience as practitioners, and each could battle with firsthand experience the misinformation campaign we were faced with.

The Oregon Psychological Association is so very, very grateful to Mario, Glenn and Morgan for taking time out of their schedules to come to Oregon and testify. Each of them was uniquely eloquent, and they formidably addressed the concerns raised by the opposition and the Senators. They were solid in their presentations, and were able to paint a picture of competence, professionalism and safety for all the populations they served. Had we gone to a vote on that day, I firmly believe we would have passed our bill out of the Senate. Unfortunately, the vote was not scheduled for that date—

and what followed led us to the current state of affairs.

In the days between that hearing and the next, the Senate Healthcare and Veteran's Affairs committee was absolutely pummeled by physicians engaged by the Oregon Medical Association. After their quiet opposition in the House, this recharged effort derailed one of our chief co-sponsors of the Bill, Senator Alan Bates, the only physician member of the Oregon Legislature. When he began to waver, the whole Bill shook to its core. Questions we thought had been answered were raised anew. Misinformation took on a whole new meaning, and questions about which "iteration" of the Department of Defense training would suffice became the standard of conversation. Stories about soldiers who died in the care of psychologists magically appeared and disappeared, but not before doubt had reared its ugly head. The demon seeds of lies, innuendos, half-truths and physician superiority had finally sunk in.

The lobbying team and the RxP Faithful rallied, but in the end we ran out of time. On the last possible day, at the last possible moment, hours away from the end of the Senate's ability to pass a bill out of Committee, we reached a compromise with the Psychiatrists. We made the very, very tough decision to gut HB 2702 and, 18 amendments later,

turn it into an interim committee that is mandated to bring legislation back in 2010. Seven of these amendments came in the last eight hours of the fight. HB 2702-A with the -18 amendment mandated the following:

- A workgroup appointed jointly by the Oregon Medical Board, the Oregon Board of Psychologist Examiners, and the Oregon Board of Pharmacy comprised of:

1. Two psychologists who have had the post-doctoral Master's training or completed the DoD
2. One psychologist who has not, but has experience working in a healthcare setting
3. Two psychiatrists, one of whom is on the faculty at OHSU
4. One primary care physician
5. One pharmacologist

- The workgroup will be mediated by a professional mediator paid for by the psychiatrists and psychologists

- The workgroup is charged with producing an agreement for psychologists to prescribe in Oregon by January 31, 2010 for legislative action in the 2010 Special Session

There are other details in this amendment, but suffice it to say, it is much better than what psychiatry proposed, and was truly one of the last options...

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Strada, Depression in Palliative Care, continued

Tricyclic Antidepressants (TCAs)

While TCAs have been shown to be effective for the treatment of depression (Spiegel et al., 1983) they are now less frequently used for depression alone given their anticholinergic, antiadrenergic and antihistaminic side effects. Therefore, they are not the first line of treatment in terminally ill patients. TCAs are more likely to be chosen for combined treatment of depression and neuropathic pain. Their effect on pain is probably the combined result of antidepressant activity, potentiation of analgesic activity, and direct analgesic effects. Amitriptyline is the most widely studied in many different types of pain. Imipramine, desipramine, nortriptyline, clomipramine, and doxepin have also demonstrated effectiveness (Pilowsky et al., 1982).

Other antidepressants

Bupropion is thought to act through reuptake inhibition of dopamine and norepinephrine. It is a generally well tolerated antidepressant, noted to have some mild stimulating effects which can significantly benefit patients who are depressed and also experiencing fatigue (Moss et al., 2006). Bupropion lowers seizure threshold, therefore it should

be used with caution in patients with CNS tumors or seizure disorders. Mirtazapine has delayed antidepressant effects through its actions at 5-HT₂ and 5-HT₃, but also causes rapid weight gain and sedation through its high affinity for H₁ receptors; it is frequently used in the geriatric population, especially when patients report no appetite and weight loss (Kast, 2001).

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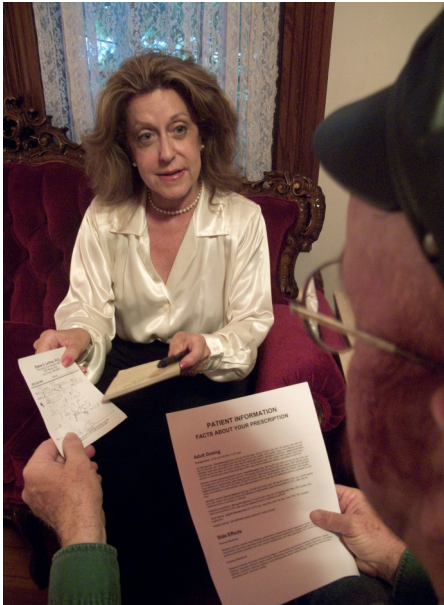
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A “New Day” for My Practice

Elaine S. LeVine, Ph.D., ABMP



Several months ago, on the Division 55 Listserve, I shared with you what I had learned as a participant of the 2009 Presidential Summit on the Future of Psychology, held May 14-17 in San Antonio, Texas. As you know, approximately 100 psychologists and 50 leaders from other professions came together to shape a vision for the future of our profession. Since then, many have referred to the theme presented by keynote speaker, Ian Morrison, that in every business there are two curves: The first involves the one you already do well and feel comfortable in; the second is the new way of approaching matters. To succeed, you have to manage both curves, doing what works now, but building for the second curve that will represent new changes in economics, technology, science, and diver-

sity in the nature of the work force.

The work of the Task Force that designed the Presidential Summit is continuing. Findings from the Summit were presented at the APA meeting in Toronto. Talks from the Summit can be obtained on the APA website. Further reports are forthcoming.

In his President's Column in the *Monitor on Psychology* from June 2009, our colleague and President of the APA, Dr. James Bray, provided an excellent overview of his thoughts in regards to the Summit. He stated that we need to make psychology primary. Recognizing that most Americans receive their mental health care at publicly-funded, non-private settings, we must diversify into Community Health Centers and other institutional practices. Further, we need to become clinical leaders to help lead health systems by designing, implementing and evaluating services, as well as managing staff.

What was very invigorating for me from the Summit was the reinforcement of the central role prescribing/medical psychologists could play in the future. As was expressed at the Summit, since economy spurs drive the society, we need to be aware of where the money is, and that certainly lies in psychopharmacology. Keynote speaker, Tillman Farley, MD, talked about his “primary

care model of mental health” set up in his Salud Family Health Centers in northern Colorado. While he indicated that, as a whole, he tends to hire clinicians trained at the Master's level to fill the mental health positions, in my personal talk with him, he mentioned how valuable and cost effective it would be to have prescribing psychologists in these settings.

With the Summit on the Future of Psychology well in mind, and a few years of prescribing ‘under my belt,’ I have undertaken a new ‘curve’ in my practice that I am very excited about and wanted to share with you. I have become the Chief Clinician /Medical Manager in a rural mental health clinic, *Pasos Adelante*, located 30 miles south of Las Cruces in the community of Berino, New Mexico. The income in Berino is among the lowest in the nation. Of the 860 core residents, and a population of 11,000 including nearby communities, only 50% of those older than 25 years have above an eighth grade education. The median household income is \$17,000 and 33% of the families earn less than \$10,000 per year. Overall, more than 55% of the community members live below the poverty line.

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**“THE WORK GOES ON, THE CAUSE ENDURES, THE HOPE STILL LIVES
AND THE DREAMS SHALL NEVER DIE [August, 1980].”**

Patrick H. DeLeon, Ph.D., JD, ABPP



**The Critical
Nature Of Per-
sonal Involvement**

I recently had the extraordinary experience of joining a number of Senate staff on the steps of the U.S. Capitol to pay a final tribute to the late-Senator Ted Kennedy as his family and loved ones made their way to Arlington National Cemetery, where he will forever rest in peace with his brothers. Standing there, I reflected upon how one becomes involved in the public policy process in order to have the opportunity to hopefully make a difference in the lives of our nation's citizens. For me personally, psychology's quest for prescriptive authority (RxP) has always been about ensuring that our patients/clients will have access to the highest possible quality of healthcare and that the all important psychosocial-cultural-economic gradient of care is appropriately recognized. RxP is fundamentally about one's personal values and an underlying belief in the right of all Americans to determine their own healthcare destiny. I have learned over the years, as Senator Kennedy clearly demonstrated, that to succeed in making fundamental change

takes time, vision, and persistence. It takes personal investment and personal commitment. It becomes one's way of life.

At our Toronto convention I was extremely pleased to learn that the Council of Representatives voted to adopt as APA policy Guidelines Regarding Psychologists' Involvement in Pharmacological Issues which, as Hawaii Council Representative Craig Robinson noted, "are intended to provide a resource on optimal psychological practice in pharmacotherapy... [and] Voted to establish an APA 'designation program' for education and training programs in psychopharmacology (as opposed to program accreditation)... [which] would be intended to provide quality assurance guidance for these programs." This is a critical step that former APA and Division President, Ron Fox, has recommended for several years. It will provide RxP students (and state legislators) with assurance that the program they select will be of the highest quality and, equally importantly, as we have collectively learned, that its graduates will be authorized to prescribe under the model APA statute. Ron's vision has been a long time in coming and his successful efforts and those of Division Presidents Morgan Sammons and Bob McGrath (who was honored in Toronto

by the Division for his Outstanding National Leadership) are extraordinarily important for all of us, and especially for our clients.

Those participating in the Division's convention activities heard from a number of prescribing psychologists within the federal sector. The three Department of Defense (DoD) services have now issued formal RxP credentialing policy documents and an increasing number of U.S. Public Health Service psychologists (especially those within the Indian Health Service (IHS)) reported positively upon their prescribing activities. I was particularly pleased to note a developing interest in prescribing from colleagues serving within state mental health systems where, once again, the need is great and the administrative authority to prescribe can generally be obtained at the local facility level. And, since over the years we have learned that the federal and state governments will almost always provide necessary resources (including ensuring appropriate reimbursement rates) for those professions for which they have accepted training responsibility, it is highly significant that Jeff Matranga reported that for the first time ever, Division 55 hosted a poster session during which 12 presentations on aspects of RxP



DeLeon, Work, Cause, Hope, Dreams, Continued

were made, many of which were by graduate students. The future for RxP is extremely bright.

Today our educational institutions are providing training experiences for enrollees across the nation, rather than being constrained by their physical locus, as has historically been the case. In January of this year, for example, under the proactive leadership of Steve Tulkin, Alliant International University graduated 61 psychologists from their Postdoctoral Master of Science Program in Clinical Psychopharmacology. Graduation ceremonies were held in three locations: Baton Rouge, with APA President James Bray serving as commencement speaker; San Francisco, with CSPP Dean Morgan Sammons as speaker; and Washington, DC, with Katherine Nordal, APA Executive Director for Professional Practice, as guest speaker and former Practice Executive Director Russ Newman officiating. Students from across the country participated in their graduation via telephone conference call lines. Alliant's new psychopharmacology class includes students from 20 states, eight of whom are IHS psychologists. There are psychologists from the U.S. Virgin Islands and from Qatar. I believe that our next significant advancement will be when our training institutions make a specifically targeted RxP didactic component readily available for gradu-

ate students during their clinical internships, perhaps on DVDs or palm pilots as professional nursing has already done. Without question, we are steadily developing that critical mass of trained colleagues.

A Transforming Experience

Few job experiences lead to a transformation. Serving as a Nurse Detailee in Senator Inouye's office was a transforming experience for me and because our Senate is so important to every American, I want to highlight a few of my Senate experiences. I began in January, 2008, which is the busy time for meetings with lobbyists and special interest groups. I realized how many needs exist, and how there just is not enough money, research, technology, or knowledge. Since I had been in the U.S. Air Force for 22 years, I was not fully aware of the vast health and education needs throughout America. Money and research were requested to fight cancer, diabetes, and cardiovascular disease. Health information technology was needed for electronic medical records and comparative effectiveness. Knowledge was needed for healthcare reform. Solutions do not come instantly. I found that bills sometimes take over a decade to become law. Staffers work hard to develop relationships, to garner support for their Senator's bills. Going for 'coffee' is not just a casual break from

the office, but an opportunity to build a relationship.

"Relationships are also important to Senators. Last year as the Senators were voting on the Medicare bill – and worrying that it was not going to get two-thirds 'ayes' – I walked Senator Kennedy, returning from his treatment for brain cancer. The clapping lasted at least three minutes, and there wasn't a dry eye in the place. After his 'yes' vote, several Senators changed their vote and the Medicare bill passed. Within the Medicare bill were provisions for psychology and nursing. Senator Inouye has always championed psychology and nursing concerns, but I did not realize how much he has done within the DoD. Since I am an Air Force nurse, this was especially significant for me. Senator Inouye made possible our Major General [two star] Chief Nurse position, Family Advocacy program, Tri-Service Nursing Research Program, and our graduate programs at the Uniformed Services University of the Health Sciences. He made the RxP program for military psychologists a reality. Each achievement became a reality through his dedication and commitment. Nothing happens by accident – another valuable lesson from the Senate.

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Progress Report on Prescriptive Authority in South Africa

B.J. Pillay, Ph.D. and Steven R. Tulkin, Ph.D., MS



Portions of this paper were presented at the symposium "Advocacy Update—Status of Prescription Privileges at the State, Federal, and International Level" at the meeting of the American Psychological Association,

Toronto, Canada. August, 2009.

The apartheid system in South Africa was a highly organised, extremely complex, repressive means of government that deprived the majority of South Africans their most basic human rights. The oppressive and dehumanising laws not only left a legacy of pervasive poverty, imbalance in wealth, poor education and lack of opportunities but also significant health disparities, particularly mental health, in the majority of people in the country. The actual cost of this oppressive system on its people is incalculable and is today often dismissed or relegated as an uncomfortable historical event. Many of the problems both in the leadership and society are related to this heinous past. The consequences of the past trauma experienced by individuals and communities (both victims and perpetrators) in South Africa are much deeper and more pervasive than is generally realised. Such sequelae will have to be confronted and managed for many decades to come. This constitutes a mammoth

task for health professionals, particularly in mental health, who have a responsibility to assist in the process of healing.

As part of the change process in South Africa (post 1994), the health system in the country underwent significant transformation in an attempt to merge the several health departments that were created for each population group and to address the significant disparities. All related statutory bodies/ institutions as well as related policies and laws had to undergo similar reform to reflect the change in the country. These changes offered psychologist new opportunities, in particular the possibility of prescriptive rights. During this period the Medicines Control Council (MCC), a statutory body that was established under the Medicines and Related Substances Control Act, 101 of 1965 to oversee the regulation of medicines in South Africa, considered Supplementary Health Practitioners being given prescriptive privileges, provided they have the appropriate training.

The Psychological Society of South Africa (PsySSA), the new nationally representative professional body for psychology, saw this as an opportune time to motivate for prescriptive rights for South African psychologist. There were several reasons for supporting this view including:

1. The academic and professional stand-

ing afforded to psychologists by the Medical, Dental and Supplementary Health Act of 1974 (Department of Health, 1999).



The Act states that 'the role of the psychologist would deal with the mental health well being of the individual'. As the work of psychologists (more especially, Clinical Psychologists) involves the diagnosis or assessment and treatment of various mental illness or physical illnesses that may have a psychological basis, it was logical that their repertoire of skills should include prescribing. This would obviate the current problem of too many practitioners being involved in treating a particular problem, and subjecting a patient to divulging personal information to several practitioners.

2. The gross shortage of psychiatrists in South Africa. Despite their strong resistance to clinical psychologists being involved in the area of prescribing, psychiatrists cannot hope to meet the mental health needs of this country for at least the next century.

3. Unnecessary cost duplication and over servicing as too many practitioners were seeing the same patient for



Pillay and Tulkin, *Prescriptive Authority in South Africa, Continued*

the same problem.

4. Role conflicts. Psychologists spend a great deal of time with patients and use a wide array of psychological diagnostic measures to evaluate a problem and decide on management. Situations frequently arise where psychologists refer patients to general practitioners with appropriate recommendations for medication, and their recommendations are not taken.

5. The significant amount of time that psychologists spend with patients in therapy, monitoring their patient's mental states. They are therefore in a strong position to monitor treatment and titrate doses of medication, without having to refer patients back to the referral practitioners, causing unnecessary inconvenience to patients, and increasing problems with adherence.

6. Emergency situations that frequently arise, where medical practitioners are not available, and decisions have to be taken, such as the administration of a simple sedative to an acutely distressed patient at night or at a trauma scene. Given the general shortage of medical practitioners in this country, this was another reason why psychologists should be allowed to prescribe.

7. Since psychologists are allowed to admit patients to hospitals, and trusted with such responsibility, a logical extension to this is to continue the medi-

cation management, if necessary, and not need to engage additional medical practitioners to be solely involved in the writing up prescriptions.

8. Psychologists have contributed to the understanding, diagnosis and treatment of mental illness, and are actively involved in the training of other health practitioners who treat mental health problems. Several fields in psychology, such as, neuropsychology, have contributed immensely to the understanding of brain-behaviour relationships. Psychologists do have competencies and knowledge that will enhance the ability to prescribe effectively.

There were also concerns against psychologist prescribing. Among these were:

1. The Psychologists' current training is insufficient to enable them to prescribe medicines, although it was acknowledged that moves were in place to rectify this in future training.

2. There are too many prescribing practitioners in the field of medicine and the world-wide excessive usage of medicines contributing to addictive behaviour and substance dependence problems as well as desensitisation to drugs.

3. Medicine does not have a cure for all ills, and the 'diseases of modern day living' involve relationships, the psyche, stress and society. Psychology, as a profession and psychologists recognise and

place much emphasis on the individual, the family and society. The fear then is that psychologists may slip into the role of prescribing medication and lose the valuable skills of psychodiagnostic testing and psychotherapy, which have taken years to develop.

PsySSA felt that in keeping with the general growth of psychology in both its academic and professional aspirations as well as meeting the needs of the community it serves, the issue of prescriptive privileges had strong relevance. Having investigated the matter for some time, PsySSA firmly decided that psychologists be granted the right to prescribe provided they had the appropriate training (Lindegger, 1999). The training of psychologists, it was felt, should follow the American Psychological Association's (APA) model given that the APA had made significant strides particularly in the development of post-doctoral training programmes in psychopharmacology and which was generously made available the PsySSA. In response, PsySSA drew up a detailed modular training programme based on the APA model.

The recommendation for prescriptive privileges was submitted to the Professional Board for Psychology (PBP), one of several Boards of the Health Professions Council of South (HPCSA).

(continued on pg. 18)

Pillay and Tulkin, *Prescriptive Authority in South Africa, Continued*

(continued from pg. 17)

(The HPCSA is a statutory body, established in terms of the Health Professions Act no. 56 of 1974 with a mandate to protect the public, all consumers of health care services, and to provide guidance on educational, professional and ethical issues to health practitioners). The then PBP considering the recommendation from PsySSA and consulting widely with psychologists in the country, supported the view. The PBP consequently submitted the recommendation in favour of prescriptive rights to the Council of the HPCSA for ratification.

This recommendation to the Council did not go down well with the many psychiatrists in the country. A delegation (August 1999) consisting of a member of the South African Medical Association and members of the Society of Psychiatrists of South Africa met with the Executive of the Medical and Dental Board and expressed their concern with regards to:

1. 'Non-medically qualified professions, in particular psychologists, lobbying to prescribe psychotropic medication for psychiatric disorders on the basis of what they term a crash courses
2. 'The consequences of prescribing powerful scheduled drugs, without medical education and training,

would put patients lives at risk since at 40% - 50% of patients requiring psychotropic medication have concurrent medical disorders which require treatment

3. 'Psychologists in South Africa seeking to set a precedent for many other countries, in particular the United States of America, where psychologists had consistently failed to obtain prescription rights
4. 'The Board taking a firm stance regarding this matter, i.e. that professionals who wanted to prescribe powerful psychotropic medication should enrol for an medical course and not a crash course in Pharmacology

The Executive of the Medical and Dental Board expressed their agreement with the Society of Psychiatrists of South Africa i.e. 'that the prescription of high (powerful) scheduled drugs by non-medically qualified persons such as psychologists, would endanger the lives of patients'; and suggested that the relevant Act regarding the prescription of scheduled drugs be obtained and be submitted to the Board. They further recommended to the Medical and Dental Professional Board, that the matter be also referred to the Council of HPCSA for consideration and decision. In respect to the matter of a 'crash course' to train non-medically qualified

health care professionals in Psychopharmacology enable such persons to prescribe scheduled drugs, they suggested that this be referred to the Forum of Statutory Health Councils for consideration and decision.

Having followed through the recommendations of the Executive, the Medical and Dental Professional Board confirmed the resolutions of the Executive Committee of the Board with regard to the matter of prescribing rights for clinical psychologists and asked the Health Professions Council of South Africa to facilitate a meeting between the Executive Committees of the Medical and Dental Professional Board and that of the Professional Board for Psychology with a view to arriving at 'a mutually acceptable agreement between the two Boards regarding the matter of prescribing rights for clinical psychologists'.

Incidentally at the meeting of the Medical and Dental Board, the Chairperson read a letter from the MCC regarding the status quo in respect of the prescribing and administering of medicines by Health Professionals other than medical, dental and pharmacy practitioners. It turned out that the Interim Medical and Dental Council had agreed to appropriate prescription and administering of medicines by members of

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Michael L. Sulkowski, M.Ed

2009 Division 55 Patrick H. DeLeon Prize



Michael L. Sulkowski, M.Ed. is a fourth-year doctoral student in the School Psychology Program at the University of Florida. He is the winner of the 2009 Patrick H. DeLeon Prize for his submission of the article, "Current Practices and Future Directions in Psychopharmacological Training and Collaboration in School Psychology." This article, of which he is the first author with Cary Jordan, M.Ed., & Matthew L. Nguyen, M.D., has been accepted to be published in the Journal of Canadian School Psychology. The following is a summary of the article.

Only 10% of practicing school psychologists believe that they should seek prescription privileges. However, almost all school psychologists (97%) report a significant need for increased training in psychopharmacology (Carlson, Demaray, & Hunter-Oehmke, 2006). This is of little surprise considering that school psychologists frequently are expected by parents, teachers, and students to have knowledge of psychopharmacology but few (20%) have taken a university-based course on psychopharmacology (Carlson et al., 2006). Furthermore, only a minority of school psychologists (42%) have had any formal instruction in psychopharmacology outside of a university-based course, such as in practicum or didactic training (Gureasko-Moore, DuPaul, & Power, 2005). Clearly, an estimable gap exists between the professional training ex-

periences received by most school psychologists in psychopharmacology and the roles they are expected to fulfill in this regard.

Recognizing this gap, I collaborated with an experienced psychiatrist and another school psychology doctoral student to compose a paper that reviews ways in which school psychologists can expand their roles in psychopharmacotherapy. Currently, there is limited research on this topic and few practice guidelines. Furthermore, no training programs have been established for school psychologists who do desire to specialize in psychopharmacology, and it is unlikely that non-PhD school psychologists will receive the requisite post-graduate training to become prescribing psychologists. However, school psychologists are uniquely positioned to aid in psychopharmacotherapy with their unparalleled access to children during the school day and presence in almost all public schools in the United States and Canada. Specifically, school psychologists can collect data on children's response to medication (or changes in medication) and provide other professionals (e.g., prescribing psychologists, physicians) with expert opinions on how a medication may be affecting a child's cognitive, social, or emotional functioning. School psychologists also can implement ad-

junctive interventions (e.g., behavior plans, self-monitoring strategies) and facilitate the transfer of information between various parties involved in the mental health treatment of students (DuPaul & Carlson, 2005). Furthermore, with training in how to conduct integrated social-emotional, behavioral, and cognitive assessments, implement evidence-based interventions, and consult with individuals from different professions and backgrounds (Carlson, Thaler, & Hirsch, 2005; Kubiszyn, 1994), school psychologists often are the most highly trained mental health professionals in small or isolated communities where few clinical psychologists or psychiatrists practice. Thus, in this role, school psychologists may indirectly advance the efforts of psychologists who advocate for increased prescriptive authority through the demonstration of professional competency, ethical behavior, and a keen awareness of psychopharmacology.

The most immediate way for school psychologists to expand their roles in psychopharmacology is through psychopharmacotherapy and consultative efforts. However, school psychologists have the potential to become major stakeholders in the medical treatment of millions of children with increases...

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LeVine, A “New Day” in My Practice, Continued

(continued from pg. 13)
<http://zipskinny.com/index.php?zip=88024&pagetype=main>)

The families of Pasos Adelante are served by counselors and behavioral management specialists who come to their homes. The counselors conduct individual, marriage, and family counseling. The behavioral managers help the families organize more practical matters; in addition, they assist in the children learning about the wider world by exposing them to a variety of activities and new ideas. The Clinic receives referrals for medication evaluation from a nearby psychiatric hospital, schools, directly from families, as well as from counselors at Pasos Adelante.

I require counselors to be present and to participate in all sessions with me. All the counselors are bilingual. Since most of the children have been in public schools in the United States for a number of years, they, too, are relatively bilingual. Many of the parents have limited English ability or are monolingual Spanish. My Spanish is improving rapidly, but I am very grateful to have the assistance of the counselors in assuring that communication is complete.

At the Practice Summit, APA CEO Norman B. Anderson discussed racial and ethnic health disparities. “Minority patients get lower-quality assessments

and treatments which provides an opportunity for psychologists to make a difference in the future.” My experiences at Pasos Adelante are certainly opening my eyes to just how limited the services are in a rural, impoverished area. Most striking to me is a culture of ‘management-by-prescriptions.’ At the local psychiatric hospital and in medical clinics, adults and children are often given medications before less intrusive means of interventions (such as working with the family, individual counseling, correcting school problems) are addressed. Most of the parents have great faith in medication, but little or no understanding of the possible side effects. One mother told me that her family care physician had said her child’s blood tests showed he had ADHD. A young girl that we had stabilized with our therapy and Prozac came in several months later complaining that the medicine was now making her tired and sick to her stomach. It took some sleuthing for the counselor and I to discover that, for the last week, her grandmother had been insisting she take all sorts of other medications with the Prozac that that the grandmother had in her medicine chest and thought might help her. As Mario Marquez often commented when we were presenting our prescriptive authority law in New Mexico, “The right to prescribe is the right to un prescribe.” I have found myself doing a great deal of

unprescribing and psychological intervention (even though I am the psychopharmacology expert) at Pasos Adelante.

A delightful part of this new position is my close work with the counselors and behavioral managers. I think that when I psychologist steps into a medication management position at a Clinic such as Pasos Adelante, it is natural to integrate skills as a clinical trainer as well as clinician with the prescribing. I now have group and individual staffings with the clinicians. Together, we develop an overall plan for each family, which always includes talking with the PCP, meeting with the school, counseling, and practical assistance, and never solely psychopharmacology. I am finding it wonderful to work with this population. The staff is among some of the most dedicated I have seen. The clientele are so appreciative of being treated in a collaborative fashion with respect for their autonomy and thoughts. Many have commented that this is the first time someone in the mental health field has explained matters to them and helped them get stronger, rather than seeing them for a few minutes and giving them medication. Each week that I travel down the valley towards Berino and meet my fascinating clients at Pasos Adelante is indeed a “new day” in my adventure of

Levine, *A New Day in My Practice*, continued

embarking on publicly-funded, interdisciplinary care.

Elaine LeVine, Ph.D., ABMP is the first psychologist in New Mexico licensed to prescribe psychotropic medications for her patients. In addition to her private practice, she is the

Training Director of the Southwestern Institute for the Advancement of Psychotherapy/New Mexico State University Masters degree program which trains psychologists from not only New Mexico but across the United States and the Netherlands in psychopharmacology. Dr. LeVine holds a part-time professor position in

the counseling psychology department of New Mexico State University. Her publications include four books and numerous articles on child therapy, law and mental health, cross cultural therapy and psychopharmacology.

Michael Tilus, Psy.D., MSCP Wins Awards!



Our own Michael Tilus, Psy.D., MSCP was honored recently with the Psychologist of the Year Award by the Psychology Professional Advisory Group of the United States Public Health Service (see picture on left with Rear Admiral Michael Milner, PA-C, CPO of the Health Services Category). This award is given to a USPHS Commissioned Officer Psychologist who demonstrates a positive, professional image, superior officership, notable leadership, and who has made a significant contribution to public health. Dr. Tilus also was recently awarded with the Indian Health Service National Behavioral Health Leadership Award (see picture on right).



**Congratulations to Division 55 Members
who reported passing the
Psychopharmacology Examination for Psychologists (PEP) in 2009**

Michael G. McBride, Ph.D., FICCPM, MP

Johna Hartnell Gerasch, Ph.D.

Kathy Parker, Psy.D.

Craig Vander Maas, Psy.D., M.S.

Sammons, *President's Column*, continued

(continued from pg. 5)

... trazodone (Desyrel) in 1982 the antidepressant market continued to be dominated by the TCAs until the introduction of the first SSRI. This period saw the emergence of biological models of mental disorders that competed for dominance, and eventually banished, earlier psychodynamically oriented explanations of mental disorders. The monoaminergic hypothesis of depression was introduced and elaborated during this period.

A fourth period began with the introduction of a "second generation" of many psychotropics, accompanied by extraordinary expansion of their use, consolidation of the biological model of mental disorders, and de-emphasis on psychotherapy. The index event for this period was, as noted above, the introduction of the first serotonin reuptake inhibitor, fluoxetine. Fluoxetine achieved the greatest notoriety of these second generation agents, but similar transformations were occurring with other drug classes. In the mid-1990s, a new class of antipsychotic drugs emerged, these drugs, although of no greater efficacy than their earlier counterparts, were and remain so popular that they continue to dominate the antipsychotic marketplace.

The fifth and current period in modern psychopharmacotherapy is character-

ized by stasis. Few novel psychotropics lie on the horizon. No new class of any agent has been clinically developed. All recently marketed psychotropics are either variants of extant drugs or, in a few instances, drugs relabeled for a mental disorder (the MAOI selegiline, for example, first developed to treat symptoms of Parkinson's disease, is now also sold as the antidepressant EmSam). Although there is some ongoing investigatory work into the role of neuropeptides or other non-amine neurotransmitters in the etiology of depression and other disorders, this has not translated as yet into any clinical breakthrough. The current period also reflects a growing skepticism about the explanatory power of biological models, accumulating evidence of the limits of pharmacological intervention, and a renewed interest in combining pharmacological and nonpharmacological interventions.

We see then that the historical development of pharmacotherapy for mental disorders has strikingly common characteristics, regardless of which mental disorder or medication class is under consideration. First, an index drug or class of agents is introduced that has some efficacy but significant toxicity or problematic side effects. Its use is therefore limited to a relatively restricted range of patients, generally with more severe variants of a disorder, with treatment provided almost exclusively

by psychiatry. Second, a new class of psychotropics is introduced, chemically related to earlier drugs but having properties that make them generally less toxic than their predecessors. Often, these drugs have more specific biological mechanisms of action. They tend to be no more efficacious than their progenitors, but enhanced safety or flexibility in administration leads to an explosion of use in non-specialty mental health settings, often for conditions not originally thought to be responsive to pharmacological treatment or for which there is less than compelling evidence of their utility. Third, increasing questions emerge about the evidence supporting the use of such agents, and the opportunity costs associated with displacement of non-pharmacological treatments in preference for newer and more costly medications.

It is clear that we are in the midst of a period of intense reevaluation of the utility of many commonly used psychotropics. The controversy surrounding the use of antidepressants in children is a handy example of how our thinking regarding antidepressant use has changed. From an earlier stance of widespread enthusiasm leading to their common (albeit unstudied and off label) use for many childhood disorders, I believe we began to critically re-examine this practice. By the early



Sammons, *President's Column*, continued

2000's evidence emerged that antidepressant use in children, at least in large-scale epidemiological models, increased the risk of suicidal behaviors in this population. This led to the introduction, in 2004, of an FDA black-box warning regarding use of antidepressants in children. For this and a variety of other reasons, antidepressant prescribing in children fell substantially. We have not seen a corresponding reduction in adult prescribing, (although the rate of rise of antidepressant prescribing has tapered considerably), but the literature is now replete with reports on the limits to efficacy of antidepressant treatment, and the need to incorporate other forms of treatment to ensure sustained remission.

We seem, however, not to have tackled the fundamental question – at least not head-on – of causality. Instead, having acknowledged the limited explanatory power of the monoamine hypothesis, we expend vast amounts of intellectual and fiscal capital in seeking out alternative causes – deficiencies in brain-derived neurotrophic hormone, adverse effects on subcortical structures caused by excess cortisol expression, or dysregulation in other neurotransmitters, to name but a few. Regardless of the level of critical scrutiny aimed at the biological model, it should be obvious to all but the most casual observer that the biological model con-

tinues to drive our most fundamental assumptions about the genesis and treatment of mental disorders.

What would happen if we loosened our embrace on the biological heuristic?

Some (e.g., Belmaker, 2009) have speculated that we might see a decline in expensive look-alike drug compounds (do we *really* need another SNRI?) and that our research endeavors might refocus on some important and still unsolved issues, like the true mechanism of action of many psychotropics. Personally, I doubt that we would return to a Luddite era where only overly simplistic dynamically oriented theories prevailed. Refrigerator moms have gone the way of chlorofluorocarbons. Our understanding has definitely increased to the point that we appreciate the manifold biological, psychological, and psychosocial complexities that cause, perpetuate, and make better, mental disorders. I also believe that re-evaluating the biological heuristic would give us the ability to critically reflect on the opportunity costs of excess reliance on pharmacological interventions, and the other forms of treatment that we might be able to offer our patients if we had the financial and research expertise that is currently overly devoted to drug investigations. Finally, we might take pause to reflect how much one investigatory paradigm – the short term randomized controlled trial - has come to dominate

our understanding of the effects of any treatment, pharmacological or not.

This might allow us as professionals to see what our lay colleagues already appreciate – that the “treatment” phase for any mental disorder, vis-à-vis a patient's lifespan, is almost always a very short period, really no more than the proverbial *eugenblick* for the vast majority of our patients. By focusing only on active treatment, rather than what happens both before and after, severely limits our understanding of our patients and robs us of the ability to incorporate the wisdom of the community into our management of these complex and disabling conditions.

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Miller, *Diagnosis of Bipolar Disorder, continued*

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... reference standards used in studies validating self-report scales. Some studies have used modifications of diagnostic interviews that have limited validation evidence (e.g. Benazzi & Akiskal, 2003), or used diagnostic tools that can have low levels of inter-rater reliability for diagnosing bipolar disorder in the general population (Williams et al., 1992). Hence, it is important to attend carefully to the psychometric qualities of the reference standard used in validation studies.

Another issue complicating the literature on self-report screening tools is the sheer variety of statistical measures available. Sensitivity, specificity, positive predictive value, negative predictive value, and area under the curve have all been reported in previous studies. This variety once again makes comparisons across studies difficult. In some cases, authors report “ideal” cutoffs for a screening tool without actually discussing what that “ideal” represents. For instance, for a screener to be effective, it should demonstrate at least 90% sensitivity to bipolar disorder (Zimmerman & Mattia, 2001). Despite this standard, published cutoffs often result in much lower sensitivity: The cutoff corresponding to the most aesthetically pleasing, or even the most statistically balanced, combination of sensitivity and

specificity is not necessarily the cutoff that results in adequate sensitivity for screening. When considering a screening tool for your clinical setting, consider whether the published cutoffs result in adequate sensitivity; if not, a lower threshold may be required. Some authors have begun the process of identifying more appropriate cutoffs for existing screening tools. For instance, Zimmerman and colleagues (2009) suggest that a much more lenient cutoff is required for the MDQ to demonstrate adequate sensitivity among outpatients, although this adjustment results in a high false positive rate.

When evaluating the literature on self-reports for bipolar disorder, careful attention must also be paid to the population under study. The MDQ, for instance, appears to perform very differently in clinical settings versus the general population (Hirschfeld et al., 2000, 2003). The prevalence of disorder is a pivotal component of this: One study demonstrated that prevalence may play a larger role in determining a screener’s usefulness than the psychometric properties of the screener itself (Phelps & Ghaemi, 2006).

In sum, there are several available self-report scales to detect bipolar disorder but each scale suffers from some conceptual and practical issues. Where does this leave us? Although scales are widely

adopted for research purposes, no self-report scale appears to be fully recommended for routine clinical use. That is, no scale consistently identifies at least 90% of those with bipolar disorder without identifying a prohibitively high number of false positives. New scales are currently under development; creating brief scales that can validly predict diagnoses of mania is an important goal with major public health significance.

As a final note, however, even the eventual development of a successful screening tool will not exempt the clinician from careful follow-up interviewing to confirm the bipolar diagnosis. Clinical interview remains the only thorough way to establish a diagnosis (Keitner et al., 1987). Ideally, all clinicians are familiar with the basic symptoms of mania, and ask clients about them whenever the suspicion of bipolar disorder exists, whether that suspicion has been derived from a self-report tool or other details of the patient’s presentation, such as a history of recurrent depression. The development of more refined screening tools, however, will help streamline this process of identifying patients in need of more careful follow-up.

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Miller, *Diagnosis of Bipolar*, continued

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Holcomb, What's Therapeutic About "Forced" Drug Switching?, Continued

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... covering the physician's preferred medication. Therapeutic substitution is distinct from generic substitution, which involves substitution of a generic version of the same medication that was prescribed, rather than a different medication in the same class (AMA, NAMI, MHA, & NCCBH, 2008).

The term "therapeutic interchange" has also been used interchangeably with the terms "therapeutic drug switching" and "therapeutic substitution." But according to Pharmacist's Letter/Prescriber's Letter ("Collaborative Drug Therapy," 2009, August), pharmacists practice therapeutic interchange, prescribing a chemically different drug that is expected to have similar effects, within a "collaborative drug therapy management" arrangement between a pharmacist and a physician. Within this arrangement the pharmacist may perform various functions such as assessing patients, managing drug regimens, and ordering drug therapy-related lab tests, depending upon state law. The standard of practice is to take into account the individual patient circumstances, such as drug interactions and medical conditions.

"Forced" drug switching practices have been implemented by insurance companies, pharmacy benefit managers,

Medicaid programs, and government health programs in an attempt to reduce health care costs. These practices have been justified by claims that they are consistent with evidence based medicine, referring to studies of comparative effectiveness within a drug class (Grisolia, 2005; Padrez, Carino, Blum, & Mendelson, 2005).

The Drug Effectiveness Research Project (DERP) (www.ohsu.edu/drugeffectiveness) by The Center for Evidence-Based Policy (CEBP) at the Oregon Health and Science University performs literature reviews of comparative effectiveness and safety profiles of drugs within a class. Among a wide range of medication classes, DERP has reviewed available research on psychotropics, including second generation antidepressants (Gartlehner, et al., 2008) atypical antipsychotics (McDonagh, Peterson, Carson, Chan & Thakurta, 2008), and antiepileptics (McDonagh, Peterson, Lee & Takhurta, 2008) used for conditions other than epilepsy, such as bipolar disorder. Reviews are updated periodically, with the latest updates on psychotropics occurring in 2008. The CEBP does not provide suggested guidelines for how the information of the DERP should be used.

DERP reviews have been used in developing Medicaid formularies (Grisolia, 2005; Padrez et al., 2005). The Kaiser

Family Foundation's Commission on Medicaid and the Uninsured reported that when DERP reviews do not find quality evidence to support that one drug is more effective or safe than another in a class, "some states automatically determine that the drugs are clinically equivalent. Such a determination gives the states what they believe to be defensible grounds to choose the least expensive drug for the PDL (Preferred Drug List)" (Padrez et al., 2005). But many studies included in the DERP reviews may not be of high enough quality to support conclusions about therapeutic equivalency or superiority for drugs in the same class (Padrez et al., 2005). For example, DERP reviews rated quality of the majority of studies comparing second generation antidepressants as only "fair" (Gartlehner et al., 2008). Also, randomized controlled trials may not be generalizable because they typically do not include a wide range of ages, ethnicities, and comorbid conditions (Grisolia, 2005).

"Forced" drug switching practices are not consistent with principals of evidence based medicine because individual differences are not considered, placing patients at risk for adverse effects (APA, NAMI, MHA, & NCCBH, 2008; Grisolia, 2005; Padrez et al., 2005; Simon, Psaty, Hrachovec & Mora, 2005). The Centre for Evidence Based Medicine (2009) at the University of



Holcomb, *What's Therapeutic About "Forced" Drug Switching?*, Continued

Oxford states that, "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.... Good doctors and health professionals use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient" (paragraphs 1 and 2). "Forced" drug switching practices were not applied for psychotropic medications in the past because of the heterogeneity of mental illness, and the risks involved in destabilizing mental illness. But psychotropics are increasingly being targeted, as their costs have risen and frequency of prescribing them has increased (Huskamp, 2003).

While direct randomized comparisons of selective serotonin reuptake inhibitors (SSRI's) have not found differences in general effectiveness, there are individual differences both in response and adverse effects which may be related, at least in part, to genetic differences (APA, NAMI, MHA, & NCCBH, 2008; Huskamp, 2005; Lynch & Price, 2007; Simon, 2001; Simon et al., 2005). For poor metabolizers of a drug, a standard dosage may cause adverse effects related to elevated drug serum levels

(Lynch & Price, 2007). African Americans and Asians have a higher prevalence of the poor metabolizer phenotype for CYP2C19, which metabolizes citalopram, an SSRI available in generic and, therefore, more likely to be on the "preferred" list (Burroughs, Maxey & Levy, 2002; Lynch & Price, 2007). Seven percent of caucasians are poor metabolizers of CYP2D6 (Lynch & Price, 2007). Fluoxetine, sertraline, and paroxetine (Paxil), all available in generic and often "preferred" on insurance formularies, are all metabolized by CYP2D6. The only generic SNRI (Serotonin Norepinephrine Reuptake Inhibitor) currently available, venlafaxine, is also metabolized by CYP2D6.

For patients in ten state Medicaid programs, prescription drug utilization management for psychotropic medications significantly increased medication access and continuity problems, and increased the rate of adverse events (e.g., emergency room visits, psychiatric inpatient admission, increase in suicidal ideation or behavior, homelessness, or incarceration/jail time) by about 20 percent (West et al., 2009). Patients required to switch to generics had a 2.7 times greater chance of experiencing an adverse event. In a systematic review on quality control for general drug management programs (some authors having affiliation with Pfizer), less than 10 percent of studies considered a clinical or

physiological disease related outcome. None of the studies looking at "forced" drug switching focused on a clinical outcome. Furthermore, there is no evidence in the literature that researchers and health plans have identified benchmarks or goals that programs should be striving to achieve to ensure that efforts to manage drug benefit resources are not compromising patient outcomes (Holtorf, McAdam-Marx, Schaaf, Eng & Oderda, 2009).

"Forced" drug switching not only negatively impacts patients but also creates significant strain for physicians. Facilitating drug switches and step therapy protocols through additional office visits, dealing with any resulting adverse drug effects, talking to pharmacists and insurance companies, and completing the paperwork involved in making appeals and requesting prior authorizations adds significantly to the workloads of prescribers, and can conflict with their ability to address an individual patient's needs (American Academy of Family Physicians, 2008). "Preferred" medications within a class often vary greatly between insurance plans, and may change over time (Shrank, Ettner, Glassman & Asch, 2004), adding further work, confusion, and frustration for prescribers.

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Holcomb, *What's Therapeutic About "Forced" Drug Switching?, Continued*

(continued from pg. 27)

"Forced" drug switching may also result in increased patient nonadherence and decrease of patient confidence (American Academy of Family Physicians, 2008), and may increase risk for medical malpractice claims when adverse effects result (Grisolia, 2005).

Closely related alternatives to standard therapeutic drug switching practices include paying physicians for switching patients from brand name to generic drugs, and increasing reimbursement rates for prescribers who increase ratios of generic prescriptions to brand name prescriptions. These practices have been criticized for violating medical ethics and for undermining patient trust in physicians (American Academy of Family Physicians, 2008; Fuhrmans, 2008).

Though "forced" drug switching practices are implemented to decrease costs for health plans, they may actually increase health care costs. From 2003 to 2005, a program in British Columbia required patients to switch to the single, lowest cost proton pump inhibitor (PPI), allowing for coverage of their original PPI only after 8 weeks of failure of the "preferred" PPI. This program resulted in increased, avoidable health care costs of up to 43.51 million dollars, related to increased health care utilization (e.g., physician and hospital

visits). Many patients who switched from an effective PPI to the preferred PPI experienced destabilization of their acid-related diseases, such as gastro esophageal reflux disease (GERD) (Skinner et al., 2009).

While "forced" drug switching practices may not cut overall health care costs, they have resulted in incredible profits for pharmacy benefit managers (PBM's), organizations that process and pay prescription drug claims, and manage formularies for sponsors of health plans. Profits of the three major PBM's (i.e., Caremark, Express Scripts, and Medco) are almost three billion dollars per year, nearly tripling over the past few years (Balto, 2009). With the power of large volume purchasing, PBM's are able to negotiate savings with pharmaceutical companies which they are then expected to pass on to their clients (e.g., insurance companies). However, PBM's have often pocketed large portions of these savings. They have also profited from charging their clients significantly more than they reimburse pharmacies for drugs, and from keeping incentive rebates from pharmaceutical companies for including particular drugs on their formularies, even switching patients from lower to higher cost drugs (Balto, 2009; National Community Pharmacists Association (NCPA), 2009b; National Legislative Association on Prescription Drug Prices (NLAPDP, n.d.). These de-

ceptive practices have led to numerous lawsuits filed against PBM's, leading to some large settlements in recent years (NLAPDP, n.d.).

Pharmaceutical companies are at the root of the problems that have led to "forced" drug switching in the United States. Prices of drugs in the United States are inflated compared to other countries (Barlett, Steele, Karmatz, Kiviat & Levinstein, 2004). Not only do drug companies offer rebate incentives to have their drugs included on formularies but newer, higher priced brand name drugs are heavily marketed, directly to patients through "ask your doctor" ads, and to physicians through informational drug lunches and by distributing "free" drug samples for distribution to patients.

The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents major drug companies, has defended the distribution of drug samples by asserting that they promote better care, help patients who are having financial difficulties, expose physicians to new treatment options, and encourage appropriate medication use (Chimonas & Kassirer, 2009). However, medication samples increase the cost of health care because they lead to prescribing more expensive medications (Kaiser Family Foundation, 2004). As in Mary's case,

Holcomb, *What's Therapeutic About "Forced" Drug Switching?, Continued*

low-income patients provided with samples at the start of treatment, along with a prescription for when samples run out, may then not be able to afford the cost of continuing the treatment (Chimonas & Kassirer, 2009).

In a survey of primary care physicians, 49% indicated they would not prescribe their preferred antidepressant to a hypothetical 45 y/o woman with new onset depression, in favor of an antidepressant for which they had samples available. They cited cost to the patient as an important factor in their decision (Chew et al., 2000), though patients who receive drug samples have more out-of-pocket prescription costs than those who do not (Alexander, et al., 2008). Internal medicine residents monitored over a 6 month period were less likely to prescribe drugs not advertised in major internal medical journals if they had access to samples than if they agreed to avoid use of samples during that time period. Residents with access to samples were also less likely to suggest over the counter medications to patients (Adair & Holmgren, 2005).

Ways Forced Drug Switching Practices are Being Addressed

The American Psychiatric Association (APA), National Association of the Mentally Ill (NAMI), Mental Health America (MHA), and the National Council for Community Behavioral

Healthcare (NCCBH), in their Joint Statement on Therapeutic Substitution (2008), argue against "forced" drug switching for psychotropic medications, and insist that the patient's overall profile should be considered in prescribing or changing medications, including medical conditions, other medications taken and possible drug interactions, and patient adherence issues.

The American Medical Association is in the process of drafting a National Health Insurer Code of Conduct which is expected to receive approval at its interim meeting in November of 2009.

This code attempts to address the problems of "forced" drug switching and step therapy, and advocates transparency, clinical autonomy, corporate integrity, and patient access and safety (Graham, 2009). It is unclear how the AMA expects to get the insurance companies to comply with the code, however.

New York Senate Bill S2398/S2398a was introduced in 2009 by Senator Jeffrey Klein (D-NY). If passed, changes would include coverage of a brand name drug if either the generic form does not have an equivalent therapeutic impact or a patient fails one alternative drug, and the prescriber determines that the single source drug (i.e., without an available generic version) is still medically necessary. Insurers would be required to submit their formularies to the insurance

commission on an annual basis, and to post them online for consumers to compare during open enrollment periods. Changes to formularies would only be allowed at a specific time annually, unless a generic version of a brand name drug becomes available, a drug is recalled by the FDA, or new safety information about a drug becomes available. If a patient is already receiving coverage for a drug which is taken off the formulary, they would not be denied coverage for that drug. The bill would also place some restrictions on copays for drugs.

Several states have passed PBM transparency laws (e.g., Maine, South Dakota, Texas), and many others are working on this (NCPA, 2009a; Sipkoff, M., 2008). For example, Maine passed the Unfair Prescription Drug Practices Act, which requires PBM's to pass along savings from negotiations with pharmaceutical companies to their clients, to get prescriber approval for a drug switch, to inform both the prescriber and the patient of the costs of both drugs, and to report the incentive rebate the PBM is getting for making the switch (Sipkoff, M., 2008). After passing PBM transparency legislation in 2004, South Dakota saved over \$800,000 in a...

(continued on pg. 30)

Holcomb, What's Therapeutic About "Forced" Drug Switching?, Continued

(continued from pg. 29)

single year (NCPA, 2009a). The National Community Pharmacists Association (2009a) has cited a number of examples of how some states and organizations who have switched from non-transparent PBM's to PBM's willing to enter into contracts with transparency, have saved or project saving millions to billions of dollars.

PBM transparency requirements are also being proposed for inclusion in the national health care reform bill that is currently in the works at the time of this writing (NCPA, 2009b; NCPA, 2009c).

Implications for "Forced" Drug Switching on the Practice of Psychopharmacology

The experience of patients like Mary, who are stable on a psychotropic medication and then "forced" to switch to a "preferred" drug, will become increasingly common if state and national government does not regulate these practices and the factors contributing to them.

We know from clinical experience and based upon the heterogeneity of mental illness, that finding a match between patient and psychotropic medication can be challenging. Once a patient is responding well to a drug regimen, it is distressing to both patient and prescriber to be "forced" to switch medi-

cations. It can take weeks to get a patient titrated to a therapeutic dosage of a new psychotropic medication, if the "preferred" medication is effective at all. Even if a patient is "allowed" to return to the original medication after a "failure" of the preferred medication (which is not always the case), the trial period of that ineffective medication can be devastating for someone whose mental health is destabilizing. And the risk of patients dropping out of treatment altogether because of "forced" drug switching may be the most tragic of all.

Psychologists with prescribing privileges can contribute to solutions to the problem of "forced" drug switching, as can all prescribers, by avoiding giving samples of higher priced medications for first line treatment when a generic alternative is available and is considered appropriate. We can all educate other prescribers of psychotropics to do the same. But psychologists can also help to contribute to solutions by promoting use of psychotherapy as a first line treatment before trying psychotropic medication, when research and the clinical situation suggest this is appropriate (e.g., interoceptive desensitization for panic disorder, prolonged exposure treatment for Posttraumatic Stress Disorder, no more than mild to moderate depressive symptoms). If patients can be treated effectively with psychotherapy, we can help them to avoid the potential

problem of "forced" drug switching altogether.

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Holcomb, What's Therapeutic About "Forced" Drug Switching?, Continued

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Henderson, Oregon RxP Update, Continued

(continued from pg. 11)

... left in our bag of tricks to keep us alive. The last thing any of us wanted to do was to die in a Senate Committee.

This bill passed out of Committee unanimously and onto the Senate floor, where it passed easily and found concurrence in the House a few days later. The Governor signed the Bill into law, and now we are on our way. Oregon should have statutory language stating psychologists will prescribe sometime after the 2010 Session. And, if the interim workgroup fails, there will be documented evidence from a neutral third party as to why we could not reach an agreement.

There are reasons for hope. This is a good outcome. We have a commitment from Oregon Legislators to hear this bill in 2010, and the expectation that a Bill will be presented. We have already educated this legislative body and the Governor—there are no elections between now and then, and in recent weeks, one House member and two Senate members have resigned. Both Senate members were opposed to this Bill—we can hope that their replacements will shine favorably upon it, or be too overwhelmed to care. And, we have a large body of Legislators who are really, really ticked that this Bill didn't pass this Session, who will be watching the performance of

this workgroup with a keen eye and a stern hand, ready to take this Bill home in 2010.

The Interim Committee was recently appointed and is comprised of:

- Robin Henderson, PsyD; Lynnea Lindsey, PhD, and Morgan Sammons, PhD representing psychologists
- Norwood Knight-Richardson, MD and George Keepers, MD, representing psychiatrists (both are faculty at Oregon Health Sciences University)
- L.J. Fangam, MD, representing physicians (and also on the faculty at OHSU)
- Ann Hamer, PharmD, representing pharmacists (and again, on the faculty at OHSU)

Mediation will be provided by the Oregon Consensus Project, and the first meeting is soon to be scheduled. Oregon stands ready to make another run at passing legislation for prescription privileges but to do so, we'll need lots of support. If you're interested in hearing about our efforts as we move forward, please feel free to send me your email address, and I'll put you on our update list.

Any article about Oregon's fight for prescription privileges is not complete without a few "thank you's." In no particular order, we would like to thank the following for their tireless support, listening ears, careful guidance and wisdom: Morgan Sammons, Glenn Ally, Mario Marquez, Elaine Levine, Deborah Baker, Dan Abrahamson, Suzie Lazaroff,

Pat DeLeon, and Steve Tulkin. I know there are many, many others, but these folks deserve a little extra thanks. We also want to thank Sandra Fisher, Executive Director of the Oregon Psychological Association, who has expertly kept us afloat and moving forward. Our lobbying team of Lara Smith, Betsy Smith-Jones and Gary Conkling (and his firm) are the BEST in the country on this issue. And finally, I want to thank the RxP Faithful—Doug Marlow, Lynnea Lindsey, David Wade and Peter Grover. The five of us have been together on this issue through three Sessions—the good, the bad, the ugly and the farcical madness that this debate can become. Their dedication to this issue is inspirational and unparalleled. The best is yet to come, my friends.

Dr. Henderson is the Director of Behavioral Health Services at St. Charles Medical Center, Cascade Healthcare Community in Bend, Oregon. She serves on the American Hospital Association's Governing Council for Psychiatry and Substance Abuse, and is a representative to the Joint Commission Behavioral Health Technical Advisory Group. She is Co-Chair of the Community Mental Health Coalition of Oregon, Chair of the Oregon Psychiatric Inpatient Committee, and has served on several interim Legislative Committees. She is a board member of the Cascades East Area Health Education Council and a member of the steering committee for the State's Behavioral Health Information Project. She is a past president of the Oregon Psychological Association, and is an active member of the American Psychological Association.



DeLeon, Work, Cause, Hope, Dreams, Continued

(continued from pg. 15)

“Best of all were the relationships his staff have solidified over the years in the Senate. We were visited by a Cabinet Secretary, Senators, a Governor, and high-ranking military. They came to our office to get senior staff views. We had several exciting lunches in the Senators’ dining room with key educators and healthcare professionals. If you define a leader as one who has influence, I definitely had the opportunity of working with them.

“The healthcare professionals and edu-

cators in Hawaii were some of the nicest people I’ve ever met. I was so impressed that I came home and entered a doctoral program. The Senator had previously encouraged me, but I was not ready for the commitment until I visited Dr. Kay Daub from the University of Hawaii (UH) at Hilo. Now I’m eagerly pursuing courses toward a Ph.D. in Nursing Education so I can teach at UH Hilo when I retire from the military.

“After realizing the health and educational needs in America, I was motivated to work toward being part of the solution. Now my life has a new direction

and purpose. The Senate experience was much more than political. For me, the social aspect was more powerful. I will forever be grateful for the many lessons about the power of relationships [Col. Robin Squellati].” Senator Edward Moore Kennedy [1932-2009], we will definitely miss you. Your vision, however, will live on.

Pat DeLeon, Ph.D., ABPP is affectionately known as the Father of RxP. He was President of the American Psychological Association (APA) in 2000. He won the Division 55 award for National Contributions to Psychopharmacology in 2001 and the Division 55 Meritorious Service Award in 2008.

Sulkowski, 2009 Patrick H. DeLeon Prize, continued

(continued from pg. 19)

... in the availability of training opportunities and increased prescriptive authority for psychologists. The public may come to expect school psychologists to possess a greater understanding of psychopharmacology in states and territories that currently provide licensed psychologists with prescription privileges as the lay public often has difficulty distinguishing between the roles of various mental health professionals.

Thus, school psychology programs ought to offer courses in psychopharmacology or allow students to obtain specialized training in this area, so that they will be prepared to meet the

needs of children’s in the 21st century. However, there are many barriers to providing this training, as few psychologists are qualified to teach psychopharmacology courses. Therefore, interested students may need to obtain training from other mental health professionals who have greater knowledge of psychopharmacology. For example, some school psychology students at the University of Florida have received instruction and collaborated with members of the Department of Child and Adolescent Psychiatry, including department faculty, psychiatry residents, and post-doctoral fellows, as a component of practicum training. As one of these students, I was fortunate to regularly at-

tend psychiatric grand rounds, attend faculty and resident case conferences, participate in didactics, observe psychiatric consultations, engage in clinical research, collaborate on cases with psychiatry residents and fellows, and receive supervision from members of the departments of Child and Adolescent Psychiatry, Clinical and Health Psychology, and the School Psychology Program. Although this is no substitution for the rigorous training received by prescribing mental health professionals, I do believe that non-standard and cross-disciplinary training experiences have the potential to increase school psychologist’s willingness...

(continued on pg. 35)

Pillay and Tulkin, *Prescriptive Authority in South Africa, Continued*

(continued from pg. 18)

the then Supplementary Health Professions subject to certain conditions.

Furthermore, the South African Medicines and Medical Devices Authority (SAMMDRA) Act (a new autonomous Drug Regulatory Authority a transformation of the MCC), which would be re-promulgated in the near future, provided for prescription rights for Health Professionals, subject to a list of appropriate medicines being promulgated in regulations in terms of the SAMMDRA Act. This list of medicines would first have to be approved by the Health Professions Council of South Africa prior to being submitted to the SAMMDRA for approval and promulgation.

At a meeting of the meeting between the Executive Committees of the Medical and Dental Professional Board, the Professional Board for Psychology and the Council of the HPCSA (April 2000), the council acknowledged that a number of Health Professionals other than medical, dental and pharmacy practitioners were currently administering and prescribing medicines under certain specific conditions. They agreed that:

1. 'The Professional Board for Psychology would submit a detailed proposal in respect of limited prescription rights for psychologists

to the Medical and Dental Professional Board, including the need for such prescription rights especially in under serviced areas

2. The principle of limited prescription rights for psychologists under the conditions defined by the Professional Board for Psychology should be debated by the Medical and Dental Professional Board prior to further discussions with the Professional Board for Psychology;
3. The needs of the patients and the rendering of an accessible service to all South Africans should be a guiding principle in the debate on prescription rights for psychologists;
4. Until the discussions relating to the prescription rights for psychologists had been finalized, no information regarding the matter would be made available to the Media for publication'.

Unfortunately the final decision taken by the Council of the HPCSA subsequently was against prescriptive rights for psychologist. This also coincided with the end of 1998-2002 PBP's term of office. A new PBP board was elected in 2003. During the new PBP elected term (2003-2008) the issue of prescriptive rights for psychologist did not receive much prominence. A new Board is to assume office for the period 2009-2014. The members of this Board are to be

announced by the minister of Health very soon.

South Africa continues to face a serious shortage of health care practitioners more especially mental health practitioners. In a recent study (Petersen et al., 2009) in which a situational analysis of mental health services in a rural district (typical of most rural districts in the country) was done, the researchers found a lack of specialist mental health staff, particularly with respect to psychiatrists and psychologists. There was no psychiatrist and only one psychologist for the entire district (i.e. 0.2 psychologist per 100 000 population). Chisholm et al. (2007) estimate the target human resource requirements to treat Schizophrenia, Bipolar Affective Disorder, Depressive Episode and hazardous Alcohol Use to be 0.5 psychiatrists and 1.0 psychologist per 100,000 population.

In South Africa, only 0.28 psychiatrists per 100 000 population and 0.32 psychologists per 100,000 are employed by the Department of Health, a division which services 80% of the population (Lund, Kleintjes, & Campbell-Hall, 2007). It is estimated that South Africa, as a whole, has 1.2 psychiatrists per 100,000 population and 4 psychologists per 100,000 population (WHO, 2005). As Peterson et al. (2009) point out limited access to and scope of mental

Pillay and Tulkin, *Prescriptive Authority in South Africa, Continued*

health services is both a product of insufficient resources, as well as inefficient use of existing resources.

A substantial revision to the existing training of psychologists to meet and to address the human resource shortages within the health care sector in South Africa is seriously required. This revision must also include training in psychopharmacology and prescriptive rights. It is incumbent on existing and future-trained psychologists to sharpen their skills and broaden their repertoire so that they may more effectively fulfill their functions and meet needs of the society they serve. In this regard, PsySSA and psychologists in the country must continue to lobby for pre-

scriptive privileges.

B.J. Pillay, Ph.D. is Head of Department of Behavioural Medicine at the Nelson R Mandela School of Medicine at the University of KwaZulu-Natal, and Chief Clinical Psychologist for the Hospital Services of the KwaZulu-Natal Provincial Administration in Durban, South Africa. He is an internationally recognized academic and clinician, represents his discipline on national and international bodies and serves on several scientific committees. He is Past President of the Psychological Society of South Africa (PsySSA).

Steven Tulkin, PhD is Professor and Director of the Postdoctoral Master of Science Program in Clinical Psychopharmacology at the California School of Professional Psychology at Alliant International University. He has served Division 55 as a member-at-large on the Board of Directors, and as Program Co-Chair for the 2008 APA convention. Dr. Tulkin is Treasurer of Division V (Psychopharmacology) of the California Psychological Association. Dr. Tulkin is working with Dr. Pillay to develop psychopharmacology coursework for the Psychological Society of South Africa (PsySSA).

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Correction

The following is in correction to the article, *How Legislative Change in Health Happens in Ontario* by Brian J. Bigelow, Ph.D., C. Psych., ABPP, FSICPP, FPPR, FICPP, from July, 2009, pg. 12:

I promised to wear my own errors.

1. Ontario and other provinces do not have senates. Only the Federal Parliament has a senate.

2. Legislative bills go through three readings, presented to the legislative assembly. After a successful third reading, bills are then proclaimed law.

Sulkowski, 2009 *Patrick H. DeLeon Prize, continued*

(continued from pg. 19)

to participate in psychopharmacotherapy and advocate for greater roles in the psychopharmacological treatment of children.

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