



# Nevada State Board of Pharmacy

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<http://bop.nv.gov>

Published to promote voluntary compliance of pharmacy and drug law.

## Board Members

- J. David Wuest, RPh, Reno .....President
- Leo Basch, RPh, Las Vegas .....Treasurer
- Keith Macdonald, RPh, Carson City.....Board Member
- Raymond J. Seidlinger, RPh, Las Vegas.....Board Member
- Kathryn Craven, RPh, Las Vegas.....Board Member
- Barry Boudreaux, RPh, Las Vegas.....Board Member
- Ann Peterson, Reno .....Board Member

## 2007 Board Meeting Schedule

- January 10-11 ..... Reno
- February 22-23 .....Las Vegas
- April 18-19 ..... Reno
- June 6-7 ..... Las Vegas
- July 25-26 ..... Las Vegas
- September 5-6 ..... Reno
- October 24-25 ..... Las Vegas
- December 5-6 ..... Reno

## Changing Faces

After nine long and often challenging years, Nevada State Board of Pharmacy President Joseph R. Kellogg, RPh, has reached his term limit. Joe tirelessly served seven years as a Board member, one of which was spent as Board treasurer, prior to a two-year stint as president, replacing Larry L. Pinson, PharmD, in October 2004. Joe was recognized at a farewell dinner in October 2006 for his unparalleled dedication and devotion to his profession and to the people it serves. Board members and staff wish him the best as he continues down his professional path followed closely by a new piece of luggage designed specifically for him.

Past President Kellogg passed the gavel to the Board's new president, J. David Wuest, RPh, of Reno, NV. Dave welcomes the upcoming challenges of the presidency as he begins his third year of service on the Board. We all wish him a long and rewarding experience.

Board Treasurer Leo Basch, RPh, of Las Vegas, NV, has been reappointed by Governor Kenny C. Guinn to a second term on the Board. Leo, a Walgreens pharmacist, has been an invaluable contributor to the Board, demonstrating unmatched dedication. Congratulations Leo on a well deserved second term.

Finally, Governor Guinn has appointed Medco Health Solutions, Inc, Director of Pharmacy Practice Barry Boudreaux, RPh, of Las Vegas, NV, to the Board. A practicing pharmacist for over 28 years with experience in retail, home delivery, and mail-order pharmacy in both Louisiana and Nevada, Barry graduated from the University of Louisiana at Monroe in 1978. An adjunct professor for several schools of pharmacy, he was nationally recognized this year by the American Pharmacists Association for his counseling skills and was recognized by Medco for his contributions during the Hurricane Katrina relief effort. Barry's wife Joan is also a pharmacist. Board staff is eager to work with Barry and feels that Nevada is fortunate to have another highly dedicated and qualified Board member.

## Words of Caution

1. We have reports of instances involving the sig "take ½ tab" being misread by patients as "take 1 to 2 tabs." This once again demonstrates the importance of patient counseling.
2. Board staff has been alerted to a number of pharmacies being contacted by phone to order pints of iodine. The caller claims to own a tattoo shop, needing the iodine for tattooing, when in reality it is most likely being used to make methamphetamine.
3. Food and Drug Administration (FDA) on October 23, 2006, announced the discovery of more counterfeit Lifescan, Inc, One Touch® blood glucose strips. The original announcement was made October 13, 2006, citing the counterfeit test strips being distributed to pharmacies nationwide by various distributors. The potential for injury secondary to improper insulin treatment due to inaccurate test results is obvious and demonstrates the need for stronger pedigree laws. (Please see page 2 of this *Newsletter* for further information.)

## About the Newsletter

The *Nevada State Board of Pharmacy Newsletter* is recognized as an official method of notification to practitioners licensed by the Board. These *Newsletters* are available on the Board's Web site <http://bop.nv.gov> and may be used in hearings as proof of notification.



## **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.

## Inspector's Corner

Proper canceling of Schedule II prescriptions: NAC 453.450(3) reads "Each prescription for a controlled substance listed in [S]chedule II must, immediately after filling, be conspicuously cancelled on its face. The cancellation must include the date on which it was filled and the signature and certification number of the pharmacist who filled it."

The regulation is very specific requiring the **date, signature, and license number** to be written on the face of the prescription. Many pharmacists miss one or more of these requirements and the facility is consequently "written up" at the annual inspection. We encourage all pharmacy managers to review this regulation with staff to hopefully remove this problem from the common problem list.

## For Your Information

1. Plan B®: On August 24, 2006, FDA approved Plan B for over-the-counter (OTC) sale. Please note the following:
  - a. Plan B is authorized for OTC sale in pharmacies to women and men 18 years of age or older with valid picture identification. Women under the age of 18 or without proof of age will still need a prescription.
  - b. Plan B will be kept behind pharmacy counters.
  - c. No special training, forms, or fact sheets are required to provide customers with Plan B.
  - d. Men can buy Plan B if they show proof of age that they are over 18; however, they do not have the option to obtain a prescription for Plan B.
2. Transition of chlorofluorocarbons (CFC)-based inhalers: As most of you are aware, the United States is a signatory to the Montreal Protocol, which bans the use of ozone-damaging CFCs. FDA is requiring manufacturers to phase out CFCs in albuterol-containing products by December 31, 2008; however, the transition to hydrofluoroalkane (HFA) albuterol inhalers is already well under way. Many manufacturers have curtailed their production of CFC-based inhalers due to uncertainty in obtaining component parts and ingredients. Unfortunately, HFA-based inhalers are more costly to the patient resulting in the genesis of some assistance programs (Schering-Plough Corporation, called SP-Cares, can be reached at 1-800/656-9485). It is

important for pharmacists to note that FDA has indicated that CFC and HFA albuterol inhalers are **not** therapeutically equivalent, therefore, requiring a new prescription if a CFC inhaler is to be changed to an HFA inhaler. Shortages, such as we are now seeing with CFC-based albuterol inhalers, are the perfect segue for counterfeit production, so we caution you to exercise prudent buying practices.

## Licensing Statistics

License or Registration Category	In State	Out of State	Total
Pharmacists	1,977	6,461	8,438
Pharmaceutical Technicians	2,288	197	2,485
Pharmaceutical Technicians in Training	480	0	480
Interns	406	85	491
Pharmacies	517	340	857
Wholesalers	31	340	371
Manufacturers	1	0	1
Warehouses	3	0	3
Controlled Substances Registrations	7,076	0	7,076
Dispensing Practitioners	179	0	179
Prescribing Practitioners	184	0	184
Medical Devices, Equipment, & Gases	190	66	256
<b>Totals</b>	<b>13,332</b>	<b>7,489</b>	<b>20,821</b>

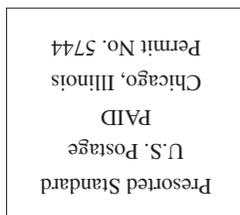
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