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Opioid Analgesics...Does High Utilization Equal Addiction?

The utilization of opioid analgesics (Lortab®, Percocet®, OxyContin®, etc.) has become the gold standard in the treatment of moderate to severe pain in patients who do not respond to non-opioid analgesics (Tylenol® and non-steroidal anti-inflammatory drugs [NSAIDs]). This popularity is due in part to the fact that opioid analgesics are generally very effective, typically easy to titrate, and have a favorable safety profile when used in a medically appropriate fashion. Of significant benefit is the fact that these agents, with few exceptions, do not have a maximum dose. The use of opioid analgesics in the treatment of pain is predicated upon the medication's ability to improve the functional status of the injured worker. As such, dosage increases of these medications are reasonable if they contribute to reduction of pain resulting in improvement of the injured worker's ability to perform job functions, activities of daily living, etc. Continued use of opioid analgesics, and certainly dosage increase, is not recommended when the injured worker's functional status fails to improve or worsens in the presence of these medications.

Although opioid analgesics can be extremely useful and effective in injured workers suffering from legitimate pain syndromes, the use of these agents for non-medical purposes has risen dramatically since the turn of the century. The Substance Abuse and Mental Health Services Administration (SAMHSA) reported an increase of illegitimate opioid utilization of 330% between 1990 and 2001, signifying that opioid analgesics may be experiencing a virtual transition from a viable treatment option for painful conditions to an object of potential abuse. Although words like, 'dependence' and 'addiction' come to mind when talking about opioid abuse situations, it is important to understand that there are drastic differences between these phenomena.

Physical dependence, often times confused with addiction, occurs with opioid analgesics as well as many other classes of medications (i.e., antihypertensives, corticosteroids, etc.). It is expected to occur in most injured workers chronically utilizing opioid analgesics. This phenomenon can be characterized as an abstinence syndrome secondary to sudden cessation of the agent, rapid reduction in dose, or presence of another antagonizing substance. Physical dependence is a normal state of adaptation brought on by the presence of consistent drug levels in the body and is typically not problematic if discontinuation of the medication is carried out over time, utilizing a gradual weaning process. Injured workers experiencing physical dependence of opioid analgesics may suffer from anxiety, irritability, nausea, and vomiting with abrupt cessation of the agent. These symptoms are avoided with continuous use of the medication. A key distinguishing feature of physical dependence when compared to addiction is the lack of drug-seeking behaviors and/or loss of control over drug utilization.

Much like physical dependence, **tolerance** develops secondary to the long-term presence of consistent drug levels in the body. Tolerance can be defined as a gradual decrease of a drug's effect over time. Again, this phenomenon is expected to occur in the majority of injured workers chronically utilizing opioid analgesics. Although tolerance is often beneficial (tolerance to respiratory depression, nausea, vomiting, and somnolence, in the case of opioid analgesics), lack of tolerance to certain adverse side effects, such as constipation, can also be problematic. Typically, tolerance to the analgesic effect of an opioid analgesic occurs in the first few weeks/months of therapy and remains fairly consistent from that point on. Because of this physiological effect, it is

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completely plausible for an injured worker to require relatively high doses of opioid analgesics for pain control without becoming addicted to these medications.

Addiction can be defined as a primary, chronic, multifactorial disease with biological, environmental, and psychological attributes. Unlike physical dependence and tolerance, addiction can be characterized by a host of drug-seeking behaviors such as impaired control over drug utilization, continued use despite harm, and the presence of cravings. The disease of addiction can take on many forms, such as obtaining multiple opioid analgesics from numerous physicians, missed office appointments with after-hours calls for prescription refills, and theft of prescriptions. Current data suggest that the prevalence of addiction is relatively low. As such, fear of addiction should not be the primary concern when deciding whether or not to implement opioid therapy in an appropriate candidate. When the unfortunate instance of addiction does occur, it is imperative that the injured worker's pain management treatment plan be reconsidered, as the use of opioid analgesics in an addicted individual is not indicated. Pain management for individuals addicted to opioids should consist of non-opioid medications, psychological interventions and other treatment modalities. Consultation with a pain management specialist is strongly recommended.

Pharmacy Benefit Managers (PBMs) can play a significant role in detecting and alerting potential addictive behaviors. PMSI

currently utilizes several clinical intervention programs to detect potential opioid misadventures and target medication usage patterns indicative of potential abuse situations. Our premier program, the Arkos Risk Management™ System, provides notification to prescribers regarding injured workers using multiple prescribers and/or multiple pharmacies for their medications, including opioid analgesics. It is widely accepted that injured workers utilizing multiple prescribers in the ambulatory setting are at risk for medication-related problems. Due to the inherent risk for medication misadventures associated with the use of multiple opioid analgesics, it is expected that the presence of multiple prescribers will intensify this risk.

Arkos, which is a retrospective drug utilization review program, allows our in-house clinical pharmacists to identify potential therapeutic concerns, such as duplicate therapies, inappropriate dose/duration of therapy, and refill-too-soon situations that can signal opioid abuse. In addition, PMSI Clinical Services is currently piloting several pharmacy programs intended to decrease inappropriate utilization of opioid analgesics by injured workers. These programs, coupled with our clients' internal case management initiatives, are on the front line of driving appropriate opioid utilization and reducing the potential for opioid abuse and diversion.



new drug alerts

Pristiq™ (desvenlafaxine)
Approved: February 2008

Wyeth Pharmaceuticals received approval from the U.S. Food and Drug Administration (FDA) for Pristiq, the newest product to join Effexor XR® (venlafaxine) and Cymbalta® (duloxetine) in the norepinephrine-serotonin re-uptake inhibitor class of antidepressant therapy. Pristiq contains the same active metabolite as Effexor XR, but does not require activation by the body to convert to the active form. Pristiq is currently FDA approved only for the treatment of major depressive disorder (MDD) in adult patients. It is thought that Pristiq may play a significant role in replacing Effexor XR for the treatment of major depression in late 2008, when it is anticipated that it will lose patent protection. In the injured worker population, Effexor XR is used primarily for the treatment of neuropathic pain; neither Pristiq nor Effexor currently have an FDA indication for neuropathic pain. Recently, Effexor XR has experienced a decline

in market share in the workers' compensation market due to aggressive marketing for Cymbalta (duloxetine), which is FDA approved for the treatment of neuropathic pain.

RELISTOR™ (methylnaltrexone)
Approved: April 2008

RELISTOR received FDA approval for the treatment of constipation caused by opioid utilization in patients with advanced disease receiving palliative care. RELISTOR was developed through a joint effort between Wyeth and Progenics Pharmaceuticals and is the first U.S. agent to target opioid-induced constipation in the palliative care population. RELISTOR has been shown to effectively reduce constipation without subsequently affecting the analgesic ability of opioid analgesics. The new drug became available in June 2008.



features

Bupropion XL Update

In the February 2008 edition of PMSInfo, we featured a story regarding investigations by the FDA into allegations of increased adverse effects in patients utilizing the popular antidepressant Bupropion XL after switching from the brand-name version, Wellbutrin XL®. On April 16, 2008, the agency released its conclusive findings after conducting an investigation regarding the bioequivalence and therapeutic equivalence of the two agents. Upon review of the 85 post-marketing reports of undesirable adverse effects (i.e., nausea, irritability, insomnia, etc.) in patients who switched from the brand-name version to the generic equivalent, the agency concluded that it was unable to discover statistically significant differences in drug concentration/release rate characteristics that would lead it to believe that the two agents were not interchangeable. The FDA reiterates the fact that all generic agents must contain the same active ingredient, dosage form, administration route, and labeling as the brand-name product. By law, generic products must be proven to be bioequivalent (same rate and extent of absorption) and therapeutically equivalent (interchangeable) to the brand-name agent.

Reference: "Review of Therapeutic Equivalence: Generic Bupropion XL 300 mg and Wellbutrin XL 300 mg." U.S. Food and Drug Administration. www.fda.gov/cder/drug/infopage/bupropion/TE_review.htm. <Accessed May 2, 2008>



DEA Gives Final Okay for Opioid Multiple Prescription Rule

The U.S. Drug Enforcement Agency (DEA) has announced that it has made its decision regarding the amendment of regulations on the issuance of multiple same-agent CII prescriptions to a patient. This announcement comes after a September 2006 proposal by the DEA to allow prescribers to issue multiple prescriptions for a schedule II substance secondary to various factors, such as limited patient access to doctor visits, travel, and the lack of need for monthly assessments in certain patients. Current federal regulations prohibit the refilling of a schedule II prescription; the new policy is intended to allow physicians to provide a 'prescription series' or a set of prescriptions providing up to a 90-day supply with wording to indicate that each prescription should only be filled after a certain date. The Controlled Substances Act (CSA) adopted in 1970 did not address this issue; however, the DEA notes that federal regulations do not and have never placed restrictions on the quantity of a controlled medication that can be obtained from a single prescription.

Reference: "Issuance of Multiple Prescriptions for Schedule II Controlled Substances" Federal Register/Vol. 72, No. 222, November 19, 2007/ Rules and Regulations. www.access.gpo.gov/su_docs/fedreg/a071119c.html. <Accessed May 19, 2008>

Teva Approval to Market Generic Prevacid Capsules Thwarted

Industry giant Teva Pharmaceutical Industries announced that it was expecting to receive approval from the FDA to market the generic version of the hugely popular proton pump inhibitor, Prevacid®. Teva Pharmaceuticals was awaiting the end of a 30-month stay issued after a patent infringement suit from Prevacid manufacturer Tap Pharmaceutical Products, Inc. If U.S. District courts rule that Tap Pharmaceutical's patent for Prevacid is not enforceable, or that it has not been infringed upon, then Teva will be given the go-ahead to begin marketing their generic equivalent, lansoprazole delayed-release capsules. In April 2008 Teva was informed that U.S. District Courts had ruled that Tap Pharmaceutical's patent was valid and enforceable; thereby, thwarting Teva's plans to market a generic equivalent, at least for the time being. Teva Pharmaceutical is currently planning to appeal this ruling. Prevacid is a proton pump inhibitor currently FDA approved for the treatment of various gastrointestinal disorders. The use of anti-ulcer therapy has seen a gradual increase due to increased awareness of the dangers of gastrointestinal ulceration secondary to the utilization of NSAID analgesics.

Reference: "Teva to Contest Prevacid Patent Challenge Ruling" www.fdanews.com. <Accessed: May 19, 2008>



King Pharmaceuticals Receives Warning Letter for Avinza Advertisements

The Food and Drug Administration recently issued a warning letter to King Pharmaceuticals secondary to potentially false and misleading advertisements regarding King's once-daily opioid analgesic, Avinza®. The FDA's Division of Drug Marketing, Advertising, and Communications claimed that King Pharmaceutical's marketing materials were misleading and de-emphasized potentially fatal risks associated with the use of Avinza. The FDA-approved product labeling for Avinza contains several warnings including the potential for fatal overdose if the agent is utilized in a manner inconsistent with the package labeling. Marketing materials produced by King Pharmaceuticals allegedly failed to effectively indicate potentially serious side effects while stating numerous efficacy claims violating the concept of fair and balanced disclosure required for direct-to-consumer advertisements. King Pharmaceuticals was given an April 2008 deadline to provide a plan of action and discontinue circulation of the materials in question.

Reference: "Avinza Warning Letter" Food and Drug Administration. March 2008. www.fda.gov/cder/warn/2008/Avinza-wl.pdf. <Accessed May 19, 2008>

clinical literature digest studies

STUDY #1: Dronabinol Added to Current Opioid Therapy Shown Effective for Chronic Pain Management

The management of chronic cancer and non-cancer pain typically involves the use of opioid analgesics. Due to the limited evidence of efficacy and safety with long-term use of these agents, research is being conducted to identify other useful medications. With the discovery of cannabinoid receptors in mammals, there has been increased interest in the use of cannabinoids for various medical conditions including chronic pain management. One such agent, dronabinol (Marinol®), is a cannabinoid approved for the management of nausea and vomiting in cancer patients. Cannabinoids have been shown to reduce neuropathic pain hypersensitivity and to have a synergistic relationship with opioids in animals.

The purpose of this study was to evaluate the efficacy of dronabinol in the management of moderate to severe chronic non-cancer pain in patients already receiving opioids. The study consisted of two phases: a single-dose, double-blinded, placebo-controlled trial (phase 1) and a multi-dose, open-label extension study (phase 2). Phase 1 compared dronabinol 10 mg and 20 mg to placebo. Total pain relief at eight hours was significantly greater in both treatment groups compared with placebo. Significant decreases were also found in evoked pain, average hourly pain relief, and average pain intensity in the treatment groups.

Participants enrolled in phase 2 were given a one-month prescription for dronabinol with specific directions on starting dose and proper dosage titration based on individual response. There was a significant decrease in average pain scores at the end of four weeks when compared to baseline. Pain relief and patient-reported satisfaction increased throughout the four-week period. There were also significant improvements in pain interference with sleep, energy/fatigue, and social functioning. The most common adverse effects reported included dry mouth, drowsiness, and dizziness. This study suggests that dronabinol may be efficacious in the management of pain when added to opioid therapy.

Narang S, Gibson D, Wasan AD, et al. "Efficacy of Dronabinol as an Adjuvant Treatment for Chronic Pain Patients on Opioid Therapy" *J Pain*. 2008; 9: 254-64.

STUDY #2: Economic Impact of Low Back Pain May Have Previously Been Underestimated

Low back pain (LBP) is a common complaint throughout the world. It is estimated that about 7% of the adult population in the UK visit their general practitioners for LBP. In the United States, LBP has been associated with 149 million lost work days annually, which results in an annual cost of approximately \$28 billion. Research on the relationship between health and work has primarily focused on return to work; however, little is known about whether patients return to the same occupation with the same daily job duties. The objective of this study was to compare the impact of LBP on self-reported return to usual employment, return to work with reduced job duties, sick leave, and unemployment due to LBP.

Patients who visited their general practitioner to report LBP during the study period were asked to complete questionnaires at baseline and at 12 months to evaluate their employment status. Employment restrictions including the need for reduced duties or sick leave secondary to LBP were assessed. If unemployment was reported, the reason was obtained. A total of 65% of participants were employed at baseline with the majority returning to their usual job (67%); 11% reported reduced duties and 22% reported sick leave. Of the 83% of patients reporting reduced job duties, the reason given for this change was due to LBP. Of those patients reporting sick leave at baseline, 88% reported that it was secondary to LBP. Of those reporting unemployment at baseline, 37% reported that it was secondary to LBP. Depression, anxiety, disability, and a longer duration of LBP were reported in patients reporting sick leave, reduced job duties, or unemployment due to LBP at baseline.

At the 12-month follow-up, 95% of patients reporting employment in their usual job at baseline remained employed. One-third of patients reporting reduced job duties secondary to LBP remained in this category at follow-up. A total of 15% of those reporting sick leave at baseline continued to report sick leave at follow-up. Of those reporting unemployment due to LBP at baseline, 90% continued to report unemployment secondary to LBP. Therefore, this study implies that the impact of low back

pain on employment status, ability to perform normal job duties, and sick leave is important and can lead to significant costs.

Wynne-Jones G, Dunn KM, and Main CJ. "The Impact of Low Back Pain on Work: A Study in Primary Care Consulters" *Eur J Pain*. 2008; 12: 180-8.

STUDY #3: Topical Amitriptyline 5% Ineffective for Neuropathic Pain Management Compared to Topical Lidocaine 5% and Placebo

Neuropathic pain is pain caused by direct damage to or dysfunction(s) of nerves. Signs and symptoms typically include spontaneous pain, numbness, weakness, and hypersensitivity. Amitriptyline (Elavil®) is an antidepressant shown to be efficacious in the management of many types of neuropathic pain. It is typically administered orally, which can result in significant systemic adverse effects. Due to these significant adverse effects, studies have been conducted to determine if topical application of amitriptyline provides pain relief. The results of previous studies have been variable, so a consensus on the efficacy of topical amitriptyline has not been determined.

The primary objective of this study was to determine if compounded topical preparations of 5% amitriptyline or 5% lidocaine were efficacious compared to placebo in neuropathic pain management. Participants were instructed to apply the study drug twice daily for one week, which was followed by a one-week washout period. This was done for each of the three treatments. A significant reduction in the patient's level of pain, as reported via the Visual Analog Scale (VAS), occurred with topical lidocaine; however, there was no significant change with topical amitriptyline or placebo. Lidocaine and placebo both produced greater reductions in pain levels than amitriptyline. The most commonly reported adverse effect was itching. This study suggests that topical amitriptyline is less efficacious than placebo; however, it remains unknown if other strengths of compounded topical amitriptyline are efficacious in the management of neuropathic pain.

Ho K-Y, Huh BK, White WD, et al. "Topical Amitriptyline versus Lidocaine in the Treatment of Neuropathic Pain" *Clin J Pain*. 2008; 24: 51-5.

FDA update

New Drug or Formulation

Luvox® CR (fluvoxamine)

Approved: February 2008

Luvox CR was approved for the treatment of social anxiety disorder and obsessive compulsive disorder. The regular-release generic formulation of this agent has been available since December 1994; however, the brand-name version (**Luvox**) has been discontinued in the United States since 2002. **Luvox CR** became available in March 2008. The introduction of this agent is likely to offer no clinical benefit over the generically available regular-release formulation.

Aplenzin™ (bupropion hydrobromide)

Approved: April 2008

Biovail Pharmaceuticals received FDA approval for **Aplenzin**, a new alcohol-resistant salt formulation of the popular antidepressant, bupropion hydrochloride. **Aplenzin** will be available in 174 mg, 348 mg, and 522 mg dosage strengths and much like **Wellbutrin XL**, will offer once-daily dosing. Biovail states that the 'alcohol resistant' nature of **Aplenzin** will allow users to consume alcohol while utilizing **Aplenzin** therapy; a strategy aimed at curbing the 'dose dumping' effect that is theoretically suggested in patients who utilize bupropion therapy and alcohol concomitantly. Due to the limited clinical significance of this phenomenon it is unlikely that this agent will offer any clinical benefit over existing bupropion formulations.

New Launches

Treximet™ (sumatriptan/naproxen)

Approved: April 2008

Treximet received FDA approval for the acute treatment of migraine headaches with or without aura in adult patients. **Treximet** is currently available as an 85 mg/500 mg combination tablet. It is unclear if the introduction of this agent will offer any significant benefit over current migraine therapy.

Generic Drug Arrivals

Combunox® (oxycodone/ibuprofen)

Approved: November 2007

The combination oxycodone/ibuprofen analgesic known as **Combunox** (formerly known as **Oxyprofen™**) is now available as a generic. Oxycodone/ibuprofen is currently FDA approved for the treatment of moderate to severe pain and is available as a 5 mg/400 mg (oxycodone and ibuprofen, respectively) combination tablet.

Prilosec® (omeprazole)

Anticipated launch date: fourth quarter 2008

It is anticipated that omeprazole 40 mg will become available late 2008 and join the already available 10 mg and 20 mg generic versions of the hugely popular proton pump inhibitor, **Prilosec**.

Wellbutrin XL® (bupropion)

Approved: May 2008

The generic version of the popular antidepressant **Wellbutrin XL** is now available in a 150 mg dosage form. The 300 mg dosage form has been available generically since 2006.

Labeling Change

Cymbalta® (duloxetine)

Approved: November 2007

Cymbalta received an expansion in labeling to include long-term maintenance therapy for major depressive disorder. **Cymbalta** has been used as adjunctive therapy for the treatment of neuropathic pain since 2005. This drug currently represents approximately 90% of all PMSI medication utilization increases within the antidepressant drug class and 7.7% of total prescription utilization increases.

FDA MedWatch Reports

Anticonvulsants and Suicidal Ideation

Posted January 31, 2008—The FDA informed healthcare professionals that the Agency has issued a warning regarding possible suicidality (suicidal thinking and behavior) with the use of most anti-epileptic medications as a result of its

evaluation of reports of suicidal behavior or ideation with several of these agents. This warning stems from an analysis of data from placebo-controlled clinical studies of 11 antiseizure agents. These medications are commonly used to treat epilepsy as well as psychiatric and other conditions. The FDA's analysis found that patients receiving anti-epileptic drugs had approximately twice the risk of suicidal behavior or ideation (0.43%) compared to patients receiving placebo (0.22%). The increased risk of suicidal behavior and suicidal ideation was observed as early as one week after starting the anti-epileptic medication and continued through 24 weeks. The results were generally consistent among the 11 drugs. Notably, the relative risk for suicidality was higher in patients taking these medications for epilepsy compared to those given these medications for psychiatric or other conditions.

Healthcare professionals should closely monitor all patients currently taking or starting any anti-epileptic drug for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts/behavior or depression. The following medications were included in the FDA's review:

- Carbamazepine (marketed as Carbatrol®, Equetro™, Tegretol®, Tegretol® XR)
- Felbamate (marketed as Felbatol™)
- Gabapentin (marketed as Neurontin®)
- Lamotrigine (marketed as Lamictal®)
- Levetiracetam (marketed as Keppra®)
- Oxcarbazepine (marketed as Trileptal®)
- Pregabalin (marketed as Lyrica®)
- Tiagabine (marketed as Gabitril®)
- Topiramate (marketed as TOPAMAX®)
- Valproate (marketed as Depakote®, Depakote® ER, Depakene®, Depacon™)
- Zonisamide (marketed as Zonegran®)

Although the 11 drugs listed above were the only agents included in the analysis, the FDA expects that the increased risk of suicidality is shared by all anti-epileptic medications and anticipates that class labeling changes will be applied.

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FDA MedWatch Reports

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Duragesic® Patch Recall (PriCara/Sandoz)

Posted February 15, 2008— PriCara and Sandoz, Inc. announced a nationwide recall of all lots of 25 mcg/hr Duragesic patches sold in the United States. The product is being recalled because the patches may have a cut along one side of the drug reservoir within the patch, which may result in the possible release of fentanyl gel that may expose patients or caregivers directly to fentanyl gel on the skin. Fentanyl is a potent CII opioid medication and exposure to the gel may lead to serious adverse events, including respiratory depression and possible overdose that may be fatal. Patches with a cut edge should not be used. These recalled patches have expiration dates on or before December 2009 and are all manufactured by ALZA Corporation.

Fentanyl Transdermal Patch Recall (Abrika/Actavis)

Posted February 19, 2008— Actavis, Inc. announced a nationwide recall of certain lots of fentanyl transdermal system CII Patches sold in the United States and labeled with an Abrika or Actavis label. The product may have a fold-over defect, which can cause the patch to leak and expose patients or caregivers directly to the fentanyl gel. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. The lots covered by this recall include doses of 25, 50, 75, and 100 mcg/hr and are listed in the firm's press release, which can be found at www.fda.gov/oc/po/firmrecalls/actavis03_08.html.

Singulair® Associated Mood Alterations

Posted March 27, 2008— The FDA informed healthcare professionals and patients of the Agency's investigation of the possible association between the use of Singulair and behavior/mood changes, suicidality and suicide. Singulair is a leukotriene receptor antagonist used to treat asthma and the symptoms of allergic rhinitis, and to prevent exercise-induced asthma. Patients should not stop taking Singulair before talking to their physician. Healthcare professionals and caregivers should monitor patients taking Singulair for suicidality and changes in behavior and mood. This early communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews of drugs. Due to the complexity of the analyses, FDA anticipates that it may take up to nine months to complete the ongoing evaluations. As soon as this review is complete, FDA will communicate the conclusions and recommendations to the public.



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