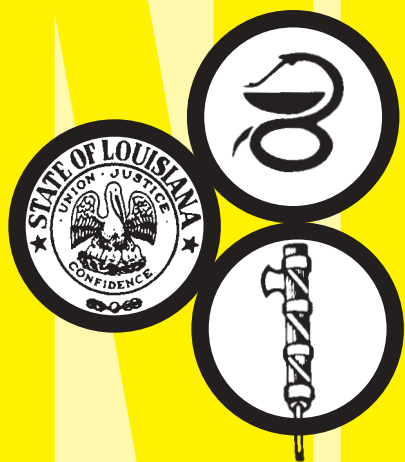


July 2003



Louisiana Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Importation of Foreign Drugs (03-07-161)

Bus trips to Mexico and Canada. Web sites representing themselves as pharmacies in Canada, Thailand, the Caribbean islands, and so many more places. Health maintenance organizations, third-party payors, and national membership organizations encouraging, or even mandating, the use of foreign drugs. Businesses soliciting domestic prescriptions for fulfillment with foreign drugs. News media advertising all of the above.

United States Food and Drug Administration (FDA) approval is required for any drug marketed in this country. That approval is specific to the manufacturer and product, and is based on the location of manufacture, source and specifications of active ingredients, formulation and processing methods, container system, and labeling content. FDA routinely inspects manufacturers for compliance with FDA's current good manufacturing practices. Shipment and storage of drugs in various distribution points must be documented; distributors are regulated by a state agency, and they are subject to inspection. Shipment of drugs from distributors to pharmacies must be documented; pharmacies are regulated by this agency, and they are subject to inspection. This "closed" distribution system is intentional in design; when properly operated it is, and has been, successful in preventing the introduction of expired, contaminated, subpotent, superpotent, and counterfeit drugs.

The importation or reimportation of prescription drugs from foreign countries generally violates one or more sections of the Federal Food, Drug, and Cosmetic Act: (1) §355 makes it illegal to introduce or deliver into interstate commerce unapproved drugs. Foreign versions of American drugs are unapproved for the reasons noted above. Even if the drug is originally manufactured in the US, the version produced for foreign markets usually does not meet all the requirements listed above. (2) §353 requires a valid prescription for dispensing prescription drugs and also makes it illegal to dispense a drug without proper labeling. (3) §331 makes it illegal to deliver misbranded, adulterated, or counterfeit drugs. (4) §381 makes it illegal for anyone other than the manufacturer to reimport a drug. In addition to the federal law, there are state issues involved as well. The Louisiana Legislature mandates that any pharmacy, regardless of location, that dispenses prescription drugs to Louisiana residents shall be permitted by, and is subject to the authority of, the Louisiana Board of Pharmacy. While we do have a number of out-of-state pharmacies, we do not have any out-of-country pharmacies on our rolls. With respect to the dispensing pharmacist's requirement to ascertain the authenticity and validity of each prescription dispensed, we remind you of the information related to prescriptions based on Internet consultations found in our July 2002 *Newsletter*.

What are the liabilities associated with violating any of the federal laws discussed above? 21 USC 333 states that a person can be

held criminally liable for violations. Other parts of that same law indicate that it is a felony to knowingly import a drug in violation of the import prohibition. 21 USC 331 states that those who can be found civilly and criminally liable include all those who cause a prohibited act. 18 USC 2371 states that those who aid and abet a criminal violation, or who conspire to violate the law, can also be found criminally liable.

Advocates of the importation of foreign drugs typically misconstrue the personal use exemption policy of FDA. The agency allows patients and physicians to import small quantities of unapproved drugs for the treatment of a serious medical condition. The policy has been applied to products that are not available to US residents; it was never intended to allow the importation of foreign versions of US-approved drugs. The policy does not change the law and does not give license to individuals to import or export foreign medications into this country.

Finally, we understand the motivation to look beyond our borders for prescription drugs. Every month, some Americans must choose between refilling their life-sustaining prescription drugs and paying for food, water, or rent. Still other Americans simply seek to take advantage of weak foreign currencies. But we submit that the answer to the high cost of prescription drugs in this country does not lie in the sabotage of our time-tested systems designed to protect our health, safety, and welfare. Moreover, such compromises provide readily accessible vantage points for those who seek to intentionally inflict harm on Louisiana residents and all Americans.

Acknowledgement: Most of the information in this article was borrowed from the National Association of Boards of Pharmacy's *Position Paper on the Importation of Foreign Prescription Drugs*, published in March 2003. That document may be viewed in its entirety at www.nabp.net.

Disciplinary Actions (03-07-162)

During its February 20, 2003 administrative hearing, the Board took final action in the following matters. Although every effort is made to ensure the information is correct, you should call the Board office at 225/925-6496 to verify the accuracy of any listing before making any decision based on this information.

Heather Dawn Richard (Technician Certificate No. 4061), Formal Hearing: Certificate was revoked. *Charges:* (1) probation violation and (2) failure to notify Board of employment change.

Jacqueline Clair Firmin (Technician Certificate No. 3464), Formal Hearing: Certificate was revoked. *Charge:* theft of prescription drugs from employer pharmacy.

Cassidi N. Beaver (Technician Certificate No. 4271), Formal Hearing: Certificate was revoked. *Charge:* theft of controlled substances from employer pharmacy.

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Jennifer Johnson Bell (Technician Certificate No. 5187), Formal Hearing: Certificate was revoked. *Charge*: theft of prescription drugs from employer pharmacy.

Markesha Renee Young (Intern Registration No. 41397), Formal Hearing: Registration was revoked. *Charge*: theft of controlled substances from employer pharmacy.

Alvin Charles McDowell (Pharmacist License No. 13667), Formal Hearing: License was revoked. *Charges*: (1) dispensation of controlled substances without prescriptions and (2) failure to notify Board of disciplinary sanctions by another state board of pharmacy.

During its May 23, 2003 administrative hearing, the Board took final action in the following matters.

Gardiner's Pharmacy (Pharmacy Permit No. 392), Voluntary Consent Agreement: Respondent was assessed \$5,000 plus administrative and investigative costs. *Charges*: (1) failure to maintain adequate records of transactions for controlled substances and (2) permitted someone in his employ to practice pharmacy in violation of pharmacy laws and regulations.

Complete Vital Care of Natchitoches (Pharmacy Permit No. 3763), Voluntary Consent Agreement: Respondent was assessed \$5,000 plus administrative and investigative costs. *Charges*: (1) failure to maintain adequate records of transactions for controlled substances and (2) permitted someone in his employ to practice pharmacy in violation of pharmacy laws and regulations.

Lawrence Edward Carver, Jr (Pharmacist License No. 17182), Voluntary Consent Agreement: License was placed on probation for one year, beginning May 23, 2003. License also assessed \$1,000 plus administrative costs. *Charge*: practiced pharmacy while reciprocity application still pending.

Amy Wallace Weems (Pharmacist License No. 16349), Voluntary Consent Agreement: License was suspended for five years, beginning April 1, 2003; all but the first ninety days of suspension were stayed, then license was placed on probation, beginning July 1, 2003. License was also assessed \$1,000 plus administrative and investigative costs. *Charges*: (1) unlawful distribution of controlled substances and (2) failure to conform to minimal standards of acceptable or prevailing pharmacy practice.

Laurie Ann Shields Nunez (Technician Certificate No. 3377), Voluntary Consent Agreement: Certificate was revoked. *Charge*: theft of controlled substance from employer pharmacy.

Maxie Joseph Borne (Pharmacist License No. 8525), Voluntary Consent Agreement: License was revoked. *Charge*: failure to report revocation of pharmacist license in another state.

Simone Renee Dorr (Technician Trainee Permit No. 7836), Voluntary Consent Agreement: Permit was revoked. *Charge*: unlawful distribution of controlled substances at employer pharmacy.

Niah Dionne Shanks (Intern Registration No. 40228), Voluntary Consent Agreement: Registration was revoked. *Charge*: theft of controlled substances from employer pharmacy.

Marco Bisa Moran (Pharmacist License No. 16442), Voluntary Consent Agreement: License was suspended indefinitely. *Charge*: theft of controlled substances from employer pharmacy.

In addition, the Board issued Letters of Reprimand to two pharmacists, one technician, and one pharmacy permit. The Board also issued Letters of Warning to four pharmacists, one technician, and five pharmacy permits.

With regard to the reinstatement of lapsed credentials, the Board granted requests from five pharmacists and four technicians.

With regard to impaired practitioners, the Board accepted the voluntary surrender of two pharmacist licenses, granted three requests for reinstatement on probation and denied one request for reinstatement, and then granted two requests for probation modification and denied one request for probation modification.

Lagniappe (03-07-163)

"Don't ever take a fence down until you know the reason it was put up."

– Gilbert Chesterton

Special Note (03-07-164)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacy interns, and pharmacy technicians credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read them carefully and keep them in the back of the *Louisiana Pharmacy Law Book* for future reference.

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