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In This Issue

Spotlight on Biosimilars

U.S. Supreme Court Ruling Is Expected to Speed Market Entry of New Biosimilars

In a unanimous 9-0 ruling on June 12, the U.S. Supreme Court removed a legal barrier that has delayed manufacturers from marketing new biosimilars until six months after the product was approved by the Food and Drug Administration (FDA). Legal and industry experts expect the ruling to speed up market entry of new biosimilars. Two cases were before the Court—Sandoz v. Amgen and Amgen v. Sandoz—and both involved provisions of the Biologics Price Competition and Innovation Act (BPCIA) that address regulatory exclusivity and patent exclusivity periods. Under the BPCIA, the manufacturer of the innovator product (i.e., reference product) has 12 years of market exclusivity, as follows:

- A biosimilar manufacturer (applicant) cannot file an application for a biosimilar until four years after the date on which the innovator product (known as the "reference product") was first approved (licensed)
- In addition, the FDA shall not approve an application for a biosimilar until 12 years after the reference product's initial licensure date.

The procedure for resolving patent disputes—commonly referred to as the "patent dance"—includes several rounds of information exchange between the parties, with strict sequencing and timing requirements. Read more.

AMCP Comments on Draft Biosimilar Interchangeability Guidance Seek Additional Clarity Prior to Finalization

AMCP submitted comments to the FDA in response to the draft guidance document "Considerations in Demonstrating Interchangeability With a Reference Product." AMCP is pleased that FDA outlined a flexible, step-wise, and totality of evidence approach to demonstrating

Advocacy Tip

Each of us has countless opportunities to express an opinion about a legislative

interchangeability and avoided being too prescriptive, recognizing that a one-size-fits-all approach is not feasible given the complexity of biological and biosimilar products. However, AMCP recommends that FDA provide additional clarity to implement the biosimilar pathway prior to finalizing the guidance document. Specifically, AMCP focused on the need for postmarketing surveillance and pharmacovigilance, the use of foreign reference products for switching studies, and several outstanding issues not considered in the draft guidance document. AMCP's full comments are available here. AMCP also joined 10 other organizations in a joint letter to the FDA.

AMCP Comments on Biosimilars Pathway at FDA Oncologic Drugs Advisory Committee Meeting

On May 25, AMCP reinforced its position in support of a robust biosimilars pathway in the United States in remarks to the FDA's Oncologic Drugs Advisory Committee meeting. The purpose of the meeting was for the FDA's appointed advisory committee to consider a biosimilar application for a potential competitor to Amgen's Epogen/Procrit (eopoetin alfa). While AMCP did not comment specifically on the merits of the biosimilar application, AMCP's comments focused on the following areas:

- Support for the flexible approach taken by FDA to consider the totality of the evidence when determining whether products meet biosimilarity requirements;
- Reiterated position in AMCP response to draft interchangeability guidance (see story above);
- Support for active post-marketing surveillance for biologics and biosimilars and the proactive measures that AMCP has taken in this area, including the formation of the Biologics and Biosimilars Collective Intelligence Consortium;
- Continued concerns with FDA's final guidance on naming that requires the use of a random four letter suffix affixed to the nonproprietary name of all biologic products; and,
- Support for educational efforts by the FDA and other stakeholders. AMCP emphasized its commitment to education by highlighting its policy neutral website, the Biosimilars Resource Center, designed to educate health care providers, including pharmacists, physicians, and nurses about biosimilars.

The Advisory Committee voted 14-1 to recommend approval of the application for the biosimilar eopoetin alfa. Now, FDA regulators must consider whether to formally approve the application.

AMCP Submits Comments on Washington State Proposed Rule for Interchangeable Biologic Products

AMCP submitted comments to the Washington State Department of Labor & Industries supporting a proposed rule that would require the dispensing of an interchangeable biological product when available unless the provider specifically indicates that substitution is not permitted for the Washington Prescription Drug Program. Moving forward, AMCP encouraged the Washington Department of Labor & Industries to ensure that any updates to laws or regulations governing interchangeable biological products continue to align with the provisions of the Biologics Price Competition and Innovation Act and its implementing regulations and guidance documents. Read the full comments here.

Federal Legislative Update

Senate Health Care Working Group Releases Reform Bill

action. A letter or phone call to the right person can be the deciding factor. Remember, you can make a difference:

- Look for opportunities to voice your support. Follow a legislator on social media.
- Attend town halls. Ask questions and voice your opinions.
- Offer support by writing or calling legislators when they sponsor a bill that reflects your interests and also let them know when their actions are not supported by you.
- Recruit your family, friends, coworkers and neighbors to show their support.
- Don't give up. Advocacy is about persistence.

A Senate working group on health care released its health care reform proposal on June 22. The Congressional Budget Office (CBO) has yet to issue a cost estimate, but reported changes include rolling back provisions of the Affordable Care Act, cutting spending on Medicaid, and offering a substantial tax cut for the health care industry and the upper income individuals. Senate Majority Leader Mitch McConnell (R-KY) has stated that he plans to schedule a vote on the Senate version before the July 4th recess.

The Senate working group consisted of Lamar Alexander (R-TN), John Barrasso (R-WY), John Cornyn (R-TX), Tom Cotton (R-AR), Ted Cruz (R-TX), Mike Enzi (R-WY), Cory Gardner (R-CO), Orin Hatch (R-UT), Mike Lee (R-UT), Rob Portman (R-OH), Pat Toomey (R-PA) and John Thune (R-SD), and McConnell.

The Senate opted to write its own legislation rather than voting on the House bill, H.R. 1628, the American Health Care Act of 2017, which passed the House on May 4 by a 217-213 vote. The CBO estimated that H.R. 1628 would reduce federal deficits by $119 billion over the coming decade and increase the number of uninsured by 23 million in 2026.

The intense focus on this legislation has put on hold other health care legislation. Between the remainder of June and July, Congress is scheduled to be in session approximately 20 days. Congress will be in recess during August and return to session on Sept. 9.

Pharmaceutical Information Exchange (PIE) Act of 2017 (H.R. 2026) Considered by E&C Health Subcommittee

During a May 17 House Energy and Commerce (E&C) Health Subcommittee markup of PDUFA, Rep. Brett Guthrie (R-KY) spoke in favor of the AMCP-supported bill, H.R. 2026, the Pharmaceutical Information Exchange (PIE) Act of 2017. Guthrie entered a statement of support into the record and encouraged committee members to discuss any concerns that they might have with the legislation with him prior to the full committee markup of PDUFA. Rep. Greg Walden (R-OR) also spoke in favor of the legislation and his remarks included a direct quote from AMCP. Rep. Walden is also the Chair of the Energy and Commerce Committee.

House E&C Committee Approves FDA Reauthorization Act of 2017; PIE Amendment Is Not Included

On June 7 during the full House E&C Committee markup, the committee voted unanimously to approve H.R. 2430 – The FDA Reauthorization Act of 2017 (FDARA), which authorizes user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products.

During the markup, E&C members considered, but did not include as an amendment, H.R. 2026. AMCP strongly supports H.R. 2026, which aims to improve patient access to emerging medication therapies by clarifying the scope of permitted health care economic and information communications between biopharmaceutical manufacturers and population health decision makers.

AMCP CEO Susan A. Cantrell, RPh, CAE, commented on the Committee's consideration of H.R. 2026:

> *"Pre-FDA-approval communications took an important step forward in the June 7 discussion of H.R. 2026. We thank Rep. Guthrie for his leadership in championing this important legislation. We also commend E&C Chairman Greg Walden (R-*

OR) and Ranking Member Frank Pallone (D-NJ) for committing to work together in a bipartisan manner to address pre-approval communications that protect and benefit patients.

The PIE Act will help AMCP members better care for the patient populations they serve by enabling the implementation of value-based contracts, aiding in forecasting and budgeting, and expediting coverage decisions for emerging therapies granted breakthrough designation immediately upon FDA approval. AMCP looks forward to working with Representatives Guthrie, Walden, Pallone, and the members of the E&C Committee in the coming weeks to move this very important issue forward."

FDARA will now be considered by the full House and then move to the Senate. AMCP will continue to advocate for H.R. 2026 and its enactment in the coming months.

Upcoming Regulatory Comment Periods

AMCP is seeking stakeholder feedback on the following proposed rules that are currently open for comment. Please provide feedback via email to Soumi Saha, Assistant Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by the dates listed for incorporation into AMCP's comments on the matter. All of AMCP's final comment letters are available on the AMCP website and also included in the Legislative-Regulatory Briefing Newsletter that is sent to all AMCP members.

Topic	Stakeholder Feedback to AMCP Due	Comments Due
FDA: Comments on Training Health Care Providers on Pain Management and Safe use of Opioids	July 5	July 10
CMS: CY 2018 Updates to the Quality Payment Program	Aug. 7	Aug. 21
FDA: Administering the Hatch-Waxman Amendments	Sept. 5	Sept. 18

State Regulatory Update

Eye on State Legislatures

Only 16 states are still in session. Of them, Michigan and New York have pending legislation on biosimilar and interchangeable biologic products. AMCP has sent letters to each of these states expressing concerns with those proposals. View the letters: Michigan, New York.

A detailed map of current biosimilar and biologic legislative activity can be found here. A full list of all state bills that AMCP is tracking may be found here. AMCP's letters can be accessed at Letters, Statements and Analysis.

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