



Kentucky Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Michael Burton: July 15, 1962 - January 30, 2006

Kentuckians suffered a tremendous loss Monday, January 30, 2006, when Mike Burton passed away at his home in Stanton, KY, of an apparent heart attack. He was 43 years old.

Burton was the senior field investigator for the state Drug Enforcement and Professional Practices Branch of the Office of Inspector General in the Cabinet for Health and Family Services. Burton dedicated his career to fighting the illegal diversion and abuse of prescription drugs. Burton headed up often complex, dangerous investigations and consulted with law enforcement agencies on drug-related issues. He had worked for the Office of the Inspector General since 1989.

"Citizens of the Commonwealth are safer today because of the skills, dedication, and professionalism of Mike Burton," said Inspector General Robert Benvenuti. "Pharmacists, physicians, patients, and law enforcement officials all benefited from Mike's devotion to duty and the values he brought to the job. He will be greatly missed both professionally and personally."

He is survived by his wife Trish and daughter Tiffany, 7; his mother Alice; and a sister, Beverly.

A 1987 graduate of the University of Kentucky (UK) College of Pharmacy, Burton also held a bachelor's degree in biology from UK.

Funeral services for Burton were held February 2, 2006, at the Stanton Christian Church Family Life Center. A Kentucky State Police honor guard offered a graveside salute to Burton and presented a flag to his family.

Stamped Signatures and Office Personnel Signing Prescriptions

The Kentucky Board of Pharmacy at its December 14, 2005 meeting reviewed a request from the Drug Enforcement and Professional Practices Branch of the Office of Inspector General in the Cabinet for Health and Family Services concerning the validity of **non-controlled substance prescriptions** with stamped signatures of the prescriber or office personnel signing the prescriptions with the prescriber's name followed by the initials of the office personnel. After discussion and review of KRS 217.015(36) the Board moved to notify pharmacists and the Kentucky Board of Medical Licensure that the Board discourages stamped signatures and office personnel signing prescriptions with the prescriber's name followed by the initials of the office personnel; however, there is nothing in the statutes or regulations prohibiting these actions. The Board reminds pharmacists that they should use due diligence to establish the validity of **any** prescription.

Warning Signs of Abuse and Dependency

Submitted by Brian Fingerson, RPh, Pharmacy Recovery Network

We all know that we may see patients who are addicted to drugs or alcohol. Do we recognize it in them? Can we say we would recognize this disease in a colleague? If we do recognize it, then what do we do? Let us begin with a definition and some signs and symptoms.

Addiction to drugs including alcohol is defined as a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following:

- ◆ Impaired control over drug use;
- ◆ Compulsive use;
- ◆ Continued use despite harm; and
- ◆ Craving.

Warning Signs of Abuse and Dependency Include:

Usage Increase – Over time, it is common for individuals taking prescription medications to grow tolerant to the effects of their prescribed dose. Increased dosage often indicates that the original amount is no longer providing relief.

Change in Personality – Changes in a person's normal behavior can be a sign of dependency. Shifts in energy, mood, and concentration may occur as everyday responsibilities become secondary to the need for the relief the prescription provides.

Social Withdrawal – A person experiencing a dependency problem may withdraw from family, friends, and other social interaction.

Ongoing Use – Patients that complain frequently about "still feeling pain" or request to extend a prescription long after the medical condition has improved should be monitored closely. Those who gripe about doctors refusing to write a prescription show signs of dependency.

Going to Great Lengths to Obtain Prescriptions – A dependent person may spend large amounts of time driving great distances and visiting multiple doctors to obtain drugs. Preoccupation with a quest for medication demonstrates that the drug has become a top priority.

Change in Appearance – Personal hygiene may diminish as a result of a drug addiction. Significant weight loss may occur and glazed eyes may be evident.

Desensitized Emotions – A dependent person may exhibit an attitude of indifference, a lack of emotion, and demonstrate disinterest in things that previously brought them pleasure.

Increased Inactivity – Hobbies and activities no longer provide the enjoyment they used to. Those suffering from dependency may feel lethargic and tend to stop engaging in athletic activities.

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DEA Releases Final Rule on Approved Narcotic Controlled Substances for Maintenance of Detoxification Treatment

According to the June 23, 2005 *Federal Register*, Drug Enforcement Administration (DEA) has amended its regulations (§1301 and §1306) to allow qualified practitioners not registered as a narcotic treatment program to dispense and prescribe to narcotic-dependent persons Schedule III, IV, and V narcotic controlled drugs approved by Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment. This final rule is in response to amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA) that are designed to increase and improve the treatment of narcotic addiction. In addition, the final rule is intended to accomplish the goals of DATA while preventing the diversion of Schedule III, IV, and V narcotic drugs approved for maintenance/detoxification treatment. This rule went into effect July 25, 2005.

Additionally, the amended regulations require the practitioner to include on the prescription the identification number or written notice that the practitioner is acting under the good faith exception of §1301.28(e). In order to be valid, a prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The prescription must also be dated as of, and signed on, the day issued and must contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use as well as the name, address, and registration number of the practitioner. Practitioners are not normally required to keep records of prescriptions issued, but DEA regulations require records to be kept by practitioners prescribing controlled substances listed in any schedule for maintenance or detoxification treatment of an individual.

Any practitioner who dispenses or prescribes Schedule III, IV, or V narcotic drugs in violation of any of the conditions as specified in §1301.28(b), may have their practitioner's DEA registration revoked in accordance with §1301.36.

Due to the potential for diversion, and in an effort to verify compliance with these regulations, DEA intends to conduct at least two regulatory investigations per field office per year of practitioners dispensing and prescribing to narcotic-dependent persons Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment.

How FDA Reviews Drug Names

By Carol Holquist, RPh, FDA, Office of Drug Safety

FDA has received approximately 18,000 reports of actual or potential medication errors since 1992 and continues to improve the process by which these errors are assessed. Over the past nine years, FDA has increased the safe use of drug products by minimizing user errors attributed to nomenclature, labeling, and/or packaging of drug products. The group in charge of these activities is the Office of Postmarketing Drug Risk Assessment (OPDRA) under FDA's Center for Drug Evaluation and Research. Ten clinical pharmacists and physicians make up OPDRA's medication error staff.

The Name Review Process

Since October 1999, OPDRA has reviewed approximately 400 drug products. Proprietary names undergo a multifactorial review designed to improve consistency and minimize risk due to sound-alike and look-alike names. The process includes:

- ◆ *Expert panel review.* An expert panel meets weekly to exchange opinions on the safety of a new proprietary name. The panel comprises OPDRA medication error prevention staff and representatives from the Division of Drug Marketing and Advertising Communications, who rely on their clinical, regulatory, and professional experiences to decide on the acceptability of a proprietary name.
- ◆ *Handwriting and verbal analysis.* These are conducted within FDA to determine the degree of confusion in visual appearance or pronunciation between the proposed proprietary name and names of other United States drugs. FDA health professionals (nurses, pharmacists, and physicians) are requested to interpret both written inpatient and outpatient prescriptions and verbal orders in an attempt to simulate the Rx ordering process.
- ◆ *Computer-assisted analysis.* Currently, OPDRA utilizes existing FDA databases to identify potential sound-alike and/or look-alike proprietary names. In the future, OPDRA plans to use validated computer software that will improve the ability to detect similarities in spelling and sound among proprietary names.
- ◆ *Labeling and packaging analysis.* OPDRA provides a safety assessment of the container labels, carton and package insert labeling, and proposed packaging of each product to identify areas of potential improvement.
- ◆ *Overall risk evaluation.* This final phase of the name review process weighs the results of each phase of the review as well as additional risk factors such as overlapping strengths, dosage forms, dosing recommendations, indications for use, storage, labeling, and packaging, and important lessons learned from the agency's post-marketing experience.

How Can You Help?

Pharmacists and other health professionals can assist FDA in minimizing medication errors by reporting any actual or potential medication errors to MedWatch, FDA's medical product reporting and safety information program launched in June 1993. All identification of reporter, institution, and patient are kept confidential and are protected from disclosure by the Freedom of Information Act.

Medication errors can easily be reported to MedWatch via telephone (1-800/FDA-1088), Web site (www.fda.gov/medwatch), and fax (1-800/FDA-0178). In addition, a standardized MedWatch adverse event reporting form (FDA Form 3500) is available to aid in submitting voluntary reports of medication errors. You should provide a complete description of the error; level of staff (eg, pharmacist, nurse, physician) involved; medication involved; patient outcome; setting of the incident (eg, inpatient, outpatient); relevant patient information (eg, age and gender); date of event; manufacturer of the drug; dosage form and strength; and size of container. Finally, you will need to check both "Product Problem and/or Adverse Event" and "other" on the form.



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

We also encourage you to include your suggestions for preventing errors. With your contributions to increased reporting and the new processes implemented by OPDRA, the agency can provide effective intervention strategies that will minimize the risks associated with medication errors.

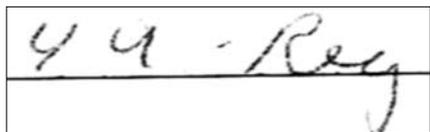
What's wrong with "U"?



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, and 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.

The use of abbreviations is always problematic when communicating medical information. All too often, medical abbreviations hinder our understanding or are misread. Insulin errors are common and can cause significant patient harm. The cause of many insulin errors is related to the use of abbreviations when communicating prescription information. The abbreviation "U" to indicate "units" has contributed to many errors when it was misread as a zero (0) or a number 4.

Over the years, numerous reports have been received through the USP-ISMP Medication Errors Reporting Program that describe the occurrence of 10-fold or greater overdoses of insulin because the



abbreviation "U" has been misinterpreted. It is not uncommon for a "U" to be misread as a zero (0). For example, prescriptions for "6U regular insulin" have been misinterpreted and administered as 60 units of regular insulin. In another report, a prescriber wrote an order for "4U Reg" (see photo); however, someone misinterpreted the "U" as a "4." The person who injected the insulin did not recognize that this was an excessive dose and proceeded to administer 44 units to the patient. The patient required glucose to reverse his acute hypoglycemia.

In order to prevent errors such as these, health care practitioners should **always** write out the word "units." Educate staff about the dangers involved with using this abbreviation. Practitioners must recognize the need for good communication skills and realize that the perceived time saved when using the abbreviation "U" for units may actually result in serious patient harm. Occasionally, while intending to do the "right thing," errors still can occur. This was the case when a physician wrote a sliding scale insulin order for a hospitalized patient with a blood sugar of 396 mg/dL. When writing the insulin order, the physician included the word "units." According to the order, this patient should have received 4 units of regular insulin subcutaneously. Unfortunately, because the letter "U" in units was separated from

the rest of the word, "-nits," the nurse read the order as 40 units and administered the dose to the patient. His blood sugar dropped to 54 mg/dL and he required dextrose to correct the hypoglycemia. The error was realized when the nursing notes were reviewed and it was documented that 40 units was administered.

Pharmacy and nursing staff must carefully review insulin prescriptions, knowing that errors involving this abbreviation are common and can result in 10-fold or greater overdoses. Clarify any questionable insulin dosages and inform the prescriber of misinterpretations that could occur due to use of the abbreviation "U" for units. In addition, whenever possible, require an independent double check of insulin prescriptions before they are dispensed or administered.

Safeguards for Severe Acne Medication Announced

Because isotretinoin (Accutane[®]) carries significant risks of birth defects for women who are pregnant or might become pregnant, FDA has unveiled safeguards for its distribution. (See related article, March 2005 NABP Newsletter, page 61.) The manufacturers of isotretinoin are launching a program called iPLEDGE[™] in which doctors and patients register with the program and agree to accept certain responsibilities as a condition of prescribing or using the drug. Wholesalers and pharmacies must also comply with the program to be able to distribute and dispense the drug.

In the wake of a February 2004 joint meeting between FDA's Drug Safety and Risk Management Advisory Committee and Ophthalmic Drugs Advisory Committee, major improvements were recommended for the restricted distribution program for isotretinoin, which has proven effective in treating severe recalcitrant nodular acne. Under the recommendations, patients who could become pregnant are to have negative pregnancy testing and birth control counseling before receiving the drug. In addition, patients must complete an informed consent form and obtain counseling about the risks and requirements for safe use of the drug. Starting December 31, 2005, all patients and prescribers must register and comply with requirements for office visits, counseling, birth control, and other program components. After October 31, 2005, wholesalers and pharmacies were required to register with iPLEDGE in order to obtain isotretinoin from a manufacturer.

Program information and registration is available at www.ipledgeprogram.com or 866/495-0654.

For the purpose of increasing available information about isotretinoin and its associated risks, FDA also issued a Public Health Advisory and revised the Patient and Health Care Provider Information Sheets that detail the new patient and practitioner restrictions and responsibilities under the program. A reporting and collection system for serious adverse events associated with the use of the drug has also been established. Pregnancy exposures to isotretinoin must be reported immediately to FDA at the MedWatch phone number (1-800/332-1088), the iPLEDGE pregnancy registry (866/495-0654), or on the iPLEDGE Web site.

Besides approving the iPLEDGE program, FDA approved changes to the existing warnings, patient information, and informed consent form to help patients and prescribers better identify and manage the risks of psychiatric symptoms and depression before and after taking the medication.

Continued from page 1

Blackout and Forgetfulness – Another clear indication of dependence is when the person regularly forgets events that have taken place and appears to be suffering frequent blackouts.

Defensiveness – Abusers who attempt to hide a drug dependency may lash out and become very defensive if they feel their secret is being discovered.

If you recognize any of these signs and symptoms in a colleague, you may refer them to the profession's program that assists those with this disease to get the help needed to treat the disease and then monitor their recovery. **You may call the Kentucky Professionals Recovery Network – Brian Fingerson, RPh, at 502/749-8385 or e-mail kyprn@insightbb.com for assistance.**

Solving the Mystery of "Orange Book"

Evaluation Codes

Submitted by Benjamin M. King, PharmD Candidate

With more than 10,000 drugs listed in the 25th edition of the "Orange Book," it is not surprising that much can arise when trying to determine if and when a drug is substitutable. Substitution of levothyroxine products is just one example of how pharmacists can get caught in the middle of a bioequivalence debate among manufacturers, physicians, and Food and Drug Administration (FDA).

There are two basic categories into which multisource drugs are placed. **A** listed drug products are considered therapeutically equivalent to other pharmaceutically equivalent drug products. **B** listed drug products are not considered therapeutically equivalent to other pharmaceutically equivalent drug products. The second letter of the therapeutic evaluation code (TE code) gives general information on why the drug is rated **A** or **B**. For example, two pharmaceutically equivalent **AA** rated drugs contain active ingredients and dosage forms that are not regarded as presenting either actual or potential bioequivalence problems or drug quality or standards issues. Drug products identified by FDA as having actual or potential bioequivalence problems will only be designated therapeutically equivalent after scientific evidence proves the two products to be bioequivalent. These products are generally assigned an **AB** rating.

A third character in the TE code is assigned when multiple sources of a single ingredient are available but not all of the sources are considered therapeutically equivalent to each other. The best example of this came about a few years ago when Procardia XL[®] and Adalat[®] CC both went off patent. Both products are listed in the "Orange Book" under the active ingredient nifedipine. These branded products are not bioequivalent to each other. In order to designate which generic products are equivalent to which brands,

FDA has assigned Adalat CC a rating of **AB1** and Procardia XL a rating of **AB2**.

The three-character system described above is the same system used to designate bioequivalence between levothyroxine drug products. Because there are multiple reference listed drugs of levothyroxine, FDA felt its traditional system of three-character TE codes could be potentially confusing and elected to provide an explanation and chart in the most recent edition of the "Orange Book."

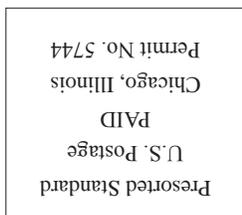
Levothyroxine products are divided into three groups (**AB1**, **AB2**, **AB3**). Therapeutic equivalence has been established between products having the same three-character rating. More than one TE code may apply to some of the products, eg, levothyroxine sodium (Mylan Laboratories Inc) is rated as **AB1**, **AB2**, and **AB3**. A common TE code indicates therapeutic equivalence between products, eg, levothyroxine (Genpharm Inc) and Synthroid[®] (Abbott Laboratories) have an **AB2**. It should be noted that Novothyrox[®], Thyro-Tabs[®], and Levolet[®] are currently **BX** rated. **BX** rated products are those that FDA considers not to be therapeutically equivalent to other pharmaceutically equivalent products.

The first publication of the "Orange Book" in October 1980 was the result of many requests from the states for FDA to assist in preparation of both positive and negative formularies. The agency could not serve the needs of each state on an individual basis and decided to provide the states with a single list based on common criteria. The "Orange Book" is no longer published in paper form but can be found, along with monthly updates, online at www.fda.gov/cder/ob/default.htm. The online version of the "Orange Book" is an easy to use, valuable tool for pharmacists with generic substitution questions.

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