January 2005

North Carolina Board of Pharmacy

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Item 2060 – Disciplinary Actions September-November 2004

Full Hearing: 1 – License suspension of pharmacist with stay order and an active suspension of 30 days.

Consent Order: 2

The Consent Orders were issued in lieu of an administrative hearing for dispensing errors committed.

Prehearing Conference

Letter of Warning: 1 [pharmacy]

The Letter of Warning was issued regarding a technician providing amitriptyline to an individual without a lawful order.

NCPRN/NCBOP Compliance Committee

Suspension of Pharmacist License with Stay Order: 2

The license suspension was issued to a pharmacist for violation of a North Carolina Board of Pharmacy order in place and to another pharmacist for embezzlement and ingestion of Schedule II controlled substances; scheme to submit false urine specimens; creating and causing fulfillment of an unlawful prescription for a Schedule II controlled substance and ingestion of that product.

Item 2061 – Conscience Concerns in Pharmacist Decisions

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 2062 – USP 797

Board inspectors and investigators have been trained in the essential elements of United States Pharmacopeia (USP) Chapter 797 standards. Inspections of locations where sterile compounding occurs will include evaluations of facilities, equipment, and educational criteria in USP 797 beginning in February of this year.

Item 2063 – Renewal Reminder

Please take note that **pharmacist renewal applications for 2005 were not mailed** to pharmacists in a general mailing again this year. **This year pharmacy permits and technician renewals may also be renewed online.** Permits and registrations expired on December 31, 2004. There is a 60-day grace period after that date that can be used, if necessary, which expires February 28, 2005. Pharmacists residing within the United States, pharmacy permit holders, and technicians may all execute their renewals online at www.ncbop.org. Visa® or Master Card® credit cards are accepted.

Renewal forms may be downloaded from the North Carolina Board of Pharmacy Web site at www.ncbop.org. Applications may also be requested by e-mailing renewal@ncbop.org or calling the Board at 919/246-0092.

Continued on page 4

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/pandemicplan. 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.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – 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) 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 as well as FDA's distributed a press release that is now available at 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.

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) 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.

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 for videos related to medication errors. See 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 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.

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 or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st 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, or contact NABP at 847/391-4406 or custserv@nabp.net.

Continued from page 1

No personal checks are accepted. Please send certified checks, money orders, or corporate checks only.

This is a reminder that it is the responsibility of the pharmacist-manager at each in-state location to be sure that all individuals who assist pharmacists in dispensing prescriptions are registered as technicians or, if already registered, renew that registration. Pharmacist-managers should be alert to the fact that they are responsible for the training of pharmacy technicians under their supervision. This includes prompt registration of all technicians who assist pharmacists in the dispensing process. It is also the pharmacist-manager's responsibility to provide a training program in terminology, calculations, dispensing systems and labeling, pharmacy law, record keeping, and proper handling and storage of medications. This training must occur within 180 days after registration of the technician. Please note that as pharmacist-manager you certify that you are responsible for conforming to all laws of this state; see Certificate B(3). Technicians who change their place of employment *must* notify the Board within 30 days of the change. A downloadable form is available on the Board's Web site, www.ncbop.org, under "Downloadable Forms."

Item 2064 – DME News

Submitted by Wayne Link, Chairperson, DME Committee

The North Carolina Board of Pharmacy Durable Medical Equipment (DME) Committee members thank Teresa Gregory for her unselfish commitment as the state Home Medial Equipment representative and for the numerous hours of contribution as the chairperson of the HME Licensure Committee.

During the September 10, 2004 Committee meeting the Board's Executive Director, David Work, presented Ms Gregory with a commemorative gavel in recognition of her years of dedicated service to the Board. Dr Work also administered the oath-of-office to Ms Marcia Ladd, who then assumed the seat being vacated by Ms Gregory.

By consensus, the Committee called for a vote on the election of a new chairperson. On nomination by Stan Haywood, seconded by Larry Lankford and with no opposing votes, Wayne Link was elected chairperson.

Item 2065 – Elections

The Board will conduct an election this spring for a position beginning in the spring of 2006. Robert L. "Bob" Crocker, the Board's current president, currently occupies this position. Members customarily spend at least 50 days per year away from their practice on Board business.

The position open for election is for the Southeastern District, which includes the following counties: Beaufort, Bladen, Brunswick, Carteret, Columbus, Craven, Cumberland, Duplin, Greene, Harnett, Hoke, Johnston, Jones, Lenoir, New Hanover, Onslow, Pamlico, Pender, Pitt, Robeson, Sampson, Scotland, and Wayne.

Pharmacists who live in these counties are eligible to run for election and require a petition of 10 pharmacists from that district to get a name on the ballot. The deadline for submission is March 10, 2005.

The *North Carolina Board of Pharmacy News* is published by the North Carolina 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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