

October 2009



# Montana Board of Pharmacy

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## **Congratulations to New Licensees**

The following individuals successfully passed the North American Pharmacist Licensure Examination<sup>®</sup> and received their licenses to practice pharmacy in the state of Montana.

Amber M. Anderson, Kellie M. Andreoli, Katie A. Baker, Philip A. Ballance, Laurie J. Barten, Curt Bertsch, Betsy M. Biggerstaff, Mary B. Borgstadt, Donald E. Brown, Kim Brownell, Dane S. Brubaker, Joy L. Burbach, Sean M. Cooper, Lisa J. Cowley, Craig D. Coy, Christina Craft, Janet M. Pierce Cunningham, Elizabeth Dale, Jaime H. Decker, Brent L. Dehring, Ronald R. Doll, Christopher S. Elizagaray, Melissa Fieldler, David R. Fisher, Claridale P. Flynn, Eman G. El Rab, Christopher D. Gates, David E. Gillespie, Richard Glatt, Kathleen Justice, Kelly M. Kain, Hye Jin Lee, Susan M. Mahoney-Weber, Jessica N. Mashayekhan, Monique Moen, Tracey B. Murrish, Dan Nicholls, Heidi M. Nielson, Michael D. O'Dazier, Amy K. Overstreet, Matthew R. Picking, Ashlie A. Pirrie, Amanda J. Pokorny, Kristen N. Potter, Jason M. Rusk, David A. Russell, David J. Sanks, Samantha A. Scherer, Mandy M. Schmidt, William I. Schuman, Nancy R. Seroski, Cory D. Slocum, James K. Smith, Michelle L. Smith, Jessica L. Sorbel, Douglas R. Stickney, Michelle Thompson, Casey L. Treis, Zachary D. Ueland, Tyler J. Vachal, Eric B. Ward, Michael K. Wells, Amie C. Wells, and Christopher C. Young.

## **FDA Labeling Should Reflect Comparative Efficacy of Drugs**

*Lang Lang, Pharmacy Intern*

Zipsor<sup>™</sup> is the new diclofenac potassium capsule with a liquid filled center. The manufacture of Zipsor, Xanodyne Pharmaceuticals, Inc,<sup>1</sup> stated that compared to a placebo, Zipsor is very effective for mild to moderate pain. However, Zipsor was not tested against current non-steroidal anti-inflammatory drug products available on the market, and it is much more expensive than the existing products.<sup>2</sup> Food and Drug Administration (FDA) should require manufacturers to provide comparative efficacy information for new drugs, along with safety and efficacy information.

In an article published on the online *New England Journal of Medicine* in August, Stafford et al<sup>3</sup> stated that the US health care expenditure has increased by 71% since 2000. The authors also stated that if health care providers are given the knowledge of the superiority of new products they will have more power in deciding

whether or not to utilize the new product. Also, if a patient knows the efficacy of the new drug compared to the existing ones on the market, he or she would be more willing to pay for the more efficacious product. Many drugs currently on the market are approved as “me-too” drugs in order to earn a portion of the market share. The efficacy of these drugs was proven against placebos; however, no clinical trials were held to compare them to drugs in the same class that already exist on the market. Also, newly approved drugs usually cost a lot more than existing products with generics available. The high costs of the new products are allowed by FDA to compensate the manufacturers for the cost of development of the drugs; it also serves as an incentive for companies to thrive for innovation of medications.<sup>3</sup> However, clinical trials conducted against a placebo only show efficacy of the new drug, but give no indication whether the efficacy of the new product is worth the cost. In other words, placebo-controlled trials give no cost-benefit relationship for the new product, and provide insufficient information for health care providers and patients.

The Food and Drug Administration Act of 1988<sup>4</sup> gave FDA responsibility for research, enforcement, education, and information regarding food and drugs. The Kefauver-Harris Drug Amendments of 1962<sup>4</sup> was passed to ensure that manufacturers are required to prove to FDA the effectiveness of their products before the drugs are approved. These two laws may enable FDA to require manufacturers to submit comparative active-controlled, along with placebo-controlled, studies and the rest of the application. With the mass of drugs currently available on the market, it would be highly beneficial for health care providers and for patients to have studies that demonstrate the superiority of a new drug in order to make educated choices and to maximize pharmaceutical therapy. Active-comparator trials would also help administrators determine the value of a new medication in regard to formularies and a preferred drug list, and to help cut unnecessary cost within health care institutions.

Reference:

1. Approvable Letter for Zipsor. Drugs.com. [www.drugs.com/nda/zipsor\\_080722.html](http://www.drugs.com/nda/zipsor_080722.html). Accessed September 9, 2009.

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## **Pharmacy Security and Safety Prove Necessary Component in Pharmacists' Training**

Pharmacy robbery – no one ever thinks it will happen to them, but those who have experienced it know it **can** happen to anyone. To address the importance of recognizing actions to follow if faced with a robbery, several boards of pharmacy have included pharmacy safety resources in their state newsletters and on their Web sites. In addition, to keep current licensees aware and up to speed on safety measures, procedures can be directly taught and reiterated in the pharmacy. Likewise, at least one college of pharmacy has begun incorporating pharmacy safety training in its curriculum and recently saw the extreme benefits of doing so.

On Wednesday, July 8, 2009, Dustin Bryan, a P2 doctor of pharmacy candidate at Campbell University College of Pharmacy and Health Sciences, quickly learned how imperative pharmacy safety training really was when he experienced a pharmacy robbery first hand. Just as Bryan and his fellow employees were preparing to close the store, two gunmen entered the North Carolina pharmacy and approached the counter demanding OxyContin<sup>®</sup>. They left with bags filled with OxyContin and Percocet<sup>®</sup>, having a retail value of nearly \$10,000.

Luckily, all employees involved remained unharmed and despite the situation, Bryan was able to remain calm, focusing on lessons he recently learned during his pharmacy management course at Campbell.

Bryan shared his experience in the university's college of pharmacy alumni e-Newsletter. In the article Bryan states, "I crouched down hoping they hadn't seen me so I could get to a safe place in an office behind the pharmacy to call the police. They saw me as I was crawling and made me come to the front of the pharmacy. My mind was running through a class Dr Cisneros taught dealing with a robbery," he explains. "I knew what type of questions the police would be asking from our lecture, and I was asking myself those very questions while the robbery was happening. It was a very intense and scary moment . . . but I am thankful for the class I had and that nobody was hurt during the whole ordeal."

In December 2008, a safety DVD, *Pharmacy Security – Robbery*, accompanied the shipments of the National Association of Boards of Pharmacy<sup>®</sup> 2009 Survey of Pharmacy Law that were sent to the schools and colleges of pharmacy. The DVD was an educational offering from Purdue Pharma L.P. provided to the schools as part of an initiative to promote pharmacy safety education. Endorsed by National Association of Drug Diversion Investigators, Federal Bureau of Investigation Law Enforcement Executive Development Association, and National Community Pharmacists Association, the 15-minute video contains information that may be critical to preparing pharmacists in the event that they are faced with a robbery.

It was this DVD that Robert Cisneros, PhD, assistant professor at the university, implemented in his pharmacy management

course – the very same course that helped Bryan stay calm during the robbery. Cisneros went a step further by arranging for the head of campus security to speak during the course.

"One of the biggest values of the DVD was pointing out things to focus on during a robbery such as the robber's appearance – clothes, height, weight – and not just focusing on the gun," states Cisneros. He was glad to have received the DVD, explaining that, "it was just the right length, added a lot to the class, and led to great discussions." Cisneros went on to share that he was surprised to learn only 50% of the students in his class this past spring had some form of training on what to do if robbed, though this was a significant increase from the less than 5% who indicated so a few years prior.

Pharmacy robberies may not be avoidable; however, with the proper knowledge, individuals faced with these frightening situations may be better prepared to avoid harm and to assist law enforcement officials in catching criminals before additional robberies occur.

The safety DVD mentioned above may be viewed on the RxPatrol<sup>®</sup> Web site at [www.rxpatrol.org](http://www.rxpatrol.org). RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze, and disseminate pharmacy theft information. The safety DVD, along with a variety of other non-branded educational materials, is also available through the Purdue Pharma Medical Education Resource Catalog, accessible at [www.partnersagainstpain.com](http://www.partnersagainstpain.com) under Pain Education Center.

## **Concerns with Patients' Use of More than One Pharmacy**



*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!<sup>®</sup> Community/Ambulatory Care Edition by visiting [www.ismp.org](http://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](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Perhaps it is not readily apparent, but medication safety could be compromised if patients practice polypharmacy to take advantage of widely publicized programs offering discounted or free medications. With tough economic times, patients may choose to fill or refill their prescriptions at multiple pharmacy



locations to save money, since taking advantage of such offers may cost less than filling their prescription at their usual pharmacy and paying the insurance co-pay.

Normally, when a customer presents a prescription, the pharmacy sends information about the drug and the patient to third-party payers and/or the patient's pharmacy benefit managers (PBM) for reimbursement.

If patients are paying out of pocket for the prescription, the pharmacy can notify the PBM so the medication can be tracked, but notification is not required. In these circumstances, the PBM and insurer may not be made aware that the prescription has been dispensed and no adjudication or drug utilization clinical screening of the prescription will be performed. Normally, medications are screened by the PBM's computer system, which includes all prescription medications regardless of where they were dispensed, and dispensing pharmacists are alerted to drug duplications, drug interactions, and some other unsafe conditions. This checking process will not occur if the prescription is not sent to the PBM. This also has an impact on hospitals that use outside vendors that obtain PBM data through Surescripts in order to populate patient medication profiles upon admissions to the emergency department or hospital. This could decrease the accuracy of drug lists collected for medication reconciliation since these vendors access their information from PBMs and insurers.

For these reasons, patients need to be educated about the importance of sharing insurance information wherever they have their prescriptions filled, even when the insurance is not being billed. Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient. This is especially necessary if the patient is only filling a prescription for a drug on the \$4 list from your pharmacy, but you suspect they may be taking other medications and obtaining them elsewhere. It is also important to expand our efforts to encourage patients to keep a complete list of medications, herbals, nutritional supplements, vitamins, and prescription drugs and to show this list to every provider of care they visit. Community pharmacies can also update patient medication profiles in their computer systems to include prescription and over-the-counter medications obtained at other pharmacies, including mail-order, and promoting and providing a written copy of this list to the patient upon request.

## **CDC Announces Get Smart Week to Help Decrease Antibiotic Resistance**

Centers for Disease Control and Prevention (CDC) is holding Get Smart Week October 5-11 to emphasize CDC's public health effort to decrease antibiotic resistance, including how pharmacists can become involved. Because antibiotic resistance is one of the world's most pressing public health problems, CDC launched the Get Smart Web site to teach about the potential danger of antibiotic resistance and what can be done to prevent it.

The Web site contains patient education materials, updated guidelines for health care providers, campaign materials, and additional resources, including information in Spanish, to help increase the public health awareness of antibiotic resistance and the importance of obtaining influenza vaccines in time for the upcoming flu season. As most states now allow pharmacists to immunize, they can help contribute to public health awareness on who should get flu shots and appropriate antibiotic use in the community. The Get Smart Web site can be accessed at [www.cdc.gov/getsmart/](http://www.cdc.gov/getsmart/).

## **FDA Approves Vaccine for 2009-2010 Seasonal Influenza and H1N1**

Food and Drug Administration (FDA) has approved a vaccine for 2009-2010 seasonal influenza in the United States. FDA has also approved four vaccines against the 2009 H1N1 influenza virus. The seasonal influenza vaccine will not protect against the 2009 H1N1 influenza virus. More information is available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements).

## **ISMP: Do Not Store Insulin Vials in Open Cartons – Risk of Mix-up High**

ISMP warns that storing insulin vials inside their cardboard cartons after the packages have been opened can lead to mix-ups, and potential medical emergencies, if vials are accidentally returned to the wrong carton after being used. The next patient care worker looking for a particular insulin product could read the label on the carton, assume that it accurately reflects what is inside, and end up administering the wrong product. To avoid such a mishap, ISMP recommends that the cartons be discarded, either in the pharmacy before the insulin is dispensed, or when it is received at the nursing station.

## **FDA Takes Actions on Pain Medications Containing Propoxyphene**

FDA announced in July that it will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products. FDA will also require manufacturers to provide a medication guide for patients stressing the importance of using the drugs as directed. In addition, FDA is requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action. In its July 7 denial of a citizen petition requesting a phased withdrawal of propoxyphene, FDA said that, despite "serious concerns . . . , the benefits of using the medication for pain relief at recommended doses outweighs the safety risks at this time." Additional information can be found at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm).

2. Zipsor [package insert]. Newport, KY: Xanodyne; 2009.
3. Stafford RS, Wagner TH, Lavori PW. New, but Not Improved? Incorporating Comparative-Effectiveness Information into FDA Labeling. *Online N Engl J Med.* 2009. <http://content.nejm.org/cgi/content/full/361/13/1230>.
4. Significant Dates in US Food and Drug Law History. US Food and Drug Administration. US Department of Health and Human Services. [www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm](http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm). Accessed September 17, 2009.

## Montana Cancer Drug Repository

Dear Montana Pharmacists,

On October 1, a new law went into effect that will help cancer patients get cancer drugs they cannot afford, help cancer centers better treat patients, and distribute thousands of dollars worth of unused medication to patients instead of destroying needed drugs. The new law establishes a cancer drug donation program, possible only through the expertise and generosity of Montana pharmacists.

In the last legislative session, House Bill 409 established a way for unused, unopened cancer drugs to be donated to participating pharmacies and dispensed to qualifying patients. The program will make available unused cancer drugs to cancer patients who otherwise could not attain them, almost always because of the astronomical cost of the drugs.

Montana pharmacists are the crux of this program. For drug donation to be successful, pharmacists knowledgeable in dosage, drug interaction, chemical structure, and effect of cancer drugs are the people who will accept and dispense cancer drugs.

The need for this new program is intense. Cancer drugs are among the most expensive pharmaceuticals on the market, and they do wondrous things: they target cancer cells to kill cancer, target the interactions between cancer cells and the host (the patient), and help with nausea from chemotherapy. Cancer drugs can also prompt the development of red blood cells, and help with a patient's energy level. But these drugs are expensive, often prohibitively expensive, and a drug is only good if it can be administered.

In testimony in the House committee in February, Dr Jack Hensold of the Bozeman Deaconess Cancer Center said that, "new cancer therapies are, without exception, very expensive, ranging from \$3,000 to \$9,000 in monthly costs. Since nearly all the oral chemotherapies are subject to 'co-pays,' all patients, independent of their insurance coverage, are placed at significant financial risk when diagnosed with cancer." Dr Hensold also said that, "within the first month of treatment, [a patient] will be liable for a \$5,000 payment for their drug."

There is very strong support for the cancer drug donation law. The executive director of the Montana Board of Pharmacy, Ron Klein, testified in support of the cancer drug donation law, as did pharmaceutical manufacturers and representatives of the Montana Medical Association, the Billings Clinic, and the Bozeman Deaconess Cancer Center.

Most importantly, patients testified in support. One patient said that she was grateful that the hearing was this year and not the previous session, because she was undergoing chemotherapy then and was bald. She appeared before the House committee with a packet of medication she wished to donate. It is an anti-nausea drug to which she developed a resistance. The drug did not work for her after two months, but she had bought a three-month supply. The remaining medication is worth many hundreds of dollars. The expiration date is 2011. She wishes to donate the drug to a patient who could use it now. She said, "it's hundreds and hundreds of dollars in my medicine cabinet. I can't bring myself to flush it down the toilet. Someone should use these!"

In the Senate hearings, a woman testified that she had been an office administrator for an oncologist for 20 years and saw the need firsthand. Four years ago, her husband, a former firefighter, was diagnosed with multiple myeloma and underwent treatment monthly. One of his prescribed medications, Velcade<sup>®</sup>, cost \$7,000 a month for 21 pills. Another of his drugs cost a co-pay of \$4,295 a month; another cost more than \$6,000 a month.

It is difficult enough to face a diagnosis of cancer. Patients who want to fight cancer but who may not have all the means – financial or pharmaceutical – to fully fight their diagnosis of cancer now have a chance to receive drugs from the new cancer drug donation program.

In its meeting in early October, the Montana Board of Pharmacy will establish rules to implement the cancer drug donation program, determine which drugs to accept and dispense, and establish qualifications for patients to participate. Cancer centers and cancer patients are anxiously waiting for the program to begin.

In Montana, the spirit of helping one another is strong. We are resilient people. There is no reason for effective cancer drugs to be wasted or destroyed for want of a process to make them available to the people who need them.

For those with cancer drugs to donate, and for the patients who desperately need the drugs, pharmacists bridge the gap. Please participate in the new cancer drug donation program.

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