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AMCP Presents at FDA Hearing on Biosimilar Competition

AMCP, Others Call for Better Education, Pharmacovigilance on Biosimilars

AMCP this month 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 [public hearing](#) 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. (www.bbcic.org); 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.



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Pharmacy Policy

AMCP Submits Comments to ASHP on Off-Label Use, Pharmacy Services in Organ Transplants

AMCP submitted comments recently to the American Society of Health-System Pharmacists (ASHP) on two draft guidances that are relevant to managed care pharmacy:

- On Aug. 24, AMCP commented on ASHP Draft Guidance on [Appropriate Off-label Medication Use](#). The comments, which were posted directly on the ASHP portal, summarized AMCP's Where We Stand position on [Off Label Use of Pharmaceuticals](#).
- On Sept. 14, AMCP commented on Draft [ASHP Guidelines on Pharmacy Services in Solid Organ Transplantation](#) summarizing our position on [Collaborative Drug Therapy Management](#).

Capitol Hill Update

Senate Passes Opioid Package, Legislation Now Goes to Conference Committee

After the House passed its version of H.R. 6 in June, the Senate voted on Sept. 17 to approve a separate version of the legislation that contains 70 different provisions to address the opioid crisis. The comprehensive bill passed late Monday, Sept. 17th, by an overwhelming 99-1 margin with Senator Mike Lee (R-Utah) the only vote against the legislation. AMCP has actively supported several provisions of the bill in both chambers and called for additions to the legislation in a final package. A Conference Committee will be appointed from both chambers to iron out differences between the two versions.

AMCP has supported several bills which were included in the legislation, such as [H.R. 4841](#) (Standardizing Electronic Prior Authorization for Safe Prescribing Act) and [H.R. 3528](#) (Every Prescription Conveyed Securely Act). Several bills which the House passed were not included in the Senate bill such as: H.R. 6082 (the Overdose Prevention and Patient Safety Act), which would allow substance use disorder records to be covered under HIPAA consent provisions; and Sec. 6102 in the House bill, which would allow

Advocacy Tip

It is important to keep a legislator and their staff cognizant of your priorities. If revisiting an office, bring up-to-date materials or articles with any new findings which could aid in their understanding of the subject.

Medicare prescription drug plans and MA-PD plans to suspend payment pending a credible allegation of fraud.

AMCP has two action alerts asking for the above legislation to be included in the final compromise package agreed upon by the Conference Committee. It's not too late to let your Senators know these are important pieces to combat the opioid crisis! Take action by going to AMCP's [grassroots advocacy page](#) and send a letter TODAY.

Please note these are separate action alerts and members can send one or both pre-written letters or write their own by using the "find officials" section at the bottom of the web page.

Status of Other Relevant Legislation: Biosimilars, CREATES Act

The House remains on recess and is set to return on Sept. 25, while the Senate returned to session on Sept. 17 after a brief recess due to Hurricane Florence. Recent health care-related legislation includes:

H.R. 6478 – the Biosimilar Competition Act of 2018: The bill was introduced July 23rd by Reps. John Sarbanes (D-MD) and Bill Johnson (R-OH). Current law requires brand and generic manufacturers to file patent settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DOJ). The intent of the filings is twofold: (1) to allow the agencies to take enforcement action on anticompetitive agreements and (2) to deter manufacturers from entering into anticompetitive settlements. The FTC uses this information to: (1) publish an annual tally of anticompetitive reverse payment settlements, and (2) sue in federal court to prevent anticompetitive settlements from going into effect. This notification requirement, however, does not extend to biologic and biosimilar manufacturers, since the statutory requirement predates enactment of the biosimilars pathway under the Biologics Price Competition Act (BPCIA) by seven years. The purpose of the Biosimilar Competition Act of 2018 is to apply the existing filing requirements to biologic and biosimilar products. AMCP joined 17 other [stakeholders in a letter](#) to sponsors supporting H.R. 6478, and promised to work with them to pass it. The stakeholders share the commitment to promote a biosimilars market that will help reduce prescription drug costs for patients, payers and taxpayers.

S. 974 – Creating and Restoring Equal Access to Equivalent Samples Act (CREATES ACT): As reported the last two months, the Senate Judiciary Committee voted in favor of the S. 974 by a vote of 15-6 in June. The bill is now on the Senate Legislative Calendar awaiting a vote by the full Senate. AMCP sent a [letter in support of the legislation](#) to each member of the Senate, and will call for AMCP grassroots advocacy in advance of a scheduled Floor vote which has not been scheduled as of yet. A similar House bill H.R. 2212 has not had any action since its introduction in April 2017.

Federal Regulatory Update

AMCP Submits Comments to FDA on Patient-Focused Drug Development for Chronic Pain

In response to an [FDA public meeting](#) held in July 2018, AMCP submitted [comments](#) on patient-focused drug development for chronic pain. The comments include recommendations from AMCP's Addiction Treatment Advisory Group (ATAG) created in 2015 with recommendations released in 2016 and the Addiction Advisory Group (AAG) created in 2018 to build and continue the work of ATAG.



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AMCP's recommendations focused on the following barriers to adequate treatment for chronic pain management:

- FDA should collaborate with Congress to align confidentiality of drug and alcohol treatment and prevention records with HIPAA and allow stakeholder access to information essential for providing comprehensive patient care. AMCP notes that it is also working with Congress to codify these provisions. Pharmacists are integral members of teams of health care providers to identify individuals at risk of substance use disorder or would be appropriate for medication assisted treatment.
- FDA should work with states to ensure that managed care organizations have access to state prescription drug monitoring programs (PDMPs).
- Patients should have public and private insurance coverage and access to medications to curb opioid addiction, including reversal agents such as naloxone. AMCP encourages FDA to conduct further research on the clinical risk factors where co-prescribing of naloxone may be appropriate.
- FDA should develop and endorse standards for electronic prescribing of controlled substance prescriptions and promote interoperability of health information technology systems.
- Integrate opioid-related Risk Evaluate and Mitigation Strategies (REMS) processes into prescriber and pharmacy workflow.
- Collaborate with other government entities to develop continuing education and training health care professionals, including pharmacists, physicians, and nurses.
- Update labeling requirements to minimize the risk of diversion.

State Legislative Action

Status of 2018 Regular Sessions

With California now adjourned for the year, most states have wrapped up the 2018 legislative session. However, Massachusetts, Illinois, Ohio, Pennsylvania, New York, New Jersey, Michigan, Wisconsin and the District of Columbia may continue to meet throughout the year as needed. In total, 46 states and the District of Columbia convened this year, with all 50 set to convene in 2019.

California Legislature Passes AMCP Supported E-Rx Bill: Both the Assembly and Senate concurred on amendments to legislation (AB 2789), which puts in place electronic prescribing requirements across the state, and the bill was signed by Governor Brown Sept. 17. AMCP and the California Pharmacists Association both supported the passage of this legislation, and many members actively engaged in AMCP's action alert to their own state Senator. Thank you to our members who participated!

Drug Pricing Summary of State Legislation: As a majority of states have adjourned, AMCP prepared a summary report of Drug Pricing legislation as of August 2018. You can access the report [here](#).

AMCP 2019 Advocacy and Policy Focus Survey

AMCP is looking for members in several states to volunteer as State Advocacy Coordinators (S.A.C.). These volunteers serve as the Academy's go-to members in each state, and are called upon to inform legislators, stakeholders and other AMCP members on advocacy efforts at both the state and federal levels. States can have more than one S.A.C., so if you are interested and there is already an S.A.C. listed for your state, please contact us. Currently, 26 states and

the District of Columbia need a S.A.C. If you would like more information on becoming a S.A.C, please [click here](#) to see the role of a S.A.C., which states are available, and to access the application form.

Grassroots Outreach: Your Voice Matters

AMCP has two active grassroots alerts open to members each targeting the passage of the federal opioid package. The message is clear, a package passed by Congress needs to include provisions which allow Medicare Plans to suspend payment pending an investigation of fraud, which is already allowed in the fee-for-service side of Medicare. Another needed provision, moving Substance Use Disorder (SUD) record sharing under HIPAA for the purposes of treatment, payment, and healthcare operations, instead of the current 42 CFR Part 2. This would allow providers full access to a patient's medical records to ensure whole-person coordinated care and prevent potentially dangerous drug-drug interactions. Almost 300 letters have been sent by AMCP members to support both of these action alerts. Let your Senator know these need to be included in the final opioid package. There's still time to take part in these alerts by visiting AMCP's grassroots advocacy page today! Every letter makes a difference! Visit <http://amcp.org/advocacy/>

Call for Diplomats

AMCP is looking for new student chapter Diplomats! Diplomats are AMCP members who volunteer to work with a school/college of pharmacy as a resource for student pharmacists and faculty. They are utilized to further the awareness and education of managed care pharmacy. Visit the [AMCP Diplomat Center](#) and [apply](#) for an open position today!

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