

Uptake and Pricing of Biosimilars & the “Rebate Wall”

A Value & Innovation Forum Multi-Perspective Briefing



About

The Value & Innovation Forum helps patients, providers and other health system stakeholders address timely, complex issues by conducting briefings that present a variety of perspectives. A June 2, 2020 briefing covered the uptake and pricing of biosimilars, and the related delivery system practices that may impact them.

Speakers

- **John M. Clymer**, Executive Director, National Forum for Heart Disease & Stroke Prevention
- **Nicole Braccio, PharmD**, Policy Director, National Patient Advocate Foundation
- **Christine Simmon, J.D.**, Senior Vice President, Policy & Strategic Alliances, Executive Director, Biosimilars Council, Association for Accessible Medicines
- **Sarah Yim, MD**, Director, Office of Therapeutic Biologics and Biosimilars, Office of New Drugs, Center for Drug Evaluation & Research, U.S. Food and Drug Administration
- **Chad Pettit**, Executive Director, Global Value Access and Policy, Amgen
- **Madelaine A. Feldman, MD**, Practicing Rheumatologist, President, Coalition of State Rheumatology Organizations

Summary

Nicole Braccio:

- National Patient Advocate Foundation has advocated for lower cost alternatives and biosimilars are just one example of that.

- “In general, patients want to be part of the discussion, and want a seamless process to access the best treatment for their condition.”

Madelaine Feldman defined the so-called “rebate wall” and why it is controversial. She argued that delivery system practices impact the pricing and uptake of biosimilars.

- Higher prices and large market share determine preferred formularies. “Right off the bat, biosimilars are behind the eight ball, with lower prices and no market share.”
- “You have a preferred drug, offering rebates. Along comes a new biosimilar, which is less expensive. How do they compete? The preferred drug will pull back all the rebates if they lose preferred status, and since they [already] have market share, the PBM will lose all that money. That’s the ‘**rebate wall**’ because it creates a boundary that prevents other products from entering the market. It doesn’t even need to be in the same therapeutic area. The manufacturer can leverage their rebates in other areas too, so it can be anti-competitive. This is completely legal. The rebates and fees are all kick-backs, but the middleman (PBM) has safe harbor from the anti-kick-back laws.”
- A manufacturer competing for formulary placement may raise its list price, and then “discount a rebate to PBM.” The higher priced drugs offering the same percentage back to PBM, look better to a PBM because they get back more money in the rebate. “Yes, there is competition, but it drives the price up.”
- “We’ve heard about rebates, but there are also fees based on the list price of the drug. These fees don’t get passed back to the employer or insurance, but are kept by the PBM.”
- There are no [marketed] Part D biosimilars and rebating is different in Part B/‘medical’ side. “We have seen biosimilar prices come down. There is success in some areas... biosimilars that are prescribed more.” Physician offices use more biosimilars than hospitals. “There is an inventory that needs to be managed. As a physician, once I purchase [a drug], I can only use [it] on the [intended] patient, and if the patient leaves, the physician needs to deal with that loss. As soon as we get other biosimilars [in rheumatoid arthritis], we can get a better idea how this rebate wall is working. There are many successes in the market.”
- Recommendation: “I would have manufacturers compete on efficacy, safety and lowest price. This would be a way to correct the fees, rebates, and price protection fees that are kept with the middleman. But no one would like this project: Manufacturers would see it as a race to the bottom, PBMs wouldn’t be able to make money, [but] the patients would benefit. If we really want free market and competition to bring prices down, this would be the demonstration that would make the most sense.”

Christine Simmon:

- The Association for Accessible Medicines (AAM)’s “purpose is to educate, advocate, and promote biosimilars. We believe [biosimilars] will provide access to needed medication, which hold the key to affordable access to needed medications. Our focus is on incentives for providers, patients, and payers to increase utilization and uptake of biosimilars.”
- Only 17 of the 26 FDA-approved biosimilars are currently on the market. “We want to do whatever we can to improve utilization. It’s not just about leveling the playing field, but actively promoting.”
- Simmon supports incentives for prescribing biosimilars, citing support for pending legislation that “might help Medicare Part B by creat[ing] an incentive of 8% (from [ASP+6%].”
- “Pure players” are companies that only make branded or biosimilar products but not both.” For them, the rebate trap is “a huge problem.” “The pervasive problem with biosimilar utilization, and therefore biosimilar development and investment, is the lack of transparency in how the rebate wall is really impacting payers and patients.” She cited a Journal of Medical Affairs (JAMA) article from last month, “show[ing] biosimilars are only preferred 14% of the time by major payers. Considering

that biosimilars are 30% cheaper than reference biologics, that is a disheartening rate of coverage. I do not think biosimilars are doing fine. I think there is tremendous potential, and the ones on the market are delivering value and savings for patients and increasing access.”

- Simmon called for a policy “something like a **shared savings program**, so that both patients and providers can share in Medicare B, an opportunity to do a demonstration program that AAM and others across the industry would like to see CMS take up, to lower prescription prices and incentive biosimilars in Medicare Part B. There are also opportunities in Medicare Part D where out of pocket savings can be made by providing Additional formulary tiering.”
- “We are hoping CMS could implement a model to give providers and patients an opportunity to share in the savings, at a rate depending on data when a biosimilar is prescribed. This would benefit not only the Medicare Part B [program], but also providers and patients. Win-Win-Win across the board.” She noted that this was tried successfully in the EU, where it was called “gain sharing.”
- She referenced newly released, AAM-supported report on lessons learned from the EU (see references).
- Simmon agreed with Pettit’s data. “The price reductions are noticeable when there are multiple biosimilars for a reference product.”

Chad Pettit:

- Amgen has a robust product portfolio, a growing number of biosimilar products... [having]... “invested \$2B in a portfolio of 10 biosimilars, a far larger stake than most companies.”
- “We see the US [biosimilars] marketplace taking off, and we are experiencing that at Amgen.” “[W]hen we launched biosimilars [for two oncology reference products], we saw payers move very quickly. In terms of market access, we’ve got coverage in most national accounts and Medicare. In one case, we had a commercial insurer make a decision to prefer both products over the reference products. In terms of revenue, Amgen’s biosimilars [revenue] is over \$1B, realizing 30% or more market share. We haven’t experienced a rebate wall.”
- Pettit disagreed with Simmon: Amgen does not see a need to force biosimilar prescribing or new policy. “Manufacturers just need a level playing field to compete. We are seeing pretty good uptake in terms of competition. The EU is a “decade ahead of us, [so] if we were to time adjust US launches to EU, we are actually ahead on regulatory approvals. At the same point in time, they had 18 and we have 26. The rebate issue is important, but in our experience has not been a detriment to us.”
- Manufacturers need to compete on more than price, including real world data, clinical data, manufacturing expertise, reliably supplying, manufacturing patient support and education. “Product attributes are also important; issues like packaging, storage, stability, excipients, dosage forms, strengths, how the devices are designed (e.g. self-injectable devices). All are important in the broader competition.”
- Agreed with Feldman’s point on Part D versus B rebating, “[W]e are seeing prices declining in both the innovators and the biosimilars. He provided some interesting statistics. “As examples, we have seen a 36-45% decline in average selling price vs originator selling prices at launch where biosimilars have been on the market for 2 years. Where biosimilars have been on the market for 1 year, we see a 12-22% decline in price. Reference prices are coming down as well: [reference product that treat anemia saw a] 19% decline once the biosimilar entered the market. We are seeing innovator prices and biosimilar prices are providing savings for Medicare and commercial payers, which I think works its way through the patients.”
- Responding to Simmon and Feldman proposals, Pettit said “I agree things that put more money in patients’ pockets would be constructive.” However, “we don’t feel [legislation creating advantages for biosimilars] is needed in the US marketplace.” He opposed government intervention, saying it

could hinder a “thriving marketplace.” He opposed any legislation that would reimburse with a preferential add-on payment for biosimilars.

- Responding to comments about the EU, Pettit said “my personal take away is that EU is not a country. It’s actually many countries with many different systems. If we look at extremes in EU, there are examples of companies that have forced prices down to generic level.” He argued this has led to fewer bids in the EU. “The sustainability needs competition to find price point.” But we have also seen that competition works in the EU. For examples in the UK, they use a tendering system which is multi-winner. Kind of like a ‘parity formulary’ here. [It] allow[s] the physicians to choose what is right for their patients.” He shared that both Norway and Mexico have started to walk back their approach to comparing products on just price.

Sarah Yim provided background on the law that “set the regulatory framework for reference products, biosimilar products, and interchangeable products.

- Subject to state laws, interchangeable biosimilars can be substituted for one another without the intervention of the health care provider.
- “[B]iologics are more complicated to think about than chemicals, which is why misleading statements are so easy to make. I have heard that ‘biosimilars are not the same.’ But neither are the original biologics.”
- FDA “has limited ability to do anything about pricing. FDA is collaborating with FTC to deal with anticompetitive behavior.” She noted the joint FDA/FTC Workshop on March 9, 2020, and the guidance out on promotional labeling. She also mentioned Congress’ passage of the CREATES act in Dec 2019. “That is about reference product sponsors that use their REMS [Risk Evaluation and Mitigation Strategies] to prevent biosimilar sponsors from getting samples to develop biosimilars. “Now there is a law that gives the ability to take them to court if they can’t get samples. So, there are a number of things that are improving on anti-competitive behavior.”

Resources:

- [FDA Biosimilars](#) for access to educational materials and information about biosimilar and interchangeable products.
- [Drugs@FDA](#) for information on all FDA approved drug products, including labeling and review information.
- [FDA Advisory Committees](#) for drug advisory committee meetings and materials related to biosimilars
- [FDA Purple Book](#) a database of Licensed Biological Products for information on biological products, including if products are biosimilar to a reference product.
- [Amgen Biosimilars](#)
- [Lessons for the United States on Europe’s Biosimilar Experience](#)
- [Formulary Construction in America: ‘Perfectly Legal’ and ‘Perfectly Wrong](#)
- [Op-Ed: Debate Over Pharmacy Benefit Managers a Matter of Price vs. Cost](#)
- [Washington Must Change the System That Encourages High Drug Prices](#)

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