Modeling the impacts of proposed drug pricing policies on the biopharmaceutical industry

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Forecasting the possible effects of the Inflation Reduction Act (IRA) and proposed future modifications to it on drug industry productivity requires one to simulate the effects on the industry's portfolio of drug development programs. However, available models from government, academic, and industry-affiliated groups are limited to individual assets, designed too opaquely to foster constructive debate, and/or based on theoretical portfolios that are not grounded in real industry data.

To address developed frameworks' shortcomings and increase modeling accuracy, we developed an industry-wide R&D portfolio Monte Carlo simulation model. The model is drug/indication-centric: it mimics drug development workflow from Phase 1 to the market to transform data about each drug/indication pair in the R&D pipeline into metrics of future industry performance. The model utilizes a decision tree framework with binary stochastic outcomes (success, failure) after each development phase, based on published industry benchmarks, and incorporates rules reflecting the IRA negotiation algorithm. It models financing of future R&D for the existing pipeline and future new ("virtual") drugs/indications via a combination of a fraction of revenue from marketed drugs plus a contribution from venture capital investment, both derived from industry benchmarks.

The data for the model is generated from several sources. The starting portfolio, derived from a snapshot of the global biopharma industry obtained from Evaluate Pharma, includes over 5,000 drugs/indication pairs from Phase 1 to marketed characterized by multiple attributes such as therapeutic area, phase of development, small molecule vs. biologic, primary vs. secondary indications, projected revenues, and whether it represents a potentially novel new molecular entity (NME). Assumptions about a drug/indication pair's cost and time of R&D, as well as projected revenues and revenue trajectories if it reaches the market, are taken from a combination of Evaluate data and published industry benchmarks.

We are now using this model to forecast the effects of enacted and proposed policy initiatives on the number of approved drugs per year and the biopharma industry's aggregate financial performance over a 20-year window. Preliminary results indicate, for example, that increasing

the number of drugs subject to negotiated price reductions under the IRA beyond current levels would reduce the median expected number of novel new drug approvals annually starting after the 10th year of the modeling horizon and increase the odds that current levels of R&D investment would yield reduced financial returns. This effort establishes an analytic framework that can help key stakeholders analyze how various biopharma policies might affect the drug industry.

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