

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

## IN THIS ISSUE

That's a Wrap: First-Ever Virtual Convention  
2020 Award Winners

Meet the 50-Year Pharmacists



FALL EDITION 2020

**South Dakota Pharmacists Association**

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# Calendar

## OCTOBER

### AMERICAN PHARMACISTS MONTH

- 12 Native American Day
- 20 National Pharmacy Technician Day
- 18–24 National Pharmacy Week
- 18–19 National Community Pharmacists Association (NCPA) Virtual Meeting

## NOVEMBER

- 11 Veteran's Day
- 26 Thanksgiving Day

## DECEMBER

- 11 South Dakota Board of Pharmacy Meeting  
Sioux Falls, SD  
9am–noon
- 24 Christmas Eve
- 25 Christmas Day
- 31 New Year's Eve

## SAVE THE DATES

- > **LEGISLATIVE DAYS**  
January 26–27, 2021  
Pierre, SD
- > **SDPhA 134th ANNUAL CONVENTION**  
September 17–18, 2021  
Spearfish, SD

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: [www.sdpha.org](http://www.sdpha.org).

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# Director's COMMENTS

Amanda Bacon // Executive Director



Dear Friends,

I'm not sure how we got here, but the view outside the SDPhA office window strongly suggests it's Fall. It's also utterly spectacular around the Capitol grounds right now. It's a perfect reminder to me that if you look, you'll find the beauty in the hard seasons. Because let's be real - 2020 seems like the quickest, yet longest year of my life, and I'm guessing you can relate.

I want to start by saying thank you to all who joined us for the **134th Annual Convention**. I'm quite certain if you would have told the association founders the world would one day possess the technology for us to meet and carry out the business of the association "virtually," there's more than one from that original gathering who would've (politely, I'm sure) scoffed at that notion. It was so important to the board and I to keep the tradition of this meeting alive, and we want to thank you for working with us to adapt and overcome. While we sorely missed coming together in person, we are so grateful for the opportunity, even in the upside down in which we now live, to come together and learn from each other, and move forward with the work of advancing the profession.

It seems fitting that as we celebrate **American Pharmacists Month** this October, we highlight your work on the front lines in our communities. We hope you have seen our social media posts and ads highlighting how pharmacists, pharmacy technicians, and pharmacy staff have stepped forward throughout this pandemic – even at risk of their own COVID-19 exposure. You are essential providers, and have remained the most accessible members of the healthcare team since the very inception this pandemic.

Our patients, and our lawmakers are taking note of how pharmacists continue to show up inside this new reality. We continue to fight, alongside our national and state partners, to maintain the flexibilities and authorities extended to pharmacists by the federal government during the COVID-19 emergency. As the nation prepares for the approval of a COVID-19 vaccine, we continue to work to ensure pharmacists are allowed to provide the vaccine to patients without unnecessary barriers. SDPhA will serve

as the state immunization manager's central point of contact for independent pharmacies and regional chains.

While the overall policy landscape is particularly polarized and complex right now, we see many areas of opportunity – especially in the areas of immunizations, testing and payment. This new era of advocacy has us looking to utilize some new ways for you to engage in these efforts, both at the state and national level. We will soon rollout a communications/advocacy platform called **Voter's Voice**. This program will allow us to communicate with you via different methods of your choosing, including an opt-in for text messages, something many have asked us for. These messages will contain ready-made tools for you to quickly communicate with both state legislators and our congressional delegation when it matters most. You can look for this in your inbox and social media in the coming weeks.

Finally, please join me in a huge round of applause for our 2020 award winners. We have highlighted them here in the Journal, and you can check out the virtual awards ceremony on the **SDPhA Member News and Announcements Group** page on Facebook. It is our hope that we can give these outstanding honorees a proper in-person ovation next year at the **135th Annual Meeting in Spearfish**. Likewise, I want to say thank you to all the members of the 2019-2020 SDPhA Board, especially to Lori Ollerich, our now past president. In a year of unprecedented challenge and change – she was steadfast, yet brought the perfect amount of levity to every situation. The pharmacy profession in this state is better and stronger because of her leadership.

We know this pandemic is far from over. We knew it would be a marathon, not a sprint. With that in mind, I continue to encourage you to take good care of yourselves. You can't pour from an empty cup. Self-care is anything but selfish – it may well be what saves you. It may well be what gives you the capacity to continue to show up, and serve others. This is a particular passion of mine, so you're right, it's not the first time you've heard it here from me. It likely won't be the last.

Stay Safe,

**AMANDA BACON**

SDPhA Executive Director



# President's PERSPECTIVE

Dana Darger, RPh // SDPhA Board President



Good Morning Dear Friends in Pharmacy,

This morning as I am sitting here thinking about one of my family telling me that they "just want things to get back to normal" and my realization that things are not going to go back to "normal". There are all kinds of famous quotes on change and there are many people famous for the change they created in our world.

The question for me is can I change and adapt quickly enough to not be left behind.

How will you respond to change that is out of your control? Will you resist and talk about getting back to the way it used to be or will you reinvent yourself to find satisfaction and happiness with the way things are? You can resist, but in the end change will win. The challenge is to try to understand what tomorrow might look like and accept it for what it is and quit sulking because you don't like it.

Besides COVID there are many stresses on our profession at the present time. Too many for me to touch on every one of them in this letter. One that we truly need to continue to work on that we can control is adoption of USP 800. My recommendation is to do everything you can do to become USP 800 compliant now rather than waiting for USP to lift the "not compendially applicable" flag that it is currently under. Depending on whether or not USP 795 or 797 applies to you, you may not be able to be fully compliant with 800, but you should be doing everything you can to meet 800.

Pharmacies will be in the "official" COVID vaccinators for our communities. There will be many opportunities over the next month or so to learn more. The Association and the Board will do their best to ensure that everyone is aware of these opportunities, so that you are fully aware of what is going on. That being said, many of these opportunities happen with minimal notice. My goal will be to make sure you are aware as soon as possible.

Many of you are being impacted by the changes several manufacturers are putting on the 340B contract pharmacy prescriptions. It does not appear that there is a fix in the immediate future for this problem. The crux of the whole issue is the manufacturers trying to avoid selling pharmaceuticals at 340B prices and still paying rebates to the PBMs is to be able to have their drugs on the PBM formulary. My challenge to the manufacturers is to consider decreasing their rebates to the PBMs rather than hurting our hospitals and pharmacies. The only piece of the pharmaceutical supply chain with increasing margins are the PBMs. Pharma margins are fairly flat, your margins are decreasing and PBMs.....

I looked for a profound quote on change to finish this letter to you with. I found this one, "Yesterday I was clever, so I wanted to change the world. Today I am wise, so I am changing myself."

– Rumi

It spoke to me, but wasn't quite right.

Then there was this one, "Life is a series of natural and spontaneous changes. Don't resist them; that only creates sorrow. Let reality be reality. Let things flow naturally forward in whatever way they like."

– Lao Tzu

Those of you who know me well will understand why I picked this one... "Here's to the crazy ones. The misfits. The rebels. The troublemakers. The round pegs in the square holes. The ones who see things differently. They're not fond of rules. And they have no respect for the status quo. You can quote them, disagree with them, glorify or vilify them. About the only thing you can't do is ignore them. Because they change things. They push the human race forward. And while some may see them as the crazy ones, we see genius. Because the people who are crazy enough to think they can change the world, are the ones who do."

– Rob Siltanen

Take care my friends. Have a great day and stay safe!

**DANA DARGER, RPh**

SDPhA Board President

# South Dakota BOARD of PHARMACY

Kari Shanard-Koenders // Executive Director



## BOARD WELCOMES NEW REGISTERED PHARMACISTS/ PHARMACIES

Congratulations to the following **45 candidates** who recently met licensure requirements and were licensed as new pharmacists in South Dakota: Sarah Antrim, Christina Becker, Kali Bendix, Samantha Boeck, Miranda Boraas,

Bailey Buenger, Muhammed Ceesay, Andi Clayton, Amanda Dickinson, Scott Dingus, Sarah Gee, Kyle Gibbons, Amishi Jain, Mikinze Jones, Shaymous Juhnke, Taylor Kelsey, Kyle Kirby, Megan Klueber, Lily Koob, Jessica Kotschegarow, Jonathan Kusnierz, Abigail Mechtenberg, Sara Morrison, Madyson Muller, Brooke Nibbelink, Punam Patel, Holly Polak, Xiaoxiao Qi, Shelby Retzer, Eric Revak, Heidi Ringling, Brittany Ryan, Darin Scheele, Megan Schliesman, Bailey Schroeder, Kelcy Sorensen, Katherine Vakshteyn, Nicholas Van Peurse, Morgan Vasquez, Liya Vazhappilly, Cassandra Vettleson, Oswaldo Villarreal, Patrick Watchorn, Matthew Wiemann, and Courtney Younge. There were no full-time or part-time pharmacy licenses issued during the period.

## BOARD MEMBER DIANE DADY'S THIRD TERM ENDS IN OCTOBER

Diane Dady was appointed by Governor Dugaard in November 2011 and served on the **South Dakota Board of Pharmacy** selflessly for nine years. Diane has been an insightful and forward-thinking board member. She will be greatly missed by her fellow board members and board staff as her term ended on October 1, 2020. Diane has been dedicated to fulfilling her board duties and to ensuring that South Dakota pharmacists will protect the health and safety of our residents now, and for years to come. Thank you and best wishes Diane! Governor Noem will be appointing a new member soon.

## NALOXONE STANDING ORDER BECOMES A REALITY FOR SOUTH DAKOTA PHARMACISTS

Through collaboration between the Board and the SD Departments of Health and Social Services, a standing order issued by Mary S. Carpenter, MD, will allow Naloxone to be requested by patients and dispensed by pharmacists in South Dakota to any person who is either an individual at risk of experiencing an opioid-related overdose; and/or a family member, friend, or close third party to a person at risk of experiencing an opioid-related overdose without a separate prescription or protocol. Pharmacists will now play a heightened critical role in preventing opioid deaths by increasing access to Naloxone. See the Board website at [www.pharmacy.sd.gov](http://www.pharmacy.sd.gov) for more information.

## OFFICIAL LICENSE V. LICENSE PRIMARY SOURCE VERIFICATION

The Board of Pharmacy office receives frequent calls regarding the pharmacist license. Some think that a print of the verification page is equivalent to a copy of the official license. Board inspectors also see that the document posted in pharmacies is not the license but is a print of the verification page. The verification page on our website is for employers and others to have access to a pharmacist's licensure credentials. The verification does not provide a copy of official license and does not have immunization certificate information on it like the actual license does. After submitting the license renewal information into the **iGov Solutions website** and once the license has been approved, an email states the approval and sends the user to the board website. Users then need to log back into the iGov Solutions licensing platform and select print to obtain a copy of the license.

## NEW PHARMACIST WALL CERTIFICATES by Beth Windschitl, Sr. Secretary

The Board of Pharmacy would like to congratulate all pharmacists who received their initial South Dakota pharmacist license in 2020. During the first quarter of 2021, the Board of Pharmacy will contact individuals, via email,

regarding an opportunity to order a 10 x 15 **Registered Pharmacist Wall Certificate issued by the Board**. A form to request the wall certificate will be provided in the communication and should be completed and returned to the Board by the stated deadline.

## BOARD IS PROMULGATING RULE CHANGES TO ARSD CHAPTER 20:51

The Board of Pharmacy and board staff have been working to **revise ARSD Chapter 20:51** for over two years and it is finally coming to fruition. The Board conducted two hearings, two comment periods, and recently presented the rules to the Interim Legislative Rules Review Committee to make these substantial changes. Thank you to all who commented, sent questions, and worked with us on drafting. We received supportive and constructive comments of which we incorporated many into the final product. The rules make cleanup changes to many sections which should be beneficial to practicing pharmacists. At the Interim Rules Review Committee, the legislators reverted several rules back to a previous step but did allow a few rules to move to becoming active. The rules that moved forward are: allowance for dialysate to be delivered to patient homes from manufacturer or manufacturer's agent with a physician order; changed pharmacist to intern ratio from 1:1 to 1:2 to allow for increased use of interns in pharmacies, more intern training sites, workforce needs; and, the immunizations chapter, in 20:51:28 had its review completed and could move forward. This chapter added authority for pharmacists to administer immunizations other than influenza by prescription or protocol, added authorization for interns to administer immunizations, and removed the requirement that the immunization must be reported to practitioner. We will revisit this in the spring.

## BOARD THANKS DEPARTMENT OF HEALTH

The Board thanks the South Dakota Department of Health for their work in the **management of COVID-19** and for providing personal protective equipment (PPE) for the health licensing boards to send to licensees who were unable to obtain it. The Board delivered 28,920 pieces of PPE in the form of KN95 masks, surgical masks, and face shields to pharmacies. Many were thankful for this distribution.

## BOARD MEETING DATES

Please check our website for the time, location and agenda for future Board meetings. Board meeting minutes are also on the website.

## BOARD OF PHARMACY DIRECTORY

### BOARD OF PHARMACY

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### PDMP DATA ACCESS

<https://southdakota.pmpaware.net/login>

### PDMP DATA SUBMITTERS

<https://pmpclearinghouse.net>

### NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

[www.NABP.pharmacy](http://www.NABP.pharmacy)

# South Dakota BOARD of PHARMACY

( continued )

## PDMP UPDATE

by Melissa DeNoon, PDMP Director

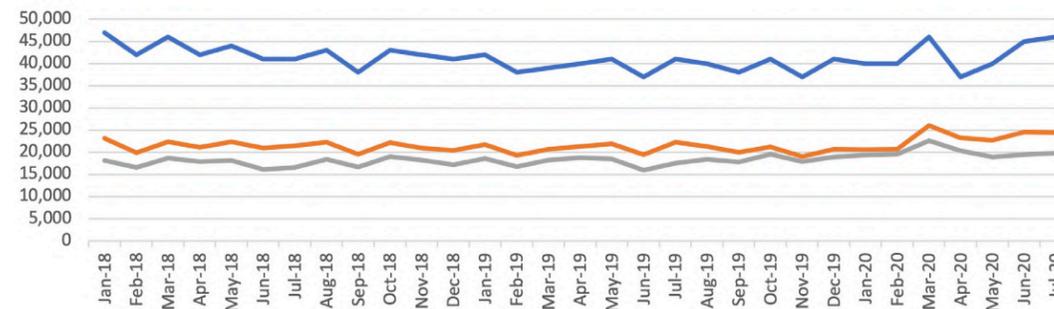
The PDMP is excited to announce **interstate data sharing** has been set up with Wyoming! Puerto Rico has also been added which brings the total to 33 other PDMPs available for querying. Each month the PDMP compiles program data for informative and evaluative purposes. The following are some of the data sets from these analyses.

### Trending Top Ten Most Prescribed Controlled Substances to SD Patients

Year 2019 Top Ten Controlled Substances (CS) to SD Patients	RXs	Quantity	Days of Supply	Avg Quant/Rx	2018 Rank	2017 Rank
HYDROCODONE BITARTRATE/ACETAMINOPHEN	161,646	9,146,677	2,035,499	57	1	1
TRAMADOL HCL	124,753	8,045,714	2,108,104	64	2	2
LORAZEPAM	81,896	3,518,556	1,753,507	43	3	3
DEXTROAMPHETAMINE SULF-SACCHARATE/AMPHETAMINE SULF-ASPARTATE	78,817	3,594,353	2,341,336	46	6	6
ZOLPIDEM TARTRATE	75,543	2,553,925	2,552,752	34	4	4
CLONAZEPAM	75,164	4,138,613	2,192,892	55	5	5
METHYLPHENIDATE HCL	60,102	2,602,126	1,795,948	43	7	8
ALPRAZOLAM	53,005	2,787,688	1,347,747	53	8	7
OXYCODONE HCL	50,186	2,925,212	714,573	58	9	9
LISDEXAMFETAMINE DIMESYLATE	40,430	1,223,940	1,208,929	30	10	10

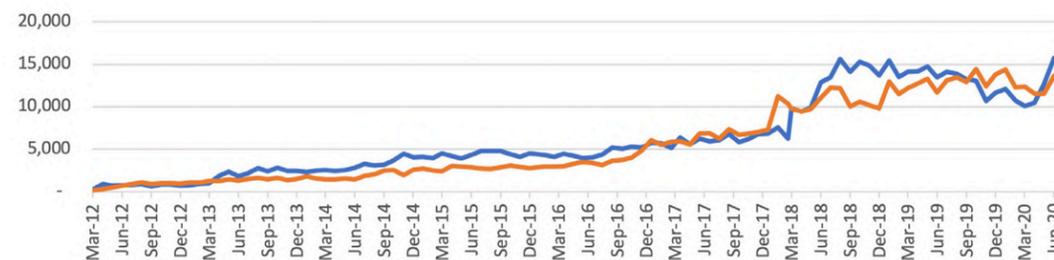
### SD Patients' Trending Prescription Counts

— Opioids  
— Benzodiazepines  
— CNS Stimulants



### Pharmacist and Prescriber AWARe Web Portal Queries Over PDMP Life

— Pharmacists  
— Prescribers



Respectfully submitted, for the Board, Stay Safe and Healthy,

**KARI SHANARD-KOENDERS, RPh, MSJ**

SDBOF Executive Director

# SDSU COLLEGE of PHARMACY and ALLIED HEALTH PROFESSIONS

## Dan Hansen, PharmD // Interim Dean and Professor



Greetings from the College of Pharmacy and Allied Health Professions! It is hard to believe but Dean Emeritus Jane Mort retired over three months ago now. She left some big shoes to fill but with the help of the faculty, staff, and administrators here at the College, we continue to take strides forward. I am excited to share some of that news with you.

We are **welcoming 70 students** into the Pharm.D. program and 19 students into the on-campus MLS program, all with outstanding academic backgrounds. Over the course of the last 3-4 months we have been busy putting together plans to resume in-person instruction in fall 2020. In the end we landed on a plan that will allow us to provide every student participating in an on-campus program a mix of in-person and remote learning within the lecture component of the curriculum and a complete in-person approach in the lab environment. To assist in this process, we have taken several safety measures, including installing sneeze guards in the classrooms, providing each student with a cloth face covering and a face shield, controlling traffic flow within the building, and creating cohorts within each of the classes to assist in contact tracing. While the mode of instruction and the classrooms may look a little different, our commitment to quality and our ability to deliver the curriculum through the help of amazing faculty and preceptors remains the same.

As we **prepared for the start of the fall semester**, we also had four different programs at various stages in the accreditation process. Our MLS program recently had their 5-year interim report accepted by NAACLS, meaning that they continue to meet NAACLS standards and are good to move forward until our next site visit in 5 years. Our PGY1 residency in community practice received a positive review

from the virtual accreditation site visit this summer. Our follow-up report has been submitted to ASHP and we are scheduled to receive a final decision sometime later this spring. In other exciting news, our joint Master of Public Health program with USD is seeking first-time accreditation through CEPH. The self-study has been submitted, and we had our virtual site visit September 30-October 2. On the pharmacy side, ACPE complete a comprehensive review every 8 years. SDSU's Pharm.D. program is scheduled for 2022-2023. In preparation for this review, the College held a kickoff meeting in May. Section leaders and committees have been assigned to each standard and plans have been devised for the review process. Faculty, staff, students, and stakeholders will be active participants throughout the process.

Speaking of programs within the College of Pharmacy and Allied Health Professions, we added another one. In July 2020, the respiratory care program at Dakota State University transitioned to the College of Pharmacy and Allied Health Professions, finding a home in the Department of Allied and Population Health. With this program, we **welcomed five faculty to our College**. These faculty are housed at three locations within the state. Lacy Patnoe, Program Director, and Abby Wortman, Instructor, are located at Monument Health in Rapid City. Mary Reinesch, Director of Clinical Education, and Kaylee Johnson, Instructor, are located at Sanford Health in Sioux Falls. Jill Olson, Clinical Lecturer, is located at Avera McKennan Hospital in Sioux Falls.

The **Respiratory Care program** includes an accredited associate degree and BS degree (not accredited, but plans include seeking accreditation in the future). The Respiratory Care program was recently selected by the Commission on Accreditation for Respiratory Care (CoARC) to receive the Distinguished RRT Credentialing Success Award. This award recognizes a program's success in inspiring its graduates to achieve their highest educational and professional aspirations.

( continued on page 10 )



# SDSU COLLEGE of PHARMACY and ALLIED HEALTH PROFESSIONS

( continued )

Students in all our programs continue to accomplish outstanding work. **Kjersten Sankey**, current P4 student and president of SCCP, was chosen to serve in a national position. Kjersten was selected as a Student Liaison for ACCP's Women's Health Practice and Research Network (PRN). This is quite an honor for her to be selected out of a highly qualified pool of candidates! In addition, she wrote a Student Perspective article about the transition to online learning and it was published in the Summer 2020 PRN Newsletter.

Three P4 students (**Ellen Hulterstrum**, **Abby Lingle**, and **Samantha Smith**) advanced to Round 3 of ACCP's Clinical Pharmacy Challenge, which features the top 32 teams in the nation! Unfortunately, they will not get to compete in the 4th round based on score cutoffs, but it's a testament to the great instruction and students we have here at SDSU that they were able to get this far in the competition.

We also continue to see growth and success on the research side. **Dr. Aaron Hunt** (Project Director), **Dr. Erin Miller** (Co-Project Director), **Dr. Yen-Ming Huang** (Co-investigator) and **Dr. Jennifer Ball** (Co-investigator) were awarded \$1,000,000 from the Rural Communities Opioid Response program sponsored by the Health Resources and Services Administration (HRSA). This three-year project is a collaboration between faculty from the Allied and Population Health and Pharmacy Practice Departments and several community partners. The project is designed to lessen the burden of the opioid epidemic in rural areas in the state. The team will implement the START-SD Program (Stigma, Treatment, Avoidance, and Recovery in Time), which will work to prevent and improve outcomes for individuals and family members impacted by opioid use disorder (OUD) in Brookings, Codington, and Hughes Counties in rural South Dakota.

As part of their grant with the Department of Health and CDC, multiple TV channels started airing a commercial created by folks in the Allied and Population Health Department, surrounding the theme, "**Your Pharmacist Knows.**" The intent of the campaign is to increase patient

awareness of clinical services pharmacies can provide and help patients better understand the role that pharmacy services play in improving their health. This ad will run for a couple months across the state.

Finally, due to a couple of retirements and a few recent departures, we do have a **handful of open positions**. Searches are underway for the following positions: Dean, Experiential and Continuing Education Coordinator, Research Associate, Instructor for Respiratory Care and a Program Assistant in the Department of Pharmaceutical Sciences. We will certainly provide updates as those positions are filled in the coming months.

In closing, we have a lot to be proud of here in the College. While COVID has caused us to pivot several times over the last six months, I am proud of the resilience the faculty, staff, and students have shown over that time. I have the honor and privilege of working, teaching, and learning alongside this group every day and I could not be more thankful for that.

Thank you!

**DAN HANSEN, PharmD**

Interim Dean and Professor  
College of Pharmacy & Allied Health Professions

# SDSU's Student Collaboration for the ADVANCEMENT and PROMOTION of PHARMACY

Anna Mohr // SCAPP/APhA-ASP SDSU Chapter President



Happy American Pharmacists Month! The semester has gotten off to a great start for Student Collaboration for the Advancement and Promotion of Pharmacy (SCAPP) at South Dakota State University. There have been challenges with the COVID-19 pandemic, but we have taken our theme, Embracing Change, to heart. We are currently holding our bi-weekly chapter meetings

over Zoom which is a change from in-person meetings, but has been a good opportunity to utilize technology to our advantage. We are very glad that we are still able to meet as an organization and connect with each other. Through Zoom we have hosted interview and application nights for prepharmacy students, an APPE rotation panel for P4 students, and social events for everyone.

Fortunately, SCAPP is able to complete patient screenings in-person by using face shields, masks, gloves, and other PPE to keep our patients and ourselves safe. We kicked off the semester with our annual state fair screenings and were able to provide 288 total blood pressure, blood glucose, and cholesterol screenings. Simplify My Meds is another ongoing patient care opportunity that we have been working with the Medicap pharmacy in Hartford, SD. In this program, pharmacy students have been contacting patients on their barriers to adherence and providing education on methods to overcome those barriers. Patient care is a core value of SCAPP and we are thankful to be able to continue to care for patients during this challenging time.

We have a lot of great events planned this American Pharmacist's month. Dr. Garrett Schramm, an SDSU alumni and the Director of Pharmacy Education and Academic Affairs at Mayo Clinic, will be presenting to SCAPP later



this month. Additionally, throughout the month of October, SCAPP members are assisting local pharmacies with providing influenza immunizations. This year more than ever, it is important to promote and increase influenza vaccinations throughout South Dakota. We have been utilizing our social media platforms to provide education on the pharmacy profession and to increase awareness of pharmacists' role as an essential health care worker during the COVID-19 pandemic.

Thank you, SDPhA for your continuous support of our chapter. We really appreciate all you do for us and are excited for what the rest of the year has to bring!

Best,

**ANNA MOHR**

SCAPP/APhA-ASP SDSU Chapter President

# South Dakota SOCIETY of HEALTH- SYSTEM PHARMACISTS

Haylee Allen, PharmD, BCPS, BCPP // SDSHP President



Greetings from the South Dakota Society of Health-System Pharmacists!

At SDSHP, we were happy to hear that it was still game on for **SDPhA's Annual Convention** despite the ongoing pandemic. Congratulations on the successful first virtual convention ever in SDPhA's history! This year has brought many challenges to our health systems and pharmacy

organizations, but has also given us the opportunity to adapt, get creative, and grow stronger together.

One of our usual highlights at this time of year is our **SDSHP Annual Conference**. While we did not have the chance to host our 44th Annual Conference in Sioux Falls due to the initial stages of the pandemic, we did have the chance to connect with our membership base using virtual technology for our business meeting. During the business meeting the new Board Members inducted included Joseph Berendse as Past President, myself as President, Jeremy Daniel as President-Elect, Chance Wachholtz as Secretary, Khia Warzecha as Treasurer, Jordan Baye and Stephanie Iverson as Board Members-at-Large, Jodi Sterrett as Technician Board Member, and Dustin Moon and Emma Smith as Student Board Members. Douglas Smith was recognized as this year's recipient of the Gary W. Karel Lecture Award. Doug will receive his award and have the opportunity to give his lecture at our next Annual Conference.

Other events included the **8th Annual SDSHP Statewide Residency Conference** which was held virtually this year in light of COVID-19. Content was split up and presented on July 8th and July 9th. Pharmacy residents throughout the state were invited to this conference, which provided the residents an opportunity to network with others and gain knowledge on topics that will benefit them throughout their residency year. A big thank you to our outgoing resident liaison – Khia Warzecha – for her efforts in not only coordinating this event, but also in being flexible and resilient with the changes for this year's conference!

The **19th Annual Gary Van Riper Society Open Golf Classic** was held at the Central Valley Golf Course in Hartford, SD on Friday, July 24th. Thirty-six players braved the heat and humidity for a fun day of golfing! This event supports SDSU student pharmacists by providing academic scholarships and funding for travel to the ASHP Clinical Skills Competition in December. SDSHP would like to extend a special thank you to our Platinum Sponsors: Gary & Sharon Van Riper, Tyler & Kristin Turek, First Premier Bank, Pharmacists Mutual, and South Dakota State University College of Pharmacy and Allied Health Professions. Thank you to all the participants, and a special thanks to Tyler Turek for planning and coordinating this successful event!

#### UPCOMING EVENTS:

- **The Dakota Night Reception** at the ASHP Midyear Clinical Meeting will be virtual this year, as the meeting itself is virtual. More details to come, so keep an eye on your e-mail's!
- **45th Annual SDSHP Conference:** Mark your calendars! Our annual conference is scheduled for April 9-10th, 2020. Format is still being determined between in person (the Holiday Inn City Centre in Sioux Falls, SD) versus virtual. We will keep you updated as soon as a decision is made.
- **CE & SPF:** Dates for the resident CE events and SPF sessions have not been set yet. Please watch your e-mail for more information within the next month or two!

We invite you to stay engaged by visiting SDSHP's website at [www.sdsph.com](http://www.sdsph.com). There you can learn more about SDSHP and find a current list of upcoming events!

Respectfully submitted,

**HAYLEE ALLEN,**  
PharmD, BCPS, BCPP

SDSHP President

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technicians university

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PHARMACISTS  
ASSOCIATION



## PHARMACY TECHNICIANS UNIVERSITY

### THE BEST-IN-CLASS TRAINING PROGRAM FOR PHARMACY TECHNICIANS

#### FAQS

##### What is Pharmacy Technicians University (PTU)?

A comprehensive online pharmacy technician training program, designed for technicians of all levels that includes exam prep for the PTCE® and ExCPT exams, as well as the CSPT™ exam. PTU is engaging, self-paced, and interactive!

##### What does it cost?

SDPhA is committed to providing this program at the most reasonable rates possible. For more information: [sdpha@sdpha.org](mailto:sdpha@sdpha.org)

##### Why should I use PTU?

You will get:

- Easy-to-use and interesting course materials like videos and slides
- Modules divided into short parts you can complete at your own pace
- Knowledge checks and learning activities to help you remember what you learned
- Web-based training for access from any Internet-connected computer
- Thorough exam prep for PTCE®, ExCPT, and CSPT™ exams

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PHARMACY  
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UNIVERSITY  
PTU ELITE: CSPT®  
PREP PROGRAM

PREPARE YOUR TECHS FOR SUCCESS ON  
THE PTCB STERILE COMPOUNDING EXAM

The *Pharmacy Technicians University (PTU)* Elite CSPT® (Compounded Sterile Preparation Technician) Prep Program provides an efficient and affordable program to prepare your PTCB-certified techs to pass the PTCB CSPT® exam. This new online exam prep program includes didactic and simulation courses on essential compounding knowledge standards, and is convenient, interactive, and easy to use.

BENEFITS

- \* **Shorter Prep Time:** Trainees who complete this PTCB-recognized program can sit for the CSPT® exam with just 1 year of experience in compounded sterile preparation (versus the standard 3-year requirement)
- \* **High-Quality and Comprehensive:** Curriculum aligned with PTCB's high standards for CSPT® certification. Courses cover all relevant topics, including compliance requirements for USP <797> and USP <800>
- \* **Top Pass Rates:** PTU grads boast a 77% pass rate on the PTCE® exam — 20% higher than the national average

Now, currently-practicing, nationally-certified pharmacy technicians can participate in the *PTU* Elite CSPT® Prep Program, saving you money and saving your technicians time. Plus, you'll be better prepared for Board of Pharmacy audits and reviews, and to demonstrate your commitment to quality, medication safety, and a higher level of patient care.

The program curriculum includes 27 didactic hours and 32 simulation hours. See reverse for complete curriculum list.



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PTU ELITE: CSPT PREP PROGRAM CURRICULUM

INTRODUCTION

- \* Introduction & Orientation
- \* CSPT Training Questionnaire

BASIC PHARMACEUTICS

- \* Parenteral Dosage Forms
- \* Ratios
- \* Proportions

DOSAGE CALCULATIONS

- \* Weight-Based Dosages
- \* Dosage Calculations: Parenterals
- \* Dosage Calculations: Milliequivalents and Units

COMPOUNDING CALCULATIONS I

- \* Compounding Calculations
- \* Percentage Calculations
- \* Drug Concentration Calculations
- \* Dilution Calculations

COMPOUNDING CALCULATIONS II

- \* Infusion Calculations
- \* Alligation Calculations

PHARMACOLOGY REFERENCES

- \* CSPT® Medications List
- \* Pharmacology Key Points Reference
- \* Injectable Anticoagulants
- \* Dispensing Insulin and Other Injectable Medications

MEDICATION SAFETY

- \* Safety Data Sheets

INSTITUTIONAL PHARMACY PRACTICE

- \* Hospital: Medication Preparation
- \* Hospital: Medication Delivery
- \* Medication Disposal in the Hospital
- \* Dispensing Medications for Surgeries
- \* Medication Delivery in the Hospital
- \* Using Barcodes
- \* Hospital: Patient Safety Practices

REVIEW

- \* CSPT Practice Exam

STERILE COMPOUNDING I

- \* Sterile Compounding
- \* Sterile Compounding: Personal Protective Equipment
- \* Sterile Compounding: Aseptic Handwashing
- \* Simulation: Aseptic Hand Washing
- \* Sterile Compounding: The Laminar Flow Hood
- \* Laminar Flow Hood Simulation

STERILE COMPOUNDING II

- \* Sterile Compounding: Syringes and Needles
- \* Sterile Compounding: Supplies and Equipment
- \* Preparation of Sterile Compounds
- \* Using Aseptic Technique for Sterile Compounding
- \* Quality Standards and Requirements
- \* Maintaining Environmental Processes for Sterile Compounding
- \* Simulation: IV Fluid Preparation
- \* Simulation: IV Piggyback
- \* Simulation: IV Push
- \* Simulation: Manipulate Ampules
- \* Simulation: Reconstitute Lyophilized Powder
- \* Simulation: Parenteral Nutrition

STERILE COMPOUNDING SUPPLEMENTAL RESOURCES

- \* ASHP's Guidelines on Compounding Sterile Preparations
- \* ISMP's Guidelines for Safe Preparation of Compounded Sterile Preparations

CHEMOTHERAPY COMPOUNDING

- \* Chemotherapy Overview
- \* Chemotherapy Prep
- \* Simulation: Chemotherapy Agent Preparation

HAZARDOUS MEDICATION HANDLING

- \* ASHP's Guidelines on Handling Hazardous Drugs
- \* NIOSH List of Antineoplastic and Other Hazardous Drugs

DRUG INFORMATION RESOURCES

- \* Package Inserts Part I
- \* Package Inserts Part II
- \* Drug Information Resources

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PTU ELITE: SOFT  
SKILLS PROGRAM

SHARPEN YOUR TECHS' SOFT SKILLS TO  
IMPROVE TEAMWORK AND PATIENT CARE

Designed exclusively for the pharmacy technician role, the *Pharmacy Technicians University (PTU) Elite: Soft Skills Program* helps techs build and develop essential competencies that lead to safer, patient-centered care and improved staff retention.

With a focus on communication, empathy, leadership, conflict management, and teamwork, this online program combines practice-ready clinical resources with multimedia modules to foster harmonious, well-rounded pharmacy teams.

BENEFITS

- \* **Enhance patient care** - Technicians learn actionable communication tactics to defuse tense situations, acknowledge sensitive topics, and put patients at ease.
- \* **Improve teamwork** - Technicians gain skills in collaboration, managing up, leadership, and more.
- \* **Support career development** - Investing in well-rounded technicians leads to lower turnover and higher job satisfaction.

The *PTU Elite: Soft Skills Program* is an 11-didactic-hour online solution that builds soft skills competency using video simulations, case studies, and real-world scenarios that are specific to pharmacy technicians and the pharmacy setting. Each student receives a certificate upon successful completion of the program.



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PTU ELITE: SOFT SKILLS PROGRAM CURRICULUM

Interactive learning modules in each course make implementation of new skills easy, and include highly-relevant, concise, technician-specific information. Each student receives a certificate upon successful completion of the *PTU: Elite Soft Skills Program*.



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# 134th Annual CONVENTION

## GAME ON

# AWARD WINNERS

### Doug Johnson 2020 Bowl of Hygeia Award



The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) presented the Bowl of Hygeia Award to Tyndall, South Dakota pharmacist Doug Johnson. Johnson has a long history of service to both his community and the profession. He graduated from South Dakota State University School of Pharmacy in 1969 and went to work for

the pharmacy he had worked for while going to school—Kendall's Pharmacy in Brookings. In 1970, he was called to the service (he had been in the ROTC while at SDSU) and spent two years serving in the Vietnam War. Returning home from Vietnam in 1972, he returned to his post at Kendall's. From there, life took him to Statz Drug in Mitchell for one year and then back home to the farm where he was raised outside of Tyndall. While farming, he did relief pharmacy work for the Human Services Center in Yankton and also for Bill and Greg Hoch at Hoch Drug in Tyndall. He eventually took full-time employment at Hoch Drug. In 2003, he was presented with an opportunity (he explains it as an adventure) whereby the Bon Homme Clinic and St. Michael's Hospital approached him and said, "We've got an empty room...make it into a pharmacy." He did just that and was the Pharmacist in Charge there until his retirement in 2010. Retirement just expanded his reach as he shared his profession in a radius of 120 miles, becoming a relief pharmacist and thus greatly in demand in Winner, Gregory, Burke, Wagner, Tyndall, Scotland, Parkston, Vermillion and Elk Point. We are all very grateful this was his calling—relief pharmacists are extremely valuable to rural South Dakota pharmacies.

### Lori Ollerich 2020 Husted Award



The Husted Award recognizes exceptional contributions and accomplishments to the pharmacy profession in South Dakota. Lori Ollerich has worked at Pharmacy Specialties in Sioux Falls since she graduated from SDSU in 2007 - a true testament to her loyalty, dedication and strong work ethic. Compounding requires out-of-the-box thinking, which is the many reasons Lori is so suited to this work. She

is tasked with knowing what medication the doctor wants to use, but she helps the patient to receive the medication in the best way possible. Compounding offers medication problem solving with alternative dosage forms. The patient, pharmacist, physician triad is important to Lori and her resourcefulness is vital. Her compassion for patients in need of alternative medications make her one of the best. She will always face a task head on, and even when there is not an easy solution, she will take the route of what is best for her patient. Lori has served this past year as President of the South Dakota Pharmacists Association, and has been active in SDPhA since college – moving through the various chairs of the association board. Just as in the pharmacy, at SDPhA, Lori is always a team player. Her fellow board members describe her as an outstanding leader who never shies away from the complicated or complex legislative or other advocacy issues. A true servant-leader, she's always there until the job is done, and will never have you work alone.

### Brenda Jensen 2020 SDPhA Pharmacy Technician of the Year



Brenda Jensen owns her own consulting business that develops standard operating procedures for sterile and nonsterile compounding pharmacies, and has worked with more than 300 pharmacies in 45 states on compliance and training to achieve or maintain PCAB/NABP VPP or UCAP accreditation and/or compliance with USP or state laws. She's assisted more than 150 pharmacies through the PCAB

accreditation or re-accreditation process, and provides onsite ACPE-accredited trainings. Jensen has paved the way to bring technicians to the table in a very big way – with appointments to the USP <797> Sterile Compounding Expert Panel, USP Compounding Expert Committee and the USP <825> Compounding – Radiopharmaceuticals Expert panel. She's also served in various capacities with IACP, APC, APhA and ASHP – among others. In addition, she volunteers around the world for Habitat for Humanity Global Village.

### Tim Arnold 2020 SDPhA Outstanding Industry Salesperson of the Year



Collaborative, fair and honest – Tim Arnold has gone above and beyond to support South Dakota pharmacists in 2020. At the beginning of the COVID-19 crisis, when demand was extremely high, and disinfecting alcohol products were impossible to find, he and his team secured a large quantity for one of our state's regional chains and did so in a fair and ethical way – with no prices increases – in

spite of the work and the increased demand. This work took a huge burden off of a number of pharmacists, and showed exceptional support for the profession during some very trying and stressful times.

### Josh Ohrtman 2020 SDPhA Distinguished Young Pharmacist



This award is dedicated to a pharmacist practicing for less than 10 years, who shows exceptional commitment to the profession and their community. This year's recipient has gone above and beyond to advance the profession and serve his community. Josh Ohrtman has been the champion and Luminary for the South Dakota Community Pharmacist Enhanced Services Network

(CPESN). Ohrtman has been instrumental in negotiating contracts and setting service sets with national and state payors for the network. That excellent work has made the South Dakota network a gold standard for other small states to follow such as Wyoming, Montana, Idaho, and even Minnesota. Ohrtman has been a national leader in defining care plan programming for community pharmacy. He also secured a grant from NCPA for the CPESN South Dakota Network pharmacies in the Flip the Pharmacy program. This past year he also started a pre-hypertension, and pre-diabetes program in conjunction with the South Dakota Department of Health for which the pharmacies get reimbursed for their positive outcomes.

# PLEASE THANK

## our Virtual Convention Sponsors and Exhibitors, listed on page 36.



# 50

## YEAR PHARMACISTS

Welcome to the most exclusive club in South Dakota pharmacy – those who have been licensed for 50 or more years. This year we have 4 pharmacists originally licensed in South Dakota who join that exclusive club. Our thanks to these dedicated professionals!

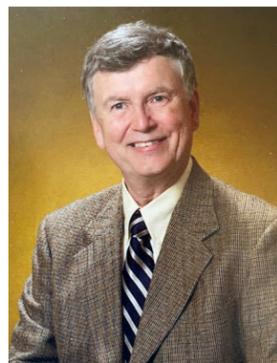
### Doug Johnson / Tyndall, SD



I graduated from SDSU in 1969 from the College of Pharmacy. After finishing my internship, I took the state boards in 1970 and went to work for Kendall Drug in Brookings, SD. From there I worked for Statz Drug in Parkston, SD and also farmed in the Tyndall area. I continued to do pharmacy relief work until I went to work for Hoch Drug in Tyndall which lead to becoming the Director of Pharmacy at

St. Michael's Hospital and Bon Homme Pharmacy. After retiring, I went back to doing pharmacy relief work, and continue to this day. I have had the privilege of working with many great Pharmacy Techs and Pharmacists over the years and I believe the profession of Pharmacy is being served very well by each new generation of professionals.

### Dennis Jones / Sioux Falls, SD



I graduated with a BS in Pharmacy from SDSU in 1969. My first job as a pharmacist was with Osco Drug in Albert Lea, MN. A year later, I accepted a position at St. John's Hospital in Huron, SD. After ten months, I was asked to be the Director of Pharmacy. For several years, I taught pharmacology to students attending St. John's School of Nursing.

I served as a preceptor to many students from SDSU and was honored with Preceptor of the Year Award in 1987. Attended most annual State Association functions which provided opportunities to make friends and share information; district (Huron) president many times. I was referred by the Pharmacy Association to Gov. Mickelson to serve on the State Board of Pharmacy, reappointed by Gov. Janklow and Gov. Miller; board member from 1987 to 1997, president several times. Active in NABP, member of Nomination and NAPLEX Committees.

In 1997, appointed Executive Secretary of the State Board of Pharmacy; moved the SD Board of Pharmacy office from Pierre to Sioux Falls. During my time on the board we worked through many challenges and changes. Computers

transformed the way we were able to collect data, communicate and conduct business, which required updating many old regulations and statutes, and allowing for telepharmacies to serve remote locations. Authorization for pharmacists to administer the flu vaccine without a prescription is another highlight.

I was privileged to receive the 2005 SDPhA Honorary President Award, 2007 Board of Pharmacy 20 years of Service Award, the 2008 Pharmacist of the Year Award from the Society of Health System Pharmacists, and 2008 Husted Award for Pharmacist of the Year from SDPhA.

I liked being a pharmacist. Not a day went by without being presented or learning something of interest. I enjoyed the challenges of my job and strived to positively impact people's lives. Thanks to Dean Heitbrink for teaching me much of what I learned as a student, and for all he did for pharmacists and the PharmD program. The Board was also instrumental in moving the administration of President Wagner to seek legislative approval for the program. Thank you to my fellow Board Members with whom I served, and all the pharmacists and support staff that I was fortunate to work with over the years. I want to thank Rene Hixon, my faithful secretary who deserves much credit for what was accomplished while I was the Executive Secretary of Pharmacy. Most of all, thank you to my wonderful and supportive wife, Karen and our three children Zach, Sarah, and Adam. It has been an honor to be a pharmacist and serve in the profession for fifty years!

### Robert Lewis / Sioux Falls, SD



Graduate SDSU 1969.

Registered South Dakota 6/25/1970.

Started at McKennan Hospital 2/1/1971 retired 6/13/2014 added an additional 5 years as parttime/prn with officially retiring 2/14/2020.

President of the SD Society of Health System Pharmacists 1979.

Pharmacist of the year SD

Society of Health System Pharmacists 2006.

I have enjoyed the many years of attending the conventions and the friendships that I have developed over the years.

### Richard Amundson / Watertown, SD

## 2019/2020 COMMERCIAL & LEGISLATIVE DISTRICT DUES CONTRIBUTIONS

FIRST NAME \_\_\_\_\_ LAST NAME \_\_\_\_\_

ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP CODE \_\_\_\_\_

HOME PHONE \_\_\_\_\_ MOBILE PHONE \_\_\_\_\_

EMPLOYER / COMPANY \_\_\_\_\_

WORK ADDRESS \_\_\_\_\_

WORK CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP CODE \_\_\_\_\_

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Do you wish to receive SDPhA email alerts regarding important pharmacy issues?  YES  NO

### COMMERCIAL & LEGISLATIVE FUND Memberships set by SDPhA C & L Executive Committee, 2007

### PHARMACY OR BUSINESS MEMBERSHIP \$100.00 Includes One Individual Membership

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### CORPORATE MEMBERSHIP \$200.00 Two or more stores of the same corporation

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NAME OF INDIVIDUAL INCLUDED \_\_\_\_\_

### INDIVIDUAL MEMBERSHIP

\$50 LEVEL  \$75 LEVEL  OTHER \$ \_\_\_\_\_

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ROSEBUD - \$10.00    SIOUX FALLS - \$20.00    WATERTOWN - \$20.00    YANKTON - \$15.00

### TOTAL ENCLOSED

\$ \_\_\_\_\_

MAIL TO: SD PHARMACISTS ASSOCIATION, BOX 518, PIERRE, SD 57501-0518 / FAX: 605-224-1280

## Pharmacist Consult: CDC–Hepatitis A, Part 2: Prevention & Vaccinations

Knowledge-based CPE

**Course Sponsorship:** This course is sponsored by the South Dakota State University College of Pharmacy and Allied Health Professions, Brookings, SD.

**Course Development:** The following material was published by the Centers for Disease Control and Prevention (CDC): *Hepatitis A Questions and Answers for Health Professionals*.

Permission has been granted by the CDC for the use of this material in Continuing Pharmacy Education for pharmacists.

**GOAL:** To enhance pharmacists' knowledge hepatitis A vaccination recommendations.

### LEARNING OBJECTIVES:

1. Identify the currently available hepatitis A vaccines and describe their protection benefits;
2. Evaluate the hepatitis A vaccines safety profile for both concurrent use with other vaccines and administration to patients with coincidental medical conditions;
3. Counsel patients on the availability of hepatitis A vaccines and place in therapy;
4. Counsel patients on the place in therapy for immune globin pre- or post-hepatitis A virus (HAV) exposure.

**OVERVIEW & STATISTICS:** Hepatitis A Questions and Answers for Health Professionals

### What is the case definition for acute hepatitis A?

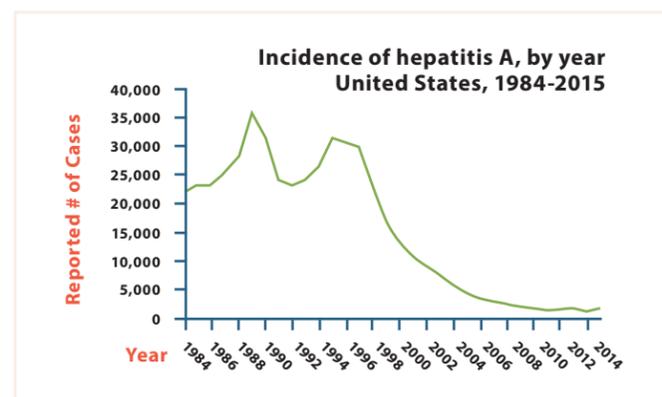
The clinical case definition for acute viral hepatitis is discrete onset of symptoms consistent with hepatitis (e.g., nausea, anorexia, fever, malaise, or abdominal pain) AND either jaundice or elevated serum aminotransferase levels.

Because the clinical characteristics are the same for all types of acute viral hepatitis, hepatitis A diagnosis must be confirmed by a positive serologic test for immunoglobulin M (IgM) antibody to hepatitis A virus, or the case must meet the clinical case definition and occur in a person who has an epidemiologic link with a person who has laboratory-confirmed hepatitis A (i.e., household or sexual contact with an infected person during the 15–50 days before the onset of symptoms).

### How common is hepatitis A virus infection in the United States?

Hepatitis A rates in the United States have declined by more than 95% since hepatitis A vaccine first became available in 1995. (National Notifiable Diseases Surveillance System (NNDSS), [https://www.cdc.gov/mmwr/mmwr\\_nd/index.html](https://www.cdc.gov/mmwr/mmwr_nd/index.html))

In 2015, a total of 1,390 cases of hepatitis A were reported to CDC from 50 states, a 12.2% increase from the number of reported cases in 2014. However, the overall incidence rate in 2015 was 0.4 cases per 100,000 population, the same as 2014. After adjusting for under-ascertainment and under-reporting, an estimated 2,800 hepatitis A cases occurred in 2015.



### HEPATITIS A VACCINATION

#### Who should be vaccinated against hepatitis A?

The Advisory Committee on Immunization Practices (ACIP) recommends that the following persons be vaccinated against hepatitis A:

- All children at age 1 year,

- Persons who are at increased risk for infection,
- Persons who are at increased risk for complications from hepatitis A, and
- Any person wishing to obtain immunity (protection).

### Children

ACIP recommends that all children in the United States receive hepatitis A vaccine at 1 year of age (i.e., 12-23 months) to avoid interference by passive maternal anti-HAV that may be present during the first year of life. In the United States, children who are not vaccinated by 2 years of age can be vaccinated at subsequent visits; vaccination can be considered for children 2 to 18 years old and for anyone who wants protection against hepatitis A infection. Booster doses are not recommended. More information is available at: [www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm)

### Persons at Increased Risk for Hepatitis A Infection

#### Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A.

Persons who travel to developing countries are at high risk for hepatitis A, even those traveling to urban areas, staying in luxury hotels, and those who report maintaining good hand hygiene and being careful about what they drink and eat (see <https://wwwnc.cdc.gov/travel/yellow-book/2018/infectious-diseases-related-to-travel/hepatitis-a-for-more-information>).

**Men who have sex with men.** Men who have sex with men should be vaccinated.

**Users of injection and non-injection drugs.** Persons who use injection and non-injection drugs should be vaccinated.

**Persons who have occupational risk for infection.** Persons who work with HAV-infected primates or with HAV in a research laboratory setting should be vaccinated. No other groups have been shown to be at increased risk for HAV infection because of occupational exposure.

**Persons who have chronic liver disease.** Persons with chronic liver disease who have never had hepatitis A should be vaccinated, as they have a higher likelihood of having fulminant hepatitis A (i.e., rapid onset of liver

failure, often leading to death). Persons who are either awaiting or have received liver transplants also should also be vaccinated.

**Persons who have clotting-factor disorders.** Persons who have never had hepatitis A and who are administered clotting-factor concentrates, especially solvent detergent-treated preparations, should be vaccinated.

#### Household members and other close personal contacts of adopted children newly arriving from countries with high or intermediate hepatitis A endemicity.

Previously unvaccinated persons who anticipate close personal contact (e.g., household contact or regular babysitting) with an international adoptee from a country of high or intermediate endemicity during the first 60 days following arrival of the adoptee in the United States should be vaccinated. The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee. More information is available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5836a4.htm>.

**Persons with direct contact with persons who have hepatitis A.** Persons who have been recently exposed to HAV and who have not previously received hepatitis A vaccine should be vaccinated. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm>

### Which hepatitis A vaccines are licensed for use in the United States?

Two single-antigen hepatitis A vaccines and one combination vaccine are currently licensed in the United States. All are inactivated vaccines.

#### Single-antigen hepatitis A vaccines

- HAVRIX® (manufactured by GlaxoSmithKline) PDF–16 pages
- VAQTA® (manufactured by Merck & Co., Inc) PDF–18 pages

#### Combination vaccine

- TWINRIX® (manufactured by Glaxo-SmithKline): Combined hepatitis A (in a lower dosage than single-antigen formulations) and hepatitis B vaccine. PDF–14 pages

(continued on page 22)

## HAVRIX®<sup>1</sup> Licensed dosages and schedules for HAVRIX®<sup>1</sup>

AGE	DOSE ELISA units <sup>2</sup>	VOLUME mL	NO. OF DOSES	SCHEDULE mos <sup>3</sup>
12 mos - 18 years	720	0.5	2	0, 6-12
≥19 years	1,440	1.0	2	0, 6-12

<sup>1</sup>Hepatitis A vaccine, inactivated, GlaxoSmithKline. <sup>2</sup>Enzyme-linked immunosorbent assay units. <sup>3</sup>0 months represents timing of the initial dose; subsequent numbers represent months after the initial dose.

## VAQTA®<sup>1</sup> Licensed dosages and schedules for VAQTA®<sup>1</sup>

AGE	DOSE U <sup>2</sup>	VOLUME mL	NO. OF DOSES	SCHEDULE mos <sup>3</sup>
12 mos - 18 years	25	0.5	2	0, 6-18
≥19 years	50	1.0	2	0, 6-18

<sup>1</sup>Hepatitis A vaccine, inactivated, Merck & Co., Inc. <sup>2</sup>Units. <sup>3</sup>0 months represents timing of the initial dose; subsequent numbers represent months after the initial dose.

## TWINRIX®<sup>1</sup> (HepA/HepB) Vaccine Schedule (Not recommended for post exposure prophylaxis) Licensed dosages and schedules for TWINRIX®<sup>1</sup>

AGE	DOSE ELISA units <sup>2</sup>	VOLUME mL	NO. OF DOSES	SCHEDULE
≥18 years	720	1.0	3	0, 1, 6 mos
≥18 years	720	1.0	4	0, 7, 21-30 days + 12 mos <sup>3</sup>

<sup>1</sup>Combined hepatitis A and hepatitis B vaccine, inactivated, GlaxoSmithKline. <sup>2</sup>Enzyme-linked immunosorbent assay units. <sup>3</sup>This 4-dose schedule enables patients to receive 3 doses in 21 days; this schedule is used prior to planned exposure with short notice and requires a fourth dose at 12 months.

## How long does protection from hepatitis A vaccine last?

The exact duration of protection after vaccination is unknown. Anti-HAV has been shown to persist for at least 20 years in adults administered inactivated vaccine as children with the three-dose schedule (19), and anti-HAV persistence of at least 20 years also was demonstrated among persons vaccinated with a two-dose schedule as adults (20). Detectable antibodies are estimated to persist for 40 years or longer based on mathematical modeling and anti-HAV kinetic studies (20, 21).

## Can hepatitis A vaccine be administered concurrently with other vaccines?

Yes. Hepatitis B, diphtheria, poliovirus (oral and inactivated), tetanus, typhoid (oral and intramuscular), cholera, Japanese encephalitis, rabies, and yellow fever vaccines can be given at the same time that hepatitis A vaccine is given, but at a different injection site (22, 23–25).

In studies among young children, simultaneous administration of hepatitis A vaccine did not affect the immunogenicity or reactogenicity of diphtheria-tetanus-acellular pertussis; inactivated polio; measles, mumps, rubella (MMR); hepatitis B; and Haemophilus influenzae type b vaccines. (22, 26–27)

## Can a patient receive the first dose of hepatitis A vaccine from one manufacturer and the second (last) dose from another manufacturer?

Yes. Results of several studies indicate that the response of adults administered hepatitis A vaccine according to a schedule that mixed the two single-antigen vaccines currently licensed in the United States was equivalent to that of adults vaccinated according to the licensed schedules with the single vaccine (28–29).

## What should be done if an infant receives the first dose of hepatitis A vaccine at an age younger than 12 months?

Although no known harm is associated with giving hepatitis A vaccine to infants, the hepatitis A vaccine dose(s) administered prior to 12 months of age might result in a suboptimal immune response, particularly in infants with passively acquired maternal antibody (30–31). Therefore, hepatitis A vaccine dose(s) administered at <12 months of age are not considered valid doses.

The hepatitis A vaccine two-dose series should be initiated starting at least 6 months after the last invalid dose and when the child is at least 1 year of age.

## What should be done if the second (last) dose of hepatitis A vaccine is delayed?

The second dose should be given as soon as possible. Even if the second dose is delayed, the first dose does not need to be repeated.

## Can hepatitis A vaccine be given during pregnancy?

Yes. Hepatitis A vaccine is recommended for pregnant women with additional medical conditions or other indications for hepatitis A vaccine. The Adult Immunization Schedule by Medical and Other Indications is available at: <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html>

A recent review of the Vaccine Adverse Event Reporting System (VAERS) did not identify any concerning patterns of adverse events in pregnant women or their infants after hepatitis A vaccination (HAVRIX, VAQTA) or hepatitis A and B combined vaccination (TWINRIX) during pregnancy. (32) Pregnant women at risk for HAV infection during pregnancy should also be counseled concerning all options to prevent HAV infection.

## Can Hepatitis A vaccine be given to immunocompromised persons (e.g., persons on hemodialysis or persons with AIDS)?

Yes. Because hepatitis A vaccine is inactivated, no special precautions need to be taken when vaccinating immunocompromised persons.

## Is it harmful to administer an extra dose(s) of hepatitis A vaccine or to repeat the entire vaccine series if documentation of vaccination history is unavailable?

No. If necessary, administering extra doses of hepatitis A vaccine is not harmful.

## Is it worthwhile to administer the first dose of hepatitis A vaccine if the timing of the second dose cannot be assured?

Yes, It is not known for how long protection from one hepatitis A vaccine dose lasts, but it has been shown to last for at least 10 years (33). One dose of single-antigen hepatitis A vaccine administered at any time before International travel can provide adequate protection for most healthy persons. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm>

## Should prevaccination testing be performed before administering hepatitis A vaccine?

To reduce the costs of vaccinating people who are already immune to hepatitis A, prevaccination testing is recommended only in certain persons, specific circumstances to reduce the costs of vaccinating people who are already immune to hepatitis A, including:

- Persons who were born in geographic areas with high or intermediate prevalence of HAV infection;
- Older adolescents and adults in certain population groups (i.e., American Indians, Alaska Natives, and Hispanics); and
- Adults in groups that have a high prevalence of infection (e.g., injection-drug users).

Prevaccination testing might also be warranted for older adults. The decision to test should be based on 1) the expected prevalence of immunity, 2) the cost of vaccination compared with the cost of serologic testing, and 3) the likelihood that testing will not interfere with initiation

of vaccination (33). Additional information is available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm>

## Should postvaccination testing be performed?

No. Postvaccination testing is not indicated because of the high rate of vaccine response among adults and children. In addition, not all testing methods approved for routine diagnostic use in the United States have the sensitivity to detect low, but protective, anti-HAV concentrations after vaccination. Additional information is available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm>

## Which groups do NOT need routine vaccination against hepatitis A?

**Food service workers.** Foodborne hepatitis A outbreaks are relatively uncommon in the United States; however, when they occur, intensive public health efforts are required for their control.

Although persons who work as food handlers have a critical role in common-source foodborne outbreaks, they are not at increased risk for hepatitis A because of their occupation. Consideration may be given to vaccination of employees who work in areas where community-wide outbreaks are occurring and where state and local health authorities or private employers determine that such vaccination is cost-effective.

**Sewage workers.** In the United States, no work-related outbreaks of hepatitis A have been reported among workers exposed to sewage.

**Health-care workers.** Health-care workers are not at increased risk for hepatitis A. If a patient with hepatitis A is admitted to the hospital, routine infection-control precautions will prevent transmission to hospital staff.

**Children under 12 months of age.** Because of the limited experience with hepatitis A vaccination among children in this age group, the vaccine is not currently licensed for children age <12 months.

**Child care center staff.** The frequency of outbreaks of hepatitis A is not high enough in this setting to warrant routine hepatitis A vaccination of staff. Hepatitis A vaccination is recommended for all children at 1 year of age, including children attending child day care centers.

## IMMUNE GLOBULIN

### What Immune Globulin product is licensed in the United States?

GamaSTAN™ S/D is the only immune globulin (IG) product approved by the U.S. Food and Drug Administration (FDA) for hepatitis A virus prophylaxis. GamaSTAN™ S/D (Grifols Therapeutics, Inc., Research Triangle Park, North Carolina) is a sterile, preservative-free solution of IG for intramuscular administration and is used for prophylaxis against disease caused by infection with hepatitis A, measles, varicella, and rubella viruses.

More information on GamaSTAN™ S/D is available at <https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM371376.pdf> [PDF – 8 pages]

### What dose of immune globulin should be used for pre- and post-exposure hepatitis A prophylaxis?

In July 2017, the prescribing information for GamaSTAN™ S/D was updated. Changes were made to the dosing instructions for hepatitis A pre- and post-exposure prophylaxis indications. These changes were made because of concerns about decreased HAV immunoglobulin G anti-body (anti-HAV IgG) potency, likely resulting from decreasing prevalence of previous HAV infection among plasma donors, leading to declining anti-HAV antibody levels in donor plasma (35).

More dosing information is available in the table below and at [https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm?s\\_cid=mm6636a5](https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm?s_cid=mm6636a5)

#### Indications and dosage recommendations for GamaSTAN S/D human immune globulin for preexposure and postexposure prophylaxis against hepatitis A infection

INDICATION	DOSE
Preexposure prophylaxis	
Up to 1 month of travel	0.1 mL/kg
Up to 2 months of travel	0.2 mL/kg
2 months of travel or longer	0.2 mL/kg
	(repeat every 2 months)
Postexposure prophylaxis	0.1 mL/kg

## HEPATITIS A AND INTERNATIONAL TRAVEL

### Who should receive protection against hepatitis A before travel?

All susceptible persons traveling to or working in countries that have high or intermediate rates of hepatitis A should be vaccinated or receive immune globulin (IG) before traveling. Persons who travel to developing countries are at high risk for hepatitis A. Even those traveling to urban areas, staying in luxury hotels, and those reporting that they maintain good hand hygiene and are careful about what they drink and eat are at high risk.

For more information on international travel and HAV, see CDC's travel page at <https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/hepatitis-a>, or ACIP updated recommendations on Prevention of Hepatitis A after Exposure to Hepatitis A Virus and in International Travelers at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm>

### How soon before international travel should the first dose of hepatitis A vaccine be given?

The first dose of hepatitis A vaccine should be administered as soon as travel is considered. For optimal protection, older adults, immuno-compromised persons, and persons with chronic liver disease or other chronic medical conditions who are planning to depart in ≤2 weeks should receive the initial dose of vaccine and also can simultaneously be administered immune globulin at a separate anatomic injection site.

Information on immune globulin dosing is available at [https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm?s\\_cid=mm6636a5](https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm?s_cid=mm6636a5)

Additional information on hepatitis A vaccine and travel is available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm>

### What should be done if a traveler cannot receive hepatitis A vaccine?

Travelers who are allergic to a vaccine component, who elect not to receive vaccine, or who are aged <12 months should receive a single dose of immune globulin, which provides effective protection against Hepatitis A virus infection for up to 2 months depending on the dosage given.

Information on immune globulin dosing is available at [https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm?s\\_cid=mm6636a5\\_e](https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm?s_cid=mm6636a5_e)

### What should be done for international travelers <12 months of age?

Because hepatitis A vaccine is currently not approved for use in this age group, immune globulin is recommended. Information on immune globulin dosing is available at [https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm?s\\_cid=mm6636a5\\_e](https://www.cdc.gov/mmwr/volumes/66/wr/mm6636a5.htm?s_cid=mm6636a5_e)

The two-dose hepatitis A vaccine series should be initiated when the child is at least 1 year of age.

## POSTEXPOSURE PROPHYLAXIS FOR HEPATITIS A

### What are the current CDC guidelines for post-exposure protection against hepatitis A?

Persons who have been exposed recently to hepatitis A virus (HAV) and who have not been vaccinated should be administered one dose of single-antigen hepatitis A vaccine or immune globulin (IG) as soon as possible, **within 2 weeks after exposure**. The guidelines vary by age and health status:

- For healthy persons aged 12 months–40 years, single-antigen hepatitis A vaccine at the age-appropriate dose is preferred to IG because of the vaccine's advantages, including long-term protection and ease of administration, as well as the equivalent efficacy of vaccine to IG.
- For persons aged >40 years, IG is preferred because of the absence of information regarding vaccine performance in this age group and because of the more severe manifestations of hepatitis A in older adults. The magnitude of the risk of HAV transmission from the exposure should be considered in decisions to use vaccine or IG in this age group.

# CONTINUING EDUCATION *for* PHARMACISTS

- Vaccine can be used if IG cannot be obtained. IG should be used for children aged <12 months, immunocompromised persons, persons with chronic liver disease, and persons who are allergic to the vaccine or a vaccine component (see **Footnote**).

## Footnote:

IG is indicated for persons at increased risk of severe or fatal hepatitis A infection. These persons include adults >40 years of age (particularly adults 75 years and older), persons with chronic liver disease (e.g., cirrhosis), and those who are immunocompromised.

- IG is indicated for persons with decreased response to hepatitis A vaccine, such as immunocompromised persons. Immunocompromised persons include, but are not limited to persons:
  - with congenital/acquired immunodeficiency;
  - with HIV/AIDS;
  - with chronic renal failure/undergoing hemodialysis;
  - who have received solid organ, bone marrow, or stem cell transplants;
  - who have iatrogenic immunosuppression (diseases requiring treatment with immunosuppressive drugs [e.g., TNF-alpha inhibitors], including long-term systemic corticosteroids and radiation therapy. Immune status relative to the dose of immunosuppressive drugs should be assessed by the provider); and
  - who are otherwise less capable of developing a normal response to immunization.

CDC does not have official guidance to define all subgroups of persons recommended to receive IG. Further clinical guidance should be obtained for patients whose immune status is unclear.

## ACTIVE LEARNING QUESTION

**True / False:** For **post-exposure protection** among persons aged >40 years, IG is preferred because of the absence of information regarding vaccine performance in this age group and because of the more severe manifestations of hepatitis A in older adults.

## Who requires protection (i.e., immune globulin (IG) or hepatitis A vaccine) after exposure to HAV?

**Close personal contacts.** Close personal contacts of persons with serologically confirmed hepatitis A (i.e., through a blood test), including:

- household and sex contacts and
- persons who have shared injection drugs with someone with hepatitis A.

Consideration should also be given to providing IG or hepatitis A vaccine to persons with other types of ongoing, close personal contact with a person with hepatitis A (e.g., a regular babysitter or caretaker).

## Child-care center staff, attendees, and attendees' household members.

- Post-exposure prophylaxis (PEP) should be administered to all previously unvaccinated staff and attendees of child-care centers or homes if 1) one or more cases of hepatitis A is recognized in children or employees or 2) cases are recognized in two or more households of center attendees.
- In centers that provide care only to older children who no longer wear diapers, PEP should be administered only to classroom contacts of the index patient (not to children or staff in other classrooms).
- When an outbreak occurs (i.e., hepatitis A cases in three or more families), PEP should also be considered for members of households that have diaper-wearing children attending the center.

**Persons exposed to a common source, such as an infected food handler.** If a food handler receives a diagnosis of hepatitis A, post-exposure prophylaxis (PEP) should be administered to other food handlers at the same establishment. Because transmission to patrons is unlikely, PEP administration to patrons typically is not indicated but may be considered if 1) during the time when the food handler was likely to be infectious, the food handler both directly handled uncooked foods or foods after cooking and had diarrhea or poor hygienic practices, and 2) patrons can be identified and treated within 2 weeks of exposure.

In settings in which repeated exposures to HAV might have occurred (e.g., institutional cafeterias), stronger consideration of PEP use might be warranted.

## If a case of hepatitis A is found in a setting providing services to children or adults, such as a school, hospital, office setting, corrections facility or homeless shelter, what should be done?

PEP is not routinely recommended when a single case of hepatitis A is identified in a school (other than a child care setting in which children wear diapers), in an office or other work setting, a corrections facility, or homeless shelter, and if the source of infection is outside of the setting.

Similarly, hospital-based health-care workers are not recommended to receive PEP when a person who has hepatitis A is admitted to the facility; instead, careful hygienic practices should be emphasized. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm>

If it is determined that hepatitis A has been spread among students in a school or among patients and staff in a hospital, PEP should be administered to unvaccinated persons who have had close contact with an infected person. Similarly, if hepatitis A has spread among occupants or staff in a homeless shelter or corrections facility, PEP should be administered to unvaccinated persons who have had close contact with an infected person.

## Should hepatitis A vaccine be recommended for individuals displaced by a disaster?

Although hepatitis A vaccine is recommended for all children in the United States at age 1 year (i.e., 12-23 months) and high-risk adults, evacuation itself is not a specific indication for hepatitis A vaccination of previously unvaccinated children or adults unless exposure to hepatitis A virus is suspected. Persons who evacuate their homes under orderly conditions to a congregate setting where sanitary conditions prevail should not require hepatitis A vaccine as a result of their evacuation status, unless they have been evacuated from an area where exposure to hepatitis A virus is likely or have been exposed to persons with suspected or proven hepatitis A infection. Additional information is available at <https://www.cdc.gov/disasters/disease/vaccine/displaced.html>

## ACTIVE LEARNING QUESTION

**True / False:** Travelers who are allergic to a vaccine component, who elect not to receive vaccine, or who are aged <12 months should receive a single dose of immune globulin, which provides effective protection against Hepatitis A virus infection for up to 2 months depending on the dosage given.

**Disclosure:** The developers and reviewers of this course have had no financial relationships with any commercial entities having a vested interest in this topic.

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## Pharmacist Consult: CDC–Hepatitis A, Part 2: Prevention & Vaccinations

..... Learning Assessment – Post-test. Select correct answer(s) for each question.

- For a clinical case definition of acute viral hepatitis, symptoms should include:
  - One of more of the following: nausea, anorexia, fever, malaise, or abdominal pain)
  - Either jaundice OR elevated serum aminotransferase levels.
  - Both jaundice AND serum aminotransferase levels
  - A and B
- ACIP recommends that all children in the United States receive hepatitis A vaccine \_\_\_\_\_ ,
  - at 6 months of age.
  - at 1 year of age (i.e., 12-23 months) to avoid interference by passive maternal anti-HAV that may be present during the first year of life.
  - In the United States, children who are **not** vaccinated by 2 years of age should **not** be subsequently vaccinated against HAV.
  - All of the above.
- Select the **correct** statement(s):
  - A positive serologic test for immunoglobulin M (IgM) is one of the diagnostic criteria for confirming a hepatitis A infection
  - An estimated 2,800 hepatitis A cases occurred in 2015.
  - Hepatitis A rates have declined by more than 95% since 1995 when the hepatitis A vaccine first became available.
  - All of the above
- Select the **correct** statement(s):
  - HAVRIX® and VAQTA® are inactivated vaccines
  - TWINRIX® is a single antigen hepatitis A vaccine
  - VAQTA® is a combination hepatitis A vaccine
  - All of the above.
- The following persons are at increased risk and should be vaccinated against hepatitis A
  - People with chronic liver disease
  - Users of illegal drugs
  - Men who have sex with men
  - Persons with clotting factor disorders
- Select the **correct** statement(s) below:
  - HAVRIX® is a single-antigen vaccine, to be administered in a 2-dose series.
  - VAQTA® 1 is a single-antigen vaccine, to be administered in a 2-dose series.
  - TWINRIX® is a combination HepA/HepB vaccine, to be administered in either a 3-dose or 4-dose series.
  - All of the above are correct.
- All susceptible persons traveling to or working in countries that have high or intermediate rates of hepatitis A should be vaccinated or receive immune globulin (IG) before traveling.
  - True
  - False
- Travelers who are allergic to a vaccine component, who elect not to receive vaccine, or who are aged <12 months should receive a single dose of immune globulin, which provides effective protection against Hepatitis A virus infection for up to 2 months depending on the dosage given.
  - True
  - False
- Persons who have been exposed recently to hepatitis A virus (HAV) and who have not been vaccinated should be administered one dose of single-antigen hepatitis A vaccine or immune globulin (IG) as soon as possible, any time within 6 weeks after exposure.
  - True
  - False
- Hepatitis A vaccine dose(s) administered to children <12 months of age are considered valid doses.
  - True
  - False
- Since hepatitis A vaccines is are inactivated vaccines, they are not safe for administration to immunocompromised persons.
  - True
  - False
- Hepatitis A vaccine is recommended for pregnant women with additional medical conditions or other indications for hepatitis A vaccine.
  - True
  - False

## Pharmacist Consult: CDC–Hepatitis A, Part 2: Prevention & Vaccinations

Knowledge-based CPE

To receive 2.0 Contact Hours (0.2 CEUs) of continuing education credit, preview and study the attached article and answer the 12-question post-test by circling the appropriate letter on the answer form below and completing the evaluation. A test score of at least 75% is required to earn credit for this course. 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: #0063-0000-18-029-H06-P.

**Learning Objectives for Pharmacists:** 1. Identify the currently available hepatitis A vaccines, and describe their protection benefits; 2. Evaluate the hepatitis A vaccines safety profile for both concurrent use with other vaccines and administration to patients with coincidental medical conditions; 3. Counsel patients on the availability of hepatitis A vaccines and place in therapy; 4. Counsel patients on the place in therapy for immune globulin pre- or post-hepatitis A virus (HAV) exposure.

**Circle Correct Answer:** 1. A B C D    4. A B C D    7. A B    10. A B  
2. A B C D    5. A B C D    8. A B    11. A B  
3. A B C D    6. A B C D    9. A B    12. A B

**COURSE EVALUATION:** must be completed for credit.

**DISAGREE**                      **AGREE**

Material was effectively organized for learning: 1 2 3 4 5 6 7

Content was timely and applicable for re-licensing / recertification: 1 2 3 4 5 6 7

Each of the stated learning objectives was satisfied: 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: \_\_\_\_\_

Course material was evidence-based, balanced, noncommercial: 1 2 3 4 5 6 7

List any details relevant to commercialism: \_\_\_\_\_

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

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 #: \_\_\_\_\_

STREET: \_\_\_\_\_ CITY: \_\_\_\_\_ STATE: \_\_\_\_\_ ZIP: \_\_\_\_\_

EMAIL ADDRESS: \_\_\_\_\_ PH: \_\_\_\_\_ INTEREST IN ADDITIONAL CE COURSES? Y / N

e-PROFILE ID NUMBER (ePID): \_\_\_\_\_ DATE OF BIRTH (MMDD): \_\_\_\_\_

Course release date: March 29, 2018 / Expiration date: March 29, 2021 / Target audience: Pharmacists

Please mail this completed answer sheet with your check of \$12.00 to SDSU College of Pharmacy-C.E. Coord., Box 2202C, Brookings, SD 57007. Office Ph: 605-688-4242 / [Bernie.Hendricks@sdstate.edu](mailto:Bernie.Hendricks@sdstate.edu)

# PHARMACY & 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.

## CORRESPONDING RESPONSIBILITY

The opioid crisis, and the multitude of court cases around the country that followed from it, have placed additional scrutiny on the duty of Corresponding Responsibility for pharmacists. This concept is not new. The regulation has been in effect for many years. The regulation states;

“ A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. ”  
(emphasis added)

Recent activity in the Multi District Litigation (MDL) court in Ohio focused on Corresponding Responsibility. Judge Dan Polster issued an order on August 6, 2020 denying the pharmacy defendants' motion to dismiss the complaint against them. The pharmacy defendants' motion to dismiss asserted that the duty of Corresponding Responsibility falls on the pharmacist, not on the pharmacy. Therefore, the pharmacies had no duty to take any action during the opioid crisis. The judge disagreed and denied the motion.

The judge then went on in his ruling to outline what steps the pharmacies should have taken and the information that should have been provided to their staffs. His opinion was very detailed and involved data mining and data analytics. The pharmacy defendants filed a motion to reconsider on August 25, 2020 because they believed the requirements outlined by the judge were excessive and beyond the requirements imposed by statute and DEA regulations. The motion to reconsider was denied on September 22, 2020. However, the judge did acknowledge that his previous order was not intended to prescribe the actions that the pharmacy defendants should have taken. The question of whether the actions they did take were sufficient under the law is a question of fact for the jury to decide.

The Corresponding Responsibility regulation does specifically cite pharmacists. However, the assertion by the pharmacy defendants to say that they have no duty here seems to be an extreme position. Pharmacies are registrants too. As registrants under the Controlled Substances Act, pharmacies also have a duty to prevent abuse and diversion of controlled substances. The Administrator of the DEA has the authority to suspend or revoke a pharmacy's registration if it appears to create a danger to the public health or safety to allow the pharmacy to continue. While the Corresponding Responsibility regulation refers to pharmacists, it seems unrealistic to leave the dispensing pharmacist unsupported in the performance of their duty. The judge's initial ruling also seems to be an extreme position. As is many times the case, the best solution is somewhere in the middle.

Pharmacy owners need to be clear with their staff about diversion and addiction prevention. Establishing a culture of judicious and sensible dispensing of controlled substances starts with owners and managers of the pharmacy. Owners who concentrate on volume will get less discernment from their staff pharmacists as the staff will likely feel pressure to fill all controlled substance prescriptions. The DEA believes that the law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. The pharmacist is making a real-time decision with the conflicting pressures of prevention of diversion or addiction and patient care. It seems unreasonable that the pharmacy has no duty in this situation. Yes, the pharmacist is on the frontline and has to make the decision, but the pharmacy and its owner create the environment where this decision must be made. The pharmacists can't make these decisions in a vacuum. Discussion with the prescriber will probably be necessary. Perhaps discussions with the patient will also be necessary. The pharmacist can then use this information in conjunction with their professional knowledge, experience and judgment.

Another portion of the filings in this case discussed the pharmacy's duty to train their staff pharmacists to properly handle prescriptions for opioids and to establish policies and procedures to prevent their pharmacies from facilitating the diversion of opioids. While this duty is not explicitly spelled out in the DEA regulations, it seems to be implied in the pharmacy's duty to protect public health and safety. The judge's initial ruling went into a lot of detail on what he thought was acceptable and went far beyond what someone could easily infer from the regulations. The judge stepped back from this initial position when he denied the motion for reconsideration.

What can we learn from this case? There will be a continued focus on the doctrine of Corresponding Responsibility going forward. The law continues to evolve and yesterday's solution will not be sufficient for tomorrow. Pharmacists have an independent duty to the patient and are not merely order takers for the physician. Following the physician's orders is no longer a sufficient defense when a patient is harmed by a prescription when the pharmacist could have intervened. The pharmacy needs to create a team atmosphere and assist their pharmacists as they make these important patient care decisions.

© 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.

# 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.

## REBALANCING Your PORTFOLIO

Should investors make regular adjustments?

Everyone loves a winner. If an investment is successful, most people naturally want to stick with it. But is that the best approach? It may sound counterintuitive, but it may be possible to have too much of a good thing. Over time, the performance of different investments can shift a portfolio's intent as well as its risk profile. It's a phenomenon sometimes referred to as "risk creep," and it happens when a portfolio's risk profile shifts over time.

**Balancing.** When deciding how to allocate investments, many begin by considering their time horizon, risk tolerance, and specific goals. Next, individual investments are selected that pursue the overall objective. If all the investments selected had the same return, that balance – that allocation – would remain steady for a time. But if the investments have varying returns, over time, the portfolio may bear little resemblance to its original allocation.<sup>1</sup>

**How Rebalancing Works.** Rebalancing is the process of restoring a portfolio to its original risk profile. There are two ways to rebalance a portfolio. The first is to use new money. When adding money to a portfolio, allocate these new funds to those assets or asset classes that have fallen.<sup>1</sup> The second way of rebalancing is to sell enough of the "winners" to buy more underperforming assets. Ironically, this type of rebalancing forces you to buy low and sell high. As you consider the pros and cons of rebalancing, here are a couple of key concepts to consider. First, asset allocation is an investment principle designed to manage risk. It does not guarantee against investment losses. Second, the process of rebalancing may create a taxable event. And

the information in this material is not intended as tax or legal advice. It may not be used for the purpose of avoiding any federal tax penalties. Please consult a professional with legal or tax expertise regarding your situation. Periodically rebalancing your portfolio to match your desired risk tolerance is a sound practice regardless of the market conditions. One approach is to set a specific time each year to schedule an appointment to review your portfolio and determine if adjustments are appropriate.

Pat Reding and Bo Schnurr may be reached at 800-288-6669 or [pbh@berthelrep.com](mailto:pbh@berthelrep.com).

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