

February 2005



# Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.



## 2005 Fifty-year Pharmacists

The Alabama State Board of Pharmacy recognizes and takes great pride in congratulating the 50-year milestone of pharmacists licensed in Alabama. This is an outstanding career accomplishment in the pharmacy profession and service contribution to their communities.

William Henry Jones, Jr  
Ray Neil Riddle  
Elias Harilaos Ladas  
William Wilkie Camp  
Robert Spencer Higdon  
James F. Loyd Holcomb  
John Palmer Beasley  
Bernard Calvin York  
Gene Wayne Smith  
Robert Moses Zarzaur  
Charles Goodrich Gammill  
John D. Maund  
Jerry O. Brown  
Roger A. Everett  
Richard L. Morgan  
Clemont Carpenter  
Marcia Underwood Gullett  
Mary Carolyn White Hale  
Donald Ray French  
William A. Rawls



## Frequently Asked Questions

**Prescription orders for Schedule II:** No prescription order for a controlled substance (CS) in Schedule II may be refilled and such prescription orders must be kept in a separate file. The partial dispensing of a Schedule II CS is permissible if the pharmacist is unable to supply the full quantity called for in a written prescription order. Drug Enforcement Administration allows **a portion of the quantity** requested to be provided if a notation of the quantity supplied is documented on the prescription order and the pharmacist so advises the authorizing practitioner. **The remaining portion may be dispensed within 72 hours of the first dispensing.** No further quantity may be supplied beyond the 72 hours except on a new prescription.

**Prescription orders for Schedules III-V:** Prescription orders for CS III, IV, or V may be issued either orally or in writing from a practitioner and may be re-dispensed if so authorized. Such prescription orders may not be dispensed or re-dispensed more than six months after issued, or be refilled more than five times after the issue date. After refilling a prescription order for any CS in Schedules III, IV, or V, a pharmacist must enter his or her initials, the date the prescription order was refilled, and the amount of drug dispensed on such refill. If the pharmacist merely initials and dates the prescription order, he or she shall be deemed to have dispensed a refill for **the full face amount** of the original prescription order. **Partial dispensing** of prescription orders for CSs in Schedule III and IV is permitted if the pharmacist dispensing or refilling the prescription order sets forth the quantity dispensed and he or she initials the prescription order. In addition, the partial dispensing may not exceed the total amount authorized in the prescription order and the dispensing of all refills must be within the six-month limit.



## **The Effects of the Flu Vaccine Shortage**

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- ◆ Persons aged 65 years or older;
- ◆ Children six to 23 months of age;
- ◆ Residents of long-term care facilities and nursing homes;
- ◆ Persons two to 64 years of age with chronic medical conditions;
- ◆ Health care workers involved in direct patient care;
- ◆ Household contacts and out-of-home caregivers of children less than six months of age;
- ◆ Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- ◆ Pregnant women.

Although not appropriate for everyone, FluMist® (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu® (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza® (zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- ◆ Washing your hands frequently to avoid the spread of viruses and bacteria;
- ◆ Avoiding contact with people who may be sick;
- ◆ Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- ◆ Covering your mouth and nose when coughing or sneezing;

- ◆ Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at [www.hhs.gov/nvpo/pandemic-plan](http://www.hhs.gov/nvpo/pandemic-plan). Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy® (NABP®) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

FDA Flu Information – [www.fda.gov/oc/opacom/hottopics/flu.html](http://www.fda.gov/oc/opacom/hottopics/flu.html).

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – [www.cdc.gov/flu](http://www.cdc.gov/flu).

## **FDA Urges Consumer Education About Counterfeit Drugs**

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site ([www.fda.gov/cder/consumerinfo/counterfeit\\_all\\_resources.htm](http://www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm)) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at [www.pfizer.com](http://www.pfizer.com) as well as FDA's distributed a press release that is now available at [www.fda.gov](http://www.fda.gov).



Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit [www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html](http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html).



## Diabetes or Alzheimer's Disease?

*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).*

Several reports of mix-ups have been reported in which the antidiabetic agent AMARYL® (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication REMINYL® (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer

order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

## Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access [www.ismp.org/Pages/FDAVideos.htm](http://www.ismp.org/Pages/FDAVideos.htm) for videos related to medication errors. See [www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm) for a complete list of all broadcasts.

## 2005 Survey of Pharmacy Law Now Available

NABP's 2005 Survey of Pharmacy Law CD-ROM is now available. Eight new questions were added to this year's Survey; topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

The Survey can be obtained for \$20 from NABP by downloading the publication order form from [www.nabp.net](http://www.nabp.net) and mailing in the form and a check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. If you do not have Web access or would like more information on the Survey, please contact NABP at 847/391-4406 or via e-mail at [custserv@nabp.net](mailto:custserv@nabp.net).

## NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at [custserv@nabp.net](mailto:custserv@nabp.net) or call 847/391-4406.

## Register Now for NABP's 101<sup>st</sup> Annual Meeting

Register now for NABP's 101<sup>st</sup> Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at [www.nabp.net](http://www.nabp.net), or contact NABP at 847/391-4406 or [custserv@nabp.net](mailto:custserv@nabp.net).

## **Administrative Hearings – August 2004 Through November 2004**

### **Technicians**

Retraction: Due to an unintentional oversight, the Board's November 2004 *Newsletter* stated that **Kevin W. Woodard** #T11747 was charged with theft of property, possession of a CS. This is not correct. Mr Woodard was only charged with theft of property.

**Lindsay Brooke Gogan** #T11461, **Lucy Allen** #T12443, **Gregory Thomas Williams** #T10810, **Jimmy Lawayne King** #T11897, **Nora Dean Stewart** #T14487, **Jill Marie Ban** #T12329, **Cathy Lynn Cotney** #T14479, **Japonika Monyette Quinn** #T13291, **Patricia Ann Manning** #T00190, **Ashley Nabors Hulsey** #T13215, **Tiffany Monique Wedgeworth** #T13800. Action – Registrations revoked.

**Steven Christopher Barnes** #T00113. Action – Registration revoked, \$2,750 fine.

**Sharon Hawkins Schafer** #T15733 – Removing prescriptions without authorization. Action – Probation one (1) year, \$375 fine.

**Khelsi Sheneae Harvest** #T10788 – Obtained registration by fraudulent means. Action – Suspended five (5) years, may revert to probation with compliance, \$625 fine.

### **Technician Applicants**

**Alesia Monye Phillips, Melinda Gandy** – Conviction of a misdemeanor involving moral turpitude. Action – Application granted, probation two (2) years, \$250 fine.

### **Pharmacists**

Retraction: Due to an unintentional oversight, the Board's November 2004 *Newsletter* stated that **Jerry Donald Rogers** #7797 was charged with dispensing both CSs and legend drugs without a prescription. This is not correct. Mr Rogers was charged only with dispensing legend drugs without a prescription.

**George Martin Yeager** #10749 – Dispensing CS without authorization. Action – Suspended license thirty (30) years, may apply for probation after ten (10) years, \$7,000 fine.

**Frank P. Ammirata** #12230 – Reinstatement hearing. Action – Suspension removed, \$250 court cost.

**George Stephen Gillard** #11902 – Dispensing legend drugs without authorization. Action – Probation two (2) years, \$500 fine.

**Kevin E. Beightol** #11726 – Conviction of a felony involving the selling and furnishing of Schedule III drugs without a prescription. Action – Suspension thirty (30) years, may apply for probation after five (5) years, \$8,250 fine.

**William Ralph McKinnon, Jr** #5360 – Dispensing legend drugs without authorization. Action – Probation two (2) years, \$2,500 fine.

**Matthew Meade Mabrey** #11905 – Unlawful dispensing of legend drugs. Action – Probation two (2) years, \$1,250 fine.

**Stephen Alan Henderson** #9797 – Violated various provisions with dispensing CS. Action – \$250 fine.

**Donald Larry Glock** – Reciprocity hearing. Action – Licensure granted contingent upon compliance requirements, \$750 fine.

### **Pharmacies**

**Blountsville Pharmacy** #101610 – Inaccurate records of prescription medications. Action – License suspended ten (10) years, immediate probation with compliance, \$7,000 fine.

**McKinnon Pharmacy** #106355 – Inaccurate records of prescription medications. Action – Probation two (2) years, \$2,500 fine.

**Rite Aid 7179** #110380 – Allowing pharmacy technician to work without a current technician license. Action – \$500 fine.

**CVS 4864** #110851 – Allowing a pharmacy technician to work without a technician registration. Action – \$500 fine.

### **Retail Medical Oxygen Supplier**

**Azalea City Medical Services, Inc** #900556 – Operating without a 2004 permit. Action – \$500 fine.

## **Scheduled Board Meetings For 2005**

- |                  |                   |
|------------------|-------------------|
| ◆ January 18-20  | ◆ July 19-21      |
| ◆ February 15-16 | ◆ August 16-17    |
| ◆ March 15-16    | ◆ September 20-21 |
| ◆ April 26-27    | ◆ October 25-26   |
| ◆ May 17-18      | ◆ November 8-9    |
| ◆ June 21-22     | ◆ December 20-21  |

## **680-X-3-.10 Facsimile Prescription Drug Orders for Controlled Substances**

Reads in part. . . .

- (1) A prescription drug order which is transmitted by an electronic device which sends an exact copy image to the receiver (pharmacy) over telephone lines.
- (2) Faxing Schedule II prescriptions:
  - (a) Faxing a Schedule II for a home infusion and/or I.V. pain therapy patient – A prescription, written for a Schedule II substance to be compounded for the direct administration to a home infusion patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, may be transmitted directly from the prescribing practitioner or the practitioner's agent to

the pharmacy by facsimile. The facsimile serves as the original written prescription. This exception does not apply to other dosage forms.

- (b) Faxing a Schedule II for a long[-]term care patient – ***A prescription written for a Schedule II substance, for long-term care patients, which include hospice patients, may be transmitted directly from the prescribing individual practitioner, by the practitioner or the practitioner’s agent, to the provider pharmacy by facsimile.*** The facsimile serves as the original written prescription.
- (3) Faxing for a long-term care patient to a pharmacy.
  - (a) A pharmacist may accept a fax prescription for a long[-]term care patient provided:
    - 1. For Schedule II drugs, all requirements of a written prescription are met, including the prescriber’s signature on the faxed order and it is faxed by the nurse/person the physician has designated as his/her “agent” to transmit the order, and must contain the nurse/person’s signature.
    - 2. For drugs other than Schedule II, the order is faxed by the nurse/person the physician has designated as his/her “agent” to transmit the order, and must contain the nurse/person’s signature.
    - 3. The pharmacist verifies the fax is from the machine of the designated nurse/person.

## **Alabama State Board Continuing Education Requirements**

**Pharmacists** shall obtain no less than 15 hours of approved continuing education (CE), three hours of which shall be of “live” exposure. Hours in excess of the minimum annual requirement may be carried forward to the succeeding calendar year; however, no more than 12 hours shall be carried over and no less than three “live” hours shall be obtained in each calendar year.

**Consultant pharmacists** shall obtain annually no less than six “live” consultant approved hours in not less than two “live” hour increments. No “live” consultant hours can be carried over from each calendar year.

**Preceptor pharmacists** must attend a preceptor approved training seminar at least once every three years.

**Parenteral pharmacists** shall have attended a one-time, five-hour approved parenteral certification course, including didactic and hands-on experience, requiring a written exam as part of the training.

**Nuclear pharmacists** shall attend no less than a one-hour, nuclear approved CE course each year.

**Registered pharmacy technicians** shall obtain not less than three hours of approved CE, one hour of which shall be of “live” exposure. No hours in excess of the minimum requirement may be carried forward to the succeeding calendar year.

CE is essential to maintain professional competency and to improve professional skills. Programs submitted for CE require prior approval and must be received no later than 30 days prior to the presentation, along with a copy of the program, outline, etc, if available. A copy of the Continuing Education Credit Submittal Form is on the Web at [www.albop.com](http://www.albop.com).

## **DEA Policy Regarding Information That Can be Changed on a Schedule II Prescription**

The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consultation with the prescribing practitioner, the pharmacist is permitted to add the dosage form or change the patient’s address, drug strength, drug quantity, and directions for use. The pharmacist is permitted to make information additions that may be provided by the patient or bearer, such as the patient’s address, and such additions should be verified.

The pharmacist is never permitted to make changes to the patient’s name, CSs prescribed (except for generic substitution permitted by state law), or the prescriber’s signature. These types of changes challenge the necessity of the original prescription and would require a new prescription from the prescribing practitioner.

The pharmacist should always document the time and date that the prescriber was contacted about the correction, and should always ask the prescriber to document the change in the patient’s chart so that both the prescriber and the pharmacist have a record of the conversation.

## **Quality Improvement Note**

Effective data collection and benchmarking is crucial to an environment that is developing staff training or team change initiatives that monitor self assessment in patient safety and risk management. Commit time and resources to evaluate your safe practice performance approach to the preparation and dispensing of medications. All pharmacists and technicians working should be familiar with specific “patient safety” initiatives in their place of practice.

## **680-X-2-.31 Regulation of Daily Operating Hours**

Any person who receives a community pharmacy permit pursuant to 34-23-30, and commences to operate such an establishment shall, for the benefit of the public health and

Continued from page 5

welfare, keep the prescription department of the establishment open for a minimum of twenty (20) hours per week. A sign in block letters not less than one inch in height shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. Such sign shall state the hours the prescription department is open each day.

Author: Jerry Moore, JD, RPh, Executive Director

Statutory Authority: Code of Alabama 1975, 34-23-92

History: Adopted December 17, 2004; Effective January 18, 2005

### **Alabama State Board of Pharmacy's Web Site**

The Alabama State Board of Pharmacy's Web site contains all the pharmacy laws, forms for registration, and other pertinent information, which we hope will be useful to pharmacists, technicians, and permit holders. Our Web site address is [www.albop.com](http://www.albop.com).

### **Board Members/Drug Investigators for 2005**

- Lynda Staggs, President..... Huntsville
- Jack Como, Vice President ..... Birmingham
- Rick Stephens, Treasurer .....Northport
- Roland Nelson, Member.....Birmingham
- Tammy Rogers, Member .....Lillian
- Joyce Altsman, Director Education/Compliance .... Pelham
- Henry Burks, Jr, Chief Investigator ..... Pelham
- Eddie Braden, Investigator ..... Pelham

- George Grubbs, Investigator..... Springville
- Richard Lambruschi, Investigator .....Harvest
- Glenn Wells, Investigator ..... Trussville
- Mark Delk, Investigator..... Pelham

### **Do You Know a Pharmacist or Technician Who Needs Help?**

Call the Committee on Rehabilitating Impaired Pharmacists help line at the voice mail of Steve Moore at 205/975-8548. All calls are confidential.

Page 6 – February 2005

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