Do Better Drugs Make More Money? Evidence from Newly-Launched Drugs in the US

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Background

The potential for high revenues drives investment in prescription drug development by for-profit manufacturers. But unlike its peer countries, the US lacks a centralized process for ensuring that prices of new drugs are justified by the health improvements they offer relative to existing treatments. Thus, it is unknown whether drugs with added therapeutic benefits generate higher revenue in the US.

Methods

Among newly-launched drugs FDA-approved from 2012 to 2020, we measured their cumulative US net sales in the first five years after launch from public manufacturer financial reports. For each drug, we collected added-benefit ratings from health technology assessment (HTA) agencies in Germany and France using data from Navlin (Eversana). Drugs were classified as high-added benefit if either agency rated the first approved indication as high benefit relative to existing therapies; to be conservative, we used the best rating across subpopulations. For Germany, this included major or considerable added benefit; for France it included Amélioration du Service Médical Rendu (ASMR) ratings I-III (major advance, important improvement, and moderate improvement). We compared five-year revenue between high- and low- added benefit drugs using a two-sided Wilcoxon rank-sum test. We then estimated the aggregate US spending on high- and low-added benefit products. Revenue was adjusted to 2025 dollars using the Bureau of Labor Statistics Consumer Price Index.

Results

Our sample included 217 newly-launched prescription drugs, with median 5-year net revenue of $1.1 billion (interquartile range, IQR $0.4-3.3 billion). Fifty-nine drugs (27%) were classified as high-added benefit, 120 (55%) as low, and 38 (18%) were not assessed in Germany or France. Of the $656 billion in aggregate five-year US net sales, high-benefit drugs accounted for $310 billion (47%) low-benefit drugs for $316 billion (48%), and unrated drugs accounted for $30 billion (5%) [**Figure 1**]. Median (IQR) five-year revenue was $3.1 billion ($0.8-5.7 billion) for high-benefit drugs, compared with $1.1 billion ($0.5-2.8 billion) for low-benefit drugs and $0.4 billion ($0.1-1.0 billion) for unrated drugs ($p<0.001$) [**Figure 2**].

Conclusions

Only 27% of newly approved drugs in the US were classified as high-added benefit, but these drugs earned higher revenue than products offering no or minor added benefit over existing alternatives. The fact that drug development incentives in the US were loosely aligned with therapeutic value suggests the current market rewards investment in and development of high-benefit drugs. However, many low-added benefit drugs earned billions of dollars in revenue, suggesting opportunities to better align financial incentives with clinical need through a less fragmented drug coverage and payment system and adoption of a formal HTA process in the US.

Figure 1: Share of drugs and 5-year US net revenue for newly launched drugs (2012-2020)

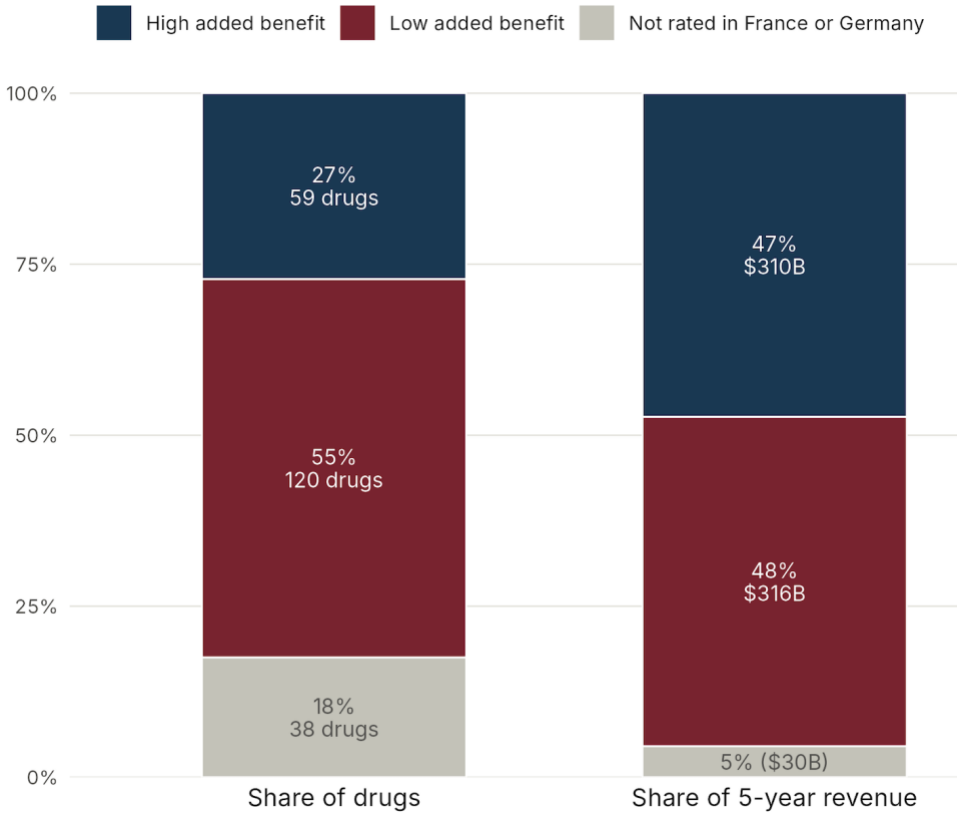


Figure 2: Revenue for high-added benefit, low-added benefit, and unrated drugs

