CANCER DRUG INNOVATION: EVIDENCE, ACCESS, AND PRICES

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EXTENDED ABSTRACT

I. Research question and contribution

Assessing the U.S. medical innovation system requires evidence on the health gains produced by new treatments, the timing of patients' access, and the prices paid for therapeutic improvements. Clinical oncology and cancer drug development provide a setting in which these questions can be studied together. The United States often authorizes new oncology therapies before peer countries, while cancer drug launch prices have risen substantially. Whether novel cancer drugs provide good value for money depends on the magnitude and credibility of incremental health gains, the patients who receive treatment during periods of earlier availability, and the share of price changes attributable to improvements in treatment quality. This paper examines these questions through three linked analyses. The first evaluates the evidence used to measure the economic value of cancer drugs. The second combines that cost-effectiveness evidence with international approval timing and U.S. utilization to estimate the health and welfare gains attributable to earlier access to novel cancer drugs. The third constructs quality-adjusted price measures to assess how the cost of cancer treatment has changed after accounting for therapeutic benefit.

Published cost-effectiveness analyses are both the object of investigation and an empirical input. The primary data source is a systematic review of comparative oncology drug economic evaluations identified through PubMed, Embase, and EconLit. The dataset covers 1,379 publications from 1985-2024, with more than 30 extracted study characteristics. The analysis organizes these records at the treatment-comparator-indication-country level and retains information on publication year, sponsorship, modeling approach, analytic perspective, time horizon, discounting, and the

underlying clinical evidence. Incremental costs, life-years, and quality-adjusted life-years (QALYs) were extracted separately from reported incremental cost-effectiveness ratios (ICERs).

II. Credibility and interpretation of cost-effectiveness evidence

The first analysis asks how reported economic value varies with sponsorship, clinical context, and methodological choices. I estimate associations with incremental cost, incremental QALYs, and the ICER separately. Hierarchical models and comparisons within matched treatment-comparator groups distinguish variation across therapies from variation in how the same clinical comparison is evaluated. Explanatory variables include sponsorship, time horizon, analytic perspective, comparator selection, publication period, and the maturity of survival evidence. Within paired analyses, I compare cost per life-year gained with cost per QALY gained to determine how incorporating quality of life affects rankings and threshold classifications. Separately, I compare treatment choices based on incremental QALYs alone with choices based on net monetary benefit at specified cost-effectiveness thresholds. I found approximately 25% lower adjusted ICERs in industry-sponsored studies and a higher likelihood of reported favorable cost-effectiveness at $100,000 per QALY. Study sponsors almost never found their own products to be cost-ineffective or to otherwise represent poor value for money. A subset of paired cost-per-life-year and cost-per-QALY estimates have a rank correlation of 0.91, with different value for money classifications in only 8% of comparisons at a common willingness-to-pay threshold of $100,000. Choosing the health-maximizing option within each treatment-comparator pair disagrees with the net-monetary-benefit choice in less than 20% of eligible comparisons at $100,000 per QALY.

III. Health and welfare gains from earlier US access to novel cancer drugs

The second analysis asks how much population health and welfare gains are attributable to earlier U.S. availability of cancer drugs and how the resulting value is distributed. I link FDA, European Union, Swissmedic, and Japanese authorization records to evidence on U.S. commercialization, drug use, and therapeutic benefit. For drugs first available in the United States, the counterfactual

delay is the interval from U.S. availability to the earliest launch in another included jurisdiction. Product-specific U.S. utilization is reconstructed from consistent revenue and net-price measures, supplemented by labeled dosing and treatment-duration information, which is then combined with matched estimates of discounted lifetime QALY gains to estimate population health benefits. Gross health value is then calculated over alternative monetary values per QALY. Values from $50,000 to $1 million per QALY provide a broad range of estimates, with $100,000 and $150,000 as base cases.

FDA approval occurred first for 93% of recently approved new cancer drugs. Among FDA-first drugs, median authorization lags were 8.6 months in Europe, 9.7 months in Switzerland, and 13.9 months in Japan. Discrete health gain estimates for novel cancer drugs were highly heterogeneous, but overall relatively small (median of 0.56 QALYs). During a relatively brief measurement period, I estimate approximately 600,000 treatment starts for a set of novel cancer drugs during their US exclusive access intervals. Subsequent estimates suggest that these treatments produced approximately 277,000 additional QALYs, corresponding to $41.55 billion in gross health value.

IV. Quality-Adjusted Cancer Drug Prices

The third analysis asks how U.S. cancer drug prices evolve after accounting for therapeutic improvement. Following Dunn, Hall, and Dauda (2022), I link longitudinal net prices to labeled treatment regimens and my dataset of disaggregated incremental cost and health estimates to construct conventional price trends and health-adjusted price indices that value improvements relative to an explicit reference treatment. The primary money-metric calculation adjusts treatment spending by the monetary value of incremental health. Alternative reservation-price, price-per-health gain, and hedonic specifications show how conclusions depend on the index concept. Changes in prices for continuing products, the entry of new treatments, and changes in treatment mix are reported separately, with explicit disease and utilization weights. The primary measures are a utility-based Laspeyres cost-of-living index (L) and Paasche reservation-price index (R). Let $C_0 > 0$

denote total comparator cost, $C_1 = C_0 + \Delta C$ total innovative-treatment cost, ΔQ incremental QALYs, and λ a constant monetary value per QALY. With the comparator normalized to 100, I report both indices and their arithmetic average (A) as:

$$L = 100\,\frac{C_1 - \lambda \Delta Q}{C_0}, \qquad R = 100\,\frac{C_1}{C_0 + \lambda \Delta Q}, \qquad A = \frac{L+R}{2}.$$

I vary the QALY valuation and test sensitivity to sponsorship and evidence maturity. Following Dunn et al.'s aggregation framework, a time-series extension combines unadjusted indices of cancer treatment expenditures with innovation indices, adoption diffusion measures, and cancer-specific expenditure weights. I find that quality-adjusted prices decreased approximately 2.5 percent per year from 2015 to 2020.