

WHITE PAPER

Potential Ripple Effects of IRA MFP Negotiation on the US Generic Market

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The Inflation Reduction Act (IRA) is a landmark legislation that was passed by U.S. Congress and signed into law in 2022. One of its key provisions is to allow the Centers for Medicare and Medicaid Services (CMS) to conduct direct negotiation of select branded drugs that meet eligibility criteria. As the biopharma industry continues to better understand the impact of the Maximum Fair Price (MFP) on branded drugs, with round 1 completed and round 2 in negotiation, generic manufacturers need to assess the potential downstream effect and implications on their investment strategy.

Understanding the IRA's Medicare Direct Negotiation Policy Provisions

To be eligible for MFP negotiation under the IRA, drugs must lack "bona fide" generic competition and have annual Medicare Part B or Part D spending exceeding $200 million. Small molecule drugs become eligible seven years after U.S. Food and Drug Administration (FDA) approval, with negotiated prices taking effect two years later. The first negotiation cycle for 10 Part D drugs concluded in 2024, with new prices taking effect in 2026. CMS estimates an average 22% net spending reduction for these 10 drugs based on 2023 Medicare spending data. CMS has published the list of 15 Part D drugs to be negotiated in 2025, which will be followed by an additional 15 Part B or Part D drugs per year from 2026 to 2028 and 20 drugs per year from 2029 onward. Of the first 25 negotiated Part D drugs, 23 are small molecules. CMS is negotiating the largest drugs first. The first cycle of 10 negotiated drugs had an average gross Medicare expenditure of $5.6 billion, and BCG estimates that the gross Medicare expenditure for negotiated drugs will reach the statutory minimum of $200 million in 2031. As a result, most current small molecule blockbusters will be negotiated over the next five to six years, and future blockbusters will likely be negotiated in their first year of eligibility.

Generic Price Erosion Patterns

Generic pricing is highly complex given the number of players in the value chain and the complicated flow of products and dollars. This flow also varies depending on whether products are reimbursed through insurance or paid by patients through direct cash pay or prescription discount cards (click the following link to see more details in our article, "**The Cash Generics Opportunity in Health Care**"). Regardless of the price to patients and payers, generics manufacturers are paid by wholesalers or pharmacies.

Generic drugs are typically priced at a discount to the reference brand price prior to loss of exclusivity, and the price paid to manufacturers is largely driven by the level of generic competition. On average, single-source generics maintain the highest prices as a percentage of the reference brand, up to 70%–80%. As competition increases to two to four suppliers, there is then generally a linear decline down to 20% to 40% of the reference brand price. Between five and six suppliers, price variation can be more pronounced, often influenced by product-specific factors. Beyond six competitors, there is a diminishing impact as more players enter the market, with prices typically stabilizing well below 10% of the undisturbed reference brand price.

Key factors contributing to the level of competitive intensity include product dosage form and brand size. On average, oral solid dose products see 10 to 12 competitors, injectables see five to seven, and semi-solids and liquids see six to eight. More complex dosage forms, such as inhalation and peptides, see four to six or even fewer. Brand size also plays a role, with products generating over $1 billion in revenue often facing 10+ competitors, compared to an average of three to six for smaller brands.

Impact of the IRA on Generics

We explored two questions to understand the potential impact of the IRA on generics:

1 How might MFP negotiation impact overall generics pricing?

If branded drug prices are impacted by MFP negotiation, the price point for generics would likely also decrease. Two possible scenarios emerge:

- While individual generic product revenue, net present value, and return on investment could decrease, manufacturers decide to lower investment decision thresholds systematically and remain in development despite lower brand pricing. This would likely have **limited impact to industry pipelines and the level of competition for new generic launches**.

- Some manufacturers could decide to maintain existing thresholds and no longer develop certain generic products. If enough generic manufacturers decide not to pursue a given product, **reduced generic competition could lead to increases in the price paid to generic manufacturers by customers**.

2 How might the IRA impact Paragraph IV challenges?

Paragraph IV (P-IV) certification is a mechanism that allows generic manufacturers to challenge existing patents of brand-name drugs with the incentive of 180-day exclusivity. Based on FDA data from 2019 to 2024, P-IV challenges that are eligible for exclusivity typically represent ~15%–25% of FDA first generic approvals.

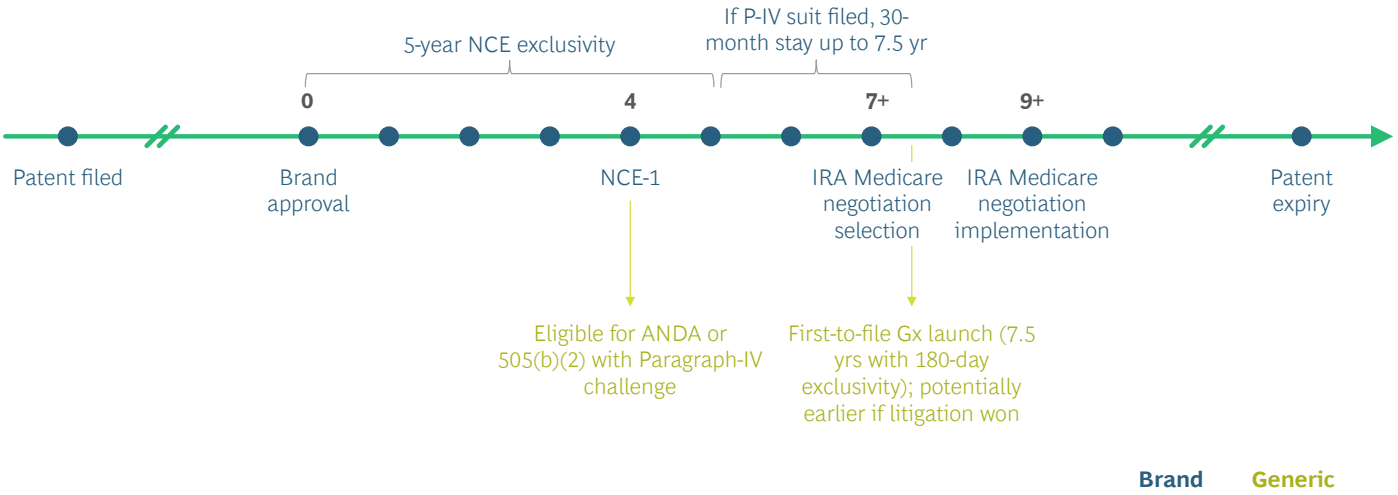
Generic manufacturers can file P-IV challenges four years after a brand's approval (known as the NCE minus 1 (NCE-1) date). If the brand manufacturer files an infringement suit against the generic applicant within 45 days, it triggers a 30-month stay that postpones generic entry while litigation is ongoing equivalent to 7.5 years post-brand approval (see Figure 1). Depending on the outcome, the generic may win, lose, or settle.

Historically, 70% of first-to-file P-IV generics launch within five years of submission, based on 2015–2024 FDA Paragraph IV Certification data. If this pattern continues to hold, since MFP-negotiated prices for small molecules take effect in year nine, most successful P-IV challenges filed on the NCE-1 date are expected to launch before brand price reductions are implemented. If a bona fide marketed generic enters before a brand drug is selected for negotiation, the brand is exempt. If it enters after selection but before negotiation concludes, no MFP will be negotiated; and if it enters after an MFP is set and negotiated, the MFP applies for up to two years, after which the drug is no longer subject to an MFP.

For P-IVs that fail to launch before year nine, the value of the 180-day exclusivity period may decline as the reference brand price drops due to the negotiation. Beyond the 180-day exclusivity period, pricing dynamics will depend on the level of competition, as previously described.

EXHIBIT 1

Paragraph IV challenge timeline



Source: CMS; FDA Paragraph IV certifications; KFF; BCG analysis.

What the IRA Means for Generic Manufacturers

Companies need to evaluate both how the IRA may impact the branded products for which they are developing generics and the potential timing of generic entry if they are pursuing a P-IV certification. Ultimately, success in the U.S. generic market still depends on early entry during market formation, supply quality and reliability, and maintaining competitive costs of goods sold. Manufacturers should consider the impact of the IRA as they decide on their R&D investment strategy and understand downstream implications on manufacturing capabilities and capacity.

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