Volume 2 | Issue 4
**March 2017**

# NYS-ACCP Insider

**University at Buffalo School of Pharmacy and Pharmaceutical Sciences**

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## UBSPPS-ACCP Student Chapter Updates

Looking back on our second full year as a student chapter here at UBSPPS, there is a lot that our SCCP chapter can be proud of. With so many different organizations in our school, it is often difficult to provide new and unique opportunities to our members, but we have a few programs that we would like to highlight.

One part of our SCCP chapter that we are proud of is our "Dinner and Discussion" program. Dinner and Discussion stemmed from the idea that in classes we often do not get to experience all that clinical pharmacy has to offer, and what better way to learn more about clinical pharmacy than to do it over some Wegmans sub sandwiches?

For our Dinner and Discussion program, we invite pharmacists to talk about special topics that are not always taught in our core curriculum. It gives our members and our guest speakers a chance to talk about different topics in an informal setting. We provide food to our members, usually Wegmans sub sandwiches, and the discussion usually lasts about a half hour. We started this program

a year ago and since then, we have had many pharmacists talk about a variety of different aspects of clinical pharmacy. For our very first program, Brian Kersten, PharmD, BCPS from Kaleida Health-Buffalo General Medical Center talked about a critical care case. In the Fall of 2016, Nicholas Fusco, PharmD BCPS, BCPPS discussed a pediatric case and Alice Ceacareanu, PharmD, PhD talked about her extensive oncology research. We have two planned for this semester; Nicole Albanese, PharmD, BCACP will be talking about insulin pumps and diabetic nutrition counseling and Juliane Nguyen, PharmD, PhD will be presenting on a pharmaceutical sciences topic at the end of the semester.

So far, this program has been very successful and we hope to continue it into the future. Through this program, our members have the opportunity to learn more about interesting and current topics in the field of pharmacy. We think it is a great way to get involved in our chapter and network with pharmacists within the school and from the area.

**-Anna Morien, PharmD Candidate, UBSPPS Class of 2018, UB SCCP P3 Student Liaison**

There is always an exam to study for or a practicum to prepare for. This is what it means to be a pharmacy student. The workload can sometimes make us lose perspective of why we chose this profession— to take care of our patients and keep them safe.

This past fall semester, our UB SCCP chapter participated in Extra Life, a gaming marathon with all proceeds going toward the Women and Children's Hospital of Buffalo. We wanted to give students an opportunity to enjoy themselves, while giving back to the community in a unique way.

Rather than pharmacotherapy slides, we projected Call of Duty on the Xbox One onto our large screens. We added in several board games, and transformed our largest lecture hall into a miniature game room. With the help of Dr. Fred Doloresco, PharmD, MS., we were able to turn a separate classroom into the perfect space to experience the newest Virtual Reality releases on the HTC Vive.

Our event succeeded in raising over $200.00 for the Women and Children's Hospital. The popularity of this first event has inspired us to participate annually, and hopefully we will continue to draw in larger crowds and more donations.

**-Shahrier Hossain, PharmD Candidate, UBSPPS Class of 2019, UB SCCP President-Elect**

# New Drug Review: Epclusa® (sofosbuvir/velpatasvir)

In June 2016 the FDA approved Gilead's Epclusa®(sofosbuvir/velpatasvir) for the treatment of adult patients with chronic Hepatitis C viral infection both with or without cirrhosis. Epclusa® is indicated for treatment of all six hepatitis C genotypes (GT-1,GT-2,GT-3, GT-4, GT-5, and GT-6).[1]


Hepatitis C virus (HCV) infection impacts millions of people across the nation.[2] Hepatitis is a viral infection impacting the liver and can be transmitted via injectable-drug use, exposure to infected blood, or sexual contact. HCV begins as an acute infection and progresses to a chronic disease state causing long-term liver complications such as cirrhosis and hepatocellular carcinoma.

Vaccinations are available for hepatitis A and B but not for hepatitis C. Recently a number of pharmaceutical companies have focused their resources on developing novel therapies for HCV, one of these being Epclusa® recently released by Gilead Sciences.[3] Epclusa® is a fixed dose combination of sofosbuvir (400 mg) and velpatasvir (100 mg). Sofosbuvir is a nucleotide analogue inhibitor of HCV NS5B RNA polymerase and was released as a monotherapy for HCV by Gilead in 2013. Velpatasvir is an HCV NS5A replication complex inhibitor. Epclusa® is the first available pangenotypic therapy used to treat all six genotypes of HCV. Epclusa® is dosed as a once-a-day pill and is recommended as monotherapy for patients without cirrhosis or with compensated cirrhosis. For patients with decompensated cirrhosis, Epclusa® should be given in combination with ribavirin.

The safety and efficacy of Epclusa® was demonstrated in Phase 3 clinical trials with a total study-size of 1,558 patients.[4,5] Efficacy was evaluated based on cure of HCV, defined as the number of patients with undetectable HCV in the blood three months after the completion of a 12-week treatment period. Trial 1 was a randomized, double-blinded, placebo-controlled test consisting of 740 patients with HCV genotype 1, 2, 4, 5, or 6 who received either Epclusa® or placebo for 12 weeks. Results demonstrated 98% cure for genotype-1, 100% for genotype-2, 100% for genotype-4, 97% for genotype-5 and 100% for genotype-6. In trial 2 and trial 3, investigators conducted randomized open-label studies consisting of 266 patients with genotype-2 and 552 patients with genotype-3. In both trials patients either received Epclusa® or sofosbuvir/ribavirin for 12 weeks and results demonstrated cure rates of 99% for genotype-2 patients and 95% for genotype-3 patients.[6]

The most common side effects of Epclusa® include headache and fatigue. When Epclusa® is given in combination with ribavirin for patients with decompensated cirrhosis, common side effects include anemia, nausea, insomnia and diarrhea. A serious side effect is bradycardia especially when taken with amiodarone. Epclusa® has a black box warning for the risk of hepatitis B reactivation in patients coinfected with HBV and HCV. Before starting treatment, healthcare providers should test patients for evidence of current or prior Hepatitis B Infection because reactivation of HBV can occur during and after treatment and lead to hepatic failure and death.[4]

**-Jessica Greger, PharmD Candidate, UBSPPS Class of 2019, UB SCCP P2 Student Liaison and Atul Dilawri, PharmD Candidate, UBSPPS Class of 2020**

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## ACCP interview with Dr. Kathleen Tornatore, PharmD, FAST, FCCP, Professor of Pharmacy Practice; University at Buffalo; School of Pharmacy and Pharmaceutical Sciences

**1. Why did you initially get involved with ACCP in your career? And how did it help you achieve your goals?**
I became involved as a junior member after I completed my fellowship. I was fortunate that during my ASHP Hospital Residency at the University of Nebraska Medical Center that our pharmacy mentors and faculty discussed many different pharmacy organizations and our potential interface. Since these pharmacy faculty were involved in the initial ACCP organization, we quickly learned about the goals of this innovative organization. The early goals of ACCP fostered the development of clinical pharmacists and pharmacy research scientists within health care facilities and schools of pharmacy. ACCP helped me achieve my professional goals through the research mentoring, poster and platform presentations, and educational or research sessions. Through these annual meetings, I networked with senior pharmacy practitioners and researchers and learned a systematic research approach to answer clinical questions that could impact patient care.

**2. How were you involved in ACCP in the past, or currently? How has the organization changed over the years?**
I was involved in ACCP in a variety of avenues that include abstract reviewer, Research Committee, Research Institute Grant Review Panel in the areas of nephrology and transplantation, journal reviewer, Membership Committee, Annual Program Committee, development of specific symposium, annual meeting moderator and lecturer, Mock PharmD Interviews, MERIT reviewer for clinical pharmacy proposals, member of PRNs for Immunology and Transplantation and Women's Health and Research Institute Liaison. I was also involved in the Development, Steering and Membership Committees for the early NYS-ACCP chapter. ACCP has grown significantly with goals that reflect the needs of clinical pharmacy practice and education. The organization has developed more focused mentoring programs to address professional needs for junior practitioners and/or faculty such as MERIT, FIT; review materials and sessions for Board Certification in Pharmacotherapy; global health issues; clinical pharmacy management and program development in these arenas.

*"My advice to PharmD students is to think outside the box and be willing to be an asset in any endeavor they undertake."*

**3. Exactly what does it mean to be a Fellow of ACCP? How did you become one?**
An ACCP Fellow is committed to the discipline of clinical pharmacy through service, education or research and demonstrates a focused and objective commitment to ACCP goals through their professional contributions. This is exemplified through support and participation in specific areas of ACCP where the member's skills and strengths can be best utilized. I became an ACCP Fellow based upon my continued and sustained participation in the organization through research presentations, publications and focused work on committees for this organization and my interface with other medical/pharmacy specialties.

**4. Currently Transplant Pharmacy Practice is petitioning to be approved by BPS as a specialty. What are your thoughts on this? How do you think it will impact practice?**
The AST Transplant Pharmacy Community of Practice and ACCP PRN in Immunology and Transplantation have grown rapidly over the last 15 years. These transplant pharmacists are required members of the multi-disciplinary transplant team for each accredited solid organ transplant program. The petition from these transplant pharmacists to the Board of Pharmacy Specialties (BPS) is important and timely to standardize the training, education and services provided. The pharmacy services needed include all aspects of pharmaceutical care pre and post transplant for the recipient and living donor. The BPS process of recognition as a specialty is a notable and exciting step toward formalizing inclusion of these pharmacists as essential members of the transplant team and will facilitate reimbursement for their services.

**5. And lastly, some advice for students. For anyone thinking about research, what advice do you have for them? And what about any advice in general for students?**
My advice to PharmD students is to "think outside the box" and "be willing to be an asset" in any endeavor they undertake. There are many opportunities to gain novel experiences in pharmacy practice and clinical research within their respective schools of pharmacy as well as through the pharmacy community.

# The PRECISION Trial: A Summary

**Introduction**

The PRECISION trial evaluated the cardiovascular safety of NSAIDs, particularly celecoxib, for treatment of arthritis pain. It was published in the *New England Journal of Medicine* in November 2016. Prior to this study there were cardiovascular safety concerns for selective COX-2 inhibitors after the withdrawal of rofecoxib from the market in 2004. The United States Food and Drug Administration (FDA) required the manufacturer of celecoxib, Pfizer, to complete this Phase IV safety trial. Ultimately the data collected from this study showed that moderate doses of celecoxib had a similar risk of cardiovascular outcomes compared to naproxen and ibuprofen. Secondary analyses showed that celecoxib had lower risk of GI events compared to naproxen and ibuprofen, and a lower risk of renal events compared to ibuprofen. These new findings may change treatment guidelines or make providers more aware of the safety profiles of these agents.

**Pharmacology**

Nonsteroidal Anti-inflammatory Drugs (NSAIDs) are a commonly prescribed drug class for their anti-inflammatory and analgesic properties. They are indicated for many disease states including osteoarthritis and rheumatoid arthritis, which were the focus of this study. NSAIDs work by inhibiting the cyclooxygenase enzymes in the body, which act on an early step in the arachidonic acid cascade to form prostaglandins, prostacyclins, and thromboxanes. There are two different forms of the COX enzyme found in the body; COX-1 and COX-2. Both enzymes produce mediators of pain, inflammation, and fever, whereas only COX-1 is involved in producing prostacyclins that are involved in platelet activation and protection of the gastric mucosa.

**Inclusion/Exclusion Criteria**

The key inclusion criteria of this study were males or females age ≥ 18 years old, a duration of osteoarthritis (OA) or rheumatoid arthritis (RA) ≥ 6 months, a requirement for a chronic analgesic regimen ≥ 6 months, and a requirement of chronic, daily NSAID therapy to control arthritis symptoms. These patients also had established cardiovascular disease or increased risk for cardiovascular disease.

The main exclusion criteria for this trial was arthritis pain that is adequately managed with acetaminophen.

**Trial design**

This study was prospective, multi-center, randomized, parallel, double-blind, non-inferiority Phase IV trial that was stratified according to diagnosis (OA vs. RA), aspirin use, and geographic region. Patients were randomized to groups taking either celecoxib 100 mg twice daily, ibuprofen 600 mg three times daily, or naproxen 375 mg twice daily. Those with RA could up-titrate their study medication if needed at follow-up visits. Each patient also received esomeprazole 20-40 mg once daily to prevent GI side effects. Any patients taking low dose aspirin were permitted to continue therapy. There were 24,081 total patients enrolled over 13 countries.

The primary endpoint was the Antiplatelet Trialists Collaboration (APTC) composite of cardiovascular and hemorrhagic deaths, nonfatal MI, or nonfatal stroke. Secondary objectives were to compare incidence of clinically significant gastrointestinal events, effects on renal function and blood pressure, and the drugs' efficacy for arthritis.

**Statistical analysis**

The primary comparator for the assessment of noninferiority of celecoxib was naproxen, but comparisons with ibuprofen were included as well. Noninferiority required a hazard ratio of 1.12 or lower, with an upper 97.5% confidence limit of 1.33 or lower for the intention to treat population, and 1.4 or lower for the on-treatment population. The FDA set the interval limits for this particular study, and also recommended the study to provide 80% power after it was originally set for 90%.
Cox proportional hazards model with adjustment for stratification factors were used to calculate the hazard ratios and confidence intervals.

**Results**

**On-treatment analysis:**

The hazard ratio for the primary APTC outcome in the celecoxib group when compared to naproxen was 0.90 (95% CI, 0.71-1.15; P<0.001 for noninferiority) and for celecoxib versus ibuprofen was 0.81 (95% CI, 0.65 to 1.02, P<0.001 for noninferiority).

**Intention-to-treat analysis:**

The hazard ratio for the primary APTC outcome in the celecoxib group when compared to naproxen was 0.93 (95% CI, 0.76-1.13; P<0.001 for noninferiority) and for celecoxib versus naproxen was 0.85 (95% CI, 0.70-1.04; P<0.001 for noninferiority).

The risk of GI events was significantly lower with celecoxib than with naproxen (P=0.01) or ibuprofen (P=0.002), and the risk of renal events was also significantly lower with celecoxib than with ibuprofen (P=0.004) but was not significantly lower with celecoxib than naproxen (P=0.19).

## Critiques

Retention was a big issue in this trial; 68.8% of patients discontinued the trial and 27.4% of patients were lost to follow up. The authors believed this was due to the challenges faced when treating painful conditions in patients long-term: patients may experience frustration with unresolved symptoms and switch therapies or leave the trial. Although the retention was low for trials that assess cardiovascular outcomes, it is not uncommonly found in pain studies.

Another concern is the moderate doses of celecoxib that were utilized. The dose was mostly limited to 200 mg per day, while some studies have assessed doses of 400-800 mg per day. This is due to the FDA's involvement in the trial and an inability to use more than the approved dose for osteoarthritis indication, which accounted for approximately 90% of the study subjects.

It is worth noting that the authors reported 95% confidence intervals even though they set their upper limits with 97.5% confidence intervals typical of a noninferiority study.

## Conclusion

This trial provides good quality evidence that moderate doses of celecoxib do not appear to increase the risk of cardiovascular outcomes compared to other, non-selective NSAIDs. These findings may begin to ameliorate practitioner's concerns in using moderate doses of celecoxib in patients with a complex medical history.

**-Rachel Meyer, PharmD Candidate, UBSPPS Class of 2018, UB SCCP Treasurer &**
**Rachel Klosko, PharmD Candidate, UBSPPS Class of 2019, UB SCCP P2 Student Liaison**

In 1976, the Board of Pharmacy Specialties (BPS) was founded as a post-licensure certification agency for pharmacists. It is their goal to improve patient care by identifying those pharmacists who have exceptional skills and abilities to practice pharmacy at the highest level. As the field of pharmacy is ever growing and pharmacists are accepted into more specialty areas, BPS has expanded to encompass specialty certifications to ensure outstanding patient care. This article will briefly outline certifications that will be added in the near future as well as existing certified pharmacy specialties.

Pharmacists who were already Board Certified Pharmacotherapy Specialists (see later for requirements) were previously eligible for two Added Qualifications: Cardiology (BCPS-AQ CV) and Infectious Disease (BCPS-AQ ID). Having these add-ons signified that the pharmacist had extensive experience in that specific field; above and beyond general BCPS requirements. To earn these qualifications, candidates (already board certified in pharmacotherapy) were required to apply to BPS. Ideal candidates would be involved in relevant research and education, and satisfy other practice criteria. This barred a significant number of pharmacists from pursuing the qualifications. In February 2012, ACCP, along with APhA and ASHP, petitioned for both Infectious Disease and Cardiology to become stand-alone specialties. The petition was officially accepted by BPS in February 2017. BPS hopes to administer the first round of certification exams September 2017, and end the Added Qualifications program on December 31, 2017.

Cardiology pharmacy specialists are involved with direct patient care as part of an interprofessional team. Their primary role is to use medications to prevent and treat cardiovascular disease, while minimizing and managing any side effects of therapy. They are not limited by where they can work, as cardiology pharmacists are in high demand in settings such as ICUs, CCUs, emergency rooms, outpatient clinics, etc.

Infectious disease pharmacy specialists are also involved in direct patient care. However, their role is to individualize antimicrobial therapy by optimizing PK/PD principles, minimizing side effects, and adequately monitoring therapy. They are essential in the efficient treatment of infections and minimizing inpatient stay which ultimately benefit both the healthcare system and the patient. On a larger scale, infectious disease pharmacists are also pivotal members in the fight against antimicrobial resistance thus protecting public health. For more information about each of these specialties, as it is released, visit http://www.bpsweb.org/.

In addition to these two new and upcoming certifications, in October of 2016, the Commission for Certification in Geriatric Pharmacy (CCGP) announced that the Certified Geriatric Pharmacist (CGP) credential would move under the BPS and become the Board Certified Geriatric Pharmacist (BCGP) credential. CCGP was an organization that offered a board certification in geriatric pharmacy (separate from BPS certification). These pharmacists recognize that older patients have multiple disease states and require multiple medications, and these pharmacists are qualified to manage such patients. The transition will occur over the course of 2017. Four exam dates will be available for the CGP exam throughout 2017 and it is expected that the BPS will start administering the examination twice yearly during normal BPS testing windows. More information about the transition of this credential can be found at: http://www.bpsweb.org/bps-specialties/geriatric-pharmacy/

All existing board-certified specialties require graduation from an ACPE accredited school of pharmacy and an active license to practice pharmacy. They all require a passing score on their respective specialty certification examinations with recertification every 7 years. A comprehensive list of all existing Board Certifications is listed below;

Ambulatory Care Pharmacy (BCACP): These pharmacists who are accountable for addressing medication needs, developing sustainable relationships with patients and who practice in the context of family and community. These pharmacists have the knowledge and experience to care for patients who may have concurrent illnesses and take multiple medications. They are responsible for managing patients between provider visits and engage their patients in general health promotion and wellness. Requirements of practice include either 4 years of practice experience with at least 50% of time spent in ambulatory care services, completion of a PGY1 residency* plus one additional year of practice with at least 50% of time spent in ambulatory care services or completion of a PGY2 specialty residency* in ambulatory care services.

66% of “ambulatory care services” are defined as pharmacotherapy, collaboration and patient advocacy. The remainder includes use of evidence-based medicine, knowledge of practice models and population and public health

Critical Care Pharmacy (BCCCP): These pharmacists work with an interprofessional healthcare team to ensure safe and effective use of medications in critically ill patients. These pharmacists have the ability to quickly review, analyze multifaceted clinical and

technological information to make reasoned decisions for highly dynamic patients whose pharmacokinetic and pharmacodynamics parameters differ substantially from those who are not critically ill. Requirements of practice include either 4 years of practice experience with at least 50% of time spent in critical care pharmacy activities, completion of a PGY1 residency* plus two additional years of practice with at least 50% of time spent in critical care pharmacy activities, or completion of a PGY2 specialty residency* in critical care pharmacy.

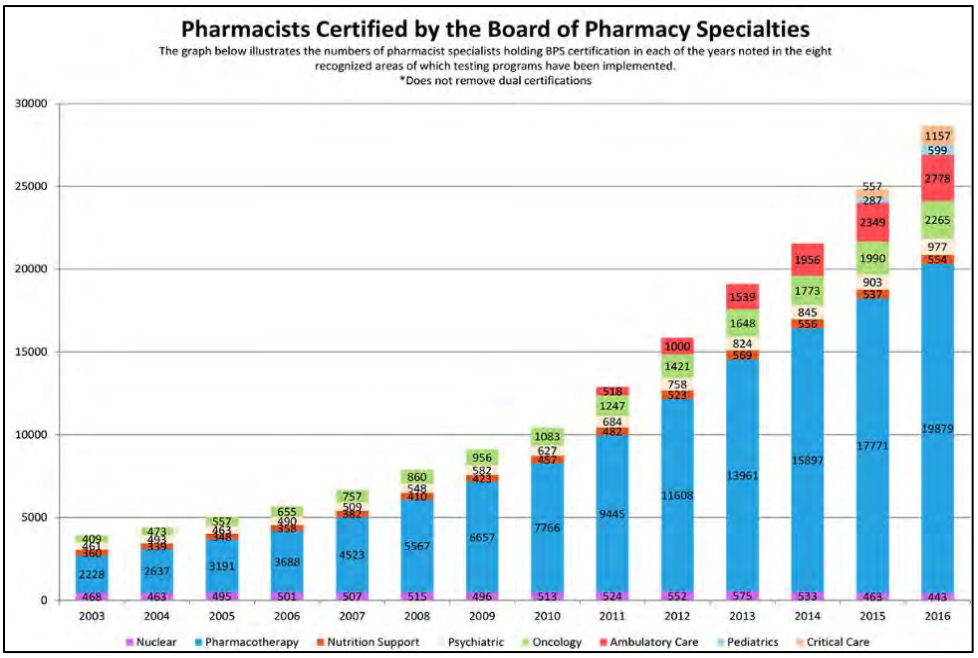
66% of "critical care pharmacy services" are defined as clinical skills and therapeutic management. The remainder includes practice administration and information management and education.

Nuclear Pharmacy (BCNP): These pharmacists seek to improve and promote public health through the safe and effective use of radioactive drugs for diagnosis and therapy. They are specialist in the procurement, compounding, quality control testing, dispensing, distributing and monitoring or radiopharmaceuticals. They also play a major role in minimizing error and patient exposure to radiation. Practice requirements include 4,000 hours of training/experience in nuclear pharmacy practice. These hours can be achieved in an academic setting (up to 2,000 hours) or in training or clinical practice (up to 4,000 hours). Academic hours include undergraduate or post-graduate courses in nuclear pharmacy, or obtaining a MS or PhD degree (2,000 hours awarded). Training/practice experience can be obtained from a residency in nuclear pharmacy (up to 2,000 hours), an internship in a licensed nuclear pharmacy.

Nutrition Support Pharmacy (BCNSP): These pharmacists address the care of patients who require specialized nutritional support, including parenteral and enteral nutrition, and promote the maintenance/restoration of optimal nutrition through design and modification of individualized treatment plans. They should be able to provide direct patient care including assessment, dosing, and monitoring nutritional support in both the acute care setting and in transition to a facility/home. Requirements of practice include either 3 years of practice experience with at least 50% of the time spent in nutrition support or completion of a PGY2 specialty residency* in nutrition support pharmacy.

63% of "nutrition support" are defined as clinical practice (assessment, design, implementation and monitoring) and the remainder includes other information pertaining to practice such as practice management, policy and protocol management, etc.

Oncology Pharmacy (BCOP): These pharmacists are required to find, provide and use evidence based medication therapy management as well as direct patient care for individuals with cancer. This includes treatment assessment and monitoring for potential adverse events and drug interactions. These pharmacists should be able to recommend, design, implement, monitor and modify pharmacotherapeutic plans and recognize and respond to adverse physical and emotional issues that may arise during treatment. Requirements of practice include either 4 years of practice experience with at least 50% of time spent in oncology pharmacy activities, completion of a PGY1 residency* plus 2 years of practice where at least 50% of time was spent in oncology pharmacy activities, or completion of a PGY2 specialty residency* in oncology.




79% of "oncology pharmacy activities are defined as patient management, therapeutics, or research/education. The remainder includes practice management and public health knowledge.

Pediatric Pharmacy (BCPPS): These pharmacists are responsible for the safe and effective use of medication for children of all ages (from neonates to adolescents). This includes direct patients care for children, which are often provided through interprofessional healthcare teams, as well as advocacy and education for children and their families. Due to the sparse data about drug use in pediatrics, BCPPS pharmacists should understand the differences in PKPD parameters in pediatrics and extrapolate what we know about medications, to this population. They are an integral part in advocating for and educating children and their

families about medications. Requirements of practice include either 4 years of practice experience with at least 50% of time spent in pediatric pharmacy activities, completion of a PGY1 residency* plus 2 additional years of practice with at least 50% of time spent in pediatric pharmacy activities, or completion of a PGY2 specialty residency* in pediatric pharmacy.

52% of "pediatric pharmacy activities are defined as patient management, and 20% are practice management. The remainder include information management, public health, and patient advocacy.

Pharmacotherapy Specialist (BCPS): These pharmacists ensure the safe, appropriate, and economical use of medications as part of interprofessional treatment teams. They have advanced knowledge and expertise in the optimization of medication use, improving patient outcomes, and they serve as an evidence based source for therapeutic information and recommendations. They should also be well versed in making suggestions about diet and lifestyle changes to help patients better manage their health. Requirements of practice include either 3 years of practice experience with at least 50% of time spent in pharmacotherapy activities or completion of a PGY1 residency*

55% of "pharmacotherapy activities" are defined as patient-specific pharmacotherapy and 25% as drug information and evidence based medicine. The remaining 20% includes standards of practice and population based pharmacotherapy.

Psychiatric Pharmacy (BCCP): These pharmacists address the pharmaceutical care of patients with psychiatric-related illnesses and disorders. They have critical knowledge and experience to optimize drug treatment and patients care and are able to monitor a patient's response and recognize drug-induced problems. Most importantly BCCP pharmacists are able to design, implement, monitor, and modify treatment plans for individuals. Requirements of practice include either 4 years of practice experience with at least 50% of time spent in psychiatric pharmacy or completion of a PGY2 specialty residency* in psychiatric pharmacy.

Each year, more and more pharmacists are becoming board certified by BPS (see figure 1). This may be due to the increase in the number of residency programs and therefore pharmacist who are qualified and prepared for the examination. Regardless, the exponential increase in board certified pharmacists is quite exciting and promising, especially in a pivotal time in healthcare. BPS certification can help pharmacists to continue to develop their role in the healthcare profession.

* denotes ASHP accredited or new programs who are granted Candidate Status

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**A special thanks to:**
UB School of Pharmacy and Pharmaceutical Sciences – Student ACCP Chapter E-Board
Calvin Meaney, PharmD, editor
Kathleen Tornatore, PharmD, FAST, FCCP, clinical spotlight
Rachel Meyer and Anna Morien PharmD Candidates, UBSPPS Class of 2018, layout, design and graphics