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Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.



2006 Fifty-year Pharmacists

The Alabama State Board of Pharmacy recognizes and takes great pride in congratulating the pharmacists who have been licensed in Alabama for 50 years. This is an outstanding career accomplishment in the pharmacy profession and a great service to their communities.

William Russell Armistead
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D. Arnold Caylor, Jr
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Harvey Russell Collins, Jr
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Bartlett H. Ford, Jr
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James Kenneth Guin
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Henry Marion Hutcheson
Charles Alexander Isbell
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Eugene McLemore
James Fairley Morton
James Lloyd Norris
Howard Tillman Plott
Norman L. Reed
Charlie Hudson Scarbrough
Kenneth Gay Sims
John Ernest Wintter



Pharmacies Must Register to Dispense Isotretinoin

Pharmacies must register to continue dispensing isotretinoin products. United States Food and Drug Administration (FDA) has approved iPLEDGE™, an enhanced risk management program designed to minimize fetal exposure to isotretinoin. iPLEDGE will require mandatory registration of prescribers, patients, wholesalers, and pharmacies to further the public health goal to eliminate fetal exposure to isotretinoin. Starting **December 30, 2005**, unregistered and activated pharmacies were no longer able to dispense Accutane® (isotretinoin), Amnesteem®, Claravis™, or Sotret® to people with severe acne without enrolling in FDA's new iPLEDGE program through a physician who is enrolled.

Pharmacies have two steps in preparing their pharmacies to dispense isotretinoin prescriptions under iPLEDGE: "registration" and "activation." (After a pharmacy registers for iPLEDGE on www.ipleadgeprogram.com or by calling **1-866/495-0654**, the "Responsible Site Pharmacist" is sent a follow-up mailing, which contains instructions on how to activate their pharmacy.)

Pharmacies that have not registered and activated by December 30, 2005, will not be eligible to order isotretinoin from their wholesaler and must return all unused products to the manufacturer.

Patient registration began December 30, 2005. Patients currently being treated with isotretinoin may register in the iPLEDGE program or continue in their current program until February 28, 2006.

Starting March 1, 2006, all patients taking isotretinoin must be registered in the iPLEDGE program.

Wholesalers that did not register by December 30, 2005, are not be eligible to order isotretinoin from manufacturers and must return all unused product to the manufacturer.

Continued on page 4



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.

Additional requirements include 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

Food and Drug Administration (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 with soundalike and lookalike 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 analyses.* 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 soundalike 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/med-watch), 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

Compliance News

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(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.

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"?

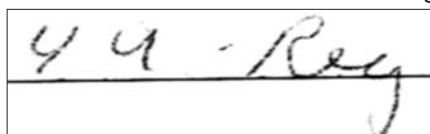
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and



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, 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) and, 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, healthcare 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 being dispensed or administered.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse as part of the National Institutes of Health (NIH) has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the United States and the trend of non-medical use of prescription drugs.

For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

NABP's 102nd Annual Meeting – Save the Date

Register now for the National Association of Boards of Pharmacy's 102nd Annual Meeting, April 8-11, 2006, at the Westin St Francis in San Francisco, CA.

Attendees will have the opportunity to earn Continuing Education Credits during the meeting. Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's Business Sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in the Alcatraz Island spouse/guest tour and the annual Fun Run/Walk.

To register, or for more information, visit NABP's Web site at www.nabp.net, or contact NABP by calling 847/391-4406 or e-mailing custserv@nabp.net.

Prescribers who have not registered and activated by March 1, 2006, will not be eligible to prescribe isotretinoin for patients.

Be sure to let dermatologists in your area know that your pharmacy is authorized to dispense isotretinoin.

To register and activate your pharmacy, visit www.ipledgeprogram.com or call 1-866/495-0654.

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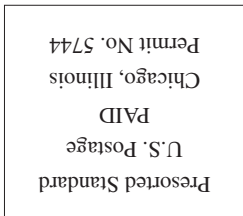
**Alabama Department of Public Health
Prescription Drug Monitoring Data
Collection and Tracking**

Act 2004-443, SB35, authorizes the Alabama Department of Public Health to establish, create, and maintain a controlled substances (CS) prescription database program and a controlled substances prescription database advisory committee. The Act requires the reporting of (CS) prescrip-

tion data to the department by pharmacies, physicians, and other practitioners who are authorized to prescribe [CS] and enumerates the data elements to be reported. The Act lists persons and entities permitted access to the database, provides for the confidentiality of all information maintained in the database, and prescribes penalties for the unauthorized disclosure of information contained in the database. The Act assesses a surcharge of \$10 per year on the [CS] registration certificate of each licensed medical, dental, podiatric, optometric, and veterinary medicine practitioner to be used by the Department of Public Health for the development, implementation, operation, and maintenance of the database. The Act provides that the database will be operational within 12 months after the state health officer certifies that sufficient funds are available to implement and operate the database, and also provides that persons or entities required to report information to the database are not liable for any claim of damages as a result of such report.

The *Alabama State Board of Pharmacy News* is published by the Alabama State 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.

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