SPECIAL REPORT

The Biosimilars Market in 2023:
Important Trends and Milestones for Chronic Disease Patients

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Late last year, Patients Rising hosted a roundtable to discuss the future of the biosimilars market and why many experts and observers believe 2023 could be a game-changing year for biosimilars.

The roundtable panelists discussed several unique marketplace developments and scheduled shifts in public policy relating to biosimilars that could have a significant impact on patients hoping to improve the quality of their care and reduce their health costs.

These developments include:

- The end of market exclusivity and the introduction of competing biosimilars for Humira, the top-selling medication in the world
- Implementation of the Inflation Reduction Act, including provisions designed to promote biosimilars and reduce drug costs
- Supreme Court consideration of certain labeling practices for biosimilars

After a discussion of these issues – and their potential ramifications for patients – this report will provide a broad overview of the current state of the biosimilars marketplace in the United States. Finally, it will offer general guidance to patients on how to consider their options when determining which biologic treatments are right for them.
Roundtable Panelists

Robert Popovian, PharmD
Chief Science Policy Officer
Global Healthy living Foundation

Sameer Awsare, MD
Executive Director
The Permane Medical Group

Wayne Winegarden, PhD
Sr. Fellow & Director for Medical Economics
Pacific Research Institute

Peter Pitts
President
Center for Medicine in the Public Interest

Vickie Wilkerson
Patient Advocate

Terry Wilcox
CEO
Patients Rising

MacKay Jimeson (Moderator)
Executive Director
Patient Access & Affordability Project

The Biosimilars Market in 2023
Biosimilar Competition for the World’s Top-Selling Medication

After several years of anticipation and litigation, AbbVie’s period of exclusivity for Humira – a biologic immunosuppressive and the world’s top selling medication – has expired and at least seven biosimilar alternatives will be launched over the course of the coming year (See FIGURE 1).

**Figure 1: Humira Biosimilar Launches Expected in 2023**

(As of January 15, 2023)

*Boehringer Ingelheim’s Cyltezo will be the first Humira biosimilar launched with an “Interchangeable” designation from the Food and Drug Administration. Pfizer’s Abrilada will be the second.*

What does this mean for patients?

The introduction of so many competing biosimilars for a medication like Humira presents something of a test case – not only for patients hoping market competition will lower their costs, but also for observers looking to assess the strengths and weaknesses of the regulatory system for biosimilars. While some project that Humira biosimilars could generate nearly $20 billion in total savings over the next two years, it is unclear how much of those savings will directly benefit patients.

“This biosimilars have largely been covered and priced under medical benefits and now more of them are going to be covered by pharmacy benefits. Patients tend to feel the financial pain more severely in the pharmacy benefit than they do in the medical.”

-Terry Wilcox

This is true for several reasons.

In the past, most available biosimilars have been for biologic originators administered in a clinical setting by a healthcare professional. In such cases, the provider bills an insurer and coverage is provided under the patient’s medical benefit. This model offers transparency, allowing for a direct comparison between the average sales price of an originator biologic and any biosimilars. Data gathered under Medicare Part B’s medical benefit show how increased competition from biosimilars can bring down prices and lower patients’ out-of-pocket costs.
However, because Humira is delivered through specialty pharmacies, it is covered under a patient’s pharmacy benefit, which means, for most patients, coverage and pricing are determined by pharmacy benefit managers (PBMs). Through private negotiations and confidential contracts with manufacturers, PBMs set coverage limits and prices with very little transparency.

"The retail price or the average wholesale prices for the biosimilars are going to be similar to Humira’s current price. What you will see is fierce competition on the back end. The three largest PBMs, which manage about 80-90% of the market will compete to get huge concessions from the manufacturers."

-Dr. Robert Popovian

The interests of patients and those of the third parties controlling their pharmacy benefits do not always align. While it would intuitively be in a PBM’s best interest to negotiate lower prices for medications, they often receive rebates from manufacturers based on the list prices. If a PBM places a lower cost biosimilar on a higher preference tier than its originator, it could lose out on rebates. This can create an incentive for some PBMs to negotiate in favor of higher rebates – and steer patients toward more expensive originator biologics – instead of lower costs. Or, because these arrangements are decided behind closed doors, a PBM can simply opt to reduce its own costs by offering coverage for more biosimilars without passing along those savings to patients.

The added competition of so many Humira biosimilars will almost certainly bring down costs. But, it is the largest PBMs - not patients - that will likely end up being the primary beneficiaries.

According to recent surveys of insurers, most plans intend to cover Humira and its biosimilars in one of three ways: 1) set higher preferences for the originator name-brand product; 2) offer coverage for both the originator and a set number of biosimilars without any preference; 3) set higher preferences for specified biosimilars. Patients will ultimately have little say in the coverage options offered by their plans. Every insurance plan could produce a different list of Humira-related products that it will cover to varying degrees. Therefore, patients should be prepared for possible changes if their current treatment regimen includes Humira.

"We (Kaiser Permanente) have never supported rebates. We just say: Lower the price."

-Dr. Sameer Awsare
Some biosimilar manufacturers conduct additional clinical studies to obtain an “interchangeable” designation from the FDA. Much like generic drugs, interchangeable biosimilars can be substituted for the reference product at a pharmacy without prior approval from the prescribing doctor, subject to the limits and requirements of state law. Patients should consult with their doctor and pharmacist to determine what rules apply in their state.

Doctors can prescribe whatever medication they think is appropriate for their patients, regardless of any interchangeable designation from the FDA. Patients should consult with their doctors to answer any questions before switching to a biosimilar.

The first biosimilar for Humira with an “interchangeable” designation will be launched in the U.S. in July 2023, with another set for release in December. (See FIGURE 1).

“There is really no such thing as automatic substitution by the pharmacy. Benefit design will drive the patients to take a generic or a biosimilar, because, the way plans are designed, out-of-pocket costs are going to be significantly higher for the brand name drugs.”

- Dr. Robert Popovian

Patient Questions & Concerns About Humira Biosimilars
New Options on the Market

Humira Biosimilars: Safety & Effectiveness

Any patient being treated with Humira or any other originator biologic should consult with their doctor about switching to a biosimilar. This is true whether the change is the result of insurance coverage or a patient’s desire to lower their own costs.

However, they should also know the FDA applies rigorous standards when approving biosimilars. Manufacturers must present extensive clinical evidence to demonstrate that patients treated with a biosimilar will experience the same safety and efficiency profile with no clinically meaningful differences from the originator product.

Interchangeable: What does it Mean?

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Starting in October 2022, doctors administering biosimilars with a lower average price than their originator have received a two-percent increase in reimbursements under Medicare Part B’s medical benefit. This change - which is designed to promote the use of biosimilars over more expensive options - will remain in effect for the next five years.

However, when it comes to Medicare and drug pricing provisions in the IRA, most have focused those allowing the Department of Health and Human Services (HHS) to negotiate prices under Medicare Part D’s prescription drug benefit. Under that section, biologics that have been on the market for 13 years or more could be subject to negotiation, which will essentially dictate lower prices for Part D beneficiaries.

There are differing views among stakeholders about the potential impact of price negotiation for the biologics market. Several industry leaders – many of whom represent companies that produce both originator biologics and biosimilars – believe it will reduce the number of biosimilars in development. They argue that if negotiations – or the threat of future negotiations – force manufacturers of originators to lower prices, biosimilars will lose some of their competitive advantage and there will be less incentive to bring them to market.

Proponents of the IRA argue the Medicare negotiation system is designed to encourage more rapid introduction of biosimilars. Starting in October 2023, HHS will identify and select 10 medications – biologics or otherwise – for future negotiations, based on pricing and the competitiveness of the market.

Under the law, biologics will not become subject to price negotiation unless they are past their statutory exclusivity period and there are no biosimilars set to enter the market within the next two years. Supporters of price negotiation believe this will prevent producers of originator biologics from taking steps to slow down the introduction of lower cost biosimilars.
What does this mean for patients?

At this point, the real-world impact of the IRA’s drug-pricing provisions remains unclear. It is probably safe to assume prices for the medications selected for negotiation will be going down within the next few years. Stakeholders – including patients – will likely have to wait a few more years to determine what ramifications these changes will have on the production, marketing, and pricing of biosimilars in the future.

“What you’ve done is impose a tax on research and development. When you tax something, you get less of it. The bottom line is price controls discourage R&D and that’s to the detriment of patients and the broader healthcare system.”

-Dr. Wayne Winegarden

“The question becomes: Who exactly is recognizing all of these savings? And obviously it’s the payers. You can go through complicated mathematics and talk about trickle down effects, but at the end of the day, when copays and premiums don’t go down, it’s a lot of hot air for patients.”

-Peter Pitts
The Supreme Court and the Future of Patent Rules for Biosimilars

The U.S. Supreme Court is currently considering whether to take up a dispute over “skinny labels” for generic drugs and biosimilars. The decision by the Court on whether to hear this case – let alone a final ruling – could have a rippling effect on biosimilar markets.

Put simply, U.S. law gives a manufacturer of an originator biologic 12 years of market exclusivity for their product. However, in some cases, the manufacturers of an originator can take steps to delay the launch of biosimilars, including petitioning for supplemental exclusivity to cover new indications for the product that were developed after its initial approval and launch. Essentially, this gives the originator added years of exclusivity for new uses of their medication that may continue long after their original grant of has expired. To prevent companies from using this approach to block competition, the FDA often approves “skinny-label” biosimilars that can be marketed and prescribed for a limited range of uses where the originator’s exclusivity has expired.

The case currently under consideration at the Supreme Court is a dispute between the manufacturer of a heart medication and a producer of a generic version of the same drug. The FDA approved the generic with instructions to exclude from its label several uses for the original medication that were still covered by the patent.
In the initial lawsuit, the generic company argued that it followed the FDA’s instructions, but the jury ultimately decided its label and marketing materials encouraged doctors to prescribe the generic in a way that infringed on the patent. This decision was ultimately affirmed by a higher court.

In October, after the generic manufacturer petitioned for review of the case, the Supreme Court asked the Biden Administration for its views on the matter. It is unclear at this point whether the Court will decide to hear the case. However, the Biden Administration called for a joint meeting on January 19 between the U.S. Patent Office and the FDA to gather input from patients, caregivers, industry, and the public at-large. Patients can submit written comments to the agencies on this topic up until February 6 (link below).

“*It’s a frontal assault on intellectual property rights. It is extremely dangerous.*”
- Peter Pitts

### What does this mean for patients?

While the case does not directly involve biologics, more than half of the biosimilars approved by the FDA before 2022 were launched with a skinny label. So, if the Court opts not to hear this case, it will effectively let a $235 million judgment against a generic drug manufacturer stand. This could have a chilling effect on both generics and biosimilars as companies will have to factor in additional risks of infringement claims relating to their labels. Manufacturers may avoid releasing a biosimilar altogether until the originator’s exclusivity has expired entirely. Yet, if the court takes up the case and then issues an unfavorable ruling for medications approved with skinny labels, the chilling effect could be even more severe. Either outcome would likely mean more delays for the introduction of competing biosimilars and reduced near-term savings for patients and the overall health system.

*Click [HERE](#) if you would like to submit a comment for the record of the joint meeting between the FDA and the U.S. Patent Office. The Deadline is February 6.*
The regulatory system providing a shortened pathway for the approval and marketing of biosimilars was established by Congress in 2010. The FDA approved the first biosimilar in the U.S. in 2015. Over the next five years, the number of biosimilars approved and marketed increased dramatically (See FIGURE 3).

While biosimilar approvals slowed down in 2020 and 2021 – due to COVID-19 pandemic and other factors – the numbers rebounded in 2022 and most observers expect both approvals and launches will return to their pre-pandemic levels in the near future. As of the end 2022, the FDA has approved 40 biosimilars for 11 different reference products. Of that number, 25 of have been introduced into the market by manufacturers. Currently, there are more than 100 proposed biosimilar products listed in the FDA’s development pipeline.

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Evidence strongly suggests the increase in the number and variety of biosimilars has created significant savings in the U.S. healthcare system. Biosimilars in U.S. markets typically launch with initial list prices that are 15% to 35% lower than their reference products. Competition from biosimilars has also lowered prices of reference biologics by an estimated average of 56 percent. According to Amgen’s most recent Biosimilar Trends Report, biosimilars have saved the U.S. healthcare system roughly $21 billion over the past six years.

Once again, the impact of biosimilars on patients’ out-of-pocket costs is much less clear. The system for approving and marketing biosimilars was ostensibly designed to lower costs for patients. However, decisions regarding pricing and coverage are often made by third parties – like insurers, PBMs, and other payers – whose interests do not always align with the interests of patients.

"In institutions where incentives are aligned, patients will see the savings. But we know that, in the current system that covers 90% of the patients, that’s not the case. Patients are not going to see the savings at the point of sale and the premiums are not going to be impacted. So, whenever a PBM says the net price is lower, the question should be: For whom?"

-Dr. Robert Popovian

### Figure 3: Biosimilars Approved & Released in the U.S.

<table>
<thead>
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<th>Year</th>
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<th># of Biosimilars Released in the U.S. Market</th>
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Source: FDA-Track Dashboard
Conclusion - Guidance for Patients

America leads the world in medical innovation largely because we reward meaningful advances in science and medicine with short term market exclusivity to let them recoup their investments. One of the benefits of this system is that, when those terms expire, competitors can turn these effective treatments into commodities, allowing more patients to access them at lower costs.

We know biosimilars are creating meaningful savings for the health system and the promise for future savings is even greater. The question that remains is whether insurance plans will allow patients to meaningfully participate in these savings. This is the critical question for lawmakers, regulators, health insurers and health systems as the next phase of the biologics market – which includes meaningful biosimilar competition – unfolds.

Whenever a patent expires on any medication, patients being treated with the originator should see their out-of-pocket costs go down as competition enters the market. But, when a new biosimilar becomes available, there is often significant differences among insurers and PBMs regarding coverage and preference tiers. They may also set widely different rules for switching to biosimilars – where one insurer might set a preference for an originator over a biosimilar, another could require patients to switch to a biosimilar with little explanation or notification. Due to these and other factors, it is difficult for patients to determine whether competition from biosimilars offers financial as well as treatment benefits.

For those looking to navigate these potential changes, attention and frequent consultations will be essential. Patients currently being treated with biologics should feel confident that an FDA-approved biosimilar will provide the same benefits and safety profile of a name brand biologic. However, they should consult with their doctors to better understand how switching to a biosimilar will impact their treatment. In addition, physicians should work to assuage patient concerns about subtle differences – including packaging and marketing materials – between an originator biologic and a biosimilar.

“In the Kaiser Permanente system, the choice of whether to use a biosimilar is not really made by the insurance company or the PBM. It is made by physicians. They’re directly involved in the research with the pharmacists. If a new drug was inferior, our physicians would never give that to their patients.”
- Dr. Sameer Awsare

“Patients want to know the side effects. They want to know what’s in a drug. They want to know the possible risks of taking that drug.”
- Vickie Wilkerson
The Patient Access & Affordability Project

The **Patient Access & Affordability Project** - a signature program of **Patients Rising** - offers policies and solutions to help legislators, regulators, payers, and employers incorporate the needs and perspectives of patients when making critical coverage and access decisions for those with rare and chronic diseases.

As new and innovative medicines are approved, we focus on ensuring patients get access to the best possible care at affordable costs. Our primary objective is to establish a health system that can evolve with new advances in medicine, technology, and finance in the 21st Century without discriminating against patients.

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