# PHARMACIST

#### **IN THIS ISSUE**

Celebrating American Pharmacists Month Important Update: USP Rules Jam Session – That's a Wrap!

FALL EDITION 2019



#### SOUTH DAKOTA PHARMACISTS ASSOCIATION

320 East Capitol, Pierre SD 57501 605-224-2338 // 605-224-1280 fax www.sdpha.org

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

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4001 W. Valhalla Blvd. Ste. 106 Sioux Falls, SD 57106 605-362-2737 // www.pharmacy.sd.gov

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Melissa DeNoon, Director Melanie Houg, Assistant

Calendar

#### OCTOBER

#### AMERICAN PHARMACISTS MONTH

- Aberdeen District Fall Meeting 9 The Flame, Aberdeen
- 14 Native American Day
- National Pharmacy Technician Day 15
- National Pharmacy Week 20-26
- National Community Pharmacists Association 26-29 (NCPA) Annual Convention San Diego, CA
  - 29 Yankton District Fall Meeting Minervas – Yankton, SD

#### NOVEMBER

- Veteran's Day 11
- Thanksgiving Day 28

#### DECEMBER

- South Dakota Board of Pharmacy Meeting 6 Sioux Falls, SD from 8 am-12 pm
- Christmas Eve 24
- 25 Christmas Day
- 31 New Year's Eve

#### SAVE THE DATES

- January 28–29, 2020 1. Legislative Days, Pierre, SD
- September 25–26, 2020 2. SDPhA 134<sup>th</sup> Annual Convention, Brookings, 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**.

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### DIRECTOR'S Comments



#### Amanda Bacon // Executive Director

#### It's Your Time to Shine!

Welcome to American Pharmacists Month! October is when we recognize all our pharmacists contribute to the world of healthcare in our communities. In my tenure here, I've learned much about this community of humble, resilient, hard-working, problem-solving, life-changers and life savers I have the privilege of coming to work for each day. I love any opportunity to share the

awesome work you all do, and the lengths to which you are willing to go to ensure your patients are not just taken care of, but compassionately cared for. While you are so often the unsung heroes of the healthcare team, this month is your time in the spotlight, and we will do our best to show all the reasons you shine!

If you watch our public Facebook page, this month you'll find posts several times a week that showcase the many components of your vital role as a member of the health care team and provider of patient services. Those are all designed as patient-friendly pieces you can share on your personal pages, as well as on your business platforms. It's essentially a ready-made social media campaign. All you have to do is take a few seconds to click, share.

In addition to the social media pieces, SDPhA is pleased to once again partner with SCAPP/APhA-ASP on an American Pharmacists Month campaign. You'll find billboards located in the state's two largest communities. Watch for them, snap a picture and post them to our pages – it's another fun way to spark some great conversation.

Finally, the American Pharmacists Month campaign website pharmacistsmonth.org has some great ideas on how to participate and celebrate no mater your practice setting, and pharmacistsforhealthierlives.org has some fantastic videos you can share as well.

#### **IMPORTANT UPDATE: USP RULES**

The South Dakota Board of Pharmacy has an important update on the status of USP chapters 795, 797, 800, and 825. Make sure you refer to page 6 for the latest.

#### CONVENTION RECAP

I have to be honest - it felt a little like all were missing was the plague of locusts as convention kicked off Sept. 13-14

in Deadwood. Tornados and flooding forced some of our speakers to cancel, and others to find cancelled flights. I'm thankful for a fantastic board – always willing to pitch in and do whatever is needed, a fleet of SDSU student pharmacists always at the ready to serve, and the good fortune to have the amazing Bailey Buenger on rotation with me who stepped up to handle many of the details so I could keep the plates spinning. In spite of it all – we had a fantastic weekend of fellowship, networking and education. We also left with a much-needed update to the SDPhA bylaws, and a new At-Large Board member—welcome, Jessica Strobl! (By the way, I'm not really the superstitious sort, but that will be the last time we hold a convention on a Friday the 13th...)

#### FALL DISTRICT MEETINGS

We do have a few districts planning to hold Fall Meetings. Make sure you check the events calendar here and online for updates to see if your district is one of them! If you were in the Hot Topics Segment at convention, you heard Past President Erica Bukovich and I address some of the challenges we've heard from our district officers, as well as some exciting opportunities on the horizon. We're working on some things here in the office we truly feel will poise us to provide optimal support to our district leaders and members. More to come on that so stay tuned!

#### **LEGISLATIVE SESSION 2020**

The 95th South Dakota Legislative Session opens Jan. 14, 2020 and we're already preparing for this coming legislative session. If your district is having a fall meeting - this a good way to learn more about this process, and what you can expect from us in the coming months. If you want to come to Pierre and see it all first-hand, Legislative Days Jan. 28-29, 2020 is the perfect time. This is a prime opportunity to meet your lawmakers, show them why your work matters.

#### LAST BUT NOT LEAST

As we celebrate all the amazing ways you care for others this month, I want to encourage you to find some moments, however small they may be or seem, to take care of you. You all work so very hard, but you can't serve from an empty cup – I hope you can find some opportunities this Fall to rest, renew and replenish.

Respectfully, AMANDA BACON SDPhA Executive Director

# PRESIDENT'S Perspective

#### Lori Ollerich // SDPhA Board President



Happy October! I hope this finds each of you enjoying all that fall has to offer... beautiful foliage, warm days, cool nights, football, and most importantly, American Pharmacists Month! Each year there are more reasons to be thankful for our wonderful pharmacists and technicians, so make sure you take some time

Our Executive Director, Amanda Bacon, is amazing. Her this month to focus on promoting work ethic is top notch - she excels at communication, our profession and to celebrate stays on top of legislative happenings, is a wonderful our many contributions! coach, competent business manager, and truly cares about not only our people, but our profession. If I had to describe In September, we were jammin' at the 133<sup>rd</sup> SDPhA convention her in one in one word, I would say: ROCKSTAR. Thank you in Deadwood. While tornados and flooding affected the doesn't seem to be enough for all that she does for all of travel plans of some of our speakers and attendees, we had the people involved with the association - I look forward to wonderful CE sessions, productive and informational meetings, the year ahead and working with her as well as the rest of as well as some collaboration opportunities. Another the board. highlight of convention was the chance to recognize some of the most deserving individuals for their contributions This year, please watch for ways to stay involved with the to pharmacy in South Dakota. Congratulations to the Association. A *C&L* Contribution Challenge may be making 2019 award winners: its way to an inbox (or mailbox) near you. Please mark your

- Pharmacy Technician of the Year: Jerrie Vedvei
- Distinguished Young Pharmacist: Eric Grocott
- Industry Salesperson of the Year: John T. Ackerman
- Bowl of Hygeia: **Donald Frank**
- Hustead Award: Dana Darger

A big thank you to the students who volunteered - especially those that helped serve SDSU ice cream - our favorite! We look forward to seeing everyone in their blue and gold to cheer on the Jacks as we'll be back in Brookings (in conjunction with a home football game – at least that's what we're told!) September 25th and 26th, 2020.

In closing, by the time you read this, the days will be shorter, temperatures cooler, and the signs of winter starting to draw nearer. Each October marks an Convention also marks the transition of the board. It is an opportunity to celebrate and promote our profession. honor to be selected as the President of the South Dakota How are you celebrating this year? We would love to Pharmacists Association. A big thank you goes out to Past hear from you this month and year! President Erica Bukovich for all of her time and effort supporting the association and the profession this past Respectfully, year. Between home and work activities, there's not much time left in a day, yet Erica spearheaded the by-law revision, LORI OLLERICH collaborated with other healthcare practitioners on SDPhA Board President multiple committees, and attended the national meeting in Seattle, just to name a few. Thanks again Erica! In addition, the entire Board has been an incredible group

of professionals to work with and I cherish the time spent and memories made with this dedicated group. The experience has been rewarding and I have already gained so much from working with each of you, and will continue to reach out for your guidance this coming year. A special thank you to Eric Grocott for his contributions over the past several years on the Board, and big welcome to new member Jessica Strobl!

calendars for Legislative Days on January 28-29, 2020 in Pierre, SD. Plan to attend and see our wonderful students in action at the State Capitol.

In the meantime, please remember that the Association loves to hear from you. We encourage you to reach out with any issues or questions, or with ideas to become involved. SDPhA will continue to monitor and engage on issues related to our profession, so watch for updates throughout the year.

# South Dakota BOARD of PHARMACY



#### **BOARD WELCOMES NEW REGISTERED** PHARMACISTS/

PHARMACIES

Kari Shanard-Koenders // Executive Director

Congratulations to the following candidates who recently met licensure requirements and were licensed as pharmacists in South Dakota: Anna Bills, Kylie Brooks, Michaela Bunde, Kayla Clark, Joshua Collett, Megan

Czmowski, Rachelle Davis, Cheryl Day, Hilary Deragisch, Brady Dively, Megan Dorsey, Katie Ferguson, Shelby Foley, Miranda Frank, Kassandra Friese, Corrina Hemmer, Stefanie Kellogg, Adam Kolander, Austin Kott, Amanda Kuhn, Kylea Larsen, Spencer Lehmann, Yi Pin Liu, Jenna Lund, Rhianna Mehrer, Travis Meinders, Renee Nierngarten, Cherisse Norberte, Kiara Oltman, Mackenzie Patterson, Meghan Perry, Hannah Poppen, Nicole Rasmussen, Ashlyn Riedesel, Erika Roby, Dalton Rowden, John Rust, Brooke Schotters, Amanda Smith, Whitney Specht, David Sy, Ruth Taylor, McKayla Thieman, Shannon Vorthmann, Theresa Wallace, Khia Warzecha, Jeffrey Ward, and Justine Wilson.

Three full-time pharmacy licenses were approved and issued during the period. They are Avera on Louise Inpatient Pharmacy, dba Avera McKennan, Sioux Falls; Family Pharmacy of Mobridge Inc dba Family Pharmacy-Downtown, Mobridge (change of ownership); and Family Pharmacy of Mobridge Inc dba Family Pharmacy-Clinic, Mobridge (change of ownership).

#### **BOARD THANKS LISA RAVE FOR EXEMPLARY 9 YEARS OF SERVICE**

Board member Lisa Rave has served for three 3-year terms on the South Dakota Board of Pharmacy. She is a past president of the Board and has served the Board with professionalism and grace. Her third term ends in October. Thank you, Lisa, for your service and friendship to the Board - we will miss you!

#### **BOARD SAYS GOODBYE TO JESSICA NEAL**

After nearly five years of service Jessica Neal has resigned to spend more time with her husband and three (soon to be four) children. Jessica has been a real asset to the Board office, and we say Thank You!

#### USP DELAYS ENFORCEABILITY DATE FOR NEW AND REVISED **USP GENERAL CHAPTERS**

USP issued an update on the USP compounding standards on September 23, 2019 stating that there will be a delay in the date that the documents become enforceable due to ongoing appeals of the chapters. The currently official versions of General Chapter <795> (last revised in 2014) and General Chapter <797> (last revised in 2008) remain official until further notice. General Chapter <800> will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. See complete official notice at https://www.uspnf.com/notices/compounding-chapterspostponement. The Board had issued an intent to promulgate rules in order to incorporate the USP new and revised general chapters into rules, by reference, but has since pulled the rules due to the USP delay.

#### PDMP UPDATE by Melissa DeNoon, PDMP Director

The South Dakota Prescription Drug Monitoring Program (SD PDMP) is excited to announce the launch of NarxCare, the 'next gen' PDMP enhancement, and Statewide Gateway Integration. NarxCare is one of the program's 2018 Comprehensive Opioid Site-based Program Grant projects and went live on July 15, 2019. This enhancement is available to users accessing PMP AWARxE through the web portal and PMP Gateway clinical workflow integrations (Gateway access is dependent on meeting API requirements). NarxCare provides the 'Narx Report' and 'Resources'. The Narx Report is comprised of five sections:

- 1. Narx Scores Numerical representations of the patient's PDMP data for three drug classes; narcotics (opioids), sedatives, and stimulants. Scores range from 000-999 with the last digit of each score representative of the number of active prescriptions of that drug type according to the dispensation information in the PDMP.
- 2. Overdose Risk Score Incorporation of relevant PDMP data into an advanced and customized predictive model to calculate a patient's risk of overdose. Scores range from 000-999 with higher scores equating to an increased risk of unintentional overdose.
- 3. Additional Risk Indicators
- 4. Prescription Graph Visualization of the patient's PDMP data in an interactive graph that color codes prescriptions based on five drug types including narcotics (opioids), buprenorphine, sedatives, stimulants, and other. The graph is in reverse time order displaying the most recent prescriptions on the left side and the oldest on the right side.
- 5. PDMP Data The classic view of the dispensation information in the PDMP.

The Resources tab has an access to treatment section and an educational resources section. The access to treatment section utilizes a SAMHSA supported buprenorphine treatment locator that will generate a listing of the 30 providers found closest to the entered zip code. The educational resources section provides printable CDC pamphlets to assist practitioners in patient engagement and education.

Statewide Gateway Integration is the program's second 2018 Comprehensive Opioid Site-based Program Grant project and went live on August 26, 2019. All current SD PMP AWARxE users were sent an announcement email detailing this exciting opportunity for all healthcare entities (HCEs) in South Dakota to integrate the SD PDMP's PMP AWARxE platform into their clinical workflow utilizing Appriss Health's PMP Gateway service. Grant funds will pay all PMP Gateway fees for the two-year grant period. Please complete the integration request form found here to start the process for your HCE!

#### PHARMACOGENOMICS AND THE COMMUNITY PHARMACIST by Theresa Wallace, Pharm. D.

Pharmacogenomics (PGx) is the study of how genetic factors affect the metabolism, transport or drug receptors in individuals. Variations in our DNA cause different responses to medications. A poor metabolizer may have a high concentration of medication in their body, causing increased adverse effects, while a rapid metabolizer may end up with sub-therapeutic levels of medication. If the medication is a prodrug such as clopidogrel or codeine, the opposite effect will occur. A poor metabolizer will not convert the prodrug to the active form of the medication, thus the patient will likely have little response to the medication. Rapid metabolizers will have excess medication concentrations, causing moderate to severe adverse effects. In the community pharmacy setting, we see many commonly prescribed drugs that may have significant drug-gene interactions (Figure 1). Pharmacogenetic testing and results are not intended to be used to treat or diagnose but can be a valuable tool for providers and pharmacists to help determine the best course of treatment for our patients.

# South Dakota BOARD of PHARMACY

#### (continued) =

Figure 1 GENE	MEDICATION
CYP2C9	warfarin (with VKORC1)
CYP2C19	clopidogrel, voriconazole, amitriptyline, clomipramine, doxepin, imipramine, trimipramine, citalopram, escitalopram
CYP2D6	codeine, tramadol, tamoxifen, desipramine, nortriptyline, paroxetine, fluvoxamine, fluoxetine, atomoxetine
DPYD	capecitabine, fluorouracil
SLCO1B1	simvastatin
ТРМТ	mercaptopurine, azathioprine, thioguanine
VKORC1	warfarin (with 2C9)

Pharmacogenomics testing is a DNA-based test of gene variations associated with risk of adverse response or drug response. The number of genes tested on a pharmacogenomics panel varies greatly by institution. Testing is available to patients through local providers, Sanford or Avera. Other options for testing include direct to consumer vendors such as 23andMe and GeneSight, or other healthcare systems such as Mayo Clinic. Patients are encouraged to discuss PGx results with their provider to ensure that they have the proper understanding of the results.

information. The first is through the Clinical Pharmacogenomics Implementation Consortium (CPIC).<sup>1</sup> CPIC is an international group of volunteers and staff that work to create evidence-based, peer-reviewed gene-drug clinical practice guidelines. These guidelines are free and are updated regularly on their website (https://cpicpgx. org/). The second resource is the Pharmacogenomics Knowledgebase (PharmGKB) (https://www.pharmgkb. org/).<sup>2</sup> This organization is a National Institutes of Health (NIH) funded resource that provides information regarding genetic variations and how they affect response to medication. PharmGKB gives prescribing information, drug label annotations, pathways that explain how the medication is metabolized as well as clinical and variant annotations. You may also access CPIC guidelines via the PharmGKB website. For a broader look at pharmacogenomics you can review the National Institutes of Health (https:// <u>ghr.nlm.nih.gov/</u>) and the Food and Drug Administration (FDA) (https://www.fda.gov/Drugs/ScienceResearch/ ucm572617.htm) websites.<sup>3,4</sup>

In order to understand how community pharmacists are able to assist patients, let's consider a case. Mrs. Jones enters the pharmacy with her PGx results. She has just been to her provider and was prescribed codeine for pain. Her PGx results show that she is an ultra-rapid metabolizer of CYP2D6. Since codeine is a prodrug and she is an ultra-rapid metabolizer, we know that she is most likely metabolizing the prodrug into supra-therapeutic levels of morphine, which put her at risk for toxicity and severe adverse effects such as respiratory depression, even with a relatively low dose of codeine. CPIC guidelines recommend that a patient such as this be taken off codeine.<sup>1</sup> Alternative therapies such as tramadol, hydrocodone and oxycodone are not recommended by CPIC due to their metabolism via CYP2D6. Safer medication options could include NSAIDs or acetaminophen. If more pain control was necessary, tapentadol or morphine could be considered. As mentioned previously, pharmacogenomics testing is a tool. The use of clinical judgement and prudence is necessary. We would not want to jump to fentanyl (especially in an opioid naïve patient) just because they are an ultra-rapid metabolizer of CYP2D6.

- we are usually seen by our patients more often than they see their other healthcare providers and we are easily accessible. This give us the opportunity to educate patients on how to interpret their PGx results and to ensure that the medications that they are prescribed are appropriate and safe. Pharmacogenomics can be an extension of medication therapy management services that are already being completed in the community setting.<sup>5</sup> As more and more of our patients are accessing PGx testing, it will become increasingly important that we understand the basics of PGx testing and know where to find the resources to help our patients.

#### **REFERENCES:**

- 1. Clinical Pharmacogenomics Implementation Consortium. CPIC. https://cpicpgx.org/ Accessed April 1, 2019.
- 2. Pharmacogenomics Knowledgebase (PharmGKB). https://www.pharmgkb.org/ Accessed April 1, 2019.
- 3. National Institutes of Health (NIH). https://ghr.nlm.nih.gov/ Accessed April 1, 2019.
- 4. U.S. Food and Drug Administration (FDA). Accessed April 1, 2019.
- 5. American Pharmacists Association (APhA). https://www.pharmacist.com/sites/default/files/files/ mtm integrating

Pharmacogenomics.pdf. Accessed April 10, 2019.

Respectfully Submitted for the Board, **KARI SHANARD-KOENDERS** Executive Director

There are several great resources for pharmacogenomics

Community pharmacists have a unique position in healthcare

#### **BOARD MEETING DATES**

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

#### **BOARD OF PHARMACY** DIRECTORY

**DIRECTOR, SD PDMP** Melissa DeNoon melissa.denoon@state.sd.us

#### **PHARMACY INSPECTORS**

Tyler Laetch tyler.laetsch@state.sd.us Paula Stotz paula.stotz@state.sd.us Carol Smith carol.smith@state.sd.us

#### SENIOR SECRETARY

Beth Windschitl beth.windschitl@state.sd.us

#### **PDMP ASSISTANT**

Melanie Houg melanie.houg@state.sd.us

#### **EXECUTIVE DIRECTOR**

Kari Shanard-Koenders kari.shanard-koenders@state.sd.us

#### **BOARD OF PHARMACY**

605-362-2737 | 605-362-2738 fax www.pharmacy.sd.gov

#### **PDMP DATA ACCESS** https://southdakota.pmpaware.net/login

PDMP DATA SUBMITTERS https://pmpclearinghouse.net/

#### NATIONAL ASSOCIATION **OF BOARDS OF PHARMACY** www.NABP.pharmacy

# South Dakota SOCIETY of HEALTH-SYSTEM PHARMACISTS Annual Report

Joe Berendse, PharmD, BCPS, BCACP // SDSHP President



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

We at SDSHP are glad to see the return of SDPhA's Annual Convention for this year's Jam Session at Deadwood – SDSHP continues to be appreciative of its close working relationship with SDPhA and looks forward to all this year's convention has to offer! As with any successful

musical ensemble, SDSHP requires the talent, efforts, and collaboration of a number of individuals to perform harmoniously. We are truly indebted to all of our volunteers, as this past year has been an amazing performance!

One of our highlights was the 43<sup>rd</sup> SDSHP Annual Conference, which was held in April in this same location – the Lodge at Deadwood. At least, that was our initial plan: we were slightly deterred by Winter Storm Wesley, which produced enough snow and ice to shut down I-90 for the days preceding the conference. Luckily, with the use of distance technology (Zoom), we were still able to provide 11 hours of ACPE-accredited CE to about 60 in-person attendees and another 20 virtual attendees. The new Board Members inducted at the business meeting included Aaron Larson as Past President, myself as President, Haylee Brodersen as President-Elect, Chance Wachholtz as Secretary, Anna Delzer as Treasurer, Rose Fitzgerald and Jordan Baye as Board Members-at-Large, Jodi Sterrett as Technician Board Member, and Alyssa Boesche and Dustin Moon as Student Board Members. At the awards ceremony, Gary Van Riper was recognized as this year's recipient of the Gary W. Karel Lecture Award. Also, because Gary stepped down from the SDSHP Board of Directors at this year's conference, he received additional recognition for his many years of service to SDSHP.

Other events included the 7<sup>th</sup> Annual SDSHP Statewide Residency Conference, which was held on Friday, July 12th at Cedar Shore Resort in Oacoma. Pharmacy residents throughout the state were invited to this conference, which provided them an opportunity to network and listen to presentations on topics that will benefit them throughout the year. Featured topics this year included a review of statistics, the *in's and out's* of residency research, and motivational interviewing. Thanks to our outgoing resident liaison – Avery Aldridge – for her efforts in coordinating this event!

The 18<sup>th</sup> Annual Gary Van Riper Society Open Golf Classic was also held at the Central Valley Golf Course in Hartford on Friday, July 26. It was a perfect day for golfing! We raised over \$1,100 for pharmacy student scholarships and funding for student travel to the ASHP Clinical Skills Competition! SDSHP would like to extend a special thank you to our Platinum Sponsors: SDPhA, SDSU College of Pharmacy & Allied Health Professions, Pharmacists Mutual, Gary and Sharon Van Riper, Tyler and Kristin Turek, and First Premier Bank. Thank you to all of the participants, and a special thanks to Tyler Turek for planning and coordinating the event!

Finally, our members continue to accomplish amazing things. We are elated to announce that former SDSHP President, Tom Johnson, has been elected as ASHP's new President-elect. Tom recently completed a term as ASHP Treasurer and served both on the Board of Directors and various ASHP national councils and committees. His term as President-elect began in early August. We eagerly look forward to all the great things he will do for ASHP, and reiterate our thanks for all he has already done for SDSHP!

We are equally proud of our own Jodi Sterrett, who currently serves on the SDSHP Board of Directors as our Technician Board Member. She was recently appointed to the ASHP Pharmacy Technician Forum – Patient Care Quality Advisory Group. This is a national group responsible for advising and creating positive change on guality measures that affect the role of pharmacy

technicians in the medication use process. We owe both Tom and Jodi our thanks for being outstanding representatives of pharmacy practice in South Dakota!

#### **UPCOMING EVENTS**

The Dakota Night Reception at the ASHP Midyear Clinical Meeting will once again take place during the ASHP Midyear Clinical Meeting in Las Vegas, NV. Pharmacists, technicians, and students are all welcome to join us for an evening of refreshments, hors d'oeuvres, networking, and socializing. Watch your e-mail for more details!

44<sup>th</sup> Annual SDSHP Conference: Mark your calendars! Our annual conference will be on April 3<sup>rd</sup>-4<sup>th</sup> in Sioux Falls at the Holiday Inn City Centre.

**Pharmacy Month Social Event:** We are in the process of planning a social event on each side of the state in the month of October. More details to follow!

**CE and SPF:** Dates for the resident CE events and SPF sessions have not been set yet. Please watch your e-mail for more information!.

We invite you to stay engaged by visiting SDSHP's website at **www.sdshp.com**. There you can learn more about SDSHP and find a current list of upcoming events!

Respectfully submitted, JOE BERENDSE PharmD, BCPS, BCACP SDSHP President



Have you ever wondered how your Well-Being compares to others? Consider investing six minutes in your well-being. The Well-Being Index is a brief online self-assessment, invented by the Mayo Clinic and brought to you through a partnership with the American Pharmacists Association (APhA), which provides you immediate individualized feedback including tools and local and national resources to address your well-being. You can set-up the frequency you wish to assess your well-being and track your progress.

Your information and score are private and your individual score will not be shared with APhA or anyone else. You do not have to be an APhA member to participate.

#### TAKE THE SURVEY NOW IN A FEW EASY STEPS:

0-

- 1. Go to: www.mywellbeingindex.org/signup
- 2. If asked for a participation code, use APHA
- 3. Register (approx. 3 minutes)
- 4. Take the survey (approx. 3 minutes)

### SOUTH DAKOTA STATE UNIVERSITY COLLEGE of PHARMACY and ALLIED HEALTH PROFESSIONS

#### Jane Mort // Dean, College of Pharmacy & Allied Health Professions



Greetings from the College of Pharmacy and Allied Health **Professions!** 

As we begin a new school year, I would like to take a moment to reflect briefly on our past and share new frontiers that are opening up before us.

Our College has a long-standing tradition in pharmacy education. In the book, A History of Pharmacy

in South Dakota, Dr. Kenneth Redman stated the College of Pharmacy has a long and illustrious existence. With its start in 1887, ... it is the eighth oldest College of Pharmacy in the United States. The first degree awarded at that time was the PhG (Pharmacy Graduate) and suffice it to say, practice was far different back in those days!

#### **DISTINGUISHED ALUMNUS – BARRY MARKL**

An example of a leader who has helped create practice transformation is the College's 2019 Distinguished Alumni award recipient, Barry Markl. After Barry received a Walgreens scholarship loan as a student, he went on to work his entire 40-year professional career with the company. He started out as an intern, then pharmacist, store manager, district manager, regional Vice President, Corporate Vice President, and ended his career as the Senior Vice President in charge of operations where he was responsible for 1,350 stores that accounted for \$12 billion in sales. His career impacted a multitude of patients and pharmacists, and he continues to serve the College and University through his leadership.

#### FLIP THE PHARMACY

Nationally, work is underway to change the nature of practice in the form of the *Flip the Pharmacy* Program. In fact, on September 4, 2019, South Dakota and 19 other states were selected to participate in the first cohort of the multi-year *Flip the Pharmacy* (FTP) Program. Community Pharmacy Enhanced Services Network (CPESN®) USA partnered with the Community Pharmacy Foundation (CPF) to serve as the Coordinating Center for Flip the Pharmacy. CPESN® South Dakota leaders are Dr. Josh Ohrtman and Dr. Curt Rising from the Medicine Shoppe.

I am pleased to share that the College of Pharmacy and Allied Health Professions will be a key network partner on this project. Dr. Ohrtman (SDSU '17) will serve as the Practice Transformation Team Lead for the FTP project. Dr. Sharrel Pinto and her research team will work with Dr. Ohrtman and CPESN<sup>®</sup> SD to help transform community pharmacy practice. The transformation project will occur over two years for a small number of CPESN<sup>®</sup> SD stores and will determine scalability and best practices for future transformation projects for other pharmacies. The FTP project will run concurrently with Dr. Pinto's Center for Disease Control – Department of Health (CDC-DOH) project. With the lessons learned from the FTP project and the funding for training/resources/site development to expand clinical services from the CDC-DOH, it won't be long before South Dakota leads other states in community pharmacy transformation.

#### **POPULATION HEALTH**

Another unique opportunity exists in the management of health care from a population basis. While the role of the pharmacist in providing direct patient care is critical, system -wide changes in medication management can impact utilization for hundreds of thousands of patients. In order to properly make these decisions, a set of fundamental skills and knowledge are required. We are extremely fortunate in our College to have the Masters in Public Health which teaches these specific skills. This online program is accessible to practitioners and students, regardless of location, and we are pursuing opportunities to deliver these skills in an even more attainable format.

Our future hinges on our imagination, working together to address challenges, and dedication to helping people live healthier lives. At the College of Pharmacy and Allied Health Professions, we are committed to these tenets and look forward to realizing that future with you.

Best regards, JANE MORT Dean, College of Pharmacy & Allied Health Professions

# SDSU's Student Collaboration for the Advancement & Promotion of Pharmacy Annual Report

#### Natalie Sovell // SCAPP/APhA-ASP SDSU Chapter President =



The Student Collaboration for the Advancement and Promotion of Pharmacy (SCAPP) at SDSU has had a successful year. This was the first year that our chapter added four more national pharmacy organizations to our

already existing chapter of the The theme for the 2018-2019 academic year was collaboration American Pharmacists' Association in order to encourage the various organizations and Academy of Student Pharmacists committees to work with each other. Each committee was (APhA-ASP). We now also include encouraged to collaborate with at another committee or the American College of Clinical organization for at least one event throughout the year. Pharmacy (ACCP), the Pediatric The theme for the upcoming 2019-2020 academic year Pharmacy Advocacy Group (PPAG), the National Community is involvement. By encouraging members to be actively Pharmacists Association (NCPA), and the American Society involved in our organization as students, we hope of Health-System Pharmacists (ASHP) to represent a wide to promote the importance of staying involved with variety of pharmacy. All of our members are a part of the national organizations throughout their pharmacy careers. Additionally, by encouraging involvement, we hope South Dakota Pharmacists' Association (SDPhA) and the South Dakota Society of Health Systems Pharmacists (SDSHP). to make every member feel that he or she has made an impact on the organization. Lastly, we wanted to thank SDPhA for all of their professionalism, and education. This past year, we completed continued support and contributions to our chapter! We could not have done it without you. We look forward

Our chapter strives to provide opportunities for members in the following four areas: patient care, community, a total number of 1,538 patient care screenings. Members were able to provide patient care screenings at the South Dakota State Fair in Huron, the Banguet in Sioux Falls, Legislative Days in Pierre, and the Harvest Table in Brookings. We are looking to expand the number of patient care opportunities and are considering performing screenings at county fairs in the upcoming year. Through the More Than A Count campaign sponsored by SDPhA, members were able to advocate for the pharmacy profession. Now is an important time for student pharmacists to advocate for pharmacy, so we will continue the More Than a Count

campaign to show the value of pharmacists in the healthcare field. Members educated the community on over-the-counter medication safety and poison prevention. This next year, we are planning on providing education to college students on opioid safety and naloxone administration on the Brookings and Sioux Falls campuses as part of Generation Rx.

Respectfully, NATALIE SOVELL SCAPP/APhA-ASP SDSU Chapter President 2019-2020

to another exciting year for student pharmacists!

# - South Dakota -ASSOCIATION of PHARMACY TECHNICIANS ANNUAL REPORT

Jerrie Vedvei, CPhT // SDAPT President =



The South Dakota Association of Pharmacy Technicians held their annual meeting

For the first time, SDAPT held their meetings in 3 different locations using DDN Network. The main location was in Pierre with Satellite locations to Rapid City Regional in Rapid City and Avera in Sioux Falls. Our numbers

were great with lots of new faces. We look forward to continuing to hold this conference using the three locations again in the future and look forward to more growth.

Your pharmacy technicians received 5 CE's, the required Law and Safety of course which was presented by the SD Board of Pharmacy Director Kari Shanard-Koenders, R.PH, with the help of Dana Darger RPh and his staff Cindy & Ashley from Rapid City Regional.

Melissa Gorecki Pharm D & Board Certified in Psychiatric Pharmacy, Presented on Anti-Anxiety & Antipsychotic Medications, Sandy Jacobson, retired RPh and former Director of Pharmacy presented on Fibromyalgia, and then the last presenters were from the Department of Criminal Investigation.

SDPHA sponsored our annual meeting with \$1,000 to help with technology and food expenses.

SDSHP sponsored 2 scholarships of \$150 each, 2 memberships to SDSHP and \$250 to SDAPT.

Scholarship winners were: Jean Masaro \$250 from SDAPT & \$150 from SDSHP, Phillip Davis received \$150 from SDSHP, and the memberships for SDSHP went to Lela Mongar and Lauren Leader Charge.

SDAPT scholarship Committee was chaired by Deb Mensing. Her committee members were Jodi Sterrett, Julie Kulesza and Deb Cummings.

Thank you to SDPHA for your generous sponsorship again this year along with our other sponsors SDSHP, Avera in Sioux Falls & Pierre and Rapid City Regional.

The SDAPT officers are: President Jerrie Vedvei, President Elect John Thorns, Treasurer Connie Mullett, Secretary Hope Showalter, and Past President Sue Dejong.

2019 is Election year for SDAPT. The nominating committee is John Thorns, Julie Kulesza, Jodi Sterrett.

The 2019 Fall conference will Saturday October 5<sup>th</sup>, 2019 with all three locations again using DDN, Rapid City Regional, Avera Sioux Falls and at the DDN Offices in Pierre SD.

Sincerely, JERRIE VEDVEI SDAPT President

#### 2019 SOUTH DAKOTA ASSOCIATION OF PHARMACY TECHNICIANS

#### **MEMBERSHIP & CONFERENCE REGISTRATION FORM**

#### **MEMBERSHIP INCLUDES**

- and snacks provided) There will be a speaker/s at each location.
- •

NAME		CELL PH	ONE ()	
STREET ADDRESS	СІТҮ		SD	_ZIP
EMPLOYER CITY_		WORK P	HONE ()	
EMAIL ADDRESS				
CPHT: YES OR NO PTCB CERTIFICATION#		SD STATE REGIST	RATION #	
PAST MEMBER OF SDAPT: YES NO	NEW MEMBER			
PLEASE LIST ANY OTHER STATE OR NATIONAL PHARMACY O	RGANIZATION(S)	YOU BELONG TO:		
ARE YOU WILLING TO SERVE ON A COMMITTEE? YES OR NO				
PLEASE CHECK ONE: \$35 MEMBERSHIP AND	CONFERENCE			
PLEASE CIRCLE THE LOCATION YOU WILL ATTEND:	PIERRE	SIOUX FALLS	RAPID CITY	
STUDENTS MAY ATTEND FOR FREE: WHERE A	RE YOU CURRENT	LY ENROLLED:		
DUE NO LATER THAN SEPTEMBER 25, 2019 (A MAKE CHECKS PAYABLE TO: SDAPT MAIL CHECK AND REGISTRATION FORM TO: SDAPT Se				alls, SD 57104

Technician registration form that is required by the South Dakota Board of Pharmacy.

14 · South Dakota Pharmacist

Annual Continuing Education Conference October 5th in Pierre, satellite locations Sioux Falls and Rapid City (light breakfast, beverages

One year's subscription of The South Dakota Pharmacist Journal and discounted rates for the South Dakota Pharmacist Association Annual Meetings An awesome opportunity to network with others in your profession ~ 5 CE's will be earned by attending including the required law and safety CE's.

Please note, this form is for the South Dakota Association of Pharmacy Technicians only. Please do not confuse this form with the SD State



The Medication Learning Company Update. Inform. Educate.™

### PHARMACY TECHNICIANS UNIVERSITY



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

Take the headache out of technician training with the No. 1 provider of online learning. Simplify the educational experience, improve efficiency, and help reduce medication errors with Pharmacy Technicians University (PTU).

#### TRAINING PROGRAM BENEFITS FOR TRAINFFS

- \* Easy to manage progress by staff with PTU administrator dashboards.
- \* Scalable to meet each state's changing regulation through 4 scalable offerings for your different locations' requirements
- \* PTU 101 provides 30 hours of dedicated hospital technician focus hours
- \* Choose training program options with fewer hours for completion to limit impact on productivity
- \* Faster path to increased staffing ratios for technicians in those states allowing increased ratios

pharmacy 🏽 🏶 technicians university

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Today, pharmacy technicians are increasingly important members of the pharmacy team. Skilled pharmacy technicians are critical for the economic and efficient function of a pharmacy. However, training requirements for pharmacy technicians change often and are becoming more complex, creating a shortage of qualified pharmacy technicians.

#### Pharmacy Technicians University (PTU) offers:

- \* Programs ranging from 80 to 600 hours of didactic, simulation, and experiential learning
- \* The highest quality technician training resources in a variety of learning modalities
- \* The only online tech training program that supports or exceeds the requirements for technician training in 50 states, including Washington D.C.

#### WHY TECHNICIANS I OVF PHARMACY TECHNICIANS UNIVERSITY:

#### Current Course Curriculum

reflects the latest industry trends and complies with state and national regulations.

#### Practice Skills with Feedback

#### Features

that allow techs to observe techniques, practice offline, and self-record demonstration of techniques.

#### Remote Instructors

review tech demonstrations and provide one-to-one feedback.

#### Motivating Scenario Simulations

give techs context for active learning and problem solving via "real-life" scenarios that facilitate appropriate information transfer and recall.

#### Innovative Course Design

helps technicians learn while developing observational and critical thinking skills.

#### Engaging Content

(including interactive exercises, learning games, and videos) is intermixed with didactic content to accommodate different learning styles.

**TRC Healthcare** 

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### THE RIGHT SOLUTION FOR YOUR TECHNICIANS

The *Pharmacy Technicians University* training platform is the first web-based learning and education solution to support the diverse requirements for pharmacy technician training across all 50 states. Using a unique combination of technology and tools, *Pharmacy Technicians University* facilitates and tracks hands-on learning conveniently online.

#### PTU 101. PTU ADVANCED. AND PTU NATIONAL STANDARDS PHARMACY TECHNICIAN TRAINING FOR:

- \* Provider and hospital settings
- \* Retail and community settings
- \* Health and wellness institutions such as long-term care and physical therapy centers

#### TAILORED CURRICULUM TO MEET YOUR ORGANIZATIONAL NEEDS

- \* "Right-sized" curriculum, program components, and practice setting-specific courses
- \* National Standards (ASHP/ACPE) program to meet state-specific compliance requirements
- \* ACE Credit recommendation of 7 college level credit hours
- \* Convenient, cost-effective online courses, including real-world scenarios, instructor feedback, and rich media content

#### FLEXIBLE OPTION PACKAGES



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# AWARD WINNERS



**Elwyn Freier** 50 Year Pharmacist

Elwyn Freier was the lone member of his class able to make it to convention, and recognized as one of five pharmacists who have served the profession of pharmacy for the last fifty years. Elwyn as well as Sandra Lavin, Thomas Lavin, William Peterson,

and James Speirs have joined the exclusive club in South Dakota pharmacy that consists of pharmacists that have been licensed in South Dakota for five decades. These pharmacists have demonstrated their dedication and service to the profession throughout their careers. Our profession would not be where it is today without these devoted professionals.



#### Jerrie Vedvei 2019 SDPhA Pharmacy Technician of the Year

Vedvei is described as dedicated, positive, compassionate, and hardworking. She has served several years on the Board of the SD Association of Pharmacv Technicians (SDAPT), where she currently serves as association president. During her tenure she has been instrumental in getting

more people involved with the Association by utilizing technology to create three meeting sites across the state for the SDAPT Annual Meeting. She does all she can to support those around her whether that means supporting customers in the store, making sure the day-to-day operations of the pharmacy run, or caring for friends or family.



Tom Ackerman SDPhA Outstanding Industry Salesperson of the Year

Ackerman is well known among his clients for his hard work, and always going the extra mile. As this year's Outstanding Industry Salesperson of the Year, Ackerman was recognized for demonstrating vast knowledge about his products, being extremely

respectful of people's time, and providing exceptional support to pharmacists and pharmacy in South Dakota.



#### Eric Grocott 2019 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. Most who know Grocott will tell you, not much grass grows under his feet. He is always

on the go. Grocott has dedicated an enormous amount of time to advancing the profession, serving SDPhA and his community. He has served on the SDPhA Board of Directors for the past 6 years and just finished his term as Immediate Past-President. Eric has traveled on behalf of the Association on multiple occasions to testify on your behalf. On both state and national levels, he has been influential regarding pieces of legislation that impact the profession.





**Donald Frank** 2019 Bowl of Hygeia Award

The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) present the Bowl of Hygeia Award to recipients selected by their Association for their excellent commitment to pharmacy and

outstanding record of community service. Frank dedicated and his team established the first telepharmacy in South 38 years as the owner of Frank Rexall Drug and more than Dakota. He has been the pharmacy director at Rapid City 50 years as a pharmacist at Avera Gregory Hospital. Beyond Regional Hospital since 2002 and has shared his work his role as a pharmacist, Don is an active member in his with data and analytics at conferences across the country. church and has a passion for baseball. He played amateur Darger has been acknowledged with many awards baseball for 17 years on teams in Burke, Winner, Gregory, including the SDPhA Innovative Pharmacist Award in and at SDSU. Don has also coached little league baseball 02011 and in 2018 as a SDSU College of Pharmacy and and has served as an umpire. In 1995, he was inducted Allied Health Professions Distinguished Alumnus. Dana into the South Dakota Amateur Baseball Hall of Fame. Frank continues to serve the profession and currently is the was surrounded by staff members, friends and family President-Elect of SDPhA. as he received his award at the 133<sup>rd</sup> Annual Convention.



Dana Darger 2019 Hustead Award

The Hustead Award recognizes exceptional contributions and accomplishments to the pharmacy profession in South Dakota. Darger has spent most of his career working to advance pharmacy practice by thinking outside the box. In fact, he

#### Pharmacist Consult: Tobacco, Nicotine, and E-Cigarettes"

#### 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: Source: National Institute on Drug Abuse; National Institutes of Health; U.S. Department of Health and Human Services.

Permission for the full use of this material has been granted by the National Institute on Drug Abuse.

#### GOAL

To enhance pharmacists' knowledge of nicotine addiction and treatment.

#### LEARNING OBJECTIVES

- **1.** Describe the primary clinical features of nicotine addiction;
- **2.** Evaluate the pharmacokinetic properties of nicotine and how they contribute to addiction;
- 3. Describe the primary treatment approaches supporting tobacco cessation.
- 4. Evaluate the effectiveness of commonly utilized tobacco cessation treatment regimens.
- 5. Explain the mechanisms of action, and evaluate the effectiveness of commonly utilized tobacco cessation medications.
- **6.** Summarize the evidence indicating a potential involvement of genetic and epigenetic factors in tobacco use.

#### NATIONAL INSTITUTE OF DRUG ABUSE (NIDA): TOBACCO, NICOTINE, AND E-CIGARETTES

#### IS NICOTINE ADDICTIVE?

Yes. Most smokers use tobacco regularly because they are addicted to nicotine. Addiction is characterized by compulsive drug-seeking and use, even in the face of negative health consequences. The majority of smokers would like to stop smoking, and each year about half try to quit permanently. Yet, only about 6 percent of smokers are able to guit in a given year.<sup>25</sup> Most smokers will need to make multiple attempts before they are able to guit permanently.<sup>22</sup>

Medications including varenicline, and some antidepressants (e.g. bupropion), and nicotine-replacement therapy, can help in many cases (see section What are treatments for tobacco dependence later in this article).

A transient surge of endorphins in the reward circuits of the brain causes a slight, brief euphoria when nicotine is administered. This surge is much briefer than the *high* associated with other drugs. However, like other drugs of abuse, nicotine increases levels of the neurotransmitter dopamine in these reward circuits,<sup>20,21,27</sup> which reinforces the behavior of taking the drug.

Repeated exposure alters these circuits' sensitivity to dopamine and leads to changes in other brain circuits involved in learning, stress, and self-control. For many tobacco users, the longterm brain changes induced by continued nicotine exposure result in addiction, which involves withdrawal symptoms when not smoking, and difficulty adhering to the resolution to quit.<sup>28,29</sup>

The pharmacokinetic properties of nicotine, or the way it is processed by the body, contribute to its addictiveness.<sup>24</sup> When cigarette smoke enters the lungs, nicotine is absorbed rapidly in the blood and delivered quickly to the brain, so that nicotine levels peak within 10 seconds of inhalation. But the acute effects of nicotine also dissipate quickly, along with the associated feelings of reward; this rapid cycle causes the smoker to continue dosing to maintain the drug's pleasurable effects and prevent withdraw-al symptoms.<sup>30</sup>

Withdrawal occurs as a result of dependence, when the body becomes used to having the drug in the system. Being without nicotine for too long can cause a regular user to experience irri-tability, craving, depression, anxiety, cognitive and attention deficits, sleep disturbances, and increased appetite. These withdrawal symptoms may begin within a few hours after the last ciga-rette, guickly driving people back to tobacco use.

When a person guits smoking, withdrawal symptoms pea within the first few days of the last cigarette smoked and usually subside within a few weeks.<sup>31</sup> For some people, however, symptoms may persist for months, and the severity of withdrawal symptoms appears to be influence by a person's genes.<sup>30,31</sup>

In addition to its pleasurable effects, nicotine also temporar boosts aspects of cognition, such as the ability to sustain attention and hold information in memory. However, long-term smoking is associated with cognitive decline and risk of Alzheimer's Disease, suggesting that short-ter nictine-related enhancement does not outweigh long-te consequences for cognitive functioning.<sup>32</sup> In addition, people in withdrawal from nicotine experience neurocogni deficits such as problems with attention or memory.<sup>33</sup> The neurocognitive withdrawal symptoms are increasingly recognized as a contributor to continued smoking.<sup>34</sup>

A small research study also suggested that withdrawal may impair sleep for severely dependent smokers, and that this may additionally contribute to relapse.<sup>35</sup>

In addition to the drug's impact on multiple neurotransmitte and their receptors,<sup>30</sup> many behavioral factors can affect the severity of withdrawal symptoms. For many people who smoke, the feel, smell, and sight of a cigarette and the ritual of obtaining, handling, lighting, and smoking the cigarette are all associated with the pleasurable effect of smoking and can make withdrawal or craving worse.<sup>36</sup>

Learning processes in the brain associate these cues with nicotine-induced dopamine surges in the reward system? - similar to what occurs with other drug addictions. Nicotine replacement thera-pies such as gum, patches, and inhalers, and other medications approved for the treatme of nicotine addiction may help alleviate the physiologica aspects of withdrawal<sup>37–39</sup>; however, cravings often persis because of the power of these cues.

Behavioral therapies can help smokers identify environment triggers of craving, so they can use strategies to avoid these triggers and manage the feelings that arise when triggers cannot be.<sup>40,41</sup>

#### ACTIVE LEARNING QUESTIONS

- 1. Nicotine increases levels of the neurotrans-mitter \_\_\_\_\_ in the specific brain reward circuits.
- 2. The severity of withdrawal symptoms may be related to a person's genetic profile. T / F

ak 1	ARE THERE OTHER CHEMICALS THAT MAY ALSO CONTRIBUTE TO TOBACCO ADDICTION?
ed ily า	Research is showing that nicotine may not be the only ingredient in tobacco that affects its addictive potential. Smoking is linked with a marked decrease in the levels of monoamine oxidase (MAO), an important enzyme that is responsible for the breakdown of dopamine, as well as a reduction in MAO binding sites in the brain. <sup>42</sup>
rm erm tive ese	This change is likely caused by some as-yet-unidentified ingredient in tobacco smoke other than nicotine, because we know that nicotine itself does not dramatically alter MAO levels. Animal research suggests that MAO inhibition makes nicotine more reinforcing, but more studies are needed to determine whether MAO inhibition affects human tobacco dependence. <sup>42</sup>
ers	Animal research has also shown that acetaldehyde, another chemical in tobacco smoke created by the burning of sugars added as sweeteners, dramatically increases the reinforcing properties of nicotine and may also contribute to tobacco addiction. <sup>43</sup>
	WHAT ARE THE TREATMENTS FOR TOBACCO DEPENDENCE?
cts	There are effective treatments that support tobacco cessation, including both behavioral therapies and FDA- approved medications. FDA-approved pharmacotherapies include various forms of nico-tine replacement therapy as well as bupropion and varenicline.
nd ent il st	Research indicates that smokers who receive a combination of behavioral treatment and cessa-tion medications quit at higher rates than those who receive minimal intervention. <sup>37,40,163–168</sup>
tal	Interventions such as brief advice from a health care worker, telephone helplines, automated text messaging, and printed self-help materials can also facilitate smoking cessation. <sup>164</sup> Cessation interventions utilizing mobile devices and social media also show promise in boosting tobacco cessation. <sup>169</sup> It is important for cessation treatment to be as personalized as possible, as some people smoke to avoid negative effects of withdrawal while others are more
	driven by the rewarding aspects of smoking.

The prevalence of tobacco use and dependence among adolescents—as well as the neurobiological impact and medical consequences of nicotine exposure—suggest that pediatric primary care settings should deliver tobacco cessation treat-ments to both youth and parents who use tobac-co.170

Current clinical guidance does not recommend medications for adolescent tobacco cessation because of a lack of highguality studies;<sup>171</sup> however, a combination of behavioral treat-ments—such as motivational enhancement and CBT—has shown promise for helping adoles-cents guit tobacco.<sup>172</sup>

More well-designed smoking cessation studies need to be conducted with adolescent smokers, particularly in the area of pharmacologic treat-ments for nicotine dependence.<sup>171</sup>

#### ACTIVE LEARNING QUESTIONS

- 1. In addition to its pleasurable effects, nicotine also temporarily boosts aspects of cognition, such as the ability to sustain attention and hold information in memory. **T** / **F**
- 2. Smoking has been linked with a marked decrease in levels of the enzyme, \_\_\_\_\_, which, under normal conditions, helps break down dopamine.
- 3. Long-term smoking is associated with cognitive decline and risk of Alzheimer's Disease, while people in withdrawal from nicotine experience neurocognitive deficits such as problems with attention or memory. T / F

#### **BEHAVIORAL TREATMENTS**

Behavioral counseling is typically provided by specialists in smoking cessation for four to eight sessions.<sup>40</sup> Both in-person and telephone coun-seling have been found beneficial for patients who are also using cessation medications.<sup>165</sup> A variety of approaches to smoking cessation counseling are available.

#### COGNITIVE BEHAVIORAL THERAPY

CBT helps patients identify triggers—the people, places, and things that spur behavior—and teaches them relapseprevention skills (e.g., relaxation techniques) and effective coping strategies to avoid smoking in the face of stressful situations and triggers.<sup>173,174</sup>

A study that compared CBT and basic health education observed that both interventions reduced nicotine dependence.<sup>175</sup> However, another study found that among smokers trying to quit with the nicotine replacement therapy (NRT) patch, patients who participated in six sessions of intensive group CBT had better guit rates than those who received six sessions of general health education.<sup>176</sup>

#### MOTIVATIONAL INTERVIEWING

In MI, counselors help patients explore and resolve their ambivalence about quitting smoking and enhance their motivation to make healthy changes. MI is patient-focused and nonconfrontational, and providers point out discrepancies between patients' goals or values and their current behaviors. They adjust to patients' resistance to change and support self-efficacy and optimism.<sup>174</sup>

Studies of MI suggest that this intervention results in higher quit rates than brief advice to stop smoking or usual care.<sup>177</sup>

#### MINDFULNESS

In mindfulness-based smoking cessation treatments, patients learn to increase awareness of and detachment from sensations, thoughts, and cravings that may lead to relapse.<sup>178</sup> In this therapy, patients purposely attend to the thoughts that trigger cravings and urges for tobacco and cognitively reframe them as expected and tolerable. Patients learn techniques that help them tolerate negative emotions—including stress and cravings—without returning to tobacco use or other unhealthy behaviors.<sup>178</sup>

Interest in mindfulness-based treatments has increased during the past decade, and studies show that this approach benefits overall mental health and can help prevent relapse to smok-ing.<sup>179</sup> However, well-controlled clinical trials are needed.

#### **TELEPHONE SUPPORT & QUITLINES**

As part of tobacco control efforts, all states offer toll-free telephone numbers (or guitlines) with smoking cessation counselors who provide information and support (800-QUIT-NOW or 800-784-8669).

Studies of quitline interventions indicate that smokers who call quitlines benefit from these ser-vices,<sup>180</sup> Future research should determine the effectiveness of particularly when a counselor calls them back for multiple different technologies for smoking cessation support among sessions.<sup>181</sup> There is limited evidence on the optimal number populations that may be hard to reach, including those of calls needed, but smokers who participated in three or of low socioeconomic status and adults older than age 50. more calls had a greater likelihood of guitting, compared with those who only received educational materials, brief Technology-based cessation interventions are particularly advice, or pharmacotherapy alone.<sup>181</sup>

Quitlines have also been shown to help smokeless tobacco cessation.<sup>182</sup> The U.S. Department of Health and Human Services provides a Smoking Quitline (877-44U-QUIT or 877-448-7848), as well as more information and tools for guitting (including text messages and other telephonebased support) at https://smokefree.gov/.

#### **TEXT MESSAGING, WEB-BASED** SERVICES. & SOCIAL MEDIA SUPPORT

Technology, including mobile phones, internet, and social media platforms can be used to provide smoking cessation interventions. These technologies have the power to increase access to care by extending the work of counselors and overcoming the geographical barriers that may deter people from entering treatment.

A review of the literature on technology-based smoking cessation interventions (internet, personal computer, and mobile telephone) found that these supports can increase the likelihood of adults quitting, compared with no intervention or self-help information, and they can be a cost-effective adjunct to other treatments.<sup>183</sup>

A technology does not necessarily have to be recent or highly sophisticated to help boost cessation rates. For example, studies suggest that adults who receive encouragement, advice, and quitting tips via textmessage—a capability on even the most basic mobile devices—show im-proved guit rates compared with control programs.<sup>184,185</sup>

Among adult tobacco users who called a state guitline, most selected an integrated phone/web cessation program in favor of a web-only inter-vention.<sup>186</sup> Participants who chose the web-only option tended

to be younger and healthier smokers, with a higher socioeconomic status. These participants tended to interact intensely with the site once, but did not re-engage as much as those who opted for the phone/web combination. A review of internet-based smoking cessation programs for adults suggested that interactive internet-based interventions that are tailored to individual needs can help people quit for 6 months or longer.<sup>187,188</sup>

relevant to young adults aged 18 to 25 - about 3.2 million of whom smoked daily in 2016.7 A systematic review and meta-analysis of published randomized trials of technologybased interventions—including computer pro-grams, internet, telephone, and text messaging for smoking cessation among this population found that they increased abstinence by 1.5 times that of comparison subjects.<sup>189</sup>

Researchers recommend embedding cessation interventions in commonly used social networking platforms,<sup>190</sup> and there has been some exploratory work in this area. Results of a trial with a relatively small number of participants suggested that Facebook was an accessible, low-cost platform for engaging young adults considering cessation. However, the study pointed to challenges in maintaining participation, retaining young people in the program, and the need for gender-specific features.<sup>190</sup>

A randomized controlled trial has been designed to test a stage-based smoking cessation intervention on Facebook tailored for smokers aged 18 to 25. Participants will be recruited online, randomly assigned to a Facebook group according to their readiness to quit, and will receive tailored daily messages and weekly counseling. The study will assess the intervention's impact on absti-nence from smoking 3, 6, and 12 months after treatment, number of cigarettes smoked, guit attempts lasting 24 hours or more, and commitment to abstinence.<sup>191</sup>

#### ACTIVE LEARNING QUESTION

1. Text-messaging tips have been shown to positively benefit smoking quit rates. T / F

#### SMOKING CESSATION FOR PREGNANT WOMEN

Given the risks associated with smoking during pregnancy, but also the challenges faced by all smokers when trying to quit, researchers have studied an array of approaches to improve cessation rates for this population. Many women are motivated to guit during pregnancy, but like other smokers, most will need assistance.

Studies show that behavioral treatments are effective, whereas pharmacotherapies have only marginal success.<sup>192</sup> A combination of incentives and behavioral counseling is most effective for pregnant women.<sup>193</sup> Adding vouchers to routine care (which included free nicotine replacement therapy for 10 weeks and four weekly support phone calls) more than doubled cessation rates during pregnancy.<sup>194</sup>

Pooled results of behavioral intervention studies indicate that treatment reduced preterm births and the proportion of infants born with low birth weight, compared with usual care.<sup>195</sup> This finding is supported by an analysis of pooled results from studies with economically disadvantaged pregnant smokers, which found that voucher-based incentives improved sonographically estimated fetal growth, birth weight, percentage of low-birth-weight deliveries, and breastfeeding duration.<sup>196,197</sup>

#### NICOTINE REPLACEMENT THERAPY

A variety of formulations of nicotine NRTs are available over the counter—including the transdermal patch, spray, gum, and lozenges—and are equally effective for cessation.<sup>37,38,198,199</sup>

NRTs stimulate the brain receptors targeted by nicotine, helping relieve nicotine withdrawal symptoms and cravings that lead to relapse.<sup>37</sup> Many people use NRT to help them get through the early stages of cessation, and those with more severe nicotine addiction can benefit from longer-term treatment. Use of NRT improves smoking cessation outcomes, and adding behavioral therapies further increases guit rates.<sup>195</sup> A combination of continual nicotine delivery through the transdermal patch and one other form of nicotine taken as needed (e.g., lozenge, gum, nasal spray, inhaler) has been found to be more effective at relieving withdrawal symptoms and cravings than a single type of NRT.<sup>37,168,199</sup>

Researchers estimate that NRT increases quit rates by 50 to 70 percent.37 Using the patch for up to 24 weeks has been shown to be safe.<sup>39</sup>

#### **BUPROPION**

Bupropion (immediate-release and extended-release) was originally approved as an antidepressant. It works by inhibiting the reuptake of the brain chemicals norepinephrine and dopamine as well as stimulating their release. Bupropion has been found to increase guit rates compared with placebo in both short- and long-term follow-up studies <sup>167,199,200</sup> and is indicated for smoking cessation. It is equally effective to NRT.<sup>168</sup>

#### VARENICLINE

Varenicline helps reduce nicotine cravings by stimulating the alpha-4 beta-2 nicotinic receptor but to a lesser degree than nicotine. Varenicline boosts the odds of successfully quitting, compared with unassisted attempts.<sup>199</sup> Varenicline increased the likelihood of quitting compared with placebo, and some studies find that it is more effective than single forms of NRT<sup>201,202</sup> and bupropion.1<sup>68</sup>

In a primary care setting, 44 percent of patients on varenicline, either alone or combined with counseling, were abstinent at the 2-year follow-up. Patients who participated in group therapy and adhered to the medication were more likely to remain abstinent.<sup>203</sup> Research also suggests that this medication may be more effective than bupropion.<sup>200</sup>

#### MEDICATION COMBINATIONS

Some studies suggest that combining NRT with other medications may facilitate cessation. For example, a metaanalysis found that a combination of varenicline and NRT (especially, providing a nicotine patch prior to cessation) was more effective than varenicline alone.<sup>204</sup> Similarly, adding bupropion to NRT also improved cessation rates.<sup>200</sup>

For smokers who could not cut down significantly by using the NRT patch, combining extended-release bupropion and varenicline was more effective than placebo, particularly for men and those who were severely nicotine dependent.<sup>140</sup>

#### OTHER ANTIDEPRESSANTS

In addition to bupropion, some other antidepressant medications have also been found effective for smoking cessation, independent of their antidepressant effects, and are considered second-line treatments. A few small studies suggest that nortriptyline is equally effective as NRT.<sup>168,200</sup>

Although nortriptyline may have side effects in some patients, the small studies for its use in smoking cessation have not reported any.<sup>200</sup> Researchers have not observed any impact of selective serotonin reuptake inhibitors (SSRIs) (e.g., fluoxetine, paroxetine, and sertraline) on smoking, either alone or in combination with NRT.<sup>200</sup>

#### PRECISION MEDICINE

Researchers have been examining ways to personalize treatment based on important individual biological differences, TMS is a relatively new approach being tested to treat including genetic differences. The field of pharmacogenetics addiction. It is a physiological intervention that noninvasively examines how genes influence therapeutic response to stimulates neural activity in targeted areas of the brain using medications, providing critical information to help tailor magnetic fields. Multiple TMS pulses given consecutively pharmacotherapies to the individual for maximum benefit. are referred to as repetitive TMS (rTMS). The FDA has approved two rTMS devices for depression treatment in adults. For example, people metabolize nicotine at different rates because of variations in several genes. Individuals who metabolize nicotine guickly smoke more, show greater Research on rTMS as a treatment for smoking cessation is in early stages but has shown promise.<sup>215,216</sup> Among adult dependence, and have more difficulty quitting.<sup>205</sup> Such genetic variation influences the therapeutic responses smokers who had not been able to guit using other treatments, to NRT and other cessation medications.<sup>205,206</sup> high-frequency TMS treatment significantly reduced the

A recent study compared rates of abstinence one week after treatment for slow, normal, and fast metabolizers of nicotine who were randomly assigned to either placebo, NRT, or varenicline. Results indicated that varenicline worked best for normal nicotine metabolizers, whereas NRT patches were most effective for slow metabolizers.<sup>206,207</sup>

#### **PROMISING MEDICATIONS** & ONGOING RESEARCH

NIDA supports research to develop new and improve current treatment options for smoking ces-sation based on a growing understanding of the neurobiology of addiction. The medical consequences of tobacco use—including In the area of medications, research is focusing on the secondhand exposure—make tobacco control and smoking receptors targeted by nicotine and the brain circuits prevention crucial parts of any public health strategy. Since and regions known to influence nicotine consumption.<sup>208</sup> the first Surgeon General's Report on Smoking and Health Newer brain targets—including the orexin and glutamate in 1964, states and communities have made efforts to signaling systems—have also shown promise for reduce initiation of smoking, decrease exposure to smoke, medication treatment.<sup>208,209</sup> and increase cessation.

Repurposing medications already on the market for other indications may also prove useful in the search for new smoking cessation therapies.2<sup>10,211</sup> This approach has been successful in the past, as bupropion was an established antidepressant before the FDA approved it as a smoking cessation medication. One current candidate is Nacetylcysteine, a medication for acetaminophen overdose, which has shown promise as a treatment for various substance use disorders—including nicotine dependence.<sup>212</sup>

Another approach that could prevent relapse and that has shown promise in early studies is a nicotine vaccine, which would generate antibodies that keep nicotine from reaching the brain.<sup>213,214</sup>

#### TRANSCRANIAL MAGNETIC STIMULATION

number of cigarettes smoked. Combining high-frequency TMS with exposure to smoking cues improved effectiveness and boosted the overall abstinence rate to 44 percent at the end of the treatment. Six months after treatment, 33 percent of participants remained abstinent from cigarettes.<sup>217</sup>

Future randomized controlled clinical trials with large numbers of patients will be needed to establish its efficacy for smoking cessation.

#### HOW CAN WE PREVENT **TOBACCO USE?**

Researchers estimate that these tobacco control efforts are associated with averting an estimated 8 million premature deaths and extending the average life expectancy of men by 2.3 years and of women by 1.6 years.<sup>18</sup> But there is a long way yet to go: roughly 5.6 million adolescents under age 18 are expected to die prematurely as a result of an illness related to smoking.<sup>13</sup>

Prevention can take the form of policy-level measures, such as increased taxation of tobacco products; stricter laws (and enforcement of laws) regulating who can purchase tobacco products; how and where they can be pur-chased; where and when they can be used (i.e., smoke-free policies in restaurants, bars, and other public places); and restrictions on advertising and mandatory health warnings on packages.

Over 100 studies have shown that higher taxes on cigarettes, for example, produce significant reductions in smoking, especially among youth and lower-income individuals.<sup>218</sup> Smoke-free workplace laws and restrictions on advertising have also shown benefits.<sup>219</sup>

Prevention can also take place at the school or community level. Merely educating potential smokers about the health risks has not proven effective.<sup>219</sup> Successful evidence-based interventions aim to reduce or delay initiation of smoking, alcohol use, and illicit drug use, and otherwise improve outcomes for children and teens by reducing or mitigating modifiable risk factors and bolstering protective factors. Risk factors for smoking include having family members or peers who smoke, being in a lower socioeconomic status, living in a neighborhood with high density of tobacco outlets, not participating in team sports, being exposed to smoking in movies, and being sensation-seeking.<sup>220</sup>

Although older teens are more likely to smoke than younger teens, the earlier a person starts smoking or using any addictive substance, the more likely they are to develop an addiction. Males are also more likely to take up smoking in adolescence than females. Some evidence-based interventions show lasting effects on reducing smoking initiation. For instance, communities utilizing the intervention-delivery system, Communities that Care (CTC) for students aged 10 to14 show sustained reduction in male cigarette initiation up to 9 years after the end of the intervention.<sup>221</sup>

#### WHAT RESEARCH IS BEING DONE ON TOBACCO USE?

New scientific developments can improve our understanding of nicotine addiction and spur the development of better prevention and treatment strategies.

#### **GENETICS & EPIGENETICS**

An estimated 50-75 percent of the risk for nicotine addiction is attributable to genetic factors.<sup>222</sup>

A cluster of genes (CHRNA5-CHRNA3-CHRNB4) on chromosome 15 that encode the  $\alpha$ 5,  $\alpha$ 3, and  $\beta$ 4 protein subunits that make up the brain receptor for nicotine<sup>222–224</sup> are particularly implicated in nicotine dependence and smoking among people of European descent. Variation in the CHRNA5 gene influences the effectiveness of combination NRT, but not varenicline.<sup>225</sup>

Other research has identified genes that influence nicotine metabolism and therefore, the number of cigarettes smoked,<sup>226</sup> responsiveness to medication,<sup>205,206</sup> and chances of successfully guitting.<sup>227</sup> For example, the therapeutic response to varenicline is associated with variants for the CHRNB2, CHRNA5, and CHRNA4 genes, while bupropionrelated cessation is linked with variation in genes that affect nico-tine metabolism.<sup>228</sup>

Smoking can also lead to persistent changes in gene expression (epigenetic changes), which may contribute to associated medical consequences over the long term, even following cessation.<sup>229</sup> Epigenetic changes may serve as a potential biomarker for prenatal tobacco smoke exposure. Researchers found tobacco-specific changes at 26 sites on the epigenome, and this pattern predicted prenatal exposure with 81 per-cent accuracy.<sup>230</sup> A large scale metaanalysis of data on epigenetic changes associated with prenatal exposure to cigarette smoke also identified many epigenetic changes that persisted into later childhood.<sup>231</sup> More research is needed to un-derstand the long-term health impacts of these change.

#### NEUROIMAGING

Cutting-edge neuroimaging technologies have identified brain changes associated with nicotine dependence and smoking. Using functional magnetic resonance imaging (fMRI), scientists can visualize smokers' brains as they respond to cigarette-associated cues that can trigger craving and relapse.<sup>232</sup> Such research may lead to a biomarker for relapse risk and for monitoring treatment progress, as well as point to regions of the brain involved in the development of nicotine addiction.<sup>29</sup>

A neuroimaging technology called default-mode or resting-state fMRI (rs-fMRI) reveals intrinsic brain activity when people are alert, but not performing a particular task. Using this technique, researchers are examining the neuro-biological profile associated with withdrawal and how nicotine impacts cognition.<sup>233</sup>

Comparisons between smokers and nonsmokers suggest that chronic nicotine may weaken connectivity within brain circuits involved in planning, paying attention, and behavioral control—possibly contributing to difficulty with guitting.<sup>234</sup> fMRI studies also reveal the impact of smoking cessation medications on the brain—particularly how they modulate the activity of different brain regions to alleviate withdrawal symptoms and reduce smoking. A review of these studies suggested that NRT enhances cognition during withdrawal by modulating activity in default-network regions, but may not affect neural circuits associated with nicotine addiction.235

Some imaging techniques allow researchers to visualize neurotransmitters and their receptors, further informing our understanding of nicotine addiction and its treatment.<sup>27</sup> Using these techniques, researchers have established that smoking increases the number of brain receptors for nicotine. Individuals who show greater receptor upregulation are less likely to stop smoking.<sup>28</sup>

Combining neuroimaging and genetics may yield particularly useful information for improving and tailoring treatment. For example, nonsmoking adolescents with a particular variant in the CHRNA5-CHRNA3-CHRNB4 gene cluster (which is associated with nicotine dependence and smoking) showed reduced brain activity in response to reward in the striatum as well as the orbitofrontal and anterior

cingulate cortex. This finding suggests that genetics can influence how the brain processes rewards which may influence vulnerability to nicotine dependence.2<sup>36</sup>

Neuroimaging genetics also shows that other genes, including ones that influence dopamine neurotransmission, influence reward sensitivity and risk for addiction to nicotine.237

<b>Source:</b> National Institute on Drug Abuse; National Institutes of Health; U.S. Department of Health and Human Services.

Accessed from: <u>https://www.drugabuse.gov/pub-</u> lications/research-reports/tobacco-nicotine-e-cigarettes/what-research-being-done-tobacco-use

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

**Directions:** Complete the answer sheet / evaluation on the following page and submit for credit to:

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#### Pharmacist Consult: Tobacco. Nicotine, and E-Cigarettes

Learning Assessment – Post Test (Select all correct answers for each question)

- 1. Nicotine addiction is characterized by the following TRUE statements:
  - Addiction involves compulsive drug-seeking Α. and continued use.
  - Most smokers would like to stop. R
  - Only 6% of smokers are able to guit in a given year. C.
  - Most smokers who quit are successful on the first try. D.
- 2. Nicotine euphoria phenomenon involves \_\_\_\_
  - A. a surge of endorphins in the reward circuits of the brain
  - a fairly brief 'high,' versus that of other drugs; Β.
  - a decrease in the neurotransmitter, dopamine in C. the reward circuits.
  - all of the above. D.
- 3. Inhaled Nicotine exhibits the following pharmacokinetic features:
  - Rapidly absorbed into the blood, guickly delivered Α. to the brain;
  - Nicotine levels peak within 10 seconds. R
  - Acute effects dissipate slowly, associated feelings of reward are relatively long-lasting
  - All of the above. D.
- 4. Being without nicotine for too long can cause a regular user to experience \_\_\_\_\_.
  - Α irritability and craving.
  - a happy, friendly, care-free attitude B.
  - cognitive and attention deficits C.
  - D. sleep disturbances, increased appetite.
- 5. With nicotine addiction, withdrawal symptoms \_\_\_\_
  - A. may begin within a few hours of the last cigarette.
  - generally peak within the first few days of quitting; Β.
  - C. usually subside within a few weeks;
  - D. may last much longer for some people, due to genetic influences.
- 6. Which of the following is/are TRUE regarding the neurologic effects of nicotine?
  - A. It temporarily boosts aspects of cognition, such as the ability to sustain attention and hold information in memory.
  - Long-term smoking is associated with cognitive R decline and risk of Alzheimer's Disease.
  - People in withdrawal from nicotine experience C. neurocognitive deficits such as problems with attention or memory.
  - D. All of the above statements are TRUE.
- 7. Which of the following statements is/are FALSE?
  - A. Smokers who receive a combination of behavioral treatment and cessation medications quit at higher rates than those who receive minimal intervention

- B. Current clinical guidance does not recommend medications for adolescent tobacco cessation
- C. It is important for cessation treatment to be as personalized as possible.
- D. All of the above statements are TRUE.
- \_ is a form of behavioral therapy which 8. helps smokers identify 'triggers' that typically spur smoking behavior.
  - A. Motivational Interviewing (MI)
  - B. Mindfulness
  - C. Behavioral treatments
  - D. Cognitive Behavioral Therapy (CBT)
- Studies on pregnant women who are motivated 9. to quit smoking show that \_
  - A. most women smokers are able to guit on their own.
  - a combination of incentives and behavioral Β. counseling is rarely effective.
  - C. behavioral intervention treatment reduced the incidence of preterm births and low birth weights.
  - D. all of the above
- **10.** Nicotine Replacement Therapy (NRT) stimulates specific brain receptors to help alleviate withdrawal symptoms and cravings. Which of the following statements is/are also TRUE?
  - A. NRT is available only in a nicotine gum formulation.
  - NRT typically leads to guit rates of 95%-100%. B
  - Use of a transdermal patch plus one other form of C. nicotine is believed to be more effective at relieving withdrawal symptoms and cravings than a single type of NRT.
  - D. All of the above
- 11. Which of the following statements about bupropion, varenicline, and SSRIs are TRUE?
  - A. Bupropion promotes the reuptake of the brain chemicals norepinephrine and dopamine.
  - B Varenicline stimulates the alpha-4 beta 2 receptor to help reduce nicotine cravings.
  - C. SSRIs do not appear to be effective, alone or in combination with NRTs, for smoking cessation.
  - Varenicline may be more effective than bupropion, D. according to some studies.
- **12.** Research has indicated that an estimated \_\_\_\_\_ of the risk for nicotine addiction is attributable to genetic factors. A cluster of genes on chromosome 15 appear to be particularly implicated in nicotine dependence and smoking among people of \_\_\_\_\_ descent. Smoking can also lead to persistent changes in

\_\_\_\_\_, which may contribute to associated medical consequences over the long term.

- (Select the correct answer combination to fill in the blanks above).
- A. 50-75%, European, gene expression
- 80-90%, European, genetic variations R
- 25-30%, North African, random cell division C.
- D. 50-75%, Asian, genetic sequencing

#### Pharmacist Consult: Tobacco, Nicotine, and E-Cigarettes

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.

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*Learning Objectives - Pharmacists:* 1. Describe the primary clinical features of nicotine addiction; 2. Evaluate the pharmacokinetic properties of nicotine and how they contribute to addiction; 3. Describe the primary treatment approaches supporting tobacco cessation; 4. Evaluate the effectiveness of commonly utilized tobacco cessation treatment regimens; 5. Explain the mechanisms of action, and evaluate the effectiveness of commonly utilized tobacco cessation medications; 6. Summarize the evidence indicating a potential involvement of genetic and epigenetic factors in tobacco use.

<b>Circle Correct Answer:</b>	1. A B C D	<b>4</b> . A B C D	7. A B C D	10	<b>).</b> A	ΒC	D		
	2. A B C D	5. A B C D	8. A B C D	11	<b>.</b> A	BC	D		
	3. A B C D	6. A B C D	9. A B C D	12	2. A	ВС	D		
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### Making a Charitable Gift from Your IRA

Is your annual IRA withdrawal a bother? If you are an affluent retiree, that might be the case. The income is always nice, but the taxes that come with it? Not so much. If only you could satisfy your yearly IRA withdrawal requirement minus the attached taxes. Guess what: there might be a way.

If you gift traditional IRA assets to charity, you could see some big tax savings. The Internal Revenue Service calls this a Qualified Charitable Distribution (QCD), and you may want to explore its potential. Some criteria must be met: you need to be at least 70½ years old in the year of the donation, the donation must take the form of a direct transfer of assets from the IRA custodian to the charity, and the charity must be qualified in the eyes of the I.R.S. Any 501(c)(3) non-profit organization meets the I.R.S. qualification, as do houses of worship.<sup>1</sup> The amount you gi can be applied toward your Required Minimum Distribution (RMD) for the year, and you may exclude it from your taxable income. If you are retired and well-to-do, a charitable IRA gift could be a highly tax-efficient move.<sup>1,2</sup>

Just how much could you save? That depends on two factors: how much you gift, and your federal income tax bracket. As an example, say you are in the 35% federal income tax bracket, and you donate \$40,000 from your traditional IRA to a 501(c)(3) non-profit organization. That \$40,000 will be gone from your taxable income, and the donation will cut your federal tax bill for the year by \$14,00 (as 35% of \$40,000 is \$14,000). Yes, the savings could be significant.<sup>2</sup> You can donate as much as \$100,000 to a qualified charity this way in a single year. That limit is per IRA owner; if you are married, and you and your spouse both have traditional IRAs, you can each donate up to \$100.000.<sup>1,2</sup>

What about the fine print? There is plenty of that, and it is all worth reading. You may be curious if you can make a QCD from a SIMPLE or SEP-IRA; the answer is no. You can make a QCD from a Roth IRA, but there is little point in it:

#### Follow the rules, and you might get a big federal tax break.

l y íft	Roth IRA withdrawals are commonly tax-free. <sup>1</sup> Regarding the asset transfer, the critical detail is that you cannot touch the money. The distribution must be payable directly to the non-profit organization or charity, not to you. (Income tax does not need to be withheld from the distribution since the amount withdrawn will not count as taxable income.) In addition, your tax preparer must identify the distribution as a QCD on your federal tax return. This is crucial and must not be overlooked, because the custodian of your IRA will probably report your QCD as a normal IRA distribution. <sup>2</sup> If you itemize your deductions, you should know that a charitable IRA gift does not count as a deductible charitable contribution. (That would amount to a double tax break.) Of course, fewer taxpayers have incentive to itemize now, since the standard deduction is so large, thanks to the Tax Cuts & Jobs Act. <sup>1,2</sup>
on	If you want to make a charitable IRA gift, start the process before the year ends. If you try to make the gift in late December, your IRA custodian might not be able to move fast enough for you, and the asset transfer may occur later than you would like (i.e., after December 31). Talk with a tax or financial professional before the year ends, so that you can plan a charitable IRA donation with some time to spare.
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### 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.

### A Pharmacist's Duty to an Unknown Third Party

A recent court decision in Michigan re-examined an issue first discussed in this column about ten years ago. In the Sanchez case from Nevada in 2009, the patient, driving while under the influence of prescription medications, hit two men, killing one. The survivor and the decedent's family sued a number of parties, including eight pharmacies, for the injuries and wrongful death. The Nevada court cited Common Law principles that a person has no duty to control another's dangerous conduct, or to warn others of that dangerous conduct absent a special relationship and foreseeable harm. The court decided that there was no special relationship because the plaintiffs in that case were unidentifiable prior to the accident.

The Michigan decision dealt with a very similar situation. In this case, a patient's car crossed the centerline and collided with another car, killing two women and injuring another. The patient had received a number of prescriptions for controlled substances, including fentanyl patches, over the previous two years. On the day of the accident, the patient received a prescription for fentanyl patches. Upon leaving the pharmacy, he put a patch in his mouth and chewed it presumably in an attempt to bypass the time-release mechanism.

The decedents' families and the survivor filed suit against both the prescriber and the pharmacy alleging that a special relationship existed between the patient and the pharmacy and that it was foreseeable that the patient would drive while intoxicated. The pharmacy filed a motion for Summary Judgment stating that no such relationship existed and that it was not foreseeable that the patient would misuse the patch. The trial court disagreed with the pharmacy's position and denied their motion.

The pharmacy appealed the ruling to the Michigan Court of Appeals. The Court of Appeals reviewed a line of pharmacy cases in Michigan dating back to 1980. The existing rule in Michigan is that a pharmacist does not have a duty to warn a patient of possible adverse events when dispensing a drug pursuant to a facially valid prescription. Based on these cases, the Court concluded, "... it would be illogical to impose such a duty on the pharmacist with respect to a third party." The Court also concluded that the pharmacy had no duty to monitor the patient's use of fentanyl. In a somewhat unusual circumstance, one judge filed a concurring opinion in which he agreed with the conclusion, but urged the Michigan Supreme Court to take up the case because he believed that Michigan case law was based on an incorrect interpretation of the law. He reviewed legislation and regulations from which he concluded that a pharmacist does have a duty to warn of possible adverse events and to monitor the patient's use of medications. The first of these was the Federal regulation under the Controlled Substances Act that created a pharmacist's corresponding responsibility to consider the validity of an order for a controlled substance. The conclusion was that the Michigan case law stating that a pharmacist has no legal duty to monitor the prescribing of controlled substances was at odds with Federal law. The judge also cited Michigan laws and regulations supporting the conclusion that pharmacists have a broader duty than the current case law outlines.

The judge urged the Michigan Supreme Court to take up the case because the Court of Appeals did not have the authority to overturn Michigan case law. However, in April 2019, the Supreme Court declined to hear the appeal and the Court of Appeals ruling stands.

While some states' case law still follows the concept of the Learned Intermediary (i.e., the pharmacist has no duty to warn the patient because of the involvement of the prescriber who is the Learned Intermediary). The concurring opinion in this case gives us a glimpse of where the law is likely to go. As pharmacists continue to expand the array of services that they can provide to patients and technological advances place more information into their hands, it seems unlikely that pharmacists will be able to continue to rely on the defense of filling a facially valid prescription. While this may not extend to a duty to unknown third parties, pharmacists should be prepared for future courts to impose a duty to warn patients of possible adverse events and to monitor their medication usage.

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

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#### WARNINGS AND PRECAUTIONS:

• Fatal splenic rupture: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

 Acute respiratory distress syndrome (ARDS): Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue UDENYCA® in patients with ARDS.

#### **FDA APPROVED**

pegfilgrastim biosimilar for patients at risk for febrile neutropenia-related infection



### ValueDifferent.

UDENYCA®—the pegfilgrastim biosimilar that delivers high-quality treatment and the reliable outcomes you expect with Neulasta® (pegfilgrastim), but with 32% cost savings for your patients and practice.\*13

#### Learn more at UDENYCA.com

\*UDENYCA® wholesale acquisition cost (WAC) of \$4175 per prefilled syringe vs Neulasta® WAC of -\$6200 per prefilled syringe.

- Serious allergic reactions, including anaphylaxis: Permanently discontinue UDENYCA® in patients with serious allergic reactions.
- · Fatal sickle cell crises: Have occurred.
- Glomerulonephritis: Evaluate and consider dose-reduction or interruption of UDENYCA® if causality is likely.

ADVERSE REACTIONS: Most common adverse reactions (≥ 5% difference in incidence compared to placebo) are bone pain and pain in extremity.

To report SUSPECTED ADVERSE REACTIONS, contact Coherus BioSciences at 1-800-4-UDENYCA (1-800-483-3692) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on the following page.

References: 1. UDENYCA® (pegfilgrastim-cbqv) package insert. Redwood City, CA: Coherus BioSciences, Inc.; 2019. 2. First Databank, Inc. Pricing Compendia. 3. Data on file. Coherus BioSciences, Inc.; 2018.

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### **UDENYCA®** (pegfilgrastim-cbqv)

#### **BRIEF SUMMARY OF FULL PRESCRIBING** INFORMATION

The following is a brief summary of the Full Prescribing Information and does not include all the information needed to use UDENYCA® (pegfilgrastim-cbgv) injection safely and effectively. See Full Prescribing Information for UDENYCA®.

#### UDENYCA® (pegfilgrastim-cbqv) injection, for subcutaneous use

**INDICATION:** UDENYCA® is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. (See Section 1 of the Full Prescribing Information.)

#### Limitations of Use

UDENYCA® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. (See Section 1 of the Full Prescribing Information.)

**CONTRAINDICATION:** Patients with a history of serious allergic reaction to human granulocyte colony-stimulating factors such as pegfilgrastim or filgrastim products. (See Section 4 of the Full Prescribing Information.)

#### WARNINGS AND PRECAUTIONS:

Fatal splenic rupture: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture. (See Section 5.1 of the Full Prescribing Information.)

#### Acute respiratory distress syndrome (ARDS):

Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue UDENYCA® in patients with ARDS. (See Section 5.2 of the Full Prescribing Information.)

#### Serious allergic reactions, including anaphylaxis: Permanently discontinue UDENYCA® in patients with serious allergic reactions. (See Section 5.3 of the Full Prescribing Information.)

Fatal sickle cell crises: Have occurred. (See Section 5.4 of the Full Prescribing Information.)

Glomerulonephritis: Evaluate and consider dose-reduction or interruption of UDENYCA® if causality is likely. (See Section 5.5 of the Full Prescribing Information.)

ADVERSE REACTIONS: Most common adverse reactions (≥ 5% difference in incidence compared to placebo) are bone pain and pain in extremity. (See Section 6.1 of the Full Prescribing Information.)

To report SUSPECTED ADVERSE REACTIONS. contact Coherus BioSciences at 1-800-4-UDENYCA (1-800-483-3692) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured by: Coherus BioSciences, Inc. Redwood City, CA 94065-1442



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### OBITUARIES

#### Ralph H. Gosch



Ralph H. Gosch, age 75, of Huron, passed away at his home on Saturday, August 3, 2019.

Ralph H. Gosch was born February 8, 1944 in Corpus Christie, Texas to Herbert Gosch and Fern Humphrey Gosch Baynes. He was raised in Huron by his maternal grandparents H.H. Humphrey Sr. and Christine Humphrey and Vice President Hubert H. Humphrey (Legal Guardian). He spent his

early childhood at the family drug store in Huron, and many summers at the lake in Waverly MN with his Uncle Hubert and Aunt Muriel and cousins. He attended grade school at Lincoln Elementary. He then attended Huron High School and graduated in 1962. After graduation he attended American University in Washington DC. He then returned back to South Dakota and finished his college degree majoring in pharmacy at South Dakota State University. Ralph was active in the ROTC Band playing the trombone while attending College. During his time in college he started dating Bonnie McIlvaine of Huron.

Bonnie and Ralph were united in marriage on June 12th 1965 in Huron They made their home in Huron and Ralph started working at the family drug store. In 1967 Ralph and Bonnie welcomed their only child Christine H. Gosch. Ralph had a passion for gardening which lead to him opening Gosch's Greenhouse where he raised plants and suppled various retail outlets in Minnesota, Iowa and South Dakota. He also started a retail stand at the South Dakota State Fair expanding into crafts and later concessions. He opened a donut shop in downtown Huron. Ralph, Bonnie and Christie spent every summer working the Concession business throughout the Midwest. After closing the pharmacy portion of the drug store, Ralph worked as a contract Pharmacist working throughout South Dakota in private pharmacies as well as Indian Health Services. He spent his later years working at the Ship Rock Indian Heath Hospital in New Mexico. Ralph retired in July of 2018. He had a passion for hunting, fishing and raising hunting dogs. He also enjoyed working and training young people.

He is survived by his wife of 54 years Bonnie of Huron, his only daughter Christie H. Gosch, MD, and her husband Jesse Echevarria; three grandchildren Nick, Kennedy and Madison all of Nixa, Missouri area and many cousins, nieces and nephews. He is preceded in death by his parents, his maternal and paternal grandparents, his sister Diane Indseth and many aunts and uncles.

#### Charity Grace Hoffelt



Sioux Falls - Sioux Falls, SD -Charity Grace Hoffelt, 41, passed August 11, 2019.

Survivors include her children, Aida, Rosabelle and Alden Hoffelt; three sisters, Catharine (Kenneth) Goodwin, Worthing, SD, Anna (John) Van Gorp, Sheldon, IA, Susanna (John) Fife, Richmond, VA; parents, Richard and Teresa Dee. She was preceded by two sisters, Christina Dee, Paula Dee

and her maternal and paternal grandparents.

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