NEWS

September 2002

Kentucky Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

23 Millcreek Park
Frankfort, KY 40601-9230

University of Utah School on Alcoholism and Other Drug Dependencies

By Brad Brown, Student Intern

On June 16, 2002, the University of Utah hosted the 51st annual session of its School on Alcoholism and Other Drug Dependencies. Since its founding in 1952, this week-long conference has been a mainstay in education for over 30,000 students and professionals from all 50 states as well as 15 foreign countries. Each discipline hosts an exclusive section based on fundamental issues inherent to alcohol and drug dependency within each area of expertise. Disciplines at the school range from medicine, nursing, pharmacy, and dentistry to criminal justice, professional treatment, and vocational rehabilitation just to name a few.

The pharmacy session at the school is attended by recovery program staff, pharmacy school faculty and administrators, recovering practitioners and students, state board of pharmacy members, pharmacy students, employers of pharmacists, pharmacy technicians, and others interested in pharmacy-related chemical dependency issues.

The school focuses on the pathophysiological aspects of chemical dependency and addiction, however, the psychosocial component was the most thought-provoking and emotionally powerful aspect of the entire session. When dealing with chemical dependency, recovery is of the utmost concern. The school covered every aspect of recovery relating to addiction and dependency by emphasizing identification, intervention strategies, treatment, monitoring, and relapse prevention.

Resources available to recovering pharmacists and students are abundant, but most new attendees did not know of the existence of these programs prior to attending, including myself. Of particular interest was a fellowship of pharmacists in recovery who gather to share experiences and serve as a source of support for each other. International Pharmacists Anonymous (IPA) meetings were charged with positive energy and spirituality and even though you did not know the majority of people sitting around you, they made you feel like family. IPA allows a discussion of pharmacy-related addiction and dependency issues to be placed in the open with the assurance that the majority of the people in the room have pharmacy expertise with an impetus toward understanding the discussion at hand. Along with regular 12-step meetings, IPA serves as an excellent supplement for pharmacy professionals recovering from addictive disease.

Of all my experiences at the Utah School, the "Group Therapy Experience" had the most profound impact on me. This part of the program involved a group of residential treatment patients who agreed to share a real-time group treatment session with the pharmacy section at the Utah School. The group consisted of patients recovering from such substances as alcohol, methamphetamine, heroin, cocaine, prescription medications, as well as numerous other illicit drugs. The atmosphere in this very large auditorium was one of seriousness and sincerity. As each patient told his or her story, I cannot remember one person in the room who did not shed a tear. The majority of the patients in the group had endured lifelong battles against drug abuse and addiction, lost loved ones, and in some instances contemplated ending their own lives due to the intense grasp of this devastating disease. I gained a true appreciation for the work of addiction counselors and specialists and the difference they make in the lives of so many people.

Pages upon pages could be written about my experience at the Utah School, but words cannot adequately describe the experience. You must attend the school for a true appreciation of its magnitude. Many of the pharmacists I had the pleasure to meet during my time in Utah wished they had the opportunity to attend this program while they were interns and reminded me how lucky I was to have attended such an unparalled occasion.

Pharmacy Compounding

On April 29, 2002, the US Supreme Court held that the Food and Drug Administration Modernization Act of 1997 (FDAMA) "prohibitions on soliciting prescriptions for advertising compounded drugs amount to unconstitutional restrictions on commercial speech." The Food and Drug Administration (FDA) has released a new compliance policy guide on pharmacy compounding in response to the Supreme Court's April 29, 2002 decision. The compliance guide describes the FDA's current thinking about how to exercise its authority in the absence of Section 503A. The FDA views the policy guide as an interim measure and intends to seek legislation in the near future. According to the *Compliance Policy Guide*, the FDA will "generally" defer to the Kentucky Board of Pharmacy to regulate pharmacy compounding. The policy guide outlines the factors the FDA will consider when determining whether to pursue enforcement action, including:

- Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amount of drugs compounded after receiving valid prescriptions.
- Compounding drugs that were withdrawn or removed from the market for safety reasons.

Continued on page 4

Continued from page 1

- Compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs without an FDA-sanctioned investigational new drug application.
- Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA registered facility.
- Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
- Using commercial-scale manufacturing or testing equipment for compounding drug products.
- Compounding drugs for third parties that resell to individual patients or offering compounded drug products at wholesale to other state-licensed persons or commercial entities for resale.
- Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products.
- Failure to operate in conformance with applicable state law regulating the practice of pharmacy.

Medical Malpractice Claims

The Department of Insurance requests licensees to remind their claims handlers, whether with insurance companies or self-insureds, that medical malpractice claims must be reported to the Department within sixty (60) days of closure pursuant to KRS 304.40-310. You may request further information by contacting the Department of Insurance at 502/564-3630 or 1-800/595-6053.

Pharmacy Security

Recent pharmacy inspections have revealed several security issues that should be considered. Some hospital pharmacies have adopted the policy of permitting non-pharmacist personnel, such as nurses, to access the pharmacy after hours to retrieve and "sign out" medicinal drugs, which they cannot readily retrieve from the floor stock or the night drug cabinet. This practice is in violation of regulations of the Kentucky Board of Pharmacy and may constitute violations of security regulations of the Drug Enforcement Administration. Pharmacists are reminded that non-pharmacist personnel are not authorized to enter a pharmacy without a pharmacist present (201 KAR 2:100), and that the pharmacy itself shall not be designated as the night drug cabinet (201 KAR 2:074). Additionally, the pharmacist-in-charge is responsible for knowing who has access to the pharmacy and to identify those persons on the application for the pharmacy permits.

The prescription department of a community pharmacy must be enclosed by a solid or solid transparent, floor-to-ceiling partition if customers or non-pharmacist personnel have access to other parts of the store while the pharmacy department is closed. If no partition exists, then no customers or non-pharmacist personnel may enter the store without a pharmacist present. Some pharmacies use an invisible barrier, such as a motion-detector alarm, to secure the pharmacy department from the remainder of the store. Use of alarms or similar technology currently requires an inspection and special approval from the Board.

Some pharmacists whose pharmacies have alarm systems are leaving the pharmacy keys and alarm codes together at a location such as the "manager's office" when relief pharmacists are scheduled to work. The practice of storing the keys and the alarm codes together is not prudent, particularly when non-pharmacist personnel would have ready access to enter the pharmacy. A more secure method should be devised to permit access to the pharmacy when relief pharmacists call ahead to obtain the alarm code, or a small combination lockbox for storing the keys and alarm codes be installed, or a tamper-evident seal be applied to the container where keys and codes are kept.

"Orange Book" Online

The Food and Drug Administration's *Approved Drug Products with Therapeutic Equivalence Evaluations,* also known as the "Orange Book," is now available online at www.fda.gov/cder/ob/.

The *Kentucky Board of Pharmacy News* is published by the Kentucy Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Michael A. Moné, JD, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Courtney M. Karzen - Editorial Manager

KENTUCKY BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc.
700 Busse Highway
Park Ridge, Illinois 60068

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744