



# Oklahoma State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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## Board Meeting – January 16, 2008

### Disciplinary Action

**Ray Dickson, Tech #1418 – Case No. 842:** *Charges:* Theft of merchandise and failing to disclose that he has a drug or alcohol related conviction that may be considered by the Oklahoma State Board of Pharmacy in reviewing qualifications of a person applying for a pharmacy technician permit. **Permit revoked.**

**Tasha D. Moore, Tech #9400 – Case No. 843:** *Charges:* Theft of merchandise and possession of a controlled dangerous substance (CDS) without a valid prescription. **Permit revoked.**

**Terry Rubottom, Tech #8862 – Case No. 844:** *Charges:* Furnishing fictitious, false, misleading, or fraudulent material in her application to the Board. **Permit revoked.**

**Amjad Nawaz, DPh #12886 – Case No. 846:** *Charges:* Receiving two or more warning notices within a twelve (12)-month period. **A Letter of Reprimand will be placed in his file for one (1) year, he must attend a law seminar in the year 2008 and view the error correction video.**

The Board took action in one (1) impaired case:

**Case 590A – DPh #11238,** respondent was granted probation.

## Board Meeting – February 20, 2008

### Disciplinary Action

**Ashley Chandler, Tech #11475 – Case No. 848:** *Charges:* Theft of merchandise. **Permit revoked.**

**Dominic Triana, Tech #9711 – Case No. 849:** *Charges:* Theft of merchandise and possession of a CDS without a valid prescription. **Permit revoked.**

**John Howard Gaddis, DPh #10613 – Case No. 851:** *Charges:* Failing to submit proof to the Board that he has participated in not less than fifteen (15) clock hours of continuing education (CE) obtained through the satisfactory completion of an accredited program of continuing professional education during the previous calendar years; failing to maintain proof of CE for a period of two (2) years from renewal date and failing to obtain and maintain verification forms of attendance and/or completion of CE programs; providing fictitious information, fraud, or misrepresentation in applying for or procuring a pharmacist license . . . or renewal of the same. **License placed on probation for two (2) years; must complete 120 hours of CE plus the required fifteen (15) hours of required CE for 2008; must attend a law seminar in the years 2008 and**

**2009; shall provide verification of fifteen (15) hours of 2007 CE within thirty (30) days; total fine of \$2,500.**

**Medical Park Center Pharmacy, #9-2507 and Gary Walter Bell, DPh #11230 – Case No. 853:** *Charges:* Receiving two or more warning notices within a twelve (12)-month period and failing to ensure that all tasks performed by pharmacy technicians are accomplished under the immediate and direct supervision of a pharmacist who is currently licensed by the Board. **A Letter of Reprimand will be placed in both respondents' files for one year. Pharmacist Gary Bell must attend a law seminar in 2008. Permit revoked.**

The Board took action in one (1) impaired case:

**Case 854 – DPh #11408,** respondent's license was revoked.

### From the Inspectors

- ◆ **Inspectors must be able to read posted licenses and permits:** Please make sure that licenses and permits are posted at a readable distance and that all license and permit numbers are clearly visible.
- ◆ **Documentation of Technician Training:** During inspections, inspectors are asking to see documentation of technician training. Pharmacists need to check that they have proper documentation on all technicians. When a technician is hired that has previously worked in another pharmacy, that technician still needs to be trained in the new pharmacy, and the training needs to be documented. This is not a new requirement.
- ◆ **Automated Pharmacy Systems:** Prior written notice must be provided to the Board of the installation or removal of automated pharmacy systems. Such notice must include, but is not limited to, the name and address of the pharmacy, name of pharmacy manager, name of the manufacturer, and model of system.
- ◆ **Phone Call Identification:** All pharmacy interns, technicians, or clerks must identify themselves as such on any phone calls initiated or received while performing pharmacy functions.
- ◆ **Phase II Technician Training:** If a pharmacy technician quits within ninety (90) days of receiving a permit, the pharmacist manager must notify the Board in writing as to whether or not the technician completed Phase II Training. If a pharmacy technician fails to complete Phase II Training within ninety (90) days, the technician permit is automatically voided.

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## **NABP Launches Pharmacy Curriculum Outcomes Assessment Program**

NABP launches its Pharmacy Curriculum Outcomes Assessment™ (PCOA®) mechanism in April 2008 for use by schools and colleges of pharmacy in evaluating their curricula. NABP invited schools and colleges of pharmacy to participate in the 2008 administration of the PCOA, scheduled for April 7-18. There will be no fee for participation in this first year of administration.

Those schools and colleges of pharmacy that participate in the April 2008 administration will receive detailed score reports for their students that sit for the assessment, as well as national comparative data. NABP developed the PCOA at the request of schools and colleges of pharmacy and accreditation stakeholders that have expressed a need for a national assessment that is psychometrically validated to assist with measuring curriculum development and student performance.

Details are posted under Assessment Programs on the NABP Web site, [www.nabp.net](http://www.nabp.net), or by contacting NABP Customer Service at [custserv@nabp.net](mailto:custserv@nabp.net).

## **An e-Educated Consumer is Your Best Customer (Patient)**



*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 Food and Drug Administration (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!**® 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 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).*

According to the Pew Internet and American Life Project, Online Health Search 2006, 80% of American Internet users, or some 113 million adults, have searched for information on at least one of 17 health topics. Many Americans turn to the Internet before, or instead of, seeking information from their doctor or pharmacist. People want to make better decisions in their lives and therefore seek more in-depth research, research that is offered online.

Patients and caregivers have a vested interest to keep up-to-date on their own or their loved ones' medical conditions. The average doctor's appointment is just 10 minutes – hardly enough time to get into lengthy conversations about treatment options and medication side effects. Long lines, busy and distracted pharmacists, and lack of privacy and confidentiality deter patients from seeking more information from their community pharmacists. It is no wonder then, when patients do not understand medical terminology or want to explore the medication treatment options that are available, they do not call their doctor or pharmacist – they just log on. In the privacy of their home they can find practical information such as lists of foods they should or should not take with certain medical conditions or certain medications. Instead of bothering busy pharmacists

who do not appear to have the time to answer questions, they can get peace of mind when dealing with chronic conditions. They surf the net for reassurance and answers to their questions.

But what about the quality of those online sources? Some are better than others; obviously, Medline offered by the National Institutes of Health is a reliable source, but what if the site is sponsored by a pharmaceutical company? How does the consumer know which information to trust? Research suggests that most health information seekers do not check the source and date of the information they find online. Most Internet users use a search engine and key words from their own limited medical knowledge and rely on the algorithms of the search engines to find them reliable Web sites and scientific articles.

How can you, the pharmacist, help your patients find a credible health care information site? Patients need an easy-to-use, comprehensive medical Web site where they can learn about health conditions and medications. Patients should look for Web sites that offer unbiased health information written by medical professionals.

Tell patients to always check sources and dates of the information provided. For example, information on hormone replacement therapy has changed significantly in the last few years. Articles offering advice and recommendations on drug therapy from 10 years ago could be detrimental to the reader.

The patient-doctor-pharmacist triad has changed. We now live in an era of the square – the patient, doctor, pharmacist, and Internet. Help patients understand what they are reading. Go to the sites yourself and confirm the information is reliable and timely. And of course, find time to answer their questions. Look for a soon to be released consumer Web site being developed by ISMP.

## **FDA Warns against Using OTC Cold Medicines in Babies**

FDA issued a public health advisory on January 17, 2008, recommending that over-the-counter (OTC) cough and cold medicines should not be used to treat infants and children younger than 2 years of age, citing the risk of "serious and potentially life-threatening side effects." FDA held a public advisory committee meeting October 18-19, 2007, to discuss the issue, after which many pharmaceutical manufacturers voluntarily withdrew cough and cold medicines marketed for use in this age group.

FDA says the agency is in the process of evaluating the safety of OTC cough and cold medicines in children 2-11 years of age and will announce its recommendations "in the near future."

The public health advisory is available on the FDA Web site at [www.fda.gov/cder/drug/advisory/cough\\_cold\\_2008.htm](http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm).

## **Bayer Diabetes Care Recalls Contour Test Strips**

Bayer Diabetes Care recently recalled test strips (sensors) for use with the Contour TS Blood Glucose Meter. The company recalled the product because test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.

This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. Strips used with other Bayer meters are unaffected.

Health care professionals are advised to check the lot number of the Contour test strips in their inventory and contact Bayer Diabetes Care for information on the return and replacement of strips.

More information is available in the manufacturer's press release at [www.fda.gov/medwatch/safety/2007/contourTS\\_recall.htm](http://www.fda.gov/medwatch/safety/2007/contourTS_recall.htm).



## **FDA Takes Action against Compounded BHRT Drugs**

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms “bio-identical hormone replacement therapy” and “BHRT” to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of “bio-identical” as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at [www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html](http://www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html).

## **Manufacturers to Restrict Distribution of Methadone**

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria.

The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

For more information, see “Studies Show Increased Methadone-Associated Mortality Related to Pain Management” in the January issue of the *NABP Newsletter*, available on the NABP Web site at [www.nabp.net](http://www.nabp.net).

## **New Compounding Standards Effective June 1; USP Offers Webinars**

New standards for sterile compounding will become effective on June 1, 2008. United States Pharmacopeia (USP) published the revised General Chapter 797, “Pharmaceutical Compounding – Sterile Preparations” on its Web site in December 2007 to give the compounding community time to implement changes before the effective date.

These revisions tighten standards and conditions for sterile compounding over the previous version of Chapter 797 to help improve patient safety. (See “Sterile Compounding ‘Checklist’ Revised to Better Protect Patient Health” in the February 2008 issue of the *NABP Newsletter*.) The revisions are included in USP 32–NF 27 and in the second edition of the *Pharmacists’ Pharmacopeia*, published in March 2008.

USP is offering a series of educational Webinars and workshops to help compounding professionals appropriately interpret and implement the newly revised standard. The Webinars will provide direct dialogue with two compounding experts and ample time to address questions related to the standard. The workshops will provide added interaction plus hands-on demonstrations related to environmental monitoring, contamination control, and aseptic testing.

Full details on these programs are available on the USP Web site at [www.usp.org/hottopics/generalChapter797.html?hlc](http://www.usp.org/hottopics/generalChapter797.html?hlc).

## **Moving? Need to Transfer Your License?**

It is easy – go to the Licensure Programs section of [www.nabp.net](http://www.nabp.net).

Questions? Call Customer Service at 847/391-4406.

*NABP – Serving Pharmacists with Licensure Transfer Since 1904*

## **CMS Names MSAs, Products for Round Two of DMEPOS Bidding**

Centers for Medicare and Medicaid Services (CMS) recently announced the metropolitan statistical areas (MSAs) and product categories for the second round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

All suppliers must meet quality standards and be accredited by a CMS-recognized accreditation organization, such as NABP, to obtain a contract under the Medicare DMEPOS competitive bidding program. The final deadline for all suppliers to obtain accreditation is September 30, 2009. However, CMS encourages suppliers to seek accreditation as soon as possible to avoid any potential difficulties that would affect their ability to bid.

The competitive bidding program is designed to improve the effectiveness of Medicare’s DMEPOS payments, reduce beneficiary out-of-pocket costs, and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services. More information, including the lists of MSAs and product categories, is available on the CMS Web site at [www.cms.hhs.gov/CompetitiveAcqforDMEPOS](http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS).

## **Adverse Event Reporting Requirements in Effect for OTC Products**

FDA recently issued new adverse event reporting requirements for manufacturers, packers, and distributors of dietary supplements and over-the-counter (OTC) drug products marketed without an approved application. The new reporting requirements, as described in Public Law 109-462, became effective on December 22, 2007.

The act, as well as the FDA *Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application*, is available via the FDA MedWatch site at [www.fda.gov/medwatch/otc.htm](http://www.fda.gov/medwatch/otc.htm).

## **FDA Rule Calls for Toll-Free Number for Adverse Events on Drug Labels**

FDA recently issued an interim final rule requiring certain medication labels to include a toll-free number for reporting adverse events. The interim final rule codifies provisions of the proposed rule “Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products” that became effective on January 1, 2008, under the FDA Amendments Act of 2007. The rule does not apply to over-the-counter medications approved as new drugs if the product packaging includes a manufacturer’s or distributor’s toll-free number for reporting complaints.

To allow manufacturers, dispensers, and pharmacies time to update their labeling and systems to comply with the new requirements, FDA will delay enforcement actions regarding these regulations until January 1, 2009.

More information is available in the *Federal Register* (Docket No. 2003N-0342) at [www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf](http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf).

◆ **New Pharmacy Law Book Available:** New law books are available. Your inspector will provide one to your pharmacy when conducting his or her routine inspection. Law books are also available for download from the Board's Web site at [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov). If you would like to order one, printed law books are available from the Board office for a fee of \$10 per book. Payment must be received in advance. Checks or money orders are accepted.

### **Citizenship Affidavit Now Required**

Effective November 1, 2007, a new state law requires **all license applicants** to verify their lawful presence by executing a sworn affidavit under the penalty of perjury. Please complete **either** Option 1 if you are a United States citizen **or** Option 2 if you are a qualified alien, and return with your application. Any application received without a signed, notarized statement will be returned.

### **Good Versus Bad**

It would appear that we have a large number of "bad" technicians. In each *Newsletter* we report several cases heard at Board meetings on pharmacy technicians. Technicians do not have as much at risk as pharmacists and some seem to be either unaware or unconcerned about the consequences of their actions. The majority of the cases involve stealing drugs or merchandise, yet pharmacists are usually shocked that a technician would steal from them or the pharmacy.

Pharmacists should also be aware that the answers technician applicants give on their Board applications are very important. If they are not truthful on their explanation of an arrest or conviction, they will be denied a permit. In addition, when hiring someone who was a pharmacy technician in the past but who does not currently have a pharmacy technician permit, keep in mind that the individual **cannot apply for a new permit but must complete an application for reinstatement.** (See [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov) under "Download Forms.")

**Pharmacists need to do a better, more professional job in training and supervising technicians!**

1. Carefully follow your technician training guidelines. (Board guidelines are available at [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov), technician training manuals are available from [www.opha.com](http://www.opha.com).)
2. Keep verification of all training in each technician's file.
3. Observe and supervise properly.
4. Have them read the technician rules and ask questions if there is something they do not understand.
5. Have them read the Board *Newsletter*.
6. Encourage them to take CE and possibly become certified.
7. Encourage them to ask questions if they do not understand something in the filling process.
8. Do not become complacent with your process in the pharmacy.
9. Be observant at all times.

As pharmacies fill more and more prescriptions, there is a need for "good" pharmacy technicians. It is the pharmacist's responsibility to see that the technicians:

- ◆ Are well trained
- ◆ Know what is expected of them
- ◆ Understand what they can and cannot do
- ◆ Are supervised properly
- ◆ Have a current permit posted with the proper picture identification attached

### **Have You Mailed Your Renewal?**

The Board mails renewal applications sixty (60) days in advance of expiration. If you do not receive a renewal by the

first of the month of the expiration date, it is *your* responsibility to obtain one. (See [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov) under "Download Forms.")

Please allow a **minimum** of seven (7) to ten (10) days processing time from the date the Board should have received your application before being concerned. Renewals are processed in the order they are received and special consideration will not be given to anyone.

For those pharmacists and technicians that are not allowed to work after their license or permit expires, you may use this *Newsletter* to show the Human Resource Department that your license or permit is **valid for 30 days after expiration.** The Oklahoma Pharmacy Act, Title 59, Chapter 8 §353.11 requires a 30-day grace period before a license is canceled. This also applies to pharmacy licenses. You may need to show this *Newsletter* to your wholesaler as well.

### **Application for Evaluation of Continuing Education**

CE programs submitted for approval **must** be submitted in their entirety with the "Application for Evaluation of Continuing Education." (See [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov) under "Download Forms.") This includes any agendas, brochures, copies of presentations, or any other materials used in the program. Applications received without documentation will be returned. The CE Committee meets quarterly or as needed.

### **Reminder**

Board rules require that all registrants (pharmacists, technicians, and interns) notify the Board in writing within ten (10) days of a change of address or employment.

### **Oklahoma Pharmacists Helping Pharmacists**

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP Help Line at 1-800/260-7574 extension 5. All calls are confidential.

### **Let Us Hear From You**

The Board welcomes your comments and questions. You may send mail to the Oklahoma State Board of Pharmacy, 4545 Lincoln Blvd, Ste 112, Oklahoma City, OK 73105, fax us at 405/521-3758, or e-mail us at [pharmacy@pharmacy.ok.gov](mailto:pharmacy@pharmacy.ok.gov). Visit our Web site at [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov).

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