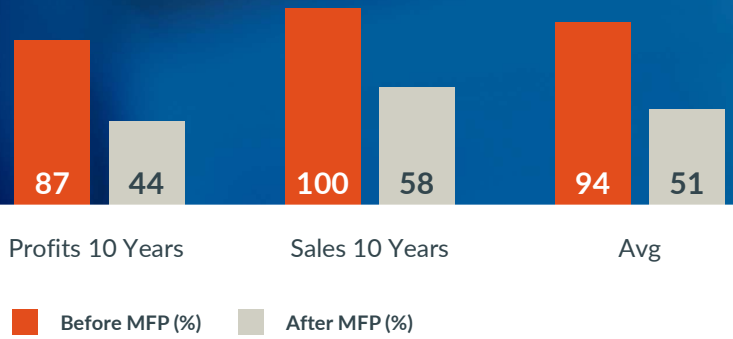
Impact of the Inflation Reduction Act (IRA) on biosimilar market entry

Overview: Competition between biosimilars and biologics has brought significant savings to patients and the overall health care system. However, policies in the Inflation Reduction Act (IRA) threaten this progress because biosimilar development investment decisions will be impacted by the uncertainty of potential government price controls on the brand product. This analysis by **Vital Transformation, LLC** explores the damaging effects of the IRA on biosimilar development.

Challenges for Biosimilars Under IRA

- **Investment Challenges:** Biosimilars require ~ **$200M** investment. Adjusting for their failure rate of 37%, and a cost of capital of 11%, leads to more than **$400M in actual development costs**[1]
- **High uncertainty** about market size and reimbursement post-MFP.

KEY FINDINGS



1 **Biosimilar Market Reduction:** MFPs will lead to **43 fewer biosimilars** entering the market, **a decline greater than 45%.** *(Before vs. After MFP Implementation)*

2 **Therapeutic Group Impact:** There are 15 biologic originators that are open to biosimilar competition. These therapeutic groups of biologics and biosimilars are not impacted equally by the IRA. We see a **67% decline** in biosimilar entry across all therapeutic groups entering the market, with **27% (4 of 15) losing all biosimilars** in their group.

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1. The cost of $446,299,061 in 2024 USD was developed for the use of a Stackelberg market entry model and derives from an NPV analysis. It is based upon an NPV of 6 years of clinical trials, where the cost in each year was computed as ($200,000,000/0.37)/6 = $90,090,090 in 2017 USD. We assume a 0.37 probability of a successful trial. Each annual cost was then adjusted to be measured in constant 2023 USD. The NPV over 6 years at 11% discount was $ 433,721,147 in 2023 USD and $ 446,299,061 in 2024 USD; the latter is the value used in the revenue and profit NPVs, where one-half of $446,299,061 was used for each of the two years before assumed entry.