

April 2013

# OSHP Newsletter

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## Letter from the President

**Ann Lloyd, Pharm.D., BCPS**

The Oklahoma Society of Health-System Pharmacists was officially granted full affiliation status after a vote by the American Society of Health-System Pharmacists Board of Directors. The re-affiliation would not have been successful without the support of the OSHP Board of Directors, committee chairs and members, and many others who offered their help in compiling all of the necessary documentation to support our petition for re-affiliation. This process allowed the OSHP Board to recognize our strengths and evaluate opportunities for future growth and development.

It has been a busy winter for OSHP. President-elect Miki Finnin attended the ASHP State Affiliate Presidential Officer Retreat in Dallas in November. She was able to network with leaders from across the country and brought back many new ideas for growing OSHP. I am looking forward to all that she will bring to the organization when she steps into the role of President next month.

At our February Board of Directors meeting, we voted to approve the updated guidelines and policies document that was drafted by the ad hoc committee under the direction of Susan Conway. I want to thank Susan and her committee for agreeing to work on revising this document that guides the day to day activities of the organization. Coupled with the bylaws update from last year, this group has provided countless volunteer hours to our organization and should be recognized for their contributions to the society.

Also in February, OSHP joined together with the Oklahoma Chapter of the American Society of Consultant Pharmacists (ASCP) to host the Oklahoma Pharmacy Alliance meeting at the Jim Thorpe Center in Oklahoma City. The purpose of this meeting, held multiple times during the year, is to discuss issues affecting the profession and network with other pharmacy organizations and groups in the state of Oklahoma. I would like to thank President-elect Finnin for her leadership in working together with the Oklahoma Chapter of ASCP to organize this event.

## President's Letter, continued

Please make plans to attend the Annual Meeting scheduled for Friday, April 12, 2013, at St. John Medical Center in Tulsa. By this time, all members should have received both an email and mailed version of the brochure for the upcoming meeting. Please take the time to register for the meeting either via mail or at our website. I would like to thank the Programming Committee under the leadership of Jennifer Wakefield for organizing what looks like another outstanding day of continuing education and networking opportunities. Please reach out to your colleagues and invite them to attend along with you.

In closing, I would like to make you aware again of an opportunity to become more involved with our organization. In keeping with our goal of recruiting and retaining new members to OSHP, I would like to call for participation in the OSHP mentorship program. The program, which began last year, provides an opportunity for OSHP members to be connected to a mentor they can reach out to for career advice, networking, and many other issues. If you are interested in participating in this program as either a mentee or mentor, please contact me.

I hope that you enjoy this edition of the newsletter, and thank you again for your support of this organization. I am proud of everything that we have accomplished this year, and I am very thankful to all who have volunteered their time to support our society. I am especially thankful for the Board of Directors, committee chairs and members, and our staff secretary, Lisa Slaton. Working with these individuals has made my job as President easy. I have enjoyed serving you as President over the past year, and I look forward to stepping into my new role as Past-president at the Annual Meeting in April. Until that time, please feel free to contact me with any ideas or suggestions for OSHP ([ann-lloyd@ouhsc.edu](mailto:ann-lloyd@ouhsc.edu)).

## 2013 OSHP Annual Meeting

The stage is set for the 2013 OSHP Annual Meeting scheduled for Friday, April 12, 2013 at St. John Medical Center in Tulsa. The agenda includes six hours of continuing education, the ever-popular awards ceremony and officer installation and a fantastic opportunity to network with colleagues from around the state. The deadline for early registration is Friday, March 29, 2013 via [www.oshp.net](http://www.oshp.net). Don't miss it!!

## 2013 Oklahoma Legislative Day

This year, the OSHP Legislative Committee is continuing progress on the overall goal of improving advocacy effectiveness. Members worked with the Oklahoma Pharmacists Association in planning and producing the 2013 Oklahoma Pharmacy Legislative Day, which was held on February 12, 2013 at the State Capitol in Oklahoma City.

This year, there are two legislators who are pharmacists: Representative David Derby (District 74 – Rogers and Tulsa counties, Owasso), and Senator Rob Standridge (District 15 – Cleveland and Oklahoma counties). Both were featured speakers during the Legislative Day debriefing. Bills of importance this year include HB 2100 – to require that pharmacy benefit managers (PBMs) doing business in Oklahoma be licensed and regulated by the Oklahoma State Board of Pharmacy. Currently, PBMs are not regulated by either state or federal statutes or regulations, yet PBMs are directly involved in providing health care services to Oklahoma consumers (as defined by the Practice of Pharmacy, Oklahoma statute). Additionally, Senator Standridge is going to introduce a similar bill in the Senate, as well as SB 522 (Compounding) and SB 1056 (Professional Services Acquisition Act). For more information on these bills, please visit the Oklahoma Legislative Web page: <http://www.oklegislature.gov/index.aspx>. You can track bills, locate and contact your legislators, and easily keep up with current measures.

The 3<sup>rd</sup> Annual Health Fair for legislators and their staff was held on the afternoon of Oklahoma Legislative Day and was well attended. Members from all Oklahoma Pharmacy stakeholders (OSHP, OPhA, both OU and SWOSU Colleges of Pharmacy, consultant pharmacists) were in attendance to perform cholesterol checks, blood pressure and blood glucose screenings, measure body fat, and provide information about advanced pharmacy practice in Oklahoma.

Please be aware that there is an Oklahoma Pharmacy Political Action Committee (PAC). While it operates within OPhA – it is crucial that ALL Oklahoma pharmacists participate. Legislative success today involves more than just knowing your legislators at the grassroots level. The reality is that legislative efforts require significant money, and the facts are basic, PAC donations get your legislator's attention. The stark reality is that politicians will listen to those who bring the most to the table. If our profession is to control its own destiny in a political society such as ours, we must support the political candidates who support us, regardless of party affiliation. If every pharmacist and pharmacy student in the state contributed a minimum of \$10, it could have a huge impact.

Please see this link for more information

<http://www.opha.com/GovernmentAffairs/PACDonationForm.aspx>

– or you can contact me with questions (t.hagemann@cox.net).

I recently spoke to the sOSHP chapter at the OU College of Pharmacy on the importance of grassroots advocacy for our profession and will be speaking to the sOSHP chapter at the SWOSU College of Pharmacy in April on the same topic. The Legislative Committee hopes to create a toolkit for all OSHP members to guide grassroots advocacy in the state. The goal is to have this available on the OSHP website by this year's Annual Meeting in April.

We look forward to continuing our progress toward reaching our broad goal for the committee. If you have comments or questions for the committee, please contact me.

**Tracy Hagemann, Pharm.D., FCCP, FPPAG**  
**OSHP Legislative Chair**

## **Clinical Pearls: Biosimilars**

**Crystal Luong, Pharm.D., PGY-1 Resident 2012-2013  
Oklahoma City Veterans Affairs Medical Center**

Biological products (i.e., biologics, biopharmaceuticals) are manufactured from living sources such as microorganisms, animals, and humans through recombinant deoxyribonucleic acid (DNA) technology, fermentation, and/or other biosynthetic methods.<sup>1,2</sup> Development of biologics began with vaccines and quickly evolved to encompass other therapeutic and diagnostic proteins such as monoclonal antibodies, hormones, and blood-derived products.<sup>3</sup> Heparins and insulin are also considered biologic agents; however, the processes for Food and Drug Administration (FDA) regulation and approval of their generic counterparts are similar to those for conventional generic medications.<sup>3</sup> The development of biologics has contributed to healthcare advancements for the prevention, diagnosis, and treatment of numerous diseases. With many biologics now having expired patents or patents approaching expiration, the introduction of generic versions of biologics, also referred to as biosimilars, follow-on biologics, or biocomparables, is much anticipated.

Questions and concerns surround the advent of biosimilars because unlike conventional pharmaceutical agents, the complex molecular characteristics of biopharmaceuticals are not easily replicated.<sup>1-5</sup> For example, consecutive batches of these agents are similar but are never identical to each other, which is why an especially high level of control is required to ensure consistency.<sup>5</sup> Although biosimilars are very much like the innovator products, they may exhibit minor differences due to the complexity of the manufacturing process and inadvertent chemical modifications.<sup>4-6</sup> The issues surrounding these minor alterations cause concerns regarding the effectiveness and safety of the biosimilar as well as the degree of therapeutic equivalence between the reference product and the biosimilar. These differences prevent biosimilars from following the same abbreviated pathways for approval as other generic medications.

In 2005, the European Union's European Medicines Agency (EMA) was the first to design regulatory processes for biosimilars.<sup>7</sup> Australia, Canada, China, and India soon followed suit basing their abbreviated approval process on that of the EMA.<sup>8</sup> Regulation of biosimilars in the United States took shape in late 2009 and early 2010 after the approval of the Patient Protection and Affordable Care (PPAC) Act. Under the PPAC, the Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service (PHS) Act to establish an abbreviated approval pathway through the Biologic License Application (BLA) for biosimilars. As a result, manufacturers developing biosimilars are required to conduct at least one clinical trial comparing their agent with the reference product to ensure similar efficacy, purity, and safety characteristics. The clinical studies are required to include immunogenic assessments as well. It is important to note that there are biosimilars that are interchangeable with the reference product and biosimilars that are not. As an incentive for development of biosimilars that are interchangeable with the innovator agent, the BLA grants the first interchangeable biosimilar exclusive marketing rights as a biosimilar for one year.<sup>6,9</sup>

The FDA is presently in the process of drafting and finalizing guidelines for the abbreviated approval process for biosimilars, consistent with the legislation that was passed. Currently there are no drugs designated as biosimilars commercially available in the US. Europe has approved several biosimilars since 2006, including erythropoiesis-stimulating agents, granulocyte colony-stimulating factor, and human growth hormone.<sup>7,8</sup> The EMA does not consider any of these marketed biosimilars interchangeable with the reference product.

## Clinical Pearls – Cont'd

The differences in regulatory pathways between countries are illustrated by the approval of Tevagrastim in Europe and tbo-filgrastim in the US. Tevagrastim (proprietary name) and tbo-filgrastim (generic name) are the same agent produced by Teva. This product is comparable to the granulocyte colony-stimulating factor, Neupogen (filgrastim). In Europe, Tevagrastim was submitted through an abbreviated application and approved as a biosimilar. In the US, tbo-filgrastim's application for drug approval was filed in 2009 at which time guidelines for an abbreviated approval of biosimilars did not yet exist. As a result, tbo-filgrastim went through the approval process for new drugs and was approved as a novel biologic by the FDA in 2012. It is not considered therapeutically equivalent to filgrastim.<sup>10</sup>

As more biologic agents begin to lose their patents and biosimilars gain approval by the FDA, other questions will be raised. Will providers accept substitution of biosimilars for reference products? How will a hospital incorporate these agents? How will insurance companies handle reimbursement? With so many unanswered questions, it is important for pharmacists to be aware of these products, their regulation, and the special concerns regarding their clinical use. Pharmacists may be asked to evaluate the differences between the products in terms of safety, efficacy, and cost, as well as interchangeability with the reference products and possible implementation of a procedure to substitute agents not considered interchangeable. Websites with useful information about biosimilars include the FDA website (<http://www.fda.gov/>) and GaBi Online (<http://www.gabionline.net/>).

### BIOLOGICS WITH EXPIRED PATENTS<sup>11</sup>

Biologic (generic name)	Manufacturer	Clinical Use
Prevnar 13 (pneumococcal conjugate vaccine)	Wyeth	Pneumococcal vaccine
Betaseron (interferon beta-1b)	Bayer	Multiple sclerosis
Humatrope (somatropin)	Pfizer	Human growth hormone

### BIOLOGICS WITH PENDING PATENT EXPIRATION<sup>11-14</sup>

Biologic (generic name)	Manufacturer	Clinical use	Exp. date
Neupogen (filgrastim)	Amgen	Neutropenia	2013
Epogen (epoetin alfa)	Amgen	Anemia	2014
Procrit (epoetin alfa)	Janssen		
Enbrel (etanercept)	Amgen	R.A., Ankylosing spondylitis, Psoriasis	2014
Neulasta (pegfilgrastim)	Amgen	Neutropenia	2015
Synagis (palivizumab)	MedImmune	Prevention of respiratory syncytial virus infection	2015
Rituxan (rituximab)	Genentech Inc/Roche	Antineoplastic agent, R.A.	2016
Humira (adalimumab)	Abbott Pharmaceuticals	R.A., Ankylosing spondylitis, Inflammatory bowel disease, Psoriasis	2016
Remicade (infliximab)	Janssen Biotech Inc	R.A., Ankylosing spondylitis, Inflammatory bowel disease, Psoriasis	2018
Avastin (bevacizumab)	Genentech Inc	Antineoplastic agent	2019
Pegasys (peginterferon alfa-2a)	Roche Pharmaceuticals	Hepatitis C	2019

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## Direct from the Director

Fred Keehn graduated from Southwestern Oklahoma State University in 1983 with his Bachelor of Science in Pharmacy. Though his initial interest was in retail, his pro-practice experience at Jane Phillips ignited an interest in hospital pharmacy. He worked there as a pharmacist until 1990 when he took a pharmacy director position at Broken Arrow Medical Center. He went back to school in 2004 to earn his Doctor of Pharmacy degree and has been the pharmacy director at St. John Medical Center in Tulsa since 2008.

I recently had the opportunity to sit down with him and ask some questions about his career path and the responsibilities of a pharmacy director.

### **What ignited your interest in pharmacy?**

When I was in 4<sup>th</sup> or 5<sup>th</sup> grade, there was a drug store in Wichita I would visit – it had the soda fountain, the raised counters and everything. The owner was genuinely kind and never got upset about anything. He inspired me to pursue pharmacy.

### **Have you always been interested in administration? What led you to that decision?**

No, not always. I originally liked the clinical side more. While I was at Broken Arrow, the director would take July off each year, and I would cover the administrative tasks during that month. I also have two brothers and sisters who are accountants, so I guess budgets and saving costs comes naturally. In 1994, Hepler and Strand, who developed the definition of pharmaceutical care, gave a talk at ASHP. That experience has played a major role in my continued interest in Pharmacy Administration.

### **What major developments have you been through or seen during your career?**

The change from a retrospective to prospective payment system for hospital services. Also, pharmacists are taking a more active clinical role. Pharmacists are now working on the floors and calling physicians to make dosage recommendations. This did not always happen in the past. One thing I do not see changing is the pharmacist's role in dispensing.

### **What are current challenges you face as an administrator?**

There are two: the expense of medications and fluctuating costs. This is especially true in cancer patients treated with chemotherapy. We have seen a dramatic rise in spending with treating these patients just over the course of the last year. This is challenging because as an administrator you are expected to treat more patients with the same budget from the year before.

Managing a large volume of employees is always challenging too. Everyone has different personalities. This is easier in a smaller hospital.

Healthcare reform and potential rationing of healthcare may lead to some interesting challenges in the future.

## Direct from the Director – Cont'd

### Do you have any advice for the aspiring pharmacy director?

It never hurts to get an administrative degree, such as an MBA, though it is not necessarily a requirement. More important is developing a knack for budgets, understanding the percentage of cost for therapeutic classes, etc. Having good interpersonal skills is a must as well.

Probably the most important thing is networking. Collaboration with peers is the best way to get better. Do not be afraid to ask questions from others, because that is how you learn.

Before and after the interview, he reiterated how pharmacy is one of the best professions out there. I'm sure we can all agree!

*Interview by Alex Cobb, PharmD, PGY-1 Resident, St. John's Medical Center*

## OSHP Member Recognized by the American College of Clinical Pharmacy



The American College of Clinical Pharmacy (ACCP) recently recognized one of our own OSHP members. The ACCP Member Relations Committee announced that Mark Mills, Pharm.D. has been featured on the ACCP Web site in recognition of his contributions to the College and the profession of pharmacy.

The ACCP Volunteer Recognition Program was instituted in 2009 to help identify members who have made notable contributions to the College and/or the profession of pharmacy through committee work, publications, presentations, or other commendable participation. Mark was nominated by his peers in the Nephrology Practice Research Network. A listing of this recognition may be viewed on the Volunteer Recognition page of the ACCP web site at <http://www.accp.com/membership/vrp.aspx>.

Mark has been an active OSHP member, most recently serving on the Board of Directors and as the Eastern District Chair from 2010 – 12. Congratulations, Mark!!

# SWOSU Spring 2013 sOSHP Chapter Highlights

Faculty Advisors: Tiffany Kessler and Nancy Williams

The Southwestern student OSHP Chapter would like to congratulate Robyn Dowdy and Lucy Wilkening for placing in the top 10 of 120 teams at the 2012 ASHP National Clinical Skills Competition held at the recent Midyear Clinical Meeting. Congratulations on a job well-done!!

Our chapter started the Spring semester by implementing a few changes. We still offered informative meetings over health-system pharmacy-related topics, but our biggest change was to move some meetings from the evening to the lunch-time hour. As a result, our membership meeting at the beginning of the semester was very successful. Many students joined immediately after the meeting and were excited about our organization. For this semester, we planned meetings that educated students about academic pharmacy, residencies, and pharmacy legislation.

At our first meeting in February, we invited a panel of SWOSU Pharmacy Practice faculty and administrators to come talk to us about academic and hospital pharmacy. Unfortunately due to weather conditions in Weatherford, the meeting was canceled. We hope to reschedule this in the upcoming Fall semester so that any students interested in academia can learn more about it.

The March meeting consisted of a panel of current PGY1 pharmacy residents. Participants included Drs. Nicole Avant, Alex Cobb, Lezlie Grimes, and Jonathan Hansen. Drs. Avant, Grimes, and Hansen are current PGY1 community pharmacy residents with the OU College of Pharmacy and various partnership pharmacies. Dr. Alex Cobb is a PGY1 pharmacy practice resident with St. John Medical Center of Tulsa. The residents all did a great job explaining why they chose to pursue residency training, what they do as residents, and how we can better prepare ourselves to apply for residencies. We had a great turnout for this meeting and were thankful they had the time to come speak to us.

Lastly, our final meeting for the semester is scheduled in April. We will elect officers for Fall 2013, and Dr. Tracy Hagemann, OU faculty, will give us an overview of advocacy and legislative initiatives in the field of pharmacy. We are looking forward to her visit!

This semester has also been busy with various service and fundraiser projects. We collaborated with Worldwide Book Drive to collect books on campus. This organization will donate the books that we collect to charitable organizations that emphasize education, literacy, and environmental protection from book waste. As fundraisers, we are selling packets of drug information cards, such as Nonprescription Drugs and Injectable Drugs, to students who are interested in having additional quick references when they go off on their rotations. Additionally, we are selling various t-shirts, totes, and tumblers. We are currently planning our professional development project and are excited about this opportunity.

We had a prolific and insightful semester. This would not have been possible without the vision and effort of our officers, as well as the guidance and support of our faculty advisors, Dr. Tiffany Kessler and Dr. Nancy Williams. The rest of the semester will be busy, and we hope that next semester will bring continued growth and change to our chapter

<b>Officers</b>	<b>Spring 2013</b>
<b>President</b>	Jennifer Le
<b>President-Elect</b>	Joanna Mach
<b>Secretary</b>	Debbie Tran
<b>Treasurer</b>	Tiffany Le
<b>Historian</b>	Kim Ly
<b>Fundraising Co-Chairs</b>	Kara Connelly Victoria Lam



Residency Panel: Dr. Jonathan Hansen, Dr. Alex Cobb, Dr. Nicole Avant, and Dr. Lezlie Grimes



Merchandise table at the College of Pharmacy



President Jennifer Le making announcements at the March meeting

# OU Spring 2013 sOSHP Chapter Highlights

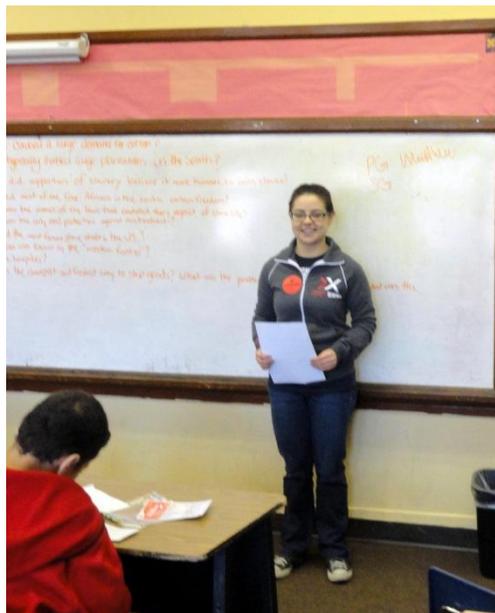
## Faculty Advisors: Michele Splinter and Ann Lloyd

At the ASHP Midyear Clinical Meeting in Las Vegas, chapter members Roshni Patel and Amy Sid developed a poster on the on-going service project of Poison Prevention at Marcus Garvey Leadership Charter School. In addition, Shivani Shah and Debbie Leung represented our college in the National Clinical Skills Competition.

The semester began with our January meeting where Dr. Tracy Hagemann spoke about legislation affecting pharmacy and how students can get involved. She informed us about some of the current issues involving pharmacy in Oklahoma, how to find our local legislators, what to do once we find them, and how to support PACs.

At our February meeting, Whitney Kemp from the Oklahoma Poison Control Center spoke about Poison Prevention Month, informing students of events going on in which they can participate. She also talked about the extent of services the Poison Control Center provides, which was beneficial information for many members.

Currently, the chapter is aiding the Children's Miracle Network through an empty prescription bottle drive. The prescription bottles will be used to collect financial donations during the Mile of Quarters event. The Marcus Garvey Project has been under preparation since last semester. A committee was formed to make changes and improvements to the lesson plan from last year. The program is designed to educate students in grades one through eight about common household poisons.



In March, we are going to participate in the Poison Prevention Awareness Day at the OKC Zoo hosted by the Oklahoma Poison Control Center. In addition, we will have a poison prevention booth set up with games and activities at the Department of Mental Health Youth and Families Systems of Care Picnic. The chapter will also be participating in the Big Event, a campus-wide community service project both in OKC and in Tulsa. In OKC, sOSHP students will be volunteering at the Children's Hospital. In Tulsa, the location will be determined closer to the event.

In Tulsa, officers are working on two potential health fairs to take place in late April: one at an elementary school, focused on good food choices and fun fitness, and one at a church, focused on diabetes and wound prevention.

At the next meeting, we will be electing new officers for the upcoming 2013-2014 school year. The 2012-2013 officers are:

	OKC	Tulsa
President	Roshni Patel	
Vice President	Amy Sid	Rebekah Panak
Secretary	Xiangyu Tan	Lindsey Crane
Treasurer	Courtney Bishop	Calli Mclean
Service Chair	Ruby Oh	Lindsay Bebout
Historian	Stephanie Garland	Alyson Votruba

## Newly Elected OSHP Officers

The results of the OSHP officer elections were recently released by the Nominations Committee after a call for nominations was sent out in early March. The following individuals will be installed into their respective positions during the upcoming Annual Meeting on April 12, 2013 at St. John Medical Center in Tulsa:

President-Elect	Rebecca Dunn	(3-year term)
Treasurer	Matthew Bird	(2-year term)
Western District Chair	Debbie Poland	(2-year term)

## Medication Shortages

In order to keep up with ongoing and/or new medication shortages, visit ASHP's home page at [www.ashp.org](http://www.ashp.org) for more information.

## Want to get Involved?

Would you like to be more involved in OSHP but maybe aren't quite sure how to go about it? There are always opportunities!!! Below are the chairs and co-chairs for the current committees, and with a new incoming President, now is the perfect time to become active for the upcoming year. We welcome additional involvement from students and technicians in our activities. You may contact any of the committee chairs below to find out how to get more involved.

<b>Committee</b>	<b>Chair</b>
Membership	Rebecca Dunn and Brooke Honey
Program	Jennifer Wakefield
Residency Showcase	Mark Gales
Vendor Showcase	Lisa Mayer
Legislative	Tracy Hageman
Newsletter	Teresa Lewis and Yvette Morrison
Nominations	Tiffany Kessler and Jamie Miller
Finance	Pete Johnson
Scholarship and Awards	Michele Splinter
Policy and Guidelines; Ad Hoc Committee	Susan Conway
Social Media and Communication; Ad Hoc Committee	Pete Johnson

You can also find this information, including email addresses, on the OSHP website at:  
[http://www.oshp.net/index.php?option=com\\_content&view=article&id=49&Itemid=59](http://www.oshp.net/index.php?option=com_content&view=article&id=49&Itemid=59)