Spring Edition 2012 Vol. 26 No. 2

South Dakota Pharmacist

In This Issue:

SOUTH DAKOTA
PHARMACIST

Volume 26 Number 2

SDPhA CALENDAR

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

South Dakota Board of Pharmacy
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(605)362-2737
www.pharmacy.sd.gov

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

8 Easter Sunday
10 Sioux Falls Spring District Meeting - 6:00 p.m.
Ramada Hotel & Suites, Sioux Falls
12 District Meeting - 6:30 p.m.
Minerva's, Watertown
26 Black Hills District Meeting - 6:30 p.m.
Minerva's, Rapid City

MAY

28 Memorial Day

JUNE

9-12 ASHP Summer Meeting, Baltimore, MD

JULY

4 Independence Day

AUGUST

1 License Renewal Window Opens

SEPTEMBER

21-22 SDPhA Annual Convention
Deadwood Gulch Resort, Deadwood, SD

Cover Photo Courtesy of South Dakota Department of Tourism

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.

SECOND QUARTER 2012
Volume 26
Number 2

CONTENTS

FEATURES

PHARMACY TOPICS

CONTINUING EDUCATION

ADVERTISERS

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DIRECTOR'S COMMENTS

Sue Schaefer | Executive Director

The Need for Speed

Wow – I believe this was the fastest Legislative Session on record! It started out a little somber and haltingly, with the unfortunate passing of former Governor Janklow. The Capitol was a sad place to be for those days when our former Commander-in-Chief lie in state. I was impressed by Governor Daugaard and his Administration's compassion and attention during a difficult time in our state's history. Soon after, however, it was important that everyone buckle down and attend to the State's business, which Bill Janklow would have respected.

Session quickly took on a fast and furious tempo. Things are still being finalized at this time, but with the State budget in much better shape, provider reimbursement may hold its own, rather than taking cuts, as we were forced to endure last year.

Pharmacy had a few bills this Session that were of significant importance…most of them brought forward by the Board of Pharmacy. Executive Director, Randy Jones, did an outstanding job of educating lawmakers about suggested changes to the Pharmacy laws. At the request of the Governor, each agency was instructed to review their laws and come up with antiquated and unnecessary laws to repeal. Randy worked hard to identify laws and rules affecting pharmacy, and his legislative efforts flew through the House and Senate and have already been signed by the Governor. Another bill required pharmacists to complete background checks. That bill also passed the Legislature in a speedy manner and has been signed by the Governor. (For more information on SDPhA's Legislative efforts, see Bob Riter's column located within this edition of the Journal.) Kudos to Randy for a job well done. We know it isn't always that easy!

Student Pharmacists – Gotta Love 'Em!

The Capitol was buzzing this year with a wonderful group of SDSU's College of Pharmacy students (and our pharmacists of course). The students provided excellent health screenings for lawmakers, lobbyists and good folks in general who happened to be lucky that day to receive great care. I can't say enough about the quality of our young pharmacy gang. They're so passionate about the profession and take time out of their busy schedules to travel to Pierre to learn about the Legislative process and how it affects them. And it does … sometimes more directly than at other times.

I was disappointed that we didn't have a pharmacy bill up in Senate Health while they were here, but they've assured me they'll be back next year, and I anticipate it could be a busy Session for pharmacy. The event was capped off when the Governor joined the SDPhA Board, SDSU College of Pharmacy faculty and students for a photo op on the Capitol stairs.

WANTED – Pharmacists and Technicians of Dakota Territory!!

It seems strange not to be running full out with preparations for our annual convention, but with the move to a September date, we're taking our time to prepare for an outstanding event! You'll see we're almost all set with our educational lineup for the meeting, September 21-22, 2012. Sleeping rooms have been reserved at the Deadwood Grand Hotel, the Super 8 and the Deadwood Gulch Resort. Unfortunately, due to construction problems at the Grand, we've had to change our actual meeting venue to the Deadwood Gulch Convention Center up the street from the Grand. We will be, however, arranging shuttle transportation for those of you staying at the Grand. For those staying at the Gulch or Super 8, it's a nice short walk to the venue.

Please remember, our event has been shortened this year at your request, so we'll have a very full day on Friday and a half day on Saturday, finishing up at noon. Our Friday luncheon will include the award recognition event, and vendors will also join us at that time.

We're hoping you take advantage of the beautiful fall weather that Deadwood has to offer in September. Whether you enjoy leaf-peeping, gambling, riding motorcycles or biking on the Mickelson Trail, we know you'll really enjoy your time in the Hills. We're planning something EXTRA special for Friday evening's casual event, so stay tuned!

APHA Annual Meeting

At this writing, President Lenny Petrik, President-elect Else Umbreit and I will soon be departing for the APHA meeting (and NASPA) in New Orleans. Hope to provide some excellent feedback to all of you following the meeting. We also always look forward to hosting the College of Pharmacy Student Pharmacists for a get-together. It's become a "family tradition" … and we're all about family AND tradition.

Take care and enjoy a wonderful spring!

Sue

PRESIDENT'S PERSPECTIVE

Lenny Petrik, Pharm. D., | SDPhA President

Greetings Pharmacy Phriends!! I hope everyone has survived our extremely difficult winter! Can you believe I was only able to get out on my motorcycle 7 days in February?! We will see what March has to offer. I know we have certainly been busy in the Pharmacy filling prescriptions and recommending OTCs for a wide variety of "sickness".

Thank you to all the pharmacists, technicians, SDSU College of Pharmacy students and faculty that helped make the 2012 Legislative Days a big success! Sue Schaefer, Bob Riter, and Randy Jones did a great job Tuesday evening and the students did awesome with the health screenings at the Capitol on Wednesday morning.

By the time you read this, I will be back from the APhA meeting in New Orleans. I look forward to making new contacts and bringing home some beneficial information to South Dakota pharmacists. I also look forward to spending time with the SDSU students and faculty attending the conference. New Orleans has a very rich pharmacy history and it is a rather fun place to hang out. I will let you know if I was able to "score" any beads!!

Please notice the change to the SDPhA 2012 Convention location that Sue mentioned in her column. The Deadwood Gulch folks have been great to work with and I am very excited for a great Convention. The educational lineup is coming together and I look forward to seeing you ALL September 21-22, 2012.

Take care and please let us know if we can help in any way!

ACADEMY OF STUDENT PHARMACISTS

Jared Sogn | APhA-ASP SDSU Chapter President

Greetings from APhA-ASP! The spring semester has been busy, but our members have been staying involved both on and off campus! We have been lucky this year to have been blessed with good weather, allowing us to make our way to Pierre for Legislative Days. After missing the event last year due to bad weather, we were excited to get the opportunity to socialize with members of SDPhA and provide screenings at the capitol. We had over 40 students attend, and we were able to provide blood pressure, cholesterol and glucose screenings, as well as provide information about vaccinations and the growing problem of prescription drug abuse to our legislators.

Our members have also been very active in service projects this semester, reaching out to many causes! The service committee has been busy each month working with the Brookings Backpack Project, helping to provide children in need with food. In February, members got together to make baby blankets, which were then donated to the Brookings hospital to give to newborn babies. In the upcoming weeks, the service committee will be busy with several other projects, including the Children's Miracle Network State-A-Thon and Relay for Life.

This February, we held our second annual International Potluck in conjunction with the International Pharmaceutical Students' Federation. We had a great turnout, and students were able to enjoy dishes from all around the world. As students were enjoying the food, we held our annual fundraising auction, with Dr. Hansen auctioning off the items. We had several exciting items up for bid, including gift baskets, golf outings with Dr. Hansen and Dean Hedge, and investment sessions with Dr. Hendricks. In addition, we will be holding our Sioux Falls fundraising auction on April 10th following the SDPhA Sioux Falls district meeting at the Ramada Inn. We hope to see you there!

Our members have also been busy with other various projects. The Generation Rx committee is preparing to have a speaker give a presentation to students about the dangers of medication abuse. Also, the Health Systems Pharmacy committee has been busy coordinating a CV swap, as well as planning the upcoming residency showcase on April 16th. The P3 committee recently held a blood pressure and osteoporosis screening in Sioux Falls. Finally, members of the Tobacco Cessation committee have been busy planning and fundraising for the annual Tobacco Cessation Middle School Lock-in Night.

Finally, we are excited to have members heading to New Orleans for the APhA National Meeting. We have over 20 members that will be attending the meeting held March 9th-12th! Everyone is looking forward to the meeting and the chance to explore New Orleans! While at the meeting, the winner of our local patient counseling competition, Kelsey Aker, will compete in the national patient counseling competition. We wish her the best of luck!

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: David Hatzell; Brianne Allison; and Nicholas Vogel.

NEW PHARMACIES

Pharmacy licenses have been issued recently to: SD Human Services Center Pharmacy-Star located in Custer; Jeffrey Herron – Pharmacist in Charge.

INFORMATION REGARDING CARISOPRODOL PRESCRIPTIONS

As most of you are aware, in December the DEA published a final rule in the Federal Register making carisoprodol a schedule IV controlled substance. The final rule became effective on January 11, 2012. Accordingly a pharmacy may only fill or refill a carisoprodol prescription if all of the following requirements are met. 1) The prescription was issued for a legitimate medical purpose and by a DEA registered practitioner. 2) The prescription contains all the information required by 21 CFR 1306.05, and 3) the number of refills authorized by the practitioner is 5 or less and dispensing does not occur after six months from the date the prescription was written. More information can be viewed on the DEA website at www.deadiversion.usdoj.gov

The Drug Enforcement Administration (DEA) has also scheduled another National Prescription Drug Take-Back Day which will take place on Saturday, April 28, 2012, 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. Locations will be available on the DEA website listed above in March.

LEGISLATIVE INFORMATION

The Governor's office contacted all agencies with instructions to review our laws and rules with the thought of repealing any laws and rules that may be outdated. This was entitled the Red Tape Repeal Initiative. Our Board and staff, in conjunction with many of our pharmacy constituents, decided two of the permits we currently issue are no longer relevant and also difficult to enforce. House Bill 1009 proposed the repeal of the Poison Permits as well as the Non-Prescription Drug Permit. Most, if not all of the chemicals listed in our poison laws are no longer issued commercially and the pesticides and insecticides are regulated by the Department of Agriculture. Non-Prescription Drug Permit is difficult to enforce. Convenience Stores are popping up all over the state, many of which are out of compliance with the regulation and are not required to obtain this permit for wholesalers to ship the store over the counter medications. As of this article, HB 1009 has passed the House and is on the Senate Floor.

Senate Bill 24, which was reported Winter Edition of the Journal, requires mandatory background checks for initial pharmacist registration. It can also be required for those licensees under disciplinary investigation. This legislation has passed both the House and Senate and will become completely effective July 1, 2012.

Legislative Days in Pierre was an extremely enjoyable event. Some of us old timers had an opportunity after the barbecue to have an informal conversation with the SDSU students about many various topics. The interaction was very positive and I would encourage all of you to attend next year and converse with our "younger" generation. They are the voice of our future in pharmacy and life in general.

PHARMACY TECHNICIAN REMINDER

A friendly reminder that any pharmacy technicians in your employment that registered with the Board of Pharmacy after July 1, 2011 have until July 1, 2014 to become Nationally Certified by one of the accrediting agencies. Employees that begin employment after July 1, 2014 will be registered with the Board as technicians-in-training for a maximum of 2 years at such time will need to provide board approved education prior to setting for one of the nationally accredited exams.

PRESCRIPTION DRUG MONITORING PROGRAM (PDMP) UPDATE

As most of you know, South Dakota has implemented a prescription drug monitoring program (PDMP) designed to track the dispensing of controlled drugs. South Dakota is now one of 43 states using PDMP in an effort to reduce the diversion and improper use of these drugs while ensuring their availability for legitimate use. Prescribers and pharmacists are able to use the patient information in the system in a variety of ways including detecting substance abuse problems, supplementing the patient's evaluation, confirming the patient's drug history, and documenting the patient's adherence to medication therapy.

The SDPDMP database includes all retail and outpatient dispensing records, except emergency room-dispensed quantities

SOUTH DAKOTA BOARD OF PHARMACY

(continued)

for 48 hours or less. In addition to drugs dispensed by South a Dakota pharmacies, it also included drugs dispensed to South Dakota residents by nonresident pharmacies. If a prescriber or pharmacist has a concern about a patient, he or she can look up the patient's history in the SDPDMP. The database will show the controlled drugs the patient has received within the specified time period, the prescriber's name and where the drugs were dispensed. Information will be available in seconds. Prescribers and pharmacists must register with SDPDMP and request access in order to utilize the online service.

Pharmacists are encouraged to use information from the SD PDMP database to assist them in making well informed decisions when dispensing controlled drug prescriptions to patients. You may register for online access by going to www.hidinc.com/sdpmp. Please call the Board office if you have any questions about this very important program.

BOARD MEETING DATES

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

BOARD OF PHARMACY STAFF DIRECTORY

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Jill Vanderbush, Sr. Secretary ..... jill.vanderbush@state.sd.us
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Board of Pharmacy Website..... www.pharmacy.sd.gov

Please read all Newsletters and keep them for future reference. The Newsletters will be used in hearings as proof of notification. Please contact the Board office at 605-362-2737 if you have questions about any article in the Newsletter. Past Newsletters are also available on the Board's website.

SD ASSOCIATION OF PHARMACY TECHNICIANS

Twila Vavra | President

Greetings from SDAPT. What a wonderful winter we have had. It seems like spring is right around the corner. On behalf of the SDAPT, I would like to invite all the Pharmacy Technicians to go to our website (www.sdapt.org) and check out what the association has to offer you for joining the SDAPT. If there is a technician you know of who hasn't joined or renewed their SDAPT membership, I would encourage them to do so. The cost is only $35.00 and the benefits of membership include reduced registration fees for the SDPhA convention, a subscription to the SD Pharmacist journal, and free registration for our SDAPT Annual Fall Business/CE meeting. At the SDAPT meeting, members also receive a meal and four to five hours of continuing education without charge. To join or renew your membership, you may go to the website and get a printable membership form. Fill it out and send it to Diane Feiner.

The SDPhA Convention will be held September 21-22, 2012. Our SDAPT annual Fall Business/CE meeting is scheduled for October 6, 2012 at the CUC Building in Pierre. Generally, after the pharmacists convention, we have four months to plan our Fall Business/CE meeting. Without an early planning meeting we are now looking for your suggestions and comments on CE topics and events. Please contact any of the board members at our email addresses at the end of this article.

In conclusion, I encourage all technicians to register for the SDSHP Conference and the SDPhA convention. These conventions offer excellent continuing education hours along with the opportunity to meet and network with others in the Pharmacy profession.

Take care and I hope to see you at our Fall meeting and conventions!

Contact Information:

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Melanie Angelos, Secretary..... moniejo@msn.com
Diane Feiner, Treasurer ..... dianefeiner@sanfordhealth.org

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.

As previously mentioned in this column, the College of Pharmacy moved to a "rolling admission" process this year for the Pharm.D. program. We were very pleased with the process and believe it was beneficial for both students and the College. Our intent is to continuing with "rolling admission" this next year with only minor modification. The College received 231 applications for the 80 seats in the Pharm. D. class, and the quality of the applicant pool remained strong.

In the area of curriculum development, the College is incorporating several interprofessional educational activities. These activities involve students from several health science programs at SDSU and USD. Additional curriculum development initiatives are in the areas of team-based learning and incorporation of technology into teaching.

The College's Ph.D. in Pharmaceutical Sciences program and research enterprise continues to grow at an impressive rate. Enrollment in the Ph.D. in Pharmaceutical Sciences program is at 20 students and research grant expenditures reached an all-time high in FY 11 at $1,490,156. Significant points of pride in this area include the licensing of several items of intellectual property, multiple research collaborations with universities, health-systems, and industry, and great progress via the Translational Research Center for Oncology Research.

The interview process to select the first resident for the community pharmacy residency program at Liebe Drug in Milbank, South Dakota has been completed. The one-year program will begin in July. In addition to practice-based activities at Liebe Drug, the resident will provide instruction to pharmacy students at SDSU in the area of community pharmacy practice.

I would also like to thank those of you that accepted our call during the annual phonathon to raise funds in support of our students and faculty. Fundraising efforts for the College continue to go quite well and we are most appreciative of the loyal support of our alumni and stakeholders. Of note, in recognition of a transformational gift to the College from Mr. Bruce Laughrey, the lecture halls of the Avera Health and Science Center will be formally named "The Laughrey Lecture Halls" at a special dedication ceremony on April 26th.

Finally, the College was very well represented during the SDSU Celebration of Faculty Excellence Awards Banquet. Dr. Chandradhar Dwivedi, Head of the Department of Pharmaceutical Sciences, received the Dr. Harold and Barbara Bailey Award for Excellence in Academic Department Leadership. In addition, Dr. Omathanu Perumal received the F.O. Butler Award for Excellence in Research and Dr. Jane Mort received the College of Pharmacy Distinguished Scholar Award that evening.

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

SD SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Erin Christensen, Pharm. D., BCPS | SDSHP Past-President

Greetings from SDSHP. By the time you receive this journal, we will have held our 36th Annual Conference on March 30th and 31st. At the business meeting, new board members were inducted and include: John Kappes, President; Kelley Oehlke, President-Elect; Erin Christensen, Past-President; Katie Bremmon, Treasurer; Tadd Hellwig, Board Member At-Large; and Kirre Wold, Student Representative. Those continuing to serve are: Gary Van Riper, Secretary; Deb Cummings, Technician Board Member; Katie Hayes, Board Member At-Large; and Kaitlyn Jude, Student Representative. I would like to thank our outgoing board members: Jan Opperman, Past President; Steffanie Danley, Treasurer; DeAnna Visser, Board Member At-Large; and Andrea New, Student Representative. These people have dedicated the past few years to serving our Society, and for that I thank them. I would also like to recognize Marilyn Eighmy, our Support Specialist, for her tireless support to the Society. Also at the business meeting on March 31st, we recognized Kelley Oehlke as Pharmacist of the Year and Amanda Pfeif as Technician of the Year. A new addition to the program this year was the presentation of the Gary W. Karel Lecture Award. This was presented to our first recipient and namesake of the award, Gary Karel. This award is in honor of his lifetime of dedication to leadership and the profession of pharmacy in South Dakota. This award shall be known as the highest lifetime achievement honor in South Dakota health-system pharmacy practice.

On February 4, we held a continuing education event at the Student Union on the SDSU campus, which was co-sponsored with SDPhA and the SDSU COP. The PGY-1 residents from Sanford and Avera McKennan presented on COPD, MRSA Guidelines and pain management. This was a well attended event, with 41 pharmacists, 7 student pharmacists and 11 technicians attending. Many also watched the SDSU men's and women's basketball teams roll over Southern Utah that evening.

In May, Mark Burgraff and I will be attending the ASHP Regional Delegate Conference (RDC). Multiple sessions are held in different locations throughout the country to allow all delegates to attend. The purpose of the RDC is to prepare the delegates for the House of Delegates at the ASHP Summer Meeting in June. The ASHP House of Delegates is the ultimate authority over ASHP professional policies. Please see the ASHP website (www.ashp.org) if you are interested in learning more.

Here are some upcoming events:
ASHP Summer Meeting June 9-12 in Baltimore, MD
ASHP Midyear Clinical Meeting December 2-6 in Las Vegas, NV
SDSHP Annual Conference April 12-13, 2013 in Rapid City, SD

Think Spring!

WANTED! Your attendance is requested at the SDPhA Annual Convention September 21-22 in Deadwood! (See Registration Form on Page 11)

Lodging Options Available:

Deadwood Mountain Grand – rates $114 (wkday) $144 (wknd)
1906 Deadwood Mountain Drive, Deadwood, SD 57732
Phone: 605-559-0386 Fax: 605-559-0446
Email: reservations@deadwoodmountaingrand.com

Deadwood Gulch Resort – rates $89/night
(Meeting venue located here!)
304 Cliff Street/85 South, Deadwood, SD 57732
1-800-695-1876 or 1-605-578-1294
Email: dgr@deadwoodgulch.com

Super 8 Motel – rates $85.39 - $139.39 (depending on room)
(Adjacent to our convention venue, the Deadwood Gulch Convention Center)
196 Cliff Street, Deadwood, SD 57732
(605)578-2535 or (800)800-8000
Email: super8@deadwood.net

Don't forget to mention you're with the SDPhA, or you will not receive the group rate mentioned here!

126th Annual South Dakota Pharmacists Association Convention

Deadwood Gulch Resort Deadwood, SD
September 21-22, 2012

Line-up (Tentative)

Friday, September 21

8:00 a.m. – 9:30 a.m.	Pharmacy Law Update Presented by Dr. Dave Helgeland
9:30 a.m. – 10:30 a.m.	Optimizing Medication Therapy for Seniors Presented by Lynn Greff, RPh
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. - 3:30 p.m.	Pharmacy Jeopardy (Preceptor Training) Presented by Dr. Teresa Seefeldt/SDSU Students
3:30 p.m. – 3:30 p.m.	SDSU Ice Cream Social
3:30 p.m. – 5:00 p.m.	New Drug Update Presented by Dr. Joe Strain
6:00 p.m. – 8:00 p.m.	Deadwood Gold Rush Reception/Social

Saturday, September 22

6:30 a.m. – 7:30 a.m.	Phun Run Whitewood Creek Walking Trail
8:00 a.m. – 9:00 a.m.	Breakfast/Second Business Meeting
9:00 a.m. – 10:30 a.m.	Pain Management Presenter TBA
10:40 a.m. – 12:40 p.m.	Immunization Discussion Presented by Dr. Kelley Oehlke and Randy Jones

South Dakota Pharmacists Association 126th Annual Convention

WANTED!

September 21-22, 2012
Deadwood Gulch Resort
Deadwood, SD

126th Annual South Dakota Pharmacists Association Convention

Registration Form

Deadwood Gulch Resort Deadwood, SD - September 21-22, 2012

All SDSU Student Registrations are FREE!
(Hotel not Included)
Registrations must be submitted prior to Aug. 21, 2012

Name:_____
Address:_____
City:_____State:____Zip_____
Business Name:_____
Business Address:_____
City:_____State:____Zip_____
Business Phone:_____
Home Phone:_____
Email Address:_____
Spouse/Guest Name:
_____

	SDPhA Member	Spouse or Guest	Children	SDAPT Member	Pharmacy Technician	Pharmacy Student	Non SDPhA Member	
Full Registration*								
Before August 21, 2012	$150	$90	$20	$90	$150	Free	$225	____
After August 21, 2012	$175	$110	$25	$110	$175	Free	$250	____
One Day Registration**								
Fri., Sept. 21, 2012	$100	$50	$10	$50	$90	Free	$150	____
Sat., Sept. 22, 2012	$50	$65	$10	$50	$50	Free	$75	____
Extra Tickets								
Fri. Lunch	$15	$15	$10	$15	$15	Free	$15	____
Fri. Supper	$15	$15	$10	$15	$15	Free	$15	____
Sat. Breakfast	$15	$15	$10	$15	$15	Free	$15	____

I would like 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#: 46-0191834

I will be participating in the phun run on Saturday Yes___ No____

FOR HOTEL RESERVATIONS CALL:

Deadwood Gulch Resort
304 Cliff Street/85 South (605) 578-1294
Deadwood Mountain Grand
1906 Deadwood Mountain Drive (605) 559-0385
Super 8 Motel
196 Cliff Street (605) 578-2535

CANCELLATION POLICY:

Cancellations will be accepted without penalty prior to September 3, 2012.
A $25 cancellation fee will be applied to all cancellations after September 3, 2012.
Refunds will be issued after October 1, 2012.

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

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

2012 LEGISLATIVE REPORT

Robert C. Riter | SDPhA Lobbyist

The 2012 legislative session was filled with much discussion regarding the amount and nature of funding for education. Fortunately, the state's revenues have improved so they were able to discuss spending limited additional monies in chosen areas.

While the legislature did appropriate additional monies for education, they devoted few additional revenues to the Medicaid system. What limited additional monies they did allocate went only to the entities who have a heavy percent of Medicaid eligible clientele.

Medicaid reimbursement for pharmacists increased by .5 of 1% of the allocation made last year. As you will recall, the allocation last year decreased monies to pharmacists by 3.8% over the prior year. Hence, while there was a small increase, the total allocated for Medicaid reimbursement is still below what it was two years ago. We will obviously continue to be actively involved in discussions to increase Medicaid funding in future years.

In **SB 41** the legislature modified the law to allow retailers to choose whether to submit pseudoephedrine purchase records electronically or in writing. Hopefully this will lessen the reporting burden on retailers. In **SB 24** the legislature included pharmacists among other healthcare professionals for a criminal background investigation upon application for licensure or during a disciplinary investigation. This brings your profession into the same license requirements as doctors, nurses, optometrists and dentists. Both of these measures were supported by the Association, and are effective July 1, 2012.

The Association was opposed to **HB 1175**, which would have provided additional exemptions allowing a parent to refuse immunization of his or her child, as well as **HB 1256**, which would have given additional authority. Both of these bills were defeated by the first committee considering them.

SB 23 included additional substances on the controlled substances list effective July 1, 2012. Additions included this year were synthetic cannabinoid, mephedrone, methylone, MDPV, Clobazam, Carisoprodol and Ezogabine.

HB 1193 proposed to regulate the sale of a substance containing dextromethorphan to persons under the age of 18 in an over the counter sale without a prescription. The prime sponsor of the bill worked with the Association prior to introduction and attempted to respond to many of our concerns. Despite his efforts, the bill ultimately was defeated on the floor of the House of Representatives.

HB 1009 removes the requirement that an entity selling a non-prescription drug has to be licensed and repeals the Board of Pharmacy's authority over certain entities selling non-prescription drugs. The bill also repeals outdated regulations regarding the sale of poisons. It passed and will be effective July 1, 2012.

The legislature did consider certain healthcare issues. In **HB 1232** it repealed the South Dakota Commission on Healthcare. That group had been previously appointed to consider healthcare issues and identify priorities for healthcare, including financing, delivery and programming. The legislature also passed **HB 1187**, which exempts a healthcare sharing ministry from the health insurance code. It allows groups to band together on a faith-based foundation to share healthcare costs, without being considered as an insurance entity subject to regulation.

While there were a number of other bills involving healthcare professionals, the bills which appear to be of particular interest to you are as expressed above.

We appreciated the opportunity to work with you again during the 2012 legislative session. We particularly appreciate the timely and energetic efforts of your executive, Sue Schaefer, as well as the active involvement of your Board of Directors. The attention given by the legislature to the issues affecting your profession confirm the impact of your effort.

Thank you.

SDPhA LEGISLATIVE DAYS 2012

January 31 & February 1 • Pierre, SD

New Law Allowing Retailers to Submit Pseudoephedrine Records Electronically or in Writing

Senate Bill 41, introduced in the 2012 Legislative Session by Attorney General Marty Jackley, was recently signed by Governor Daugaard and will take effect July 1st, 2012. This particular law will allow retail pharmacists who sell pseudoephedrine to submit monthly logs to the Division of Criminal Investigation by written ***or electronic means***. Senate Bill 41 simply modified current state statute (SDCL 34-20D passed in 2006) providing an option to submit monthly logs in an electronic format. State statute still requires that retail pharmacists, prior to selling a pseudoephedrine product, must make a record of the identification of the individual making a purchase. This record should, at a minimum, capture the date of the sale, name of individual, date of birth, product type and number of packages purchased.

The Division of Criminal Investigation (DCI) is eager to work with retail pharmacists who are interested in submitting pseudoephedrine records electronically. I believe retail pharmacists who choose to submit monthly pseudoephedrine records electronically will reduce the cumbersome burden of handling and shipping these written documents. Having the data in an electronic format will greatly improve law enforcement's ability to increase the proficiency of identifying those individuals or groups of individuals who may be intending to use pseudoephedrine or ephedrine products to manufacture methamphetamine (meth). If you are interested in submitting your pharmacy's monthly pseudoephedrine logs by such means as an Excel spreadsheet, please contact me at your convenience to discuss this option.

> "Having the data in an electronic format will greatly improve law enforcement's ability to increase the proficiency of identifying those individuals or groups of individuals who may be intending to use pseudoephedrine or ephedrine products to manufacture methamphetamine (meth)."
>
> *Brian Zeeb, Division of Criminal Investigation*

Unfortunately, methamphetamine abuse, manufacturing, and related crime continues to prove challenging in South Dakota. Individuals who are responsible for manufacturing meth are able to produce the drug with minimal equipment or knowledge. One of the major components necessary to produce meth is pseudoephedrine, often found in over-the-counter cold medicines. Education and awareness by the public, retailers, and Law Enforcement over the last few years has reduced arrests and meth lab incidents, but those numbers are on the rise. In 2004 & 2005, meth arrests in South Dakota were over 700, with a steep decline starting in 2006, culminating with a low of 162 arrests in 2008. Recently, meth arrests in South Dakota have risen to 443 in 2010, and 402 in 2011. In 2004, South Dakota had 33 lab incidents with a low of six in 2008. Meth lab incidents, similar to arrests, are on the rise with 21 incidents in the last two years.

Many states across the country, including several neighboring states, have moved to a real time electronic point of sale system providing "instant sale" or "no sale" feedback to the retailer, called Meth Check/NPLEx. South Dakota has not yet adopted this cost effective option, but hopes to do so in the future. This real time access to pharmacy logbooks from across the nation can also be utilized by law enforcement, eliminating written purchase logs. This system is provided by a company called Appriss and is currently available to your pharmacy for a monthly fee. Please contact me if you are interested or have questions about submitting your pseudoephedrine sales data by utilizing this option. This type of technology can reduce an activity known as "smurfing". In relation to meth, smurfing is a term used to describe a person or group of people who go from one store to another in order to gain enough pseudoephedrine to make meth. South Dakota laws were passed in 2006 to prohibit people from buying large quantities of pseudoephedrine at one time. Individuals who manufacture meth practice smurfing from one store to another buying just under the two package legal limit at each location until they have enough pseudoephedrine to make meth.

It is my intention to keep pseudo products available for all individuals who need it for legitimate health reasons, while at the same time making it easier for pharmacists and law enforcement to share this important information. With the passage of Senate Bill 41, adjusting the current law now provides retailers with the option to streamline their current practices and enhance the value of this data by law enforcement. Again, please feel free to contact me at your convenience to discuss current options.

Thank You.

Brian Zeeb
Assistant Director
Division of Criminal Investigation
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605-773-3331

South Dakota Foundation for Medical Care

Care Transitions: Focus and the Pharmacy Role

Susan Johannsen, PA, and Jane R. Mort, Pharm. D.

South Dakota Foundation for Medical Care (SDFMC), in the 10th Statement of Work, has contracted with the Centers for Medicare & Medicaid Services (CMS) to help communities reduce preventable hospital readmissions. The quality of transitions of care (the process of patient transfers from one health care setting or practice to another) has been found to dramatically influence hospital readmissions.

Why are transitions important?

Approximately 17.6% of patients return to the hospital within 30 days of discharge, leading to Medicare expenditures of $15 billion. It is estimated that 76% of these readmissions may be preventable.[1] In addition, poor transitions of care may result in increased patient and caregiver stress, deterioration in health, problems in medication reconciliation, redundant diagnostic testing, and increased health care costs. Therefore, CMS has set a goal of reducing preventable readmissions by 20% in the next 3 years.

Where are the best opportunities for reducing readmissions?

Based on The Remington Report[2,] care transition intervention models suggest patient/caregiver training to improve self-management will have the greatest impact on readmissions. This training will need to focus on the patient/caregiver engagement, including improved health literacy, understanding elements of care including medication reconciliation, disease knowledge, and identification of change in patient status from the provider.

Secondly, medication reconciliation by the pharmacy specialist assures correct medication use and the increased likelihood of sustaining the patient in his environment. Patient/caregiver engagement related to medication use will be the cornerstone to success in any attempt at reducing readmissions.

The third opportunity for improvement is centered on the follow-up appointment to the primary care provider or specialist. Rapid detection of change in condition allows for decreased readmission risk by initiating necessary alteration in the original plan of care.

In all of these opportunities, communication between the sender and receiver is essential. Striving for improvement in this transfer of information and development of relationships, with the needs of the other in mind, will foster improved patient care.

How can South Dakota Communities impact these readmission concerns?

SDFMC will work to create communities focusing on the reduction of preventable readmissions. Each community will be comprised of those interested and invested in the care transition process, including pharmacists, physicians, skilled nursing facilities, home health providers, hospice services, and providers of other services to the Medicare beneficiary. By selecting interventions based on the root cause of readmissions specific to the community, the team will be able to institute a community specific plan to reduce readmissions. An integral part of this plan will be to include members of the community that have expertise in all key areas.

What is the role of the pharmacist on the community team?

The pharmacist serves as an expert in the identification of medication-related issues and the creation of solutions to these challenges. The pharmacist's close ties to the various health care providers and beneficiaries will guide the selection of interventions. Identification of models specific to those needs will help integrate the pharmacy specialist into the overall plan.

SDFMC's objective is to reduce readmissions following hospitalization by 20% over the next 3 years and to create sustainable and replicable strategies to achieve high-value health care for the sick and disabled Medicare beneficiaries.

SDFMC invites you to participate in the development of a community coalition. Your expertise and contributions are needed to reduce readmissions of beneficiaries, allowing them to stay in their home. ***Don't miss being part of the team!*** Contact Sue Johannsen at 605-336-3505 or sjohannsen@sdqio.sdps.org for more information.

1. Medical Payment Advisory Commission. June 2007 Report to the Congress: Promoting Greater Efficiency in Medicare. Available at: http://www.medpac.gov/documents/jun07_entirereport.pdf. Accessed February 8, 2012.
2. The Remington Report. Improving Care Transitions and Reducing Hospital Readmissions: Establishing the Evidence for Community-Based Implementation Strategies Through the Care Transitions Theme. January/February 2010, Vol. 18; 1:24, 26-30. Available at: http://remingtonreport.com. Accessed February 9, 2012.

Rx 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.

Recordkeeping isn't that important, is it?

Terry at Midtown Pharmacy was dealing with another recurring frustration. Their usual generic brand of atenolol was backordered again. Terry ordered in a couple of 100 count bottles to hold them over until their usual brand was available again. Terry didn't bother to update their computer database to reflect this change because she would then just have to change it back again 2 days from now. The change isn't really that important anyway, right?

Wrong. Your documentation is the only thing you will have later to prove what you did today. We all forget things, especially when they come up weeks or months later. Consider the following claim scenario.

A pharmacy was sued by a former patient over some faulty transdermal fentanyl patches. The patient alleged that he was injured due to the patch releasing the medication too quickly. The patient's profile indicated that he received the patch manufactured by company A. Company A's product had in fact been recalled due to this very problem. The patient was sure that the excessive dose delivered had caused him to be hospitalized. The pharmacy staff went through months of anxiety and expense while producing records and being deposed. What everyone learned at the end was that the patch received by the patient wasn't manufactured by company A. He had received patches manufactured by company B. This was discovered when reviewing the invoices from the time period in question. Company B's product had been purchased because of the recall of company A's patches. However, the patient profile indicated that the patient had received Company A's patches. Proper recordkeeping would have most likely prevented this pharmacy from suffering through months of litigation.

A second consideration here is billing. In today's world, it is more important than ever to bill for what was actually dispensed. Third party payers expect and demand that their customers receive the product that is billed to the third party payer. While the 2 different fentanyl patches discussed above may be clinically interchangeable, they are probably not the same when it comes to acquisition cost or reimbursement rates. One of them may have been non-formulary, for example. This difference is multiplied if one product is the brand name one. Clinically, none of the differences are significant. However, we aren't talking about therapeutics. We are talking finances and recordkeeping. This sort of discrepancy can lead to repayment demands, even penalties and interest, following an audit.

The importance of recordkeeping shouldn't be overlooked. In litigation, documentation is everything. If it wasn't documented, it wasn't done. Many cases have turned on seemingly small documentation issues. Perpetual inventory totals, timecards, delivery records, pick-up logs, documentation of counseling (or refusal of counseling) are some other examples of records that have become key points in a case. The lesson here is that no record is too small or too trivial to be skipped over. Update those inventory changes as they come in. It may seem burdensome at the time, but there are potential benefits later.

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel at Pharmacists Mutual Insurance Company.

FINANCIAL FORUM

This series, Financial Forum, is presented by Pro Advantage Services, Inc., a subsidiary of 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 Reality of Investing During Retirement

As retirees live longer, their portfolios need to be stronger

Decades ago, the "typical" retiree left work for good between age 60-65 and typically passed away at about 70-75. Retirement lasted 10-12 years for many Americans. Now the picture has changed: some of us will spend 30, 40, perhaps even 50 years in retirement. (Imagine retiring at 55 and living to be 105 … it is possible.) We may live much longer than our parents, and if we do, we will need a lot more money.

A Slight Shift in Outlook

Years ago, retirees were urged to invest conservatively – often, very conservatively. The idea was to build up your savings and net worth aggressively across two or three decades, and then adopt a risk-averse investment strategy for the "golden years." But the reality of a 20- or 30-year retirement has changed that mentality.

The new presumption is that today's retirees should never retire from accumulating wealth. Most Americans will not walk away from their careers with assets equivalent to 20 or 30 years worth of income. If you have $3 million in assets today, you may think you'll have $100,000 a year to live on for 30 years. Sounds great, right? But that may not be enough. Questions of liquidity and taxes aside, what about the runaway costs of healthcare and eldercare? What about the effect of inflation across 30 years – do you remember what a gallon of gas or milk cost 30 years ago?

A New Reality

You're now seeing people in their sixties with the kind of portfolios that people used to have in their forties – portfolios with stocks, mutual funds, and other investments with appreciable risk. Sometimes they have to invest this way because they haven't accumulated sufficient wealth for retirement. Or, they are simply being pragmatic about their long-term need to sustain wealth and keep their retirement assets growing.

What kinds of investments should you retire with?

The answer to that question can only be determined after you carefully consider some variables, such as the age at which you retire, the assets you have saved up, the lifestyle you want to enjoy, family and health considerations, and how comfortable you are with certain types of investment. Be sure that you speak with a financial advisor who specializes in retirement planning before you make a decision to revise your investment portfolio. Even if you are ten or more years from retirement or plan to keep working into your seventies, I think you will find it eye-opening and useful. Most people underestimate their retirement income needs.

Provided by courtesy of Pat Reding, CFP™ of Pro Advantage Services Inc., in Algona, Iowa. For more information, please call Pat Reding at 1-800-288-6669.

Access to Good Quality Dietary Supplements

Council of the Convention Section on the Quality of Food Ingredients and Dietary Supplements

Mary H. Hager, Ph.D., R.D., F.A.D.A.
Section Chair (American Dietetic Association)
E. James Bradford, Ph.D. (AOAC-International)
Marvin M. Lipman, M.D. (Member-at-Large)
Lyn O. Nabors (International Food Additives Council)

EDUCATIONAL GOALS:

The goals of this lesson are to provide back-ground information on dietary supplements and to review proposals for consideration to further improve the quality of dietary supplements.

LEARNING OBJECTIVES:

At the conclusion of this lesson, successful participants should be able to:

1. Describe the regulatory frame-work of dietary supplements;
2. Name examples of proposals that could be considered to further improve the quality of dietary supplements..

Introduction

The 1994 Dietary Supplement Health and Education Act (DSHEA) amendments to the Federal Food, Drug, and Cosmetic Act (FDCA) provided a regulatory framework to allow marketing of vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites.

Now, more than 15 years later, a vast array of dietary supplements in different combinations and amounts are available to United States patients/consumers. Sales of dietary supplements are approaching $25 billion/year, with about $4 billion of this amount representing sales of botanicals.

While DSHEA was instrumental in providing consumers with easy access to dietary supplements, a recent U.S. Government Accountability Office (GAO) report stated that consumers of dietary supplements are not adequately protected under current U.S. law and regulations.

Pre-market oversight and registration of products are recommended in the GAO report. Outside the United States, dietary supplements are frequently considered as traditional medicines with few standards and conformity assessments to these standards. In this white paper, USP's Council of the Convention Section on the Quality of Food Ingredients and Dietary Supplements provides back-ground information on the topic and advances proposals for consideration by the Convention membership to further improve the quality of dietary supplements.

National Approaches

1. Congress: Provisions of DSHEA

Through DSHEA, Congress defined dietary supplements as "foods." As with all foods, DSHEA provisions in the FDCA do not require pre-market review of a dietary supplement by the Food and Drug Administration (FDA) if the ingredients have a safe history of use in food or supplements prior to 1994. Instead, Congress put in place a notification process for a new dietary ingredient to ensure that ingredients that do not have a safe history of use are reviewed by the FDA prior to entry into the U.S. market.

In addition, DSHEA essentially places the burden of proof on the FDA to demonstrate that a dietary supplement presents "significant or unreasonable risk of illness or injury" before it can be removed from the market.

With regard to the *United States Pharmacopeia (USP)*, Section 403(s)(2)(D) of the FDCA states that if a dietary supplement is :

1) Covered by the specifications (tests, procedures, and acceptance criteria of a monograph) of an official compendium of the United States (*USP, National Formulary [NF]*, or *Homeopathic Pharmacopoeia*),
2) Is represented as conforming to the specifications of an official compendium, and
3) Fails to so conform, then the supplement is considered to be misbranded.

Accordingly, unlike the provisions relating to prescription drugs (where conformance with USP standards is mandatory, whether labeled as such or not), Section 403(s)(2)(D) of the FDCA makes compliance with the specifications of an official compendium strictly voluntary for dietary supplement manufacturers (unless the manufacturer chooses to represent the product as conforming to *USP*).

As a consequence, this statutory reference to official compendia provides legal recognition to USP, but effectively creates a disincentive for its use, because it exposes only those manufacturers who so label (and not others who make no reference to *USP* standards at all) to a potential misbranding violation if found not to conform to *USP*.

(continued)

2. The Food and Drug Administration (FDA)

In 2007, the FDA finalized Current Good Manufacturing Practices (cGMPs) for dietary supplements. These regulations allow manufacturers to establish product specifications and to use "appropriate and scientifically valid" methods to determine whether those specifications are met.

The cGMPs do not define the words "scientifically valid" nor is validation of analytical procedures required. The FDA has indicated that "a scientifically valid method is one that is accurate, precise, and specific for its intended purpose–in other words, a scientifically valid test is one that consistently does what it is intended to do. As a result, dietary supplement manufacturers develop private procedures, tests, and assays, which may or may not receive regulatory scrutiny.

Standards for a dietary supplement under a specified name may not have comparable requirements and thus may be dissimilar in quality, benefit, and safety to consumers. The cGMPs do not require dissolution and disintegration testing, and manufacturers set their own limits for contaminants such as heavy metals, microbial limits, fungal toxins, or pesticides. *USP* has published an article describing the current regulatory scheme as one that creates "standards without standardization."

3. United States Pharmacopeial Convention

Following enactment of DSHEA in 199, the 1995 USP Convention adopted Resolution 12 that encouraged the USP to explore the feasibility and advisability of establishing standards and developing information concerning dietary supplements.

This resolution was taken up and implemented by USP's Board of Trustees and Council of Experts, resulting in a well-evolved section of *USP* for dietary supplement monographs, with allied USP Reference Standards offered in USP's catalogue.

USP32-NF27 now contains approximately 430 dietary supplement and ingredient monographs and general chapters, which cover a large percentage (+90%) of the dietary supplements commonly marketed in the United States.

USP's Council of Experts Dietary Supplement Information Expert Committee applies admission criteria together with a safety review guideline to allow exclusion of some dietary supplements from *USP*, even though they may be legally marketed in the United States.

This approach mirrors the work of the Scope Committee of the Committee of Revision (the predecessor of the Council of Experts) that ended in the 1990s. USP also includes a General Chapter on *Manufacturing Practices for Dietary Supplements* <2750>, which was developed prior to finalization of FDA's cGMPs and is generally more stringent and specific than those regulations.

In June 2009, USP introduced a separate *USP Dietary Supplements Compendium* that includes official text from *USP* (monographs and general chapters relating to dietary supplements) as well as authorized explanatory text and graphics intended to provide useful information to dietary supplement manufacturers.

International Approaches

While vitamins, minerals, amino acids, botanicals, and other plant and animal substances are available in the U.S. as dietary supplements, they are variably regulated as health products, traditional medicines, or drugs in other countries.

This varied international approach on the regulation of dietary supplements provides different paradigms for consideration and exploring options for domestic regulatory oversight.

Quality standards also are quite variable around the globe. Issues of quality are present in the international commerce of dietary supplements, which is evident in cases such as protein adulteration with melamine or dietary supplements containing toxic metals, high levels of pesticides or unapproved drugs.

Information from the World Health Organization (WHO) details the widespread consumer misconception that "natural" always means "safe," and a common belief that remedies from natural origin are harmless and carry no risk. Also of concern is that healthcare providers are frequently unaware of the dietary supplements their patients are taking; either because they do not ask, or patients do not offer the information. Under the current law and regulations, there is no way of knowing the quality standards to which each product is held, and thus, there is no way to determine whether two products with the same dietary supplement ingredients are the same or different.

Proposals

The Council of the Convention Section on Food Ingredients and Dietary Supplements suggests for consideration the following opportunities for possible USP Convention action and improvement in the regulation of dietary supplements:

(continued)

1. Public Monographs and Reference Materials

The universe of products in the market is constantly expanding, creating gaps where mono-graphs and reference materials are missing. To the extent feasible, documentary standards and reference materials offered by USP should expand to cover all the products in the dietary supplements market.

2. Adherence - Public Standards

Public quality standards arising from the open and participatory process conducted by USP con-serve both regulatory and manufacturer resources. They work to achieve consistency in the quality of a dietary supplement both within and between manufacturers, and allow updating.

This consistency is more likely to be achieved if manufacturers are required to comply with public standards. Thus, USP might consider informing and engaging in discussions with Congress about the desirability of strengthening section 403(s)(2)(D) of the FDCA to require dietary supplements and dietary supplement ingredients to con-form to the standards established in *USP-NF,* where such standards exist.

USP also might consider making Congress aware of the benefits of strengthening the adulteration provisions of the FDCA to ensure that all dietary supplements conform to the relevant standards promulgated in *USP-NF*. However, it is not clear, at this time, that industry supports such mandatory standards.

3. International Harmonization

Amidst the increasingly complex global supply of dietary supplement ingredients and products, ensuring quality and harmonization of standards is important, irrespective of how dietary supplement products are labeled and regulated– whether as traditional medicines, drugs, or supplements.

Global harmonization of public standards would ensure quality, identity, and label uniformity in international commerce, and could facilitate international commerce of good quality dietary supplements.

To start its work in this area, USP standards and analytical methods could complement the descriptions of quality, dosage, safety, and pharmacological activity of botanical monographs offered by other standards setting bodies of the world. For these reasons, USP should cooperate with international health organizations to promote standards for traditional medicines that are also dietary supplements in the United States.

Examples of such organizations include the WHO, the Canadian Natural Health Products Directorate in Health Canada, the European Directorate for the Quality of Medicines and HealthCare (EDQM), and the Indian and Chinese Pharmacopoeia Commissions.

4. Education

There is a dearth of unbiased dietary supplement information for consumers and practitioners. Gaps in practitioner training and consumer education are clear impediments to the safe use of dietary supplements.

Practitioners should receive training on proper counseling of consumers on the use of dietary supplements and consumers should be educated about the importance of disclosing such usage to healthcare providers. In this way, practitioners and consumers can monitor and prevent possible adverse effects that may occur from the combined use of certain dietary supplements and drugs.

USP could expand its educational programs to meet the needs of practitioners and patients/consumers with respect to dietary supplements. The USP Dietary Supplements Information Expert Committee earlier recommended education of practitioners regarding suitable practices for safe use and prevention of interactions with other therapeutic agents.

USP should consider developing Pharmacopeial Education courses for practitioners and consumers in this regard, and additional courses on compendial approaches to quality standards for dietary supplements to help manufacturers, testing labs, and regulators understand the value of USP public standards and reference materials.

5. Verification

USP Verification Programs could also be used to increase confidence that ingredients and products moving in the international market comply with the quality specifications to help ensure public safety, including absence of known/ identified adulterants and contaminants.

Although FDA has not endorsed the use of third party certifications of dietary supplements, it has recognized the value of third-party certifications in its recent guidance on foods. Broad implementation of USP's Verification Programs

(continued)

for dietary supplements and dietary supplement ingredients could assist in raising supplement quality, help patients make informed decisions, restore consumer confidence, and allow healthcare practitioners to recommend verified dietary supplements with some level of confidence.

The various elements of USP's Verification Programs (audits, testing, document review, and market surveillance) would act synergistically with the cGMPs already in place, thus helping conserve FDA resources. Because cGMPs provide minimum requirements, implementation of USP Verification Programs would add value for greater assurance of the quality of supplements.

The concern about the quality and purity of ingredients moving in the international market also could be addressed through a system of USP Verification Programs' inspecting companies and testing products overseas.

With sites in China, India, and Brazil, USP is very well positioned to contribute worldwide to raising the quality of dietary supplements. It is also possible that the challenges faced by regulatory differences with other countries could be addressed through credible USP Verification Programs.

6. Regulatory Oversight

Dietary supplement product registration or pre-market notification might be considered as a means of monitoring the number and type of dietary supplements moving in commerce in the U.S. and helping to assure the safety of dietary supplements prior to sale to the consumer.

To accomplish this, the FDA would need sufficient resources to adequately assess and address the safety of dietary supplement products, and the FDCA would need to be amended to provide the FDA with authority in this area.

The Council of the Convention Section on Food Ingredients and Dietary Supplements welcomes input on these proposals from the Convention, as well as additional comments on how USP might build upon its past efforts and expand its work to help assure the quality and appropriate use of dietary supplements worldwide.

CONTINUING EDUCATION QUIZ ON NEXT PAGE

CONTINUING EDUCATION QUIZ

Access to Good Quality Dietary Supplements

1. The Dietary Supplement Health and Education Act was introduced in what year?
   a. 1993 b. 1994 c. 1995 d. 1996

2. Sales of botanicals are approximately _____ of an almost $25 billion/year business.
   a. 1 billion b. 2 billion c. 3 billion d. 4 billion

3. Through the Dietary Supplement Health and Education Act (DSHEA) Congress defined dietary supplements as which of the following?
   a. Drugs b. Vitamins c. Foods d. Botanicals

4. Which of the following is considered an official compendium of the United States
   a. Unites States Pharmacopeia c. Homeopathic Pharmacopeia
   b. National Formulary d. All of the above

5. In which year was the Current Good Manufacturing Practices (cGMPs) for dietary supplements finalized by the FDA?
   a. 2000 b. 2003 c. 2007 d. 2009

6. Which of the following is false regarding cGMPs?
   a. They were finalized by the FDA specifications c. They allow manufacturers to establish product
   b. They do not define the words "scientifically valid" d. They require dissolution and disintegration testing

7. In what year did the USP Convention adopt a resolution that encouraged the USP to explore the feasibility and advisability of establishing standards and developing information concerning dietary supplements?
   a. 2005 b. 1965 c. 1995 d. 1985

8. Which of the following includes official text from USP as well as authorized explanatory text and graphics intended to provide useful information to dietary supplement manufacturers?
   a. USP Dietary Supplements Compendium c. Homeopathic Pharmacopeia
   b. Manufacturing Practices for Dietary Supplements d. None of the above

9. Which of the following is available in the U.S. as a dietary supplement?
   a. Vitamins b. Minerals c. Amino acids d. All of the above

10. Which of the following is true regarding public quality standards?
    a. They conserve only regulatory resources c. They do not allow updating
    b. They work with only certain manufacturers d. They arise from the open and USP participatory process

11. Global Harmonization would ensure:
    a. Quality b. Identity c. A + B d. None of the above

12. USP does NOT have a site in which of the following countries?
    a. France b. China c. India d. Brazil

ANSWER SHEET – E-C.E. – Pharmacists

Access to Good Quality Dietary Supplements *(Knowledge-based CPE)*

To receive 1.0 Contact Hours (0.10 CEUs of continuing education credit, read the attached article and answer the 12 questions by circling the appropriate letter on the answer form below. A test score of 75% or better is required to earn a Statement of Credit for 1.0 Contact Hours (0.10 CEUs) of continuing pharmacy education credit. If a score of 75% (9/12) is not achieved on the first attempt, another answer sheet will be sent for one retest at no additional charge.

The South Dakota State University College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The Universal Program Identification number for this program is: #0063-9999-12-006-H05-P, #0063-9999-12-006-H05-T.

Learning Objectives

Pharmacists: 1. Describe the regulatory framework of dietary supplements; 2. Name examples of proposals that could be considered to further improve the quality of dietary supplements.
Pharmacy Technicians: 1. Name the regulatory agencies dealing with quality of dietary supplements; 2. Identify possible areas to further improvement the quality of supplements.

Circle the correct answer below:

1. A B C D	5. A B C D	9. A B C D
2. A B C D	6. A B C D	10. A B C D
3. A B C D	7. A B C D E	11. A B C D
4. A B C D	8. A B C D E	12. A B C D

Course Evaluation – must be completed for credit.

	Disagree						Agree
Material was effectively organized for learning:	1	2	3	4	5	6	7
Content was applicable for practice—understanding the importance of safety standards in pharmacy practice	1	2	3	4	5	6	7
Each of the stated learning objectives was satisfied:	1	2	3	4	5	6	7
Course material was balanced, noncommercial	1	2	3	4	5	6	7
Learning assessment questions appropriately measured comprehension	1	2	3	4	5	6	7
Length of time to complete course was reasonable for credit assigned	1	2	3	4	5	6	7

*List any learning objectives above not met in this course:*_____

*List any important points that you believe remain unanswered:*_____

(Approximate amount of time to preview, study, complete and review this 1.0 hour CE course: _____*)*

Comments:

List any future CE topics of interest (and related skill needs):

Name: _____ RPh License #: _____ Technician #:_____

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CPE Monitor Program ID: _____ **Date of Birth (MMDD):** _____ States requiring CE credit:_____

Would you like to receive additional CE courses?_____ *If so, please list email address:*_____

Course release date: 3-31-12 / Expiration date: 3-31-15 / Target audience: Pharmacists , Pharmacy Technicians

Please mail this ***completed answer sheet*** *with your check of* ***$8.00*** *to:* ***SDSU College of Pharmacy – C.E. Box 2202C, Brookings, SD 57007***

OBITUARIES

Carol A Omodt, 73, of Brookings died Sunday, February 5, 2012 at the Brookings Hospital in Brookings, SD.

Carol Ann Mertens was born in Jordan, Minnesota on September 21, 1938 to LeRoy and Helen (Messerer) Mertens. She graduated from the St. Joseph Academy in 1956 and began studies in Psychology at St Catherine's University. On September 7, 1957 she was united in marriage to Gary Omodt. After living in St. Paul, Minnesota for 3 years, the couple moved to Brookings, SD where Gary took the position of Assistant Professor of Pharmacy at South Dakota State University. She was a stay-at-home mom until 1971 when she became a ward secretary at the Brookings Hospital, where she worked for 22 years. After retiring from the Brookings Hospital, she enjoyed volunteering at the United Retirement Center, bringing a smile to everyone's face, and helping with bingo and bridge.

Carol loved baking, gardening, couponing, and especially babies, she was in a world of happiness when there was a baby around. Carol was a very loving, thoughtful mother and grandmother, who always enjoyed seeing her relatives. She never missed a birthday, always getting a special card out to each and every one of her beloved children and grandchildren every year at just the right time.

She is survived by her husband, Gary, of Brookings, SD; three sons, Greg Omodt, of Sioux Falls, SD, Jeff Omodt of Mankato, MN and Steve (Gale) Omodt of Aberdeen, SD; three daughters, Stacy (Darrell) Thomas of Sioux Falls, SD, Karen (Barry) McMahon, of Sioux Falls, SD and Kelly Omodt of Sioux Falls, SD; her grandchildren, Mike, Wynter, Whysper, and Adam Omodt, Collin, Kelsey, and Marley Thomas and Jack, Thomas, and Amanda Collins; her brother, Mike Mertens of Ozark, MO and several nieces, nephews, and cousins.

She was preceded in death by her parents, one sister Marilyn, and one infant brother, Patrick.

CLASSIFIEDS

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