



The Lobbyist

Volume 4 Issue 3

Fall 2016

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An independent chapter of the American College of Clinical Pharmacy, the DC-CCP is dedicated to improvements in pharmacotherapy practice, education, and research in the District of Columbia, Maryland, and the Commonwealth of Virginia.

President's Letter

Dear Colleagues,

I hope you are all starting to enjoy this festive season with sweet treats and the warm company of your family and friends.

DC-CCP is excited to have hosted its first continuing education program at Notre Dame of Maryland University School of Pharmacy this past October. During this event, we were able to cover relevant pharmacy practice and management topics on cardiology, oncology, medical marijuana, and health policy. We were very fortunate to have leading clinical pharmacists in our region speak and share their experiences in their respective settings with practitioners and students in attendance in-person and online through our webinar. In addition, we kicked off our DC-CCP Mentorship Program, which enables current students to connect to their 'best match' clinical pharmacist mentor, in order for them to gain valuable career guidance and professional networking experience.

Moving forward, we anticipate another successful continuing education program this spring with more content that is important to your practice and we plan on creating a forum where both practitioners and students are able to share/collaborate on clinical research ideas and achievements.

As we wrap up this year, I would also like to thank you for your continued support to our organization and hope that you would do the same in the years to come with the several avenues that we strive to promote clinical pharmacy.

From our DC-CCP family to yours, Happy Holidays!

*Best Regards,
P. Tim Rocafort, PharmD, BCACP
President, DC-CCP*

New Drug Update: Sacubitril/valsartan

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Sacubitril/valsartan (Entresto®), is an angiotensin receptor-neprilysin inhibitor (ARNI) approved in 2015 for use in place of an ACEi or ARB to reduce the risk of cardiovascular death and hospitalization in patients with NYHA Class II-IV heart failure and reduced ejection fraction.¹ The first in its class, sacubitril/valsartan functions dual-mechanistically to counteract the neurohormonal activation that contributes to vasoconstriction, sodium retention, and vascular remodeling in cardiovascular disease. In addition to the RAAS-inhibitory effects of valsartan, sacubitril augments endogenous vasoactive peptide activity by preventing the breakdown of natriuretic peptides, bradykinin, and adrenomedullin by the endopeptidase neprilysin.

This novel combination was approved under the FDA's priority review program, based upon the results of the Prospective Comparison of ARNI with ACE-I to Determine Impact on Global Mortality and Morbidity in Heart Failure (PARADIGM-HF) trial. PARADIGM-HF included over 8000 adults with HFrEF randomized 1:1 to double-blinded treatment with sacubitril/valsartan or enalapril. A median follow-up of 27 months demonstrated that sacubitril/valsartan conferred a 20% reduced composite risk of death from cardiovascular causes or first hospitalization due to heart failure.² Sacubitril/valsartan significantly decreased patient-reported symptoms and physical limitations associated with heart failure, and trended toward a reduced all-cause mortality. There was significantly more symptomatic hypotension in the sacubitril/valsartan group (14%) versus enalapril group (9.2%), however, patients receiving sacubitril/valsartan experienced fewer clinically-important serum creatinine or potassium elevations.² The incidence of angioedema was not significantly different between groups.

The advantage of sacubitril/valsartan over enalapril in reducing risk of cardiovascular death and hospitalization was consistent regardless of hypertension diagnosis, atrial fibrillation, age, prior hospitalization due to heart failure, or prior treatment with an aldosterone antagonist. Notably, patients without prior use of an ACEi failed to demonstrate a favorable response to sacubitril/valsartan compared to enalapril in the composite endpoint or death from cardiovascular causes.² Minority populations including Black, Asian, and Native American did not show a significant preference in composite outcome or death from cardiovascular causes. Furthermore, patients with lower overall BNP demonstrated a more significantly favorable response to treatment with sacubitril/valsartan than patients with a more elevated BNP.

While trial results indicate a promising role of this dual-mechanistic therapy in heart failure, it is key to remember that the landmark study was funded by Novartis, the manufacturer of Entresto®, who also collected and analyzed all trial data. Sacubitril/valsartan is available in three dosage combinations, with preferred initial dose determined by current ACEi/ARB treatment. An interactive dosing algorithm is available at www.entrestohcp.com. A 36-hour wash out period is necessary when switching from ACEi therapy.³

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Use of ivabradine in reducing heart failure hospitalization

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In May 2016, the American College of Cardiology, American Heart Association, and the Heart Failure Society of America released a focused update to the 2013 Guideline for the Management of Heart Failure. Two new medications, Entresto® and Corlanor®, were added to treat patients with chronic, symptomatic heart failure.¹

Corlanor® (ivabradine) was approved in 2015 for use in stable symptomatic heart failure patients (NYHA Class II-III). It acts by selectively inhibiting the I_f current at the cardiac sinus node, thereby reducing heart rate. In the landmark SHIFT trial, researchers studied the efficacy of ivabradine against placebo for reduction of the composite endpoint of cardiovascular death and heart failure hospitalization. Patients included in the study had symptomatic heart failure with an ejection fraction ≤ 35%, normal sinus rhythm with a heart rate of at least 70 beats per minute, were hospitalized for heart failure within the previous year, and were receiving stable guideline based treatment (including a beta blocker) for 4 weeks.² Patients were randomized to receive ivabradine titrated to 7.5 mg twice daily versus placebo in addition to existing treatment. The

primary endpoint of the study was the composite of cardiovascular death or hospital admission for worsening heart failure.

Cardiovascular death or hospitalization for worsening heart failure occurred in 29% of the patients who received placebo versus 24% of patients receiving ivabradine (p<0.0001).² The reduction in the primary outcome was driven by a reduction in hospital admissions, which occurred in 16% of those patients receiving ivabradine and 21% of patients on placebo (p<0.0001). Cardiovascular death was not significantly reduced; however, there were significantly fewer deaths due to heart failure in the ivabradine group.²

One notable issue when considering the impact of the SHIFT trial is the initiation and titration of ivabradine without reaching target doses of beta blockers; only 25% of patients studied were on maximally-dosed beta blocker therapy.² It is important to attempt to titrate beta blockers to target doses first given the proven mortality benefit of higher doses before initiating ivabradine [Table 1].² *Continued on page 4*

Table 1. Dosing of ivabradine^{2,3}

Initial Dose	After 2 weeks, if heart rate is > 60 bpm	After 2 weeks, if heart rate is 50-60 bpm	After 2 weeks, if heart rate is < 50 bpm or signs and symptoms of bradycardia	Monitoring
5 mg twice daily*	Increase dose by 2.5 mg twice daily to maximum of 7.5 mg twice daily	Maintain dose at 5 mg twice daily	Decrease dose by 2.5 mg twice daily Discontinue if current dose is 2.5 mg twice daily	Symptomatic bradycardia, atrial fibrillation, luminous phenomena (phosphenes)

*For patients in whom bradycardia could result in significant hemodynamic compromise, recommended initial dose is 2.5 mg twice daily

continued from page 3

With the approval of these newer agents, treatment options for chronic heart failure will continue to advance and expand, giving patients the opportunity to have an improved quality of life.

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Food and Drug Administration's New Cautionary Language for Fluoroquinolone Toxicity

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In July 2016, the FDA issued their latest revisions to the safety warnings and recommendations on the use of oral and intravenous fluoroquinolones. Previous FDA fluoroquinolone warning labels cautioned of the potential adverse events involving muscles, tendons, cardiovascular, and peripheral/central nervous system.

This recent update of the fluoroquinolone class's *Boxed Warnings* integrates findings on the risk of developing multiple disabling and permanent side effects. To reflect the safety findings, the FDA issued a notice of approved label changes in the treatment of acute bacterial exacerbation

of chronic bronchitis in patients with chronic obstructive pulmonary diseases, uncomplicated urinary tract infections (uUTI) and sinusitis to use non-quinolone antibacterial options as first line.¹

The FDA outlines the evidence to their recommendations by assessing placebo controlled studies to evaluate efficacy of antibacterial therapy in the conditions mentioned above. Through Cochrane reviews and assessment of current treatment guidelines for chronic bronchitis and sinusitis, there is minimal support for recommending antibacterial therapy in individuals presenting with mild signs and symptoms.² *Continued on page 5*

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In contrast, uUTI shows benefit with the use of antibiotics but fluoroquinolones should be reserved as a secondary option due to risk for antimicrobial resistance. Alternative options for uUTI include a 5-day course of nitrofurantoin, 3-day course of sulfamethoxazole/trimethoprim DS, or 1-day course of fosfomycin.³ In terms of safety findings, FDA Adverse Event Reporting System (FAERS) identified 178 fluoroquinolone-related cases from November 1997- May 2015 in previously healthy individuals (commonly females and all individuals aged 30-49 years old) who developed severe adverse events in two or more organ systems. Onset of side effects can occur within hours to months after treatment initiation. Table 1 summarizes the organ systems adversely affected by each fluoroquinolone while Table 2 illustrates the number of cases and overlap between the top three reported body systems.

For primary care clinicians, the relevance of the FDA’s recommendations are significant since the fields of family practice and internal medicine prescribed 19% and 20%, respectively, of the 33 million fluoroquinolone prescriptions dispensed in 2014.² Cautious use of the quinolone agents can help minimize the prevalence of these potentially disabling adverse events.

Table 1: Percentages of Adverse Events for Each Fluoroquinolone by Organ System²

	Musculoskeletal	Neuropsychiatric	Peripheral Nervous System	Sense (Vision, Hearing)	Cardiovascular	Skin
Total Cases involved (n=178)	97%	68%	63%	32%	15%	12%
Levofloxacin (n=91)	98%	74%	52%	30%	10%	10%
Ciprofloxacin (n=65)	94%	66%	78%	31%	12%	15%
Moxifloxacin (n=19)	95%	65%	79%	30%	10%	15%
Ofloxacin (n=2)*	--	--	--	--	--	--
Gemifloxacin (n=1)*	--	--	--	--	--	--

Note: *Percentages not reported due to limited amount of cases
 Range of onset : 1 hour to 3 months
 Onset after starting fluoroquinolone: 1-2 days – n=49 (48%); 3-4 days – n=20 (20%); 5-10 days – n=21 (20%); >10 days – n=12 (12%)

Table 2: Overlap of Fluoroquinolone Adverse Events amongst Top Three Organ Systems²

Organ Systems (n=178)	Cases reported an Adverse Event
Musculoskeletal & Neuropsychiatric	67% (n=120)
Musculoskeletal & Peripheral Nervous System	60% (n=107)
Peripheral Nervous System & Neuropsychiatric	41% (n=73)
Musculoskeletal, Peripheral Nervous System, & Neuropsychiatric	38% (n=67)

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Andexanet Alfa: An Emerging Antidote for Factor Xa Inhibitors

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With the emergence of new classes of anti-coagulants to compete with warfarin, new concerns begin to arise as well. Unlike warfarin, novel oral anticoagulants (NOACs), until recently, lacked lab markers for monitoring as well as an effective reversal agent that would quickly reverse drug-induced bleeds. While idarucizumab (Praxbind®) has recently been approved as a reversal agent for dabigatran, the Factor Xa inhibitors still lack one. That is, until the emergence of AndexXa.

While not yet FDA approved AndexXa (generic name andexanet alfa), manufactured by Portola Pharmaceuticals, is an investigational drug designed to reverse anti-coagulation induced bleeding caused by Factor Xa inhibitors. As of August 2016, andexanet alfa is currently being denied approval as the FDA requests for additional information, primarily concerning the manufacturing of the drug as well as additional data to support inclusion of edoxaban and enoxaparin on the drug's label.¹

Andexanet alfa is a recombinant modified human factor Xa decoy protein that works by binding the Factor Xa inhibitor with high affinity preventing it from working at the active site. In the ANNEXA-A and ANNEXA-R trials that are discussed below, andexanet alfa was given as a 400 mg or 800 mg intravenous bolus to reverse the anticoagulant effect of apixaban or rivaroxaban respectively, followed by a two hour infusion².

In a phase III randomized, double-blind, placebo-controlled study the efficacy and safety of andexanet alfa in reversing the effects of apixaban and rivaroxaban was tested in healthy older adults (50-75 years of age).² The study looked at two trials: ANNEXA-A and ANNEXA-R. ANNEXA-A measured the efficacy and safety of andexanet alfa in reversing apixaban's anti-coagulation effects while ANNEXA-R measured the efficacy and

safety of andexanet alfa in reversing rivaroxaban's anti-coagulation effects. Both trials measured efficacy with standardized anti-coagulant biomarkers such as thrombin generation time and percent change in anti-Factor Xa activity. Safety was measured by monitoring for development of antibodies against andexanet alfa as well as side effects patients experienced after taking the drug, including thrombotic events.

The study showed that andexanet alfa reduced anti-factor Xa activity by 94% in the apixaban study compared to a 21% reduction with placebo and by 92% in the rivaroxaban study compared to an 18% reduction with placebo ($p < 0.001$ for both studies) within 2-5 minutes after a bolus administration. Similar results were observed when andexanet alfa was administered as a bolus plus a two hour infusion: anti-factor Xa activity was reduced by 92% vs. 33% with placebo in the apixaban study and by 97% vs. 45% with placebo in the rivaroxaban study ($p < 0.001$ for both studies).² Andexanet alfa's effects remained as it was continuously infused over 120 minutes however, once the infusion stopped, Factor Xa inhibitor activity returned to normal levels after 1-3 hours.² The side effects experienced by patients were minor and included flushing and constipation with no reports of thrombotic events occurring. No neutralizing antibodies developed after administration either.

In conclusion, andexanet alfa works as an effective and rapid Factor Xa inhibitor reversal agent in healthy older adults; it works almost immediately after administration and quickly clears the body (in 2-3 hours) after the infusion ends. A phase III trial, known as ANNEXA-4 is currently in progress to determine the efficacy and safety of andexanet alfa in active bleeding induced by Factor Xa inhibitors.

A recently published article in the New England Journal of Medicine about ANNEXA-4 shows how andexanet alfa is faring in this population. After bolus administration of andexanet alfa, anti-factor Xa activity decreased by 89% (95% CI, 58-94) in patients receiving rivaroxaban and by 93% in patients receiving apixaban (95% CI, 87 to 94) but it takes twelve hours for patients to achieve an “excellent” or “good” level of clinical hemostasis.³ Additionally 18% of patients experienced a thrombotic event in the 30-days after andexanet alfa administration.³ More information about the trial can be found on ClinicalTrials.gov, under trial NCT02329327.

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Zecuity® (sumatriptan iontophoretic transdermal system): How Premature Drug Approval Can Leave You Burned

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When Teva Pharmaceuticals released a newly approved product for treatment of acute migraines in September of 2015, they believed they were launching a product that showed innovation and a new solution in pharmacy drug delivery. Their new product, Zecuity®, combined sumatriptan, a commonly used medication indicated for acute migraines, with iontophoretic technology in a patch that was to be administered transdermally with the use of an ion-based current.¹ When administered, the patch delivered sumatriptan 6.5 mg transdermally over 4 hours.² The product's patch delivery system comprised of the patch itself, a microprocessor that runs on two lithium batteries, and two electrode pads (one of which was saturated in sumatriptan). To date, this technology has only been used with one other drug product, fentanyl (Ionsys®).¹

In June of 2016, reports of serious adverse events led Teva Pharmaceuticals to release an open letter calling for the suspension of sales, marketing and distribution of Zecuity®.²⁻³ The product was removed from the market after FDA surveillance reports indicated high incidence of severe adverse events including skin damage and burning. Reports collected from the Fair Adverse Event Reporting System (FAERS) revealed 117 reports of burns at the application site, 125 reports of severe pain, 63 reports of battery issues, and 59 reports of device leakage.¹

The key demand behind bringing Zecuity® to the market remains somewhat unclear. Although sumatriptan was already available in the market as an oral tablet, subcutaneous injection and intranasal spray, there was some consideration behind reaching faster systemic absorption of the medication.

The product initially appeared as a new drug application (NDA) in 2010 from a small former biotech startup known as NuPathe. When NuPathe submitted the NDA for market approval, it was rejected following a 10-month investigation that revealed several problems with the product, which included over 70 deficiencies in its chemistry and manufacturing.¹ Even at that time, investigators revealed the product exhibited potential in causing severe burns and skin lesions.¹

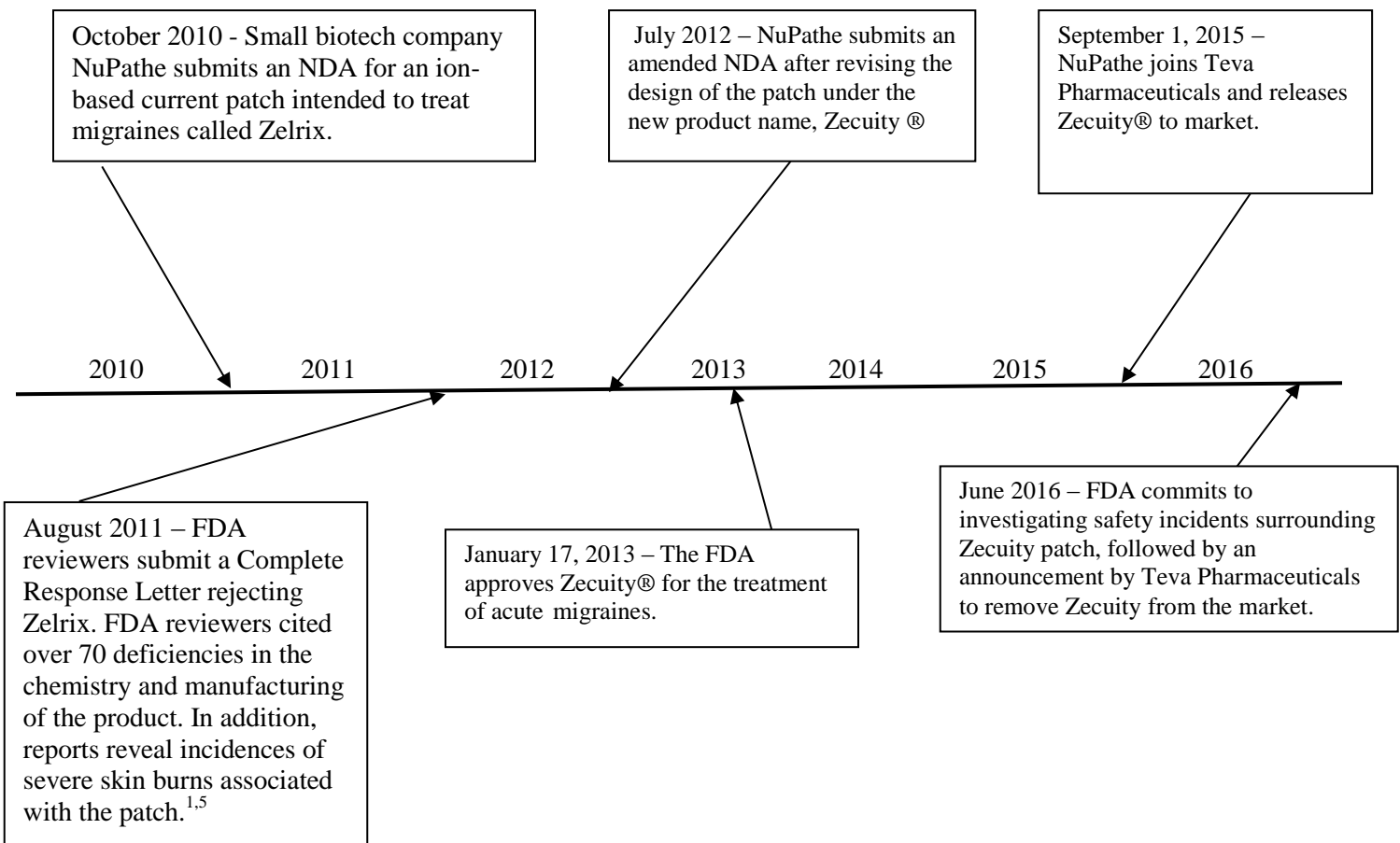
Along with safety problems, Zecuity® failed to demonstrate a real clinical benefit over existing agents on the market. Phase III trials showed that Zecuity® exhibited pain relief at 2 hours after administration in only an additional 8.5 percent of patients compared to placebo – a stark contrast compared to pain relief from the subcutaneous injection (50 percent compared to placebo) and the sumatriptan nasal spray (13-33 percent compared to placebo).^{1,4} The company underwent a redesign of the patch and resubmitted it one year later, claiming the safety issues were resolved and likely associated with improper administration of the patch.¹ The FDA accepted two usability trials that showed no evidence of burns; however, the two trials also involved relatively small sample sizes (26 subjects and 32 subjects, respectively). The drug product was approved in January 2013, but not released until September 2015 after NuPathe merged with Teva to raise the required venture capital to launch Zecuity® to the market. See Figure 1 for a guide through Zecuity's ® approval process and subsequent withdrawal.

What was the loop hole? FDA’s standard for drug approval only requires the drug show efficacy *compared to placebos*; it is not required to prove superiority or non-inferiority in head-to-head trials with comparable products. Furthermore, investigators opting for approval felt they could mitigate any safety issues through post-marketing surveillance rather than having to implement further studies.¹

Zecuity® is one example of a drug product that slipped through market approval with pre-existing issues. While the FDA does have clear established standards in place to evaluate drugs

eligible for the market, it is still possible for drugs to inappropriately pass through that may have been prematurely approved. This prompts pharmacists to take two lessons to heart: first, always do independent research of any drug newly approved to the market, especially when offering a recommendation to patients. Second, we should encourage pharmacists to both monitor and submit safety information to FDA surveillance programs. The often underestimated element of the drug approval process is post-market surveillance, which can clearly make all the difference in what products should be allowed for the public to use.

Figure 1. A Guide through the History of the Zecuity ® Patch^{1-2,5}



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DC-CCP Mentorship Program

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The DC-CCP Mentorship Program was started to foster collaboration between students and licensed pharmacists to prepare student pharmacists for future careers in clinical pharmacy. To achieve this goal, we reached out to clinical faculty members and preceptors in our community for their assistance in serving as mentors for student pharmacists in the DC-Maryland-Virginia region. This fall, we successfully matched 24 pharmacist mentors with 24 student mentees. A meet-and-greet was arranged during the Fall CE Forum so that pairs could be introduced.

We are excited about the potential benefits of DC-CCP's Mentorship Program. Student mentees can receive direct feedback and expertise on becoming an ideal residency candidate, while fostering relationships with mentors. Additionally, students can learn about the numerous job opportunities within clinical pharmacy. Mentors will have the opportunity to collaborate with colleagues and give back to the pharmacy profession. Both mentors and mentees will benefit from networking opportunities.

We encourage all members of DC-CCP to consider joining our Mentorship Program. The mentoring relationship may be as formal or informal as you like. The frequency and location of meetings can be determined after discussion between the mentor and mentee; we recommend a minimum of one in-person meeting per year. Communicating over the telephone or using technology (e.g. email, Skype) is also encouraged. This program requires commitment from both the mentor and mentee. It is expected that both parties will contribute to a plan that is mutually beneficial.

If you are interested in participating in DC-CCP's Mentorship Program, please contact Abidemi Dada (adada1@live.ndm.edu) or Katelyn Smith Quartuccio (ksmith26@ndm.edu). We look forward to hearing from you!

Get Involved!

**Interested in a leadership position
with DC-CCP for 2017?**

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**Special thanks to Communications
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**Interested in contributing an article for
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Submit an Article



About DC-CCP

DC-CCP is a non-profit professional association and an independent chapter of the American College of Clinical Pharmacy dedicated to improvements in pharmacotherapy practice, education, and research in the Washington D.C. Capital Region, including the District of Columbia, State of Maryland, and Commonwealth of Virginia. Membership will be open to any licensed or registered health care professional or health care professional student in the Capital Region. Membership in the American College of Clinical Pharmacy is not required to become a member of our organization.

Purpose and Goals of DC-CCP

- A. To promote the rational use of drugs in society
- B. To advance the principles and practice of clinical pharmacy
- C. To promote the full-time, advanced practice of clinical pharmacy
- D. To provide an advanced level of continuing education programs in the area of clinical pharmacy and therapeutics
- E. To provide a forum for the expression of opinion on pharmacy practice, education, and research from the perspective of clinical pharmacists
- F. To support, promote, and advance the goals and objectives of ACCP as outlined in its constitution and bylaws
- G. To provide a local recruiting base for ACCP

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