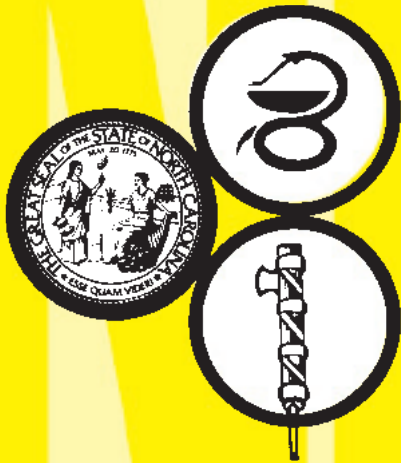


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North Carolina Board of Pharmacy

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Item 2185 – Board Elections

At press deadline for this *Newsletter*, the April/May 2009 North Carolina Board of Pharmacy election was still proceeding. Accordingly, results, when certified by the Board, will be posted on the Board's Web site and published in the next *Newsletter*.

This spring marked the debut of electronic voting for Board elections. During the election, Board staff received comments from a number of pharmacists asking whether the electronic voting system could be reconfigured so that pharmacists could log on to the Board's Web site and vote in a Board election. More specifically, pharmacists asked whether, once a pharmacist logs on to the Board Web site, a new tab could be added for electronic voting similar to the tab available for reporting continuing education online.

Board staff considered exactly this type of voting configuration for this spring's elections. Staff hesitated, however, because during the process of amending Rule .2107, two commentators argued that electronic voting would increase the risk of Board staff attempting to "un-mask" votes and determine exactly which pharmacists voted for which candidates. While Board staff felt that this professed concern was overblown, the electronic voting method was a means of minimizing the issue, if it is really an issue at all.

Accordingly, Board staff welcomes written comments from North Carolina pharmacists on the pros and cons of reconfiguring the electronic voting system so that pharmacists may log on to the Board's Web site and cast an electronic ballot. Please address your letters to Jay Campbell, Executive Director, North Carolina Board of Pharmacy, RE: Electronic Voting, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517. E-mail submissions should be sent to jcampbell@ncbop.org, RE: Electronic Voting.

Item 2186 – Progress of Drug Enforcement Administration's Controlled Substance Electronic Prescribing Rulemaking

As previously reported, in June 2008, the Drug Enforcement Administration (DEA) **proposed** a rule that would permit electronic prescribing for all schedules of controlled substances. The public comment period on the rule closed in September 2008. Numerous pharmacists have inquired about the status of this proposed rule.

After receiving comments on the proposed rule, DEA must, by statute, review those comments and determine whether to: (a) adopt the rule as proposed; (b) alter the rule in response to comments received; or (c) withdraw the rule. The number of comments submitted concerning DEA's proposed electronic controlled substance prescribing rule were, by all reports, voluminous. The process of reviewing and responding is likely to be a lengthy one. Board staff has heard some talk of a possible finalizing of the rule this fall, but this talk is not from any "official" channel.

In the meantime, DEA's current position that electronic prescriptions for controlled substances are not permitted remains in place. More information may be found at the following link: www.ncbop.org/faqs/Pharmacist/faq_ElectronicRXs.htm.

Item 2187 – Health Department Dispensing of Antiviral Medications

During the H1N1 influenza virus scare this spring, Board staff worked with North Carolina Public Health Preparedness and Response to communicate information to pharmacists in a timely fashion. As Public Health Preparedness and Response began distributing antiviral medications to state and local health departments, two

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Pharmaceutical Cargo Theft of Copaxone®

The Food and Drug Administration (FDA) Office of Criminal Investigations (OCI) reported that a shipment of approximately 14 pallets/994 cartons/5,962 packs of Copaxone® (glatiramer acetate) 20 mg, a non-controlled substance, was stolen during the week of April 13-17, 2009. The tractor trailer was recovered at a rest stop on the New Jersey Turnpike on April 20. Unfortunately the trailer was empty. Corporate security from Teva Pharmaceutical Industries Ltd recalled the remainder of lot #P53159, which has an expiration date of January 2011. If that particular product is found anywhere or offered for sale, it would be the stolen product.

Copaxone is a unique product and is used only to treat patients suffering from multiple sclerosis. If the product is not stored below 74° F and out of the sunlight, it becomes ineffective and may not be safe for use.

Immediately notify the FDA OCI if you are contacted by individuals offering to sell this product, if you have purchased this product, or if you know of anyone that may be involved with the theft and the distribution of this product.

Any information should be provided to Special Agent Gregg Goneconto or Special Agent Nancy Kennedy at OCI Headquarters (800/551-3989), or at www.fda.gov/oci/contact.html.

Failed Check System Leads to Pharmacist's No Contest Plea for Involuntary Manslaughter



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified Patient Safety Organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A former Ohio pharmacist will plead no contest to involuntary manslaughter of a two-year-old child who died in 2006 as a result of a chemotherapy compounding error.¹ The pharmacy board revoked the pharmacist's license and, after

holding a criminal investigation, a grand jury indicted him on charges of reckless homicide and involuntary manslaughter. The pharmacist faces up to five years in prison.

Prosecutors hold the pharmacist responsible for the toddler's death because he oversaw the preparation of her chemotherapy. A pharmacy technician mistakenly prepared the infusion using too much 23.4% sodium chloride. The infusion was administered to the child, who died three days later.

Though we cannot shed more light on the root causes of the error, our experiences with analyzing other errors strongly suggest that underlying system vulnerabilities played a role. Compounding the solution from scratch is error prone. Communication failures between technicians and pharmacists, IV compounding-related failures, inadequate documentation of the exact products and amounts of additives, and other system issues have contributed to numerous fatal errors. ISMP has also received reports of compounding errors and subsequent failed double-checks due to adverse performance-shaping factors such as poor lighting, clutter, noise, and interruptions. In fact, in this particular case, news reports suggest that the pharmacist felt rushed, causing him to miss any flags that may have signaled an error.²

Without minimizing the loss of life in this case, we continue to be deeply concerned about the criminalization of human errors in health care. Safety experts including ISMP advocate for a fair and just path for individuals involved in adverse events, arguing that punishment simply because the patient was harmed does not serve the public interest. Its potential impact on patient safety is enormous, sending the wrong message to health care professionals about the importance of reporting and analyzing errors. All professionals are fallible human beings destined to make mistakes and drift away from safe behaviors as perceptions of risk fade when trying to do more in resource-strapped professions. When warranted, licensing boards can protect patients from reckless or incompetent actions of health care practitioners by limiting or revoking licenses.

While the law clearly allows for the criminal indictment of health care professionals who make harmful errors, the greater good is served by focusing on system issues that allow tragedies like this to happen. Focusing on the easy target, the pharmacist, makes us wonder whether any regulatory or accreditation agency is ensuring that all hospitals learn from this event and adjust their systems to prevent the same type of error. If not, the death of this little girl is a heartbreaking commentary on health care's inability to truly learn from mistakes so that they are not destined to repeat.

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2. McCoy K, Brady E. *Rx for Errors: Drug error killed their little girl*. USA Today. February 25, 2008. Available at: www.usatoday.com/money/industries/health/2008-02-24-emily_N.htm.

NABP Wins ASAE's 2009 Associations Advance America Award of Excellence

In recognition of its efforts for educating patients on the potential dangers of buying medications online and empowering patients to make informed choices through its Internet Drug Outlet Identification program, the National Association of Boards of Pharmacy® (NABP®) recently received the 2009 Associations Advance America (AAA) Award from the American Society of Association Executives (ASAE) and the Center for Association Leadership in Washington, DC.

Launched in May 2008, the Internet Drug Outlet Identification program reviews and monitors Web sites selling prescription medications and distinguishes those sites that do and do not meet state and federal laws and/or NABP patient safety and pharmacy practice standards. Internet drug outlets that appear to be operating in conflict with program criteria, such as dispensing drugs that are unapproved and potentially counterfeit, frequently without a valid prescription, pose a significant risk to the public health. Such findings underscore the importance of this project and other efforts to contain the Web-based distribution of prescription drugs within the appropriate legal and regulatory framework.

"NABP is honored to have been selected for this prestigious award for our efforts to bring about positive change," says NABP President Gary A. Schnabel, RN, RPh. "This program represents a strong demonstration of our commitment to the NABP mission of assisting the state boards of pharmacy in protecting the public health."

NABP is one of only 21 organizations nationally to receive an award of excellence in the first round of ASAE's 2009 AAA Award program, an award that recognizes associations that propel America forward with innovative projects in education, skills training, standards setting, business and social innovation, knowledge creation, citizenship, and community service.

Consumer Directed Questions and Answers about FDA's Initiative Against Contaminated Weight-Loss Products

FDA has developed questions and answers to help consumers, health care practitioners, and the general public understand FDA's actions regarding weight-loss products contaminated with various prescription drugs and chemicals.

Many of these products are marketed as dietary supplements. Unfortunately, FDA cannot test and identify all weight-loss products on the market that have potentially harmful contaminants in order to ensure their safety. FDA laboratory tests have revealed the presence of sibutramine, fenproporex, fluoxetine, bumetanide, furosemide, phenytoin, rimonabant, cetilistat, and phenolphthalein in weight-loss products being sold over-the-counter. Enforcement actions and consumer advisories for unapproved products only cover a small fraction of the potentially hazardous weight-loss products marketed to consumers on the Internet and at some retail establishments.

Pharmacists can advise patients to help protect themselves from harm by consulting with their health care professional before taking dietary supplements to treat obesity or other diseases. Patients should be advised of the following signs of health fraud:

- ◆ Promises of an "easy" fix for problems like excess weight, hair loss, or impotency
- ◆ Claims such as "scientific breakthrough," "miraculous cure," "secret ingredient," and "ancient remedy"
- ◆ Impressive-sounding terms, such as "hunger stimulation point" and "thermogenesis" for a weight-loss product
- ◆ Claims that the product is safe because it is "natural"
- ◆ Undocumented case histories or personal testimonials by consumers or doctors claiming amazing results
- ◆ Promises of no-risk, money-back guarantees

More information is available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm136187.htm.

Jury Trial Set for Doctor Charged with Bringing Misbranded Foreign Cancer Drugs into US

A jury trial to hear the case of *USA v. Vinod Chandrashekm Patwardhan, MD* was set to begin on April 21, 2009, in the US District Court for the Central District of California. Patwardhan, an Upland, CA doctor who specialized in treating cancer patients, was arrested in August 2008 by federal authorities after being charged with introducing foreign misbranded drugs into interstate commerce. These drugs reportedly were sometimes diluted when they were administered to his patients, according to a news release issued by Thomas P. O'Brien, US attorney for the Central District of California, on the day of the arrest. The charge of delivering misbranded drugs into interstate commerce with the intent to defraud or mislead carries a penalty of up to three years in federal prison.

questions arose concerning registered nurses (RNs) dispensing at those facilities:

1. *May RNs dispense antivirals from health departments?* Board Rule .2403 provides that properly trained RNs may dispense certain types of prescription drugs from health departments. Antivirals are not among the types listed. Board staff, however, has no objection to properly trained RNs dispensing antivirals as needed to treat H1N1 influenza. Such dispensing is clearly a benefit to the public health and safety and well within the spirit of Board Rule .2403.
2. *May RNs “compound” Tamiflu® suspension if needed?* The Centers for Disease Control and Prevention has provided a document detailing Emergency Use Authorization of antivirals to treat H1N1 influenza. The document may be found at www.cdc.gov/h1n1flu/eua/. More specifically, the document contains detailed information about Tamiflu, that may be found at www.cdc.gov/h1n1flu/eua/pdf/tamiflu-patients.pdf. The first question on the second page states “What if my child or I cannot swallow capsules? For pediatric patients who cannot swallow capsules, TAMIFLU® Oral Suspension is preferred. If the oral suspension is not available, TAMIFLU® capsules may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup.” Accordingly, there is no apparent need to “compound” Tamiflu suspension from the capsules. Dispensing professionals should simply instruct parents or other patients to open the capsule and mix the contents as described. Dispensing professionals can also provide this service for parents or other patients who need it.

Board staff also discussed these and other issues with several community pharmacists around the state who were ready and willing to volunteer their time to state and local health departments during the crisis. Thankfully, the H1N1 influenza, though now classified

as a pandemic by World Health Organization, has only been of moderate severity. But the preparatory activities demonstrated, once again, how pharmacists can and should play a critical role in these emergency situations.

Item 2188 – Prescription Drug “Drop-Off/Pick-Up” Locations

Board staff has received several inquiries recently inquiring whether employers or other groups may set up “drop-off/pick-up” locations that are not located in a permitted pharmacy. For example, one inquiry was from an employer who wanted to set up a station at the work site to which a pharmacy would deliver all prescriptions for employees who would then pick up the prescriptions there either from a pharmacy technician or an unlicensed person. From time to time, Board staff has received inquiries from community pharmacies that wish to set up “satellite” drop-off/pick-up locations to be overseen by a pharmacy technician.

Such “drop-off/pick-up” sites do not comply with the North Carolina Pharmacy Practice Act. Under that statute, a pharmacy is “any place where prescription drugs are dispensed or compounded” and any such place must be permitted by the Board of Pharmacy.

Final dispensing to patients at a non-permitted site as contemplated in these inquiries would not comply with North Carolina law.