



# North Carolina Board of Pharmacy

PO Box 4560, Chapel Hill, NC 27515-4560  
6015 Farrington Rd, Suite 201  
Chapel Hill, NC 27517  
Tel: 919/942-4454 Fax: 919/967-5757  
Web site: www.ncbop.org

## **Item 2066 – Disciplinary Actions January-February 2005**

**Full Hearing: Revocation of Registration:** 1 [technician]  
Possession of Schedule IV controlled substance and embezzlement.

**Consent Order:** 1

The Consent Order was issued in lieu of an administration hearing for dispensing a controlled substance in place of the controlled substance ordered by the physician without authorization; dispensing a prescribed antibiotic product in an unlabeled vial. Consent Order: License of pharmacist suspended ninety (90) consecutive days; may not serve as a pharmacist-manager for a two (2)-year period; pharmacy permit suspended indefinitely, stayed three (3) years with active one (1)-day suspension of the permit.

**Reinstatement Order:** 4

Reinstatements granted with specific conditions to be met.

**Summary Suspension of License:** 1

**Prehearing Conference:**

Letter of Concern: 1 [pharmacy permit]

Letter of Warning: 12 [six pharmacists, six pharmacy permits]

Letter of Reprimand: 2

Consent Order: 2

License suspended indefinitely: 1

License suspended 10 days, stayed two (2) years with active one (1)-day suspension: 1

The Letter of Concern was issued for failure to maintain a pharmacist-manager on staff.

The Letters of Warning were issued for dispensing errors; failure to adequately train pharmacy staff and provide appropriate staffing levels in order to maintain records regarding dispensing and receiving of controlled substances, thereby allowing the diversion of controlled substances to occur undetected; diversion of Schedule II or Schedule IV controlled substances by a technician employed at a pharmacy.

The Letter of Reprimand was issued for a dispensing error.

The Consent Orders were issued for dispensing Tylenol® with codeine for personal consumption without authorization; two dispensing errors.

## **Item 2067 – Letters of Concern, Caution, and Warning**

The North Carolina Board of Pharmacy has authorized staff to issue letters of concern, caution, or warning in certain circumstances. In cases where a dispensing error has occurred and the product has reached the patient but there is no substantial harm involved, the members have authorized the issuance of letters of concern, caution, or warning by Board staff. This would not be considered to be a disciplinary action but could be used in the disposal of cases in the future.

Such letters frequently suggest that pharmacists take a course in error prevention such as those offered at the pharmacy schools in this state. More information can be found on our Web site at [www.ncbop.org](http://www.ncbop.org).

## **Item 2068 – Reports of Theft or Loss**

Federal regulations require pharmacists to report thefts or losses of controlled substances to Drug Enforcement Administration (DEA) on the agency's Form 106. This situation can arise where a pharmacist has diverted drugs for his or her own personal use.

The Board also requests that employers send a copy of each completed DEA Form 106 to our investigative staff for further follow-up. Please send a photocopy of such reports to Steve Hudson, Director of Inspections/Investigations, PO Box 362, Newton NC, 28658.

## **Item 2069 – Board Interpretation of Product Selection Law**

Production selection, or substitution, is voluntary and not mandatory for the pharmacist. Section 90-85.27 through 90-85.31 is the pertinent part of this statute.

The law presumes that product selection can occur unless prohibited by the prescriber in specific ways. The statute plainly states that prescribers should indicate their instruction to the pharmacist by using a prescription blank with a two-line form, the line on the left indicating that product selection is permitted and the line on the right directing the pharmacist to Dispense as Written (DAW). If the drug is prescribed by generic name, then product selection can occur regardless of which line is signed. If the prescriber signs on the DAW line, the brand prescribed must be used in dispensing.

Prescriptions for Medicaid beneficiaries are presumed to be written generically. Special procedures need to be followed in order to collect payment for brand-name drugs for Medicaid beneficiaries.

A signature on the product selection permitted line allows the pharmacist to use a generic version of the drug, but this is the decision of the pharmacist, not the customer or patient. The Board has ruled that a prescription blank in another format, such as with the lines reversed or containing a box to be checked, allows the pharmacist to use product selection at his or her discretion.

If the prescription is on a one-line blank, the pharmacist may use product selection unless the prescriber indicates DAW in his or her handwriting. In the case of oral (telephone) prescriptions, it is the prescriber's duty to indicate DAW or otherwise. In the absence of such instruction it is the pharmacist's choice as to the drug dispensed. Product selection is restricted to products with the same dosage form and the price must be less for the patient than it would have been had the brand-name been dispensed.

Drugs substituted need to be therapeutically equivalent to those prescribed and this determination is the pharmacist's responsibility

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## Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

### Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretinoin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

### Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.



## Metronidazole and Metformin: Names Too Close for Comfort

*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).*

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®



(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

## **'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient**

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association (JAMA)* published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: [www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html](http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html).

## **NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List**

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at [www.nabp.net](http://www.nabp.net). NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

## **FDA Announces New CDERLearn Educational Tutorial**

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at <http://www.connectlive.com/events/genericdrugs/>.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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following statutory provision 90-85.27(I). Product rating in the federal "Orange Book" may be useful, but equivalency is the pharmacist's decision.

The law provides for the development of a list of narrow therapeutic index (NTI) drugs. These are drugs that have less than a twofold difference in the minimum toxic concentration in the blood, or are those drug formulations that exhibit limited or erratic absorption, formulation-dependent bio-availability, and wide inpatient pharmacokinetic variability that require blood level monitoring. The North Carolina secretary of Health and Human Services, after receiving advice from the state health director, the North Carolina Board of Pharmacy, and the North Carolina Medical Board, has identified the following drug products as NTI drugs:

- ◆ Carbamazepine: all oral dosage forms
- ◆ Cyclosporine: all oral dosage forms
- ◆ Digoxin: all oral dosage forms
- ◆ Ethosuximide
- ◆ Levothyroxine sodium tablets
- ◆ Lithium (all oral dosage forms, all salts)
- ◆ Phenytoin (all oral dosage forms, all salts)
- ◆ Procainamide
- ◆ Theophylline (including all salts, all oral dosage forms)
- ◆ Warfarin sodium tablets

A prescription for an NTI drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed upon initial dispensing, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product with the prescriber and the patient give documented consent to the dispensing of the other manufacturer's product. In this case, the pharmacist must obtain documented consent of both the prescriber and patient to dispense the alternative product. The term "refilled" shall include a new prescription, written at the expiration of a prescription, which continues the patient's therapy on an NTI drug.

### Item 2070 – Conscience Clause Statement

A pharmacist should function by serving the individual, community, and societal needs while respecting the autonomy and dignity of each patient. The best practice by a pharmacist is to promote the good for every patient in a caring, compassionate, and confidential manner. Pharmacists should discuss and resolve any questions about emergency contraception prior to employment. Compassionate care and conscientious objection are not mutually exclusive.

A pharmacist has the right to avoid being complicit in behavior that is inconsistent with his or her morals or ethics. It is unacceptable,

however, for pharmacists to impose their moral or ethical beliefs on the patients they serve. Pharmacists who object to providing a medication for a patient on this basis alone, therefore, should take proactive measures so as not to obstruct a patient's right to obtain such medication.

The Board notes that although pharmacists have a right to avoid moral or ethical conflict, they do not have a right to obstruct otherwise legitimate prescription dispensing or delivery solely on the basis of conscientious objection.

Phrases and Concepts From:

- ◆ American Pharmacists Association Code of Ethics
- ◆ Cantor J, Baum K. The Limits of Conscientious Objection – May Pharmacists Refuse to Fill Prescriptions for Emergency Contraception?, *New England Journal of Medicine*, 2004; 351: 2008.

### Item 2071– Verification of Licenses/Permits/Registration

The Board now offers a process for verification of information using the Board's Web site, [www.ncbop.org](http://www.ncbop.org). The registrant's name, license or registration number, original license/registration date, and renewal date is now on the site. This should ease the process for anyone needing verification since the renewal date is now listed, which will let the viewer know if the person is current for the calendar year. This information is available for pharmacists, pharmacies (both in and out of state), and technicians.

### Item 2072 – Be Sure to Vote

Ballots for the spring election will be mailed the second full week in April. Be on the lookout for this important material. Robert L. "Bob" Crocker, the Board's current president, currently occupies this position, serving in District V. **All pharmacists residing in the state are eligible to vote.** Ballots will be counted on May 16, 2005, in the Board office. Be sure to take advantage of this important right that North Carolina pharmacists have. Mark your ballot and send it in by May 16, 2005, to make sure your vote counts.

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National Association of Boards of Pharmacy Foundation, Inc  
 1600 Feehanville Drive  
 Mount Prospect, IL 60056  
 NORTH CAROLINA BOARD OF PHARMACY