Academy of Managed Care Pharmacy®

# AMCP NEWS VIEWS

#### SEPTEMBER 2018



# AMCP Urges FDA to Issue Final Guidance on Biosimilar Interchangeability, Education

AMCP this week called on the FDA to issue final guidance on interchangeability standards for biosimilars, and to develop educational materials that include messaging on the ability of pharmacists to substitute an interchangeable biologic for its reference product. AMCP presented these and other suggestions at the FDA's Sept. 4 <u>public hearing</u> on "Facilitating Price Competition and Innovation in the Biologics Products Marketplace."

Mary Jo Carden, AMCP's Vice President of Government and Pharmacy Affairs, told FDA officials that any final interchangeable guidance should address issues such as: whether new or expanded indications for a reference product would also be considered interchangeable — including the manner in which the labels will be harmonized; naming of interchangeable biologic products; the possibility of interchangeability from biosimilar to biosimilar; dispensing standards for interchangeability; and, whether "follow-on" products approved under the 505 pathway will be considered interchangeable or biosimilars when incorporated into the 351(k) pathway.



Many of the other speakers also stressed the need for better education and robust pharmacovigilance around biosimilars. AMCP has taken a leading role in both of these areas, including through:

- **Biologics and Biosimilars Collective Intelligence Consortium (BBCIC),** which was established in 2015 to monitor biosimilars and corresponding novel biologics for effectiveness and safety. (<u>www.bbcic.org</u>); and
- Biosimilars Resource Center, which provides educational resources and information on biosimilars to health care
  providers and other stakeholders in a policy-neutral and non-promotional manner
  (www.biosimilarsresourcecenter.org)

AMCP encourages FDA to take immediate action to promote education on biosimilars and finalize reasonable interchangeability guidance. (*images: FDA officials listen to testimony on biosimilar competition; Mary Jo Carden delivers AMCP's message*).

#### Learn more about INJECTABLE MIGRAINE TREATMENT

#### CLICK HERE





AMCP Foundation Holds Key Meetings on Facilitating More Research in Health Care Trends, and Updating P&T Competition

The AMCP Foundation last month gathered dozens of experts for two important meetings: one to assist the Foundation in facilitating more innovative research around trends in health care, and the second to ensure the Foundation's Student Pharmacist P&T Competition remains the premier competition for students interested in managed care. The first meeting, on Aug. 22, gathered key opinion leaders to help the Foundation refine the direction of its emerging trends in health care project by ranking the significance of various trends, reviewing preliminary and secondary research findings, and discussing the formulation of primary research. The second meeting, on Aug. 23, bought together a cross-section of individuals for a strategic discussion on one of the Foundation's signature immersive



education programs, the Student Pharmacist P&T Competition. The meeting addressed items such as competition goals, case studies, scoring, and components for completion by students. For more information, visit <u>www.amcp.org/amcp-foundation</u>. (*Images: above, meeting on research; right, meeting on P&T Competition*)



Addressing Rising Costs Requires Multipronged Approach

A new article in Health Affairs (<u>http://bit.ly/2BQIgo9</u>) highlights the challenges that many health plans and payers face as spending on pharmaceuticals continues to rise. The report, which looked at total health care spending at Harvard Pilgrim Health Care (HPHC) from 2011 and 2016, found that spending on pharmaceuticals had increased to a full 25% of all dollars spent. It comes as no surprise that the increase was due largely to rising prices of specialty medications. The report found that while average per-member-per-month (PMPM) spending increased by only 4% for nonspecialty medications (from \$62.52 to \$65.01), PMPM spending skyrocketed by 92% for specialty drugs (from \$18.72 to \$35.85). AMCP has devoted a great deal of time and attention to the issue of rising drug costs, including in our responses to the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (<u>http://bit.ly/2wwnfYZ</u>). We believe it will take a multipronged approach to ensure that new medications remain accessible and affordable to all. (<u>Read more</u>)



Help AMCP Set 2019 Legislative & Regulatory Policy and Advocacy Focus

AMCP encourages all members to participate in a <u>survey</u> that will help the Academy set its 2019 Legislative & Regulatory Policy and Advocacy Focus Areas. Your opinion and expertise are critical as we plan for the coming year. The survey should take no more than five minutes, and everyone who completes the survey will have their name entered into a drawing to win one of two \$250 gift cards. Deadline to respond is Sept. 25!









AMCP Utah Affiliate Holds Meeting for Networking, Discussion on PIE Act

More than 60 pharmacists and health care professionals attended the Utah AMCP Affiliate Meeting, Aug 23 at Kimi's Chop & Oyster House in Salt Lake City. In addition to good food and networking opportunities, a panel of experts discussed developments with H.R. 2026, the "Pharmaceutical Information Exchange (PIE) Act of 2017," along with its potential impact on manufacturers, payers and Academy members. Presenters included: AMCP CEO Susan A. Cantrell, RPh, CAE; AMCP Immediate Past President Diana Brixner, RPh, PhD, FAMCP, Professor & Chair of the Department of the PORC in the College of Pharmacy at the University of Utah; Jeffrey Dunn, PharmD, MBA, Vice President of Clinical Strategy and Programs and Industry Relations at MagellanRx; Eric Cannon, PharmD, FAMCP, Assistant Vice President of Pharmacy Benefit Services for SelectHealth; and Julie Greely, PharmD, Senior Director, Field Excellence and HEOR at Astellas. For more information, visit <u>www.amcp.org/affiliates/</u>





#### **Call for Volunteers to Serve on Committees**

Volunteers are the heart of AMCP's work! Because of their contributions, AMCP is able to provide research, tools and education that is so important to our members. By serving on one of AMCP's committee you share your voice and expertise, you make valuable personal connections and you give back to managed care pharmacy! Consider taking an active part in AMCP by volunteering for one of AMCP's many committees. Review all the committee purposes at <u>www.amcp.org/committee</u> to decide the one that is right for you. Deadline to submit your application is Nov. 9!



#### **AMCP Members in the News**



AMCP member **Patty Kumbera** last month joined PrescribeWellness as Chief Operating Officer, a company that prompts collaboration between pharmacies, payers, providers, pharmaceutical companies and patients for better health. Kumbera has worked with AMCP to facilitate a pharmacy profession-wide consensus of definitions related to Medication Therapy Management (MTM) and SNOMED CT codes used in the creation of MTM Value Sets hosted by AMCP, PQA and PHIT Collaborative.

**Next-Gen Pharmacists Awardees:** Congratulations to AMCP members **Kim Caldwell, Kevin Ridderhoff** and longtime AMCP/Foundation friend **Eleanor Perfetto**, for being selected as finalists in the *Pharmacy Times* and Parata Systems' Next-Generation Pharmacist awards. The three were among 30 finalists for the award that honors pharmacists, student pharmacists, technicians and



industry advocates in 10 categories, including Civic Leader, Entrepreneur, Future Pharmacist, Health-System Pharmacist, Rising Star, and Lifetime Leadership. Ridderhoff is a finalist in the Civic Leader category, and Caldwell and Perfetto are finalists in the Lifetime Leadership category. Winners from each category will be announced Oct. 5 in Boston, Mass. For more information, visit <u>nextgenpharmacist.com</u>.

If you have a notable career development, we want to help share the news. Email notices to <u>nlearner@amcp.org</u>.



## Cantrell Presents at International Pharmacy Conference in Scotland

Speaking before an international gathering of health care leaders this month, AMCP CEO Susan A. Cantrell, RPh, CAE, explained how the U.S. health care system manages the utilization of complex therapies. Cantrell was a speaker at the 78th International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences conference in Glasgow, Scotland, where she presented at a session on "biological drugs and gene therapy – hot topics on regulation and policies affecting use." The session focused on new technologies and approaches in pharmacotherapy. Cantrell discussed U.S. policies and procedures on the use of these products as delivered through public and private health plans. "It was an excellent opportunity to learn from pharmacy colleagues from around the world," said Cantrell. "You quickly realize that challenges in health care are not limited to the U.S. market. It's exciting to share ideas and discuss solutions with peers from other countries." Cantrell was joined by speakers from India, Australia, Switzerland, the U.S. and Germany. FIP is comprised of 140 national organizations, academic institutional members and individual members, and represents more than 4 million pharmacists and pharmaceutical scientists around the world.



### AMCP Corporate Member Spotlight: Neurelis

AMCP News&Views caught up recently with **Chuck DeWildt**, Senior Vice President of Commercial and Market Access for Neurelis, to get his thoughts on becoming a Corporate Member, as well as how Neurelis is poised to make an impact for patients in the months ahead:

As you considered becoming a Corporate Member, what tipped the scales?

Neurelis is excited about the opportunity to partner with the Academy. Several of us within Neurelis have had a long-standing relationship with AMCP and look forward to bringing that partnership to our emerging biopharmaceutical company. Like AMCP, we have a passion for progress in meeting unmet medical needs and improving patient care. AMCP has established itself as a gateway to education for the 8,000+ members and in helping to create strong solutions for patient care. Neurelis is committed to partnering with physicians, nurses, pharmacists, and other providers of care to provide value and enhanced therapeutic



options for patients. As we look to bring our first product to the market in 2019, we also look forward to working to ensure the best care possible to the patients we serve. <u>Read more</u>.

AMCP Foundation Interns and AMCP APPE Students Present Capstone Research Projects at Alexandria, Va., Headquarters





This summer, AMCP and the AMCP Foundation hosted a series of student pharmacists at the organizations' headquarters in Alexandria, Va. The highly competitive programs offer future practitioners the opportunity to experience firsthand a broad spectrum of managed care pharmacy careers. This year's Foundation interns will join the ranks of more than 170 alumni since the Foundation began organizing internships 25 years ago. AMCP also has started hosting Advanced Pharmacy

Practice Experiences (APPE) students. All student pharmacists who visit headquarters completed capstone research projects, which they delivered before AMCP and Foundation staff. The Foundation interns will also present their research as posters at AMCP Nexus 2018, Oct. 22-25, Orlando, Fla. Kudos to all of these student pharmacists:

- AMCP Foundation/Pfizer intern **Mandy Renfro** presented "25 Years of Managed Care Leadership Development: A descriptive analysis and summative evaluation of Academy of Managed Care Pharmacy Foundation Intern Alumni."
- AMCP Foundation/Allergan intern **Eunice Kim** presented "Impact of alternative approaches to modeling the quality of life associated with monocular blindness."
- AMCP Foundation/Allergan intern **Michael Sporck** presented "Assessing Post-Surgical Outcomes Associated with Pre-Pectoral Breast Reconstruction: A Literature Review and Meta-Analysis."
- AMCP Foundation/Genentech intern **Adam O'Neil** presented "Characterizing Care Models in Alzheimer's Disease: Considerations for Early Diagnosis."
- AMCP Foundation/Genentech intern **Ileka Ifejika** presented "An Analysis of ICER's Scoping Process: The Influence of Stakeholder Input."
- APPE student pharmacist **Andrew Chayasriwong** presented "The Current State of Opioid Abuse Deterrent Formulations: Development of an Educational Grant Needs Assessment."
- APPE student pharmacist Martha Hopkins presented "The Pharmacist's Impact on Value-Based Contracting."

For more information, visit <u>www.amcp.org/amcp-foundation/internship</u> and <u>www.amcp.org/amcpappe</u>.(*image: interns and APPE students who presented in July and August*)



# **Student Chapter Spotlight: Sullivan University College of Pharmacy**

AMCP Student Pharmacist Chapters across the country hold informative programs that expose students to managed care pharmacy practices and principles. This month we feature **Sullivan University College of Pharmacy, in Louisville, Kentucky**:

Over the summer, students from Sullivan University College of Pharmacy's (SUCOP) AMCP Student Chapter had the opportunity to attend a Pharmacy &Therapeutics Committee meeting conducted by Passport Health Plan. Passport Health Plan is based in Louisville, Kentucky, providing close proximity for collaboration between SUCOP, and support of both AMCP Student Chapter and AMCP OK/KY Affiliate Chapter endeavors. Passport holds the P&T committee meetings regularly and they are always open to the public to promote



patient education and community involvement with the health plan. As members of AMCP, Sullivan University pharmacy students had the unique opportunity to observe the P&T processes, and to expand their overall knowledge of formulary development. During this committee meeting, recommendations were made on a variety of topics. <u>Read more</u>. For more information on Student Chapters, visit <u>www.amcp.org/chapters/</u>

What's New at Nexus? New Programs and Events to be Held in Orlando!



AMCP Nexus 2018 is just around the corner, and the Academy's staff has been hard at work developing new programs to benefit our attendees. New programming includes:

- AMCP Talks: Solutions for Value-Based Care: On Thursday, Oct. 25. This innovative program mixes short, focused
  presentations with interactive panel discussions. The talks will focus on value-based care and potential solutions to
  the biggest challenges in implementing value-based care management and contracts. For information, visit the
  <u>Education Session Guide</u>.
- <u>Satellite Symposia</u> will start early this year, with programs at 11am on Monday, Oct. 22. In addition, <u>Industry</u> <u>Workshops</u> and <u>Science & Innovation Theaters</u> will be held on Tuesday and Wednesday.
- <u>Student events</u> have expanded with special programming and networking opportunities, plus the <u>21st Annual</u> <u>Residency & Fellowship Showcase</u>!

Visit www.amcpmeetings.org for more information and to register.



## AMCP Foundation Annual Research Symposium: Explore New Research

Building on its groundbreaking emerging trends research, the AMCP Foundation's 8th <u>Annual Research Symposium</u> will release findings of a new comprehensive study of the factors leading health system change and their impact on varied stakeholders. The event will be held Oct. 22 before the start of the <u>AMCP Nexus 2018</u>. The research will focus on trends that could create significant changes in the health care system, including, drug pricing & spending; innovative and curative therapies; health coverage; accelerated drug approvals; specialty products and biosimilars; population health management; big data and health IT; industry consolidation; and health care public policy. Participants will identify programs to address anticipated changes, and describe the status of implementation, and consequences of inaction. For more information, <u>click here</u>. *(image: last year's symposium)* 



## Dossier Satisfaction – Views from AMCP eDossier System Payers

Dossiers continue to provide a key role in informing the formulary decision-making process. In a recent survey, most payers and other health care decision makers say that they utilize dossiers and are satisfied with them. However, more than half say that ideal timing for dossier availability is 6-12 months prior to FDA approval and that a key limitation of

dossier use is the availability of the dossier in time to prepare for a P&T decision. For more information, join us for an upcoming AMCP webinar titled, "Pre- and Post-Approval Dossiers: Making All Evidence Count" on Wednesday, Sept. 12, at 2pm EDT <u>Click here</u> to register today. Haven't registered for the AMCP eDossier System yet? Free for all health care decision makers and payers at <u>https://amcp.edossiers.com</u>. If you are a payer or health care decision maker and interested in participating in and receiving remuneration for current topics, product specific or formulary decision surveys, please login at <u>https://amcp.edossiers.com</u>. Or contact us at <u>information@amcp.edossiers.com</u>.



#### Foundation Activities at Nexus: Yoga to "Destress-sesh"

Coming to AMCP Nexus 2018? Stretch for success on the West Terrace Lawn with <u>Sunrise Yoga</u>. Join this "destress sesh" before you take in all that Nexus has to offer. Your AMCP Foundation knows how hectic a multi-day conference can be, so jump-start your morning with mind-focusing movements to build strength and flexibility. Two sessions are available: Tuesday, Oct. 23 and Wednesday, Oct. 24, 6-7am. No special registration required. Sleep is an important part of wellness, too. Choose the <u>Sleep-In for Wellness</u> option and we won't enroll you in Sunrise Yoga--but you can still support our mission and pick up an AMCP Foundation Means Well(ness) T-shirt! A separate \$20 donation for Sunrise Yoga and Sleep-In for Wellness is required to register for these programs. All participants will receive an AMCP Foundation Means Well(ness) T-shirt at the Nexus registration desk. Sign up when you <u>register for Nexus 2018</u>.



### AMCP Corporate Training Program at Nexus: New Pricing and Group Packages Available

AMCP Nexus will offer a pre-conference training program, "Value-Based Care in IDNs: Expanding Collaboration and Engagement To Improve Outcomes." The program is targeted to Account Managers, National Account Managers, Medical and HEOR liaisons and Marketers. During the program, eight faculty members—including health care consultants, subject matter experts and executives—will share insights and strategies for driving health care innovation. The program runs Monday, Oct. 22 and Tuesday, Oct. 23. The price has been reduced to \$1,995. This year's faculty includes:

- Josh Benner, PharmD, ScD, President and CEO, RxAnte
- Amanda Brummel, PharmD, BCACP, Director, Clinical Ambulatory Pharmacy Services, Fairview
- Jeff Dunn, PharmD, MBA, Vice President, Clinical Strategy and Programs and Industry Relations, MagellanRx
- Fred Goldstein, President, Accountable Health
- Jim Kenney, RPh, MBA, Manager, Specialty and Pharmacy Contracts, Harvard Pilgrim Health Plan
- Debi Reissman, PharmD, Sharp
- Terry Richardson, PharmD, Director of Product Development, AMCP
- Lori Wood, MHA, Senior Vice President of Payer Strategy, Entrée Health

To learn more about the program, click here.



and Buddies

Volunteering at <u>AMCP Nexus: Preparing for the Next Generation of Care</u> is a wonderful way to connect with your fellow managed care professionals. To learn more about the opportunities and to sign up, click <u>here</u> or click on the individual links.

• <u>AMCP Booth Volunteers</u>: Help staff the AMCP Concierge booth at AMCP Nexus 2018.



- <u>Conference Buddies</u>: This program matches interested 3rd or 4th year pharmacy students who are attending the conference with a managed care professional. Deadline to register is Oct 4th.
- <u>AMCP Foundation Poster Mentor</u>: Help poster presenters speak about their research by visiting assigned posters, asking questions of the presenters and providing feedback.
- <u>AMCP Foundation Kiosk</u>: Help promote Foundation programs, including giving opportunities and charitable initiatives like our sock drive.



AMCP Nexus 2018 Attendees Can Earn Additional CE Credit at Non- Commercial, Industry-Supported Satellite Symposia

Presented at no additional charge to registered conference attendees, Satellite Symposia extend the educational experience of conference attendees and offer continuing pharmacy education credit (CPE), continuing medical education credit (CME), continuing nursing education credit (CNE) or all three. Topics include lipid management, rheumatoid arthritis, asthma, biosimilars, Von Willebrand disease, PCSK9, ALS and oncology. All symposia will be held at the Orlando World Center Marriott in Orlando, Florida. For more information, <u>click here</u>.

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