

S O U T H D A K O T A P H A R M A C I S T



In This Issue:

- Director's Comments
- SDPhA Legislative Days
- Convention Agenda and Registration

South Dakota Pharmacists Association

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"The mission of the South Dakota Pharmacists Association is to promote, serve and protect the pharmacy profession."

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SDPhA CALENDAR

Please note: If you are not on our mass e-mail system check our website periodically for district meetings and other upcoming events. They will always be posted at: <http://www.sdpha.org>.

APRIL

- 13 Huron District Meeting – 6:30 pm
- 17 Black Hills District Meeting
Minerva's, Rapid City, SD
6 pm – Social | 6:30 pm – CE & Meeting
- 20 Easter Sunday
- 22 Sioux Falls District Meeting
Riviera by Rocco's, 26665 481st Ave., Brandon, SD
5:30 pm Reception/Dinner/Meeting/Student Auction
- 22 Aberdeen District Meeting/Presentation
Maverick's Steak & Cocktails, Aberdeen, SD
6:30 pm (presentation details on pg. 10)
- 27 Mobridge District Meeting
Conference Room at Pub 34, 4251 E. Hwy. 34, Pierre, SD
5:30 pm – Social | 6 pm – Dinner & Meeting
- 30 Rosebud District Meeting
Rumors, Dallas, SD
6:30 pm – Social | 7 pm – Dinner & Meeting

MAY

- 1 Watertown District Meeting/Program
7 p.m. – Minerva's, Watertown, SD
- 10 SDSU Graduation, Brookings
- 26 Memorial Day
- 31- 6/4 ASHP Summer Meeting, Las Vegas, NV

JULY

- 4 Independence Day

AUGUST

- 1 License Renewal Window Opens

Cover: Governor Dennis Daugaard, Lt. Governor Matt Michels, SDPhA Board Members, and SDSU College of Pharmacy Faculty and Students on the Capitol Stairs

SOUTH DAKOTA PHARMACIST

The SD PHARMACIST is published quarterly (Jan, April, July & Oct). Opinions expressed do not necessarily reflect the official positions or views of the South Dakota Pharmacists Association. The Journal subscription rate for non-members is \$25.00 per year. A single copy can be purchased for \$8.00.

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DIRECTOR'S COMMENTS

Sue Schaefer | Executive Director



Ready for Change

Happy spring!

The latest and the greatest news: On March 11, 2014, HR 4190 was introduced in the US House of Representatives to recognize pharmacists as providers under Medicare Part B.

The current legislation, introduced by Representatives Brett Guthrie (R-KY), G.K. Butterfield (D-NC), and Todd Young (R-IN), will enable patient access to, and reimbursement for, Medicare Part B services by state-licensed pharmacists in medically underserved communities. Pharmacists, as the most accessible health care professionals, are uniquely positioned to provide patients in medically underserved communities, access to health care services that are already within their scope of practice. By providing for a payment mechanism under Medicare Part B, the bill will allow pharmacists to help fill the gaps in care that have been created by shortages of health care professionals and increases in the number of Americans who are now eligible to gain health insurance under the Patient Protection and Affordable Care Act.

Provider status has been a profession-wide goal for many years. Activity began picking up in early 2013 and came to a head with the formation of the Patient Access to Pharmacists' Care Coalition (PAPCC). The coalition currently represents over 20 organizations and is continuing to grow. Members include organizations representing patients, pharmacists, pharmacies, and other interested stakeholders.

This coalition is focused on developing and helping to enact a federal policy proposal that will enable patient access to, and payment for, Medicare Part B services by state-licensed pharmacists in medically underserved communities. Their primary goal is to expand medically underserved patients' access to pharmacist services consistent with state scope of practice law.

Getting HR 4190 passed may be a long term effort (possibly even multiple years) that will require grassroots advocacy from all pharmacists. Get ready for action alerts asking you to send letters and emails and make phone calls to your congressional delegation! Your state pharmacy association will continue to work with our national partners to make sure that you are kept up to date on the progress of HR 4190 and PAPCC.

The 2014 Legislative Session remained relatively quiet for South Dakota Pharmacy. Bills tracked by SDPhA include: EpiPen in Schools legislation; scheduling of controlled substances, Pseudoephedrine reporting updates, and discussion on Medicaid expansion, to name a few. Please refer to Bob Riter's article for more detailed information.

Legislative Days was a great success, with many students, faculty and pharmacists onsite to learn about the Legislative process and hear about potential legislation that affects pharmacy. This year our Legislative Briefing and dinner was held at the RedRossa Restaurant next to the new Clubhouse Suites in Pierre. On the morning of January 29th, a light breakfast was provided in both chambers of the legislature while over 40 students from the College of Pharmacy provided information on various disease states, and provided health screenings for lawmakers, lobbyists and other folks at the Capitol. The event was capped off with a photo op of the students, faculty, SDPhA Board Members and the Lt. Governor and Governor on the steps of the Capitol! **Next year's Legislative Days is slated for January 27-28, 2015, at the RedRossa Restaurant/Clubhouse Suites & the Capitol Building. Mark your calendars to attend this important event. Pharmacy needs to be seen and heard!**

Regarding Medicaid enhancements, it looks like the Governor's suggested increase for providers has been approved by the Legislature. That means a straight across-the-board 3% increase made the final budget, however we must remember to take into account that we're still digging out from cuts from past years.

The first meeting of the Pharmacy Practice Act Working Group was held on January 28th. A great deal of discussion ensued about what a pharmacist can or cannot do within the current laws and rules. The group identified areas to concentrate on, and that education must accompany the body of work. It was also a consensus that any adjustments to current laws and/or rules should be done with great care and caution.

Board Member Dave Mentele and I recently returned from APHA, NASPA and PMG meetings in Orlando. The APHA meeting is refreshing and contains an incredible slate of continuing education and events. I was fortunate to be chosen for a second term on both the NASPA Executive Board, and the PMG (Pharmacy Marketing Group) Board of Directors. It's such an honor to serve on these important boards and represent South Dakota.

(continued on page 20)

PRESIDENT'S PERSPECTIVE

Shannon Gutzmer | SDPhA President



My previous two articles for the journal have become just too ironic. When I wrote those articles, I took two of my favorite quotes and used them as the theme. They were "Possibilities" and "Be Present."

It seems as though I have been tested from the day I wrote about being open to new possibilities. Hardly a week goes by without

something changing. Whether it is something huge that impacts the whole healthcare system like the new guidelines for lipid management and hypertension to something small like the labels we are using for our prescription bottles. Things keep changing and I have to remind myself to be open to new possibilities. When I was at a meeting this fall, I was given a two inch yellow man that stretches to remind me that these days people need to be "flexible and adaptable." Well that is a lot easier said than done and poor yellow man's head is about ripped off.

In my second article, I wrote about "Be Present." Having your mother diagnosed with breast cancer makes you live in the present. My family takes things week by week and sometimes just a few hours at a time now. We have this year planned in chemo weeks, rest weeks, surgery month and then radiation. Things will seem normal or almost normal, then my mom will get ready for bed. She will put her wig on the dresser and a hat on to keep her bald head warm. This new reality knocks you to the present moment again.

My mom would be embarrassed if she knew I was writing about her. If she would have had things her way, she would have kept her cancer a secret. Fortunately or unfortunately, fate had something else in mind. While still at the hospital, my parents told someone from the neighboring town her diagnosis. A few hours later my dad called to cancel his room for a legislative days he was suppose to attend the next day. The lady answering already new why he would not be able to make it. From that point on my family knew my mom's cancer would not be private. The lack of privacy has helped her deal with it. People stop by my parent's furniture store to see how she is doing or she lets them know on Facebook. Although the contact tires her out sometimes, I think it really makes a difference and helps her keep a positive attitude.

The kindness that has been shown to my family is unbelievable.

I have to share a few of the nice things done for them since my mom's diagnosis. Two siblings eight and six sold some of their toys at a garage sale. They took the money and bought my mom a breast cancer key chain, a balloon, made her a tie blanket along with homemade cards and gave her a \$50 gas card. They were just tickled to deliver the presents to my mom and tell her about them. Then every Sunday night my parents drive from Highmore to Sioux Falls to stay with one of the groomsmen from my brother's wedding so she can get up and have her chemotherapy the next day. Another lady brings my mom homemade soup weekly. One lady just got done with treatments for her cancer and is giving my family gas cards. These are just a few of the nice things done for them.

Many people are helping me too. My coworkers trade days with me so I can get to Sioux Falls to as many of my mom's appointments as possible. One oncology pharmacist has talked me through my mom's breast cancer from the beginning. She has answered all my questions. My fellow board members have stepped in when I had to miss a meeting to go to one of her appointments. I work with such great and caring people that truly care about how my mom and family are doing.

My family is so fortunate for many reasons. My mom found her lump after watching Good Morning America and listening to one of the reporter's talk about her breast cancer. My mom's cancer has not metastasized and her prognosis is good. My parents have cancer insurance and their coverage year started in January. Many good things have happened to us, but it will be a long battle ending sometime next fall. My mom told me a few weeks ago she just wanted things to go back to the way they used to be. I told her, "You already appreciate life more; things will never be the same again."

It's hard to think about the big picture when all you want to do is take care of your mom, make sure she gets better and does not suffer. However, life and time keep going. I am thankful for work and to be involved in SDPhA. It gives me something else to think about instead of cancer.

At the national level, pharmacists from all areas of practice are coming together to become recognized as providers. This is exciting and will take pharmacists in a new direction. At the state level, our board is finishing up the final touches for our state meeting, Resort to Excellence, which will be held in September in Chamberlain. It will be a fun meeting with a great

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SOUTH DAKOTA BOARD OF PHARMACY

Randy Jones | Executive Director



NEW REGISTERED PHARMACISTS

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Cedric Williams; Scott Bishop; Michelle McKay; Chet Messmer; Teri Bruster; Kevin Quach; Mohamed Ibrahim; Shekar Ganesh; Amanda Wiechers; Justin Jones; Mariah Fickbohm.

has more than 2.7 million prescriptions in the database! 1,710 prescribers and pharmacists have been granted on-line access to the database and 33,396 queries have been run by pharmacists and 25,570 queries have been run by prescribers in this time. In 2013, the database assisted numerous prescribers and pharmacists to provide the optimal care for their patients who take controlled substances (CS) and also provided assistance in 89 prescription drug cases. This number is down from 130 and 126 in 2011 and 2012 respectively. Law enforcement agents have requested 339 queries of which 40% have led to charges. We take this as a sign that the PDMP is becoming a very useful tool. Hydrocodone combinations remained the most popular for 2013.

SUBOXONE AND DEA REQUIREMENTS

Practitioners who wish to prescribe Suboxone (or other controlled substances) for the treatment of opioid dependence must meet the training and qualification to do so. The DEA will then issue registration certificate unique to this scope of practice. The DEA certificate will begin with the letter "X". If you receive a prescription for opioid dependence, the DEA regulations state that "X" DEA number in addition to the existing DEA number need to be included on all controlled substance prescriptions for the treatment of opioid dependence. Pharmacists can verify the prescriber's authority to prescribe for opioid dependence by calling 1-866-287-2728, or by email at info@buprenorphine.samhsa.gov.

How are pharmacists to determine if the prescription for Suboxone; 1 tablet BID # 60; is for opioid dependence or for an off-label use for (example) pain? If the prescription does not have an indication for therapy, it is the board staffs opinion to clarify the indication with the prescriber and document accordingly. 3rd payer audits look for this type of documentation.

NABP / AACP DISTRICT V ANNUAL MEETING

The District V NABP / AACP Annual Meeting will be hosted by South Dakota this year. The meeting will be held in Deadwood, SD on August 14th – 16th. The Board of Pharmacy in conjunction with the SDSU College of Pharmacy is planning an exciting event, and hope many of you can attend. District V representation consists of colleges and boards South Dakota, North Dakota, Minnesota, Iowa, Nebraska, Manitoba and Saskatchewan. Stay tuned as more information will be forth coming.

SOUTH DAKOTA PRESCRIPTION DRUG MONITORING (SD PDMP) STATISTICS FOR 2013 AND UPDATE FOR 2014

The PDMP has now been in operation for nearly 2 years and

PHARMACY TRIVIA

Did you know?

- There are 66 counties in South Dakota.
- There are 52 counties that have at least one pharmacy.*
 - o 16 counties without any pharmacies
- There are 8 counties with only one pharmacy.
- There are 31 counties with 3 pharmacies or less.
- The counties with the highest density of pharmacies:
 - o Minnehaha – 60
 - o Pennington – 33
 - o Brown – 14
 - o Lincoln – 14
 - o Lawrence – 10
 - o Yankton – 10
- With a population of approximately 815,000, there is one pharmacy for every 2,820 citizens.*

**includes full and part-time pharmacies*

BOARD MEETING DATES

Please check our website for the time, location and agenda for future Board meetings.

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Board of Pharmacy Website..... www.pharmacy.sd.gov

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SOUTH DAKOTA BOARD OF PHARMACY

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SOUTH DAKOTA PRESCRIPTION DRUG MONITORING STATISTICS FOR 2013

YTD 2013 Most Prescribed Controlled Drugs	RXs	Quantity	Quantity/Rx
Hydrocodone BIT/Acetaminophen	296,433	17,124,276	58
Zolpidem Tartrate	97,732	3,141,573	32
Lorazepam	87,372	4,187,409	48
Clonazepam	76,889	4,709,526	61
Alprazolam	60,050	3,457,152	58
Methylphenidate HCL	53,384	2,418,282	45
Oxycodone HCL	45,954	3,694,068	80
Oxycodone HCL/Acetaminophen	44,607	2,754,356	62
Acetaminophen with Codeine	32,911	1,423,356	43
Dextroamphetamine/Amphetamine	32,304	1,457,759	45

The end of year provides an opportunity to look at statistics for the year and make our "Top 10 Prescriber Trends" list.

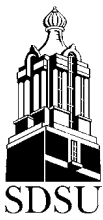
Top 10 Controlled Substance Prescriber Trends in 2013 - Statistics from SD PDMP
1. 80% of all CS prescriptions are written by 23% of all prescribers
2. 80% of CS prescriptions (by quantity) are written by 21% of prescribers
3. The top CS prescribing physician prescribed 7,058 CS prescriptions (or 28 Rxs/day) and 491,093 doses of CS which is 1,300 prescriptions and 145,000 doses more than the second highest
4. Of the top 50 prescribers of CS, only 50% have requested and obtained access to the SD PDMP
5. Only 24% of all Prescribers have requested and obtained access to the SD PDMP
6. One resident obtained CS prescriptions from 37 different prescribers
7. 21 residents obtained CS prescriptions from 20 or more different prescribers
8. 296,443 prescriptions and 17,124,276 doses of Hydrocodone/APAP were prescribed/dispensed
9. 45,954 prescriptions and 2,418,282 doses of Oxycodone (non-combo) were prescribed/dispensed
10. In October, the PDMP sent letters to 111 prescribers identifying their patients who had used > 6 prescribers and filled prescriptions at > 6 pharmacies in 90 days. 76% went to MD/DOs and 22% to PAs. New letters will be sent in January, April, July and October 2014.

PRESIDENT'S PERSPECTIVE

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line-up of speakers and some much needed relaxation. At the local level, district meetings are being held in the following weeks. Make plans to attend for the education, socialization and pharmacy updates. The dates for these meetings are on SDPhA's new website. Don't forget to nominate people for SDPhA's annual awards. There are many deserving people in our state that need to be recognized.

Life does keep going and we keep moving right along with it. "Be kind. For everyone you meet is fighting a hard battle." As people have expressed their kindness to me, I have found this quote to be so true. My hope for all of you is that your battles will be won; and you find support along the way.



SOUTH DAKOTA STATE UNIVERSITY College of Pharmacy



Dennis Hedge | Dean



Greetings from the South Dakota State University College of Pharmacy!

As we move to the latter stages of the academic year, I would like to take this opportunity to update you on several things at the College.

The Pharm.D. program admissions process for our next P1 Class was recently completed. Total

applications for admission were down slightly this past year, but the number of applications from students on the SDSU campus and from other South Dakota institutions remained consistent with prior years. The average academic statistics of the incoming class are once again very strong with an average ACT score of 27, an average cumulative college GPA of 3.75 and an average PCAT percentile score of 70.4.

Two members of our faculty were recognized at the SDSU Celebration of Faculty Excellence program this past month. Dr. Teresa Seefeldt received the 2013 Edward Patrick Hogan Award for Teaching Excellence, which is a university-wide award. Dr. Debra Farver was named the 2013 College of Pharmacy Distinguished Scholar for her work in the area of interprofessional education.

The College of Pharmacy was also well represented at the SDSU Women of Distinction Awards Tea. Ms. Ashley Potter, a P3 student in the pharmacy program, was named the 2014 SDSU Woman of Distinction in the student category. Ms. Sara Wettergreen, a P4 student, was also nominated in the student category and recognized at the event. The SDSU Women of Distinction Awards are sponsored through an SDSU Women and Giving grant.

Finally, the College is continuing to make progress on its accreditation self-study. The Accreditation Council for Pharmacy Education (ACPE) site visit will occur in October. Also of note in regard to accreditation, ACPE recently released a "draft" of new standards – Standards 2016. The new draft standards are designed to ensure that graduating students are "practice-ready" and "team-ready". If you would like to learn more about the revision process for Draft Standards 2016, please see the ACPE standards revision website at <https://www.acpe-accredit.org/deans/StandardsRevision.asp>.

As always, if you are in the Brookings area, please stop by for a visit.

Warm regards,
Dennis D. Hedge, Dean of Pharmacy

Resort to Excellence

SDPhA ANNUAL CONVENTION
SEPTEMBER 19-20, 2014 • OACOMA, SD

128th Annual South Dakota Pharmacists Association Convention

.....

Cedar Shore Resort • Oacoma, SD
September 19-20, 2014

.....

Information and Registration
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ACADEMY OF STUDENT PHARMACISTS

Ashley Potter | APhA-ASP SDSU Chapter President



As the APhA-ASP SDSU Chapter President, I am excited to share with you some spring updates! Our committees have been busy planning and executing some very exciting events.

As always, the Legislative Days was a wonderful experience for our chapter members this year. Over 40 student pharmacists participated in various screenings and educational booths reaching at the Capital in

January. We are thankful for this opportunity provided by SDPhA and proud of all of the students involved in coordinating the event! Thanks, again.

In February, we held our annual International Potluck and APhA-ASP Auction in coordination with our local American Association of Pharmaceutical Sciences Chapter. We shared food from around the world including Pakistan, Saudi Arabia, Bangladesh, China, Norway, Italy, and Africa to increase cultural awareness while our Fundraising Committee worked hard to raise funds for the chapter. February also marked a month of participation in the Script Your Future Medication Adherence Campaign. P1, Jenna Donnelly, took the lead to coordinate a letters writing campaign, radio public service announcements, pharmacist education materials, presentations and booths to promote medication adherence.

March has been focused on safe use of medication and poison prevention. Our Medication Education Committee was hard at work during poison prevention week as they held educational sessions at local schools reaching over 180 preschoolers! Also, On March 26th, Our Generation Rx Committee coordinated an APhA-ASP and SDSU College of Pharmacy sponsored guest speaker, Phil Toft, Special Assistant Attorney General with the South Dakota Division of Criminal Investigation, addressing drug diversion to over one hundred pharmacy, nursing, and medical labs science students.

Our patient care committees have been hard at work organizing screenings and booths at the SDSU Wellness Fair, the SDSU Employee Benefits Fair, and at local pharmacies and community event locations. Additionally, the Health Systems Committee has been busy presenting residency showcases, residency interview and cover letter workshops, and student organized journal clubs for P3 students in coordination with various health-systems pharmacists in Sioux Falls.

This summer, we are proud to announce that our chapter will be hosting two international students through the International Pharmaceutical Students' Federation Student Exchange Program. Alexandra (Alex) Hawker of the United Kingdom and Hui Ling (Jessica) Hah of Malaysia will be participating in various introductory pharmacy practice experiences in the Sioux Falls area from July 21st to August 8th. A local pharmacist and her husband will act as the students' host family. We would like to thank everyone who has helped to coordinate this program!

With about one month left of the school year, we are excited to be finishing the year on a high note. Please look for our next update this summer!

Save the Date

Preceptor Day at Cedar Shore!

SDSU College of Pharmacy is sponsoring a free CE event for preceptors at Cedar Shore Resort in Chamberlain/Oacoma. The day will be filled with informational sessions for preceptors on topics ranging from general information on APPE requirements and the curriculum, to round table discussions on best practices and preceptor resources.

Date: Tuesday, June 3

Time: 9:30 a.m. Light Breakfast
10 a.m. Program Starts
Day will conclude by 3 p.m.

Place: Cedar Shore Resort, Oacoma, SD

Registration information and a full schedule will be provided at a later date.

I hope you will be able to join us! Please share this with all of the preceptors at your site.

For more information, contact: jodi.heins@sdstate.edu

Jodi Heins, PharmD
Assistant Department Head and Professor
Department of Pharmacy Practice
Office of Experiential Education
Residency Program Director
South Dakota State University College of Pharmacy

SD SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Kelley Oehlke, Pharm.D., BCACP | SDSHP President



Spring Greetings from SDSHP!

Hopefully you all have had an opportunity to register for the 38th Annual SDSHP Conference to be held on April 11th & 12th at the Ramkota Hotel and Conference Center in Sioux Falls. The event will provide 11 hours of ACPE accredited continuing education and will also be offering a technician track on Saturday

morning. At the business meeting and awards presentation, we will be honoring Ron Huether as the recipient of this year's Gary W. Karel lecture award as well as the pharmacist and technician of the year. The board would like to thank the annual meeting committee, chaired by Tadd Hellwig, for all their hard work in setting up what should be another great meeting.

I am pleased to inform you that on January 17, 2014, the ASHP Board of Directors granted SDSHP ongoing full affiliation status with ASHP in accordance with ASHP's governing documents and the ASHP Guidelines for Affiliation with State Organizations. SDSHP was found to be an organization that continues to reflect

a mission, vision, and membership focus that is consistent and congruent with the purposes and mission of ASHP. SDSHP will continue to be reviewed for compliance with the ASHP Guidelines for Affiliation with State Organizations. A special thanks to John Kappes and Gary Van Riper as well as the SDSHP Board of Directors for assisting me with completion of the necessary paperwork to make this possible.

The 2013-2014 Board of Directors has been a fantastic group to work with and I want to express my gratitude for their dedication to our profession. An overabundance of time and energy is poured into these volunteer positions that is often overlooked. We have been able to accomplish many things this year, but this is only because of their dedication. A special thanks to our outgoing board members which include: John Kappes, Ann Oberg, Andrew Zwack (term completed in August) and Kirre Wold.

Finally, I would like to thank the membership for giving me the opportunity to serve as the president of SDSHP. It has been an extremely rewarding year for me both personally and professionally. I am looking forward to working with the board under the very capable leadership of incoming president Andrea Aylward.

An Invitation to Aberdeen District Pharmacists and Technicians

Please join us for a dinner discussion exclusively for Aberdeen District Pharmacists & Technicians

Insulin A to Z

Objectives:

- Assess beliefs related to behavior change
- Illustrate why insulin may be necessary in Type 2 diabetes
- Discuss traditional care model issues
- Review ADA/EASD Consensus Algorithm for the initiation and adjustment of therapy
- Discuss how to initiate, adjust and monitor insulin therapies
- Engage in a case-based example

Date: Tuesday, April 22nd, 2014

Time: 6:30 PM

Place: Maverick's Steak & Cocktails
720 Lamont Street South
Aberdeen, SD
605-225-1314
www.maverickssteak.com

Presented by:

Diana Noller, RN, CDE
Diabetes Regional Medical Liaison, Sanofi Diabetes

RSVP: by Monday, April 21st
to Trisha.Hadrick@jeantc80@hotmail.com

SD ASSOCIATION OF PHARMACY TECHNICIANS

Bonnie Small | President



It's finally spring. I think. There are a lot of new things going on in the tech world.

We have awarded our scholarship to Jena Jorgensen of Lennox, SD. She goes to Southeast Technical Institute as a Pharmacy Technician and is a Pharmacy clerk at Hy-Vee Inc. Jena also owns/is the founder of J.J. Photography. She is considering going on to become a PharmD

student. Congratulations to Jena.

Pharmacy technicians who have not received your certification, don't forget that SDPHA has endorsed an online program along with the Board of Pharmacy. This is a program with 'The Pharmacist's Letter' Pharmacy Technician University that prepares students for Pharmacy Technician certification. SDPHA has set up a link to the program on their web site at <https://www.sdpha.org/member-center> (scroll down to 'Pharmacy Technician University'). They normally charge \$480 for the course, but

SDPHA has struck a deal, and it will only cost our members and affiliates \$150 for the entire "study at your own pace" program! (Members of South Dakota Association of Pharmacy Technicians are affiliates of SDPHA and are thus eligible for this discount.)

And just another reminder of our meeting on July 12th at SDSU, Brookings, SD: looks like we'll start with 7:30 to 8:00 am registration (location to be announced). We hope to have a good showing, and the Brookings Art festival is the same weekend, so book rooms early. If you cannot get rooms please contact me at Bonnie.small@avera.org. There is new requirement for PTCB certification, a medication safety CE and Sandy Jacobson, RPh will be presenting it. We will also have a law CE and three more speakers. This will be a great opportunity to learn from other pharmacy techs *and* receive CE hours (and no tests are required). There are a lot of changes coming for pharmacy techs and we will be updating you on them at that time too. Please encourage your techs to come or if you're a tech we would like to see you there. We are updating the website (www.sdapt.com) with new information so check it out, and check us out on Facebook, too. Looking forward to seeing you all in Brookings.

When A Small Reminder Makes A Big Difference

New Labeling Standards Ensure Warnings Are Obvious and Clear

Have you ever had one of those little warning icons light up on your car's dash and you don't know what it means? You know that some signals require attention right away and others can wait. The thing is, most of the time you have to look up the icon to make that decision.

When it comes to medicines and people's lives, there is no substitute for being clear about a warning, and for injectable drugs the stakes are particularly high. Beginning December 1st, manufacturers of injectable drugs will have to comply with new labeling standards that help ensure that important warnings – warnings that can help prevent life-threatening situations – are obvious and clear. The standards were established by the U.S. Pharmacopeial Convention (USP). USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's mission is to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

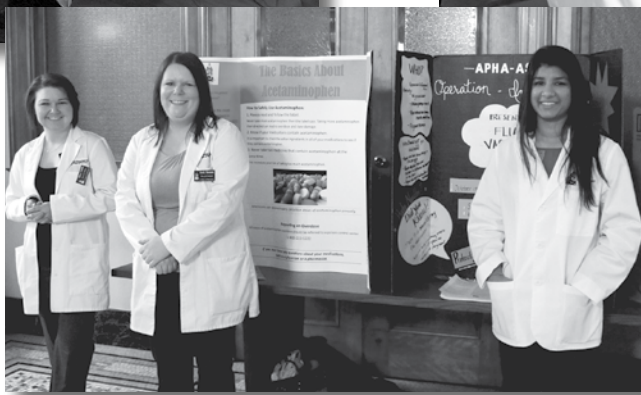
In short, this USP standard states that warning messages – for example, "Warning – Paralyzing Agent" or "Dilute Before Using" – are the only markings that should appear on ferrules and cap overseals of injectable drugs. The ferrules and cap overseals must remain clear of any markings, including logos, except for markings intended to prevent an imminent life-threatening situation. The standard goes on to say that warnings must be printed in contrasting color and clearly visible under ordinary conditions of use. Finally, products that do not require cautionary statements should be free of information, so that those with cautionary statements are immediately apparent.

With the new USP labeling standard, if a healthcare provider sees a warning on a ferrule or cap over seal, he or she will know immediately that it is a vital, possibly life-saving piece of information that must be observed and acted upon before administering the drug to the patient.

Warning messages on ferrules and cap over seals may go a very long way to helping practitioners protect their patients from harm.

SDPhA LEGISLATIVE DAYS 2014

January 28-29 • Pierre, SD



2014 LEGISLATIVE REPORT

Robert C. Riter | SDPhA Lobbyist

While the 2014 Legislative Session was rather limited in regard to pharmacy interests, there were several measures important to your Association which were acted upon. *HB 1024* is the annual bill sought by the Department of Health to place certain substances on the controlled substances schedule. It passed both Houses and was signed by the Governor on February 10. It became effective immediately upon approval by the Governor.

Of particular note to pharmacists, *SB 24* requires electronic time sensitive reporting of sales of certain products containing pseudoephedrine, ephedrine, or phenylpropanolamine. The Association worked with the Attorney General's office on the language of this proactive bill, which provides exceptions for retailers without electronic reporting capability. The bill also allows for completion of a sale if the clerk is in fear of imminent bodily harm if the sale is not completed. The Senate passed an amended version of the bill. The House passed that amended version, and the bill was signed by the Governor on March 31.

SB 81 prohibits the possession of certain items in jails, including non-authorized prescription drugs. For this section, prescription drugs include nonprescription medications authorized by the sheriff and available to inmates through authorized jail personnel or the inmate commissary. The Senate passed an amended version of the bill. The House of Representatives passed the bill as amended, and it was signed by the Governor on March 31.

HB 1167 authorizes a school to maintain a stock of epinephrine auto-injectors obtained pursuant to an authorized prescription. The injectors may be used in emergency situations by a school nurse or other designated and trained school personnel. No school district can be held liable for injury or damage resulting from the injection. The bill passed both the House and Senate and was signed by the Governor on March 12.

HB 1258 set out to allow for an affirmative defense of driving under the influence of prescription drugs in certain cases. The

bill would have amended SDCL 32-23-6, placing the burden on the state to prove beyond a reasonable doubt that the prescription drug impaired the defendant's ability to drive. The House Judiciary Committee deferred this bill until the 41st legislative day (failed).

Finally, a bill medical professionals took note of was *SB 97*, which provides for the revocation of a professional license that has been obtained in connection with the presentation of a fraudulent degree. Under this bill, a false academic degree could include situations when a degree is granted in a jurisdiction without an accreditation system, or if a degree is accredited by a foreign entity and that accreditation is brought into question. If so, the degree may be evaluated based on commonly recognized industry standards used to evaluate foreign academic credentials in the state. If a person uses his false degree, a violation of the section is a Class 1 misdemeanor and provides cause for the revocation of any license obtained in connection with the fraudulent degree. This bill was amended by the Senate Education Committee. The Senate and House both passed the bill as amended, and the Governor signed it on March 14.

While the legislature did approve a 3% increase to reimbursements to pharmacists from Medicaid funding, this is based upon the reduced level which resulted from budget cuts several years ago. Most other medical care providers received the same modest increase. All of the bills signed by the Governor, with the exception of *HB 1024*, become effective on July 1, 2014.

We appreciated the opportunity to again assist you! The efforts of your leaders, along with the efforts of individual pharmacists, again led to positive results for this Association during the 2014 Legislative Session. If you have questions about any of the measures, please do not hesitate to contact us.

128th Annual South Dakota Pharmacists Association Convention Cedar Shore Resort • Chamberlain/Oacoma, SD September 19-20, 2014

Line-up (Tentative)

Friday, September 19

- | | |
|-------------------------|---|
| 8:00 a.m. – 9:30 a.m. | Enhancing Public Safety through Partnerships
Attorney General Marty Jackley |
| 9:30 a.m. – 10:30 a.m. | Pharmacy Law
Dr. Dave Helgeland |
| 10:30 a.m. – 11:30 a.m. | Business Meeting |
| 11:30 a.m. – 1:30 p.m. | Vendor Time/Luncheon/Awards Presentations |
| 1:30 p.m. - 3:00 p.m. | Pain Management & Pharmacogenomics
Dr. Nikki Eye & Dr. Krista Bohlen |
| 3:00 p.m. – 3:30 p.m. | SDSU Ice Cream Social |
| 3:30 p.m. – 5:00 p.m. | New Drug Update
Dr. Joe Strain |
| 6:00 p.m. – 8:00 p.m. | Riverside Reception |

Saturday, September 20

- | | |
|------------------------|--|
| 8:00 a.m. – 9:00 a.m. | Light Breakfast/Second Business Meeting |
| 9:00 a.m. – 11:00 a.m. | Antimicrobial Stewardship
Dr. Katie Palmer, PharmD, BCPS |
| 11:00 a.m. – 1:00 p.m. | Appointment-based Model
SDSU Student Pharmacists |



Resort to Excellence

SDPhA ANNUAL CONVENTION
SEPTEMBER 19-20, 2014 • OACOMA, SD

128th Annual South Dakota Pharmacists Association Convention Registration Form Cedar Shore Resort | Oacoma, SD | September 19-20, 2014

All SDSU Student Registrations are FREE!
(Hotel Not Included)
Registration must be submitted prior to August 20, 2014.

Name: _____
 Address: _____
 City: _____ State: _____ Zip: _____
 Business Name: _____
 Business Address: _____
 City: _____ State: _____ Zip: _____
 Business Phone: _____
 Home Phone: _____
 Email: _____
 Spouse/Guest Name: _____

eProfile ID: _____

For Hotel Reservations Call:
 Cedar Shore Resort
 1500 Shoreline Dr. • Oacoma, SD 57365
 1-888-697-6363

Convention Registration Cancellation Policy:

Cancellations will be accepted without penalty prior to September 8, 2014.
 A \$25 cancellation fee will be applied to all cancellations after September 8, 2014.
 Refunds will be issued after October 1, 2014.

*Full Registration includes all educational sessions, exhibits, meals and evening events.

**One-Day Registration includes educational sessions, exhibits, meals, and evening event, if applicable.

	SDPhA Member	Spouse or Guest	Children	SDAPT Member	Pharmacy Technician	Pharmacy Student	Non-SDPhA Member
Full Registration*							
Before August 20, 2014	\$150	\$75	\$20	\$75	\$125	Free	\$225
After August 20, 2014	\$175	\$100	\$20	\$100	\$140	Free	\$250
One-Day Registration**							
Fri., Sept. 19, 2014	\$100	\$50	\$10	\$50	\$90	Free	\$150
Sat., Sept. 20, 2014	\$50	\$50	\$10	\$50	\$50	Free	\$75
Extra Tickets							
Friday Lunch	\$15	\$15	\$10	\$15	\$15	Free	\$15
Friday Supper	\$15	\$15	\$10	\$15	\$15	Free	\$15
Saturday Breakfast	\$15	\$15	\$10	\$15	\$15	Free	\$15

I would like to sponsor a student. I have included an additional gift of _____

I would like to contribute to the SDPhA Commercial & Legislative Fund.

I have included an additional amount of _____

Total Due \$ _____

Please send payment and registration to:

South Dakota Pharmacists Association

PO Box 518 Pierre, SD 57501

Tax ID#: 46-019-1834

Register Online at www.sdpha.org

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Thank You 2013 Contributors!

Contribute to the 2014-15 South Dakota Pharmacists Association District Dues and SDPhA Commercial & Legislative Fund! Visit our website at www.sdpha.org. Thank you for your support.

2014 AWARD NOMINATIONS

The SDPhA is accepting nominations for awards to be presented at the 2014 Convention at Cedar Shore Resort in Oacoma. Nominations should be submitted along with biographical and contact information. The following awards will be presented:

Bowl of Hygeia

The recipient must be a pharmacist licensed in South Dakota; be living (not presented posthumously); not be a previous recipient of the award and not served as an SDPhA officer for the past two years. The recipient has compiled an outstanding record of community service, which apart from his/her specific identification as a pharmacist reflects well on the profession.

Nominee: _____

Distinguished Young Pharmacist

The nominee must hold an entry degree in pharmacy received less than ten years ago, licensed in South Dakota, member of SDPhA, practiced in retail, institutional, consulting pharmacy in the year selected, involvement in a national pharmacy association, professional programs, state association activities and/ or community service.

Nominee: _____

Hustead Award

Nominee must be a pharmacist licensed in South Dakota, who has not previously received the award. The nominee shall have made a significant contribution or contributions to the profession, and should have demonstrated dedication, resourcefulness, service, and caring.

Nominee: _____

Distinguished Service Award

The nominee must be a non-pharmacist who has contributed significantly to the profession. The award is not routinely given each year, but reserved for outstanding individuals. Persons making the nomination should complete the form providing reasons why the nominee should be selected. The nomination should clearly outline why the nominee is worthy of the award. If a recipient is selected, the Association will then contact the individual to notify them of the selection and obtain biographical data.

Nominee: _____

Salesperson of the Year Award

Nominee must have made an outstanding contribution to the profession of pharmacy through outside support of the profession.

Nominee: _____

District Technician of the Year Award

Nominee has demonstrated an excellent work ethic, is reliable, consistent, and works well with other. Technician provides a valuable service to the pharmacy profession.

Nominee: _____

Fax nominations by **June 1, 2014** to (605) 224-1280 or e-mail to sue@sdpha.org. Using the criteria for each award listed, please describe in detail the reason for the SDPhA Board of Directors to consider your nominee. Include specific examples and/or details.

Name of Individual Nominating: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____ E-Mail: _____

Pharmacy/Organization: _____



AND THE LAW by Don R. McGuire Jr., R.Ph., J.D.

This series, Pharmacy and the Law, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

The Drug Quality And Security Act

Most pharmacists are aware that the Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013. Most are also aware that the law provides additional regulatory oversight over the compounding of sterile products. This comes from the Compounding Quality Act (CQA) portion of the DQSA. However, many pharmacists are unaware of the other provision in the DQSA, the Drug Supply Chain Security Act (DSCSA). This portion will increase the ability to track and trace products from manufacturers downstream to the ultimate users.

The CQA creates a new entity in the drug distribution model; the Outsourcing Facility. An Outsourcing Facility compounds sterile products and elects to register as an Outsourcing Facility under the act. A facility that compounds only non-sterile preparations cannot register as an Outsourcing Facility. An Outsourcing Facility is not required to be a licensed pharmacy. In addition, the Outsourcing Facility may or may not obtain prescriptions for identified individual patients. Registration and abiding by the provisions of the CQA allow the products compounded by the Outsourcing Facility to be exempt from the requirements of the New Drug Application process. Section 503A of the Food, Drug and Cosmetic Act contains another avenue for exemption when there is an identified individual patient who is the recipient of the compounded item, whether it is sterile or non-sterile.

The CQA provides a broad definition of compounding. Compounding includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering a drug or bulk drug substance to create a drug. The inclusion of the words diluting and reconstituting show the intent to cover everything sterile that is compounded, no matter how simple the action. Note that the inclusion of admixing shows that IV admixture programs are considered compounding.

Outsourcing Facilities will have to register with the FDA

annually. The list of registrants will be public information. Outsourcing Facilities will also have to file with the FDA reports of their activities twice per year. The contents of these reports will not be public information. Outsourcing Facilities will be subject to FDA inspection on a risk-based schedule.

The CQA will also require the implementation or completion of some lists of products/components in order for Outsourcing Facilities to be able to comply with the section. An Outsourcing Facility cannot compound a product if it is on a list of drugs that have been withdrawn or removed from the market for reasons of safety or effectiveness. Also, an Outsourcing Facility cannot compound a product that is on the Demonstrable Difficulties for Compounding list. In addition, bulk substances without an USP/NF monograph must not be used unless they are on an approved list of bulk substances. None of these lists are currently complete, but the FDA will be convening a Pharmacy Compounding Advisory Committee to help compile these lists.

The second part of the DQSA is the Drug Supply Chain Security Act. This provision will impact many more pharmacies than does the CQA. This act creates a drug product history, starting with the manufacturer that must be passed on with the product as is it sold or distributed down the supply chain. This encompasses wholesalers, third party logistics providers, trading partners, repackagers, and dispensers. The drug product history is not required to be provided by the dispenser to the prescribed patient. But the dispenser is required to have policies and procedures in place to quarantine suspect or illegitimate products, return them as necessary and notify any patients who may have received them from the dispenser.

Another provision of the act will require that a product identifier be affixed to the packaging of prescription drugs. This identifier will need to be readable by both humans and machines. The

(continued on page 20)

FINANCIAL FORUM

This series, Financial Forum, is presented by PRISM Wealth Advisors, LLC and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

How Impatience Hurts Retirement Saving

Keep calm & carry on – it may be good for your portfolio

Why do so many retirement savers underperform the market?

From 1993-2012, the S&P 500 achieved a (compound) annual return of 8.2%. Across the same period, the average investor in U.S. stock accounts got only a 4.3% return. What accounts for the difference?^{1,2}

One big factor is impatience. It is expressed in emotional investment decisions. Too many people trade themselves into mediocrity – they react to the headlines of the moment, buy high and sell low. Dalbar, the noted investing research firm, estimates this accounts for 2.0% of the above-mentioned 3.9% difference. (It attributes another 1.3% of the gap to operating costs and the remaining 0.6% to portfolio turnover within accounts)²

Impatience encourages market timing. Some investors consider “buy and hold” passé, but it has certainly worked well since 2009. How did market timing work in comparison? Citing Investment Company Institute calculations of equity account asset inflows and outflows from January 2007 to August 2012, U.S. News & World Report notes that it didn’t work very well. During that stretch, investors either sold market declines or bought after market ascents 57.4% of the time. In addition, while the total return of the S&P 500 (i.e., including dividends) was -0.13% in this time frame, equity account investors lost 35.8% (adjusted for dividends).³

Most of us don’t “buy and hold” for very long. Dalbar’s latest report notes that the average equity account investor owned his or her shares for 3.3 years during 1993-2012. Investors in balanced accounts (a mix of stocks and bonds), held on a bit longer, an average of about 4.5 years. They didn’t come out any better – the report notes that while the Barclays Aggregate Bond Index notched a 6.3% annual return over the 20-year period studied, the average balanced account investor’s annual return was only 2.3%.²

What’s the takeaway here for retirement savers? This amounts to a decent argument for dollar cost averaging – the slow and steady investment method by which you buy shares over time,

a little at a time. When the market sinks, you are buying more shares as they have become cheaper – meaning you will own more (quality) shares when they regain value.

It also shows you the value of thinking long-term. When you save for retirement, you are saving with a time horizon in mind. A distant horizon. Consistent saving from a (relatively) early age and the power of compounding can potentially have much greater effect on the outcome of your retirement savings effort than investment selection.

Keep your eyes on your long-term retirement planning objectives, not the short-term volatility highlighted in the headlines of the moment.

Pat Reding and Bo Schnurr may be reached at 800-288-6669 or pbh@berthelrep.com.

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Citations.

- 1 - finance.yahoo.com/news/p-fund-tops-p-500-142700129.html [5/3/13]
- 2 - marketwatch.com/story/7-reasons-why-retirement-savers-fail-2013-06-26 [6/26/13]
- 3 - money.usnews.com/money/blogs/the-smarter-mutual-fund-investor/2012/11/05/herd-behavior-hurts-fund-investors [11/5/12]

DIRECTOR'S COMMENTS

(continued from page 4)

The biggest bonus about attending APhA is our Saturday Night Family Dinner with the students and faculty from SDSU's College of Pharmacy! It never fails to bring lots of laughs and camaraderie, and we enjoy it very much.

South Dakota State's College of Pharmacy students really hit it big again this year! SDSU's APhA-ASP group was second runner up for the 2012-2013 Division AAA Chapter Achievement Award, after winning the award last year in Los Angeles; Ashley Potter, APhA-ASP Chapter President, received the APhA Student Leadership Award (huge!), Colleen O'Connell received an APhA Foundation Scholarship (one of only twelve in the nation), and Joe Berendse was awarded runner up (second place in the nation!) in the National Patient Counseling Competition! Sara Wettergreen, Ashley Potter, and Colleen O'Connell were formally recognized for their leadership and service on APhA-ASP standing committees for the 2013-2014 year. Finally, the chapter was recognized for receiving the 2012-2013 Region Five Operation Diabetes award in November. We're so incredibly proud of our student contingent, and they work very hard to represent South Dakota.

In other news, the Drug Enforcement Administration (DEA) has scheduled another National Prescription Drug Take-Back Day on Saturday, April 26th from 10:00 a.m. to 2:00 p.m. This is a great opportunity for those who missed the previous events, or who have subsequently accumulated unwanted, unused prescription drugs, to safely dispose of those medications.

Plans are being finalized for the Association's annual meeting, September 19-20, 2014 at the Cedar Shore Resort in Chamberlain/Oacoma.

Current continuing education topics that have been confirmed to-date are: the ever-popular New Drug Update; Pain Management & Pharmacogenomics; Antimicrobial Stewardship; to mention a few! **Our kickoff speaker will be Marty Jackley, South Dakota's Attorney General**, who will update attendees on current pseudoephedrine law changes, etc.

For more details, contact SDPHA or view the entire agenda on the website or in this Journal. Please visit www.sdpha.org to register for convention online. We look forward to seeing you there!

District Meeting scheduling is under way. Please refer to the calendar in the front of this issue of The South Dakota Pharmacist to see when your meeting has been scheduled. We've also included meeting information on our website:

www.sdpha.org, and our new Facebook page! Check us out and LIKE and FOLLOW us! We're also seeking nominations for the Husted, Bowl of Hygeia and Distinguished Young Pharmacist Awards, so put on your thinking caps. We have so many wonderful pharmacists to recognize.

And finally, I can't express how important your donations are to the Commercial and Legislative Branch of SDPHA. We need strong and continuous representation to protect the interests and concerns of pharmacists in South Dakota. We can't retain our Lobbyist, Bob Riter, without your support. This year's donations fell far short of our needs. To help keep pharmacy vibrant and protected, Log on to support the C&L fund: www.sdpha.org. To those of you, who have so graciously donated, THANK YOU!

The sidewalks are shoveled and our door is always open.

Warm and Healthy Regards,

Sue

Rx and the Law: The Drug Quality and Security Act

(continued from page 18)

act also specifically outlines the content of the drug histories. Implementation of the different requirements of the act varies according to the type of entity involved, but many items will need to be implemented no later than July 1, 2015.

The DQSA has been covered in the media primarily as a compounding law, but the tracking and tracing requirements will apply to all participants in the drug distribution chain. So it behooves all pharmacists to review the act and determine which provisions impact their practice and when that impact will occur.

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© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

Continuing Education for Pharmacists

“Women’s Health - Therapeutic Options for Relieving Symptoms of Menopause”

-Knowledge-based CPE



Laura Johnson, Pharm.D.

Disclaimer: The author has had no financial relationship over the past 12 months with any party having a commercial interest in the content of this arti-

Goal: To enhance the pharmacist’s knowledge regarding therapy options for alleviating symptoms of menopause.

Pharmacist Learning Objectives:

1. Describe the pathophysiology and symptoms of menopause;
2. List the available treatment options for alleviating menopausal symptoms;
3. Decide when systemic or local hormone therapy is appropriate based upon symptoms;
4. Determine an appropriate dose and duration for systemic and local hormone therapy;
5. Identify pharmacologic alternatives to hormone therapy.

Pharmacy Technician Learning Objectives

1. Describe the general differences between pharmacologic, nonpharmacologic, and alternative treatments for women transitioning into menopause;
2. List common lifestyle modifications for treating symptoms of menopause;
3. Identify key nonprescription and prescription products (and their dosage forms) utilized in the treatment of menopause.

Introduction:

As all women age, they will inevitably go through the menopause transition. Some experience an asymptomatic transition whereas others experience symptoms severe enough to interfere with daily life.¹ A study done by Whiteley et al. associated decreased health status, decreased work productivity, and increased use of healthcare resources with an increase in the severity and duration of vasomotor symptoms.² Considering the prevalence and potential negative impact of vasomotor and vaginal symptoms, management through pharmacologic, non-pharmacologic, and alternative treatment options provide the foundation for helping women transition into menopause.

Pathophysiology

Starting in the mid-thirties, a woman’s ovaries reduce the production of estradiol leaving the primary source of estrogen within the female body as the less active estrone.³ During this time, menses become irregular. Once menses are absent for twelve months, a woman officially transitioned into menopause. The rate of decline in the estradiol levels, not the levels themselves, determines the rapidity and degree of symptoms experienced.⁴ Menopause that

after events such as radiation or surgery usually produce the most rapid and severe symptoms as they induce an immediate drop in estrogen levels. The treatment for surgical menopause parallels the natural form but will not be the focus of this article.

Signs and Symptoms

Up to 85% of women complain of symptoms related to an estrogen deficiency including vasomotor symptoms (hot flashes and night sweats), insomnia, and vaginal dryness.¹ These symptoms show extreme variability between patients, although hot flashes and sweating are often the first symptoms experienced. About 30% of women experience hot flashes before missing any menstrual cycles. These vasomotor symptoms typically last less than five years but some women report them longer than ten years.⁴ Moderate to severe symptoms occur when a woman complains of more than seven hot flashes per day or sixty within one week. While not life threatening, they often significantly affect quality of life.²

Approximately 10-40% of women report vaginal symptoms including dryness, irritation, itching, and dyspareunia (painful intercourse). Vaginal symptoms often lead to longer periods of discomfort as they tend to be progressive and less likely to resolve on their own.⁹ Other symptoms commonly associated with menopause include anxiety, depression, impaired concentration, and arthralgias.^{1,3} While not officially linked to changes in estrogen levels, these symptoms still impact the patient due to the effect on quality of life.

Diagnosis

A diagnosis of menopause occurs after a woman reports twelve consecutive months of amenorrhea, even though symptoms often begin much earlier in the perimenopausal transition.¹ Most vasomotor symptoms correspond with a rapid decline in estrogen levels rather than a low concentration within the body. While commonly measured, levels of follicle stimulating hormone vary significantly among women both before and during the menopause transition making it an inconsistent diagnostic tool.³

Complaints of vaginal dryness, dyspareunia, itching, discharge, and pain provide the primary diagnostic tool for vaginal atrophy.⁵

Vasomotor Symptoms

Treatment for menopause-related vasomotor symptoms depends upon the severity.^{1,4} For most women experiencing mild vasomotor symptoms the recommended treatment consists of lifestyle modifications. Most women with moderate to severe vasomotor symptoms require pharmacologic therapy in addition to lifestyle modifications to receive adequate symptom relief. It is important to note that even though pharmacologic therapy helps control vasomotor symptoms there is no cure. Most women will still experience some symptoms though hopefully milder with less interference in daily life.

Lifestyle Modifications

All women should incorporate lifestyle modifications regardless of the severity of their symptoms.^{1,4,6} Lifestyle modifications manage mild symptoms in many women and provide adjunctive treatment for those with more moderate to severe symptoms. Methods to help maintain a normal body temperature include using fans, dressing in layers, consuming cold food or drinks, and lowering the room temperature. Smoking cessation and reducing alcohol intake may help by removing two potential hot flash triggers. Although not clinically proven to reduce symptoms, exercise, weight loss, and relaxation techniques may aid in the reduction of symptoms and promotion of general wellness.

Nonprescription Treatment

If lifestyle modifications provide inadequate symptom relief, the North American Menopause Society states that a trial of nonprescription agents such as an isoflavone and black cohosh are reasonable.¹ Phytoestrogens, which includes isoflavones, appear to have both agonistic and antagonistic activities on the estrogen receptors. Many believe the efficacy comes from the conversion of an isoflavones to equol which shows estrogenic properties. Even though isoflavones exhibit minimal efficacy in most women, their safety profile, particularly when

obtained from soy food, makes them an acceptable add-on therapy to lifestyle modifications. However, clinical data does not support long term use at this time. Due to the estrogenic activity, isoflavones are contraindicated include women with high risk or a history of breast cancer.

Another supplement tried by many women for symptom relief is black cohosh. Similar to isoflavones, black cohosh may have estrogenic activities however the exact mechanism of action is unknown.¹ A randomized trial published in 2009 looked at the efficacy of black cohosh when compared to placebo.⁷ The trial showed a nonsignificant reduction in symptoms, but did show the safety of black cohosh administered daily over the course of 12 months. For women with mild symptoms or those with moderate to severe symptoms that do not desire to use prescription hormonal agents black cohosh could be tried. Similar to isoflavones, black cohosh contraindications include women at high risk or with a history of breast cancer due to the possible estrogenic activity.¹ Other concerns with black cohosh include liver disorders, endometriosis, aspirin allergy, and a history of uterine cancer.¹²

Systemic Hormone Therapy - Estrogens

For women with moderate to severe vasomotor symptoms, estrogen therapy consistently shows efficacy for symptom reduction and remains the preferred treatment option.^{1,4,6} Therapy should begin at low doses and be increased as necessary to reach the lowest effective dose. For some women, full symptom relief takes as long as four weeks of treatment. All estrogen products, whether oral or transdermal, equally reduce symptoms and therefore the choice of an agent depends upon cost, patient preference, and adverse effects. The most common adverse effects associated with estrogen therapy include breast tenderness, uterine bleeding, nausea, bloating, headache, edema, and dizziness. Maintaining patients on lower doses minimizes many of these adverse effects.

Although considered to be the most effective treat-

Table 1 includes each of these contraindications and risks. Risks such as breast cancer and coronary artery disease increase when women use hormone therapy for longer than five years or begin hormone therapy years after the onset of menopausal symptoms. Women at risk of hypertriglyceridemia, hypertension, thromboembolic disease, and gall stones may benefit from using a transdermal product as these have a lower risk of exacerbating these conditions.

The duration of treatment for estrogen should be kept to the lowest effective dose for the shortest duration of time.^{1,4,6} Considering most hot flashes and vasomotor symptoms disappear on their own within five years, women should be re-evaluated at least annually to determine the necessity of treatment. While no consensus exists on the best way to discontinue therapy, an abrupt cessation leads to the return of vasomotor symptoms and tapering would likely be preferred.

Systemic Hormone Therapy – Progestins

Progestin therapy, when used alone, shows some evidence of efficacy to support its use in patients with vasomotor symptoms but does not appear to be as effective as estrogen.^{1,4,6} Women with an intact uterus must use progestin therapy in addition to estrogen therapy to prevent endometrial hyperplasia. For prevention of hyperplasia, a low dose progestin administered continuously or cyclically for ten to fourteen days each cycle provides adequate protection. Extended cycle dosing with ten to fourteen days every three months has been studied but not routinely recommended. Typical dosages include medroxyprogesterone acetate 2.5 mg, norethindrone 0.35 mg, and micronized progesterone 100-200 mg. Progesterone related adverse effect include withdrawal bleeding and dysphoria. Combination oral and transdermal products are available.

Systemic Hormone Therapy – Androgens

The Food and Drug Administration (FDA) approved only one combination estrogen and androgen product for the treatment of moderate to severe vasomo-

0.625-1.25 and 1.25-2.5 mg respectively. Androgens should only be used when a woman remains symptomatic despite adequate estrogen therapy. The adverse effects related to methyltestosterone - hirsutism, acne, alopecia, and voice deepening - limit its acceptability in many patients.

Alternative Pharmacologic Agents

For women with a contraindication to or desire not to use hormone therapy, other prescription agents are available.^{1,4,6} Low doses of antidepressants such as fluoxetine, venlafaxine, paroxetine, and desvenlafaxine showed some efficacy in relieving hot flashes.⁸ The exact mechanism relating to their benefits for use in hot flashes is unknown, but they appear to provide relief within one to two weeks which is quicker than most hormonal agents. Antidepressants also aid in treating comorbid anxiety or depression that often occurs during the menopausal transition. Table 2 provides the recommended dosages for some of the antidepressants studied and shown to have some benefit.

Recently the FDA approved the first antidepressant, paroxetine (Brisdelle®), for the treatment of moderate to severe vasomotor symptoms.⁹ The capsule contains 7.5 mg of paroxetine and is dosed once daily at bedtime. The mechanism of action is unknown, but in clinical trials this formulation lowered the frequency and severity of moderate to severe vasomotor symptoms at four and twelve weeks when compared to placebo. In one study the safety and efficacy continued for up to twenty-four weeks. All of the cautions and patient counseling associated with the use of paroxetine for psychiatric disorders apply.

Other agents such as clonidine and gabapentin are alternative options in certain patients, even though they have not shown consistent efficacy.^{1,4,6} Table 2 lists the recommended dosages and common adverse effects for these two agents. When discontinuing therapy, the dose should be gradually tapered over one to two weeks.

Vaginal Symptoms

For women with a primary complaint of vaginal symptoms including dryness, itching, irritation, and

dyspareunia the first line treatments include over the counter lubricants and moisturizers.⁵ If ineffective or if the woman experiences moderate to severe symptoms, the mainstay of treatment becomes topical estrogen therapy. Unlike vasomotor symptoms, vaginal symptoms do not diminish over time or resolve on their own therefore most women require maintenance therapy. Similar to oral estrogens, all forms of local estrogen therapy including creams, tablets, and rings equally reduce symptoms and the choice of an agent depends upon other patient specific factors. When given locally, minimal systemic effects occur even when given over longer periods, although creams may have a higher risk due to the ease of incorrect dosing. Also, at low local doses, women do not need to routinely use a progestin as the risk of endometrial hyperplasia is low. Unlike systemic therapy for vasomotor symptoms, symptom relief with topical therapy may take as long as six weeks.

Dosing of topical estrogen creams, Premarin® and Estrace®, consists of a loading dose of 2-4 grams per day given for two weeks followed by a maintenance dose of 0.5-2g given one to three times a week.⁵ As with oral estrogen, the dose should be titrated to the lowest effective for symptom relief. An alternative dosage regimen includes a cyclic regimen of three weeks on and one week off. The vaginal estradiol tablet requires daily insertion for two weeks followed by a twice weekly maintenance dose. One estradiol ring provides local therapy and remains in place for ninety days after insertion. Low dose estrogen therapy continues as long as the patient experiences discomfort from the symptoms, however safety data beyond twelve months is lacking. Common adverse effects include vaginal bleeding and breast pain/tenderness depending upon the amount of estrogen absorbed.

Recently the FDA approved a new selective estrogen receptor modulator, ospemifene (Osphena®), for the treatment of moderate to severe dyspareunia due to

ospemifene is the first approved nonhormonal prescription agent for moderate to severe dyspareunia. The medication appears to have agonistic effects on the estrogen receptors in the vagina while maintaining antagonistic effects in other tissues. The labeled dosage is 60 mg taken once daily with a meal. In the trials the common adverse effects included hot flashes, sweating, and vaginal discharge. The labeling includes all of the risks associated with systemic estrogen therapy such as thromboembolism and stroke. Ospemifene also has agonist activities on the endometrium requiring coadministration of a progestin. Considering the side effects include inducing most of the vasomotor symptoms associated with menopause without lessening any of the risks of systemic estrogen therapy, the use of this medication will likely be limited to women with only severe vaginal complaints.

Conclusion

Vasomotor and vaginal symptoms associated with menopause impact a woman's quality of life, work performance, and use of healthcare resources. Even though many women manage vasomotor symptoms with lifestyle modifications or nonprescription agents, prescription hormone therapy remains the preferred treatment option for those with moderate to severe symptoms. When women complain of primarily vaginal dryness and irritation, adequate first line treatments include moisturizers and lubricants followed by topical estrogen therapy. While no therapy eliminates the symptoms associated with menopause, adequate treatment reduces their effect and eases the menopausal transition.

Table 1. Contraindications and Risks Associated with Systemic Estrogen Therapy

Contraindications	Risks
<p>Absolute</p> <ul style="list-style-type: none"> - Current or history of breast cancer - Undiagnosed vaginal bleeding - Coronary heart disease - Thromboembolism - Stroke or TIA - Active liver disease <p>Relative</p> <ul style="list-style-type: none"> Uterine leiomyoma Migraines Seizure disorders Hypertriglyceridemia* Liver disease* Gallbladder disease* 	<ul style="list-style-type: none"> - Venous thromboembolism - Breast or ovarian cancer - Stroke - Coronary artery disease - Gallbladder disease - Endometrial cancer (unopposed estrogen with an intact uterus)

*transdermal estrogen may be acceptable in these patients. Data from references 1,4,6,11

Table 2 Selected Dosages for Nonprescription, Systemic Estrogen, and Topical Estrogen Therapy

	Dosing Range	Common Adverse Effects	
Nonprescription			
Isoflavones: Soy and Red Clover	40-80 mg daily	Nausea, vomiting, and dizziness	
Black Cohosh	20-80 mg daily		
Oral Estrogen			
Conjugated equine estrogens (Premarin®)	0.3-1.25 mg daily	Breast tenderness, uterine bleeding, nausea, bloating, headache, edema, and dizziness	
Synthetic conjugated estrogen (Cenestin®, Enjuvia®)	0.3-1.25 mg daily		
Estradiol (Estrace®)	0.5-2 mg daily		
Estropipate (Ortho-Est®)	0.75-6 mg daily		
Esterified estrogen (Menest®)	1.25 mg daily		
Transdermal			
Estradiol patch (Alora®, Climara®, Minivelle®, Menostar®, Vivelle-Dot®)	0.025 – 0.1 mg Once weekly: Climara®, Menostar® Twice weekly: Alora®, Minivelle®, Vivelle-Dot®		
Estradiol gel (Divigel®, EstroGel®)	Divigel®: 0.25 g (estradiol 1 mg) daily EstroGel®: 1.25g daily (0.75 mg estradiol)		
Estradiol emulsion (Estrasorb®)	3.48 g daily		
Estradiol spray (Evamist®)	1.53-4.59 mg daily		
Estradiol ring (Femring)	0.05-0.1 mg released per 24h - inserted every 90 days		
Alternative Prescription			
Venlafaxine (Effexor®)	37.5-75 mg	Nausea, vomiting, dry mouth	
Desvenlafaxine (Pristiq®)	100 mg	Nausea, dizziness, constipation, dry mouth	
Paroxetine (Paxil®, Brisdelle®)	Paxil: 10-20 mg Brisdelle: 7.5 mg at bedtime	Drowsiness and dry mouth	
Fluoxetine (Prozac®)	20 mg	Insomnia, headache, nervousness, and nausea	
Clonidine (Catapres®)	0.05-0.15 mg twice daily	Dry mouth, drowsiness, dizziness, sedation	
Gabapentin (Neurontin®)	300 mg three times daily	Dizziness and lightheadedness	

Intravaginal Estrogen		
Conjugated equine estrogens (Premarin®)	0.5-2g for 21 days on and 7 days off OR 0.5g daily for two weeks followed by 0.5g intravaginally twice weekly	Vaginal bleeding and breast pain/tenderness
Estradiol cream (Estrace®)	2-4 g daily for 1-2 weeks followed by a gradual reduction to a maintenance of 1 g 1-3 times per week	
Estradiol ring (Estring®)	2 mg estradiol per ring and inserted every 90 days	
Estradiol tablet (Vagifem®)	10 mcg daily for 2 weeks followed by 10 mcg twice weekly	

Data adapted from references 4,5,8,9,10,11,12

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**“Women’s Health - Therapeutic Options for Alleviating Symptoms of Menopause ”
Continuing Education Learning Assessment - Test**

1. Which is often the first and most bothersome symptom of menopause?
A. Vaginal itching B. Depression C. Insomnia D. Hot flashes
2. The level of estrogen in the body determines the severity of a woman’s symptoms. A. True B. False
3. Over the counter systemic therapies are safe and effective for severe vasomotor symptoms. A. True B. False
4. A woman comes into your pharmacy and states she is experiencing hot flashes every two hours during the day and severe insomnia due to night sweats. Provided she had no contraindications, she would be a candidate for systemic hormone therapy. A. True B. False
5. Which of the following would be an appropriate starting dose for the corresponding transdermal estrogen product?
A. Alora® 0.05 mg applied weekly C. Climara® 0.025 mg applied weekly
B. Vivelle® 0.0375 mg applied weekly D. Estraderm® 0.05 mg applied weekly
6. Which would be an appropriate lifestyle modification to suggest to a woman with mild vasomotor symptoms.
A. Dressing in layers C. Avoiding warm foods and beverages
B. Lowering the temperature of the room D. All are correct
7. Which of the following antidepressants is FDA approved for the treatment of moderate to severe vasomotor symptoms.
A. Venlafaxine B. Paroxetine C. Desvenlafaxine D. Fluoxetine
8. All women using local hormone therapy for vaginal symptoms require a progestin to prevent endometrial hyperplasia.
A. True B. False
9. Ospheña® is recommended for use in women with mild symptoms of dyspareunia. A. True B. False
10. At a minimum, how often should a woman’s symptoms be reevaluated to determine if systemic hormone therapy is still necessary?
A. Every 6 months B. Every 12 months C. Every 18 months D. Every 24 months
11. A woman who recently transitioned into menopause comes in to your pharmacy stating that she is having some mild discomfort when being intimate with her husband. She has no significant medical history and is currently treating her hot flashes with lifestyle modifications. What would you recommend for this patient?
A. Over the counter vaginal moisturizers and lubricants used as needed
B. Premarin® vaginal cream 0.5g daily for 2 weeks followed by 0.5g twice weekly
C. Esting® 2 mg vaginal ring inserted every 90 days
D. Vagifem® tablet 10 mcg daily for 2 weeks followed by 10 mcg twice weekly
12. Which of the following is NOT an absolute contraindication to systemic hormone therapy?
A. History of breast cancer C. Undiagnosed vaginal bleeding
B. Active liver disease D. Migraines

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IN MEMORIAM

Connie Gill



PEORIA – Constance S. “Connie” Gill, 76, of Peoria passed away at 11:36 a.m. Tuesday, December 24, 2013, at UnityPoint Health – Proctor. Connie was born on February 3, 1937, in Brookings, SD, to Joseph and Beatrice (Bogle) Serie. She married Stephen C. Gill on August 8, 1959 in Brookings, SD. He survives.

She is also survived by her daughter, Melissa (Mike Ennis) Gill of Peoria; two granddaughters, Briana Gill and Jessica Ennis; and one sister, Jo Anne (Charlie) Keyes of New Brighton, MN.

She was preceded in death by her parents; an older sister, Theresa

Zimmerman; a younger sister, Janet Serie; two infant daughters; and her daughter, Tia Gill.

Connie graduated from South Dakota State University, and then worked as a pharmacist in Rapid City, SD. She later worked at Greens Drug, Jack’s Pharmacy, Lovin Pharmacy, and Bogard Drugs in Peoria. She retired in 2002 from Zellar Mental Health Center, as a staff pharmacist.

She enjoyed cross-stitching, crossword puzzles, traveling, and singing in the choir. Connie was a member of St. Thomas Catholic Church, its Women’s Guild, and its choir. She was also a member of the WATCH program at St. Thomas and the Illinois Pharmacist Association.

Ron Park



Ron Park, age 84, died from brain cancer at his daughter’s home in Sioux Falls on December 29, 2013. Ronald Paul Park was born to Reuben and Esther Park at the family’s Dell Rapids area farmhouse during a blizzard on February 27, 1929. He was baptized and confirmed at Dell Rapids Lutheran Church, and graduated from Dell Rapids High School

in 1946. In 1950 he graduated from South Dakota State University having earned a degree in Pharmacy. Ron was united in marriage to Patricia Sue Olson on December 26, 1949. They began their married life in Sioux Falls where Ron worked for Dunning Drug. In 1952 Ron purchased Valley Drug in Valley Springs. The family returned to Sioux Falls in 1956 when Ron and Tom Mills formed a partnership and opened Mills Park Drug on east 10th street. They also operated two clinic pharmacies. The store became Ron Park Drug in 1974 and continued to serve its loyal customers for another twenty years. Ron was passionate about providing excellent service

and his customers and employees were a highly valued second family to him. When it was “retirement” time Ron sold his business to Lewis Drug and continued working for them at their East Gate location for another decade just so he could still see folks! Ron was active in initiating an Ostomy Club for the Sioux Falls area and he partnered with Al Pfeifle to create Unomed, the first unit dose pharmacy in Eastern South Dakota.

Ron was a sincere and unassuming man who loved helping others and spending time with his family — especially at the cabin on Lake Poinsett. Ron is survived by his wife Pat; daughters, Penny Sue (Leroy) Story of Sioux Falls; Lori Park-Smith (Will), of Willmar, MN; Juli (Mark) Kinzer of St. Paul, MN; his grandchildren, Jason (Kim) Gibson, Heather Park (Tim), Jason Story (Sarah), Jami Story (Shawn), Matthew, Harrison, and Parker Smith, Sofie and Jimmy Kinzer; and eight great grandchildren. He was preceded in death by his son, Dr. Terry Park; his siblings, Phyllis Gores, Lois Tursam and Roger Park; and his parents.

Gene K. Van Pelt

Gene Van Pelt died unexpectedly at Alegent Lakeside Hospital. He served in the U. S. Navy during World War II. Upon graduation from Bradley University in Peoria, Illinois, he began a 42-year career with McKesson Drug Co., holding several positions around the country, his longest tenure being in Rapid City, South Dakota. After retirement, with his strong work ethic he kept busy at Kohl’s

Pharmacy, Rosenblatt Stadium, Qwest Center and the Ralston Arena. He was preceded in death by his parents; 2 sisters, one brother and his son. He is survived by his wife, Audrey Van Pelt; daughters: Paula Buzzell (Myrle), Linda Carr (Michael), and Laura Peschong (Brad); 6 grandchildren; 9 great-grandchildren; nieces, nephews and sister-in-law.

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