Estimating the Impacts of Government-mandated Price Reductions on Indication Expansion for Launched Drugs—A Real-World Study

HPR171

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INTRODUCTION

- The impact of reduction in expected profits on indication expansion for launched drugs is understudied in existing analyses to quantify the impacts of drug pricing policies such as the Inflation Reduction Act (IRA).
- As indication expansion is a cost-effective way to maximize the societal benefits of innovative therapies, it is important to understand the magnitude of such impacts for more informed policymaking.

OBJECTIVE

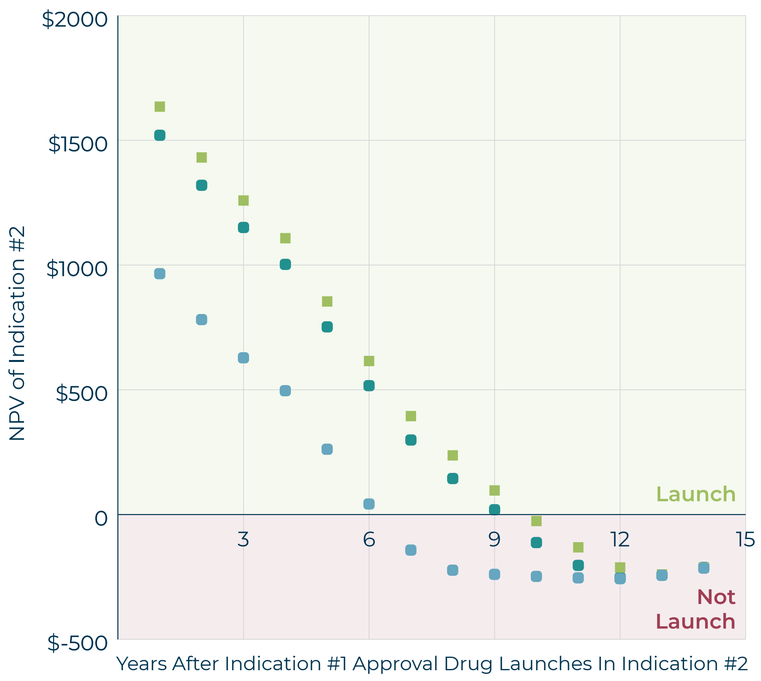
- To examine the impacts of reduced expected profits on decisions to invest in a follow-on indication.
- To explore how such decisions are impacted by timing of profit reduction and vary by:
  - Launch time of indication #2
  - Peak sales of indication #2

METHOD

- Builds on a previously presented net-present-value (NPV) model of a case example based on the launch curve of a marketed cardiovascular drug with a peak sales of 1.2 billion USD in the US[1]
- Policy reform is modeled after an IRA provision, in which US revenue is substantially reduced (-95% YOY) from years 10-14 across all indications due to Medicare price negotiations
- NPV and investment decisions are compared in the pre- and post-IRA scenarios:
  - The first part of the analysis assumes that peak sales of indication #2 are 50% of that of indication #1 and examines how decisions vary by launch time for indication #2.
  - In the second part, holding launch year of the second indication constant, we examine how investment decisions vary by peak sales.

RESULTS

- Under the IRA, expanding into follow-on indications becomes less profitable.
- Overall, indication expansion opportunities need to be larger or the decision to launch into indication #2 needs to be made earlier to justify the required investment.
- Assuming peak sales of indication #2 are 50% of that of indication #1:
  - NPV of indication #2 is reduced by an avg of ~$100M for biologics and ~$550M for small molecules in the Post-IRA scenario.
  - Decision to pursue indication #2 **must be made ~3 years earlier** for small molecules.
  - NPV reduction is more pronounced the earlier the drug launches in indication #2, but it is more impactful to the decision to pursue indication #2 the later the drug launches.
- Assuming indication #2 launches 6 yrs after initial approval in indication #2:
  - For small molecules, peak sales of indication #2 (as % of peak sales for the first indication) **must be 30% larger** to rationalize pursuing in the Post-IRA scenario.
  - NPV reduction is more pronounced the larger indication #2 is (measured by peak sales), however the reduction more negatively impacts decision to launch the second indication when the peak sales of indication # 2 is smaller.



World Wide NPV of 2nd Indication

- **Pre IRA Scenario** (14 yr LOE)
- **Post IRA Biologic** (13 yr LOE in US; 14 ex-US)
- **Post IRA Small Molecule** (9 yr LOE in US; 14 ex-US)

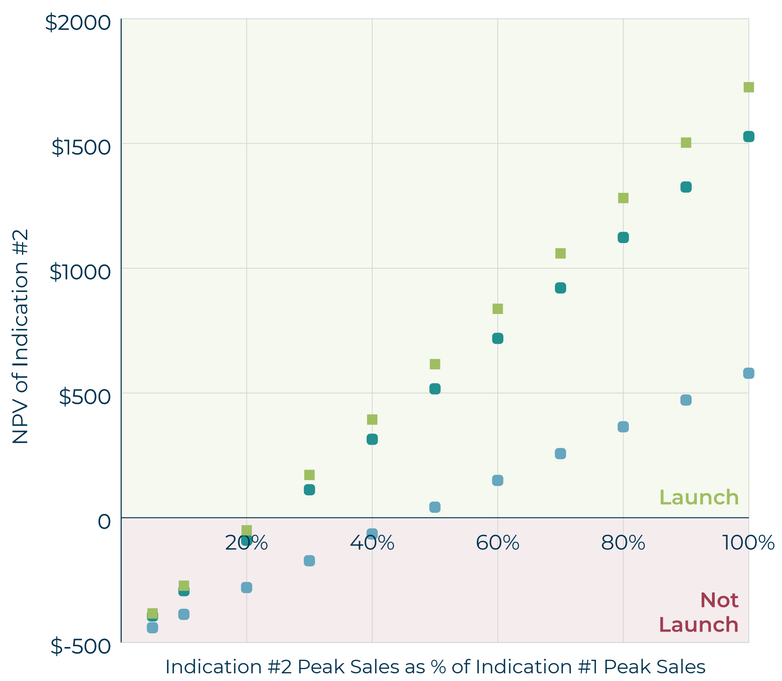


Figure 1: Value of indication expansion by launch year, before and after policy reform

Figure 2: Value of indication expansion by market size, before and after policy reform

CONCLUSIONS

- As viable indication expansion opportunities are frequently identified years post-launch, shorter decision windows from decreased profitability may reduce the overall utility of launched drugs.
- Existing studies, which focus on the impact of drug price policy on the number of new drugs launched, have likely underestimated the negative impacts of government-mandated price reduction policies on the overall utility of the future drug armamentarium.

REFERENCES

[1]Xie, R. The Impact of the Inflation Reduction Act on Early-Stage Biomedical Investment Decisions. No Patient Left Behind, 7 May 2024.

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