



# NYS-ACCP INSIDER

St. John Fisher College

Wegmans School of Pharmacy

Special Points of Interest:

- Year in Review for WSoP
- NYS Annual Meeting
- Pharmacy Fundamentals
- Eteplirsen
- Member highlight



## WSoP-ACCP Student Chapter Summary

The Wegmans School of Pharmacy (WSoP) student chapter of ACCP (SCCP) aims to educate students about different fields of pharmacy not emphasized during didactic coursework, provide resources including portfolio development workshops and volunteer opportunities, and advocacy and leadership opportunities for students seeking post-graduate training or an independent research career. One such advocacy opportunity this fall semester was a veterans health fair, in affiliation with Canandaigua/Rochester Veterans Administration (VA). Where students were able to provide free healthcare to veterans from the surrounding counties of Upstate NY. The healthcare services offered at this event included blood pressure screenings, diabetic screenings, healthy lifestyle interventions, and VA benefits sign-ups for Upstate NY veterans. WSoP students worked alongside pharmacists and other healthcare professionals from organizations including the American Diabetes Association, Trillium Health, VA, and American Red Cross. This interprofessional collaboration allowed students an opportunity to practice counseling skills as well as how to work with other healthcare professionals.

Another opportunity presented to WSoP students is the University of Rochester Medical Center (URMC) mentorship program. Through this mentorship program, students are matched with a URMC pharmacist who practices within different specialties including emergency medicine, transplant, and oncology and spend time shadowing with the pharmacist to gain an understanding of their practice area. This allows students to develop a relationship with the pharmacist and allows for mentorship throughout their WSoP training.

WSOP's chapter of ACCP also offered various student learning opportunities including participation in ACCP's clinical research and pharmacy challenges. The local winners, Jonathan Redlinski, Emily Rosenberg, and Stacy Roche, of the Clinical Pharmacy challenge were entered into the national competition. Additionally, students had the opportunity to hear from various speakers, including Dr. Alex Delucenay from Rochester General Hospital, Dr. David Hutchinson and Dr. Lauren Gashlin from URMC on their pharmacy specialty.

Upcoming 2017 WSoP student chapter of ACCP activities include a three on three basketball and dodgeball tournament organization fundraisers and volunteering at Gilda's Club of Rochester and Harbor House.

- Bethany Lane, PharmD Candidate; WSOP Class of 2019, WSoP ACCP president elect

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## **2016 NYS ACCP Annual Fall Meeting**

The 2016 NYS ACCP annual meeting was held at St. John Fisher College in Rochester, NY on Friday, November 11, 2016. Over fifty pharmacists, pharmacy residents, and students from around NYS attended the meeting. This year's keynote speaker was Dr. Elizabeth Dodds-Ashley from Duke University Medical Center who presented on updates in antimicrobial stewardship. Other program topics included affective development of pharmacy students, naloxone's role in the NYS opioid epidemic, reversal agents for direct oral anticoagulants, resident hot topic clinical pearls, and medication adverse event prevention and reduction. This year's meeting featured an inaugural student research poster session. Additional student programming included lunchtime roundtable sessions on interviewing, CV preparation, post-graduate training opportunities, and board certification.

The New York State ACCP 2016 award recipients were also announced. Winners included Dr. Amanda Engle from Bassett Medical Center as clinical practitioner of the year and Dr. Jeanna Marraffa from SUNY Upstate Medical Center as educator of the year award.

Many thanks to Travis Dick and planning committee members Nicole Acquisto, Norberto Alberto, Jack Brown, Amber Crowley, Chris Evans, Jorie Frasiolas, Daryl Glick, Christine Groth, Curt Haas, Calvin Meaney, Natasha Shinkazh, and Allison Trawinski for all of their time and efforts organizing the meeting. Upcoming details regarding next year's meeting will be available via email and on the NYS ACCP website at <http://nys-accp.echapters.com> within the next few months.

- Katherine Juba, PharmD; outgoing NYS ACCP past-president

# The Clinical Controversy of Eteplirsen

A landmark decision was issued by the Food and Drug Administration (FDA) on September 19, 2016 when eteplirsen received accelerated approval. Marketed under the brand name Exondys 51™, eteplirsen is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients with a confirmed dystrophin gene mutation amenable to exon 51 skipping.<sup>1</sup>



DMD patients had no FDA approved treatment options prior to eteplirsen. It is an X-linked, progressive disease, characterized by loss of muscle function and dramatically reduced lifespans.<sup>2</sup> The mutation responsible for DMD lies within the dystrophin gene, which codes for an important structural protein found in muscles. Eteplirsen works by binding to exon 51 and preventing its incorporation into the mRNA for the dystrophin protein.<sup>1</sup> This results in a version of the dystrophin protein that has some functionality. For a group of patients and their families with no other options available, eteplirsen is a beacon of hope.

However, the problem is not necessarily eteplirsen, but the data backing it up. According to the FDA, approval under an accelerated approval pathway is warranted if a study shows a surrogate endpoint such as a lab value, physical sign or **image that the FDA considers “reasonably likely” to indicate clinical benefit.**<sup>3</sup> The FDA requested western blot analysis from bicep samples of thirteen patients enrolled in the ongoing PROMOTI trial.<sup>4</sup> The samples were collected for analysis after 48 weeks of treatment with 30mg/kg of eteplirsen. The results found a statistically significant increase in dystrophin expression from 0.22% to 0.32% of normal. The clinical significance of this finding is a subject of debate among chief FDA scientists.

The principal disagreement occurred between Dr. Ellis Unger, Director of the Office of Drug Evaluation, and Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER). Dr. Unger and the panel of FDA scientists reviewing the evidence voted 7-6 against accelerated approval for eteplirsen.<sup>5</sup> **Disagreeing with the panel’s judgment, Dr. Woodcock exercised her authority as director of CDER and overturned the panel’s decision. Dr. Unger continued the controversy by issuing an official appeal of Dr. Woodcock’s decision to grant accelerated approval to eteplirsen.**

The debate called to question whether the demonstrated increase in dystrophin levels truly satisfied the requirements for accelerated approval. Dr. Unger and the review team were not convinced that such a small increase in dystrophin production would result in meaningful clinical benefit. Dr. Unger argued that dystrophin levels must be within 10% of normal to serve as adequate evidence of clinical benefit.<sup>4</sup> Dr. Unger did not believe the trial demonstrated a correlation between increased dystrophin expression and improved function. Claims were also made that Dr. Woodcock allowed the pressures of lobbying patients to influence her decision.

Ultimately, the decision fell to Dr. Robert M. Califf, Commissioner of Food and Drugs for the FDA. After reviewing the **evidence, Dr. Califf chose to endorse Dr. Woodcock’s decision to rely upon “the greatest flexibility possible for [the] FDA”** for approval and cited no evidence that she had succumbed to external pressures.<sup>4</sup> Dr. Califf determined that dose increases would likely increase dystrophin expression further, acknowledged that a randomized trial is underway for other forms of DMD, and noted that this circumstance would not lower the bar for future accelerated approval pathways.<sup>4</sup>

The approval of eteplirsen did come with some caveats. The FDA specifically stated in its press release that clinical benefit has not been established.<sup>2</sup> Sarepta Therapeutics, the manufacturer of eteplirsen is obligated under the accelerated **approval provisions to conduct a confirmatory trial of the drug’s clinical benefit, with the potential to forfeit approval** depending on the results.

Unfortunately, approval is not where the controversy ends. Priced at \$300,000 per patient per year, some insurance companies have chosen not to cover the drug.<sup>6</sup> **Anthem denied coverage based on the uncertainty of eteplirsen's efficacy.** Both Aetna and Express Scripts will be holding a committee review before issuing a decision, where United Healthcare has chosen to cover the medication. It remains unclear if insurance companies will choose to cover eteplirsen outright, not at all, or with stipulation.

The approval of eteplirsen has been a saga characterized by controversy. While some rejoiced with hope and optimism at **the FDA's decision, some criticized it harshly, calling the approval of drugs on ambiguous evidence counterproductive and dangerous.** For better or worse, eteplirsen has hit the market. What happens next will define the drug approval process for years to come.

- Michelle Ubowski, PharmD candidate, WSoP class of 2019

## References:

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## 2017 NYS ACCP Election Results

Congratulations to Dr. William Eggleston from SUNY Upstate Medical Center on his recent election as NYS ACCP President Elect. He won in a close election to Dr. Amanda Engle from Bassett Medical Center. The officers would like to thank all members who voted and both candidates for their interest and enthusiasm in serving our organization.

- Katherine Juba, PharmD; outgoing NYS ACCP past-president



## Phundamentals: “Are You Okay, sir?”

Sitting on a bench outside the hospital campus where my wife works basking in the early evening sunshine of the final day of summer 2016 – a day spent doing things at the opposite end of the joy that I usually experience while providing direct care to patients – I was approached by a shuttle driver as she exited her vehicle. The young 20-something woman approached me with such a look of concern I had to turn around, thinking that she may have been speaking to someone behind me! Upon lifting my head from my hand she then explained herself further, “It looks like you have the weight of the world’s problems on your mind.” Being seriously befuddled I could only muster, “Oh no, I am fine. Thanks for asking though.” She smiled broadly and wished me a pleasant evening and returned to her rig.

This brief interaction prompted several thoughts:

- Just how bad did I look to warrant such concern – from a complete stranger? Yes, the day was difficult especially at the end when my homebound Centro bus driver drove right by me and my brief run to catch him failed as the next traffic light promptly turned green and I had to resort to backup plan #2 to get home, but no big deal, really – especially when you think of the difficulties that many of our patients face.
- Her concern – very genuine and deeply felt – really registered with me – my puzzlement turned into amazement and gratitude - and persisted into my morning thoughts during my daily pre-dawn walk. I realized how wonderful it made me feel – here is a complete stranger, someone that I have never met before, who reached out to me – simply by observing my posture – as I was not prone on the sidewalk, or bleeding, or moaning. Here simple four-word phrase accompanied by HER body language truly uplifted me. I cannot recall EVER being the recipient of such direct unexpected grace.
- Now extend that feeling to our encounters with patients who are truly hurting physically, mentally, spiritually, socially – how do WE greet them? Do we ask, “What can I do for you today?” Or if we see that they are hurting, do we take the time to ask “What is bothering you today?” Whether we can do anything at all for them, it can be simply the ASKING that can have meaning and value. We are the stranger and we even get PAID to do the asking! What a wonderful opportunity we have been given!
- No matter how intricately we design our positions, how complex our systems or how many initials follow our names, it seems that the simplest things can make the biggest impact and we would be wise to remember that.

- Gregory Szymaniak BSc, PharmD, BCACP

## **Interview with Allan Batalier, PharmD Candidate: Class of 2017 WSOP SCCP Outstanding Student Chapter Member**



### **What does this award mean to you?**

From an overarching perspective, the SCCP Outstanding Student Chapter Member award is an excellent opportunity for the national organization to recognize the efforts of students most involved in advancing the profession in accordance with ACCP's values and traditions. It is an outlet by which the organization can showcase the achievements of our student members, promote the notion that students can make a difference, and empower our pharmacists-in-training to coordinate amongst each other for the benefit of the community at-large.

From a personal perspective, this award is a humbling gesture, an honor that I feel does not belong to myself alone but to an overwhelming majority of our student membership. Without their continual support and inspiration, I could not have formulated, much less execute, as many initiatives as I had been able to. So I suppose this award is less a reflection of my own accomplishments and more of a testament to the spirit and character of my fellow students in modeling themselves as pillars within the community.

### **How do you feel you exemplify ACCP's core values of extending the frontiers of clinical pharmacy and promoting dedication to excellence in patient care, research, and education?**

This is a very tough question for me to answer. I admit that I have had the unusual fortune to practice in both an inpatient and ambulatory environment associated with an innovative, compassionate healthcare system. Accordingly, I've continually enjoyed seeing how my actions can make a positive impact in the lives of my patients and their families. This has motivated me to participate in several endeavors aimed at improving patient care, including taking part in medication use evaluations, assessments of patient outreach programs, and designing hospital-wide protocols.

Equally important to me, I recognize that one of the most crucial avenues to practice in accordance with ACCP's core values is to continually attempt to invest in our colleagues, particularly our pharmacists-in-training. By providing our fellow students unique opportunities to develop professionally and personally, we amplify the ability of these talented healthcare providers to positively impact patient care and to contribute more effectively to the growing pool of pharmacy knowledge at a level unachievable by any one individual alone.

### **What projects/proposals are you most proud of participating in as an ACCP member?**

Admittedly, this is a dangerous question. How much time do you have? What projects and proposals am I most proud of participating in? This will sound cliché, but all of them. In the interest of time, though, I suppose there are three I would like to highlight. Under Past President Maria Caraballo's exemplary leadership, I took great pleasure in collaborating with her and the rest of our executive board to develop a guest speaker series featuring insights into pharmacy practice. I also enjoyed working with our very own Dr.

DelMonte, Mentor Program Chair Chris Nyiri, and numerous generous pharmacist volunteers in the community to provide a structured platform for setting up shadowing opportunities. I was pleased to work closely with Past Volunteer Coordinator Seda Donmez and President-Elect Bethany Lane, along with several community partners, in launching our inaugural Veterans Health Fair. In each case, I was excited to work with passionate individuals, to partake in helping a glimpse of their inspiring visions become reality.

### **What made you interested in joining ACCP?**

In truth, it was a combination of factors, chief among them listening to Dr. Curt Haas, Director of Pharmacy at Strong Memorial Hospital, talk about the mission and vision associated with ACCP, as well as the numerous benefits and opportunities afforded to its members. As was clearly the case for several of my fellow students, I walked away with a renewed sense of accountability and responsibility. I enjoyed a renewed sense of what it meant to hold myself accountable to my own values and beliefs surrounding the role of the practicing pharmacist, that since I believe that the pharmacist should be an integral advocate for positive change in the community, I should strive to leverage the resources available to me to benefit my colleagues and my community. ACCP not only served as an avenue to do this, it also provided me with an insightful environment to explore the many ways I could give back to others.

### **What advice do you have for other members of ACCP who are looking to get more involved in this organization?**

As cliché as it sounds, get involved. Look for opportunities for improvement and act upon them. As vague and unhelpful as that sounds, it is the best way to use this organization as a vehicle for change, personal and professional development, and participate in meetings, especially the Annual Meeting. Regardless of where you stand in your career, no program or initiative that you will encounter, however new or well-established, is perfect. There is always room for improvement, particularly when you consider that the needs of the audience are always changing, as is the healthcare landscape in general. As students and individuals least exposed to the healthcare system, our perspectives of the dynamics involved are relatively unclouded, and so our insight often serves to identify areas of concern that may be readily overlooked by others. I encourage you to bring up these areas of concern. At worst, you will have sparked a discussion that helps you gain a better understanding of why things are how they are. At best, you will have served as the catalyst for positive change to the benefit of yourself, your colleagues, and your community. Just as important and irrespective of the outcome of your speaking up, you will have learned a little bit more about yourself - perhaps what motivates you, how you communicate with and are perceived by the people you collaborate with, or how well you persist in the face of stress and attrition. These insights into who you are will serve you well as opportunities to improve upon your strengths and smooth over your weaknesses.

### **How do you believe ACCP helps prepare students for a career in clinical pharmacy?**

ACCP is smaller than some other national pharmacy organizations with a more focal outlook towards addressing topics most relevant to clinical pharmacy. Benefits for student ACCP members include free access to 2 Practice and Research Networks (PRNs), free access to a CV review service, and discounted Annual Meeting registration. On a local level, I would say that the benefits for student members are virtually limitless, dependent upon the creativity and drive of the student to involve themselves in established programs and to initiate new programs themselves. In combination, the opportunities available through ACCP stimulate the intellectual curiosity and soft skills demanded of the typical clinical pharmacist.

- Interviewed by Frank Lattuca, PharmD Candidate: WSoP Class of 2018, WSoP ACCP Student Liaison

## **Transfers of Electronic Prescriptions; NYS Law Update**

Beginning in March of 2016, electronic prescribing became mandatory for New York state prescribers. Exemption from this initiative came only if “electronic prescribing is not available due to temporary technological or electronic failure; a waiver is granted by the New York State Commissioner of Health; the prescriber reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner; or the prescription will be dispensed at a pharmacy located outside of New York State.” (NYS Education Law Article 137, Pharmacy) With the transition to electronic prescribing came the question of how a patient may transfer a prescription to another pharmacy if the original receiver was unable to immediately fill it. With a handwritten prescription a patient may travel to multiple pharmacies if one is unable to fill the prescription in a timely manner. With electronic prescribing it is only able to be sent to one pharmacy, thus limiting the patient to that single pharmacy without having to go back to their provider’s office for a new prescription. This action may be harmful for those in immediate need of a medication. Recently, bill A10448 was presented to the NYS senate to combat this issue. Bill A10448 states:

“A pharmacy that receives an electronic prescription from the person issuing the prescription may, if the prescription has not been dispensed and at the request of the patient or a person authorized to make the request on behalf of the patient, immediately transfer or forward such prescription to an alternative pharmacy designated by the requesting party.” (Bill A10448, an act to amend the public health law and education law)

This bill was initially presented to the State Senate by assemblyman Michelle Schimel in June 2016 and approved by Governor Cuomo in November 2016. With this bill’s passage, pharmacies may now transfer an electronic prescription to a pharmacy of the patient’s choice as long as the prescription has not been previously filled. This bill’s approval highlights a major omission from New York State’s electronic prescribing system since there is no available software for pharmacies to communicate with one another. Pharmacies are forced to call and transfer a single refill, as was done prior to electronic prescribing. An alternative solution posed by the department of health is a cloud based storage system for prescribers to send an electronic prescription. This secure intermediate site would allow pharmacies to download or transfer prescriptions.

Until a system in which communication is possible between multiple pharmacies and a prescriber’s office is possible, the ability to transfer will not be accessible or utilized. Pharmacists will need to continue verbally transferring one refill at a time between pharmacies. Until an updated system is available across New York State, the ability of a patient to directly transfer a prescription to another pharmacy for immediate dispensing will continue to be a distant thought.

- Bethany Lane, PharmD candidate, WSoP class of 2019