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Medical Marijuana and the Vermont Pharmacist

Portions of this article have been previously published in the July 2011 Montana Board of Pharmacy Newsletter *and are reprinted here with permission.*

In 2004, the Vermont General Assembly passed S 76, An Act Relating to Marijuana Use by Persons With Severe Illness. The legislation creates an exemption in state law from criminal penalties for the use of marijuana to alleviate the symptoms or effect of certain debilitating medical conditions. The rules to implement the legislation, known as "Rules Governing the Vermont Therapeutic Use of Cannabis Program," went into effect on June 8, 2012.

Regardless, marijuana remains a Schedule I controlled substance and its use is illegal under federal law. As the rules to implement the legislation have gone into effect, this is an appropriate time to review the drug and the pharmacist's role in medication therapy.

Various therapeutic indications have been attributed to marijuana and they fall into five general categories:

1. Severe nausea and vomiting associated with cancer chemotherapy and other causes;
2. Weight loss associated with debilitating illness including HIV infection and cancer;
3. Spasticity associated with neurologic illnesses;
4. Pain syndromes; and
5. Other uses, such as glaucoma.

Marijuana is associated with a number of adverse effects that impair the cardiovascular, respiratory, and nervous systems. Its use may cause a number of visual disturbances and lead to psychological dysfunction and addiction.

Cardiovascular effects may include tachycardia, hypertension, syncope, palpitations, orthostatic hypotension, stroke, and atrial fibrillation. Central nervous system (CNS) effects reported may include dry mouth, flu-like symptoms, nausea, drowsiness, numbness, dizziness, nightmares, and difficulty sleeping.

While documentation of drug interactions with marijuana is limited, the available information indicates that marijuana can interact with a number of drugs including opioids, barbiturates, CNS depressants, protease inhibitors, selective serotonin reuptake inhibitors, sildenafil, theophylline, tricyclic antidepressants, anticholinergics, sympathomimetics, and others. Opioids used in combination with marijuana can lead to cross tolerance and mutual potentiation effects.

Marijuana may also adversely affect patients with certain diseases or conditions including immunosuppression, psychiatric disturbances, cardiac or respiratory disease, vertigo, cancer, pregnancy, and obesity. It may exacerbate psychiatric disorders in patients, and patients using the drug are four times more likely to develop depression.

The pharmacist is a medication expert and serves to ensure safe and appropriate medication use. Medical marijuana poses a unique challenge as well as an opportunity for the Vermont pharmacist to promote patient care. Patients using medical marijuana should be advised to follow all appropriate laws and procedures with attention to detail. Patients should be advised to consult regularly with their physician and pharmacist and maintain a bona fide physician-pharmacist-patient relationship. While certain amounts of marijuana are, at present, considered to be legal in Vermont, large amounts can be considered evidence of intent to distribute and can lead to criminal prosecution. In addition, medical necessity is not an accepted defense for violations of the Controlled Substances Act.

Pharmacists should conduct thorough medical and social histories, including asking about the possible use of medical marijuana, especially here in Vermont where the use of the drug is currently legal. If a patient appears to have a drug-induced disease, the pharmacist should explore the possibility of marijuana as the causative agent. Patient records should be carefully maintained and any use of marijuana should be kept in the strictest confidence. All records should comply with the Health Insurance Portability and Accountability Act.

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Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at *www.fda.gov/Safety/Recalls/ucm357909*.

Barcoding Technology for Community Pharmacy

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology[1] and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006[2] study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.[3] Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at *www.ismp.org/AHRQ/Default.asp?link=sa.*

[1]*Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." Joint Comm J Qual Pt Safety. 2007;33(5):293-301.*

Ukens C. "New study sheds light on medication errors." Drug Topics. 2002;146(21):33.

[2]*Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." J Amer Pham Assoc. 2006; 46(2):154-160.*

[3]*American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at:* www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR,* as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at *www.ismp.org/newsletters/longtermcare.*

FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.*

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm*.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit *www.nabp.net/programs/accreditation/vawd.*

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."

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While pharmacists can communicate the legal status of medical marijuana in Vermont and can present the available evidence in support and against its use, they should do so with care. As previously stated, marijuana remains illegal under the Controlled Substances Act.

Pharmacists should develop a systematic approach in dealing with their patients concerning the use of medical marijuana. The following are a suggested strategy:

1. Keep up to date on federal and state laws regarding medical marijuana.
2. Be informed and conversant with any policies and procedures of your employing institution, company, or corporation.
3. Develop a working knowledge of the risks and benefits of medical marijuana.
4. As appropriate, conduct a thorough medication history including possible illicit drug use.
5. Consider the possibility of medical marijuana use in patients with serious and chronic disease states.
6. As appropriate, screen patients for drug and/or disease interactions with medical marijuana.
7. As appropriate, advise patients about possible addiction or dependency.
8. If your patient is using medical marijuana, be sure he or she is under appropriate medical supervision.
9. Be conversant with medical and pharmaceutical literature so as to answer questions concerning drugs and marijuana in a timely manner.
10. Never recommend a source or provide information on how to obtain marijuana.

Information for this article was taken from "Medical marijuana and the developing role of the pharmacist," *American Journal of Health-System Pharmacy*, Volume 64, Issue 10, 1037-1044. See the article for more information.

Display of Licenses

The Vermont Board of Pharmacy reminds all licensees that their license, as well as the facility registration, must be displayed at their place of employment. Pharmacists must have documentation of current registration available for inspection when practicing. The applicable portion of the Administrative Rules of the Vermont Board of Pharmacy is reprinted below for your reference.

8.5 Display of Licenses

(a) The drug outlet's current license shall be displayed in a conspicuous manner visible to the public.

(b) All pharmacists, pharmacy interns, and pharmacy technicians shall display their current licenses or registrations in a conspicuous manner visible to the public.

(c) Pharmacists employed in more than one drug outlet may elect to have their current license displayed at either drug outlet. The wallet portion of the license must be available for examination by any consumer, Board inspector, or law officer upon demand.

Pharmacist Vaccinations

Vermont pharmacists are reminded to review the present rules regarding immunizations administered by pharmacists, in Part 9.34 of the Administrative Rules of the Vermont Board of Pharmacy.

Pharmacists may only administer vaccinations to patients 18 years of age and older, and only those vaccines recommended by the Centers for Disease Control and Prevention.

The Board has proposed changes and amendments to these rules; however, those rules are not in effect at this time and pharmacists must abide by the rules currently in effect.

The *Vermont Board of Pharmacy News* is published by the Vermont Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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