NYS-ACCP Insider

St. John's University College of Pharmacy and Health Sciences

Volume 3 | Issue 4

February 2018

In this Issue:

SJU-ACCP Student Chapter Highlights

As an ACCP student chapter with Vincentian values at St. John's University, we commit ourselves to the value of service to our community while orienting our students to the practice of clinical pharmacy. Our goal is to provide information regarding career opportunities, to promote excellence in patient care, research and education, and to develop the skills necessary to work on a multidisciplinary team. Take a look at the events that shaped our amazing 2017 year!

APPE Advice Panel

SCCP collaborated with various other pharmacy organizations to host the APPE Advice Panel where students who hadn't yet gone on their clinical rotations could speak to upper-classman about their experiences. Each sixth-year pharmacy student had a unique experience that they brought to the table and it led to a fruitful discussion between students of all different years.

Organ Donor Drive and Solid Organ Transplant Panel

We had the pleasure of collaborating with New York Presbyterian Hospital to host an organ donor drive for National Donate Life month. Pharmacy PGY-1 and PGY-2 residents, Dr. Nicholas Lange, Dr. Nadine Breslin, Dr. Natalie Hendon, and Dr. Krista Mecadon worked together with members to raise organ donor awareness and register organ donors on our college campus. Together were able to register over 20 organ donors! After the drive residents shared their insights and experience on residencies and PGY-2 Solid Organ Transplant residency.

Pharmacy Lobby Day

Our members joined other student pharmacy leaders in Albany, NY to lobby for 3 bills giving pharmacy interns the ability to immunize, expand the pharmacist's scope of vaccinations, and certifying/registering pharmacy technicians.

Peer Mentoring Research Project Showcase

Our annual peer mentoring showcase is a culmination of a year's worth of work by our peer mentoring groups. Groups were paired according to their interests at the beginning of the year and chose a topic to work on longitudinally. Topics included, but were not limited to, education on common and rare disease states, interviewing tips, and clinical pearls. We held our showcase on April 28th, 2017 and invited all members and groups to attend and present their projects.

University Service Day at New Life Fellowship Church Health Fair

In collaboration with APhA, SCCP members volunteered at the New Life Fellowship Church. Students practiced taking community members' blood pressure, height, and weight, as well as gained some experience conducting a brown bag review of medicines.

SCCP Alumni Dinner

Our chapter invited alumni dating back to our founding members for our first alumni dinner event. Current students had the opportunity to dine and chat with SCCP alumni in various fields today. Our guests shared how their involvement and experiences as students led them down their career paths in pharmacy residency, community and even medical school today. It was a festive dinner, excellent reunion for our alumni, and great learning opportunity for our current students.

Sim Man

Sim Man is an interprofessional event we host with Dr. Bill Maidhof, Dr. Sharon See, and Dr. Pamela Gregory-Fernandez, in which a case is presented using Sim Man to Pharmacy and Physician Assistant students. Students of both professions must work together to work up the patient, stabilize them, and counsel upon discharge. This semester we had an asthma exacerbation case and were able to have each student practice their own inhaler technique to gain a better understanding of their patients.

Rho Chi Post Newsletter Collaboration

We decided to try something new this year by collaborating with the Rho Chi Post for our student chapter's second NYS ACCP newsletter. The Rho Chi Post is an award-wining, monthly, electronic, student-operated newsletter founded and developed by our school's Rho Chi Beta Delta Chapter back in 2011. Alongside our current SCCP executive board and senior members, editors from the Rho Chi Post team graciously volunteered their expert eyes to review our articles. Check out their website and newsletter here!

-Victoria Hom, PharmD Candidate 2018

Meet our NYS – ACCP Officers

President: William Eggleston, PharmD, DABAT

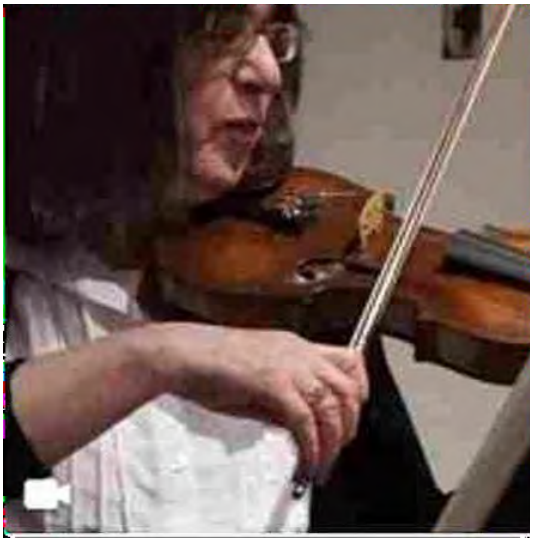
William (Willie) Eggleston is a Clinical Assistant Professor at the Binghamton University School of Pharmacy and Pharmaceutical Sciences and a Clinical Toxicologist at the Upstate New York Poison Center in Syracuse, New York. He earned his PharmD from the Wilkes University Nesbitt College of Pharmacy and completed a two-year fellowship in Clinical Toxicology and Emergency Medicine at SUNY Upstate Medical University and the Upstate New York Poison Center. His research interests include opioid use disorder prevention, treatment, and harm reduction. He is an avid triathlete, perpetual optimist, and connoisseur of fine chocolate milks.

President-Elect: Amanda RM Winans, PharmD, BCPS, CACP

Amanda McFee Winans earned her PharmD in 2007, graduating from Albany College of Pharmacy. She completed a postgraduate Pharmacy Practice Residency with an emphasis in Pain and Palliative Care at Bassett Medical Center in Cooperstown, New York. Dr. Winans currently serves as the primary pharmacist clinician of the outreach Anticoagulation Management Service at Bassett Healthcare, caring for cardiology and cancer patients alike. She continues to support the pain and palliative care practice at Bassett Medical Center through the Pain Management Committee and related quality improvement initiatives. Dr. Winans holds adjunct faculty appointments with multiple Colleges of Pharmacy and holds Clinical Faculty appointment in Pharmacology at Columbia University College of Physicians and Surgeons. She has authored and contributed to numerous peer-reviewed manuscripts related to anticoagulation, and pain and symptom management

Secretary/Treasurer: Amanda Engle, PharmD, BCPS

Amanda Engle received a Bachelor of Science in Biochemistry from Syracuse University followed by a Doctor of Pharmacy degree from the University of Maryland, Baltimore with honors placement in and completion of the Johns Hopkins Clinical Pharmacy Practice Development Program. She then completed residency training at St. Peter's Hospital in Albany, New York and achieved Board Certification as a Pharmacotherapy Specialist. For the past 5 years, Dr. Engle has practiced as a Clinical Pharmacy Specialist at Bassett Medical Center in Cooperstown, New York where she specialized in Pain and Palliative Care. While there, Dr. Engle lead the development of numerous interdisciplinary quality improvement initiatives aimed at reducing risk with opioid use, as well as development of several interdisciplinary pharmacist practice models. Dr. Engle is actively engaged in various local, state and national organizations to advance pharmacy practice on the interdisciplinary team. In February 2018, Dr. Engle will be joining Albany College of Pharmacy and Health Sciences as a full-time faculty member in a shared role with Albany Medical College, where she will begin expanding the interprofessional education program and rounding on the internal medicine team at Albany Medical Center Hospital. In her free time, she enjoys hiking, cooking, and playing games with friends and family.



Technology Director/Website Administrator: Roberta Schnur, R. Ph.

Roberta Schnur grew up on a farm in central New Jersey, went to public schools in the then rural local area, and received a BS degree from Rutgers University College of Pharmacy in 1961. She practiced as a pharmacist for more than 15 years in community, manufacturing, hospital, and insurance adjudication settings, and spent more than 35 years working with computers as a systems analyst, designer and developer. She returned to practice in 2008 and currently serves the healthcare provider community through the World Professional Association for Transgender Health. Roberta is Communications Officer and Website Administrator for the New York State Chapter of the American College of Clinical Pharmacy, a member of the national ACCP, and is active in the New York City Medical Reserve Corps and New York City Radiological Reserve Corps.

Past-President: Travis Dick, PharmD, BCPS

Travis Dick is the Associate Director of Pharmacy at the University of Rochester Medical Center-Strong Memorial Hospital where he is responsible for Clinical Pharmacy Services. Travis is a Board-Certified Pharmacotherapy Specialist that has published peer-reviewed manuscripts and presented at state, national, and international meetings. He is passionate about innovating new clinical services and positioning pharmacists as leaders in patient care and comprehensive drug therapy management. He believes pharmacists should practice at the top of their competence and maximize both pharmacotherapeutic and pharma-coeconomic outcomes.

Prior to his current role, Travis was a clinical pharmacy specialist in solid organ transplantation before advancing into the role of clinical coordinator for the transplant team at Intermountain Medical Center. There he served as site coordinator for the PGY1 Pharmacy Residency Program and as a preceptor for students, PGY1, and PGY2 residents where he advocated for pharmacist accountability in patient care. While there, Travis completed coursework to earn a Master's degree in Business Administration at the University of Utah. Prior to that, Travis completed both PGY1 and PGY2 residencies at Duke University Hospital where he specialized in Solid Organ Transplantation after he graduated from the Doctor of Pharmacy program at the University of North Carolina—Chapel Hill. Travis earned a Bachelor's degree in Biochemistry with a minor in Communication from the University of New Mexico before entering the pharmacy field.

ACCP's Annual Meeting Summary

The New York State Chapter of the ACCP held another successful Annual Meeting on October 27th. Pharmacists and pharmacy students from Rochester, Buffalo, Binghamton, Albany, and New York City (just to name a few) convened in warm and sunny Syracuse ("…just remember, it's not a lie if you believe it." – George Costanza). Well over 70 attendees had the opportunity to hear from engaging expert speakers from all over the state. The day started with an inspirational keynote address from Daniel Aistrope, the Director for Clinical Practice Advancement for ACCP. He left attendees with the tools and strategies to move our profession forward locally and nationally. Pharmacists from NYU Langone Medical Center, the Binghamton University School of Pharmacy and Pharmaceutical Sciences, SUNY Upstate Medical University, the Upstate New York Poison Center, and the St. John Fisher Wegmans School of Pharmacy covered a variety of topics, including the role of pharmacists in patients receiving ECMO, emerging antibiotics, and even how to engage difficult students (which of course doesn't include any of our excellent student members)! The day highlighted rising clinicians in the state with a student research poster session and clinical updates given by residents from the University of Rochester Medical Center and New York-Presbyterian Hospital. We also recognized Rachel Schult, a Clinical Toxicologist and Emergency Medicine Pharmacist at the University of Rochester Medical Center, with the New York State ACCP Educator of the Year award. At the end of the day everyone left with their brains full of knowledge and their CE logs filled with 6 more hours of content! We hope you enjoyed your time at the meeting and look forward to seeing you at the Annual Meeting this fall. For those of you who missed out make sure to register for another great experience this fall!

-William Eggleston, PharmD, DABAT – NYS ACCP President

NYS ACCP Past-President Travis Dick presenting Rachel Schult, PharmD, DABAT from the University of Rochester Medical Center with the NYS ACCP Educator of the Year Award (top right).
NYS ACCP Past-President Travis Dick opening the Annual Meeting in Syracuse (top left).
New York State Pharmacy students presenting their research during the student poster session (bottom left).

The CVS Health and Aetna Merger

At the beginning of December, CVS Health announced the execution of a merger agreement with Aetna, at a total transaction value of $69 billion.[1] CVS will buy Aetna, combining one of the largest retail drug stores and a pharmacy benefit manager with one of the largest health insurers in the country. [3]

In the press release, CVS stated that the merger presents an opportunity to access lower cost, high-quality care in various settings. How exactly? Possibly through the development of "community-based clinics" which will be able to provide direct care, "one-stop shopping" for their employees' health insurance, and deliver care using the health information and technology that is available through both companies.[3] This will connect Aetna's network of providers with greater access to consumers through CVS Health's 1,100 MinuteClinic walk-in clinics and over 9,700 CVS Pharmacy locations.[1]

CVS claims it will not only reduce cost and improve access, but also provide individualized patient care by allowing pharmacists, nurses, and others to counsel patients about their medications and to do lab work necessary to diagnose a condition. Thus, patients will be able to save not only by going to a retail store to treat acute illnesses like a sore throat but also to better understand their chronic illnesses such as diabetes and heart diseases.[3] These changes are not only intended to improve health at a lower cost, but also prevent unnecessary hospital readmissions.

While the merger may offer some benefits, the deal may hurt consumers as well as others in healthcare. The merger may decrease or limit patients' choices such as where they receive their care or where they fill their prescriptions.[3] Small pharmacies will also struggle even further as the deal would most likely force Aetna's 20 million patients to get their prescriptions from CVS or Caremark (CVS' mail order service).[4] This may make it more difficult for patients to get specialty medication, which are usually carried by smaller pharmacies and not large retailers. Lastly, as a result of the merger and CVS expanding its services, the deal will possibly hurt the nation's hospital emergency room because CVS and Aetna claim that visit may be avoided or cared for in an outpatient location.[2]

The deal is expected to close in the second half of 2018, although regulators and shareholders of both companies must still approve it. Experts are skeptical and warn that federal antitrust officers who worry the deal may lessen competition will be able to block the deal. It, therefore, remains to be seen if the merger will come to fruition.[1]

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-Ji Min Son, PharmD Candidate 2019
-Daniela Farzadfar, PharmD Candidate 2020

Impact of GOP Tax Bill on Current Healthcare System

The Affordable Care Act (ACA) is a healthcare reform law aimed to increase access to health insurance by expanding Medicaid and reducing cost. Research has shown that ACA had decreased the number of uninsured Americans and had substantially improved access to care for those who gained coverage[1]. The individual mandate clause in ACA had increased insurance enrollment. People who did not follow the individual mandate to buy insurance would have had a tax penalty imposed on them. With a larger number of people sharing the cost, insurance premiums were expected to decrease for seriously ill patients. However, in December 2017, the Senate passed a GOP tax bill that repealed the individual mandate in ACA. Without it, the healthy are less likely to buy insurance, causing adverse selection in which only health compromised people buy insurance. This will drive up costs leading to decreased insurance coverage and increased premiums for everyone.

The Congressional Budget Office estimated that repealing the individual mandate would decrease the number of people with health insurance by 4 million in 2019 and 13 million in 2027 and would increase average premiums in the nongroup market by about 10 percent[2]. As a result, government spending on healthcare would be reduced by $338 billion in a decade[2]. However, the underlying concern is that fewer people would be purchasing insurance and thus preventive care, including immunizations and vaccines, physical evaluations, and screenings. This puts financial pressure on hospitals due to increased expensive emergency room visits. Toni Preckwinkle, the president of Cook County Board of Commissioners, stated, "We expect to see an increase in the number of uninsured patients coming to us with devastating conditions whose severity or stage is a consequence of an individual not seeking care earlier due to inadequate resources"[3].

Moreover, even though the GOP tax bill did not address a cut in Medicare spending, concerns have been raised due to the Pay-As-You-Go Act of 2010. This bill requires cuts to certain federal programs if Congress passes legislation that creates a deficit. As a result, the GOP tax bill may force a cut of $25 billion to Medicare[4].

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-WingSze Liu, PharmD Candidate 2021

Stricter Regulations Ease Pharmacist Recommendations on Homeopathic Products

Aside from the typical role pharmacists play behind the counter, they are also trained in medications that can be obtained without a prescription, better known as Over-the-counter medications (OTC). Despite what is commonly thought, only products regulated by the Food and Drug Administration (FDA) for safety and efficacy are given the term. All other products, including homeopathics and vitamins, are not regulated for safety and efficacy. Using evidence-based medicine, pharmacists provide recommendations by utilizing the Pharmacists' Patient Care Process which becomes a problem when patients come to the pharmacy looking for homeopathic and dietary supplements that have no FDA evidence-based testing. The FDA recently published stricter regulations regarding homeopathic medications, replacing guidelines from 1988. The purpose is to reduce the increased rate of side effects and deaths associated with such products, giving pharmacists a little more confidence when counseling patients. [1]

For decades, homeopathic medications have had their own standards and regulations. Under these conditions, homeopathics must contain active ingredients that are listed in the Homeopathic Pharmacopoeia of the United States and follow labeling and advertising laws set forth by the FDA and the Dietary Supplements Compendium (DSC). Since homeopathic medications are regulated by the FDA but are not evaluated for safety or effectiveness, they must have the statement, "These uses have not been evaluated by the Food and Drug Administration".[4] The reasoning behind the differences in regulations between OTC and homeopathic products is due to their strength. The amount of active ingredients in homeopathic products are so minimal that it is improbable for a therapeutic effect to take place but instead, a placebo effect.[2] The dilution of active ingredients in homeopathic products comes from a 200-year-old principle which suggests that a substance that caused symptoms in a healthy person can be used in diluted form to treat illness (like-cures-like) and that the more diluted the substance, the more potent it is (law of infinitesimals).[1] After several recent cases, the FDA announced stricter regulations in December 2017 on homeopathic products as they introduce a new, risk-based enforcement approach in order to protect the public; especially the most vulnerable populations. Under this approach, the FDA

will be focusing its time on unapproved products labeled as homeopathic that have the greatest potential for risk to patients; products with routes of administration other than oral and topical, and products intended to treat chronic conditions like diabetes. [5]

While these regulations will not completely ensure that a product is safe and effective for use, the push for stricter manufacturing and a crackdown of products out on the shelves is the first step in protecting the public from potentially harmful formulations. [5] With fewer products available for patients, pharmacists can feel slightly more comfortable that these products will not put their patients in danger. Some tips and guidelines for pharmacists recommending or speaking with patients inquiring about homeopathic medication include: reminding patients to always keep an updated list of all homeopathic products they are taking, encouraging special patient populations to avoid such products all together, and counseling patients to never use homeopathic remedies in place of a proven effective treatment. [3]

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-Katharine Russo PharmD Candidate Class of 2021

Clinical Spotlight: Jason Babby, Pharm.D.

Assistant Director of Clinical Services at Mount Sinai Beth Israel Hospital

1. **What are your current practices/roles and what responsibilities do they entail?**

As the Assistant Director of Clinical Services at Mount Sinai Beth Israel, I am responsible for the planning, directing, implementing and supervising of all clinical pharmaceutical activities in order to optimize drug therapies. I also provide leadership and oversight of the clinical specialists and their development to make certain that patients' needs are met. I serve as the ASHP accredited PGY-1 Residency Program Director to ensure that all accreditation requirements are met as well as coordinate all resident and student activities.

2. **Where did you complete your PGY-1 and PGY-2 residencies and how did your experiences shape your perspective on pharmacy practice?**

I completed my PGY-1 Pharmacy Residency at Hunterdon Medical Center in Flemington, NJ followed by a PGY-2 in Drug Information at Robert Wood Johnson University Hospital/Rutgers, The State University of New Jersey. Both residencies showed me how pharmacists have vital roles on the patient care team and how it is important for us to continue to expand our roles as health care is changing.

3. **Which organizations are you currently involved in?**

I am currently involved in the New York City Society of Health System Pharmacists (NYCSHP), ASHP, and ACCP. I hold leadership roles in NYCSHP (Immediate Past President) and ASHP (Member, Pharmacy Practice Experiences Section Advisory Group).

4. How do you keep up with the latest findings and advancements in clinical pharmacy?

I use the ASHP Daily Briefing to provide daily updates on advancements in clinical pharmacy. The daily briefing summarizes the most relevant news stories from thousands of sources and contains news from sources that may not be monitored or known to ASHP members. Also reading journals such as American Journal of Health-System Pharmacy and Pharmacotherapy help keep up with new practices.

5. What advice would you give to a student interested in pursuing a career in clinical pharmacy?

Join national pharmacy organization such as ASHP and ACCP and get involved in your local SJU chapters. NYSCHP is also another great organization to get involved in. You can choose a local chapter (i.e. New York City, Royals, or Long Island) and attend their chapter programs and network with pharmacists. As you network, you'll get to learn about the different opportunities there are in pharmacy. In your last year of school, choose challenging rotations in different specialty areas which help you see where your interests are.

-Shireen Farzadeh, PharmD Candidate 2019

New Hypertension Guidelines

The 2017 American College of Cardiology (ACC) and American Heart Association (AHA) Hypertension Guidelines are the first comprehensive update on high blood pressure guidelines since the JNC 7 in 2003.[2] The most profound update was the change in the definition and classification of hypertension. In previous guidelines, stage one hypertension (HTN) was defined as a blood pressure (BP) ≥140/90mmHg, while this guideline defines stage one hypertension as a BP ≥ 130/80mmHg.[1] Lowering the HTN definition accounts for complications that can occur at lower numbers. By redefining HTN as ≥ 130/80mmHg, interventions can be made earlier to lower CV risk in patients. This decreased cutoff will lead to nearly half of the US adult population (46%) being diagnosed with HTN, having the greatest impact on younger patients.[5] It is recommended that patients newly diagnosed with HTN based on the current cutoff be managed with lifestyle modifications, with only a small portion requiring BP-lowering medication.[4] Stage two hypertension is defined as ≥140/90mmHg where treatment with both pharmacological and nonpharmacological therapy is recommended.[4]

The decision to treat a patient with BP-lowering medication is now based on BP readings along with their risk of developing heart disease and stroke. Their risk is determined through the use of the atherosclerotic cardiovascular disease (ASCVD) risk calculator.[1] Patients with stage one HTN and a < 10% risk for ASCVD are recommended to make lifestyle changes.[6] However, if the patient has stage one HTN and a risk > 10% for ASCVD or has a known comorbid condition (CVD, diabetes, and CKD), they are recommended to make lifestyle changes and take a single BP-lowering medication.[2] Patients with stage two HTN, regardless of comorbidities, are recommended to make lifestyle changes and take at least two different classes of BP-lowering medications.[2]

The new ACC/AHA guidelines also emphasize accurate BP measurement and HTN diagnosis. In addition to measurements taken in the doctor's office, physicians are suggested to utilize at home and ambulatory BP measurements in order to identify "white coat" hypertension.[2] Before diagnosing patients, it is important to obtain the average of ≥ two BP readings at more than one session. The guideline's focus on a having a proper diagnosis minimizes unnecessary treatment and inappropriate therapy. While these new guidelines introduce a new BP cutoff, it is still important to tailor BP goals to each patient.[3] It is important to consider these guidelines as simply a guide and focus mainly on each patient's specific factors and CV risk factors.

New Hypertension Guidelines, Continued

Blood Pressure (mmHg)	ACC/AHA Guideline Treatment Recommendations
Normal: < 120/80	Maintain healthy lifestyle habits
Elevated: 120 - 129/< 80	Encourage lifestyle changes and check for meds that can increase BP (NSAIDs, SNRIs, estrogen, etc.)
Stage 1 hypertension: 130 - 139/80 - 89	Implement lifestyle changes alone if ACC/AHA 10-year CV risk < 10%; Use BP meds for patients with CV disease, diabetes, chronic kidney disease, or 10-year CV risk ≥ 10%
Stage 2 hypertension: ≥ 140/90	Reinforce lifestyle changes and use BP meds

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-Gina Daniel, PharmD Candidate 2018
-Jayed Momin, PharmD Candidate 2020

Shingrix® Vaccine Approval

Shingles is a painful and potentially dangerous viral disease affecting 1 in 3 people in the United States.[1] Shingles is caused by the varicella zoster virus, the same virus that causes chickenpox.[1] After a person recovers from chickenpox, the virus stays dormant in the nervous system and can reactivate at any time. The risk and severity of shingles increase with age, as the immune system loses its ability to produce a strong and effective response against the virus.[1] Shingles is most often associated with long-term nerve pain, painful lesions, scarring, bacterial infections, vision impairment, and hearing problems.[1]

In October 2017, the Food and Drug Administration approved GlaxoSmithKline Biologicals' Shingrix® vaccine, a recombinant zoster vaccine, adjuvanted. Unlike Zostavax® (zoster vaccine live), Shingrix® is not a live vaccine so issues should not arise when administering to immunocompromised patients.[2] Shingrix® is indicated for the prevention of herpes zoster (shingles) in adults aged 50 years and older.[2] Shingrix® has been shown to boost the varicella-zoster virus-specific immune response, which is thought to be the mechanism by which it protects against the disease.

Approval for Shingrix® was based on a comprehensive Phase III clinical trial evaluating its efficacy, safety, and immunogenicity in more than 38,000 patients.[2] It was shown to have greater than 90% efficacy rate and sustained efficacy during the four-year follow-up period.[2] The zoster vaccine (recombinant) significantly reduced the incidence of developing herpes zoster (HZ) by 97.2% in subjects older than 50 years and reduced the incidence of HZ by 91.3% in patients older than 70.[2] In addition, Shingrix® also reduced the overall incidence of post herpetic neuralgia, a form of chronic nerve pain and the most common complication associated with shingles, by 88.8% for those 70 years and older.[2]

The Advisory Committee on Immunization Practices (ACIP) voted Shingrix® as the preferred vaccine for healthy adults 50 years and older to prevent shingles and related complications.[3] According to ACIP guidelines patients that have received Zostavax® vaccine should still receive Shingrix®.[3] Shingrix® is administered as a two-dose vaccine series, 0.5 mL intramuscularly for each dose, the second dose is to be administered anytime between two to six months after the first dose.[2] In patients that have already received Zostavax®, Shingrix® can be administered 8 weeks after Zostavax®.[3]

Shingrix® is available for ordering and costs $336 for two doses; broad payer coverage is not expected until April 2018, but insurances are expected to cover the cost.[4] The significant benefits of Shingrix® have led it to become the ACIP-preferred vaccine for shingles prevention.

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-Kiranjit Luther, PharmD Candidate 2018
- Jeffrey Thomas, PharmD Candidate 2020

Luxturna™ New Drug Approval

On December 19, 2017, Luxturna™ (voretigene neparvovec-rzyl) became the first FDA-approved directly-administered gene therapy that targets a disease caused by a specific gene mutation. The drug manufacturer, Sparks Therapeutics Inc., has received the Orphan Drug, Priority Review, and Breakthrough Therapy designations for its drug application, along with the 13th Rare Pediatric Disease Priority Review Voucher given since the voucher program began.[1]

Luxturna™ is indicated to treat confirmed biallelic *RPE*65 mutation-associated retinal dystrophy in patients with viable retinal cells. The *RPE*65 gene is responsible for producing *RPE*65 isomerase, which converts all-*trans*-retinyl ester to 11-*cis*-retinol in the retinoid (vision) cycle. A deficiency in this enzyme disrupts the retinoid cycle, thereby impairing vision.[1] This condition affects 1,000 to 2,000 patients in the U.S. Most patients develop the condition at childhood, with vision deterioration progressing over time into complete blindness.[1]

Luxturna™ is created using recombinant DNA techniques to modify a naturally occurring adeno-associated virus, which then delivers a normal copy of the *RPE*65 gene to the host's retinal cells.[1] Prior to administration, a 1:10 dilution must be performed to obtain the recommended dose for each eye, 1.5×10^{11} vector genomes (vg).[2] It is administered as a subretinal injection to each eye on separate days within a close interval that is no less than 6 days.[2] A 7-day course of oral corticosteroids equivalent to 1 mg/kg/day of prednisone (max 40mg/day) is recommended to be started 3 days before the administration of Luxturna™ to each eye, followed by a 10-day taper.[2] Common adverse reactions include eye redness, cataract, increased intraocular pressure, and retinal tear.[2]

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-Maria Zdravkova, PharmD Candidate 2018
-Joan Cheung, PharmD Candidate 2020

Abilify MyCite: America's First Digital Pill

In this day and age, there is no doubt that technology has become increasingly intertwined in the daily lives of citizens across the United States. From smartphones to smart cars, technological advancements have integrated themselves into countless areas of everyday living. With the Food and Drug Administration's recent approval of the first digital pill, it appears that modern technology has finally found a role in the realm of pharmacy.

Approved by the Food and Drug Administration in November of 2017, Abilify MyCite represents the first medication in the United States to contain a digital ingestion tracking system.[1] The system functions through the cooperation of four essential components. These components include the tablet, a wearable patch sensor, a smartphone application, and a web-based dashboard. The Abilify MyCite tablet is an aripiprazole tablet containing an embedded Ingestible Event Marker (IEM) sensor, which is first ingested by the patient.[2] Upon contact with gastric fluid in the patient's stomach, the IEM sensor is activated and transmits a signal to the MYCITE Patch, a sensor patch worn by the patient while the drug is being ingested.[2] Communication between these sensors enables the collection of objective data such as the date and time of tablet ingestion, as well as the drug's activity level.[2] Information transmitted to the patch is then relayed to the patient's MYCITE smartphone application.[2] From the MYCITE APP, patients can review the objective ingestion data with their doctor, select whether other healthcare professionals and family members may access the data, and may even report their current mood and quality of rest.[2] Physicians with permission to view the data are given their own method of access through a web-based dashboard.[2]

Currently, Abilify MyCite is indicated for the treatment of adults with schizophrenia, bipolar I disorder, and in the adjunctive treatment of adults with major depressive disorder.[3] However, the medication does include a black box warning of increased mortality in elderly patients with dementia-related psychosis, suicidal thoughts and behaviors, and neither safety nor efficacy have been proven in pediatric populations, which is the same black box warning for aripiprazole itself.[3] While Abilify MyCite's ability to improve adherence to treatment has yet to be established,[3] the new technology poses exciting possibilities for the future of "smart" medications and will likely raise interesting new bioethical questions as technology grows ever closer to pharmacy.

References

1. Food and Drug Administration. FDA approves pill with sensor that digitally tracks if patients have ingested their medication. Press Announcements. Published November 13, 2017. Accessed January 5, 2018.
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