

**February 2015**

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**Points of Interest:**

Stay up to date on NVSHP news and events. Email changes to contact information to: [nvshp@nvshp.org](mailto:nvshp@nvshp.org)

**Message From The President**

Happy New Year! I would like to thank all of the people who attended this year’s annual meeting in Las Vegas. We had a great turn out and excellent speakers. We also received support for the organization by several vendors and other sponsors.



I would like to extend a special thank you to our education committee which is lead by our DAL, Alana Whittaker, and her team for planning and organizing the meeting and to all of the NVSHP board members for participating throughout the meeting.

I would like to congratulate Roseann Visconti for receiving the pharmacist of the year award as well as Susan Nguyen for receiving the 2014 president’s award. Roseann was nominated by her peers for her contributions in both her clinical practice as well as in the community. She has served for several years on the NVSHP board of directors and created a bridge between the past and the future of the organization. Susan Nguyen received recognition for her work on the legislative committee. She organized a provider status night which was a joint effort between the COP students and NVSHP and she successfully engaged our political representatives to attend the event. She continues to serve on the state BOP committee for provider status. I invite all members to reach out to Susan and share your ideas and thoughts with her on this subject.

Lastly, I would like to challenge everyone reading this newsletter to get connected. You can get connected by becoming a member of a pharmacy organization, mentoring an up and coming pharmacist or technician, attending the BOP meetings, and most importantly staying informed of legislative issues pertaining to our profession. These are all examples of what NVSHP already provides for its members.

In 2014 NVSHP has hosted a few social events, a DO breakfast, and a CEU event involving our local residents. In addition, several of our board members are participating in the state board of pharmacy committees working on revising the hospital regulations as well as provider status in the state of Nevada. I encourage you to get involved and stay engaged to help position the profession of pharmacy to be the most valued resource in the healthcare system as the paradigm shifts into its new “norm”.

## **NVSHP Officers**

### **Immediate Past President**

Robin Hager, Pharm. D.

### **President**

Reed Howe, Pharm. D.  
([president@nvshp.org](mailto:president@nvshp.org))

### **President-Elect**

Roseann Visconti, Pharm.D.

### **Secretary**

Jennifer Mungcal, Pharm.D., BCPS  
([secretary@nvshp.org](mailto:secretary@nvshp.org))

### **Treasurer**

Ragini Bhakta, Pharm.D., BCPS  
([treasurer@nvshp.org](mailto:treasurer@nvshp.org))

### **Directors-at-Large**

Alana Whittaker, Pharm.D.  
Della Bahmader, Pharm.D.  
Susan Nguyen, Pharm.D.

### **Technician Representative**

Nicole Brown

### **Student Representative**

John C DeVilbiss Pharm.D.  
Candiate 2016

## **Message from the Board**

### **Election Results:**

President Elect: Roseann Visconti, Pharm.D.

Secretary: Jennifer Mungcal, Pharm.D., BCPS

Treasurer: Ragini Bhakta, Pharm.D., BCPS



Have a topic you are passionate about and would like to present to fellow pharmacists, students, and nurses? NVSHP would like to hear from you! Please email [nvshp@nvshp.org](mailto:nvshp@nvshp.org) if you would like to present a CE or know of someone who would be interested.. Also, please submit any topics that you would be interested in learning about through a CE.

## **Like us on Facebook**

The site is up. Now you can like us on Facebook, and stay up to date on upcoming events, and the latest news. Just go on Facebook, and type NVSHP in the search bar. Then invite your friends to like us too.

# Updates in Nevada Legislation

Meeting summary of the Nevada State Board of Pharmacy

From: Adam Porath, PharmD, BCPS, BCACP

December 3, 2014

- Christopher Shea, PharmD was presented the Bowl of Hygeia. Chris has practiced throughout Nevada as a geriatric consultant pharmacist. He volunteers his time to educating providers and patients on geriatric pharmacotherapy. He has served as a preceptor for pharmacy students for many years. Congratulations to Chris!
- NAC 453.520 and 453.530 were amended to mirror the recent Federal changes rescheduling hydrocodone combination products to Schedule II
- There was a workshop on NAC 453.510 to add a few new synthetic compounds to Schedule I at the request of LV Metro Police Department.
- There was a discussion regarding the return of drugs to a pharmacy. Currently this practice is prohibited by Nevada regulation. Given the recent push at the Federal level to increase access to patient to locations to dispose of their medications it was discussed that the current Nevada regulation would need to be amended.
- There were also various discussions regarding the licensing of Third Party Logistics (3PL) and FDA licensed Outsourcing Facilities in the State. Regulation changes would be necessary to create any new license classifications.
- Next Board Meeting: January 21-22, 2015 – Las Vegas

## Upcoming Board of Pharmacy Meetings

**Continuing Education:** CE credit of 4 hours, including 1 hour of law, will be given per day of Board meeting attendance. You are required to attend the board meeting for a full day to receive CE credit including the law credit. Remember to sign in for attendance.

Reno Meetings start at 9AM and are held at: Hyatt Place, 1790 E. Plumb Ln, Reno NV

Las Vegas meetings start at 9AM and are held at: Hilton Garden Inn Las Vegas Strip South, 7830 S. Las Vegas Blvd, Las Vegas, NV

- January 21 & 22: Las Vegas
- March 4 & 5: Reno
- April 15 & 16: Las Vegas
- June 10 & 11: Reno
- July 22 & 23: Las Vegas
- September 2 & 3: Reno
- October 14 & 15: Las Vegas
- December 2 & 3: Reno

# New pregnancy category changes: When an “A” doesn’t make the grade

Written by: Della Bahmandar, Pharm. D., MBA

## Introduction

On December 3<sup>rd</sup> 2014, the Food and Drug Administration (FDA) issued a final rule which changes the way pregnancy and breastfeeding labeling information is presented for prescription medications.<sup>1</sup> This new labeling rule replaces the current letter risk categorization system —A, B, C, D and X—with more detailed information designed to improve risk versus benefit assessments. Information will now be organized under the subheadings: fetal risk summary, clinical considerations, and data.<sup>1</sup> The new system also provides clinical considerations on the potential risks of not treating a given condition during pregnancy or breastfeeding. Scheduled to take effect on June 30, 2015, manufacturers of newly approved drugs will be required to use this labeling immediately, while new labeling will be phased in gradually for previously approved products.<sup>1</sup> This new pregnancy categorization was created in response to decades of criticism of the oversimplification and ambiguous nature of the current risk categories.

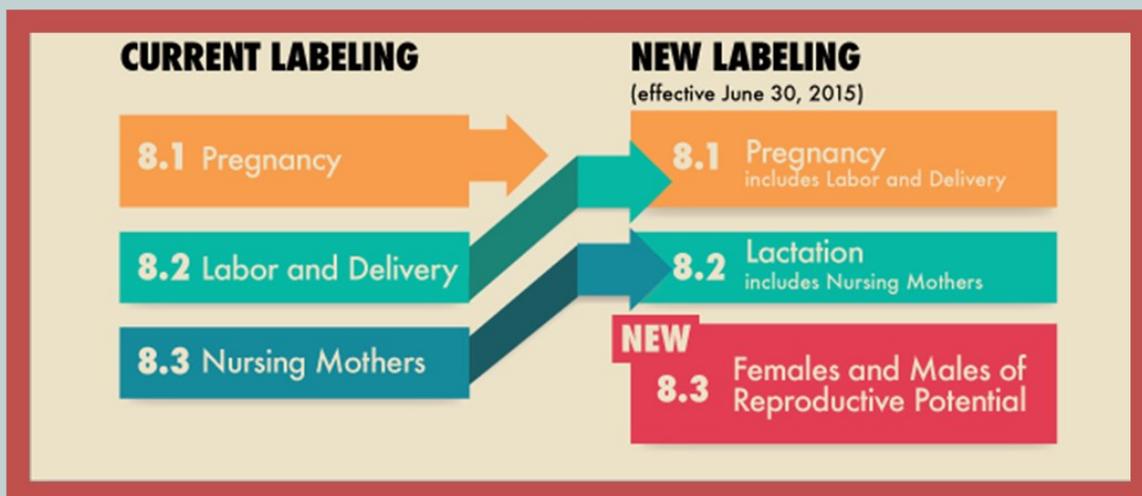
## Problems with our current system?

In regards to the current labeling system, there have been several notable concerns. First, it does not reflect the effects of drug exposure at various times of pregnancy.<sup>5,6</sup> For example, exposure to lisinopril during the first trimester does not appear to present a significant risk, but fetal exposure in the second/third trimester is associated with severe toxicity, including death.<sup>7</sup> Next, it can be misconstrued that all medications in the same risk category carry equal risk.<sup>5,6</sup> For example, warfarin and oral contraceptives are both listed as category X; however, warfarin carries up to a 25% risk of serious defects, whereas oral contraceptives carry a low absolute risk of fetal harm.<sup>7,8</sup> Furthermore, it is frequently misinterpreted that the successive categories represent increasing severity of malformation.<sup>5,6</sup> However, lisinopril is category D with known teratogenic effects, and oral contraceptives are category X without documented teratogenicity.<sup>6,8</sup>

## Whole new look

To address these concerns, the FDA has newly proposed the Pregnancy and Lactation Labeling Rule (PLLR) shown in Figure 1.<sup>10</sup> Continued on Page 5.

Figure 1: Changes in Pregnancy Labeling Section<sup>10</sup>



# New pregnancy category changes: When an “A” doesn’t make the grade

## Whole new look (continued)

The first subsection, labeled *Pregnancy*, will include pertinent information related to the use of the drug during pregnancy such as dose adjustments, maternal and fetus disease-associated risk, adverse reactions affecting the mother and/or fetus, and the effect of the drug on labor and delivery. Additionally, information on pregnancy exposure registries will be included, if one exists, to improve data collection in pregnant women.<sup>10</sup> The second subsection on *Lactation* will not only include information on the presence of the drug in breast milk and its effects on the breast-fed child, but also its effects on milk production.<sup>10</sup> The third subsection, *Females and Males of Reproductive Potential*, will provide information when pregnancy testing and/or contraception is required and will include data, when available, relating the effects of the drug on fertility.<sup>10</sup> An overview of the new pregnancy and lactation labeling changes can be seen in Table 1.

## Things to keep a closer eye on

In a large undertaking that will take several years, companies will be required to remove the pregnancy letter categories from the labeling of all prescription drugs and biological products and, for many of them, revise the labeling with updated information. The new Rule outlines a phased removal of all pregnancy risk category labeling for prescription drugs. Drugs approved before

June 30<sup>th</sup>, 2001, will be required to remove the pregnancy category from their labeling within 3 years, while drugs approved on or after June 30<sup>th</sup>, 2001, will be required to remove the pregnancy category and replace it with the new subsections within 3 to 5 years. Labeling for over-the-counter (OTC) medicines will not change, as OTC drug products are not affected by the final rule. During the implementation phase, the current pregnancy category risk stratification and the new system will be in effect which may lead to confusion. In summary, the long-awaited shift in the FDA’s pregnancy category labeling has arrived, and practitioners must begin to acclimate to this new system, which, while vastly different from previous, will ultimately serve to support and enhance improved clinical decision making in the pregnant and breastfeeding populations.

**Table 1. Overview of New Pregnancy and Lactation Labeling<sup>10</sup>**

| General Information  |
|--|
| <ul style="list-style-type: none"><li>• General statement about background risk and contact information if pregnancy registry available</li></ul>  |
| Fetal Risk Summary   |
| <ul style="list-style-type: none"><li>• Summarizes the likelihood that the drug increases the risk of developmental abnormalities in humans and other relevant risks</li></ul>   |
| Clinical Considerations  |
| <ul style="list-style-type: none"><li>• Inadvertent exposure: known or predicted risk to the fetus from inadvertent exposure to drug early in pregnancy</li><li>• Prescribing decisions for pregnant women:<ul style="list-style-type: none"><li>○ Describes any known risk to the pregnant woman and fetus from the disease or condition that the drug is intended to treat</li><li>○ Information about dosage adjustments during pregnancy</li><li>○ Maternal adverse reactions unique to pregnancy or increased in pregnancy</li><li>○ Effects of dose, timing, and duration of exposure to drug during pregnancy</li><li>○ Potential neonatal complications and needed interventions</li></ul></li></ul> |
| Data   |
| <ul style="list-style-type: none"><li>• Describes study type, exposure information [dose, duration, timing], any identified fetal developmental abnormality, or other adverse effects</li></ul>  |

## References

- <sup>1</sup>U.S. Food and Drug Administration [Internet]. FDA News Release: FDA issues final rule on changes to pregnancy and lactation labeling information for prescription drug and biological products. [updated 2014 Dec 12; accessed 2015 Jan 4]. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm425317.htm>
- <sup>2</sup>Bonner L. New pregnancy, lactation drug labeling will replace letter categories. Pharmacy Today [Internet]. [2014 Dec 5; accessed 2015 Jan 4]. Available from: <http://www.pharmacist.com/new-pregnancy-lactation-drug-labeling-will-replace-letter-categories>
- <sup>3</sup>CDC. Treating for two: data and statistics. [updated 2014 Feb 1; accessed 2015 Jan 6]. Available from: [www.cdc.gov/pregnancy/meds/treatingfortwo/data.html](http://www.cdc.gov/pregnancy/meds/treatingfortwo/data.html).
- <sup>4</sup>Mitchell AA, Gilboa SM, Werler MM, Kelley KE, Louik C, Hernandez-Diaz S, et al. Medication use during pregnancy, with particular focus on prescription drugs: 1976-2008. Am J Obstet Gynecol 2011;205(1):51.
- <sup>5</sup>Wood W. FDA Pregnancy Categories: Help or Hindrance?. Ment Health Clin 2013;3(2):100. Available from: <http://cpnp.org/resource/mhc/2013/08/fda-pregnancy-categories-help-or-hindrance>. Accessed January 6, 2015.
- <sup>6</sup>Ramoz LL and Patel-Shori NM. Recent Changes in Pregnancy and Lactation Labeling: Retirement of Risk Categories. Pharmacotherapy 2014;34(4):389-95.
- <sup>7</sup>Lisinopril. Lexi-Drugs Online. Hudson, OH: Lexi-Comp, Inc. [updated 2015 Jan 8; accessed 2015 Jan 10] Available from: [http://www.crlonline.com/lco/action/doc/retrieve/docid/patch\\_f/7185](http://www.crlonline.com/lco/action/doc/retrieve/docid/patch_f/7185).
- <sup>8</sup>Briggs GG, Freeman RK, Sumner JY. Coumadin. Drugs in pregnancy and lactation: a reference guide to fetal and neonatal risk, 9<sup>th</sup> ed. Philadelphia, PA: Lippincott Williams & Wilkins, 2011.
- <sup>9</sup>Briggs GG, Freeman RK, Sumner JY. Oral contraceptives. Drugs in pregnancy and lactation: a reference guide to fetal and neonatal risk, 9<sup>th</sup> ed. Philadelphia, PA: Lippincott Williams & Wilkins, 2011.

## 2014 NVSHP Annual Meeting

Written by: John C DeVilbiss PharmD Candidate, NVSHP Student Representative  
Class of 2016, Roseman University of Health Sciences

This year we held the annual meeting at the Springhill Suites Convention Center in Las Vegas, NV. In attendance were pharmacists, technicians and students. Pharmacists and Technicians were able to receive CE credit for the event.

NVSHP was proud to welcome Christopher Tolopeski, Director of Federal Regulation affairs of American Society of Health System Pharmacists (ASHP), who gave a very informative, update on provider status. He was followed by Dr. Justin Kullgren, associate professor of pharmacy practice at South University College of Pharmacy and a Hospice and Palliative Care Clinical pharmacist. His presentation titled 'Management of medications in a Hospice and Palliative Care Patient' was insightful, and informative.

Dr. Jacob Frick, clinical pharmacist at Banner MD Anderson Cancer center gave a presentation titled 'Melanoma: Considerations in Pharmacotherapy'. He spoke about exiting new regimens for the treatment of melanoma, and the future of cancer treatment. Closing out the evening Dr. Heather Mooney-Magallon, clinical pharmacy specialist in mental health and ambulatory care at the Sierra Nevada VA gave a presentation titled 'Management of Bipolar Disorder' where she explored the therapies available for the treatment of bipolar depression.

During the lunch hour, representatives from various drug companies were available to display, and answer questions about their products. After the meeting a Residency Roundtable was held for students seeking residency were a panel of current residents was available for questions.

Several pharmacists were also recognized for their achievements and contributions to the profession of pharmacy: Dr. Susan Nguyen was awarded the presidents award. The Pharmacist of the Year award went to Dr. Roseann Visconti, and Matt Nelson, Nestle Austero, and Keith Wellman (Pharm. D. Candidates) were honored and recognized for their participation in the provider status night held earlier this year at Roseman University.



## NVSHP Student Jeopardy Competition

A Student Jeopardy competition was held at the Annual Meeting. After making it past the preliminary rounds that were held earlier in the year, three teams made it to the final round.

Dr. Susan Nguyen, the moderator for the event, kept the audience engaged, and laughing with her unique humor, and the funny sounding buzzers. It was a well received event, that was fun, and educational.

Congratulations to the winners Rebecca Kim, and Farzad Hatanian!



# NVSHP Student Corner

## Guest Speaker: Ms. Caryn Bing

Written by: Sherley Tsang, Pharm.D. Candidate, Class of 2016, Roseman University



As a former program director of 5 residencies across the U.S., a past president of NVSHP, and now a mentor on behalf of ASHP-SSHP, Dr. Caryn Bing made an appearance at Roseman University on November 10, 2014 to provide information to students interested in a residency and currently struggling with the application process. She taught students how to prepare for, and benefit from attending Midyear, the process of applying, and also offered helpful tips, supplemental readings, and other resources to successfully achieve residency.

## Student Alliance Sets New Record For Influenza Vaccines

Written by: : Susan Huynh, Pharm. D. Candidate Class of 2016, Roseman University

In preparation for the flu season, Student Alliance has continued to team up with Dr. Dan Heller from Albertsons Sav-On Pharmacy to give immunizations to members in the Nevada community. In addition, we also had some students volunteere with RiteAid to help immunize our Roseman faculty. As of today we have given **1618** immunizations. These partnerships with Albertsons and RiteAid have allowed many of our students to not only practice their immunization skills, but also keep the community healthy for the upcoming year.



# NVSHP Student Corner

## October is American Pharmacist Month

Written by: Nha Judy Chau, Pharm. D. Candidate, Class of 2016, Roseman University

We returned to UNLV again this year and promoted our profession to current undergraduate students who are pursuing a career in pharmacy. Early in the day, we passed out flyers to inform undergraduate students about the pharmacy profession. Later in the afternoon, Dr. Helen Park, our Director of Admissions, provided a presentation about Roseman's application and enrollment process, the various career options, and what Roseman University has to offer to help students become successful pharmacists. The purpose of this event was not only to celebrate American Pharmacists Month, but also to encourage undergraduate students who are interested in the field of pharmacy to reach out to us for questions and guidance.



## American Lung Association - Smoking Cessation Training Session

Written by: Yu Mao, MBA/Pharm. D. Candidate, Class of 2016, Roseman University



Pharmacists are often underutilized in providing preventative care services. To help with this issue Student Alliance welcomed the American Lung Association (ALA) to provide students with a one-hour course on smoking cessation interventions. The project was created this year and has been a success; more than fifty students were trained and certified by ALA. As the project expands, Student Alliance hopes to provide these services at community outreach events to further improve patient wellbeing and emphasize the importance of Pharmacists' in providing preventative care.

# Congratulations!!!

## ASPH Presents Outstanding Professional Development Project Award to Roseman Students

Congratulations Nestle Austero, Yu Mao, Matt Nelson, and Keith Wellman for winning the award through their coordination and submission of Provider Status Night event held on May 8, 2014 at our Henderson campus. The following is a congratulatory message from our Student Alliance advisors, Drs. Decerbo and Visconti:

“This comes on the heels of last year’s 2013 “Best Practices” Award from ASHP which our Chapter also earned—any one of these honors is noteworthy, but to win these two different titles in back-to-back years is a testament to your hard, extensive planning, and flawless execution. We are all very proud of your work on behalf of our Chapter and University. This is an incredible accomplishment from more than 130 colleges of pharmacy in the U.S.”



Their winning project was presented for recognition at the 2014 ASHP Midyear Clinical Meeting during the Student Society Showcase.

## ROSEMAN ADVANCES ON TO ASHP CLINICAL SKILLS COMPETITION FINALS



Congratulations to our third year students **Ai Thi Nguyen** and **Anna Bonebrake** for winning the Clinical Skills Competition from both Henderson and South Jordan campuses. Both students represented Roseman University of Health Sciences in the finals at the ASHP Midyear Clinical Meeting last December.



### **Become involved with NVSHIP!**

NVSHIP is seeking members who would like to actively participate in changing the profession of pharmacy. We would love to have you serve on one of our standing committees, Education, Membership and Legislation. If you are interested in becoming more involved, please email us at [nvshp@nvshp.org](mailto:nvshp@nvshp.org).