In This Issue

Clinicians’ Corner
Four “New” Antidepressants. Or Are They?
Jim Phelps & Daniel Carlat
2
Low Dose Doxepine for Insomnia: Silenor® or Generic
Noelle Bassi Smith & James D. Calvert
10

Perspectives
Vision for the Future—The Importance of Involvement
Patrick Deleon
16

President’s Podium
Plan to Attend Division 55 Programs at the 2011 APA Convention
Glenn Ally
21

Legislative Updates
A Long Legislative Session in Montana...
Michael R. Butz
23
In Brief—New Jersey
Sean R. Evers
27

From the Editors
Statistical Significance, Effect Size, and Clinical Relevance for RxP
James D. Calvert, Editor
28
It’s Poison I Tell You, It’s Poison
Nicholas Patapis, Associate Editor
30
What’s new in antidepressant treatment? Not much. Some existing antidepressants have received new FDA indications. For example, duloxetine (Cymbalta) was approved for generalized anxiety disorder in 2009 and for chronic musculoskeletal pain in 2010. Also in 2009, quetiapine extended release (Seroquel XR) was approved as an adjunctive treatment for major depression, joining aripiprazole (Abilify), which was approved for this indication in 2007. Other recent approvals have included escitalopram (Lexapro) for depression in adolescents, and Symbyax, the combo of olanzapine and fluoxetine, for treatment resistant depression.

In terms of “new” medications, in this article we will examine four recent additions. Two are essentially old wines in new bottles (Oleptro and Silenor), one is a reissue of an MAOI (Marplan), and one is actually a new molecule (Viibryd). You may have heard some buzz about agomelatine as well, a unique melatonin agonist, but it is too far away from FDA approval (probably 2012 at the earliest) for us to cover it here.

Viibryd (vilazodone)
Vilazodone (Viibryd) was approved by the FDA in January of 2011, and should hit pharmacy shelves around the time that you are reading this article. The manufacturer, Clinical Data, Inc, is marketing it as “a new molecular entity” and “the first and only selective serotonin reuptake inhibitor and 5-HT1A recep-
tor partial agonist."

Is the drug effective? The company conducted two eight-week, randomized, double-blind, placebo-controlled studies of vilazodone at a dose of 40 mg/day. One of these studies was published (Rickels K et al, J Clin Psychiatry 2009;70(3):326–333), while the other was posted on [http://clinicaltrials.gov](http://clinicaltrials.gov), along with less detailed results. Both studies were standard clinical trials, with the usual exclusion criteria—ie, patients were required to have at least moderate depression but no suicidal ideation, and they were excluded if they had any other psychiatric conditions, with the exceptions of generalized anxiety disorder, social phobia, and simple phobia. As usual, the devil is in the detail of the methodology of these studies, and these strict exclusion criteria limit how generalized the results are to your patients, depending on the nature of your practice.

As you can see from the table, “Vilazodone vs Placebo for Major Depression,” vilazodone yielded significantly more improvement in both depression symptom scores and response rates than placebo. These numbers are similar to those posted by other FDA-approved antidepressants. Vilazodone appears to be an effective antidepressant, though no more effective than any of its competitors, most of which are available generically at a fraction of the cost.

<table>
<thead>
<tr>
<th>Study</th>
<th>Improvement in MADRS Score</th>
<th>MADRS Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial NCT00683592 (<a href="http://bit.ly/hOheGg">http://bit.ly/hOheGg</a>)</td>
<td>-13.3</td>
<td>43.7%</td>
</tr>
<tr>
<td>Vilazodone (n=231)</td>
<td>-10.8</td>
<td>30.3%</td>
</tr>
<tr>
<td>Placebo (n=231)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>J Clin Psych study (Rickels <em>ibid</em>)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vilazodone (n=205)</td>
<td>-12.9</td>
<td>40.4%</td>
</tr>
<tr>
<td>Placebo (n=205)</td>
<td>-9.6</td>
<td>28.1%</td>
</tr>
</tbody>
</table>

*(All differences were statistically significant)*

So why would you choose to prescribe this new antidepressant? There are two potential reasons: 1. The rumor that vilazodone has few sexual side effects; and 2. The idea that it has a unique mechanism of action.

The low sexual side effect rumor is based on the Rickels et al study. In that study, all enrolled patients were given the five item ASEX sexual dysfunction scale, and after eight weeks, there was no difference between placebo and

The only conclusion to be drawn is that neither vilazodone nor placebo made preexisting sexual problems any worse.
vilazodone in changes in the score. Unfortunately, these data mean little, because most patients who entered the vilazodone trials already had sexual dysfunction (perhaps caused by the depression itself or other factors). Therefore, the only conclusion to be drawn is that neither vilazodone nor placebo made preexisting sexual problems any worse.

To understand how uninformative this study was regarding sexual side effects, let’s take a peak at a similarly designed study of two antidepressants that are well known to cause sexual dysfunction: paroxetine (Paxil) and escitalopram (Lexapro). In an eight week randomized controlled trial comparing these two drugs, the average patient began the study with a high ASEX score of 20 (the higher the score, the worse the sex). After eight weeks, the ASEX scores increased only slightly over baseline, and after 27 weeks, they actually decreased. This study did not prove that these drugs are sexually inert, it simply showed that there is a ceiling effect—at a certain level of decreased libido, nothing is going to make it any worse (Baldwin DS et al, *Int Clin Psychopharmacol* 2006;21(3):159–169).

Of course, the obvious way to find out if a drug causes a side effect is to prescribe it to patients who don’t already have the side effect in question. This is the method used in the various studies showing that bupropion (Wellbutrin) is sexually cleaner than SSRIs. These studies enrolled only depressed patients without sexual dysfunction, randomized them to bupropion vs sertraline (Zoloft) or escitalopram, and reassessed them several weeks later. Using this methodology, bupropion vastly “outsexed” both sertraline (Segraves R et al, *J Clin Psychopharmacol* 2000;20(2):122–128) and escitalopram (Clayton AH et al, *J Clin Psychiatry* 2007;67(5):736–746).

According to Dr. Laughren of the FDA, vilazodone has not met the standard required in order to make claims that it does not cause sexual dysfunction

The FDA agrees with our skepticism. In an email to *The Carlat Psychiatry Report*, Dr. Thomas Laughren, who is the director of psychiatric products at the FDA, described for us the standards the FDA requires for antidepressant makers to claim their products do not cause sexual dysfunction—and he assured us that “vilazodone has not met that standard.” Clinical Data has been officially barred by the FDA from touting vilazodone as a low sexual side effect antidepressant.

The other potential selling point of vilazodone is that it is the “one and only” antidepressant with the following dual mechanism of action: it is both an SSRI (ie, it is an antagonist) and a “5-HT1A partial agonist” which is neurotransmitter- speak for buspirone (BuSpar), the only commonly used 5-HT1A partial agonist on the market. The implication is that vilazodone is sort of like combining an SSRI and buspirone in one pill, with the putative benefits of an augmented antidepressant response and an anti-anxiety effect. This is all theoretical, of course, since there are no data showing that vilazodone is better than any other antidepressant for...
either anxiety or depression. We eagerly (but, suspect, futilely) await results of such future head-to-head trials!

**Viibryd—At a Glance**

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Vilazodone</th>
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<tbody>
<tr>
<td>Manufacturer</td>
<td>Clinical Data, Inc</td>
</tr>
<tr>
<td>Approval date</td>
<td>January 21, 2011</td>
</tr>
<tr>
<td>Approval indication</td>
<td>Major depressive disorder</td>
</tr>
<tr>
<td>Available in pharmacies</td>
<td>Sometime between April and June 2011</td>
</tr>
<tr>
<td>Dosages available</td>
<td>10 mg, 20 mg, 40 mg tablets</td>
</tr>
<tr>
<td>Target dose</td>
<td>40 mg once a day</td>
</tr>
<tr>
<td>Average cost</td>
<td>No cost information yet</td>
</tr>
<tr>
<td>Likely marketing points</td>
<td>Lower side effects, new mechanism of action</td>
</tr>
<tr>
<td>Advantages over existing antidepressants</td>
<td>Probably none</td>
</tr>
</tbody>
</table>

*The Carlat Psychiatry Report’s Verdict:* Vilazodone: Effective, but be wary of low side effect claims.

**Oleptro (trazodone extended-release)**

Oleptro is an extended release formulation of trazodone (Desyrel). While we have come to think of trazodone as a non-addictive sleeping pill at doses ranging from 25 mg to 150 mg at night, the pill’s only actual indication is for the treatment of major depression, which it received approval for decades ago. Of course, we rarely use it for depression, because the doses required (300 mg to 400 mg, in divided doses, according to the prescribing information) would cause our patients too much sedation to make it worth using.

Which brings us to the question of why Labopharm, Oleptro’s maker, would think that a branded, expensive, extended release version of trazodone would find a place in our quiver of drugs? In other words, why would one want to experience the side effects of trazodone all day, instead of confining them to an overnight period in which one is hopefully asleep? Labopharm USA’s chief medical officer Jeff Dayno, MD, explained to *TCPR* that by spreading release over a 24-hour period, they hoped to decrease the sedation and allow for delivery of antidepressant dosages.

So what do the Oleptro clinical trials show? Thus far, only one randomized trial has been published (Sheehan DV et al, *Psychiatry (Edgmont)* 2009;6(5):20–33), and no others are listed as being in progress at http://clinicaltrials.gov. In this trial, 406 depressed outpatients were randomized to active drug or placebo. Exclusion criteria were similar to the vilazodone studies described previously, so generalizability to standard clinic patients is problematic. Titration began at 150 mg nightly, increasing every three to four days by 75 mg, up to a maximum of 375mg.
How did patients in this study fare? Oleptro outperformed placebo: starting from a baseline HAM-D-17 score of 23, Oleptro patients’ scores decreased by 11 points, versus a nine point drop for placebo. How much of a difference is two points? Big enough to be statistically significant (P=0.012)—but is this clinically significant?

Is Oleptro useful as an antidepressant? It depends on if you believe a 2-point difference between Oleptro and placebo on the HAM-D is clinically significant.

The effect size in the Oleptro study was 0.28 (not presented in the report but confirmed with Labopharm by email). A two point difference in the HAM-D scale is considered by some researchers to be clinically meaningful (for example, a 1.7 to 1.9 point change in HAM-D was defined as clinically meaningful in one review—Khan A et al, *Neuropsychopharmacol* 2003;28(3):552–557). But other researchers, as well as Britain’s National Institute for Clinical Effectiveness (NICE), have adopted a three-point difference on the HAM-D as the threshold for clinical significance. Therefore, depending on your definition of “significant,” Oleptro may or may not be a useful antidepressant.

How was the drug tolerated? Daytime somnolence was the main problem, affecting 31% of the Oleptro group versus 16% of the placebo group. Other significant side effects were dizziness and nausea, occurring at roughly twice the rate of placebo. While sexual dysfunction was not thoroughly assessed, long experience with trazodone suggests that this will not be a major problem.

Interestingly, a recent small trial endorsed trazodone as potential treatment for sexual dysfunction associated with SSRIs (Stryjer R, *Clin Neuropharmacol* 2009;32(2):82–84). But this was only a small open trial (15 patients); the power of suggestion may have been the active ingredient, not the 5-HT2 antagonism about which the authors speculate.

So—is Oleptro worth using as an antidepressant? In patients who cannot tolerate the sexual dysfunction from most other antidepressants, and who don’t become overly sedated, Oleptro may have a place—but at about $150 for a month’s supply, insurance companies will be reluctant to foot the bill.
TCPR’s Verdict: Oleptro: For most patients, not enough efficacy to justify side effects and cost, but necessary head-to-head studies with existing antidepressants are lacking.

Silenor (doxepin)

Silenor is a branded version of doxepin, a tricyclic antidepressant that has been available in the U.S. since the 1960s or so. Doxepin is the generic name, and it is also sold by Pfizer under the brand name of Sinequan. Doxepin is such an old drug that one of its current official FDA indications is: “Psychoneurotic patients with depression and/or anxiety.”

Like other tricyclics, doxepin blocks the reuptake of norepinephrine, but it is also a very potent antihistamine, meaning that one of its main side effects is sedation. Accordingly, over the years doxepin has become a favorite non-addictive insomnia medication, usually used in very low doses (it comes as low as 10 mg).

The drug company Somaxon patented a technique for packaging generic doxepin into even smaller dosages (1 mg, 3 mg, and 6 mg), and did clinical trials showing that these work better than placebo for sleep maintenance (for example, see Scharf M et al, *J Clin Psychiatry* 2008;69(10):1557–1564). On the basis of these trials, they now have an FDA indication for insomnia at the 3 mg and 6 mg doses.

There’s not too much more that’s worth saying about Silenor. It would be hard to imagine a patient for whom 3 mg or 6 mg of Silenor will pose an advantage over 10 mg of generic dox-
epin. True, doxepin can cause a range of anticholinergic side effects, but recall that the standard doxepin dose for depression is from 75 mg/day to 150 mg/day. Given that scale, a 5 mg difference would seem unlikely to yield significantly more or less side effects. Of course, Somaxon could have answered this question scientifically in their clinical trials if they had randomized some of their patients to generic doxepin 10 mg. Presumably they chose not to do so because they were afraid of what they would find. A month’s supply of Silenor at 3 mg or 6 mg costs $214, according to Boston area pharmacies we contacted. On the other hand, a month’s supply of doxepin 10 mg costs $4 at Walmart. The rare patients who cannot tolerate 10 mg of doxepin can reduce the dose by opening up the capsules and mixing some of the powder in juice. The generic also comes in a 10 mg/ml liquid dose.

<table>
<thead>
<tr>
<th>Silenor—At a Glance</th>
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<tbody>
<tr>
<td>Generic name</td>
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<tr>
<td>Approval indication</td>
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<tr>
<td>Dosages available</td>
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<tr>
<td>Target dose</td>
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<tr>
<td>Average cost</td>
</tr>
<tr>
<td>Likely marketing points</td>
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<tr>
<td>Advantages/ disadvantages</td>
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</tbody>
</table>

TCPR’s Verdict: Silenor: Just as good as the generic, and 50 times the price!

**Marplan (isocarboxazid) is being reissued as a branded drug**

A “new” monoamine oxidase inhibitor (MAOI)? Well, not really. Isocarboxazid has been around since 1959. It disappeared in 1994 when the FDA called for updated data to maintain an indication. Its manufacturer, Hoffman Laroche, chose not to continue it, according to an interesting account in a voicemail response to TCPR from James Hunter, president of its new marketer, Validus Pharmaceutical. Apparently Validus spotted a commercial opportunity in reissuing Marplan as a branded drug. (According to several pharmacies contacted by TCPR, isocarboxazid is not available as a generic at this point.) The price for a 10 mg tablet averages more than $3 per pill, and given a target dose of 40 mg/day, the monthly cost could be well over $300.
Is isocarboxazid more effective than phenelzine (Nardil) or tranylcypromine (Parnate), the available generic MAOIs? Apparently not. The last comprehensive review was published 15 years ago and concluded that isocarboxazid is as effective as its competitors for outpatients, but may be ineffective for inpatients (Thase et al, *Neuropsychopharmacol* 1995;12(3):185–219). Unfortunately, because of the lack of availability of this medication for the last decade, no more recent comparative data are available.

Are you one of the 2% of psychiatrists who actually use MAOIs regularly (Balon et al, *Psychiatr Serv* 1999;50(7):945–947)? If not, whichever MAOI you choose, you’ll need a handy list of foods and medications to avoid. You can download one from the TCPR website at http://bit.ly/eNyoyl or read it in *TCPR*, November 2006.

<table>
<thead>
<tr>
<th>Marplan—At a Glance</th>
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<tr>
<td><strong>Brand name</strong></td>
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<tr>
<td><strong>Manufacturer</strong></td>
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<tr>
<td><strong>Approval date</strong></td>
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<td><strong>Likely marketing points</strong></td>
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<tr>
<td><strong>Advantages over existing antidepressants</strong></td>
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**TCPR’s Verdict:** Marplan: A welcome reissue, but expensive.

*Expensive medicines are always good—if not for the patient, at least for the druggist* — Russian Proverb
The treatment of insomnia warrants special attention as it is extremely prevalent in the population and can cause significant disruptions in everyday functioning. One year prevalence estimates reveal that roughly 30-45% of adults endorsed complaints of insomnia (American Psychiatric Association; APA, 2000). Approximately 10% of adults and 25% of elderly suffer from chronic insomnia and an additional 30% of the population suffers from transient insomnia (Doghramji, 2007).

Research suggests that low dose doxepin may be helpful in treating chronic and transient insomnia in both adults and elderly. Reviews of low dose doxepin indicate that it is efficacious in improving sleep maintenance, including wake time after sleep onset, total sleep time, and sleep efficiency, calculated using the total time spent sleeping and the total time spent in bed (Weber et al., 2010), with no evidence of changes to sleep architecture, tolerance, withdrawal or discontinuation symptoms or rebound insomnia (Lankford, 2010).

Doxepin is a tricyclic antidepressant that recently received approval from the U.S. Food and Drug Administration (FDA) for transient and chronic insomnia in adults and the elderly. Previously, higher doses of doxepin (150-300 milligrams) were prescribed to treat depression and anxiety, but dosage levels used to treat depression and anxiety can have significant anticholinergic side effects such as blurred vision, confusion, constipation, dry mouth and urinary retention. In higher dose ranges, other side effects include dizziness, drowsiness, nausea, and changes in appetite. The significant and often intolerable side effect profile combined with better alternatives in mood and anxiety treatment is largely why the use of higher doses of doxepin has declined. However, in significantly lower dose ranges (1-6 mg), doxepin appears to be efficacious in the treatment of insomnia characterized by difficulty with sleep maintenance.

At high doses, doxepin has properties of inhibiting reuptake of serotonin and norepinephrine, as well
as being an antagonist at histamine, alpha adrenergic and muscarinic receptor sites (Stahl, 2008). Yet at lower doses, the mechanism appears to be much more limited and specific. Doxepin is unlike other psychiatric medications because it works selectively on $H_1$ (histamine) receptors at very low doses. Histamine plays an important role in wakefulness, and selective antagonism at the $H_1$ receptor has been associated with sedating properties (Lankford, 2011) and is closely linked to the initiation and maintenance of sleep (Weber, Siddiqui, Wagstaff, & McCormack, 2010). When histamine acts on the $H_1$ receptors, it activates a chain of events that results in wakefulness and pro-cognitive alertness (Stahl, 2008). In the presence of an $H_1$ antagonist, such as doxepin, the chain of events is altered resulting in sedation, drowsiness, sleep or more generally the interference of wakefulness-promoting actions. The highly selective and specific binding properties of doxepin with histamine $H_1$ receptors are the hypothesized mechanisms underlying why doxepin helps to treat insomnia, as well as the reason why there are so few side effects to low-dose doxepin. Selective $H_1$ antagonism does not interfere with other neurotransmitters and the natural release of histamine upon awakening overrides the residual effects (Lankford, 2011).

In addition to the highly selective and potent nature of doxepin for the $H_1$ receptor, changes in cortisol levels are also a hypothesized mechanism behind the efficacy in reducing insomnia and sleep difficulties. Compared to a placebo, intravenous and oral applications of 25 mg of doxepin significantly improved sleep and reduced mean cortisol levels. The inactive period of cortisol rhythm was prolonged following the administration of 25 mg of doxepin, suggesting that the sleep-improving effects may be partially explained by the normalization of the hypothalamic-pituitary-adrenal (HPA) axis (Rodenbeck et al., 2003).

Using a crossover design, Roth and colleagues (2007) examined the efficacy of 1 mg, 3 mg, and 6 mg doses of doxepin in adults with chronic primary insomnia. All three doses of doxepin were significantly better than the placebo on at least some measures of sleep initiation and maintenance. While all three doses of doxepin appeared to be helpful in improving sleep efficiency throughout the entire night, the results suggest low dose doxepin may be particularly helpful for sleep maintenance during the final third of the night. On the primary outcome measure, wake time during sleep, only 3 mg and 6 mg doses of doxepin were significantly better than placebo. On measures of residual sedation, such as psychomotor functioning and next-day alertness, there were no differences between any of the doses of doxepin and placebo. Additionally, there were no differences in the incidences of adverse effects. Headaches and somnolence were the two most commonly reported adverse events. Overall, the results support the efficacy and safety of low dose doxepin, particularly 3 mg and 6 mg doses, in the treatment of insomnia in adult populations. Scharf and colleagues (2008) found very similar results with elderly patients.
Given the higher prevalence of insomnia in elderly, efficacy, safety, and tolerability with this population is particularly important. Krystal and colleagues (2010) conducted a longer 12-week trial and examined the effects of 1 mg and 3 mg doses of doxepin in elderly individuals using patient reports, clinician ratings, and objective measures obtained through polysomnography. Although 1 mg of doxepin improved a limited number of outcome measures at several time points, 3 mg of doxepin significantly approved a greater number and range of sleep parameters and revealed sustained effects. The 3mg dose of doxepin was significantly better than placebo on objective measures, such as wake time after sleep onset, total sleep time, and sleep efficiency. Additionally, 3 mg of doxepin was also associated with significant improvements in subjective efficacy data, meaning the patient’s self-reported sleep mirrored objective outcomes. Clinical and patient global impressions were also significantly improved suggesting the changes were noticeable by the individuals and clinicians, and that there were improvements in the overall functioning of the individuals suffering from insomnia. Notably, incidences of side effects were low; there were no significant carryover effects or next-day residual symptoms, nor were there reports of memory impairment, weight gain or significant anticholinergic effects. The 12-week trial also provides support for the long term use of low dose doxepin in elderly populations.

**Given the high prevalence of insomnia among the elderly, finding a safe, effective, and tolerable medication is especially important for this population**

In transient insomnia, lasting between a single night and a few weeks, 6 mg of doxepin appears to alleviate sleep difficulties as well. Compared to individuals receiving a placebo, individuals administered 6 mg tablets of doxepin demonstrated improved sleep onset, as defined by a reduction in the time between lights out and persistent sleep. Sleep maintenance, sleep duration, and sleep quality were also significantly better than the placebo condition on both objective and subjective measures. Doxepin appeared to reduce early morning awakenings and did not consistently reveal any carryover sedation on the next day, which suggests the effectiveness and tolerability of doxepin in adults with transient insomnia (Roth et al., 2010).

Other medications besides doxepin have generally been considered to be first line treatments for insomnia (Lankford, 2011; Pinto et al., 2010). Popular medication choices for insomnia include non-benzodiazepine options such as zolpidem (Ambien CR®) and eszopiclone (Lunesta®). A recent meta-analysis by Buscemi and colleagues (2007) examined the efficacy and safety of insomnia drug treatments using benzodiazepines, non-benzodiazepines, and anti-depressants, including four studies with doxepin. The meta-analysis revealed that benzodiazepines, non-benzodiazepines, and antidepressants significantly decreased sleep onset latency as defined by the amount of time between going to bed and falling asleep, in both self-report and polysomnography. Benzodiazepines and non-benzodiazepines were significantly better than placebos on measures of wakefulness after sleep onset, sleep efficiency, total sleep time, and sleep quality. For
antidepressants, results from the polysomnography revealed significant differences from the placebo, but there were only a small number of sleep diaries on which to base the comparison of subjective reports. Benzodiazepines, non-benzodiazepines, and antidepressants were not significantly different from each other, except that non-benzodiazepines were more efficacious than antidepressants on sleep onset latency using polysomnography. Unfortunately, the meta-analysis included studies examining doxepin in the 25 mg to 50 mg dose range, so the interpretations of the findings are limited, especially because newer research indicates that it is very low dosages of doxepin (1-6 mg) that appear to be most helpful because of the selectivity for H₁ receptors at very low dose ranges.

Low dose doxepin provides several advantages over other pharmacological possibilities. Most importantly, it appears to be safe and tolerable for individuals, including the elderly. It has been shown to be efficacious on a number of sleep parameters measured by polysomnography, patient report, and clinician report. Because it is not a controlled substance, there is a low potential for abuse. Studies suggest it is acceptable for long term use, and there are no restrictions on duration of use or evidence of tolerance with prolonged usage. With the conceptualization that insomnia must be treated chronically (Stahl, 2008), the safety and efficacy over long term use of doxepin is especially appealing. If discontinued, there are no signs of physical withdrawal symptoms or rebound insomnia. Once daily 3 mg or 6 mg oral dose within thirty minutes of bedtime is well tolerated with the most frequent side effects being somnolence, headaches and grogginess (Weber, Siddiqui, Wagstaff, & McCormack, 2010), although these side effects were not reported at rates higher than placebo for all studies (e.g., Roth et al, 2007). Significant and potentially intolerable side effects such as weight gain or psychomotor impairment were not exhibited in trials with low dose doxepin.

As discussed, low dose doxepin offers a number of elements that are advantageous in general, but particularly for elderly populations. Due to the highly specific affinity for histamine H₁ receptors, there are very few drug interactions, although low dose doxepin should not be taken in conjunction with monoamine oxidase inhibitors (MAOIs; Somaxon Pharmaceuticals, 2010; USFDA, 2010). Low dose doxepin also offers sustained control of symptoms and patient-reported improvements in sleep quality (Weber et al., 2010). Additionally, as elderly individuals may be especially susceptible to some side effects, it is particularly noteworthy that low dose doxepin was not associated with anticholinergic side effects or memory impairments.

In March 2010, The U.S. Food and Drug Administration approved Silenor® (manufactured by Somaxon Pharmaceuticals) for the treatment of insomnia characterized by difficulty of sleep maintenance (Somaxon Pharmaceuticals, 2010; USFDA, 2010). Silenor® is a low dose of doxepin that comes in 3 mg and 6 mg oral tablets. Somaxon Pharmaceuticals pointed out in their press release that Silenor® is advantageous as it al-
allows for specifically measured and controlled dosing of doxepin. Silenor® provides a convenient and controlled option for ensuring that the individuals receive the intended dose (Somaxon Pharmaceuticals, 2010). Prior to March 2010, the lowest dose of doxepin was 10 mg in either capsule or oral suspension form. Either the capsule or oral suspension can be divided into smaller doses to approximate the 3-6 milligram range that appears to be within the therapeutic window for transient and chronic insomnia.

But is Silenor® any more effective than generic doxepin?

The approval of Silenor® aroused concern from many (e.g., Phelps & Carlat, 2011; Carlat, 2011; Krohn, 2010) since it was essentially taking an older generic drug that has been used for many years as an off-label treatment for insomnia and making it available as an expensive brand name medication by repackaging it in 3 mg and 6 mg tablets. Indeed, the only difference between generic doxepin and Silenor® is that Silenor® is available in 3 mg and 6 mg tablets, while generic doxepin is only available with the lowest dosage of 10 mg. The research indicates that 3 mg and 6 mg dosages work well without significant side effects. The concern is that as dosages are increased, the likelihood of side effects also increases. However, it appears that splitting the dosage of generic doxepin places the dosage within the 3-6 mg range that has been shown to be effective in the treatment of insomnia.

There is no evidence that Silenor® is more effective than generic doxepin

When making a decision between Silenor® and generic forms of low dose doxepin, it appears to come down to cost versus exact dosing. Online drug prices show that generic doxepin costs less than 20 cents per 10 mg capsule as compared to $5.50-$6.50 per 3 mg tablet for Silenor®. These costs may vary depending on insurance benefits. Splitting the 10 mg dose of generic doxepin is not as exact as taking a 3 mg or 6 mg tablet, but it appears that dosages in the 3-6 mg range are safe and effective, so exact dosing may not be necessary. As Carlat (2011; also reprinted in the current issue of The Tablet) points out, there appears to be little advantage to Silenor® given the ease of dividing generic doxepin dosages. Since there will be some small variation in dosage whenever medication is divided by patients, future research comparing 3 mg and 6 mg Silenor® with patient-divided generic doxepin capsules would outline advantages, if any, for prescribing Silenor® instead of the more cost-effective generic doxepin.

References


The Department of Health and Human Services: In presenting her Fiscal Year 2012 budget, Secretary Sebelius (HHS) expressed her enthusiasm for effectively implementing President Obama’s landmark Patient Protection and Affordable Care Act (PPACA) in a timely fashion. “In President Obama’s State of the Union address he outlined his vision for how the United States can win the future by out-educating, out-building and out-innovating the world so that we give every family and business the chance to thrive. His 2012 budget is the blueprint for putting that vision into action and making the investments that will grow our economy and create jobs. At the Department of Health and Human Services [HHS] this means giving families and business owners better access to health care and more freedom from rising health costs and insurance abuses. It means keeping America at the cutting edge of new cures, treatments and health information technology. It means helping our children get a healthy start in life and preparing them for academic success. It means promoting prevention and wellness to make it easier for families to make healthy choices. It means building a health care workforce that is ready for the 21st century health needs of our country. And it means attacking waste and fraud throughout our department to increase efficiency, transparency and accountability. Our 2010 budget does all of this.”

Visionary health psychologist Susan McDaniel and APA Executive Officer Norm Anderson have long been urging our colleagues to become more personally involved in educating society’s leaders and the public regarding the importance of the psychosocial-economic-cultural gradient of quality health care, as well as the increasingly emerging scientific and clinical evidence supporting the critical nature of the social determinants of health. The Secretary clearly has a similar vision. Her budget redirects and increases funding within the Centers for Disease Control and Prevention (CDC) targeted towards reducing chronic disease. Rather than splitting funding and making separate grants for heart disease, diabetes, and other chronic diseases, she has proposed one comprehensive grant that will allow States to address chronic disease more effectively.
Similarly, the prevention resources within SAMHSA would be redirected to fund evidence-based interventions and better respond to evolving needs. States and local communities would benefit from the additional flexibility while funds would still be competed and directed toward proven interventions.

We would rhetorically ask: How many of our colleagues who are primarily in private practice share Division President Glenn Ally’s vision and have developed collaborative relationships with their local state or county health authorities? Glenn, along with two other medical psychologists, works closely with his local Community Mental Health Center; other Louisiana medical psychologists in private practice work with their Children’s and State Psychiatric Hospitals, not to mention serving on numerous State Boards and Committees/Commissions. It is only by becoming active community participants and visionary leaders that psychology will ultimately be well positioned to effectively engage in the policy discussions that determine local plans for implementation of PPACA on a collegial and equal basis with other health care disciplines, interested stakeholders, and government and business community leaders. The President’s vision provides the Administration and States with considerable flexibility to develop local strategies for successfully meeting broad-reaching national objectives. As Jim Quillin keeps reminding us, “All politics are local.”

The HHS Secretary further pointed out that PPACA expands access to affordable coverage to millions of Americans and strengthens consumer protections to ensure individuals have coverage when they most need it. Focusing upon ensuring access to quality, culturally competent care for vulnerable populations: “The budget includes $3.3 billion for the Health Centers Program, including $1.2 billion in mandatory funding provided through the Affordable Care Act Community Health Center Fund, to expand the capacity of existing health center services and create new access points…. (This) will enable health centers to serve 900,000 new patients and increase access to medical, oral, and behavioral health services to a total of 24 million patients.” Her Innovation Center, in coordination with private sector partners wherever possible, will pursue new approaches that not only will improve quality of care, but also lead to cost savings for Medicare, Medicaid, and CHIP. We suspect that very few of our colleagues truly appreciate the long term implications for their daily practices of the PPACA established Patient-Centered Outcomes Research Institute which will be funding research and getting relevant, high quality information to patients, clinicians, and policy-makers, so that they can make informed health care decisions. The Institute of Medicine (IOM) estimates that almost 40% of Americans possess only “basic” or “below-basic” health literacy skills. Thus, their ability to make informed
decisions without concerted assistance will become increasingly difficult as the volume and complexity of data available to them increases. The Patient-Centered Outcomes Research Trust Fund will fund this independent Institute and related HHS activities. Approximately $620 million will be allocated during the coming year as investments in core patient-centered health research activities and to disseminate research findings, train the next generation of patient-centered outcome researchers, and improve data capacity.

The HHS budget also includes $78 million for the Office of the National Coordinator for Health Information Technology to accelerate health information technology (HIT) adoption and promote electronic health records (EHRs) as tools to improve the health of individuals and transform the health care system. One focus will be assisting health care providers in becoming meaningful users of health information technology. One of the Secretary’s priorities should be of particular interest to APA. Her budget provides HRSA with $163 million for Health Workforce Diversity programs to improve the diversity of the nation’s health workforce and improve care to vulnerable populations. These funds will support training programs and scholarship opportunities for students from disadvantaged backgrounds who are enrolled in health professions and nursing programs.

The Department of Defense: “As this year’s Military Nurse Fellow, I was thrilled to attend the Senate Committee on Appropriations defense subcommittee hearing on the DoD Fiscal Year 2012 Health Programs. During this hearing, Senators heard testimony from the Nurse Corps Chiefs and the Surgeons General from the Army, Air Force, and the Navy. Not at all surprising was a universal concern voiced by the Senators regarding the behavioral health of our troops and their families. The Surgeons General and the Nurse Corps Chiefs all mentioned during their testimony that preserving the psychological health of service members and their families is one of the greatest challenges the services face today. The military is not immune to mental health issues or concerns; behavioral health issues affect military members and their families just as they affect the civilian community, perhaps even more so.

“Programs that support, prevent, diagnose, mitigate, and treat behavioral health issues are paramount to ensuring the optimal health of our communities, whether civilian or military.” - 2010 Military Nurse Fellow Lt. Col. Maureen Charles, USAF

“Tragically, the wars in Iraq and Afghanistan have produced a group of combat veterans who face a lifelong struggle to cope with the severe physical and psychological traumas of war. The invisible scars of war cut deep and transcend through military members to their families who are desperately trying to assist their loved ones to cope. The military health system as a whole strives to provide the very best ongoing healthcare for military members and their families including mental health services and support. It is clear that early identification of mental health risks through surveillance, education, and training is a key compo-
The Tablet
Volume 12, Issue 2     July 2011
Page  19

The Army has developed an approach to strengthen their soldiers’ and families’ behavioral health and emotional resiliency through a campaign to align various behavioral health programs. The long term goals of this Comprehensive Behavioral Health System of Care is to protect and restore the psychological health of soldiers and their families and prevent adverse psychological and social outcomes like family violence, DUIs, drug and alcohol addiction, and suicide.

“Citing that no one is immune to the stresses and strains of life, the Air Force testimony identified that one important aspect of patient-centered preventive care includes preserving the mental health and well-being of service members and improving their resilience. Initiatives have been developed to support and train front line supervisors to recognize when an individual may be having difficulties. Counseling services have also been expanded beyond traditional avenues. Other initiatives aimed at addressing behavioral health and resiliency included utilizing a targeted approach that recognizes different risk groups. An overarching theme identified was the utilization of ‘best practice’ programs to help service members become more resilient. An example of this is teaching the afflicted to realize that seeking help is a sign of strength, not a sign of weakness.

“The Navy keyed in on the fact that service members and their families are usually mentally and emotionally strong at baseline, but the long conflict (war) and other related deployment challenge this resilience. Thus, the Navy implemented programs for early detection of stress injuries, which includes focusing on leadership’s role in monitoring the health of their people. Additionally, the programs include providing leaders with tools they may employ when service members are experiencing mild to moderate symptoms and the utilization of multidisciplinary expertise for members more seriously affected.

“It is evident from the testimony that psychological health issues cut across all walks of life. Programs that support, prevent, diagnose, mitigate, and treat behavioral health issues are paramount to ensuring the optimal health of our communities, whether civilian or military. The services are working hard to change the ‘culture’ and are striving to ensure military members are a healthy, fit and resilient force!” (Lt. Col. Maureen Charles, USAF).

The Department of Agriculture: The U.S. Department of Agriculture recently announced a $25 million grant to the College of Agriculture at the University of Hawaii in order to develop obesity prevention strategies among native populations in the Pacific Region, thereby continuing its commitment to meet the rising challenge of obesity in our nation. The Secretary: “We know that in order to win the future, we have to win the race to educate our children. That means that our kids must be healthy so they can learn and thrive. Improving childhood nutrition remains a key priority of the Obama Administration as we work to ensure our kids are ready to out-compete in an increasingly globalized

$25 million grant for the prevention of obesity
world.” This five year initiative will use a community-based participatory research approach that engages communities to prioritize obesity prevention strategies. Researchers will work with the communities to develop community needs assessments and establish sustainable nutrition and health-promoting programs. Specifically, the team will identify specific environmental factors leading to childhood obesity in selected schools and daycare facilities. Intervention strategies will be attuned to culturally-specific needs and goals, and focus on physical activity, nutritional intake, and the amount of sleep children get each night. This is a health psychologist’s dream.

The implications of the similar visions expressed by the leadership of these three federal Departments should be quite exciting for psychology, as long as our practitioners, scientists, and educators are actively engaged in shaping the specifics of the implementation strategies as they gradually unfold. The behavioral sciences have much to contribute to these important national agendas and our visionaries have provided a solid scientifically-based foundation for their success. Involved we must be. Aloha.

**Do something. If it works, do more of it. If it doesn’t, do something else. — FDR**

Do you have a clinical review or grand-round case presentation? If so, we would like to consider it for publication in THE TABLET. Please contact Jim Calvert, Tablet editor, at jcalvert@calvertpartners.com to discuss your ideas.
We are fast approaching the APA Annual Convention, which this year will be held in Washington, DC. I would encourage all of my colleagues who plan to attend to include as much Division 55 programming in your plans as possible. We have a great line up of programs that I believe will be of interest to anyone involved in the RxP movement.

Division 55 programming will start off Thursday, August 4th with an Invited Address, with Dr. Elaine LeVine as Chair, discussing “Five Years Experience With Prescriptive Authority in an Independent Practice.” Following that will be a presentation chaired by Dr. Mike Tilus regarding Prescribing Psychologists Working in the Federal Government. This offering should prove important to anyone interesting in using psychopharm training in the federal system. Later that day, Dr. Alessandra Strada and I will present a luncheon for graduate students and early career psychologists on How to Become a Prescribing Psychologist. Subsequently, Dr. Steve Tulkin will chair a symposium on Psychologists who Prescribe in Primary Care and some of the challenges and experiences encountered in that setting.

On Friday, August 5th, Division 55 programming will start with a very interesting program exploring Psychopharmacological Models of Forensic Practice co-chaired by Drs. Wagdy Loza and David Nussbaum. Later, Dr. Alessandra Strada will chair a discussion on psychopharm in the treatment of patients with cancer, “From Diagnosis to End-of-Life.” Rounding out Division 55 programming on Friday will be a discussion of Adolescents Receiving Multidisciplinary, Residential Care.

Those interested in hearing the latest updates on state legislative issues dealing with RxP will not want to miss the presentations co-chaired by Drs. Beth Rom-Rymer and Jeff Matranga. This will be presented Saturday morning, August 6th. Next, Dr. Jacqueline Gray will chair a symposium on the Circle of Care-Building an American Indian Research Team. Of course, we plan on having a fantastic poster session and
want to encourage everyone to drop by and learn about some of the on-going research related to psychopharmacology.

After lunch on Saturday, I will be delivering an Invited Address on Psychopharmacology and Integrated Care with a look to the future. Later, at 5 p.m., Division 55 will hold our Business Meeting for members followed by the Division 55 Social Hour and Awards Ceremony. You will not want to miss that!

Wrapping up our convention programming on Sunday, August 7th, we will hear an Invited Address chaired by Dr. Anthony Marsella on the Pioneering Work of Dr. Martin Katz in the treatment of Depressive Disorders.

I am truly excited about the line up of very important and informative convention programs that will be available during our annual convention in Washington, DC. This will be an opportunity to not only learn, but to network with colleagues who are interested in psychopharm, those who are teaching and training in psychopharm, those who are using psychopharm training in their daily practices, and those who have prescriptive authority. Please make plans to attend the convention and, by all means, plan to attend all of the excellent Division 55 programming.

Oh, and make sure when you see Dr. Wyatt or Dr. Tulkin, please make sure you express your appreciation for their tireless efforts in putting together this superb line up of Division 55 programming. Hope to see everyone there.

### Division 55 — 2011 Board of Directors

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<tr>
<th>Position</th>
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<tr>
<td>President</td>
<td>Glenn Ally</td>
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<td>Kevin M. McGuinness</td>
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<td>Secretary</td>
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<td>Beth Rom-Rymer</td>
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Before I describe the events of our long legislative session in Montana, I must tell you that there were a number of standout contributions offered by many, some who you may know and others you may not know through the association.

Obviously, first of all Earl Sutherland and his colleagues at Indian Health Service were diligent in their efforts to get our Prescriptive Authority bill through. In fact, in one meeting the four of us actually convinced ‘the representative’ sent by Montana Medical Association to support our bill – that’s how good they were! However, as a subsequent conversation I had with this representative revealed, the Montana Medical Association was not convinced, despite their designated representative’s feedback. This psychiatrist then got up and opposed the bill at the next Committee Hearing.

Our Executive Director, Marti Wangen, and her crew of lobbyists, Sue Weingartner, Gary Spaeth and Tom Rasmussen, did an outstanding job and their endurance and stalwart approach to the Prescriptive Authority bill was heartfelt and a feat, in the face of daunting odds, that we will never be able to fully repay. Then we have the collective efforts of our Board and those of George Watson, Chair of the Board of Psychologists and our Federal Advocacy Coordinator here in Montana. Throughout, they supplied ongoing support and diligence in the face of a series of most challenging circumstances.

Among those outside of the state, we have the crew at APA, Katherine Nordal, Daniel Abrahamson, Deborah Baker, Susie Lazaroff, and in short, CAPP. We have our colleagues from New Mexico, Elaine LeVine, Mario Marquez and Robert Sherrill, as well as our colleagues from Alliant International University/California School of Professional Psychology, Steven Tulkin and Morgan Sammons, among many others.
There will be those I can simply not get to, and for that I do apologize, but I cannot emphasize enough how important it is for all of these groups and individuals to work together on an effort such as this, and, our deep gratitude for it all.

For those of you not from Montana, here’s part of a brief we supplied to our legislature that outlines the problems we are facing here in Montana, and literally why we took up Prescriptive Authority to begin with in 2007. In fact, we did not even plan to introduce the bill then; we were asked to take up the matter by one of our Senators:

**Prescriptive Authority for Psychologists in Montana (Senate Bill 272)**

**What’s The Problem?**

**Provider Shortage.** There is a critical shortage of qualified prescribers capable of providing appropriate psychiatric medication treatments. The majority of psychotropic drugs are prescribed by primary care physicians, physician assistants and advanced practice nurses who have limited mental health training. **Wait times** to see a psychiatrist typically range from 3 months to a year. Many psychiatrist’s practices are simply closed to new patients. Primary care providers are also becoming increasingly scarce. Anyone in crisis, someone in danger a attempting suicide, having thoughts about harming others or in need of immediate intervention, cannot wait. The most obvious example of the mental health services crisis in Montana is that we have the **second highest suicide rate (Alaska is first)** in the nation. **This means that an average of one Montanan every other day is dying by suicide. Fifty (50) Montanans will die by completing suicide during this legislative session.**

Since that time, we had done our homework and prepared diligently for this Legislative Session; but as many of you know Legislatures across the country in 2011 were not your ‘average’ Legislatures. In fact, here in Montana we had 49 freshman Legislators out of a total of 150 Legislators, and the Legislature only meets every other year.

As I stated at the State Leadership Conference (SLC) in mid-March with some humility and deference to all those named above, all of our hard work and preparation paid off as the bill came sailing out of the Senate on a vote of 36-13 on Second Reading, and 35-15 on Third Reading when we only needed 26 votes.

Earl Sutherland and I were in the gallery when the vote occurred, and the shift in the chamber was palpable when it was being argued. Watching the board where the votes are recorded, it was stunning to
see the vote count quickly reel past 26 and on to 36 the day we were there. As I wrote in my legislative newsletter article for May, all of us made this happen.

The House, however, was a different matter. While we knew we had challenges, it was actually on my plane flight back from SLC in the Denver Airport that I first became aware of how influential bald-faced politics and power struggles were going to be in interfering with the progress of our bill. As it turns out, the House became a place where politics and power supplanted the value of human life, literally. What I can tell you bluntly is that what stymied this bill had nothing to do with the merits of the bill, nor the efforts of those in opposition to the bill. It had to do with politics. Powerful forces within the House literally held the bill hostage for votes on another matter. It’s as plain as that.

While our collective efforts in the weeks following the vote on the Senate floor had prepared the bill for a Hearing in the Business and Labor Committee, on March 14th the bill was voted out of that Committee into the Human Services Committee by literally “one” vote. We felt that our work had been sufficient to get the bill out of the Business and Labor Committee, but this political move thwarted all the work that had been done on that front in the weeks and months before. We did appeal the bill’s movement into the Human Services Committee but our appeal was denied.

There in the Human Services Committee, despite solid testimony on our behalf and a strangely extended period of opposition testimony which lasted twenty minutes longer, the bill was voted down 14 to 1. The oddity of these circumstances was underscored by the fact that this vote has never been recorded on the state’s legislative website and the audio recording of it was not available for weeks after the Hearing (typically available the next day).

Ms. Wangen, our Executive Director, and our lobbying crew said it wasn’t over yet and told me that there was still work to be done, much to my surprise. Our House Sponsor, Representative Roberts, and others felt that we could ‘blast’ the bill out of Committee. In Montana this meant that we would need a 3/5th vote on the House Floor in order to accomplish this task (roughly between 58 and 60 votes depending who was in attendance), and that this would resurrect the bill out of the Human Services Committee onto the House Floor. So, all of us went to work — Board, Members, etc.

We did what was viewed as a trial blast on the 30th of March to see who would vote in favor and who would vote against it. Ultimately this motion failed on a vote 39 to 56. We recognized then the similarity of the vote that put the bill in the Human Services Committee to begin with, and that in order to shift the track of this vote we would have to work against the aforementioned powerful political interests in the House in
order to even get to a simple majority (49 to 51 votes depending who was in attendance).

We still had a chance to “blast” the bill out of committee

After a great deal of work, we were ready for another blast, and while we had the commitment of almost 60 Representatives, in the waning days of the 2011 Legislative Session it seemed that either these Representatives were not good on follow-through or did not understand that the bill, which they had agreed to vote for, was again up for vote. With a vote of 50 to 47 (4/18/11) we did achieve a simple majority, and had this bill gone through conventional routes we would have been out of the House on such a vote.

But bald-face politics had sequestered the bill in the Human Services Committee where it would remain until the matter was confronted one more time with another blast that again achieved a simple majority (49 to 48) and fell short of the 3/5ths boost needed to exit it from the Committee on 4/20/11. Looking at these voting results, what most will not realize is that across these blast attempts we had 62 Representatives vote in favor of the bill, just not all on the same day! As maddening as this may be, one might argue there’s something to be said for voting consistently.

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It is important to understand that putting forth an effort such as this in the face of powerful political forces, where certain Representatives make other Representatives ‘pay’ for voting their conscience, was difficult and tricky for all involved. In the face of these odds it was certainly commendable at the very least. In addition, we were also confronting stiff and uncompromising opposition throughout, which spoke volumes to the efforts of our supporters, members, Board, lobbyists, and our Executive Director. We got into this bill to help save lives, reduce suffering, and provide treatment alternatives. This level of effort honored those whom we meant to serve.
What is disconcerting, to put it mildly, is that in the final analysis there was no viable safety argument against Prescriptive Authority, and now our fellow Montanans are left without desperately needed services with the second highest per capita suicide rate in the nation. Yet politics, power struggles, Montana’s NAMI (unlike some other states), Montana Psychiatric Association, and the Montana Medical Association stood against the bill — in effect, continuing to allow one Montanan to die every other day from a completed suicide and thousands more to suffer because of lack of access to care. This, in my mind, is deplorable and violates the foundation of public service and a healthcare provider’s moral obligation.

I would hearten all of you within Division 55 to hold the lessons of our Legislative Session near, and to continue to work conscientiously to improve the quality of care and hold entities like those above accountable for the suffering they continue to allow in favor of the politics of power. Again, our thanks go out to all who assisted us in this effort and in our future efforts to get prescriptive authority passed in Montana.

**Legislative Update—In Brief**

**New Jersey** — In the last year New Jersey has made significant progress towards gaining prescriptive authority. The New Jersey Academy of Medical Psychologists with the full support of the New Jersey Psychological Association has taken the lead in the RxP battle. RxP legislation, based upon the APA model legislation, has been introduced in to the State Assembly and the State Senate. The bills A3745 and S2860 are identical. Our lobbyist who has been instrumental in moving our legislation is experienced in scope of practice issues having been successful in increasing the scope of practice of other medical professions. Our sponsors in both houses are experienced politicians and familiar with the special challenges a scope of practice bill entails.

- Sean R. Evers, PhD, MSCP, Executive Board, New Jersey Academy of Medical Psychologists

Do you have a legislative update regarding RxP? If so, please send it to Jim Calvert, Tablet editor, at jcalvert@calvertpartners.com
I was sitting in a continuing education workshop two weeks ago. The presenter was discussing his research and proudly declared that he was getting significant findings. He presented us with correlations of .21 and .23, which were significant because he used hundreds of subjects for his study, and he presented these correlations as very important. He further told us that these correlations meant that the variables he was discussing shared 21% and 23% of the variance with each other, respectively. As you no doubt recognize, correlations of .21 and .23, while possibly statistically significant given a large subject pool, are rather small and probably insignificant in “real world” terms. He also forgot (never knew?) that he should have used $r^2$ for shared variance, meaning that his variables shared about 4%-5% of the variance with each other, a far cry from the 20+% he was claiming.

This workshop wasn’t about psychopharmacology, but it got me to thinking about the importance of understanding research methods and statistics for psychopharmacology. It’s not that we need to be research gurus, but it is important to understand research. Indeed, it is psychologists’ understanding of research that puts us at the forefront of understanding the efficacy, or lack thereof, of medications. There is no other clinical healthcare profession that requires as in-depth an understanding of research as psychology. Think about how many courses you had to have on research methods and statistics in undergraduate and graduate school. Even if you don’t conduct research now, this preparation helps you understand research and make better clinical decisions for your patients.

In their article on “new” antidepressants (see the first article in this issue), Drs. Phelps and Carlat highlight concerns with research on medications. They point out that recent research has shown that persons on Oleptro showed an 11-point decrease on the HAM-D measure of depression, while those on placebo showed a 9-point decrease. Statistically, that two-point spread is significant and indicates that Oleptro was
better than placebo at decreasing depression. However, as pointed out by Drs. Phelps and Carlat, the effect size is quite small (d=0.28). Such a small effect size indicates that the “significant” difference is not very robust and is unlikely to be clinically significant. Because of concerns that many treatment studies are able to show statistically significant differences that may not be clinically significant, more journals are now requiring that researchers also publish the effect sizes since increasing sample size increases the chances of finding significant differences but effect size computations are not affected by sample size.

But how many clinicians know the issues and concerns about finding a statistically significant difference but having a small effect size? Many healthcare professionals, including physicians, when presented with information that Drug A is statistically superior to Drug B and/or placebos, would assume that Drug A is clearly the drug to choose. They wouldn’t even think to consider effect size or other factors. And with many medications showing questionable clinical significance over other drugs or even placebo (e.g., Oleptro, Pristiq), understanding the research is more important than ever in being responsible prescribing professionals.

**We need to be the vanguard of modern evidence-supported pharmacotherapy**

As the healthcare professionals with the most extensive training in research, psychologists need to use their knowledge to connect pharmacology research with clinical practice. Psychologists have been leaders in developing guidelines for evidence-supported psychotherapy and therapeutic relationships, and we have codified it by publishing these guidelines. However, for the most part, psychologists have been relegated to the sideline when developing pharmacotherapy guidelines. As we move into the clinical realm of pharmacotherapy, we need to be the vanguard of modern evidence-supported pharmacotherapy.

Treatment algorithms for pharmacotherapy, such as the Texas Implementation of Medication Algorithms (TIMA), have helped guide medication selection by prescribing professionals. There are many other guidelines and algorithms that are already published, but many are only loosely based on research findings or are quickly becoming outdated. Our training in research puts us in an ideal position to develop pharmacotherapy guidelines based on the best research.

On a very practical level for RxP, developing drug treatment guidelines from within our profession helps establish psychologists as the treatment experts for mental health. We can tell the public and legislators all day that we are knowledgeable about medications and capable of prescribing, and even though we have demonstrated our capabilities, until we are perceived as experts in psychopharmacology, it will be difficult to convince those outside of psychology. Developing respected, research-based guidelines will help establish that expertise in the eyes of those outside of psychology.
“It’s poison I tell you, it’s poison!” These were the words said by a young George Bailey (played by Jimmy Stewart in It’s a Wonderful Life) as he was being beaten by Old Man Gow-er, a well-intentioned yet absent minded pharmacist who had mistakenly filled a child’s prescription with cyanide. The process of filling prescriptions has changed significantly since the 1930s as it was portrayed in the 1947 classic “It’s a Wonderful Life.” Today, medica-tions are manufactured under pristine, sanitized conditions, packaged, sealed and sealed again. Each prescription pill, tablet or capsule is required to be marked with identifying in-formation that can be used to quickly ascertain the medication and the dosage by anyone almost anywhere. For the purposes of this discussion let us assume that this process has eliminated all of the potential errors that could occur between the writing of a prescription and what ultimately enters a patient’s body.

However, even with careful manufacturing, marking, and packaging, we still find that over 2,200,000 Americans made visits to the emergency room in 2009 even though they took the medication they were sup-posed to take as they were directed. These patients had also taken one or more additional medications as directed, leading to a negative drug-interaction (Drug Abuse Warning Network [2011]. National estimates of drug-related emergency department visits: 2004-2009. Center for Behavioral Health Statistics and Quality, SAMHSA: Rockville, MD). Outcomes for these patients ranged from treat-and-release to mortality, and these numbers do not include patients who sought non-emergency care or did not seek care.

What can we do with this data? We can be dismissive because there are too many possibilities that could also account for the 2.2 million ER than just drug-interactions, even though drug interactions played a role in these visits. We can get infuriated with the prescriber who added the second, third, or fourth medication that caused the arrhythmia, hypotensive crisis, hyperthermia, loss of consciousness, liver failure, stroke, and so-on and so forth. Or, we can beat young George in the head until he shuts up and takes his medicine.

Of course, being dismissive, becoming infuriated, or blaming the victim doesn’t help solve the prob-lem. And in some ways, the fact that these 2.2 million got help is better than the untold millions who have a bad drug reaction and never tell anyone. The truth of the matter is that aside from the several thousand suc-
cessful malpractice claims and the handful of cases that were successfully prosecuted criminally, most clinicians will never know that their prescription seriously harmed a patient. In many cases the side effects are mild and the patient never tells anyone or doesn’t even realize his problems were created by the drug interactions. In some cases the side effects are chalked up to other problems besides drug interactions. As prescribing psychologists it is incumbent on us to be aware of drug interactions so we can prescribe in order to reduce negative interactions and recognize symptoms should interactions occur.

In the next issue of The Tablet we want to start a dialog on drug interactions. To help keep us focused, let’s start with Serotonin Syndrome (SS). Why SS? Because the muscle relaxant your patient’s orthopedist prescribed is also a tricyclic SNRI (cyclobenzadrine). Several of your patients may be prescribed narcotics analgesics such as fentanyl or meperidine and others tramadol or the NSAID indomethecine. In fact, medications from methylene blue to anti-fungals and anti-virals are being implicated as the 2nd or 3rd culprits in cases of severe and sometimes lethal SS.

All of the medications cited above were identified in PubMed (National Library of Medicine) using the search terms “serotonin syndrome” and “drug interaction.” Each medication was posited to have been a causative factor of SS in a case-study or case series. However, is there enough evidence in the peer-reviewed literature to warrant concern? In the next issue we will look at the signs and symptoms to look for in traditional models of SS (e.g., MAOI-TCA interactions). We will also discuss recent compelling arguments that SS is synonymous with Neuroleptic Malignant Syndrome.

We want your input about SS. Have you encountered SS in your practice? Do you have research on SS? Please send comments or feedback to Nick Patapis, Psy.D. at nick@patapispsychological.com.

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