



# Alaska Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Clarifications Made to Changes on a Class II Prescription**

As stated in the last *Newsletter* there is a contradiction in Drug Enforcement Administration's (DEA) stance on what can be changed on a Class II prescription. DEA responded to this contradiction with a "Dear Colleague" letter dated October 15, 2008, by Joseph T. Rannazzisi, deputy assistant administrator/deputy chief of operations, Office of Diversion Control, acknowledging that DEA's written guidance documents are in conflict and a cause for confusion. DEA goes on to state that it plans to resolve this matter through future rulemaking. However, "until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber." As of March 2009, this is the official stance of DEA according to the Liaison and Policy Section, Office of Diversion Control, DEA. A copy of the letter can be found online at [www.ascp.com/advocacy/federal/upload/DEA\\_Letter%20on%20prescription%20changes.II.pdf](http://www.ascp.com/advocacy/federal/upload/DEA_Letter%20on%20prescription%20changes.II.pdf).

Since the Alaska Board of Pharmacy had no official stance on what can be changed on a Class II prescription, the last Alaska Board of Pharmacy *Newsletter* made the following clarification.

A pharmacist can modify or add the following information to Schedule II prescriptions after oral consultation with the prescribing practitioner (not his agent):

- ◆ Date of issue – may be added but not changed
- ◆ Patient's address
- ◆ Drug strength
- ◆ Drug dosage form
- ◆ Drug quantity – may be modified in conjunction with change in strength only, but not to exceed the original total dosage prescribed
- ◆ Directions for use

A pharmacist may never change the name of the drug (except to generic), name of the patient, or the signature of the practitioner.

Since federal law trumps state law, this clarification will be in place until DEA clarifies their rules.

## **Pharmacy Vending Machines**

Many pharmacies have had multiple phone calls from patients requesting refills and transfers of prescriptions that were originally dispensed from pharmaceutical vending machines. These

vending machines have been popping up around the state in various doctor offices and clinics. These machines are Prescription Medication Dispensers that have a variety of medications prepackaged within. After entry of information from a doctor or agent the patient's insurance is charged and the prescription is labeled and dispensed like a can of pop.

There has been much question to the validity of these machines. Regulations clearly state a facility or provider cannot legally represent themselves as having a pharmacy or pharmacist based solely on the presence of a pharmaceutical vending machine.

It is also noted that the Securities and Exchange Commission (SEC) states a physician cannot "refer to him/herself for financial gain." The use of pharmaceutical vending machines in a physician's office is an infraction of this SEC regulation.

There are several illegalities resulting from the use of pharmaceutical vending machines and numerous questionable practices related to their use. Clinics and facilities with these devices are to cease and desist from continued statutory violations.

## **Job Shadowing**

The Board was extremely pleased with the quantity and quality of public comments received on the topic of job shadowing. Each comment was reviewed in its entirety and the proposed regulations were created with your comments in mind. The Board's objectives were to streamline the paperwork, account for how job shadowing was being utilized by school systems and higher education, address public comments, and clarify Health Insurance Portability and Accountability Act obligations in the proposed regulations. Thank you for your interaction and participation in this process.

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**NABP**Celebrating  
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1980-2010



# National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Compendium and can only be ascertained by examining the original article.)

## **FDA Updates 'Medicines in My Home' Patient Education Resources**

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at [www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm).

## **DEA Releases e-Prescription for Controlled Substances Interim Final Rule**

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

## **Confirmation Bias**



*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](http://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 a 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](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see [www.ismp.org/Tools/confuseddrugnames.pdf](http://www.ismp.org/Tools/confuseddrugnames.pdf) for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when *Norvasc*® is entered into the computer, a formulary note screen appears, alerting the pharmacist that *Norvasc* often looks like *Navane*® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

## **FDA-TRACK Provides Public Access to Agency's Performance Data**

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at [www.fda.gov/AboutFDA/WhatWeDo/track/default.htm](http://www.fda.gov/AboutFDA/WhatWeDo/track/default.htm). FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at [www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm](http://www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm), Center FDA-TRACK Program Areas available at [www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm](http://www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm).



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## **Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications**

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at *www.imirus.com/tmp/2536/2501/1001/pm2536.pdf*. An APhA news release, available at *www.pharmacist.com/AM/Template.cfm?Section=News\_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117*, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

## **California PMP Data Shows Frequency of Doctor Shopping**

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26<sup>th</sup> Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

## **Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns**

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor<sup>®</sup> (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm*.

## **New OxyContin Formulation to Help Prevent Abuse of the Drug**

FDA has approved a new formulation of the controlled-release drug OxyContin<sup>®</sup> which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at

preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm*.

## **Use of e-Prescribing Grows Dramatically**

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

## **Study Shows e-Prescribing Reduces Prescriber Errors**

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5% to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at [http://weill.cornell.edu/news/releases/wcmc/wcmc\\_2010/02\\_26\\_10.shtml](http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml).

## **Counterfeit Drug Investigation Leads to Two Arrests**

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at [www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm](http://www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm).