The Brink of the Biosimilar Revolution

Although biosimilars have not had the immediate uptake in the United States that they have had in Europe, health plans expect these products will become a staple of therapy for some diseases by 2020—if the price is right.

Since the first biosimilar was approved in the United States in 2015, brand marketers have been bracing for the impact, given Europe's fairly broad adoption of these products. But so far, biosimilars have not had a seismic effect on the U.S. market. This has been disappointing for both medical and pharmacy directors in U.S. health plans, who are eager to reap potential cost savings from biosimilars.

So why has the biosimilar revolution been on hold in the United States? There is no single reason; rather, there are multiple factors, including:

1. Pharma in-fighting over patents and other issues;
2. Aggressive discounting and rebating by innovator companies; and
3. Regulatory uncertainty and lack of interchangeable products on the market (Figure 1).

Figure 1
Three Types of Factors Have Derailed U.S. Biosimilar Adoption

Pharma in-fighting

- Market entry of approved biosimilars has stalled due to patent litigation between biosimilar and innovator companies.
- Arguments between companies, including disagreements over naming conventions to accusations of counter-detailing practices, have complemented ongoing legal battles.

Pricing and contracts

- Biosimilar discounts did not meet payer expectations upon launch.
- Innovator companies have proactively re-negotiated existing contracts to preserve brand formulary placement.

Regulatory uncertainty

- Lack of early FDA guidance in biosimilar adoption.
- Current biosimilars have not been deemed "interchangeable" and therefore can not be automatically switched at the pharmacy level.

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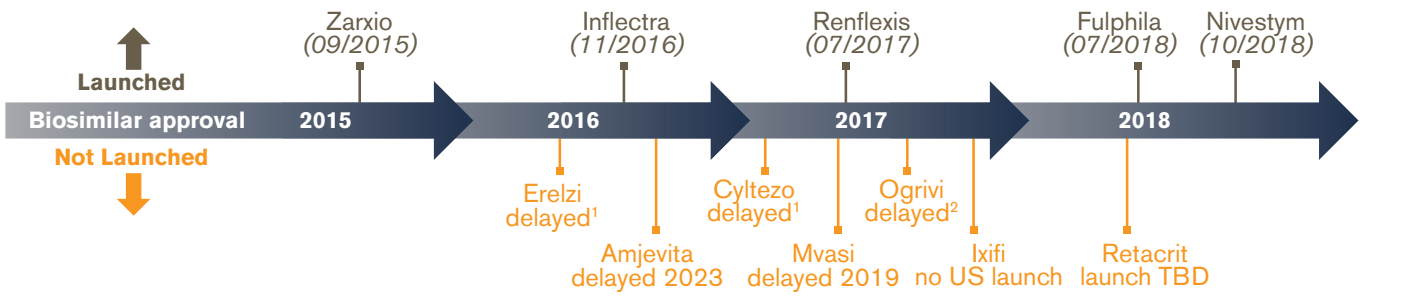
Following are explanations of each factor.

Pharma in-fighting over patents and other issues. Pending patent litigation between innovator companies and biosimilar developers has been a key factor in slowing biosimilar adoption in the United States (Figure 2). Legal battles over naming conventions, as well as accusations of counter detailing practices, also have stalled the biosimilar revolution. As a result, only three biosimilars—Sandoz/Novartis's Zarxio and Pfizer's Inflectra and Renflexis—have been fully launched and marketed in the United States as of mid-2018.

Figure 2
Biosimilars Approval Timeline: Approval Has Not Led to Launch



[1]Ongoing litigation.
[2]Undisclosed settlement agreement.

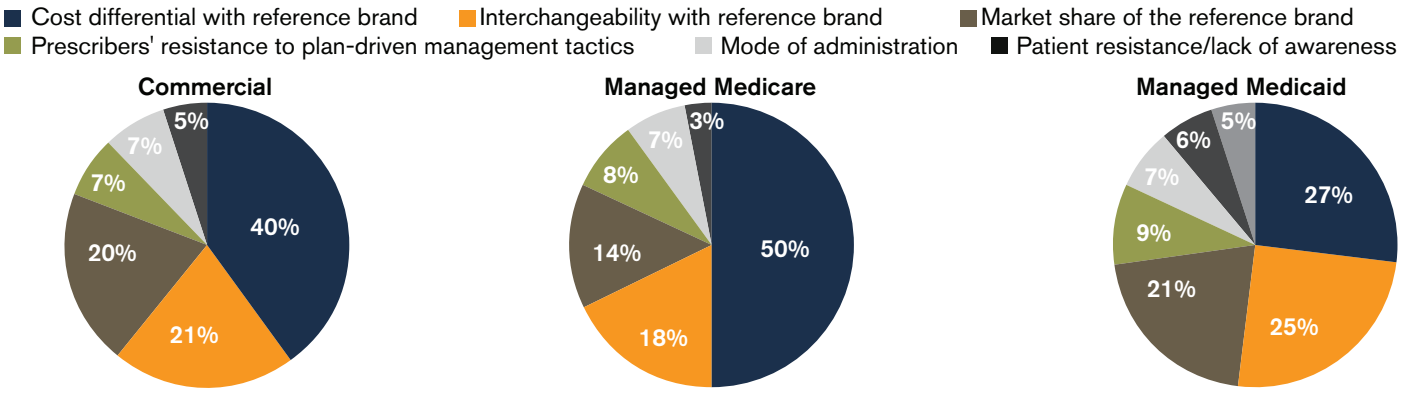
Aggressive discounting and rebating by innovator companies. In addition to company squabbles, the pricing and contracting strategies of innovator companies also have slowed biosimilar adoption in the United States. Innovator companies have discounted their reference products aggressively, giving health plans little incentive to switch to biosimilars. For example, health plans continue to favor Janssen's Remicade despite biosimilar competition. The company's aggressive contracting and pricing tactics convinced many commercial payers, especially national plans, to keep Remicade as their preferred infliximab product in 2018.

In general, health plans say the net cost differential between biosimilars and reference drugs has the greatest influence on their decisions to drive or not drive biosimilar use. And biosimilar companies are catching on. The recent launches of Mylan's Fulphila and Pfizer's Nivestym included deeper discounts—at least 30% off the reference brand wholesale acquisition cost (WAC)—than the three previously marketed biosimilars.

Regulatory uncertainty and lack of interchangeable products on the market. Health plans also blame the lack of biosimilars deemed "interchangeable" by the U.S. Food and Drug Administration (FDA) for their slow uptake of these products (Figure 3). To date, there are no interchangeable biosimilars on the market in the United States, in part because FDA guidance on demonstrating interchangeability has created confusion for biosimilar makers. As one health plan pharmacy director put it, "The lack of interchangeability has hurt existing biosimilars, but also the parents of the reference drugs have been very good at giving discounts."

Figure 3
High Cost and No Interchangeability Impede Access

(Average level of importance of factor in health plan decision making)



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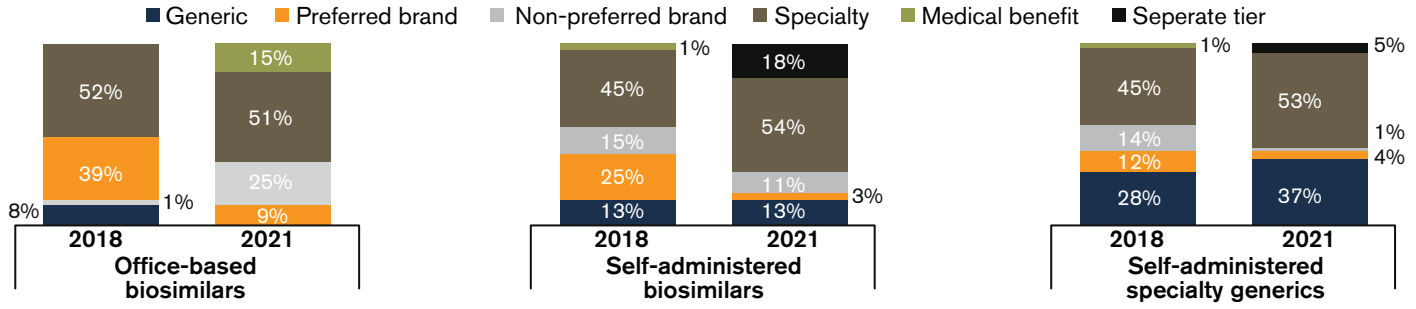
Biosimilars, Reference Drugs Often Share the Same Tier

For the most part, commercial health plans have been hesitant to advantage biosimilars due to the aggressive contracting strategies of companies with reference brands. In the absence of significant cost savings, plans view biosimilars as new competitors in their classes and often place them on the specialty or non-preference brand tier (Figure 4). As one pharmacy director said, "It's a matter of contracting. It's almost like dealing with another brand. We are in a situation where most biosimilars are on the same tier as the innovator."

Figure 4
Pharmacy Benefits Include Biosimilars on Specialty Tier

(Percentage commercial plans covering agents by tier, weighted by lives)



In recent biosimilar launches that did not include significant discounts, health plans have favored soft management tactics (Figure 5). These include educating patients and providers on the benefits of biosimilars or providing lower cost sharing for biosimilars.

Still, one-quarter of commercial plans maintain coverage of the reference brand—excluding the biosimilar completely—thanks to aggressive contracting by innovator companies.

Figure 5
Plans Implement Multiple Tactics to Manage Biosimilars

(Percentage health plans indicating using tactic to promote biosimilars/specialty generics after launch)

	Commercial	Managed Medicare	Managed Medicaid
Actively switch patients from reference brand to biosimilar/speciality generic	22%	20%	18%
Require biosimilar/speciality generic for newly diagnosed patients	4%	9%	19%
Require trial of the biosimilar/specialty generic before allowing access to the reference brand	25%	16%	21%
Provide lower cost sharing for biosimilar/speciality generics	7%	2%	1%
Provide incentives or preferential reimbursement to motivate prescribers	10%	1%	5%
Educate patient/providers on the benefits of biosimilar/speciality generics	26%	67%	56%
Will not cover biosimilars–will maintain reference brand at current coverage status	**25%**	**2%**	**6%**

A Shifting Political Climate

Recent events suggest that the biosimilar revolution finally could be coming to the United States. The Trump administration has signaled a willingness to implement policies that tip the scale toward biosimilars. For example, the FDA has launched a multistep process to increase competition in the biosimilar market. In July 2018, the FDA released its Biosimilar Action Plan to streamline the approval process, provide more guidance for companies, and limit tactics by innovator companies to delay competition. That same month, the FDA also issued final guidance on biosimilar labeling and promised to update guidance on how biosimilar developers can delineate between specific indications against reference brands.

Meanwhile, the Centers for Medicare & Medicaid Services (CMS) has changed its Medicare Part B policy so that biosimilars are no longer required to be grouped in the same billing code as reference biologics. And in August 2018, CMS indicated that Medicare Advantage plans could use step therapy for Part B drugs, including biosimilars. Additionally, biosimilars are now eligible for Medicare's Part D coverage discount gap program.

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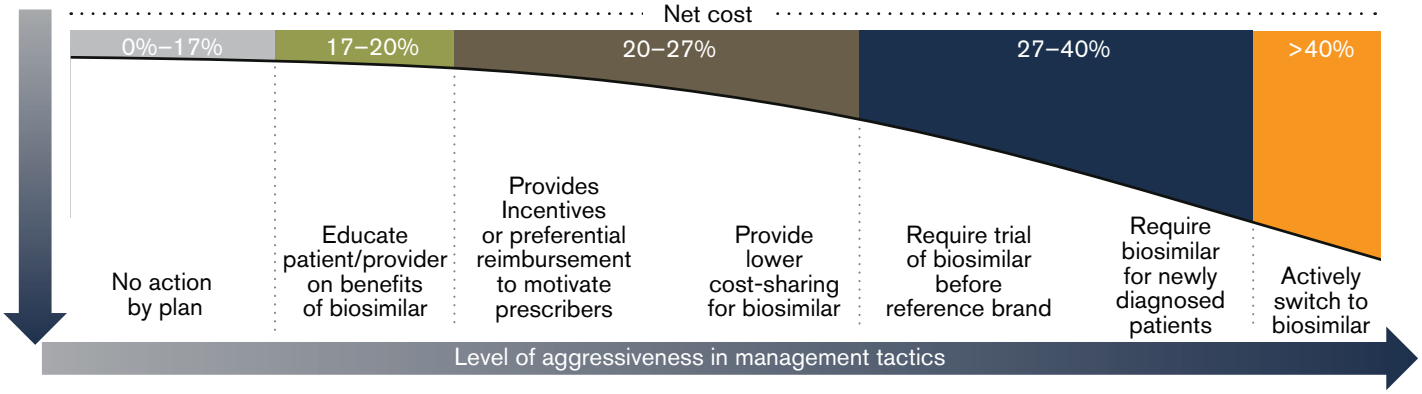
Looking Ahead

Although biosimilars have not had the immediate uptake in the United States that they have had in Europe, health plans expect these products to become a staple of therapy in some therapeutic categories—namely oncology and autoimmune diseases—by 2020. Organized providers are also on board. Concerned about rising healthcare costs, providers say they are more willing to prescribe biosimilars, especially in light of a growing body of data supporting the use of these products.

But before the revolution can occur, biosimilar companies will need to offer steeper discounts to health plans. Pharmacy and medical directors say they will require at least 40% off net cost to actively switch from brands to non-interchangeable biosimilar injectables (Figure 6). If biosimilar companies choose to offer smaller discounts, health plans will still take some action to advantage biosimilars—such as providing lower cost sharing or requiring a trial of a biosimilar before the reference brand—but they will be less likely to actively switch to biosimilars.

Figure 6
Non-Interchangeable Biosimilar Injectable

(Average percent discount off net cost required for health plan to implement tactic)



The robust biosimilar pipeline also will help fuel the revolution. Once multiple biosimilar competitors become available for each reference brand, health plans will expect meaningful discounts from biosimilar makers. Pfizer's Nivestym is a good example. To help differentiate Nivestym from another biosimilar, Sandoz/Novartis's Zarxio, Pfizer introduced its product with a WAC price lower than those of both Zarxio and the reference biologic, Amgen's Neupogen.

If other companies follow suit as more biosimilars are approved in each class, the biosimilar revolution may finally reverberate through the U.S. market.

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