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SOUTH DAKOTA
PHARMACIST

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

South Dakota Board of Pharmacy
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(605)362-2737
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SDPhA CALENDAR

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

JANUARY

1 New Years Day
10 Legislative Session Begins
16 Martin Luther King, Jr. Day

FEBRUARY

17-19 Midwest Expo, Des Moines, IA
20 Presidents Day

MARCH

12 Daylight Savings Begins
14-15 RxIMPACT Meeting, Washington DC
24-27 APhA Annual Meeting, San Francisco, CA

APRIL

16 Easter Sunday

SOUTH DAKOTA PHARMACIST
The *SD PHARMACIST* is published quarterly (Jan, April, July & Oct). *Opinions expressed do not necessarily reflect the official positions or views of the South Dakota Pharmacists Association.*

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DIRECTOR'S COMMENTS

Sue Schaefer | Executive Director

Happy New Year!

South Dakota's 92nd Legislative Session has just begun and it looks like your association will be busy tracking pharmacy-related bills. It's too early to know exactly how many bills will be introduced, but we'll do our best to keep you apprised via our weekly legislative update. We'll update you via Constant Contact (email) and Facebook, and the update will also be available on our website at www.sdpha.org.

As Trisha mentioned in her article, we cancelled Legislative Days this year due to the uncertainties of Initiated Measure 22. We hope that things get resolved quickly so we can get things in place for the 2018 Legislative Session. Legislative Days has become an integral part of educating lawmakers, students, pharmacists, technicians and the public in general, on what pharmacy can do to improve patient lives. We hope you continue to support your Commercial & Legislative Branch (C&L) so Bob Riter and I can continue to represent your interests during Legislative Session.

Specific legislative bills to watch will be House Bill 1043 and 1044, which have been introduced by the South Dakota Board of Pharmacy. Please review and follow this legislation and let us know if you have any thoughts or concerns. The Association had an opportunity to review the bills and offer suggested changes, and we are thankful the Board accepted many of our recommendations. It will first be heard in the House Health & Human Services Committee on January 17th at 7:45 a.m.

This year, we were invited back for the second annual flu shot clinic for legislators. We all hope that most of our lawmakers have already been vaccinated as they arrive for the upcoming legislative session, but it was nice to provide an extra opportunity for legislators to receive some protection, with influenza cases rising sharply in recent days. Our sincere thanks, again, to Rob Loe who provided the vaccine and immunized around twenty individuals. This is a wonderful opportunity to share our story with our legislators and prove that pharmacists can do so much more!

Work continues with the Department of Health's Chronic Disease/Diabetes Care office and the "Diabetes Toolkit", which was sent to all PICs in South Dakota pharmacies. Our pharmacists were engaged to help design the toolkit, and hope you are all finding it useful in your pharmacies. If you've got a particular success story to share regarding its use and value, please do share with us! We want to make sure the program is a success and are hoping it leads to more pharmacy involvement with the Department of Health.

On the national level, provider status is once again come to the forefront. We hope to engage your support in the coming weeks as pharmacy works to educate congress on the importance of pharmacist services and patient-centric care.

We also continue to join with the Iowa Pharmacists Association to promote this valuable winter conference, which will be held February 17-19, 2017 in Des Moines, Iowa. The Midwest Expo is a comprehensive event offering a great deal of excellent CE for pharmacists and technicians. In exchange for our endorsement and promotion, our pharmacists will have access at a great rate to attend, and allows us to offer more benefits for our members.

The SDPhA Executive Board and staff are busy working on the agenda for the Annual Convention, September 22nd and 23rd at the Lodge at Deadwood, so please save the date!

Warm and Healthy Regards,

Sue

PRESIDENT'S PERSPECTIVE

Trisha Hadrick | SDPhA President

Happy New Year! I hope you had a very Merry Christmas! It's often hard to find the time to enjoy the Holiday season, but I hope you had at least a few moments to do so.

I will start out with some disappointing news. If you haven't already heard, Legislative Days were cancelled for this year. Holding the event would have put Legislators in violation of Initiated Measure 22 (IM 22) if they had attended the screenings at our event. It appears as though it was one of many unintended consequences of IM 22 that was passed in November. Since there was no guarantee an injunction would be issued we felt it was important to cancel soon enough to not put the hotel, restaurant, etc. in a difficult spot. Please mark your calendars for January 23-24, 2018 as we hope to not run into any of the same issues. Thank you for understanding!

Even though Legislative Days were cancelled please don't hesitate to get involved in the Legislative process. The Board of Pharmacy has brought forward a bill, HB 1043, to "clean up" the pharmacy practice act. It will first be heard in the House Health & Human Services Committee on January 17th at 7:45 a.m. Prior to this hearing please review the bill and let the Association know of any concerns you may have. Your Association officers, executive director, and legal counsel were made aware of this bill just before Christmas and have all been working to review it as efficiently as possible. Your Legislator(s) may have questions for you regarding the changes so please be informed and ask the Association if you need any further information. Most Legislators have multiple ways in which you can reach out to them as well. Be watching for the emails with the Legislative Update which will be coming your way.

Thank you to the students at SDSU who were involved in designing the billboards that went up during American Pharmacists Month! I hope many of you were able to view them in person. We appreciate the efforts of the students and know that they are the future of our profession!

While attending NCPA in October I was able to hear Lee Zurik from FOX 8 News in New Orleans speak about several of his medical waste investigations. A majority of his recent investigations involve pharmacy related issues. Check out this website http://www.fox8live.com/category/314285/medical-waste-a-lee-zurik-investigation to see or read some of the issues he is bringing to the public's attention.

The attendance at Convention and at District meetings has been growing. It is very encouraging to see more pharmacists supporting our Association and the work we do for all pharmacists! The connections Sue Schaefer, our executive director, has at not only the state level, but at the national level is a wonderful asset to our profession.

Please be sure to Save the Date of our upcoming conventions. We are currently working on the schedule of events for September 22-23, 2017 at The Lodge in Deadwood. While you are marking your calendars, be sure to note in 2018 we will be at the Sioux Falls Ramkota on September 21-22nd. Our conventions and district meetings are great opportunities to further your education, visit and learn from each other, and stay informed of things going on in pharmacy that you may not see in your workplace on a day-to-day basis.

SOUTH DAKOTA BOARD OF PHARMACY

Kari Shanard-Koenders | Executive Director

BOARD WELCOMES NEW BOARD MEMBER

The South Dakota Board of Pharmacy is pleased to announce that Governor Dennis Daugaard has re-appointed Lisa Rave and has newly appointed Dan Somsen to serve on the SD Board of Pharmacy. Dan has a long career in both hospital and retail pharmacy and is the co-owner of Yankton Rexall. Dan is replacing Jeff Nielsen, who was on the Board for 9 years. Thank you for your time and talents - Jeff and welcome Dan!

BOARD WELCOMES NEW REGISTERED PHARMACISTS/PHARMACIES

The following 12 candidates recently met licensure requirements and were registered as pharmacists in South Dakota: John Chesney, Jacqueline Hanna-Youssef, Joseph Hurley, Paul Kallman, Amy Kareta, Andrew Kim, Celia Nguyen, Amanda Page, Hugh Rim, and Richard Wallace. New pharmacy permits issued over the same time period are: Avera St. Mary's Campus Pharmacy – Pierre; Rambo LTC Inc., dba Brothers Pharmacy LTC – Brookings; and Sioux Falls Specialty Hospital Pharmacy LLP(2) – Sioux Falls.

HIGHLIGHTS FROM A VISIT BY THE DEA by Paula Stotz, R.Ph., Inspector

A regional DEA Diversion Investigator team was in western South Dakota for several days in November 2016 conducting inspections. Key take-a-ways and good reminders to registrants from the visit include the following:

Background checks:

DEA registrants may not employ an employee who has access to controlled substances (CS), any person who has been convicted of a felony offense relating to CS. The DEA recommends that pre-employment inquiries be made concerning employees criminal records. Certain questions are assumed to be included as part of an employer's comprehensive employee screening program. Please refer to the DEA website: https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm

Biennial Inventories:

Biennial inventories of CS must be conducted at least every 2 years. The biennial inventory may be taken on any date which is within 2 years of the previous biennial inventory date. The inventory is to be taken on a specific date, within the 2 year period; and not over several days. The entire biennial inventory must be completed within 1 day.

- All CS on hand on the inventory date must be included. For example, outdated CS returns not yet sent to the reverse distributor, any CS received on the day the inventory is taken, dispensed medications not yet picked up by the patient and any located in an automated dispensing device.
- Each biennial inventory must contain a complete and accurate accounting of all CS on hand on the date the inventory is taken and shall be maintained in written, typewritten or printed form at the registered location for 2 years. A separate inventory record shall be maintained by the registrant for each area where CS are stored. Inventories and records of CS must be maintained separately from all other records of the registrant.
- The inventory may be taken either as of opening of business or as of the close of business on the inventory date and must be indicated on the inventory.
- An exact count or measure is required for all Schedule II substances.
- An estimate is allowed for Schedule III, IV, and V for containers less than 1,000 units. If the container hold more than 1,000 capsules, tablets etc., an exact count of the containers contents is required.
- The date and signature of the person or persons conducting the CS inventory is required.

CSOS or DEA 222 Ordering and Receiving:

When receiving or fulfilling a Schedule II drug order, the number of containers and the date must be recorded on the CSOS or 222 on the day the controlled substances are received or filled.

DEA 222 Forms:

DEA 222 forms may not be signed in advance. The DEA 222 form must be completed, dated and signed on the day it is executed and must accompany the medications as they travel.

LTC Facilities:

Pharmacies may accept a faxed Schedule II prescription as the original prescription from a provider as long as it is manually signed and is for a "LTC" or "terminally ill" patient. If the provider does not document that the patient is "terminally ill" or a "LTCF patient" the pharmacist must record it on the prescription after verifying with the provider. Document who verified, date, time, etc. A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Controlled Substances Act.

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(continued from page 6)

Remote Pick Up Locations:
There may be not Controlled Substance prescriptions dispensed to a remote pick up location.

PDMP UPDATE
by Melissa DeNoon, R.Ph., PDMP Director

The CDC states, "Prescription Drug Monitoring Programs continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk." South Dakota health care practitioners' trending utilization of the South Dakota Prescription Drug Monitoring Program (SD PDMP) follows this belief. The SD PDMP hit record numbers of online queries performed by both pharmacists and prescribers, 5,286 and 3,985 respectively, in October, 2016. Therefore, it is essential that the prescription information in the database is current, accurate, and complete for all stakeholders utilizing this tool.

Pharmacists are key stakeholders as both PDMP users and gatekeepers of the data submitted. The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) examined issues relating to prescription data and found that data integrity and quality are dependent on several factors. One of these factors is pharmacy data entry errors. Pharmacy data entry errors can be broken down into 4 categories: patient, prescription, prescriber, and others. The SD PDMP has recently encountered both patient and prescriber pharmacy data entry errors. The types of patient errors were in the categories of misspelled names and wrong patient. Misspelled name errors can be caused by: compound last names with a space or hyphen; first, middle, and last names entered out of order; variations in name spelling and/or nicknames, e.g. Kathryn, Kathy, Cathie or Richard, Dick; and use of an alias. It is imperative the pharmacy uses the same name the patient uses at the prescriber's office, which is preferably the patient's legal name. Our office was alerted of the misspelled name incident by a prescriber who did not see on the patient profile report the prescription the prescriber had written. After investigating, our office discovered the pharmacy was using a nickname in the patient's profile and had submitted the data with that nickname. Since the doctor was searching with the patient's legal name, which was also being used at a different pharmacy, the profile returned did not contain the prescription in question. An example of such names is Christine and Tina. The resolution for this scenario involved our office calling the pharmacy to explain the situation, the pharmacy updating the patient profile to the legal name, the pharmacy explaining the need for this to the patient, and our office consolidating the two patient profile records in PMP AWARxE. Wrong patient errors can be caused by selection of the incorrect patient out of a pick list and filling veterinary prescriptions under the owner's name instead of the animal's name. The wrong patient error our office was alerted to occurred because the pharmacy has two patients with the same first and last names. In this case, the prescription was dispensed to the correct "Jane Doe" but had been processed under the wrong "Jane Doe's" profile and therefore was also submitted to the SD PDMP under the wrong patient. Fortunately, the pharmacy discovered the error and performed an error correction to remove the incorrect record and submit the correct record. If this type of error goes undetected, care of both patients is negatively affected. Accessing a patient profile utilizing date of birth vs. name may lessen the chance of this type of error involving the wrong selection out of a pick list. Prescriber pharmacy data entry errors fall into the categories of incorrect DEA number and wrong prescriber. The SD PDMP has recently had two cases of wrong prescriber error. PMP AWARxE has a functionality for prescribers, "My Rx", that allows a search of prescribing history for a prescriber's own DEA number. Our office encourages prescribers to periodically utilize this function to alert them to errors or inappropriate use of their DEA number. Two prescribers contacted our office after utilizing this function to report a prescription submitted under their DEA number in error. In both cases, the pharmacy that filled the prescription was contacted and asked to review the prescription in question. Both pharmacies verified having submitted the wrong prescriber to the SD PDMP with the reason of illegible prescriber signatures. These pharmacies also performed error corrections for these records. These errors reinforce the importance of verifying a prescription's prescriber when there is any doubt and the necessity for careful selection of the prescriber from a pick list.

The role of a pharmacist is multi-faceted and now includes a share of the responsibility for the integrity and quality of prescription data submitted to PDMPs which will result in PDMP data being more dependable for use by all stakeholders.

NABP CHANGES ALL DOMAIN NAMES WITHIN ORGANIZATION TO .PHARMACY

NABP launches .pharmacy Top-Level Domain (TLD). NABP has changed their websites and email to the .pharmacy domain. Pharmacies and other entities are able to apply to use the .pharmacy TLD and NABP is encouraging this. Using the .pharmacy TLD for its primary domain name and email address enables a pharmacy to assure patients at a glance that their online interactions are safe and legitimate. In a time when rogue internet drug outlets have become a widespread public health threat, having a fraud-proof .pharmacy domain puts a pharmacy steps above many of its online competitors. As of November 18,

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SOUTH DAKOTA STATE UNIVERSITY

College of Pharmacy and Allied Health Professions

Jane Mort | Acting Dean

Greetings from the College of Pharmacy and Allied Health Professions. It has been an exciting fall and I am continually impressed by the outstanding work of our students, faculty, and staff. Let me highlight just a few of their amazing accomplishments.

In October we hosted the 26th Annual Pharmacy Research Presentations and Keo Glidden Smith Fall Pharmacy Convocation which included 23 posters authored by two undergraduate students, 18 graduate students, and three postdoc/visiting scholars. This event also included a presentation by Dr. Ronald Borchardt, Professor Emeritus from the University of Kansas. In other news, we hosted a successful Pharmacy Days student recruitment event in October. This event involved 21 employers and included over 110 interviews of fourth year pharmacy students. We appreciate the opportunity to interact with our employer stakeholders and gain feedback regarding our graduates.

This fall we received NAPLEX results for our 2016 graduates. While our pass rate was 98.7% (75 of 76 passing), this compared very favorably to a national first time pass rate of 87.8%. Since our first PharmD graduating class in 1998, the national first time pass rates have ranged from 91% to 97% while the pass rate for all of our PharmD graduates (1,117) is 99.4%. The lower national first time pass rate reported this year coincides with revision of the NAPLEX blueprint and modification of the passing standard.

December marked the first SDSU graduate from the Master of Public Health (MPH) program. The MPH program continues to experience significant growth in enrollment, and efforts are underway to obtain accreditation for the program.

As stated in our mission, "The College seeks to advance societal well-being and the profession of pharmacy through research, scholarship, and graduate education." To that end, the departments reported publication of 66 articles and provision of 61 national/international presentations over the last academic year. In addition, the College received nearly 1 million dollars in grant funding during this timeframe.

We are not only excited about the amazing work of our current faculty, but we also are looking forward to the addition of two new endowed positions. Specifically, we will be recruiting for the William R. Hoch Family Endowed Professorship in Community Pharmacy Practice position. The faculty member in this position will focus on advancing community pharmacy practice through innovation and research. In addition, we are in the middle of our search for a faculty member to fill the Kevin and Lorie Haarberg Endowed Chair in Oncology Research. These new additions will work alongside our talented faculty to continue our outstanding research trajectory.

This fall we celebrated the inauguration of Barry Dunn as SDSU's 20th President. Over the next year we will embark on our strategic planning process that marks an exciting opportunity to set the direction for the University and the College.

Thank you for your continued interest and support of the College of Pharmacy and Allied Health Professions.

Did You Know?

As pharmacists, you can submit immunization information to the South Dakota Department of Health's Immunization Registry?

Contact Tammy LeBeau to get registered! Tammy is the Coordinator for South Dakota's Immunization Information System (SDIIS) and can be reached at her direct extension, 605-773-4783.

SD SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Rhonda Hammerquist, Pharm.D., BCPS | SDSHP President

Happy Holidays from the South Dakota Society of Health-System Pharmacists!

ASHP Midyear Clinical Meeting

I recently had the opportunity to attend the 51th ASHP Midyear Clinical Meeting in Las Vegas, NV. This meeting drew over 20,000 pharmacy professions from 86 countries! The meeting provided plenty of CE, networking opportunities, and Peyton Manning as the Keynote Speaker! In cooperation with the SDSU College of Pharmacy and Allied Health Professions, North Dakota Board of Pharmacy, and NDSHP, we sponsored another very successful "Dakota Night" reception with well over 100 in attendance.

Continuing Education

The South Dakota pharmacy residents will be presenting upcoming CE programs. SDSHP members please take advantage of these opportunities for free CE and to support the residents of South Dakota. Visit our website at www.sdshp.com for more information on topics, location, and registration details. Upcoming dates are:

- January 21st, 2017 in Brookings at the Avera Health and Science Center on the SDSU Campus
- February 25th, 2017 in Sioux Falls at Avera McKennan Hospital
- March 11th, 2017 in Rapid City at Rapid City Regional Hospital

41st Annual SDSHP Conference

The 41st Annual SDSHP Conference will be held on April 7-8th, 2017 at the Holiday Inn City Centre in Sioux Falls, SD. The Annual Meeting Committee is doing an excellent job getting a variety of CE topics as well as planning a technician track session on Saturday, April 8th. Poster presentations and exhibit theatre are scheduled to take place on Friday. Again, please visit www.sdshp.com for further details and registration.

Statewide Pharmacotherapy Forum – SPF

SDSHP is introducing the Statewide Pharmacotherapy Forum (SPF) as an additional opportunity for learning and networking in the state. Each month there will be a learning activity open to SDSHP members via teleconference. The activity may include a journal club, topic review, or other formats up to the presenter. Each month a different site will host the forum so the date and time will vary each month. Call-in and topic information will be provided in advance, with the handouts for the presentation or discussion being e–mailed to SDSHP members one week prior. Our first SPF will be hosted by Avera on Tuesday, January 24 at 1:00 pm CST: "Pharmacogenomics of Cardiovascular Pharmacotherapy & the Implications" presented by PGY-1 Jessica McManus.

Get Involved!

SDSHP is seeking nominations for several positions on the executive board. If you have any questions about the SDSHP Board or positions available – please reach out to any of the current board members.

ACADEMY OF STUDENT PHARMACISTS

Nicole Stenzel | APhA-ASP SDSU Chapter President

We have had another exciting three months with APhA-ASP! In October, we had an extremely successful American Pharmacist's Month. We participated in the annual Hobo Day Parade by "unveiling" the new name of the College of Pharmacy and Allied Health Professions. We would like to say thank you to our very hardworking designers Madicen Fanslau and Kylie Moret. We also held a number of large screenings during the month of October around the city of Brookings. In November, we continued our hard work by submitting our annual PharmFlix video to the national competition with APhA-ASP. You can see our video by searching "Pharm Flix 2016 – Together We Can" at www.youtube.com. A big thank you goes out to our members Josh Collett, Trevor Treglia, Hadley Cropsey, Shelby Rabenberg, Brandon Nigg, and Ty Moody for your hard work on this project. In December, we took part in creating a social media campaign for National Influenza Vaccination Week. Thanks to the hard work of members Jade Kutzke and Bailey Buenger, we reached over 100,000 people through our campaign. We have had a very busy semester, and I am very fortunate to be able to work with such great individuals. At our last meeting, we celebrated achieving our goal of 50 members present at each chapter meeting with pizza. It was a well-deserved treat! We are wishing you all a great holiday season, and are busy decompressing at home from a hectic finals week. Happy holidays, and as always – go BIG, go BLUE, go JACKS!

Pictured above: Josh Collett, Madicen Fanslau, Dillon Schenkel, Kenton Welbig, Analisa Buysse, and Kelly Beneke on the 2016 Hobo Day float.

SD ASSOCIATION OF PHARMACY TECHNICIANS

Sue DeJong | President

Hello from SDAPT!
Hoping this article finds you all warm and cozy this winter.

SDAPT held our annual Fall Conference on Oct. 1st in Sioux Falls at the Avera Prairie Center. Approximately 48 SDAPT members were in attendance, as well as 29 non-SDAPT members. What a great turnout! Thank you to all who attended. The SDAPT board hopes that you enjoyed all of the CE offered as well as the comradery of your fellow technicians. It was an informative and fun day!

SDAPT offers a yearly scholarship to a student in a technician program at one of our state's technical schools. It was decided at our business meeting to increase that scholarship from $100.00 to $150.00 for next year. We're happy to be able to promote education and opportunity for pharmacy technicians.

We have already reserved the date and setting for our 2017 Fall Conference. It will be held Oct. 7 at Avera in Sioux Falls. Please mark your 2017 calendars now for the conference. Your board members are planning and preparing a great day of continuing education (and great food!) for all of you.

Your 2017 officers are:
Susan DeJong - President - sdejong99@hotmailcom
Jerrie Vedvei - President Elect - jvedvei@nvc.net
Deb Mensing - Treasurer - damens55@hotmail.com
Lynna Brenner - Secretary - lynnabrenner@hotmail.com
Bonnie Small - Immediate Past President

Please feel free to contact any one of us if you have questions or suggestions (or answers!).

Visit sdapt.org or our Facebook page for more information throughout the year.

Seizing Winter (well, kind of),
Sue DeJong
SDAPT President

ATTN: Pharmacists!

Shirley Guthmiller would like to share some information about the Dominican Republic medical mission trip that she's been a part of for the last two years.

- For those of you who may be interested, registration is starting now.
- At least three to four pharmacists are needed. The dates are June 19-27, 2017.
- According to Shirley, this is also an opportunity for family members to join, as there is a need for non-medical people to help facilitate other areas of the mission.
- You can register on the website at www.hopeinternationalministries.org. It provides an overview of last year's trip.
- PLEASE call Shirley with any questions! **Shirley Gengerke Guthmiller, Aberdeen, S.D., 605-225-1357**

Pharmacists provide Influenza Immunizations at the 2017 Legislative Session Opening

Pharmacist Rob Loe took care of unvaccinated lawmakers on Thursday, January 12th when he provided immunization protection for legislators and interns who had yet to receive a seasonal flu shot.

Seventeen individuals were vaccinated in a flu shot clinic provided by pharmacists at the State Capitol Building in Pierre.

Executive Director Sue Schaefer received a wonderful thank you from legislative leadership following last year's first ever clinic, as was asked if the pharmacists could repeat the successful event in 2017. Rob stepped in again and offered to provide this special example of excellent patient care.

Loe and SDPhA's Executive Sue Schaefer also made sure to verify that each immunization would be recorded with the lawmaker's primary care provider and also to the SDIIS (South Dakota Immunization Information System).

Schaefer offered, "We hoped that everyone had already received their flu shot earlier in the season at home, but for those who ran out of time, this offered them some protection and support as they face a sometimes-stressful and tiring legislative session."

According the State Epidemiologist Lon Kightlinger, South Dakota flu cases have just spiked, and are predominantly H3N2, so the flu clinic will hopefully prove valuable in keeping our legislators healthy.

According to Loe, this was once again, a wonderful opportunity to educate patients and let lawmakers know that pharmacists are trained to do so much more. Let's keep the momentum going!

Pictured (top to bottom):

1. *Representative John Mills smiles after receiving his flu shot at the SDPhA 2nd Annual Flu Clinic for legislators in Pierre.*
2. *Representative Tim Rounds fills out the required paperwork before receiving his vaccination for influenza.*
3. *Senator John Wiik of District 4 relaxes after receiving his vaccination.*
4. *Rob Loe ready to provide flu shots in SDPhA's second annual vaccination clinic.*

COMMERCIAL AND LEGISLATIVE (C&L) & DISTRICT DUES CONTRIBUTIONS
2016/2017

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

2016 - 2017 Commercial & Legislative (C&L) Fund

(Memberships set by SDPhA C & L Executive Committee, 2007)

Pharmacy or Business Membership ($100.00)
(Includes One Individual Membership)

Name of Pharmacy/Business _____

Name of Individual Included _____

Corporate Membership ($200.00)
(Two or more stores of the same corporation)

Name of Corporation _____

Name of Individual Included _____

Individual Membership

☐ $50 Level ☐ $75 Level ☐ Other $_____

District Dues
(Circle your District)

Aberdeen-$10.00	**Black Hills**-$20.00	**Huron**-$10.00	**Mitchell**-$10.00	**Mobridge**-$10.00
Rosebud-$10.00	**Sioux Falls**-$20.00	**Watertown**-$20.00	**Yankton**-$15.00	

TOTAL ENCLOSED $ _____

Mail to SD Pharmacists Association • Box 518 • Pierre, SD 57501-0518 • FAX: 605-224-1280

Pharmacy Associations Highlight Pro-Patient Priorities Amid ACA Review

Letter to president- and vice president-elect, congressional leadership emphasizes pharmacy access to improve patient outcomes and prevent higher healthcare costs

Washington, D.C.—In a letter to the new power structure in Washington, D.C., the National Association of Chain Drug Stores (NACDS), the National Community Pharmacists Association (NCPA), the American Pharmacists Association (APhA), and the National Alliance of State Pharmacy Associations (NASPA) have detailed steps necessary to leverage pharmacy patient care and prevent higher costs that result from untreated conditions.

"As the incoming Administration and Congress consider potential changes to the Medicare and Medicaid programs, we ask that you ensure that beneficiary access to pharmacies is protected. Policies that reduce local pharmacy access lead to poorer health outcomes, ultimately resulting in increased future healthcare costs," the associations wrote to President-elect Donald Trump, Vice President-elect Mike Pence, Senate Majority Leader Mitch McConnell (R-KY), Senate Minority Leader Charles Schumer (D-NY), Speaker of the House of Representatives Paul Ryan (R-WI), and House of Representatives Minority Leader Nancy Pelosi (D-CA).

The letter highlighted:

- the accessibility of pharmacists;
- their role in boosting medication adherence, which relates to taking medications as prescribed;
- the importance of maintaining patients' choice of pharmacies;
- the importance of assuring fair and accurate Medicaid pharmacy reimbursement, according to average manufacturer price (AMP)-based federal upper limits (FULs) that were enacted in the Affordable Care Act; and
- opportunities to build on pharmacists' vaccination success story by improving patient access to pharmacist services for underserved Medicare beneficiaries.

"Nearly all Americans (91%) live within five miles of a community pharmacy. As Americans' most convenient and accessible healthcare provider, we look forward to continuing to work with you to ensure that Medicare and Medicaid patients can continue to receive cost-effective pharmacy services. As the demand for healthcare services continues to grow, pharmacists have expanded their role by collaborating with physicians, nurses, and other healthcare providers to meet patients' needs," the associations wrote.

While noting the opportunities that exist in newer pharmacist-provided services, the associations emphasized that jeopardizing pharmacy access for medication services threatens health outcomes and healthcare affordability.

The associations explained, "The importance of medication-related services and maintaining access to community pharmacists for the Medicare and Medicaid populations cannot be overstated. Improving medication adherence can help Congress achieve its goals of better managing care for Medicare and Medicaid beneficiaries while lowering the overall costs of healthcare. Medications are the primary method of treating chronic disease, and are involved in 80% of all treatment regimens. Unfortunately, medication-related problems, including poor adherence, costs the nation approximately $290 billion annually – 13% of total healthcare expenditures – and results in health complications, worsening of disease progression, emergency room visits, and hospital stays, all of which are avoidable and costly."

# # #

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit www.NACDS.org.

The National Community Pharmacists Association (NCPA®) represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an $81.4 billion health care marketplace and employ more than 314,000 individuals on a full or part-time basis. To learn more, go to www.ncpanet.org, visit facebook.com/commpharmacy, or follow NCPA on Twitter @Commpharmacy.

The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

The National Alliance of State Pharmacy Associations (NASPA), founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

FINANCIAL FORUM

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

Are Gen Xers Planning for Retirement the Right Way?

Some are planning wisely, but others are beset by mistakes

Generation X has become the new "sandwich" generation. Many Americans born during the years 1965-80 are finding themselves caring for aging parents and growing kids at once, with little time to devote to their personal finances or their retirement planning. Broadly speaking, that time shortage has hindered their retirement saving and planning efforts. Some members of Gen X are on track to reach their retirement money goals; others are making mistakes that may greatly undermine their progress. What kind of mistakes, specifically?

Procrastination. In a recent survey of 36- to 49-year-olds commissioned by the Transamerica Center for Retirement Studies, 39% of respondents said they would prefer to tackle retirement investing when they were nearer to retirement age.[1] If you are in your thirties or forties, this is a mistake you cannot afford to make. When it comes to retirement saving, time is your friend – perhaps the best friend you have – and the earlier you start, the more years of compounding your invested assets can receive. That is not to say all hope is lost if you start saving and investing at forty, however. You just have to save considerably more per month or year to catch up. A very simple compounding example bears this out. Let us take a 25-year-old, a 35-year-old, and a 45-year-old. From this day forward, each will contribute $1,000 a month for a 10-year period to a retirement account yielding 7% annually. At the end of those ten years, they will stop contributing to those accounts and merely watch that money grow until they turn 65 (not recommended, but again this is a simple example). Under these conditions, the person who saved for just ten years starting at age 25 has $1,444,969 at 65. The person who saved for ten years starting at 35 has but $734,549, the person who saved for ten years starting at 45 only $373,407.[2]

Raiding the retirement fund. Think of your retirement fund as your financial future, or at least a large part of it. Many instances may tempt you to draw it down: your children's education expenses, student loan debt, eldercare costs. Refrain if at all possible. Work on creating an emergency fund so you can avoid this (if you already have one, great). Every loan you take from a workplace retirement account leaves you with fewer invested dollars, fewer dollars that may grow and compound faster than inflation via the equities markets. Your forties, in particular, represent a prime time to ramp up your saving effort as your salary and/or compensation presumably increase.

Undervaluing catch-up contributions. Beginning in the calendar year you turn 50, you are permitted to contribute an extra $1,000 to your IRA per year, and an extra $6,000 per year to a typical 401(k), 403(b) or 457 plan. An extra $1,000-$6,000 per year may not sound like much, but if you have both an IRA and a workplace retirement plan, this gives you a chance to save an additional $50,000-$100,000 (or more) for retirement between now and when you presumably wrap up your career. Those dollars can benefit from compounding as well. Even the opportunity to direct an additional $1,000 into an IRA each year should not be dismissed. Sadly, some savers will enter their fifties not knowing about catch-up contributions or not valuing them enough - but you will consistently make them, right?3

Not planning with the "end" in mind. Many Gen Xers are saving for retirement without defined financial objectives. They do not yet know how large their nest egg needs to be in order to generate worthwhile retirement income. They have not really thought about what they want their money to accomplish. Even using a free online retirement calculator (there are some really good ones) might yield some food for thought.

Foregoing consultations with financial professionals. One of the demerits of DIY investing is the learning curve. Investing for retirement without any help is akin to trying to find a street address without help from a map: you might get close, you might get there, but most of the time you may not know how

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Financial Forum

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close or far away you are from your goal. A meeting with a financial professional can lead to an overview of where you stand, and give you a firm idea of what you need to do as you pursue your retirement goals further.

The good news? Gen Xers are making a solid effort to save. In the aforementioned Transamerica survey, 83% of Gen X respondents said they were building up a retirement fund, and 20% of them had amassed more than $250,000 in retirement savings prior to age 50.[1]

Citations.

1 - forbes.com/sites/nextavenue/2014/08/28/7-retirement-mistakes-gen-x-is-making/print/ [8/28/14]

2 - moneyunder30.com/power-of-compound-interest [2/27/15]

3 - shrm.org/hrdisciplines/benefits/articles/pages/2016-irs-401k-contribution-limits.aspx [10/22/15]

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SOUTH DAKOTA BOARD OF PHARMACY

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2016, NABP has approved 420 domain names for registration in the .pharmacy TLD. To find out more and how to apply, see the web site www.safe.pharmacy.

NABP NEWSLETTER IS NOW DIGITAL

The NABP Quarterly Newsletter has gone digital! The newsletter is being delivered by on-line format going forward. NABP will send an email with a link to the newsletter each quarter to remind you that a new newsletter is available. Please check your email near the beginning of every quarter. They also will provide a link to change your email. Also, if you don't get emails from the Board, please update your email address with us. Use the "Change of Name, Address, or Employment" form on our website at this link: http://doh.sd.gov/boards/pharmacy/assets/ChangeAddressForm.pdf. We need to be able to communicate with you!! There will also be a copy of the newsletter on the Board's website at www.pharmacy.sd.gov and on the NABP Website at https://www.nabp.net/publications/state-newsletters/. We realize that not everyone has access to email and computers. Please ask a family member to help if needed. This is a significant cost saving measure as well as an environment saving measure.

BOARD MEETING DATES

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

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STANDING COMMITTEES

92nd Legislative Session Meeting Schedule – 2017

TIME	ROOM	MONDAY WEDNESDAY FRIDAY	TUESDAY THURSDAY
8:00 a.m. – Noon	**Appropriations Room 362**	**Appropriations** *Sen. Tidemann & Rep. Anderson, Co-Chairs* *Annie Mehlhaff, Jason Simmons, Stephanie Gruba, Jeff Mehlhaff, & Lucas Martin, Staff*	
7:45 a.m. – 9:45 a.m.	**414**	**House State Affairs** *Rep. Rhoden, Chair* *David Ortbahn, Staff*	**House Taxation** *Rep. Haggar, Chair* *Fred Baatz, Staff*
7:45 a.m. – 9:45 a.m.	**413**	**House Education** *Rep. Johns, Chair* *Clare Charlson, Staff*	**Senate Judiciary** *Sen. Russell, Chair* *Wenzel Cummings, Staff*
7:45 a.m. – 9:45 a.m.	**412**	**Senate Local Government** *Sen. Langer, Chair* *Emily Kerr, Staff*	**House Health & Human Services** *Rep. Steinhauer, Chair* *Clare Charlson, Staff*
7:45 a.m. – 9:45 a.m.	**423**	**Senate Transportation** *Sen. Ernie Otten, Chair* *Amanda Jacobs, Staff*	**Senate Education** *Sen. Bolin, Chair* *Jessica LaMie, Staff*
7:45 a.m. – 9:45 a.m.	**464**		**House Ag & Natural Resources** *Rep. Herman Otten, Chair* *Amanda Jacobs, Staff*
10:00 a.m. – 12 Noon	**414**	**Senate State Affairs** *Sen. Ewing, Chair* *Fred Baatz, Staff*	**House Local Government** *Rep. Conzet, Chair* *Clare Charlson, Staff*
10:00 a.m. – 12 Noon	**413**	**House Judiciary** *Rep. Stevens, Chair* *Jessica LaMie, Staff*	**House Transportation** *Rep. Duvall, Chair* *David Ortbahn, Staff*
10:00 a.m. – 12 Noon	**412**	**Senate Health & Human Services** *Sen. Soholt, Chair* *Emily Kerr, Staff*	**Senate Ag & Natural Resources** *Sen. Cammack, Chair* *Fred Baatz, Staff*
10:00 a.m. – 12 Noon	**423**	**Senate Taxation** *Sen. Monroe, Chair* *Amanda Jacobs, Staff*	**Senate Commerce & Energy** *Sen. Jensen, Chair* *Doug Decker, Staff*
10:00 a.m. – 12 Noon	**464**	**House Commerce & Energy** *Rep. Rounds, Chair* *Wenzel Cummings, Staff*	
At the Call of the Chair		**Government Operations & Audit** *(Chairs: Rep. Hunhoff & Sen. Peters/Auditor General)* **Legislative Procedure** *(Chairs: Rep. Mickelson & Sen. Greenfield/Jason Hancock)* **Retirement Laws** *(Chairs: Sen. White & Rep. Tieszen/Stephanie Gruba)*	

This schedule and all Legislative Research Council session documents are available on the LRC home page http://legis.sd.gov.

92nd SOUTH DAKOTA LEGISLATIVE SESSION CALENDAR

2017 ◈ 38 Legislative Days

South Dakota Legislature
Legislative Research Council

Please refer to the Joint Rules, Chapter 17 for complete information.

	Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
January 2017	1	2	3	4	5	6	7
	8	9	10 Session Opens 12 Noon (CST) *State of the State* L.D. 1	11 *State of the Judiciary* L.D. 2	12 *State of the Tribes* L.D. 3	13 L.D. 4	14
	15	16 *Martin Luther King Jr. Day*	17 Executive orders filed (Constitution, Art. IV, Sec. 8) L.D. 5	18 L.D. 6	19 *Jt. Memorial Service 3:00 pm* L.D. 7	20 Concurrent Resolution limited introduction deadline (J.R. 6B-3) L.D. 8	21
	22	23 L.D. 9	24 L.D. 10	25 L.D. 11	26 Last day for unlimited bill & joint resolution introduction (J.R. 6B-3) Must be at the front desk TWO HOURS prior to session. L.D. 12	27	28
February 2017	Jan 29	Jan 30	Jan 31 All bill drafts with sponsors due back in LRC L.D. 13	Feb 1 L.D. 14	2 Last day for introduction of individual bills and joint resolutions Must be at the front desk TWO HOURS prior to session. L.D. 15	3 Last day for introduction of committee bills and joint resolutions Must be at the front desk TWO HOURS prior to session. L.D. 16	4
	5	6 L.D. 17	7 L.D. 18	8 Last day for JCA selection of general fund revenue targets (J.R. 7-11.1) L.D. 19	9 L.D. 20	10	11
	12	13 L.D. 21	14 L.D. 22	15 L.D. 23	16 L.D. 24	17	18
	19	20 *Presidents Day*	21 Last day to use J.R. 5-17 L.D. 25	22 Last day to move required delivery of bills or resolutions by a committee to the house of origin L.D. 26	23 Last day to pass bills or joint resolutions by the house of origin Last day for introduction of concurrent resolutions L.D. 27	24 L.D. 28	25
March 2017	Feb 26	Feb 27 L.D. 29	Feb 28 Last day for an appropriations committee to move required delivery of special appropriation bills to house of origin L.D. 30	Mar 1 Last day for house of origin to pass special appropriation bills delivered by an appropriations committee L.D. 31	2 Last day for introduction of commemorations J.R. 5-13 in effect L.D. 32	3	4
	5	6 Last day to move required delivery of bills or resolutions by a committee to the second house L.D. 33	7 Last day for a bill or joint resolution to pass both houses L.D. 34	8 Reserved for concurrences or conference committees L.D. 35	9 Reserved for concurrences or conference committees L.D. 36	10 L.D. 37	11
	12	13 ←	14	15 Recess	16	17 →	18
	19	20 ←	21	22 Recess	23	24 →	25
	26	27 Reserved for consideration of gubernatorial vetoes L.D. 38	28	29	30	31	

Prepared by the South Dakota Legislative Research Council

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

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

The Learned Intermediary Doctrine

It is almost impossible to attend a pharmacy law conference and not have a discussion about the Learned Intermediary Doctrine. The Doctrine was first expressed in a lawsuit against a drug manufacturer in 1966. The Doctrine states that a drug manufacturer has no duty to warn a patient about the risks of a drug. The manufacturer's duty is fulfilled by informing the prescriber (the "Learned Intermediary") of the drugs risks and benefits. The prescriber then has the responsibility of choosing the appropriate therapy because the prescriber has knowledge of the patient's medical condition.

Through the years, the Learned Intermediary Doctrine was expanded to include pharmacists. This was done through court decisions, by statute, or other procedural means. Specifically, courts held that pharmacists had no duty to warn patients of the risks of a particular drug. The Learned Intermediary Doctrine put that responsibility on the physician. There was fear that the pharmacist would somehow interfere in the physician-patient relationship. Under the Doctrine, the pharmacist discharged their duty by correctly filling the physician's prescription for the patient.

As the different states have looked at the Learned Intermediary Doctrine, they have taken different approaches to it; some adopted it, some rejected it, and some created exceptions to it. And as things usually go in the law, the different states didn't agree on the exceptions. So what is a practicing pharmacist supposed to do?

This is where I give you a different answer depending on whether I'm wearing my lawyer hat or my pharmacist hat. A common exception to the Learned Intermediary Doctrine in states that have adopted it is situations where the pharmacist has specific information about the patient's condition (e.g., she is pregnant or he is allergic to penicillin). My advice as a lawyer in these situations would be to advise my pharmacist clients to know as little about their patients as possible. That way you can fall under the protection of the Learned Intermediary Doctrine. As a pharmacist, this advice is contrary to the direction that the pharmacy profession is headed. We are trying to become more involved in patient care, not less.

At these same conferences, there are also many discussions about gaining provider status. How can pharmacists make a case to be considered health care providers and hide behind the Learned Intermediary Doctrine at the same time? Cases rejecting the Learned Intermediary Doctrine state that pharmacists are not merely order-fillers and want to discourage robotic compliance with the physician's order.

So what is the pharmacist to do? Relying on the Learned Intermediary Doctrine is not necessarily a good strategy. The courts have not consistently applied the Learned Intermediary Doctrine. My review of cases leads me to conclude that courts really don't understand what pharmacists can and are supposed to do. For example, one case reached the right answer for the wrong reason. There are exceptions to it and you don't want your case to be the one in which the court creates another exception. Many of the cases were decided before OBRA '90 and its resulting regulations were implemented. Few discussions today talk about OBRA's impact on the Learned Intermediary Doctrine, but I believe that it is underestimated. It is beyond the scope of this article to recite a detailed history of these decisions. Suffice it to say that relying on the Doctrine is a risky strategy because it is too difficult to predict the court's outcome.

The better option is for the pharmacists to use their training, experience, and expertise for the benefit of the patient. Protecting patients from harm is a strategy within the pharmacist's control. Intervene when you see something that raises a red flag. Protecting your patients ultimately protects you. Additionally, utilizing our expertise and making a positive impact on patient outcomes is a more persuasive way of convincing payers, patients, and regulators that pharmacists are a vital part of the health care team. Let's move into the 21st Century.

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

Continuing Education for Pharmacists

Hepatitis C: Overview and Treatment with Direct Acting Antivirals *(Knowledge-based CPE)*

Course authors:

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Goal: To upgrade pharmacists' knowledge of hepatitis C infection, risk factors, diagnostic testing, and treatment.

Learning Objectives:

1. Describe the disease progression of hepatitis C virus (HCV) infection;
2. List risk factors of HCV;
3. Explain the results of the diagnostic tests for HCV.
4. Identify recommended treatment regimens and monitoring for HCV.
5. Summarize the general dosing and adverse effects of the direct-acting antiviral (DAA) agents.

INTRODUCTION

Recently, hepatitis C has been making a big splash in the health care world. With the many new drugs that offer impressive cure rates for the most common blood-borne infection in the United States, it is hard not to get excited. Approximately 3.5 million people in the United States are infected with hepatitis C virus (HCV).[1]

Globally, HCV is estimated to affect 3% of the world's population.[2] These numbers, however, likely fall short of the true values due to underreporting and lack of diagnosis due to asymptomatic infections.[1,2] In addition, about 50% of those infected with HCV in the U.S. are unaware that they are indeed infected.[1]

Hepatitis C is a viral disease of the liver. Initial exposure often leads to an acute infection which is typically self-limiting and seldom leads to severe outcomes such as liver failure.[3] Once an acute infection is contracted, 75-80% of people will eventually develop a chronic infection.[2] Chronic HCV is a serious progressive disease that causes cirrhosis in approximately 20% of patients and may lead to liver failure or hepatic cancer.[2,3] In fact, chronic HCV is the leading cause of liver transplantation in the US.[2] It is evident that hepatitis C is a major concern in the medical field today.

In this continuing education course, general disease information such as risk factors and clinical presentation will be summarized, treatment options and patient counseling points will be discussed, and a brief perspective on the pharmacoeconomic standpoint of the newer HCV

agents will be given. It is important to keep in mind that the management of HCV is continually changing with multiple pharmaceutical agents emerging frequently. Be sure to stay updated on the most recent recommendations by following the American Association for the Study of Liver Disease (AASLD) and Infectious Disease Society of America (IDSA) Hepatitis C guidelines.[1]

PATHOPHYSIOLOGY/GENOTYPES

HCV is a single-stranded, enveloped RNA virus that can be found throughout the body, but selectively replicates in hepatocytes.[4] The human body's immune system attempts to attack HCV, but due to continuous RNA mutations created during the replication process, these attempts often fail to clear the virus.[4] This is thought to be why acute infections so commonly result in chronic infections.[2] Once replicated, HCV fuels the production and release of cytotoxic T-cells and cytokines leading to inflammation and eventually hepatocyte necrosis.[4] Functional hepatocytes are replaced with nonfunctional fibrotic tissue, causing the progressive degenerative symptoms of HCV over the course of many years.[5]

Six separate genotypes of HCV have been identified.[2] These genotypes can then be broken down into more than 50 subtypes.[2] The most prevalent genotype in the US is genotype 1, followed by genotype 2 then genotype 3, respectively.[5] Although no genotype is thought to be more severe than another, genotypes respond differently to different treatments.[2] Therefore, testing of genotypes is necessary prior to treatment to determine both the best medication regimen and treatment duration.[2]

CLINICAL PRESENTATION

Both acute and chronic infections are often asymptomatic or subclinical (80%).[2] If symptoms present, they usually occur around 4-12 weeks after exposure but can appear any time within 2-24 weeks.[2] The most prevalent symptoms are fatigue and abdominal pain, but patients may also have jaundice, nausea and vomiting, loss of appetite, or malaise.[2,5]

In chronic infections, approximately 20% of patients will develop cirrhosis after a 20 to 30 year timeframe.[2] Determinants of accelerated fibrosis include both modifiable and nonmodifiable factors. The modifiable factors are alcohol consumption, nonalcoholic fatty liver disease, obesity, insulin resistance, and coinfection with hepatitis B virus or HIV. Nonmodifiable factors are fibrosis stage, inflammation grade, older age at time of infection, male sex, and organ transplant.[1]

Upon diagnosis, the most common signs observed are hepatomegaly, splenomegaly, and anorexia.[5] Extrahepatic symptoms may include palmar erythema, purpura, and portal hypertension indicated by peripheral edema or dilated chest or abdominal veins.[5]

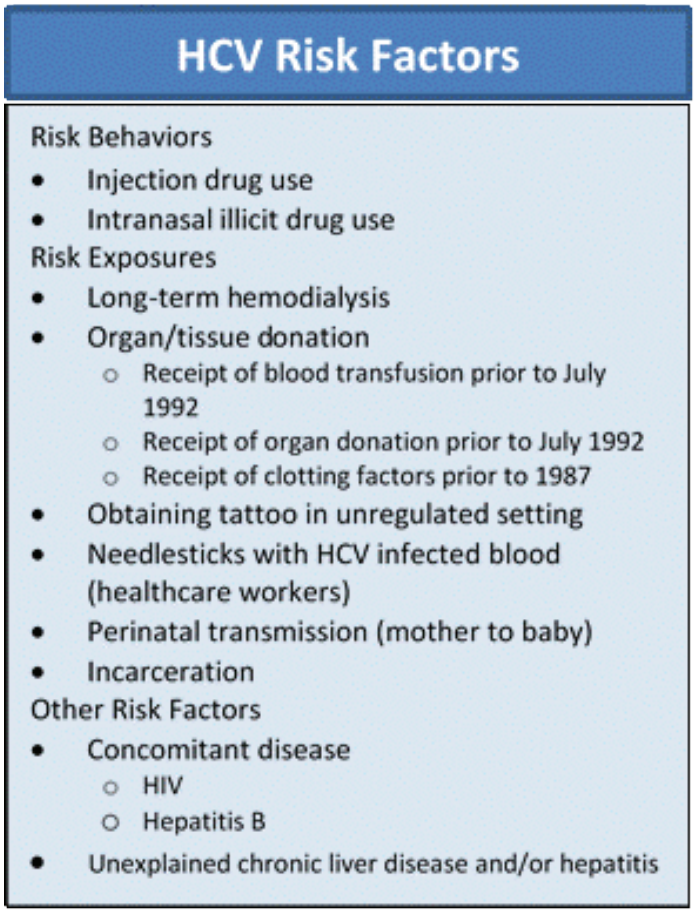
RISK FACTORS

Because so many people are unaware of their infection, it is crucial to be able to identify those with risk factors to allow for proper testing and treatment of those patients. When assessing a patient, providers must consider both risk exposures and risk behaviors. HCV is transmitted through the blood.[1] Therefore, any possible exposure to contaminated blood is a risk factor for HCV.

Injectable drug use is the biggest cause, being responsible for 60% of new acute cases in the United States.[1] Other exposure risk factors include long-term hemodialysis, receipt of blood transfusions or organs before July 1992, receipt of clotting factor before 1987, obtaining a tattoo in an unregulated setting, and healthcare needlesticks with HCV infected blood.[1] Sexual transmission of HCV is possible but typically only concerning among HIV-infected men who have sex with men (MSM).

Another less common cause is transmission to babies being born to HCV-positive mothers.[1] (See risk factor summary in Figure 1)
Patient demographics with the highest prevalence of HCV are male, non-Hispanic blacks, age 30-49 years, and concomitant HIV or hepatitis B infections.[1] HCV antibodies do not protect against future infections; therefore, patients previously infected and then cured must still avoid any exposures to HCV to prevent reinfection.[2]

Figure 1: HCV Risk Factors[1]



TESTING AND DIAGNOSIS

All patients with risks factors or patients born between 1945 to 1965 should have a one-time screening for HCV.[2] Persons who use injectable drugs or HIV-infected men who have sex with men should be screened annually due to the high prevalence of HCV in these patient populations.[1] Other patients who have ongoing risk factors should be tested periodically.

Two main blood tests are used to test for HCV. The first is an HCV antibody test, and the second is an HCV RNA quantitative viral load test.[5] Positive antibody tests indicate that the patient has been previously exposed to the HCV virus whether or not they currently have an active infection.[2] This test should be done first. If it is positive, continue with the HCV RNA test.[1] If the antibody test is negative, generally it can be concluded that the patient does not have an HCV infection nor have they been exposed to HCV.[1]

However, patients who are suspected to have been exposed to HCV within the past 6 months or are immunocompromised are likely to yield false negative antibody tests. Thus, this patient population should be retested with the HCV antibody test in 4-6 months or should be immediately tested with the quantitative HCV RNA before HCV can be ruled out.[1] When the quantitative RNA test yields detectable levels of viral load, the patient has an active infection with replicating virus.[2] Therefore, if both tests are positive, the patient has an active acute or chronic infection.[2]

If the HCV antibody test is positive, but the HCV RNA test is negative, the patient has cleared the virus either spontaneously or through successful treatment.[2] In this situation, patients who continue to have HCV risk exposures should be re-tested regularly and should bypass the HCV antibody test and be tested with the RNA test since it is expected that the antibody test will be positive due to past exposures.[1]

Finally, if both tests are negative, it can be concluded that no HCV infection is present.[2] Prior to antiviral treatment, a quantitative RNA test should be performed to develop a baseline viral load along with genotype testing to help guide proper treatment selection.

Table 1: Interpretation of HCV Diagnostic Tests[2]

		HCV Antibody Test	
		Positive	**Negative**
Quantitative RNA Viral Load Test	**Detectable Levels**	Active acute or chronic HCV infection	Chronic HCV infection in immunocompromised patient or early acute HCV infection
	Undetectable Levels	Eradicated HCV spontaneously or through successful treatment	HCV infection not present)

Active Learning question

Patients with ongoing HCV risk exposure should bypass the _____ test and instead be re-tested regularly with the _____ test, due to the likelihood of a positive antibody test from past exposures.

Treatment

The primary goal of treatment is to reduce all-cause mortality and liver-related health adverse consequences including end-stage liver disease and hepatocellular carcinoma through the achievement of virologic cure.[1] Sustained virologic response (SVR), synonymous with virologic cure, is defined as an undetectable viral load in the blood 12 weeks following completion of antiviral therapy.

Clinical benefits from curing HCV include reduction of liver inflammation leading to fibrosis, reduction of hepatocellular carcinoma risk, and improvement of portal hypertension, splenomegaly, and quality of life. Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy.

Prior recommendations prioritized treatments with the new direct-acting antiviral (DAA) agents to those with greatest needs, but those recommendations were based on budgeting financial resources and limited data on clinical benefit. Since then, studies have shown benefit from initiating treatment in patients with earlier sages of fibrosis (FIB-4 score < 3.25) including likelihood of treatment success and mortality reduction. [1]

Acute HCV Treatment

The high safety and efficacy associated with interferon (IFN) sparing HCV treatments, which have only been studied in chronic infections, eliminates the efficacy advantage of early treatment in most situations.[1] A randomized controlled trial published in 2013 showed that delaying treatment, if adherence can be assured, had similar response rates to immediate treatment with an IFN-based regimen.[6]

The benefits of early treatment with IFN-based regimens may outweigh draw-backs of delaying treatment in certain situations: 1) Preventing risk of transmission in patients that inject drugs; 2) Preventing further complications in patients with compensated cirrhosis; or 3) Patients at risk of being lost to follow-up.

If the physician and patient decide to delay treatment, guidelines recommend monitoring HCV RNA viral load every 4-8 weeks for spontaneous clearance for at least 6 months before initiation of treatment. Patients who are delaying treatment after acute infection should be counseled on the importance of abstaining from behaviors that could increase risk

of transmission to others. Patients unable to spontaneously clear the virus and have detectable HCV RNA levels at 6 months should be managed according to the chronic HCV treatment guidelines.[1]

Chronic HCV Treatment

There are three main classes of DAA agents used in the treating chronic HCV infection: NS3/4a protease inhibitors, NS5A inhibitors, and NS5B RNA polymerase inhibitors. The selection of a particular agent within these classes is mainly based on the virus genotype, prior treatment with a pegylated interferon and ribavirin regimen, and the status of cirrhosis. See Table 2 for medications / combinations.

Table 2. Common medications and combinations used to treat chronic HCV [8, 9, 10, 11, 12, 13, 14]

Generic Name	Mechanism of Action	Dosing	Adverse Effects
peginterferon alfa-2a (Pegasys®)	Immunomodulation, inhibition of viral replication and cell proliferation	180 mcg SC weekly *renally dosed	Flu-like symptoms, depression, irritability, injection site reactions, neutropenia, alopecia, thrombocytopenia, insomnia, metabolic abnormalities, nausea, anorexia
peginterferon alfa-2b (Intron A®)		1.5 mcg/kg SC weekly *renally dosed	
ribavirin (Copegus®)	Synthetic nucleoside analog with antiviral activity against RNA viruses	≤75 kg: 1000 mg/day in 2 divided doses >75 kg: 1200 mg/day in 2 divided doses	Hemolytic anemia, nausea, vomiting, diarrhea, constipation, anorexia, rash/dry skin, cough
simeprevir (Olysio®)	Direct-acting antiviral; NS3/4A protease inhibitor	150 mg PO daily with food	Photosensitivity, rash
daclatasvir (Daklinza®)	NS5A replication complex inhibitor	60 mg PO daily	Headache, fatigue, nausea, diarrhea
sofosbuvir (Sovaldi®)	Direct-acting antiviral; NS5B polymerase inhibitor	400 mg PO daily	Headache, fatigue, nausea
sofosbuvir/ ledipasvir (Harvoni®)	Direct-acting antiviral fixed dose combination; NS5A replication complex inhibitor + NS5B polymerase inhibitor	90 mg/400 mg PO daily	Headache, fatigue
elbasvir/grazoprevir (Zepatier®)	Direct-acting fixed dose combination; NS5A inhibitor + NS3/4A protease inhibitor	50 mg/100 mg tablet PO daily	Fatigue, headache, nausea, ALT elevation
ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets (Viekira Pak®)	Direct-acting antiviral fixed dose combination; NS5A polymerase inhibitor + NS3/4A protease inhibitor + NS5B polymerase inhibitor (ritonavir increases plasma concentration of paritaprevir)	Two ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg tablets PO once daily (in the morning) and one dasabuvir 250 mg tablet PO twice daily (morning and evening)	Fatigue, nausea, itching, skin rash, insomnia, asthenia, drug-induced liver injury
ombitasvir, paritaprevir, and ritonavir tablets (Technivie®)	Direct-acting fixed dose combination; NS5A inhibitor + NS3/4A protease inhibitor + CYP3A inhibitor	Two tablets PO once daily (in the morning) with a meal	Asthenia, fatigue, nausea, insomnia, drug-induced liver injury

The HCV guidelines defined decompensated cirrhosis as moderate or severe hepatic impairment - Child Turcotte Pugh (CTP) class B or C.[1]

Treatment regimens according to the three main criteria are organized in Table 3.

Table 3. Recommended treatments by genotype[1]

Gen.	Prior Treatment	Drug Regimen	Rating* (class/level)
1a	Treatment-naïve	elbasvir/grazoprevir x 12 wks (no cirrhosis or compensated)	I/A
		ledipasvir/sofosbuvir x 12 wks (no cirrhosis or compensated)	I/A
		paritaprevir/ritonavir/ombitasvir + dasabuvir + RBV x 12 wks	I/A
		simeprevir + sofosbuvir x 12 wks	I/A
		daclatasvir + sofosbuvir x 12 wks	I/B
	Treatment-experienced	elbasvir/grazoprevir x 12 wks (no cirrhosis or compensated)	I/A
		ledipasvir/sofosbuvir x 12 wks (no cirrhosis) or ledipasvir/sofosbuvir x 24 wks (compensated cirrhosis) or ledipasvir/sofosbuvir + RBV x 12 wks (compensated cirrhosis)	I/A
		paritaprevir/ritonavir/ombitasvir + dasabuvir + RBV x 12 wks	I/A
		simeprevir + sofosbuvir x 12 wks	I/A
		daclatasvir + sofosbuvir x 12 wks	IIa/B
1b	Treatment-naïve	elbasvir/grazoprevir x 12 wks (no cirrhosis or compensated)	I/A
		ledipasvir/sofosbuvir x 12 wks (no cirrhosis or compensated)	I/A
		paritaprevir/ritonavir/ombitasvir + dasabuvir x 12 wks (no cirrhosis or compensated)	I/A
		simeprevir + sofosbuvir x 12 wks	I/A
		daclatasvir + sofosbuvir x 12 wks	I/B
	Treatment-experienced	elbasvir/grazoprevir x 12 wks (no cirrhosis or compensated)	I/A
		ledipasvir/sofosbuvir x 12 wks (no cirrhosis) or ledipasvir/sofosbuvir x 24 wks (compensated cirrhosis) or ledipasvir/sofosbuvir + RBV x 12 wks (compensated cirrhosis)	I/A
		paritaprevir/ritonavir/ombitasvir + dasabuvir x 12 wks	I/A
		simeprevir + sofosbuvir x 12 wks	I/A
		daclatasvir + sofosbuvir x 12 wks	IIa/B
2	Treatment-naïve	sofosbuvir + RBV x 12 wks (no cirrhosis) or x 16-24 wks (compensated cirrhosis)	I/A (no cirrhosis) IIa/C (comp.)
		daclatasvir + sofosbuvir x 12 wks (no cirrhosis) or x 16-24 wks (compensated cirrhosis)	IIa/B
	Treatment-experienced	sofosbuvir + RBV x 12 wks (no cirrhosis) or x 16-24 wks (compensated cirrhosis)	I/A (no cirrhosis) IIa/B (comp.)
		daclatasvir + sofosbuvir x 12 wks (no cirrhosis) or x 16-24 wks (compensated cirrhosis)	IIa/B

Table 3. Recommended treatments by genotype[1]—continued

3	Treatment-naïve	sofosbuvir + RBV + PegIFN x 12 weeks (no cirrhosis or compensated)	I/A
		daclatasvir + sofosbuvir x 12 wks (no cirrhosis) or daclatasvir + sofosbuvir ± RBV x 24 wks (compensated cirrhosis)	I/A (no cirrhosis) IIa/C (comp.)
	Treatment-experienced	daclatasvir + sofosbuvir x 12 wks (no cirrhosis) r daclatasvir + sofosbuvir + RBV x 24 wks (compensated cirrhosis)	I/A (no cirrhosis) IIa/B (comp.)
		sofosbuvir + RBV + pegIFN x 12 wks (no cirrhosis or compensated)	I/A
4	Treatment-naïve	paritaprevir/ritonavir/ombitasvir + RBV x 12 wks (no cirrhosis or compensated)	I/A (no cirrhosis) I/B (comp.)
		elbasvir/grazoprevir x 12 wks (no cirrhosis or compensated)	IIa/B
		ledipasvir/sofosbuvir x 12 wks (no cirrhosis or compensated)	IIa/B
	Treatment experienced	paritaprevir/ritonavir/ombitasvir + RBV x 12 wks (no cirrhosis or compensated)	I/A
		ledipasvir/sofosbuvir x 12 wks (no cirrhosis) or ledipasvir/sofosbuvir x 24 wks (compensated cirrhosis) or ledipasvir/sofosbuvir + RBV x 12 wks (compensated cirrhosis)	IIa/B
		elbasvir/grazoprevir x 12 wks (virologic relapse) or elbasvir/grazoprevir + RBV x 16 wks (on-treatment failure)	IIa/B
5 or 6	Treatment-naïve	ledipasvir/sofosbuvir x 12 wks (no cirrhosis or compensated)	IIa/B
	Treatment-experienced	ledipasvir/sofosbuvir x 12 wks (no cirrhosis or compensated)	IIa/C

RBV = ribavirin; PegIFN = peginterferon; Treatment experienced = failed treatment with pegIFN and RBV regimen
*Ratings are adapted from the American College of Cardiology and the American Heart Association Practice Guidelines

HCV guidelines also include treatment regimens based on unique patient populations such as severe renal impairment and decompensated cirrhosis. Currently, there is no DAA agent on the market that is approved to treat every HCV genotype. However, the once-daily combination agent of sofosbuvir/velpatasvir is currently in the process of being approved by the FDA, and it has shown efficacy in achieving high rates of SVR at 12 weeks with minimal side effects in HCV genotypes 1 through 6 in the ASTRAL clinical trials.[7] This is a breakthrough in therapy, as it may eliminate the need for genotyping and make treating genotype 3 patients easier, as current treatments are either very expensive or contain ribavirin and pegylated interferon. FDA approval of sofosbuvir/velpatasvir is expected in June 2016.

Active learning question *(select all that apply)*

The selection of a particular medication within the three classes of DAA agents is based mainly upon:

A. The virus genotype
B. Prior treatment with a pegylated interferon and ribavirin regimen
C. The status of cirrhosis

Monitoring

Specific assessments are recommended prior to and during antiviral therapy (See Table 4)

Table 4

MONITORING

Recommended assessments **prior to** treatment with antivirals:[1]

- Assessment of potential drug-drug interactions with antiviral and concomitant medications.
- Lab tests within 12 weeks of starting antiviral therapy:
  - CBC, INR, hepatic function panel, TSH if IFN will be used, and GFR.
- Lab tests any time prior to starting antiviral therapy:
  - HCV genotype and subtype, quantitative viral load.
- Prior to treatment with elbasvir/grazoprevir
  - Testing for presence of baseline NS5A resistance-associated variances or RAVs (polymorphisms at amino acid position 28, 30, 31, or 93) for patients with genotype 1a
  - Increase in NS5A RAVs by 5-fold increase significantly reduces rates of SVR in 12 week course of elbasvir/grazoprevir.
  - Do not withhold treatment if testing is not available.
- Prior to treatment with NS3 protease inhibitor (paritaprevir, simeprevir, grazoprevir)
  - Assessment of history of decompensated liver disease and severity of liver disease using a CTP score
  - Patients with a history of decompensated liver disease or CTP score ≥ 7 should not receive treatment.
  - Patients with a CTP score of 5 or 6 who cannot be closely monitored for symptoms during treatment should not be initiated on paritaprevir/ritonavir.
- Prior to treatment with daclatasvir
  - Testing for presence of baseline NS5A RAVs for patients with genotype 1a with cirrhosis.

Recommended monitoring **during** antiviral therapy:[1]

- Clinic visits or telephone contact as clinically indicated to monitor medication adherence, adverse events, and possible drug-drug interactions.
- Labs after 4 weeks of treatment and as clinically indicated:
  - CBC, creatinine, GFR, and hepatic function
  - A 10-fold increase in ALT or signs and symptoms of hepatic impairment (weakness, nausea, vomiting, jaundice, or increased bilirubin, alkaline phosphatase, or INR) at week 4 should prompt discontinuation of treatment.
- In patients taking elbasvir/grazoprevir
  - Hepatic lab testing should be performed prior to therapy, at week 8, at week 12 (for patients receiving 16 weeks of therapy), and as clinically indicated.
- In patients receiving pegylated interferon:
  - TSH every 12 weeks
- Quantitative HCV viral load testing after 4 weeks of therapy and at 12 weeks following completion of therapy.

CONTRAINDICATIONS, PRECAUTIONS, AND DRUG-DRUG INTERACTIONS

The following table provides concise drug information on HCV medications for providers.

Table 5: Drug-Specific Contraindications/Precautions/Interactions

Drug	Contraindications/Precautions/Interactions
peginterferon alfa-2a/2b (Pegasys®/ Intron A®)	Interferon ineligible is defined as one or more of the following: intolerance to IFN, autoimmune hepatitis and other autoimmune disorders, hypersensitivity to PEG or any of its components, decompensated hepatic disease, major uncontrolled depressive illness, baseline neutrophil count below 1500 µl, baseline platelet count below 90,000 µl, baseline hemoglobin below 10 g/dL, or a history of preexisting cardiac disease.[1]
ribavirin (Copegus®)	Ribavirin is teratogenic and, therefore, is labeled as pregnancy category X. Males or females should be off therapy for at least six months before considering having children. Women of child-bearing age taking ribavirin are recommended to use two forms of contraception during treatment and for 6 months after discontinuation.[1]
simeprevir (Olysio®)	Drugs that are moderate or strong inhibitors or inducers of CYP3A may affect the plasma concentration of simeprevir.[9] Avoid coadministration with sofosbuvir and amiodarone—may lead to serious symptomatic bradycardia.[9]
daclatasvir (Daklinza®)	Strong inducers of CYP3A (phenytoin, carbamazepine, rifampin, St. John's wort) are contraindicated—may decrease the efficacy of daclatasvir.[10] Avoid coadministration with sofosbuvir and amiodarone—may lead to serious symptomatic bradycardia.[10]
sofosbuvir (Sovaldi®)	Concomitant use with p-glycoprotein inducers such as St. John's wort and rifampin are not recommended as sofosbuvir is a p-glycoprotein substrate.[8] Avoid coadministration with amiodarone and simeprevir or daclatasvir—may lead to serious symptomatic bradycardia.[8]
sofosbuvir/ ledipasvir (Harvoni®)	Acid suppressing agents may decrease the concentration of ledipasvir as increases in pH decreases solubility of the drug. Recommend separating antacids and Harvoni® by 4 hours. H_2 receptor antagonists, at a dose that does not exceed famotidine 40 mg twice daily, may be administered simultaneously or 12 hours apart. Proton pump inhibitors at doses comparable to omeprazole 20 mg or lower can be administered simultaneously.[11] Coadministration with rosuvastatin is not recommended as Harvoni® may significantly increase the concentration of rosuvastatin which is associated with increased risk of myopathy, including rhabdomyolysis.[11] Avoid combination with amiodarone and simeprevir or daclatasvir as it may result in serious symptomatic bradycardia. If alternative treatments are unavailable, the FDA recommends heart monitoring in an inpatient setting for the first 48 hours.[15]

A good resource for assessing hepatitis C drug interactions is: http://hep-druginteractions.org

Table 5: Drug-Specific Contraindications/Precautions/Interactions—continued

elbasvir/ grazoprevir (Zepatier®)	Contraindicated in patients with moderate or severe hepatic impairment (Child -Pugh B or C), and concomitant use with OATP1B1/3 inhibitors, strong CYP3A inducers, and efavirenz.[12] ALT elevations greater than 5 times the upper limit of normal occurred in approximately 1% of clinical trial participants. Recommend hepatic lab testing prior to therapy, at week 8, at week 12 for patients receiving 16 weeks of therapy, and as clinically indicated.[12]
ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets (Viekira Pak®)	Significant interaction with salmeterol and concurrent administration is not recommended due to an increased risk of cardiovascular events including QT segment prolongation.[1] Contraindicated in patients with Child-Pugh class B or C hepatic impairment and concomitant use with drugs highly dependent on CYP3A for clearance and strong inducers and inhibitors of CYP2C8.[13] Drug-induced liver injury mostly occurred during the first 4 weeks of therapy and involved a rapid increase in bilirubin and liver enzyme levels. Close monitoring of total and direct bilirubin levels and transaminase levels every 1-2 weeks during the first 4 weeks is recommended along with patient education on the possible symptoms of hepatic impairment.[1]
ombitasvir, paritaprevir, and ritonavir tablets (Technivie®)	Contraindicated in patients with moderate to severe hepatic impairment and co -administration with drugs highly dependent on CYP3A for clearance.[14] Drug-induced liver injury mostly occurred during the first 4 weeks of therapy and involved a rapid increase in bilirubin and liver enzyme levels. Close monitoring of total and direct bilirubin levels and transaminase levels every 1-2 weeks during the first 4 weeks is recommended along with patient education on the possible symptoms of hepatic impairment.[1]

PATIENT COUNSELING

Counseling a patient who is infected with HCV is crucial in a proper treatment plan. When counseling an HCV patient, it is important to discuss measures to be taken to avoid transmission to other persons, means of protecting the liver from further harm, and necessary education on the medication regimen.

An HCV infected patient must be aware of the appropriate cautions to take in order to avoid transmission of the infection to another person. HCV is transmitted via blood-to-blood contact; thus, any contact with infected blood should be avoided. HCV is not spread through sneezing, coughing, personal touch such as hugging or holding hands, or sharing eating utensils or drinkware.[2]

Patient's should be advised not to share personal items that may come in contact with blood such as razors or toothbrushes.[2] Any abrasions or cuts of the skin should be covered until healed. If household items or surfaces become contaminated with HCV-infected blood, the area should be cleaned with a 1:9 bleach to water solution.[1]

Patients should be aware that although sexual transmission is uncommon, the possibility is still present.[1] Patients in long-term relationships may not need to start using barrier protection, but those with multiple sex partners should practice

safe sex methods.[1]

HCV patients are unable to donate blood, and viral HCV serostatus must be thoroughly discussed prior to the donation of body organs, tissues, or semen.[1] Finally, illicit drug-users should be encouraged to stop.[1] Those who continue injectable drugs should be advised to never reuse or share needles, cotton, water, or other paraphernalia that come in contact with blood.[1] They should clean the injection site with clean alcohol swabs and safely dispose of blood contaminated items after one use.[1]

To prevent further damage to the liver, patients must take excellent care of their liver. They should avoid alcohol which is known to cause cirrhosis and end-stage liver disease.[2] Patients should be advised to talk to their doctor or pharmacist before taking any over-the-counter, herbal, or prescription medications to ensure they will not harm the liver.[2]

The most common medication associated with liver damage is acetaminophen.[16] Antibiotics or NSAIDS are other classes of drugs that may be hepatotoxic.[16] Herbal medications that may impair the liver commonly include Chinese remedies and teas such as kava.[16]

A searchable database of medications and herbal products is provided by the National Institute of Health called LiverTox and can be utilized by pharmacists or other providers in treating or recommending products to HCV patients.[16] LiverTox can be accessed for free at **www.livertox.nih.gov/**.

Vaccinations

Vaccinations represent another important prevention recommendation. Vaccination against hepatitis A and hepatitis B is recommended for all susceptible persons with HCV infection (IIa/C). Vaccination against pneumococcal infection is recommended to all patients with cirrhosis (IIa/C).[1]

Patient Counseling

Patients must be comprehensively counseled on their medications before beginning the treatment regimen, specifically informing patients about the common side-effects of HCV treatments.

Direct-acting antivirals are generally well tolerated, but patients taking ribavirin or peginterferon may develop fatigue, hematologic abnormalities such as anemia or thrombocytopenia, flu-like symptoms, or dermatologic problems.[3]

Pharmacists should emphasize to patients the importance of complete compliance with their HCV regimen. Patients should be counseled to never stop taking a medication without first consulting with their doctor.

If not taken properly, the HCV virus could become resistant to the medication, reducing a patient's chance of being cured. [3]

Patients should also be advised that treatment failure and/or resistance may occur in a small percentage of patients treated for hepatitis C. If a patient does fail treatment, RAV testing may be useful. RAV testing and expert consultation will help direct future hepatitis C therapy for q given patient.

Pharmacoeconomics

Although the DAA treatments offer exceptional efficacy with over 90% cure rates, they come at a high dollar price. Many 12-week regimens can cost tens of thousands of dollars based off the wholesale acquisition cost (WAC). However, because of rebates and price negotiations between pharmaceutical companies and pharmacy benefit managers (PBMs), rarely is the WAC price paid. In fact, it is estimated that the average negotiated price is 46% on the WAC.[1]

Unfortunately, price negotiations are considered private business contracts; thus, it can be difficult to determine the exact price being paid for specific HCV treatment regimens.[1]

Cost-effectiveness analyses have been performed on the various HCV treatments in various patient populations. Due to the high cure rates of these regimens, it was found that DAA treatments are generally cost-effective regardless of whether the patient is cirrhotic or not.

Although the advanced stage fibrotic or cirrhotic patients proved to have greater cost-effectiveness, initial treatment in earlier stage patients were still cost-effective and should be treated. Nevertheless, some insurance companies may still require patients to be in those advanced stages before they are covered.

Increasing numbers of manufacturers are beginning to offer rebates, discounts, or co-pay card programs, and some non-profit organizations are offering assistance programs to increase patient access to HCV treatment.[1]

Course Development

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The authors and planners of this course have no relevant financial relationships to declare.

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"Hepatitis C: Overview and Treatment with Direct Acting Antivirals"

Learning Assessment post-test

1. Which of the following is FALSE regarding the prevalence of HCV?
   A. Chronic HCV infection is the most common cause of liver transplants in the US.
   B. Genotype 2 is the most common genotype in the US.
   C. HCV is the most common blood-borne infection in the US.
   D. Current rates of HCV are likely underestimated because many people are unaware that they are infected with HCV due to lack of symptoms.

2. What is the most likely reason that acute HCV infections often lead to chronic HCV infections?
   A. HCV does not produce antibodies, so the immune system cannot protect against it.
   B. Mutations made during the replication process of HCV prevent the immune system from completely eradicating HCV.
   C. The increased production and release of cytokines weaken the immune system, preventing it from clearing the virus.
   D. HCV leads to necrosis of hepatocytes which subsequently destroys the immune system.

3. Which patient is the MOST at risk for developing chronic HCV infection?
   A. 1-year-old infant born to an HCV-positive mother
   B. 60-year-old male who received a kidney transplant in 2004
   C. 33-year-old female heroin user
   D. 20-year-old male who recently got a dragon tattoo on his arm from a reliable facility

4. Which of the following is TRUE of the clinical presentation of acute or chronic HCV?
   A. Both acute and chronic HCV infections are often asymptomatic.
   B. If symptoms present, they typically present 1 year after the initial exposure.
   C. Common symptoms include tremor, fever, heart palpitations, and night sweats.
   D. It is rare for HCV patients to present with anorexia or splenomegaly.

5. A 39-year-old male African-American patient is seen in the clinic today for HCV workup. His HCV antibody test comes back negative, but his HCV RNA quantitative viral load test comes back with detectable levels of virus. The patient is not immunocompromised. What can you interpret from these results?
   A. The patient does not have an active HCV infection.
   B. The patient has never been exposed to HCV.
   C. The patient has chronic HCV infection.
   D. The patient probably has an early acute HCV infection.

Questions 6-10 continued on next page

"Hepatitis C: Overview and Treatment with Direct Acting Antivirals"

Learning Assessment Post-test ***(continued)***

6. Which one of the following patients would be interferon ineligible?
   A. 44 year old female patient who has hypothyroidism; TSH within normal limits on levothyroxine
   B. 66 year old male patient with controlled hypertension
   C. 56 year old male patient recently diagnosed with chronic HCV who also has bipolar disorder and currently prescribed medications include lisinopril, lithium, and multivitamin
   D. 51 year old female patient who has decompensated cirrhosis

7. How often is Harvoni® (sofosbuvir/ledipasvir) dosed?
   A. 90/400 mg tab PO daily
   B. 90/400 mg tab PO twice daily
   C. 90/400 mg tab PO three times daily
   D. 90/400 mg SC injection weekly

8. JR is a 42 year old male patient (6'2", 100 kg) diagnosed with genotype 1a chronic HCV 7 months ago. Currently, his viral load is 7 million IU/mL, so his PCP would like to begin treatment. He is currently treatment-naïve and his liver is in healthy condition.
   Which of the following medication regimens is the BEST choice for JR?
   A. Peginterferon alfa-2b + ribavirin for a duration of 12 weeks
   B. Sofosbuvir + peginterferon alfa-2b for a duration of 12 weeks
   C. Sofosbuvir/ledipasvir for a duration of 12 weeks
   D. Ombitasvir, paritaprevir, ritonavir, and dasabuvir tablets + ribavirin for a duration of 24 weeks

9. Which of the following medications is known to cause anemia?
   A. Harvoni®
   B. Olysio®
   C. Sovaldi®
   D. Copegus®

10. Which of the following medications should not be taken with sofosbuvir/ledipasvir and simeprevir to prevent symptomatic bradycardia?
    A. Amiodarone
    B. Lisinopril
    C. PDE-5 inhibitors
    D. Dabigatran

Complete answer sheet / evaluation on next page and send in for credit.

"Hepatitis C: Overview and Treatment with Direct Acting Antivirals"

(Knowledge-based CPE)

To receive 2.0 Contact Hours (0.2 CEUs) of continuing education credit, preview and study the attached article and answer the 10-question post-test by circling the appropriate letter on the answer form below and completing the evaluation. A test score of at least 70% is required to earn credit for this course. If a score of 70% (7/10) is not achieved on the first attempt, another answer sheet will be sent for one retest at no additional charge.
Credit upload to a participant's eProfile account will be completed within 2 weeks following successful completion of this course.

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Learning Objectives - Pharmacists*: 1. Describe the disease progression of hepatitis C virus (HCV) infection; 2. List risk factors of HCV;* ***3.*** *Explain the results of the diagnostic tests for HCV; 4. Identify recommended treatment regimens and monitoring for HCV; Summarize the general dosing and adverse effects of the direct-acting antiviral (DAA) agents.*

Circle the correct answer:

1. A B C D	**5. A B C D**	**9. A B C D**
2. A B C D	**6. A B C D**	**10. A B C D**
3. A B C D	**7. A B C D**	
4. A B C D	**8. A B C D**	

Course Evaluation *– must be completed for credit.*

	Disagree						Agree
Material was effectively organized for learning:	1	2	3	4	5	6	7
Content was applicable for re-licensing / recertification:	1	2	3	4	5	6	7
Each of the stated learning objectives was satisfied:	1	2	3	4	5	6	7

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

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

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

List any instance of perceived bias _____

Learning assessment questions appropriately measured comprehension	1	2	3	4	5	6	7
Length of time to complete course was reasonable for credit assigned	1	2	3	4	5	6	7

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IN MEMORIAM

Tom Bartholomew

Tom Bartholomew, 77, of Faulkton, passed away Thursday, November 3, 2016 at Avera McKennan Hospital in Sioux Falls.

Celebration of Tom's Life was held at 10:30 a.m., Wednesday, November 9, 2016 at St. Thomas the Apostle Catholic Church, Faulkton, with Father Christopher Hughes officiating. Burial followed at St. Thomas Cemetery, Faulkton. A prayer service was held at 7:00 p.m., Tuesday, November 8, 2016 at St. Thomas the Apostle Catholic Church, Faulkton.

"How does one measure the worth of one's life? Is it how much money you make, or how famous you are, or how big a house you live in, or how expensive a car you drive? I don't think so...you ask yourself: if you've helped a few people along the way, if you've provided for your family and tried to be a good example for them, if maybe you end up leaving your one small corner of the world better than you found it, isn't that what it's all about?" - Tom Bartholomew

Robert Thomas "Tom" Bartholomew - loving son and brother, devoted husband, caring father, passionate outdoorsman and athlete, man of faith and fellowship and a true friend to all - passed away Thursday, November 3, 2016 at Avera McKennan Hospital in Sioux Falls. He was 77.

Tom was born September 8, 1939 in Phillip, SD to George and Grace (Bessie) Bartholomew. The second of eleven siblings, Tom grew up in Lemmon, SD. He graduated from Lemmon High School in 1957 and was an All-State basketball player his senior year. Tom received his Bachelor of Science in Pharmacy from South Dakota State College in 1961. In June of the same year, he married Linda Johnson - the love of his life - and in October 1961 they moved to Faulkton, SD. Tom had selected Faulkton for its great pheasant hunting, and many noon lunch breaks found him out in the fields, with Linda at the wheel and Tom "riding shotgun."

First hired as a pharmacist for the Faulkton Rexall Drug, Tom and Linda bought the business in 1965, which they owned and operated as husband and wife for over forty years. Under their stewardship, the drugstore became the hub of the community and "Drugstore Tom" quickly became an integral part of the community. Not only did he dispense medication, he gave out daily doses of humor, trivia, wisdom, advice and love. Tom was a gifted storyteller and an equally generous listener to everyone who crossed his path.

In 1962, Tom and Linda welcomed their daughter Stacey into the world. Sons Scott and Steven followed in 1963 and 1966. Tom spent mornings, lunch breaks, evenings and weekends with his children, fishing, shooting hoops, playing catch or simply going for a country drive. He cherished time around the table, whether for a dinner of roast beef and potatoes or a glass of Crown Royal.

His love of sports was always at the forefront of his life. When the local high school boys would hang out at the store, he reveled in talking with them about how things were going - be it football, basketball, baseball or track. For many years, he would pack his car with kids and take them to the State "B" basketball tournament in Sioux Falls or Rapid City. Lasting friendships were forged during these years and continued into their adulthood.

Tom's fervent devotion to the Minnesota Vikings and Minnesota Twins lasted his entire life. With innumerable trips to Metropolitan Stadium, the Metrodome and Target Field, Tom proudly waved purple and gold flags, red and blue pennants and was the proud owner of the infamous "Viking Car." Through the wins and losses, Tom found joy in the camaraderie that his beloved Twins and Vikings provided.

When his own boys were old enough, he started the tradition of taking the grade school basketball teams to the YMCA tournament in Aberdeen. For many of these kids, Tom gave them their first chance to go out of town, stay in a motel and play basketball against kids from across the state. Although it's been many years since Tom stopped coaching, the YMCA trips continue and include girls' basketball teams as well.

Upon moving to Faulkton, Tom immediately became involved in all aspects of the community. He joined organizations, participated in league bowling and played basketball in the winter and baseball in the summer for the local amateur teams. He worked six days a week as a pharmacist and business owner. He acted in Community Theater and was a NOAA award-winning weatherman. He became involved with - and held offices in - Knights of Columbus, the Community Club, the Arts Council and the Lions Club. He coached Little League baseball and boys' basketball, instructed the Hunter's Safety Course, was coordinator of the local chapter of Ducks Unlimited, served on the Campaign Steering Committee for the Faulkton Area Medical Centers and was a lector at St. Thomas Apostle Catholic Church. When the community was struggling because of a shortage of healthcare professionals a number of years ago, this man was the "go-to" guy if someone needed medical advice. Even after retiring, he would still get calls and answer questions.

Tom exemplified helping others. He took kids out fishing - many catching their first fish with Tom. He hired kids to work at the drugstore and mentored many future pharmacists. On countless occasions, he delivered medicine to someone in need, even when they couldn't pay. Many were the nights when his children would find a wayfaring stranger sleeping in their house, having been welcomed by Tom in their moment of need.

Tom made his small corner of the world better.

Survivors include his wife of 55 years, Linda Bartholomew; their children: Stacey Bartholomew, Arvada, CO, Scott (Lydia) Bartholomew, Denver, CO, and Steven (Andrea) Bartholomew, Narragansett, RI; siblings: Marie Wolbach, Palo Alto, CA, Jean (Larry) Fritz, Lemmon, SD, Ralph (Fern) Bartholomew, Powell, WY, Chuck (Leslie) Bartholomew, Las Vegas, NV, Susan Schopp, Cavalier, ND, Ken (Twyla) Bartholomew, Ft. Pierre, SD, Don (Sue Fraiser) Bartholomew, Chandler, AZ, David (Marian) Bartholomew, Faulkton, SD, and Teresa Bartholomew, Faulkton, SD; grandchildren: Thomas and Bethany Fristad (Stacey), Denver, CO, Justin O'Donnell and Anna Bartholomew (Steven), Narragansett, RI; and many nieces and nephews.

He was preceded in death by his parents, George and Grace Bartholomew; brother, Bill Bartholomew; sister-in-law, Liz Bartholomew; and brother-in-law, Bob Wolbach.

In lieu of flowers, memorial donations may be sent to the Faulkton Area Medical Center Foundation, PO Box 100, Faulkton, SD 57438, and/or the Faulkton Area Foundation (economic development), PO Box 458, Faulkton. The most impactful way you can honor Tom's memory is to continue to love, serve, tell stories, take a kid fishing, and share a smile. The family would cherish any favorite "Tom stories" that you wish to send them.

Luce Funeral Home of Faulkton has been entrusted with Tom's arrangements.

IN MEMORIAM

Richard "Dick" LeRoy Gulseth

Richard "Dick" LeRoy Gulseth was born on Tuesday, October 9, 1945. He passed at the age of 71 on Monday, November 14, 2016.

Grateful for having shared his life are his wife, Kathy; his daughter, Nikol, her husband, Jim, and their son, Ian; his son, Josh; extended family; and dear friends. He succumbed to cancer after a long battle. Our hearts are broken. We rejoice knowing he is whole again.

A memorial service will be held on Saturday, November 19 at 2 pm at Heartland Funeral Home. Condolences may be sent to 5122 S Ostro Ave, Sioux Falls, SD 57108.

Mary Helen Hopponen

Mary Helen Hopponen, 85, of Brookings, SD, passed away Saturday, December 17, 2016 at Brookings Health System, Brookings, SD. Memorial Services will be held 10:30am Wednesday, December 28, 2016 at Rude's Funeral Home, Brookings, SD. Visitation will be from 9:30am until the time of services at the funeral home. Rude's Funeral Home is assisting the family with the arrangements.

Mary Helen Robinson was born January 17, 1931 in Greensburg, KS, the daughter of John H and Lois H (Griffith) Robinson.

Mary Helen was an educator for 25 years in the Education and Counseling Department at South Dakota State University.

She was a member of the South Dakota Sports Hall of Fame because of her part in taking legal action to give girls and woman the right to play sports in South Dakota. She helped to change the laws protecting abused persons, women, children and men in the state of South Dakota. She brought about and changed forever woman's position.

Mary Helen had experience and reality in the United Methodist Church, first in allowing Women to be Ushers, then allowing Women to be Ministers.

She was a loving mother to her children, Lisa (Barnhart), Andy and Susan.

She was also a friend, companion and caretaker of 37 years to Mychal.

She worked to bring about enlightenment to the reality of gender acceptance, understanding and equality in the lives of women, men, girls and boys. She was a tireless agent of social change and enlightenment service.

Survivors include her daughter, Lisa H. Barnhart (Dan) of Delaware, OH; friend and companion of 37 years, Mychal K. Blue of Brookings, SD and grandsons, Chad Bach of Sioux Falls, SD, RJ, Nathanael and Tryphon Barnhart of Delaware, OH.

Mary Helen was preceded in death by her daughter, Susan Anne Hopponen; son, Andy Hopponen; brother, John G. Robinson and her parents, Lois and John H. Robinson.

In lieu of flowers please consider a donation to the Alzheimers Association.

Paul Rumpca

Paul Rumpca, 35, of Hartford, SD died Tuesday, January 17, 2017.

Visitation with the family present to greet friends will be from 3:00-4:00 pm with a 4:00 pm Liturgical Wake Service on Sunday, January 22, at St. George Catholic Church in Hartford, SD.

Funeral Mass will begin at 10:30 am Monday, January 23 at St. George Catholic Church.

Graveside Service will be 11:00 am Tuesday, January 24, at St. Mary Catholic Cemetery in Watertown, SD.

Paul David Rumpca, son of James and Diane (Brandriet) Rumpca, was born on October 16, 1981, in Watertown, SD. He grew up in Watertown and graduated from Watertown High School in 2000, where he had served as Class President. He continued his education at South Dakota State University in Brookings where earned his Doctor of Pharmacy in 2006.

He began his pharmacy career at Walmart in Brookings. On November 1, 2006, he gave the gift of life to his sister Tracy, by donating one of his kidneys for transplant.

Paul was united in marriage with Kari Heinricy on August 23, 2008, in Colman, SD, and to this union they were blessed with a son, Kade. The family lived in Dell Rapids.

In 2007, he transferred to Walmart in Sioux Falls where he has worked since. He was united in marriage with Krista Meyer on June 12, 2013, in the Bahamas.

Paul enjoyed playing recreational soccer in college and was on the championship baseball team in his younger years. . He was an avid fan of the Jackrabbits and the San Francisco 49ers. He liked to go hunting and fishing but especially cherished time spent with his son Kade. Paul loved being outside doing almost anything. He and Kade went on many adventures. Paul's most joyous moments were spent with his precious little boy.

Grateful for having shared his life are his wife Krista, Hartford, SD; son Kade, Madison, SD; step-children Degan and Reese Bublitz, Hartford, SD; parents James Rumpca and Diane Rumpca, both of Watertown, SD; sisters Jennifer Sutton, her husband Jason, and their children Maya, Hadley, and Hudson, Sioux Falls, SD, Tracy Ducoff and her husband Drew, Watertown, SD; father and mother-in-law Ed and Barb Meyer, Bridgewater, SD; sisters-in-law, Brenda Schaffer, her husband Lee, and their children Kirsten and Ryan, Elk Point, SD, Andrea Addy, her husband Chad, and their children Emma and Brinley, Bridgewater, SD; brother-in-law Craig Meyer, his wife Carolyn, and their children Curt, Cari, Cate, Cara, and Casey, Bridgewater, SD; and many other relatives and friends.

Paul was preceded in death by his grandparents Paul and Veronica Rumpca, Charles and Elizabeth Brandriet; uncle Urban Rumpca; and aunt Marie Roe.

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