

Publications

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New Biosimilar Legislation Addresses Inflation Reduction Act Delay Provision

Key Update

- The Biosimilars Access and Affordability Act has been reintroduced in both chambers, which would create clearer criteria for delaying Medicare price negotiation of a reference biologic when a biosimilar is expected to reach the market within two years.

Why It Matters

- The proposal could give reference biologic and biosimilar manufacturers greater certainty about when the IRA's biosimilar delay applies, while making launch timing more consequential to negotiation exposure, potential rebates and settlement strategy.

Next Steps

- Manufacturers should evaluate how the proposed delay standard could affect development, launch and settlement planning, including the potential negotiation and rebate consequences if a biosimilar does not enter the market within the two-year window.

The Biosimilars Access and Affordability Act (H.R. 10628/S. 5571) has been reintroduced in both the House and Senate. The bill would alter when biosimilar biological products are eligible for price negotiations under Medicare.

The Inflation Reduction Act's (IRA) biosimilar delay provision allows Medicare to temporarily defer selecting a reference biologic for negotiation when a biosimilar competitor is expected to enter the market. Current law allows for a delay of up to two years, but the Centers for Medicare & Medicaid Services (CMS) has generally implemented it through separate one-year determinations and applied narrow and somewhat subjective qualifying criteria.

The bill would retain the two-year maximum while creating a clearer qualifying pathway based on concrete evidence that a product is moving toward market, such as FDA

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acceptance or approval of an application. Manufacturers would certify their expected launch information, with legal consequences for false certifications. A separate pathway remains for manufacturers that fall outside those criteria but can show their biosimilar is highly likely to reach market, and an ongoing patent suit alone would not disqualify a biosimilar. If the biosimilar is not licensed and marketed within the two-year period, the reference biologic enters the negotiation program and the reference manufacturer owes rebates covering the delayed years.

Takeaways for In-House Counsel Based on the Proposed Language of the Bill

- **Separate IRA eligibility from patent litigation.** Unresolved patent litigation may make a biosimilar launch appear uncertain, but the proposed legislation expressly prevents the existence of litigation, by itself, from defeating an IRA biosimilar delay. The relevant inquiry instead becomes whether the manufacturer can satisfy the applicable statutory pathway and support an anticipated launch within the two-year window.
- **Reassess litigation and settlement economics.** Under the language of the bill, reference biologic manufacturers should evaluate the potential negotiation and rebate consequences if timely biosimilar entry does not occur, including where patent enforcement affects the anticipated launch date. Both reference and biosimilar manufacturers should assess settlement launch dates, payments and quantity restrictions against the IRA's existing agreement restrictions and the separate proposed antitrust legislation.

There has been growing congressional attention on biosimilars this Congress:

- The Biosimilar Red Tape Elimination Act would eliminate the separate interchangeability designation;
- The Expedited Access to Biosimilars Act would confirm that certain comparative clinical studies are not a default expectation for approval; and
- The Preserve Access to Affordable Generics and Biosimilars Act is a bipartisan antitrust measure that would bar branded manufacturers from paying biosimilar developers to delay entry. It has cleared Senate Judiciary.

These bills show where Congress's focus is on lowering barriers to biosimilars. The Biosimilars Access and Affordability Act is notable for taking up the IRA itself. Sponsors are framing it not as a reopening of the negotiation program but as a correction restoring the delay provision's original intent.

Manufacturers should expect biosimilar policy to remain active into 2027 and may want to consider how a changed delay standard would interact with development and launch planning. Polsinelli's Washington, D.C. Public Policy Group closely follows federal activity affecting drug developers and pharmaceutical market access and would be pleased to serve as a legislative and regulatory resource. Please contact Eli Greenspan, Sylvia Kornegay, Corey Casey or your preferred Polsinelli attorney.