WILL POTENTIAL IRA PRICE LIMITS DELAY DRUG LAUNCHES?

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BACKGROUND

- The Inflation Reduction Act (IRA) is designed to reduce drug prices and revenues as soon as 9 years after launch.
- Orphan drugs are excluded from IRA price limits, if they have ONLY a single approved indication.
- For orphan drugs with subsequent approvals for any indication, the clock to CMS-imposed price limits begins at the first launch. We refer to such products as "orphan-first".
- Previous researchers[1] have claimed that CMS price limits will not impact launch strategies for orphan-first products.

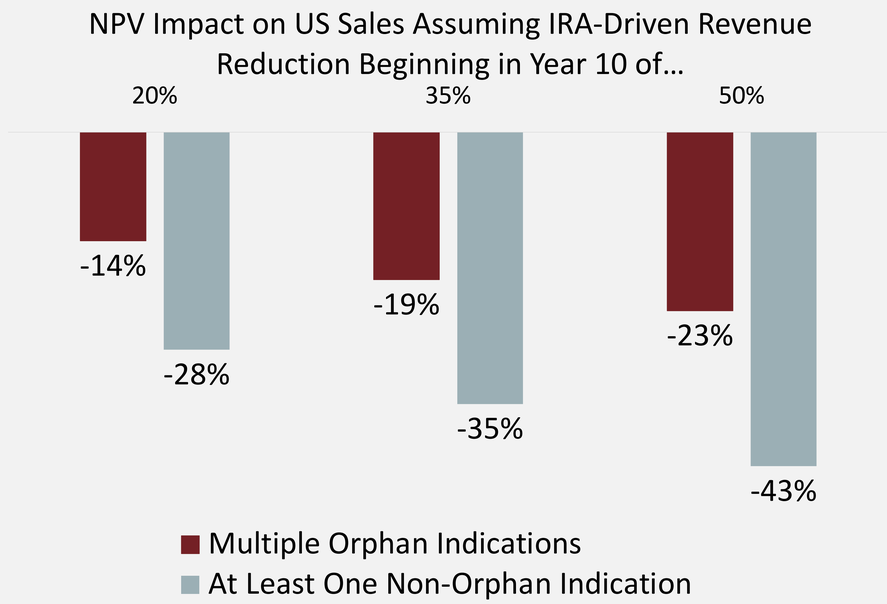
OBJECTIVE

Use historical data to analyze how IRA price limits will impact returns and launch incentives for orphan-first products.

METHODS

- We collected data for 77 drugs that were *first* launched with an orphan indication between 2003 and 2017 with at least $250m in peak annual sales.
- We collected data on annual US sales beginning the first full year of launch for each drug.[2] We calculated the average change in sales for each year within three categories: drugs with just the one orphan indication (51%), with multiple orphan indications (22%), and with at least one non-orphan indication (27%).
- To model the IRA's impact, we assume that sales are reduced by 35% in year 10, with an additional 10% reduction in each of the following 5 years. We calculate the change in the net present value (NPV) of lifetime sales using a 10% discount rate.
- We calculate the NPV impact of launching an orphan drug 1, 2, or 3 years later, applying the standard sales curve after allowing for one additional year to "catch up" to the prior sales curve. For a one-year delay, the sales in year 2 are the same as year 1 in the non-delay case, and in year 3 the sales are the same as in the delay case.

Looming price limits will reduce returns for multi-indication orphan drugs…



…penalizing "orphan-first" launches with potential non-orphan indications

Firms cannot know if an orphan product will eventually receive a non-orphan indication (27% of our sample received one so far). Today, orphan-only launches provide valuable real-world data, reducing risk in later trials and encouraging more investment into broad-based indications. Now, firms developing products with potential for both orphan and non-orphan indications face the following commercial tradeoffs:

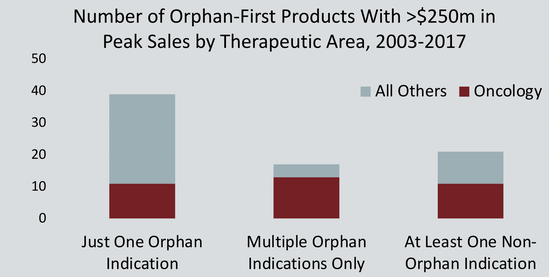
Eventual Commercial Outcome	NPV Impact of One-Year Delay	NPV Impact of Two-Year Delay
Only One Orphan Indication Approved	-5.5%	-12.4%
Multiple Orphan Indications Approved	-1.2%	-4.4%
At Least One Eventual Non-Orphan Approval	**+5.5%**	**+10.0%**

The likely result will be fewer orphan-first launches and, without such launches, riskier trials for broader indications.

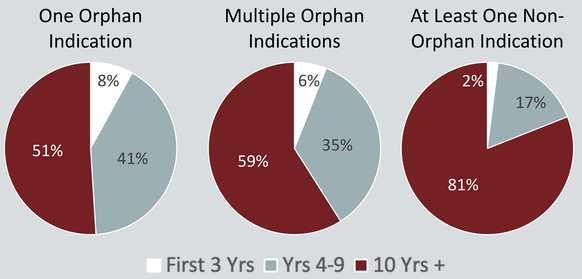
This research was sponsored by PhRMA.

RESULTS

- The most common indication for orphan-first launches is oncology, but each category addresses a variety of conditions:



- A significant portion of sales for orphan-first drugs occur well after 9 years, and the share of sales in the first 3 years is very small:



CONCLUSIONS

Firms with orphan drug treatments do not know whether they will earn subsequent indications until years after launch. The IRA penalizes companies pursuing multiple indications by starting the "countdown clock" to negotiations in the early years, when sales are relatively minimal. Firms face strong incentives to focus on big indications first, even if it means waiting two or more years to pursue approval. This implies that research on broader indications will be riskier (with less real-world data from earlier orphan launches) and that orphan research will also face higher commercial hurdles due to the ticking clock toward price limits.

REFERENCES

1. Vogel, Matthew et. al., "Will Medicare Price Negotiation Delay Cancer-Drug Launches"? *New England Journal of Medicine* 389; 17, October 26.2023.
2. Sales data from IQVIA. Information on indications and orphan status from FDA sources.

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