

November 2008



# NEWS

## Oregon State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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### **No. 441: Electronic Newsletter – Final Notice**

In order to facilitate a smooth transition from the printed to the electronic version of the Oregon State Board of Pharmacy *Newsletter*, the Board will continue to communicate its plan to “go electronic” through a variety of methods. Notices are being posted for licensees and other interested parties on the Board’s Web site at [www.pharmacy.state.or.us](http://www.pharmacy.state.or.us). Also, licensees will be notified through direct mailings when license renewal notices and license certificates are sent. The August 2008 *Newsletter* revealed the Board’s plan for the *e-Newsletter* and Board of Pharmacy staff continue to spread the word during their presentations and exhibits at association events around the state.

Please take note that **this current November 2008 issue is the final issue** that will be printed and mailed to pharmacists. Beginning February 2009, the quarterly *Newsletter* will only be available online. To find the most current *e-Newsletter*, as well as past issues, visit the Oregon State Board of Pharmacy Web site at [www.pharmacy.state.or.us](http://www.pharmacy.state.or.us) or the National Association of Boards of Pharmacy® (NABP®) Web site at [www.nabp.net](http://www.nabp.net). This will provide direct access to the *e-Newsletter* for Oregon licensed pharmacy technicians, pharmacy interns, and pharmacists, as well as any others interested in Board of Pharmacy news. Anyone wishing to subscribe to an e-mail alert that will indicate when a new issue of the *e-Newsletter* is available can send an e-mail to [OregonBOPNewsletter@nabp.net](mailto:OregonBOPNewsletter@nabp.net) with the word “Subscribe” in both the subject line and body of the e-mail.

The Board will continue to provide printed versions of the quarterly *Newsletter* to the community and institutional pharmacies that currently receive them. Remember, pharmacies are required to maintain copies of the *Newsletter* on site for three years. Pharmacists who wish to continue receiving the printed version by mail may do so by notifying the Board of their request in writing.

Once again, the November 2008 Oregon State Board of Pharmacy *Newsletter* will be the final printed version for circulation to Oregon pharmacists. Please read the *e-Newsletter* quarterly and be aware that current and past issues are available on the Board of Pharmacy and the NABP Web sites for reference.

### **No. 442: Board President Receives NABP District Nod**

Oregon State Board of Pharmacy President Cathryn Lew

received the nomination from NABP’s District 7 states during its annual meeting September 18, 2008 in Park City, UT, for the district’s upcoming Executive Committee member position. In May 2009, Cathryn will complete her final year of the two-year unexpired term she was elected to at the 103<sup>rd</sup> NABP Annual Meeting on May 22, 2007 in Portland, OR. Carrying the district’s nomination, she will run for election to a full three-year term during the 105<sup>th</sup> NABP Annual Meeting in Miami, FL, May 16-19, 2009.

Board of Pharmacy Executive Director Gary Schnabel, having been elected to the position of NABP president-elect at the Annual Meeting in Baltimore, MD, in May 2008, will be installed as NABP president during the Miami meeting in May 2009. Following his year as president, Gary will become chair of the Executive Committee for a single term of one year.

### **No. 443: Certified Oregon Pharmacy Technicians**

The transition from **pharmacy technician to certified Oregon pharmacy technician** has finally come to a close. As of October 1, 2008, all qualified applicants for renewal as a certified Oregon pharmacy technician have received their annual license. Many new applications from nationally certified pharmacy technicians are being received in the Board of Pharmacy office every day.

As of October 1, 2007, applicants who have not passed one of the national certification examinations began receiving a one-year nonrenewable “pharmacy technician” license. This allows them to work as a pharmacy technician in Oregon for up to one year. If one of the national certification examinations is not passed within this year, the technician license will not be renewed and the individual may not work as a technician until he or she can provide evidence of certification to the Board. No person may perform the duties of a pharmacy technician in Oregon unless licensed by the Board of Pharmacy as either a pharmacy technician or a certified Oregon pharmacy technician.

As of October 6, 2008, the Board has 4,427 currently active Oregon certified pharmacy technicians, and the number of currently active one-year nonrenewable pharmacy technicians licensed is 1,093. The number of applications received and pending for a certified Oregon pharmacy technician license to date is 141. The Board receives between 130 and 150 techni-

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## Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

## Testing Medication Names Prior to Marketing



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and FDA in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**<sup>®</sup>*

***Community/Ambulatory Edition** by visiting [www.ismp.org](http://www.ismp.org). If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://www.ismp.org)) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medi-*

*cation Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper ([www.fda.gov/cder/drug/MedErrors/meeting\\_names.pdf](http://www.fda.gov/cder/drug/MedErrors/meeting_names.pdf)) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of



errors and potential errors caused by look-and-sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc<sup>®</sup>, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to [www.med-errs.com](http://www.med-errs.com) and click on "Become a Reviewer."

## **Coalition Looks to Pharmacies, Regulators to Reduce Diversion**

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain state-wide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

## **FDA Encourages Pharmacists to Use Patient Safety News**

*FDA Patient Safety News* is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the

latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at [www.fda.gov/psn](http://www.fda.gov/psn) or by sending an e-mail to [PSNews@cdrh.fda.gov](mailto:PSNews@cdrh.fda.gov).

## **Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban**

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair<sup>®</sup> HFA Inhalation Aerosol, Proventil<sup>®</sup> HFA Inhalation Aerosol, and Ventolin<sup>®</sup> HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex<sup>®</sup> HFA Inhalation Aerosol. More information is available on the FDA Web site at [www.fda.gov/cder/mdi/albuterol.htm](http://www.fda.gov/cder/mdi/albuterol.htm).

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cian applications per month. On October 1, the beginning of the 2008-2009 licensing period, 1,355 existing technician licenses were not renewed. This is slightly lower than the average number of technicians who fail to renew each year.

### **No. 444: Emergency Schedule II Prescriptions**

Approximately one year ago, the Board of Pharmacy presented an article to the Oregon Board of Medical Examiners for inclusion in its newsletter describing the practitioner's responsibility when calling in an emergency verbal prescription order for a Schedule II controlled substance. Authorization for a pharmacist to accept a telephone order for a Schedule II prescription, as described in 21 CFR 1306.11(d), applies to **emergency situations** only. Under this rule, the prescription order can be accomplished by verbal instructions from the practitioner. The pharmacist must immediately reduce the verbal prescription order to writing, and the quantity dispensed can only be sufficient to cover the emergency period. Therefore, an additional prescription order must be executed for any continuation of therapy. The prescriber who initiated the emergency verbal prescription order must provide the pharmacist with a manually signed prescription for the emergency supply within seven days. The signed emergency prescription must have written on its face, "**authorization for emergency dispensing**" and the date of the verbal order.

In an emergency situation, direct communication between the prescriber and the pharmacist is crucial because a variety of questions may need to be clarified before the prescription can be accurately dispensed. Prescribers are strongly urged to call the pharmacist to avoid a delay in dispensing the medication to the patient. This also applies to orders that are communicated by the prescriber to the long-term care facility that is in turn faxed to the pharmacist.

As a reminder, a manually signed and faxed Schedule II prescription order may serve as the original for a patient residing in a long-term care facility.

### **No. 445: Refill Authorization**

Recent confusion has been brought to the Board's attention regarding who in the pharmacy may accept oral instructions for a prescription refill from a prescribing practitioner. More specifically, the question was, "Can a non-licensed pharmacy employee

such as a clerk accept refill authorization over the telephone?" The short answer is no. A non-licensed employee or clerk can retrieve a faxed refill authorization from the fax machine for the pharmacist. However, only a pharmacist, pharmacy technician, or pharmacy intern can accept oral instruction for prescription refills. The follow-up question was asked, "Can a clerk enter patient data into the computer record? The short answer is yes. A clerk can enter demographic or billing information into the computer records for a patient. However, a clerk cannot enter clinical information such as allergies, diagnosis, or medical condition, etc.

### **No. 446: Labeling Errors**

An interesting and completely preventable medication labeling error has been reported to the Board. The correct medication label had been applied directly to the container, which was then inserted back into the manufacturer's box for dispensing. This medication was not picked up by the patient and was returned to stock unused. On a later date, when another prescription for the same medication for a different patient was received, the pharmacist labeled the box without looking at the container inside and dispensed it to the patient. When the patient got home, the box was discarded and the patient noticed that the label on the medication contained somebody else's name. This same type of error has been reported to the Board twice in recent months. Pharmacists, pharmacy technicians, and interns must continually be aware of potential hazards and always, always double check.

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