COMMENTARY

Generic Tofacitinib: Will It Be a Bellwether for the Future of Expensive Generics?

Rheum for Action

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DISCLOSURES | March 28, 2025

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When tofacitinib (Xeljanz), the first Food and Drug Administration-approved Janus kinase inhibitor, comes off patent exclusivity in the United States in 2026, the accessibility and affordability of its generic versions may serve as an important test for efforts to counter exorbitant pricing of "specialty" generic drugs by pharmacy benefit managers (PBMs), which often make these drugs available only through their own specialty pharmacies.



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There's a long history of controversy surrounding the generic drug industry in the United States that serves as a stark reminder of how susceptible our drug supply chain is to manipulation for profit. In the 20th century, many of the concerns about the generic drug industry centered around the prevention of counterfeiting, misbranding, and adulteration of branded drugs, as well as improvements to the approval process to address concerns about corruption and the bioequivalence of generics to branded products. More recent concerns in the 21st century have come in the form of a price-fixing scandal and now currently, the high pricing of generics sold by PBM-owned specialty pharmacies.

The Generic Cartel

Over the last 15 years, the generic marketplace has not escaped controversy. Normally, when a generic drug comes to market, the generic price would be slightly lower than the branded drug. Once a second generic drug was introduced, the price would drop about 50%, and then after the third or more generic came to market, the price would drop to around 20% of the branded drug. That is how generic competition worked, at least until 2012-2013.

Between 2012 and 2016, the United States experienced a price-fixing scandal involving generic drug manufacturers, which later became known as the "generic drug cartel." The scandal came to light when federal investigators uncovered evidence of widespread collusion among major generic drug makers to inflate the prices of hundreds of commonly prescribed medications. The conspiracy spanned several years and involved numerous companies, including some of the largest players in the generic drug industry. One of the early investigators, Attorney General of Connecticut William Tong, described it this way: “What we discovered is that the generic drug industry, without exaggeration, is the largest corporate cartel in history. ... [These pharmaceutical companies] run a cartel like OPEC does, like the major illicit drug cartels do. They meet. They talk. They divide up their customers. They set prices. And all of that is extraordinary illegal.”

According to the US Department of Justice, companies coordinated to raise the prices of drugs, sometimes by as much as 1000% on some products. The conspiracy was particularly harmful to consumers, as many of the drugs targeted by the cartel were essential treatments for chronic conditions, such as heart disease, diabetes, and infections.

This conduct violated antitrust laws and sparked a wave of lawsuits from state and federal authorities, as well as consumers and insurers. Several high-ranking executives from these companies have faced criminal charges and hefty fines. Some have even pleaded guilty to charges related to price-fixing and agreed to pay millions of dollars in settlements.

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The Importance of Being Special

This leads us to the sad tale of what happened when a branded, small molecule drug named imatinib mesylate (Gleevec) went generic in 2016. Gleevec was launched in 2001 with a price of $2200 per month. By February 2016, the price had risen to $11,800 per month, right before the first generic version was launched. Gleevec is mainly used to treat a variety of hematologic cancers, and it was thought that when generics came to market the price of imatinib would go down significantly. That is not what happened. In fact, the pricing of generic imatinib offers clues as to what might happen when tofacitinib, another "blockbuster" small molecule, goes generic.

Imatinib is labeled as a specialty drug by the PBMs. As it turns out, it is very difficult to find a specific and uniform PBM definition of what makes a drug "special." While there are a number of criteria that are used to justify the specialty label for medication, the most popular is that it is high priced.

Why is that important? As we know, the three big PBMs (Express Scripts, CVS Caremark, and OptumRx) own their specialty pharmacies. Because PBMs set the prices for drugs sold through their special pharmacies, the higher the prices they set, the more money they make because they can "buy low and sell high," putting more money in their coffers at the expense of their clients, such as self-funded employers and state-funded plans.

PBMs often steer patients to use their “in-house” pharmacies. And while self-steering is not allowed in Medicare, a study out of *JAMA* in 2025 revealed that 37.1% of specialty pharmacy spending in Medicare Part D occurred through pharmacies owned by Cigna, CVS, Humana, and UnitedHealth Group. In the commercial market, where there are many fewer anti-steering regulations, the percentage of patients steered to PBM-owned specialty pharmacies is much higher.

‘Stunning’ Findings

An analysis of the price spread for imatinib across a number of state Medicaid programs showed some “stunning” findings. In one example, near the end of 2018 — 2 years after imatinib went generic — CVS Caremark paid $20 for a 400-mg pill of imatinib and then turned around and charged Kentucky Medicaid $233 for the same pill.

A *Wall Street Journal* article from September 2023 reported pricing data showing that “CVS Health and Cigna can charge $6,600 a month for Gleevec (imatinib) prescriptions. They are able to do that because they set the prices with pharmacies, which they sometimes own.” In fact, CVS’s and Cigna’s prices were on average at least 24 times higher than what the drug’s manufacturers charge. All of this points to the power of PBM-owned specialty pharmacies in determining generic specialty drug pricing.

The Mark Cuban Effect

In 2021, when the Mark Cuban Cost Plus Drugs (CPD) company came online, the difference in pricing between CPD and other pharmacies for certain generic drugs was, once again, stunning. As of mid-March, the price of a 30-day supply of imatinib 400-mg tablets at CPD is $34.50 vs $9,657.30 at other pharmacies. Clearly, Cuban’s CPD offers imatinib at a much lower cost than other pharmacies. The sad part is that many self-funded employer plans have little knowledge of less expensive alternatives to the high prices charged by the big three PBMs and their “in-house pharmacies.”

The question becomes: Will the “Cuban Effect” lower the prices of other expensive small molecule specialty medications when they go generic?

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This certainly will become important when tofacitinib goes generic in 2026. (The patent is supposed to expire in December of this year, but I have been told by Pfizer sources that because of a pediatric extension there is a delay until 2026.) There are several questions that need to be answered before we can celebrate a real change in the US drug supply chain:

- Will there be a very low-priced generic that is affordable without insurance?
- Will it be available in pharmacies like CPD?
- Will generic manufacturers have the courage to price it low and sell it to pharmacies like CPD?
- Will PBMs threaten to drop generic manufacturers from their formulary if they sell to pharmacies like CPD?
- Will self-insured plans be allowed to go outside (carve out certain drugs) of the big three’s PBMs and specialty pharmacies to purchase a much cheaper medication?
- Will physicians have a problem with generic tofacitinib?

What Does the Future Hold?

Although it is not as egregious as the price-fixing behaviors of the generic drug cartel, PBMs’ price setting of generic specialty drugs, followed by steering of prescriptions to their in-house specialty pharmacies, has led to patients and self-funded plans overpaying significantly for certain generic specialty drugs.

No one really knows what will happen when generic tofacitinib hits the market. I asked Mark Cuban if he would carry generic tofacitinib. Essentially, he said if he can get it, he will carry it.

What we do know is that continued vigilance and advocacy are necessary to ensure that people are no longer exploited by the very industry designed to provide them affordable medication and ensure their healthcare.

Let's hope that the Patients Before Monopolies Act, which, as written when first introduced in the last Congressional session, would force PBMs to divest themselves of all pharmacies, will be reintroduced and passed by this Congress. If the bill is reintroduced, the CSRO will definitely have it up as an Action Alert on our website to make it easy for you to write your member of Congress in support of that bill.