September 2005

Kentucky Board of Pharmacy

NEWS

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Frankfort, KY 40601-9230

Published to promote voluntary compliance of pharmacy and drug law.

Board of Pharmacy Office to Move

The Kentucky Board of Pharmacy will be moving its office from Frankfort to Lexington on September 19-20, 2005. The new address for the Board will be:

Kentucky Board of Pharmacy
Spindletop Administration Building
2624 Research Park Dr, Suite 302
Lexington, KY 40511

The new Board office will provide additional space, especially the boardroom, which will allow seating for 60 to 70 individuals. Currently, there is seating for approximately 30 to 35 individuals.

The Board office will be sending postcards to all pharmacists, pharmacies, and drug manufacturers/wholesalers notifying them of the new address and new telephone numbers.

Board of Pharmacy Retreat

The Kentucky Board of Pharmacy will be hosting a retreat on Saturday and Sunday, November 12-13, 2005, at the Cincinnati Marriott at River Center in Covington, KY. As of this date the agenda for the retreat has not been established. All pharmacists and interested individuals are invited to attend. If you have a suggested item for the agenda, please forward it to the Board office or if you have questions, please contact the Board office at your convenience.

Contraindications with Duragesic Usage

Submitted by Anthony B. Tagavi, PharmD Candidate

Across the country, the recommendation and usage of Duragesic® (fentanyl) prescriptions have been linked to many instances of medication errors. Particularly in the Commonwealth of Kentucky, there have been numerous incidents of patients that were prescribed and dispensed Duragesic improperly. Because of the recent cases, Janssen Pharmaceutica, the manufacturer of Duragesic, has released a black box warning in the package insert of their product. Like many other opioids, Duragesic has several contraindications that, as pharmacists, we need to analyze and inform patients about.

Opioid analgesics are very potent medications that have a specific mechanism of action. These opioids bind with stereo specific receptors at many sites within the central nervous system. More specifically, Duragesic interacts with opioid mu receptors located in the brain, spinal cord, and other tissues. When these receptors are agonized within the central nervous system it increases pain threshold, alters pain reception, and inhibits ascending pain pathways. Unlike most other analgesics, opioids are strong respiratory depressants. Because of this side effect, it is highly recommended that the patient meets several requirements before using Duragesic. As pharmacists, we must make sure that the patient is eligible before she or he receives any treatment from this opioid.

The black box warning indicates that Duragesic is contraindicated in:

- Opioid intolerant patients;
- Management of acute or post-operative pain;
- Management of intermittent pain;
- Management of mild pain;
- In situations of significant respiratory failure; and
- Patients with acute or severe bronchial asthma.

A thorough knowledge of the delivery system, pharmacokinetics, and pharmacodynamics of Duragesic is imperative to the safe prescribing of this Schedule II controlled substance. Fentanyl comes in multiple forms: intravenous, transdermal, and even lozenges. The transdermal system provides a continuous flow of fentanyl to the body for 72 hours. It is a transparent patch comprised of a multilayer system covered by a pull back transparent peel strip. Before use, the strip is removed and applied to a dry portion of the skin. The patch is then attached by a silicone-based contact adhesive. Initially, a loading dose is absorbed and then a maintenance dose of fentanyl is continuously diffused and delivered from a drug reservoir, which is located behind a rate-control membrane. After the fentanyl crosses the skin barrier, a depot is accumulated in the upper skin layer which then further diffuses into the dermis and ultimately systemic circulation occurs. In adults, minimal effective concentration times range anywhere from 1.2 to 40 hours, and the time to reach maximum serum concentrations ranges from 12 to 48 hours. After 72 hours, when the patch is removed, fentanyl continues to be absorbed into the systemic circulation (from the cutaneous depot). It takes an additional 13 to 22 hours for the serum fentanyl concentration to decline about 50%.

There are numerous prescriptions of Duragesic in Kentucky that present potential problems to patients. The most important aspect of fentanyl usage is that the patient has already received opioids in the past. Opioid "naïve" patients are strongly urged not to begin pain management with fentanyl because of the risk of fatal respiratory disease. Also, the dosing schedule of fentanyl is extremely important. Because of the pharmacokinetics, the transdermal fentanyl release system provides therapeutic levels for 72 hours. A prescription for Duragesic every 48 hours is highly questionable and should not be routinely prescribed and/or dispensed. A dosing schedule of every 48 hours will likely cause toxic levels of opioids. Finally, the

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New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.

Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

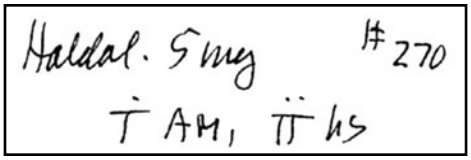
Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for

the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as "phenobarbital 32.400MG tablet." The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily. The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.



Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- Always include a leading zero for dosage strengths or concentrations less than one.
- Never follow a whole number with a decimal point and a zero (trailing zero).
- Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to "fax noise." Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

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usage of cut or damaged transdermal patches is strictly prohibited in this product. If the integrity of the patch is compromised, it can lead to rapid release of the contents of the patch and absorption of a potentially fatal dose of fentanyl.

Even though physicians prescribe numerous medications daily, pharmacists must recognize and monitor the ensuing drug therapy of each and every one of them. As drug experts, it is our duty to ensure patient safety. Since Duragesic is such a powerful medication, each prescription should be scrutinized and each patient screened. With a more concerted effort with physicians, pharmacists can play a monumental role in the enhanced welfare of patients on Duragesic.

Adding or Changing Information for a Schedule II Controlled Substance

After consulting with the prescribing practitioner, a pharmacist may add or modify the following items:

- Date of issue – may be added but not changed;
- Drug strength;
- Quantity – may be modified **only** in conjunction with a change in strength **and** the total quantity dispensed must not exceed the total dosage authorized;
- Quantity check-off box marked; and
- Directions for use.

If a pharmacist is presented with a prescription for Percocet® 5/600 (oxycodone and acetaminophen), which is commercially unavailable, the pharmacist may change it to the appropriate strength of acetaminophen once the practitioner has been consulted.

A pharmacist may **never** change or add the patient's name, the name of the controlled substance (except generic substitution permitted by state law), or the signature of the practitioner to a prescription.

Both state and federal law still require professional judgment by the pharmacist on every prescription filled. Caution and documentation is advised whenever a change or addition is made to any prescription.

2005 Drug Manufacturers/Wholesaler Permits Renewal

Drug manufacturer and wholesaler permits expire September 30, 2005. The Board is pleased to announce that for the first time a drug manufacturer or wholesaler may renew and pay their permit online. Renewal notices were mailed out the first week of August in order to allow time for processing. Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site at www.pharmacy.ky.gov.

Pharmacy Technician Proposed Statute

At its June 8, 2005 meeting, the Board reviewed proposed legislation for the registration of pharmacy technicians. The Board's position and a copy of the proposed legislation may be found on the Board's Web site at www.pharmacy.ky.gov. Please review the proposal and forward any comments to the Board office.

Kentucky Pharmacy Law Continuing Education

With the cooperation of the University of Kentucky College of Pharmacy and Medicine Continuing Education Department, local pharmacy districts, and the Board of Pharmacy staff, continuing education (CE) programs concerning Kentucky pharmacy law are being planned. Currently, two programs have been scheduled for this year. The first one is September 27, 2005, at the Sheraton Suites in Lexington. The second one is November 3, 2005, at Mariah's Restaurant in Bowling Green. Two hours of CE credit can be earned. Please contact Kim Page, senior conference coordinator, University of Kentucky College of Pharmacy and Medicine Continuing Education Department at 859/257-5320 ext 80340 or at krpage00@email.uky.edu.

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