OCTOBER 2021

SOUTH DAKOTA STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

South Dakota Board Welcomes Newly Registered Pharmacists and Pharmacies

Congratulations to the following 62 candidates who recently met licensure requirements and were licensed as new pharmacists in South Dakota: Kelli Aughenbaugh, Madison Bader, Julia Bales, Danielle Blais, Alyssa Boesche, Cole Borchardt, Kathryn Brumels, Hannah Christensen, Richard Chung, Nicholas Cook, Colton Cunning, Sean Curley, Emily Davison, Jacob DeJong, Jennifer DeMasi, Drew Diedrich, Lauren Dolly, Andrew Flint, Anthony Fountoulakis, Samantha Frear, Adam Goetz, Ashley Golden, Seth Golden, Elizabeth Hansmann, Jordan Harra, Melanie Heeren, Jessica Henter, Sydney Hirschkorn, Kailyn Hochstein, Whitney Hutchison, Robert Juenemann, Sarah Jungers, Chase Kern, Diana Kim, Abigail Knapp, Lucas Kraemer, Kaila Kuehn, Alexandra Lakness, Abby Lingle, Nathan Matlock, Chelsea Morken, Jace Muramoto, Lindsay Newenhouse, Kristopher Nguyen, Micah Olson, Philip Ostrem, Sabrina Oweisi, Rachel Propst, Jena Rathert, Molly Schmidt, Kelli Semerad, Samantha Smith, Valerie Smith, Natalie Sovell, Mackenzie Stekl, Joshua Thurow, Colton Trowbridge, Jenna Van Beek, Artur Volkotrub, Shelby Vosburg, Chloe Williams, and Michael Zucarelli.

In addition, there were two South Dakota full-time pharmacy licenses issued: Avera St Luke's, dba Avera State Street Pharmacy, License #100-2074, Aberdeen, SD (change of ownership); and Lewis Drugs, Inc, dba Lewis Drug #16, License #100-2075, Howard, SD (telepharmacy). There was one South Dakota part-time pharmacy license issued: Yankton Medical Clinic, PC, dba Yankton Medical Clinic, PC ASC, License #200-1741, Yankton, SD. There were no new South Dakota domiciled wholesale licenses issued in the quarter.

FDA's First Interchangeable Biosimilar Is Approved

By Caleb Whitmyre, P4 Regulatory Intern

First, to provide background on what an interchangeable biological product is, biological products are products that are meant to treat disease states and medical conditions. They are developed by biotechnology and are more complex, larger molecules than most drugs.

Some examples of biological products include monoclonal antibodies and vaccines. Biosimilar products are biological products that are "highly similar" to a reference biological product with no clinically meaningful differences. A reference product is a biological product that has already been approved by Food and Drug Administration (FDA) and is used as a comparison base for biosimilar approval. To be "highly similar" to a reference product, the structure of the biosimilar product must only contain very minor differences in inactive components of the molecules. To show that the biosimilar product has no clinically meaningful differences, pharmacokinetic and pharmacodynamic studies must be done to show that there are no differences in safety or efficacy between it and the reference product. To be classified as an interchangeable product, a biosimilar product must meet extra requirements to show that it will have the same effect as the reference product in all patients. These extra requirements include proving that there is no added risk to people who may switch between the reference product and the biosimilar product, as well as showing that patients will have the same clinical outcome no matter which product they take. Visit FDA's website for Biosimilar and Interchangeable Products.

So, why does this matter? FDA has recently approved the first interchangeable biological product: Semglee®. Semglee is also known as insulin glargine-yfgn, and it is interchangeable with the reference insulin glargine product, Lantus®. This is a big development because insulin products were not classified as biological products until recently, and this is FDA's first biologic interchangeable approval. Interchangeable biosimilars may be substituted at the pharmacy level like substituting a brand-name medication for its approved generic medication. To ensure that a medication has an interchangeable biologic product, FDA provides a database of biological products known as the "Purple Book." The "Purple Book" may be utilized for biologic products much like the "Orange Book" can be used to determine therapeutic equivalence for drug products. See FDA's press announcement.

To gain FDA approval as an interchangeable product, Semglee underwent a switch study where patients who were currently taking Lantus were randomized to either continue to take Lantus, or switch between Lantus and Semglee for three different phases over a 36-week trial. Both groups had an equivalent change in HbA1c, and both groups had similar rates of adverse reactions. This proved to FDA that Semglee can be used interchangeably with Lantus.

The approval of Semglee as an interchangeable biological product is important to pharmacists because of the impact that it will have on the cost of insulin products. Having a new competitor in the market will likely drive insulin glargine prices down due to pharmacists having the ability to choose which product will be given to each patient without needing a new prescription. See South Dakota Codified Law §36-11-46.9. Semglee is the pioneer for interchangeable biological products, and there will likely be many more to follow, which will also have an impact on the market.

References

1. *Blevins T, et al. Efficacy and safety of MYL-1501D versus insulin glargine in people with type 1 diabetes mellitus: Results of the INSTRIDE 3 phase 3 switch study.* J of Diabetes, Obesity and Metabolism. *2020; 22:365-372.*
2. *Heise T, et al. Pharmacokinetic and pharmacodynamic bioequivalence of proposed biosimilar MYL-1501D with US and European insulin glargine formulations in patients with type 1 diabetes mellitus.* J of Diabetes, Obesity and Metabolism. *2020;22:521–529.*

PREP Act Amendments

Eighth Amendment Adds Influenza Vaccine

Effective August 4, 2021, the United States Department of Health and Human Services (HHS) Secretary Xavier Becerra amended section V of the Public Readiness and Emergency Preparedness Act (PREP Act) for medical countermeasures against the coronavirus disease 2019 (COVID-19) to clarify that qualified pharmacy technicians may administer seasonal influenza vaccines, under the supervision of a pharmacist, to adults within the state where they are registered to practice. This adds to the list of other countermeasures for which the PREP Act allows and provides immunity. See Eighth Amendment *Federal Register.*

Ninth Amendment Adds COVID-19 Therapeutics to Countermeasures

On September 9, HHS announced the ninth amendment to the COVID-19 PREP Act Declaration. The ninth amendment provides liability immunity to and expands the scope of authority for licensed pharmacists to order and administer COVID-19 therapeutics to populations authorized by FDA. In addition, the amendment also authorizes pharmacy technicians and pharmacy interns to administer COVID-19 therapeutics when certain criteria are met. See Ninth Amendment Fact Sheet.

PTCB Changes From Online-Proctored Exam to In Person Only

William Schimmel, executive director and chief executive officer of the Pharmacy Technician Certification Board (PTCB), states that the organization has had risk-related issues arise in the online-proctored exam and is now requiring technicians to take the examination in person at a Pearson VUE test center. For more information, visit *PTCB.org.*

USP Compounding General Chapter Revisions Now Open for Comment

Article content reprinted from a USP press release published on September 1, 2021

On September 1, 2021, US Pharmacopeial Convention (USP) published revisions to Compounding General Chapters <795> Pharmaceutical Compounding–Nonsterile Preparations and <797> Pharmaceutical Compounding–Sterile Preparations for an extended 150-day public comment period until January 31, 2022.

In addition, the USP Compounding Expert Committee (CMP EC) is hosting four Open Forum sessions in September 2021 and January 2022 to discuss questions from interested stakeholders. The CMP EC has also published several informational documents intended to supplement the proposed chapters and explain the CMP EC's rationale behind the revisions.

Revisions to USP Chapters <795> and <797> reflect public health considerations, scientifically robust approaches, and numerous stakeholder engagement activities. The CMP EC engaged health care practitioners, regulators, academicians, and other key stakeholders in various sessions including semi-structured interviews with stakeholders, a small roundtable discussion with invited participants, and a broader open forum discussion. These engagements helped the CMP EC consider a wider range of perspectives to inform the revisions while maintaining scientific rigor and accounting for today's public health and practice needs. For more information on the USP Compounding General Chapters, visit *www.usp.org/compounding.*

SD PDMP License Integration

By Melissa DeNoon, PDMP Director

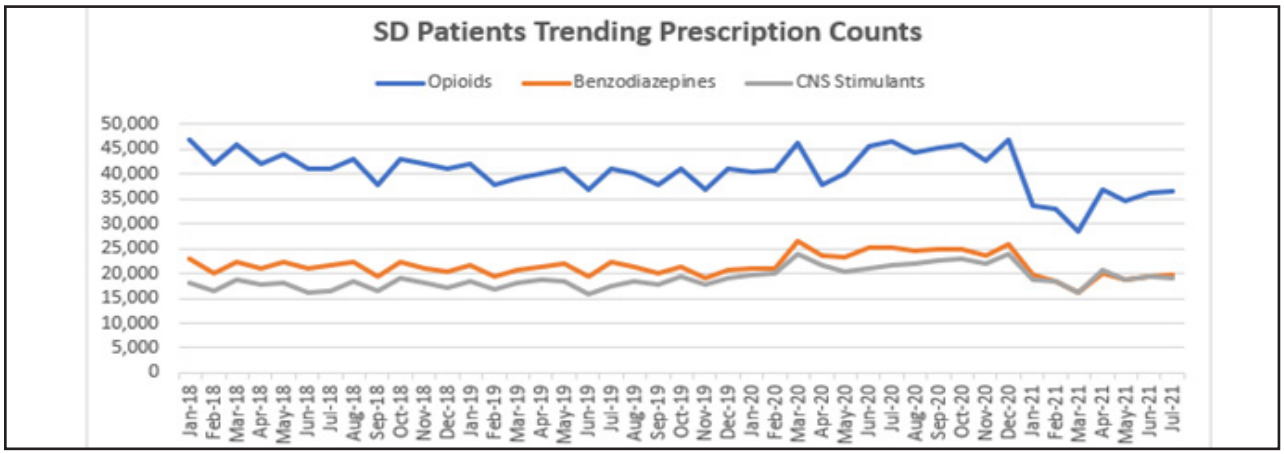
The South Dakota Prescription Drug Monitoring Program (SD PDMP) has partnered with South Dakota professional licensing boards in a license integration project. This project enables: 1) auto-approval of new PDMP accounts if required criteria are met; and 2) daily reverification of all current users. This project benefits program users, SD PDMP staff, and ultimately South Dakota patients. Program applicant prescribers and pharmacists no longer must wait to access this clinical decision-making tool. Upon submission of the online account application and successful automated verification with professional licensing board data, accounts are auto-approved and ready for immediate access, positively impacting patient care. SD PDMP staff is now able to shift the significant amount of time previously spent in the manual account approval and reverification processes to other program priorities. South Dakota patients also benefit from the elevated program user integrity that this project provides to assist in ensuring appropriate patient access. The SD PDMP encourages all pharmacists without an account to register now and take advantage of being auto-approved.

SD PDMP Statistical Update

By Melissa DeNoon, PDMP Director

July Top Ten Controlled Substances (CS) to SD Patients	RXs	Quantity	Days of Supply	Avg Quant/Rx
HYDROCODONE BITARTRATE/ACETAMINOPHEN	12,246	665,978	155,360	54
TRAMADOL HCL	9,672	592,252	165,153	61
DEXTROAMPHETAMINE SULF-SAC/AMPHETAMINE SULF-ASP	7,753	348,594	231,294	45
LORAZEPAM	6,522	277,621	142,240	43
CLONAZEPAM	6,068	329,690	179,543	54
ZOLPIDEM TARTRATE	5,927	208,579	207,373	35
METHYLPHENIDATE HCL	4,774	203,480	142,976	43
OXYCODONE HCL	4,440	228,424	55,580	51
ALPRAZOLAM	4,104	214,420	106,582	52
PREGABALIN	3,444	269,430	120,227	78

Opioid Prescriptions to SD Patients	RXs	% of all CS RXs	Quantity	Days of Supply
January 1, 2016 - December 31, 2016	599,667	46.57%	39,437,769	9,343,889
January 1, 2017 - December 31, 2017	581,550	47.00%	41,318,924	8,708,079
January 1, 2018 - December 31, 2018	511,271	44.50%	33,876,217	7,532,863
January 1, 2019 - December 31, 2019	485,323	43.10%	29,952,344	7,085,767
January 1, 2020 - December 31, 2020	512,176	41.00%	29,803,046	7,635,288
January 1, 2021 - January 31, 2021	33,638	39.40%	1,848,008	498,202
February 1, 2021 - February 28, 2021	32,922	39.90%	1,832,060	485,420
March 1, 2021 - March 31, 2021	28,406	39.50%	1,579,067	417,042
April 1, 2021 - April 30, 2021	36,838	40.20%	2,054,045	536,524
May 1, 2021 - May 31, 2021	34,750	40.60%	1,923,375	505,338
June 1, 2021 - June 30, 2021	36,325	40.50%	2,030,763	536,373
July 1, 2021 - July 31, 2021	36,418	39.70%	2,041,069	536,746



Board Meeting Dates

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

Board of Pharmacy Members

- Ashley Hansen, Aberdeen, SD
- Cheri Kraemer, Parker, SD
- Tom Nelson, Spearfish, SD
- Leonard Petrik, Rapid City, SD
- Dan Somsen, Yankton, SD

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National Pharmacy Compliance News Now Available!

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

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