



Montana Board of Pharmacy

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New Board Inspector

As of October 2015, the Montana Board of Pharmacy has a new Board inspector, John Douglas. John lives in Missoula, MT, and has an extensive practice background as a pharmacist working in hospital, community, and Indian Health Service settings. Most recently, he served as the pharmacy manager for Community Rx, which is the outpatient pharmacy at Community Medical Center in Missoula. He also owned an independent pharmacy – and worked in a variety of settings – in the United States commonwealth of Saipan. John is a graduate of Montana State University and received his pharmacy degree from the University of Montana Skaggs School of Pharmacy. He replaces Bob Stenberg, who retired last year. Welcome, John!

Effective January 1, 2016: NPLeX Pseudoephedrine Sales Reporting

Effective January 1, 2016, pharmacies and other retailers selling over-the-counter pseudoephedrine and ephedrine products in Montana are required to electronically report such sales pursuant to Senate Bill 48. The new law amends 50-32-501 and 50-32-502, Montana Code Annotated (MCA), and is regulated by the Montana Department of Justice. **In October 2015, all Montana community pharmacies should have started to receive email letters from Attorney General Tim Fox indicating training and registration through the National Precursor Log Exchange (NPLeX) in order to comply with registration and electronic reporting requirements.**

As outlined in the letter from Attorney General Fox, the NPLeX program is free of charge and provides real-time tracking in accordance with the Combat Methamphetamine Epidemic Act regulated by the United States Drug Enforcement Administration (DEA). The letter also provides information about point-of-sale integration and the following links:

- ◆ NPLeX website: www.nplexservice.com.
- ◆ Registration: <http://nplex.appriss.com/registration>; once registered, visit the link for the “NPLeX Retail Portal Training Video.”
- ◆ Contact Appriss, Inc, and the Montana NPLeX implementation team at MTNPLeX@appriss.com or 855/675-3966.

Again, implementation and communication is facilitated by the Montana Department of Justice (not the Board of Pharmacy within

the Montana Department of Labor & Industry). The electronic reporting system is NPLeX, which is administered by the vendor, Appriss.

Pharmacy Disposal Grant Recipients

In September, Attorney General Fox announced grant recipients as part of the Montana Pharmacy Safe Medication Disposal Initiative. Grants totaling \$26,000 were awarded to 13 pharmacy locations to engage in prescription drug disposal opportunities and take-back locations as authorized by DEA. Recipients are listed at <https://dojmt.gov/attorney-general-fox-awards-26000-in-grants-to-fight-prescription-drug-abuse>. For a list of current pharmacy and law enforcement disposal drop-off locations, visit Operation Medicine Cabinet’s website at <https://dojmt.gov/consumer/prescriptiondrugabuse/operation-medicine-cabinet>.

New Final Rule on Immunizations and Scheduling Controlled Substances

On September 24, 2015, the Board issued a final rule adopting exactly as proposed Montana Administrative Register (MAR) Notice No. 24-174-66, effective September 25, 2015, as part of the Administrative Rules of Montana (ARM). The final rule adopts the following:

- ◆ Amends ARM 24.174.503, Administrations of Vaccines by Pharmacists, to clarify and align the rule with statute (37-7-105, MCA) regarding administration of certain vaccines without a collaborative practice agreement.
- ◆ Amends ARM 24.174.1412, Additions, Deletions, and Rescheduling of Dangerous Drugs; this revises the schedule of controlled substances (CS) in statute Title 50, Chapter 32, MCA, to similarly control drugs based on recent scheduling activities by DEA in the Code of Federal Regulations.
- ◆ Repeals ARM 24.174.1420 through 24.174.1424, regarding scheduling of dangerous drugs in Schedules I-V; this repeals the listing of CS in rule that are already listed in statute Title 50, Chapter 32, MCA.

The proposed and final rule notices are located on the Board’s website at www.pharmacy.mt.gov (click on Regulations then Rule Notices). As of November 10, 2015, the final rule pages are not available online but will be integrated into ARM updates as administered by the Montana Secretary of State. The following is the final language for the adopted rules:

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FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when

vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.



Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to

customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that “injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs.” More information about this recall is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- ◆ benzocaine;
- ◆ benzocaine and antipyrine;
- ◆ benzocaine, antipyrine, and zinc acetate;
- ◆ benzocaine, chloroxylenol, and hydrocortisone;
- ◆ chloroxylenol and pramoxine; and
- ◆ chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.

24.174.503 Administration of Vaccines by Pharmacists

- (1) An immunization-certified pharmacist may prescribe and administer those immunizations listed in 37-7-105, MCA, without a collaborative practice agreement in place, as required by the statute.
- (2) An immunization-certified pharmacist must have a collaborative practice agreement with a practitioner authorized to prescribe drugs to administer immunizations not listed in 37-7-105, MCA, to persons 18 years of age or older; or, in the case of a public health emergency, a directive from the State Medical Officer of the Montana Department of Public Health and Human Services.
- (3) An immunization-certified pharmacist, as defined in 37-7-105(3)(a), MCA, shall:
 - (a) provide a copy of the immunization certificate and current basic cardiopulmonary resuscitation (CPR) certification to the board for initial endorsement on license; and
 - (b) maintain documentation of immunization endorsement and current CPR certification on file at the practice site.
- (4) In order to administer immunizations, with or without a collaborative practice agreement, an immunization-certified pharmacist must:
 - (a) administer vaccinations in accordance with established protocol that includes site-specific emergency measures;
 - (b) have access to a current edition of the United States Centers for Disease Control and Prevention (CDC) reference "Epidemiology and Prevention of Vaccine-Preventable Diseases";
 - (c) provide a copy of the most current vaccine information statement (VIS) to the patient or the patient's legal representative, as required by 37-7-105(2)(b), MCA;
 - (d) maintain the following:
 - (i) written policies and procedures for the types of immunizations administered;
 - (ii) specific description of the procedures, methods, and decision criteria to follow for administering the immunization;
 - (iii) a detailed description of the procedures and patient activities to follow in the course of administering immunizations;
 - (iv) training for staff procedures and record keeping requirements; and
 - (v) disposal of used or contaminated supplies;
 - (e) ensure that the individual immunized is assessed for contraindications to immunization, as required by 37-7-105(2)(a), MCA;
 - (f) report any significant adverse events to the primary care provider if one is identified by the patient, and to the Vaccine Adverse Events Reporting System (VAERS), if applicable, as required by 37-7-105(2)(c), MCA; and
 - (g) maintain the following information in the patient's medical records for a period of at least three seven

years, as required by 37-7-105(2)(d), MCA, which shall be considered confidential information:

- (i) the name, address, allergies, and date of birth of the patient;
 - (ii) the date of administration;
 - (iii) the name, manufacturer, dose, lot number, and expiration date of the vaccine;
 - (iv) the vaccine information statement provided;
 - (v) the site and route of administration;
 - (vi) the name or identifiable initials of the administering pharmacist; and
 - (vii) any adverse events encountered.
- (5) The authority of a pharmacist to administer immunizations may not be delegated; however, a pharmacy intern may immunize under the direct supervision of a an immunization-certified pharmacist or other healthcare provider qualified in vaccine administration and deemed appropriate by the preceptor upon meeting the immunization-certified requirements listed in 37-7-105, MCA, and this rule.
 - (6) The board shall randomly select renewal notice forms of immunization-certified pharmacists for audit and verification of the requirements listed in this rule.

(History: 37-7-201, MCA; IMP, 37-7-101, 37-7-105, 37-7-201, MCA; NEW, 2002 MAR p. 794, Eff. 2/1/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07; AMD, 2010 MAR p. 74, Eff. 1/15/10; AMD, 2011 MAR p. 1148, Eff. 6/24/11; AMD, 2012 MAR p. 896, Eff. 4/27/12; AMD, 2015 MAR p. 1491, Eff. 9/25/15.)

24.174.1412 Additions, Deletions, and Rescheduling of Dangerous Drugs

- (1) In addition to those dangerous drugs scheduled in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, the board adds the following to dangerous drug schedules after considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA:
 - (a) Schedule I:
 - (i) none at this time;
 - (b) Schedule II:
 - (i) none at this time;
 - (c) Schedule III:
 - (i) methasterone;
 - (ii) perampanel; and
 - (iii) prostanazol;
 - (d) Schedule IV:
 - (i) tramadol;
 - (ii) alfaxalone;
 - (iii) suvorexant; and
 - (iv) lorcaserin;
 - (e) Schedule V:
 - (i) ezogabine.
- (2) The board deletes the following dangerous drugs from the schedules in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA, after considering

federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA:

- (a) Schedule I:
 - (i) none at this time;
 - (b) Schedule II:
 - (i) naloxegol;
 - (c) Schedule III:
 - (i) 50-32-226(4)(c) and (d), MCA (hydrocodone combination products);
 - (d) Schedule IV:
 - (i) none at this time;
 - (e) Schedule V:
 - (i) none at this time.
- (3) After considering federal regulations and/or the criteria enumerated in Title 50, chapter 32, part 2, MCA, the board reschedules the following dangerous drugs from those scheduled in 50-32-222, 50-32-224, 50-32-226, 50-32-229, and 50-32-232, MCA:
- (a) Schedule I:
 - (i) none at this time;
 - (b) Schedule II:
 - (i) none at this time;
 - (c) Schedule III:
 - (i) none at this time;
 - (d) Schedule IV:
 - (i) modafinil;
 - (e) Schedule V:
 - (i) none at this time.

(History: 50-32-103, 50-32-203, MCA; IMP, 50-32-103, 50-32-202, 50-32-203, 50-32-209, 50-32-222, 50-32-223, 50-32-224, 50-32-225, 50-32-226, 50-32-228, 50-32-229, 50-32-231, 50-32-232, MCA; NEW, Eff. 9/16/71; EMERG, AMD, Eff. 5/5/74; AMD, Eff. 9/4/75; AMD, Eff. 2/5/76; AMD, Eff. 3/7/76; AMD, Eff. 4/5/76; AMD, Eff. 9/5/76; AMD, 1978 MAR p. 393, Eff. 3/25/78; AMD, 1978 MAR p. 1740, Eff. 12/29/78; AMD, 1979 MAR p. 199, Eff. 3/1/79; AMD, 1980 MAR p. 1720, Eff. 6/27/80; AMD, 1981 MAR p. 625, Eff. 6/26/81; TRANS, from Dept. of Prof. & Occup. Lic., Ch. 274, L. 1981, Eff. 7/1/81; AMD, 1984 MAR p. 589, Eff. 4/13/84; AMD, 1984 MAR p. 1567, Eff. 10/26/84; AMD, 1985 MAR p. 1017, Eff. 7/16/85; AMD, 1986 MAR p. 1957, Eff. 11/29/86; AMD, 1988 MAR p. 271, Eff. 2/12/88; AMD, 1989 MAR p. 1193, Eff. 8/18/89; AMD, 1995 MAR p. 2689, Eff. 12/8/95; AMD, 1999 MAR p. 344, Eff. 11/20/98; AMD, 2002 MAR p. 178, Eff. 2/1/02; TRANS, from Commerce, 2002 MAR p. 904; AMD, 2010 MAR p. 2968, Eff. 12/24/10; AMD, 2015 MAR p. 1491, Eff. 9/25/15.)

24.174.1420 Schedule I Dangerous Drugs (Repealed)
(History: 50-32-103, MCA; IMP, 50-32-103, MCA; NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.)

24.174.1421 Schedule II Dangerous Drugs (Repealed)
(History: 50-32-103, MCA; IMP, 50-32-103, MCA; NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.)

24.174.1422 Schedule III Dangerous Drugs (Repealed)

(History: 50-32-103, MCA; IMP, 50-32-103, MCA; NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.)

24.174.1423 Schedule IV Dangerous Drugs (Repealed)
(History: 50-32-103, MCA; IMP, 50-32-103, MCA; NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.)

24.174.1424 Schedule V Dangerous Drugs (Repealed)
(History: 50-32-103, MCA; IMP, 50-32-103, MCA; NEW, 2012 MAR p. 896, Eff. 4/27/12; REP, 2015 MAR p. 1491, Eff. 9/25/15.)

Vitamin D Utilization

By Montana Hemling, 2016 PharmD Candidate, University of Montana

Patients may be taking excessive amounts of vitamin D, some as a result of prescribing and transcription errors. These excessive amounts can cause vitamin D toxicity.

With the increased focus on vitamin D replacement, more prescriptions have been generated for 50,000 unit capsules. This strength is usually dosed at one capsule **weekly** for a specific number of weeks (usually six to eight weeks) or one capsule **monthly**. After the prescribed time frame, the dose is usually reduced to a maintenance dose of at least 800 units daily. The dosage of 50,000 units daily may be indicated for a small percentage of patients with chronic malabsorption conditions, but these patients should be monitored closely by a provider to watch for toxicity.

Presentation of toxicity:

- ◆ Confusion
- ◆ Polyuria
- ◆ Polydipsia
- ◆ Anorexia
- ◆ Vomiting
- ◆ Muscle weakness
- ◆ Nephrocalcinosis
- ◆ Bone demineralization
- ◆ Renal failure

To keep patients safe, please check any prescription written as vitamin D 50,000 units **daily** with the prescribing provider to ensure correct dosing and a plan for careful monitoring.

The following is an excerpt from UpToDate regarding vitamin D repletion from the monograph "Vitamin D deficiency in adults: Definition, clinical manifestations, and treatment." The literature review is current through October 2015, and this topic was last updated on May 8, 2014.

Vitamin D Repletion

Preparations . . . Two options are commonly used [to treat vitamin D deficiency], vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol). Although there is debate about what form should be used we suggest vitamin D3. . .

- ◆ Vitamin D3 (cholecalciferol) is available in 400, 800, 1000, 2000, 5000, 10,000, 50,000 unit capsules. It is available in some countries as an intramuscular injection, which can be extremely painful.
- ◆ Vitamin D2 (ergocalciferol) is available for oral use in 400 and 50,000 unit capsules or in a liquid form (8000 unit/ml [200 mcg/mL]). . .

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Multiple preparations of vitamin D and its metabolites are available for the treatment of vitamin D deficiency. Vitamin D . . . is used when possible since the cost is less. . . [Two options are commonly used,] vitamin D3 (cholecalciferol) and vitamin D2 (ergocalciferol). In a meta-analysis of seven randomized trials evaluating serum 25-hydroxyvitamin D (25[OH]D) concentrations after supplementation with cholecalciferol versus ergocalciferol, [cholecalciferol increased the greatest difference in serum concentrations compared to daily dosing.] The difference is of uncertain clinical significance, however, particularly in patients with normal baseline serum 25(OH)D levels. In addition, the trials in the meta-analysis used varying doses and treatment periods, resulting in significant heterogeneity among studies.

Dosing – Oral dosing of vitamin D depends upon the nature and severity of the deficiency. In patients with normal absorptive capacity, for every 100 units (2.5 mcg) of added vitamin D3, serum 25(OH)D concentrations increase by approximately 0.7 to 1 ng/ml (1.75 to 2.5 nmol/L), with the larger increments seen in patients with lower baseline 25(OH)D levels. The increment declines as the 25(OH)D concentration increases above 40 ng/ml (100 nmol/L).

- ◆ For high risk individuals with serum 25(OH)D concentrations <20 ng/ml (50 nmol/L), it is common clinical practice to treat with 50,000 international units (units) of vitamin D2 or D3 orally once per week for six to eight weeks, followed by the dose needed to maintain the target 25(OH)D level, often at least 800 units of vitamin D daily thereafter . . .
- ◆ For high risk individuals with serum 25(OH)D levels 20 to 30 ng/ml (50 to 75 nmol/L), initial supplementation with 600 to 800 units of vitamin D3 daily may be sufficient to maintain levels in the target range . . .
- ◆ For patients with malabsorption, oral dosing and duration of treatment depend upon the vitamin D absorptive capacity of the individual patient. High doses of vitamin D of 10,000 to 50,000 units daily may be necessary to replete patients with gastrectomy or malabsorption. Patients who remain deficient or insufficient on such doses will need to be treated with hydroxylated vitamin D metabolites because they are more readily

absorbed, or with the sun or sunlamp exposure . . .

The above recommendations are largely in agreement with Endocrine Society practice guidelines on the treatment of vitamin D deficiency. In adults with vitamin D deficiency, however, the Endocrine Society guidelines suggest a maintenance dose of vitamin D2 or D3 (1500 to 2000 international units daily) to maintain a serum 25(OH)D concentration above 30 ng/ml (75 nmol/L) . . .

Board Updates

- ◆ **Next Board Meetings:** The Board's next meetings are scheduled for January 8, 2016, at the Yellowstone Conference Center at the Big Sky Resort in Big Sky, MT, in conjunction with the Montana Pharmacy Association Winter CE & Ski Meeting; and April 8, 2016, and July 8, 2016, in Helena, MT. Meeting information is available on the Board's website at www.pharmacy.mt.gov (click on Board Info tab, then Board Meetings).
- ◆ **Receive Board Emails:** To receive communications from the Board about meetings, rules, hearings, and other information, request to be added to the Board's "Interested Parties" list by sending an email request to dlibsdp@mt.gov.
- ◆ **Newsletter Access:** The *Montana Board of Pharmacy Newsletter* is mailed to pharmacies and facilities within the state in addition to out-of-state mail-order pharmacies. The *Newsletter* is emailed to those who have signed up through the National Association of Boards of Pharmacy® (NABP®). To sign up, send an email to MontanaBoPNewsletter@nabp.net and type "Subscribe" in the subject heading. In addition, *Newsletter* issues from 2009 to present are available on the Board's website at www.pharmacy.mt.gov (click on Board Info, then Newsletters) and through NABP's website at www.nabp.net/publications/state-newsletters.

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