

January 2007



# Kansas State Board of Pharmacy

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900 Jackson, Room 560  
Topeka, KS 66612  
[www.kansas.gov/pharmacy/](http://www.kansas.gov/pharmacy/)

Published to promote voluntary compliance of pharmacy and drug law.

## ***Disciplinary Actions***

**Case No. 06-23** – Licensee was disciplined for diverting controlled substances (CS). By order of the Kansas State Board of Pharmacy the license was suspended for 230 days.

**Case No. 06-45** – Licensee was disciplined by imposition of a restriction on his license.

**Case No. 06-38** – Pharmacist license denied based on revocation of license from state of California.

**Case No. 05-68** – Consent Agreement to close pharmacy based on illegal Internet operation.

**Case No. 06-64** – Licensee was disciplined by order of the Board by requiring participation in the Pharmacy Impaired Provider Program.

**Case No. 05-27** – Licensee was disciplined by Board entering an order recognizing the previous suspension of license, placing the license on a 60-month probation period, and assessing an administrative fine of \$15,000.

**Case No. 06-14** – A medical care facility pharmacy was disciplined for failing to maintain records regarding CS for a period of at least five years by the Board entering an order assessing a fine of \$500.

**Case No. 06-48** – Licensee entered into Stipulation requiring contract with Committee on Impaired Pharmacy Practice.

**Case No. 06-34** – Pharmacy fined \$500 for failure to register pharmacy technician.

**Case No. 06-40** – Pharmacy fined \$500 for failure to register pharmacy technician.

**Case No. 06-68 – Dorothy C. Smith, #14-01640** – Pharmacy Technician, Wichita, KS. Registration revoked for adding a refill to a CS prescription.

**Case No. 06-62** – Pharmacy fined \$500 for failure to register pharmacy technician.

**Case No. 06-42** – Pharmacy fined \$500 for failure to register pharmacy technician.

**Case No. 06-41** – Pharmacy fined \$500 for failure to register pharmacy technician.

**Case No. 06-32 – Jay Parker, RPh, #1-08993** – Pharmacist License, Oskaloosa, KS. License revoked for insurance/Medicare fraud.

**Case No. 06-32B – Parker Pharmacy, #2-05080** – Pharmacy License, Oskaloosa, KS. License revoked for insurance/Medicare fraud.

(Specific information on these cases can be found in the Board minutes or on the Board's Web site.)

## ***Board Member Reappointed***

Congratulations to pharmacist JoAnne Gilstrap of Kansas City, KS, who was reappointed to a three-year term on the Kansas State Board of Pharmacy by Governor Kathleen Sebelius. JoAnne is a graduate of the University of Missouri-Kansas City and is employed at Wal-Mart Pharmacy. She has been a licensed pharmacist in Kansas since 1975. The Board looks forward to working with JoAnne for an additional three years.

## ***Beware of Internet Prescriptions***

Recent investigations by the Board have identified various pharmacies filling prescriptions they were receiving via an Internet Web site. Pharmacies are being approached by the Web site to enter into an agreement offering the pharmacy as many prescriptions as they wanted. One to three physicians who are located in states outside of Kansas issued all the prescriptions. The patients were located in many different states around the country.

This serves as counsel to pharmacists to beware of the Internet "deals" or drug purchasing offers that sound too good to be true. Prescriptions received via the Internet or through Internet intermediaries are not legitimate unless there is a patient/physician relationship. The Board is issuing a warning that pharmacies involved should know that multiple prescriptions a day from the same physician issued for patients around the country are not legitimate and pose a serious threat to the public health and safety. Federal regulators are also taking an active role in stopping this practice. Pharmacies may be subject to serious disciplinary action by the Board if it is determined that the prescriptions are not legitimate.



## **FDA Issues Nationwide Alert on Counterfeit One-Touch Blood Glucose Test Strips**

In mid October 2006, United States Food and Drug Administration (FDA) alerted the public to counterfeit blood glucose test strips being sold in the US for use with various models of LifeScan, Inc, One Touch Brand Blood Glucose Monitors. The counterfeit test strips potentially could give incorrect blood glucose values; either too high or too low. At press time, no injuries have been reported to FDA.

Consumers who have the counterfeit test strips should be instructed to stop using them, replace them immediately, and contact their physicians. Consumers with questions may contact the company at 1-866/621-4855. The counterfeit test strips were distributed to pharmacies and stores nationwide – but primarily in Ohio, New York, Florida, Maryland, and Missouri – by Medical Plastic Devices, Inc, Quebec, Canada and Champion Sales, Inc, Brooklyn, NY.

The counterfeit test strips and their characteristics are:

- ◆ One Touch Basic®/Profile®
  - ◆ Lot Numbers 272894A, 2619932, or 2606340
  - ◆ Multiple Languages – English, Greek, and Portuguese text on the outer carton
  - ◆ Limited to 50-Count One Touch (Basic/Profile) Test Strip packages
- ◆ One Touch Ultra®
  - ◆ Lot Number 2691191
  - ◆ Multiple Languages – English and French text on the outer carton
  - ◆ Limited to 50-Count One Touch Ultra Test Strip packages

LifeScan has alerted the public via a press release and has notified pharmacists, distributors, and wholesalers through a letter. In its letter, the company advises customers to contact their original source of supply for restitution. For more information, visit [www.GenuineOneTouch.com](http://www.GenuineOneTouch.com).

## **New DEA Number Assignments; Updated DEA Practitioner's Manual Released**

In early November 2006, Drug Enforcement Administration announced that due to the large Type A (Practitioner) registrant population, the initial alpha letter "B" has been exhausted. The Agency, therefore, has begun using the new alpha letter "F" as the initial character for all new Type A (Practitioner) registrations. For more information, visit [www.deadiversion.usdoj.gov/drugreg/reg\\_apps/new\\_reg\\_number110906.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/new_reg_number110906.htm).

Additionally, in August 2006, the Agency released the Practitioner's Manual, An Informational Outline of the Controlled Substances Act, 2006 Edition. The Manual, prepared by the Agency's Office of Diversion Control, is designed to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession. The Manual can be accessed at [www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual090506.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual090506.pdf).

## **Optimizing Computer Systems for Medication Safety**



*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](http://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](mailto:ismpinfo@ismp.org).*

Computers that are used by pharmacists are essential professional tools that can increase staff efficiency and support effective drug utilization review and therapeutic drug monitoring. At the same time, pharmacists must not place sole reliance on this tool as a means to protect patients from drug-induced harm.

Many of today's computer order-entry systems provide vendor-defined and user-defined alerts that remind or warn staff about potential drug-related problems during order entry. The Institute for Safe Medication Practices (ISMP) often recommends these alerts as a way to inform staff about potential errors. However, pharmacists have expressed concern that the sheer number of warnings that appear on the screen during order entry can be overwhelming and slow the process. In many cases, clinically insignificant warnings are as likely to appear as those that are vital. As a result, staff may inadvertently bypass critical warnings, especially when the workload is high. This is easy to do with many systems.

In an informal survey on computer systems, we found that all too often it simply requires striking the "enter" key to bypass an alert, even those that could prevent serious or fatal errors. Also, if the system forces a response to the warning, practitioners who feel pressured to rush through order entry may select the first reason listed on the screen instead of appropriately addressing the issue. Another issue is that when pharmacists are properly alerted to a potential allergic reaction or harmful drug interaction, they may erroneously assume that the prescriber is already aware of the problem and fail to alert the prescriber directly.

When practitioners become accustomed to receiving unimportant or clinically irrelevant warnings they often ignore these "false alarms," or turn them off, at least mentally. Here are some strategies that can be used to optimize the effectiveness of alerts and minimize the possibility of overlooking the more significant ones:

- ◆ Use a tiered system for interactive warnings that allows staff to view and consider possible warnings but easily bypass less serious issues, if appropriate. Require a text entry to describe the response to more significant alerts.

# Compliance News

Compliance News to a particular state or jurisdiction should not be assumed (the law of such state or jurisdiction.)



- ◆ Pharmacies should assign pharmacists who enter orders the task of noting any warnings that they feel are not clinically significant. The severity level of certain alerts may need to be changed in order not to “overload” the pharmacist. However, wholesale changing of severity levels according to vendor specifications should be done with caution. Check with your vendor to fully understand how they assign severity levels before making any changes to ensure you are not missing warnings you deem to be critical.
- ◆ Make significant alerts as visible as possible. Some systems may allow large screen fonts in a contrasting color, flashing messages, sounds, or other means of distinguishing the alert.
- ◆ Maximize a system’s capabilities whenever possible by incorporating serious error-prone situations that have been reported in this column as well as other publications.
- ◆ Review non-interactive pop-up messages on an ongoing basis, such as the ones we suggest for avoiding drug name mix-ups. Delete any that are no longer applicable.
- ◆ Apply auxiliary labels to drug packages and storage shelves to warn about unclear or confusing labeling and packaging, instead of using certain messages in the computer system.
- ◆ Consider printing warnings on drug labels or medication storage areas instead of building alerts into the order entry process. For example, print “Topical or External Use Only” warnings on drug labels for all drugs that can be administered safely only by this route.
- ◆ Many systems are capable of providing reports about all warnings that have been overridden. Assign a clinician or manager to review the report daily and periodically identify those warnings that are continually overridden. Share report results with staff members before changes are made to the computer system. Consider focusing on one or two common but critically important warnings to monitor the effectiveness of the computer’s alert system and the response to the alert.

## **Revised Coumadin Labeling and Medication Guide**

FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin®, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern.

Information about all currently approved Medication Guides is available at [www.fda.gov/cder/Offices/ODS/medication\\_guides.htm](http://www.fda.gov/cder/Offices/ODS/medication_guides.htm).

To access the new Medication Guide, revised prescribing information and supplemental supporting documents, visit [www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin](http://www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin).

## **FTC and FDA Act Against Internet Vendors of Fraudulent Diabetes Cures and Treatments**

The Federal Trade Commission (FTC) and FDA, working with government agencies in Mexico and Canada, have launched a drive to stop deceptive Internet advertisements and sales of products misrepresented as cures or treatments for diabetes. The ongoing joint campaign has so far included approximately 180 warning letters and other advisories sent to online outlets in the three countries.

The joint diabetes initiative to stop commercial sale of fraudulent therapies originated with a Web surf for “hidden traps” by the International Consumer Protection and Enforcement Network, an organization of law enforcement authorities, members of the Mexico, United States, and Canada Health Fraud Working Group (MUCH), and the attorneys general offices of Alaska, Michigan, Ohio, Virginia, and Wisconsin. MUCH, which consists of regulatory officials from health, consumer, and competition protection agencies in the three North American countries, had previously conducted a campaign against fraudulent weight-loss products. Using the results of the Internet sweep, FTC sent warning letters for deceptive ads to 84 domestic and seven Canadian Web sites targeting US consumers, and referred an additional 21 sites to foreign governments. About a quarter of the firms have already changed their claims or removed their pages from the Internet, and several others are in contact with FTC.

FTC also announced a new consumer education campaign to teach consumers how to avoid phony diabetes cures. The materials encourage consumers to “Be smart, be skeptical!” and will be available in English, Spanish, and French. One component is a “teaser” Web site available at <http://wemarket4u.net/glucobate/index.html>. At first glance, the site appears to be advertising a cure for diabetes called Glucobate, but when consumers click for more information on ordering the product, it reveals information about avoiding ads for phony cure-alls in the future. The new education materials, including a bookmark and consumer alert, were introduced to coincide for Diabetes Awareness Month in November.

## **FDA Implements Strategy for Phony Dietary Supplement Claims**

FDA has developed a strategy to focus its enforcement efforts in the area of dietary supplements. The strategy was designed to address illegal dietary supplement ingredients and ensure integrity and truthful labeling of dietary supplements. One emphasis is on claims aimed at patients with serious diseases such as cancer and diabetes. Over an approximate 12-month time frame, the Agency has sent more than 100 warning letters and other advisories to Internet firms and has seized products at one firm. In addition, the Agency maintains special Web sites, in English and Spanish, which amplify the Agency’s counsel to consumers to check with their doctor, nurse or pharmacist before trying any new health care product. These materials cover a broad range of subjects of special interest to patients with diabetes ([www.fda.gov/diabetes/](http://www.fda.gov/diabetes/); [www.fda.gov/diabetes/pills.html](http://www.fda.gov/diabetes/pills.html); [www.fda.gov/opacom/lowlit/diabetes.html](http://www.fda.gov/opacom/lowlit/diabetes.html); [www.fda.gov/opacom/lowlit/sdiabetes.html](http://www.fda.gov/opacom/lowlit/sdiabetes.html)), as well as more general health care information.

## **DEA Form 106 Reporting Theft or Loss**

Immediately upon discovery of a theft or significant loss of a CS, a pharmacy must contact the Drug Enforcement Administration (DEA) field office and provide DEA with Form 106 (Report of Theft or Loss of Controlled Substances). You need to keep a copy of Form 106 for your records. A copy of DEA Form 106 can be found on the Board's Web site under a link for Applications and Forms or on the DEA Diversion Control Web site. Although the term "significant loss" is not defined, it is up to the individual registrant to use his or her best judgment and take appropriate action.

## **Cancer Drug Repository**

Last year, the Kansas legislature passed a law that would improve cancer patients' access to prescription drugs by allowing the donation of unused medications. The intent of the legislation was to increase the amount of medications available and provide more help to individuals who need it. Cancer treatment can be expensive, and the goal is to get these drugs to people who are uninsured, underinsured, or cannot afford them. Large amounts of prescription drugs and medical supplies are destroyed each year after a cancer patient no longer needs them. Cancer patients are sometimes forced to purchase large amounts of prescription drugs and do not use all of them either because the drugs do not work for them or because they no longer need them.

Under the program, persons may donate to participating medical facilities, pharmacies, and doctors' offices their unused, unopened, cancer drugs; drugs used to treat the side effects of cancer; and supplies needed to administer cancer drugs. Donated drugs must be in their original, unopened tamper-evident packaging. Tamper-evident packaging is unit-dose packaging. CS cannot be donated. CS cannot be returned according to federal law so the program will not accept scheduled drugs. Drugs that have been compounded are not eligible for donation or drugs that have been previously dispensed from a cancer drug repository cannot be used again. Donated drugs may not be commingled with drugs that are sold from the pharmacy.

Pharmacies that wish to participate in accepting donations or dispensing donations must sign an application with the Board of Pharmacy. Pharmacies may charge a handling fee for dispensing donated cancer drugs, but they may not resell donated drugs.

Any Kansas resident diagnosed with cancer may receive the donated medicine by contacting a participating pharmacy, doctor's office, or medical facility. The Board of Pharmacy Web site will maintain a list of all participants in the program. It is strictly voluntary, and there is no fee for participation. The specific rules and regulations regarding this program along with the forms that are to be used can also be found on the Board's Web site.

## **Kansas Board of Pharmacy 2007**

### **Meeting Dates**

March 6-7 .....	Lawrence, KS
June 12-13 .....	Topeka, KS
September 11-12.....	Topeka, KS

### **Pharmacy Inspector Opening**

The Board of Pharmacy has an opening for a pharmacy inspector for the Wichita, KS, area. If you are interested send a resume to the Board office or contact Debra Billingsley, executive secretary at 785/296-4056.

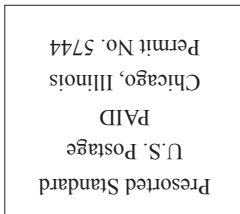
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