The value of speed for drug developers

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The priority review voucher program was created in 2007 to provide an incentive for companies developing drugs for neglected tropical diseases. In 2012, the program was expanded to also award vouchers for new drugs approved by the FDA for rare pediatric diseases. Through the program, the sponsor of a new drug approved by the US Food and Drug Administration (FDA) receives a transferable and saleable voucher that entitles the bearer to receive priority review from the FDA for another drug, with an expected timeframe of up to six months compared with up to ten months for standard review. The expectation for the program was that a priority review voucher would have sufficient value through use or sale to incentivize the development of drugs that would otherwise have insufficient expected commercial return to justify the required investment. In 2026, prices for priority review vouchers reached $200 million, about twice the average price in 2023 (Fig. 1). That is a striking sum for a mechanism that shortens FDA review by only about four months.

Why might four months matter? Earlier approval shifts sales forward and increases revenue over several years because drug sales typically grow over time. The voucher value therefore comes not only from sales during the initial four months but also from sales in later years. Earlier approval can also create a lasting advantage in physician familiarity, patient uptake, and payer coverage. In addition, because expiry of a patent for the drug is tied to the filing date rather than its launch date, earlier approval increases the time on the market before generic or biosimilar competition arrives.

Here, we estimate the value of a four-month acceleration in market launch using data on all 17 new drugs (including combination products) approved by the FDA between 2009 and 2022 for which priority review vouchers were used (Supplementary Table 1). We also examine 10 high-revenue drugs for which vouchers were not used to assess whether some companies forwent

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opportunities in which a voucher could have generated substantial value (Supplementary Table 2), as well as whether those companies later used vouchers for other drugs.

Analysis

For drugs for which priority review vouchers were used, the median estimated value of priority review was about $212 million, and the mean exceeded $500 million (Fig. 2a). The value exceeded $3 billion for Mounjaro (tirzepatide; Eli Lilly) and $1 billion for Biktarvy (bictegravir, emtricitabine, tenofovir alafenamide; Gilead) and Vabysmo (faricimab; Roche). Even outside these cases, the median estimate remained high relative to typical voucher prices (Fig. 1, Fig. 2a).

The same pattern appears among drugs for which vouchers were not used. For these products, the median forgone value exceeded $400 million (Fig. 2b). For these drugs, the implied value of four months comfortably exceeded likely voucher prices. The companies that did not use vouchers for one of these high-revenue drugs later used a voucher on another drug.

A useful heuristic from the model is that the value of priority review is about 18% of expected peak annual net sales. On that basis, paying nearly $200 million for a voucher could be justified for a drug expected to generate more than $1 billion in annual net sales.

Buying speed at the regulatory review stage is not the only way to accelerate a drug's launch. Sponsors can also invest earlier in development to shorten timelines. For example, they can prepare for phase III trial recruitment before phase II trials are complete. These investments are risky because they may be wasted if the drug fails in phase II. For example, spending $25 million during phase II to speed up phase III by four months has an expected present value that is about the same as paying $200 million for a voucher at submission (see Supplementary information). For a drug with expected peak sales of more than $1 billion, the firm should be willing to choose either investment. For a drug with expected peak sales of more than $2 billion, the firm might benefit from doing both. However, a $25 million investment is not guaranteed to accelerate trials by four months.

Discussion and outlook

We show that, among priority review voucher users, the average value of a voucher exceeded its price. We also find that several firms forwent vouchers that would have generated value above the market price. These firms later used vouchers for other drugs, consistent with learning about the value of vouchers.

Vouchers were not profitable for every buyer. For a few drugs, the estimated voucher value was below the purchase price. Consider two lower-value uses: Ajovy (fremanezumab; Teva) and Praluent (alirocumab; Regeneron). Both drugs faced competition from earlier generations of drugs that had become generic, and insurers restricted access to them, encouraging patients to use cheaper alternatives. Ajovy and Praluent also faced within-class competition from products that launched at about the same time. The companies may have bought vouchers because this competi-tion made speed-to-market especially appealing. Yet that same competition also limited revenue, reducing the realized value of the voucher.

The price trends are consistent with three distinct periods. From 2014 to 2016, prices rose sharply as buyers learned about the voucher program and gained confidence in it. Prices roughly doubled with each sale, rising from $67.5 million to $125 million and then to $250 million, before exceeding $300 million (Fig. 1).

From 2017 to 2024, prices fell from about $300 million to about $100 million. This decline is consistent with an increase in voucher supply without a corresponding increase in demand. As the US Congress expanded voucher eligibility, supply increased, putting downward pressure on prices.

Since 2024, prices have risen from about $100 million to about $200 million. Because voucher supply did not decline, the increase may reflect stronger demand. Buyers may have come to recognize that vouchers can be valuable not only for new molecular entities but also for new indications. Some firms may also have learned from earlier decisions not to buy vouchers. For example, Novo Nordisk did not buy a voucher for Ozempic (semaglutide) but later bought vouchers for other drugs. If prices of priority review vouchers remain near $200 million, they could provide substantial incentives for drug development for tropical and rare pediatric diseases.

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Competing interests

The authors declare no competing interests.

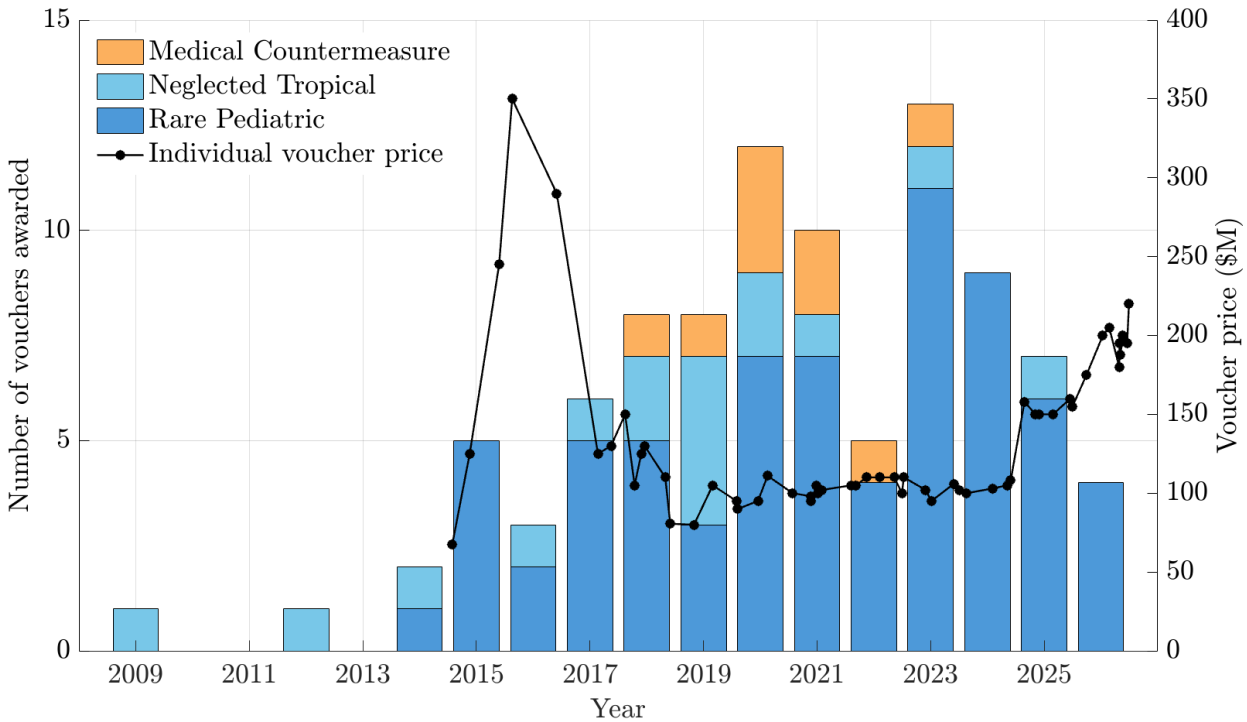
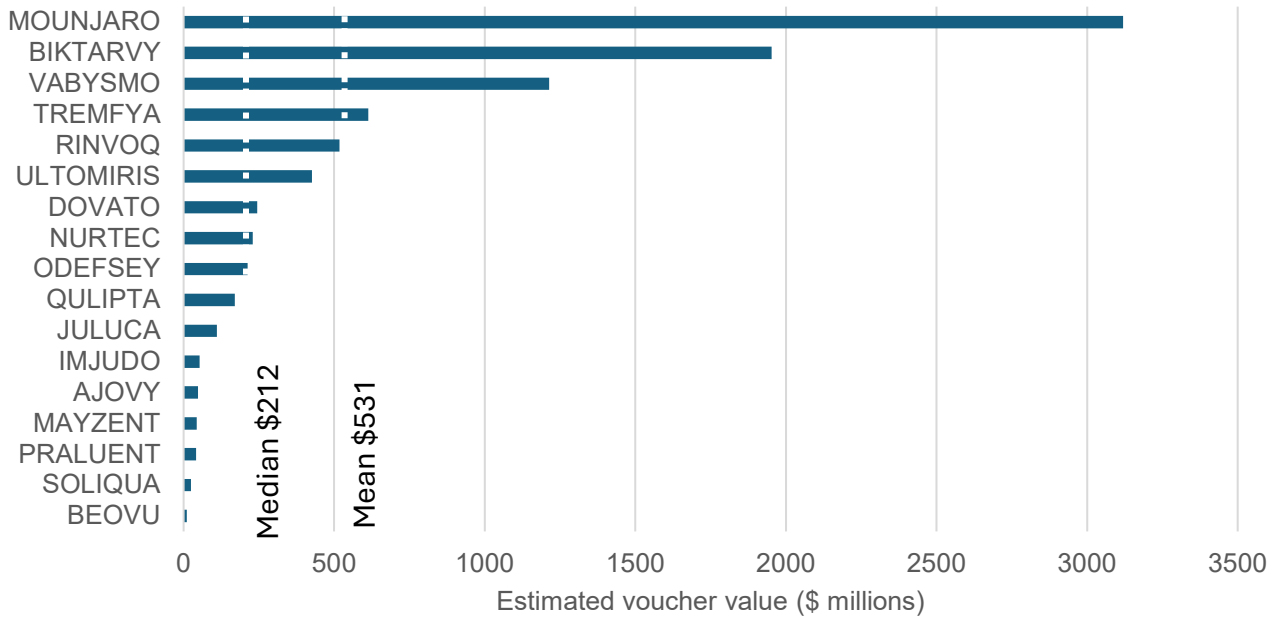


Figure 1. Priority review voucher awards and prices from 2009 to June 2026. Prices are shown for publicly disclosed transactions. See Supplementary information for details.



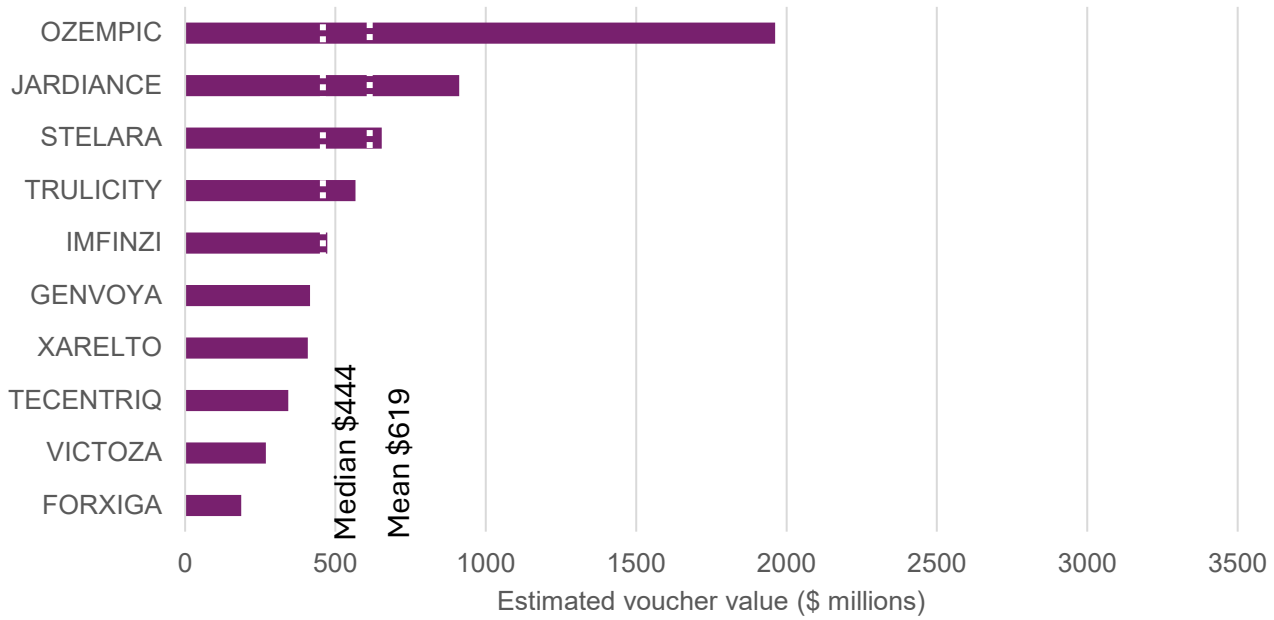


Figure 2a. Estimated value of priority review for all new drugs, including combination products, that used vouchers between 2009 and 2022. Figure 2b. Estimated foregone value for ten drugs that did not use vouchers. See supplementary information for details.

Supplementary Material

Data and methods

Sample selection

We included all new molecules for which FDA priority review vouchers were used and that were launched between 2009 and 2022. We identified the drugs from the FDA's Compilation of Center for Drug Evaluation and Research New Molecular Entity and New Biologic Approvals [1], which reports approval dates, review designations, and voucher use. We excluded voucher-using drugs approved in 2023 or later, because we have limited post-launch sales data. We supplemented it with combination products documented to have used vouchers: Dovato, Juluca, Odefsey, and Soliqua [2]. We assigned therapeutic classes using the Anatomical Therapeutic Chemical system. A total of 17 voucher-using products were included (Supplementary Table 1).

We also included 10 top-selling drugs that did not use vouchers (Supplementary Table 2). We selected these products from IQVIA's lists of top-selling drugs in 2018 and 2023. We retained drugs that received standard review and launched after 2008, the first full year of voucher eligibility. This comparison sample is intended to assess whether some high-revenue products forwent vouchers and, in hindsight, whether some firms left substantial value on the table.

We also report all voucher prices and sale dates that were disclosed publicly.

Sales data

We used sales net of rebates because rebate-adjusted sales provide a more accurate measure of revenue [3]. Annual net-of-rebate sales data for 2014–2023 were obtained from IQVIA Analytics Link.

We supplemented the IQVIA sales data with US net revenue figures reported in each company's annual financial filings. Annual report data for 2024 and 2025 were available for 19 of the 27 drugs. We were missing observations for drugs sold by privately held firms, such as Boehringer Ingelheim. For companies reporting revenues in currencies other than US dollars, we

converted figures using exchange rates as of July 1, 2024. For example, for Novo Nordisk, we applied an exchange rate of 1 DKK = 0.1440 USD [4].

The panel includes 214 drug-year observations.

Sales projections and loss of exclusivity

For each drug, we constructed a revenue trajectory covering at least 13 years from launch. Under standard review, we assumed 13 years of branded sales (Supplementary Table 3). For drugs using priority review, we assumed sales began 1.3 quarters earlier but ended at the same time.

For products with fewer than 13 observed years, we projected forward using the sales-growth curve estimated in prior work (Supplementary Table 4) [5]. These curves implicitly incorporate the average contribution of factors such as additional indications.

We did not project sales beyond 13 years. Instead, we conservatively assumed sales fell to zero after year 13, consistent with evidence that the typical period of market exclusivity before generic entry is approximately 13 years [6]. This assumption has little effect on the value of priority review for two reasons. First, sales after generic or biosimilar entry occur roughly 13 or more years after launch and are therefore heavily discounted. Second, our baseline assumes that a voucher accelerates launch but does not change the date of entry for generics or biosimilars. When the relevant patent expiration date is fixed, the standard-review and priority-review sales paths erode in the same way. In that case, sales after generic entry will increase total sales but not affect the incremental value of priority review.

For three non-voucher drugs approved before 2014, we backcast early post-approval years using 2014 sales data and the FDA approval date. Because these products had observed sales beyond year 13, we retained those realized values.

Taxes, costs, and early-mover competitive advantage

We assumed a marginal corporate tax rate of 21%, the US rate and a reasonable benchmark, given that many manufacturers are US-based (Supplementary Table 3). This assumption is conservative: firms operating in jurisdictions with lower tax rates, such as Ireland’s 13%, would have higher net sales and correspondingly higher voucher values.

We assumed a cost-of-goods-sold share of 25% [7]. We included production costs because they scale with unit sales. We excluded costs that do not vary with review timing, such as manufacturing, because they cancel when comparing scenarios with and without priority review.

Early launch can provide a persistent advantage within a therapeutic class. Two of the first three vouchers purchased were used in close races to market. We assumed that reaching the market one quarter earlier would increase market share by 0.009, based on research previously reported in this journal [8]. Priority review shortens approval by 1.3 quarters, implying a 1.2% absolute increase. For a product with a baseline market share of 50%, this is roughly a 2.4% relative increase in sales.

Net present value calculations

When computing expected net present value, we accounted for approval risk. We assumed a 95% probability of approval for drugs using vouchers. We chose this value because firms typically redeem vouchers for candidates with the strongest clinical and commercial prospects. If vouchers had been allocated at random across development programs, a lower success probability (for example, 90%) would have been more appropriate [9].

Let t index years from launch and let $T = 13$. Let r denote the annual discount rate, c the cost-of-goods share, and κ the corporate tax rate. Let τ^{hold} denote the time holding the voucher, τ^{std} denote the standard review duration, and τ^{pri} denote the priority review duration. The extra time on the market is $\Delta\tau = \tau^{\text{std}} - \tau^{\text{pri}}$.

A drug using a priority review voucher sells at the branded price for $T + \Delta\tau$ years. Because net sales were available only at an annual frequency, we approximated the additional period of exclusivity as a fraction $\Delta\tau$ of annual peak net sales in the final year. (In all specifications, the estimated additional time on the market, $\Delta\tau$, is strictly less than one year. We used annual sales data and assumed a January launch date, even when the true launch occurred later in the year, which was a conservative assumption).

Accordingly, the baseline case assumes $T = 13$ years of branded sales, whereas the priority-review case assumes the same sales path shifted forward by 1.3 quarters, with an additional 32.5% of annual peak net sales at the end of year 13.

The baseline net present value (NPV) without a voucher is

$$\mathrm{NPV}_{\text{no voucher}} = \rho \sum_{t=1}^{T} \frac{(1-\kappa)(1-c)s_t}{(1+r)^{t+\tau^{\text{hold}}+\tau^{\text{std}}}}.$$

With a priority review and competitive advantage, where m_0 denotes market share in the therapeutic class, the NPV is

$$\mathrm{NPV}_{\text{voucher}} = \frac{\rho(1-\kappa)(1-c)\left(1+\frac{4\cdot \Delta m \cdot \Delta\tau}{m_0}\right)}{(1+r)^{\tau^{\text{hold}}+\tau^{\text{pri}}}}\left[\sum_{t=1}^{T}\frac{s_t}{(1+r)^t} + \frac{\Delta\tau \cdot s_T}{(1+r)^T}\right].$$

The voucher value equals the net present value under priority review minus the baseline net present value without a voucher.

Robustness checks

We varied the values by 20% to decrease or increase the net present value. For the exclusivity period, we used 10 and 16 years as the lower and upper bounds, respectively, instead of applying an exact 20% adjustment, in order to use integer values. For the probability of approval, we considered a narrower range, with the lower bound set at 90% [9] and the upper bound at 100%. We did not conduct a robustness check for $\Delta\tau$, as it is defined as the difference between τ^{std} and τ^{pri} and therefore cannot be varied independently.

Value relative to peak sales

We also estimated voucher value as a share of expected peak annual net sales to inform prospective voucher buyers. This calculation used projected peak sales and the average rebate across products.

Value relative to other mechanisms

We compared voucher value with the cost of speeding a drug earlier in development. Instead of buying a voucher, a firm could invest earlier to shorten clinical testing. For example, a firm could

spend money in phase II to speed recruitment for phase III even before phase II finishes. That upfront spending is wasted if phase II testing fails and the drug is abandoned. A voucher lets the firm commit later to spending money on speed, after phase III testing is complete.

Consider a risk-neutral firm with a drug in phase II. The firm can (i) pay now to shorten phase III by four months, or (ii) wait three years and, conditional on reaching submission, use a priority review voucher at submission. Let the voucher price be $200 million, the probability of reaching submission be 0.17 [10], and the annual discount rate be 0.105 [9]. The maximum up-front payment equivalent (in expected present value) to buying the voucher later is $(0.17 \times 200)/(1.105)^3 = \$25.2$ million.

Under these assumptions, spending roughly $25 million now to speed phase III is equivalent (in expected present-value terms) to buying a $200 million voucher at submission.

Limitations

The net present value estimates depend on key parameters: the discount rate, cost-of-goods, corporate tax rate, and the early-mover advantage. Our main conclusions are robust to plausible variation in these inputs.

Several conservative assumptions might cause our estimates to understate true voucher values. First, we treated all launches as occurring in January. For products that actually launch mid-year, this timing overstates discounting. For example, we treated sales occurring 1.5 years after approval as if they occurred 2 years after approval and were thus too heavily discounted. This assumption also shortens the exclusivity period by half a year. Second, we set sales to zero after 13 years of branded sales. Third, we assumed a 21% corporate tax rate; manufacturers with lower effective tax rates would retain more net revenue and therefore generate higher voucher values.

IQVIA Analytics Link sales data are proprietary and cannot be publicly redistributed, which limits direct replication of results. To promote transparency, we provide code and all nonproprietary inputs necessary to reproduce our calculations and to re-run sensitivity checks under alternative assumptions.

Results

Selected drugs

The final sample includes 27 drugs: 17 that used vouchers and 10 top-selling drugs that did not. Voucher users are concentrated in analgesics, antivirals, diabetes and obesity treatments, immunology, and ophthalmology (Supplementary Table 1, Supplementary Figure 1). Among non-users, five treat diabetes or obesity, and several others are in the immunology or oncology classes (Supplementary Table 2).

Value of faster review for voucher users

Across the 17 drugs for which vouchers were used, the median commercial value of priority review is $212 million, and the mean is $531 million (Supplementary Table 1). Biktarvy, Mounjaro and Vabysmo each gain more than $1 billion in net present value from reaching the market four months sooner, far above the prices paid for their vouchers. At the other end, Beovu generates less than $20 million in estimated voucher value.

Manufacturers paid a median of $130 million and a mean of $163 million for vouchers. Ten of the 17 voucher-using drugs generated value above the purchase price, while seven generated less. Supplementary Figure 3 uses Juluca to illustrate how priority review shifts the sales curve forward and creates value.

Foregone value for non-users

Top-selling drugs for which vouchers were not used could have benefited from faster review. The median forgone value is $444 million, and the mean is $619 million (Supplementary Table 2). We estimate that Ozempic would have gained $1 billion or more from using a voucher. These findings indicate that some firms left substantial value unrealized by not using a voucher. However, the firms later used vouchers. For example, Novo Nordisk, the maker of Ozempic, used a voucher for Wegovy.

Robustness checks

To assess sensitivity, we focus on a representative drug with annual sales based on [5], and vary key parameters by $\pm 20\%$ one at a time. Results are summarized in Supplementary Figure 2. The estimated voucher value is most sensitive to assumptions about review duration. For example, reducing the FDA's standard review time by 20% (from 3.3 to 2.64 quarters) decreases the estimated voucher value by approximately 50%. In contrast, varying the assumed exclusivity period has a relatively small effect on estimated value, as revenues further in the future are heavily discounted. This reinforces that the value of vouchers is driven primarily by regulatory timing rather than cost structure or tax assumptions.

Value relative to peak sales

The estimated voucher value is about 18% of expected peak annual net sales (Supplementary Table 5). This heuristic follows from the model and its assumptions. It can help firms and investors approximate voucher value when detailed projections are unavailable. For example, a phase III drug with expected peak annual net sales of more than $1 billion could justify paying about $200 million for priority review.

Value relative to other mechanisms

We also compare voucher value with the cost of accelerating development earlier in the pipeline. Rather than buying a voucher, a firm could invest in phase II to shorten phase III, for example by speeding recruitment before phase II is complete. That spending is riskier because it occurs before uncertainty is resolved and is lost if the drug fails. A voucher allows the firm to pay later, after phase III is complete.

Under the assumptions in our example, spending roughly $25 million in phase II to accelerate development by four months is equivalent, in expected present value terms, to buying a $200 million voucher at submission.

Data availability

Code and non-proprietary inputs required to reproduce the analysis are available at the project GitHub repository (https://github.com/chenxi-xu/voucher_value). IQVIA data are proprietary and available to researchers through IQVIA under licensing terms.

Supplementary Table 1. Commercial value of vouchers

Drug	Manufacturer	Class	FDA Approval	Price (MM$)	Value (MM$)
MOUNJARO	Eli Lilly	Diabetes & obesity drugs	2022	80	3,120
BIKTARVY	Gilead	Antivirals	2018	290	1,952
VABYSMO	Roche	Ophthalmologicals	2022	NA	1,214
TREMFYA	Johnson & Johnson	Immunosuppressants	2017	NA	613
RINVOQ	AbbVie	Immunosuppressants	2019	350	518
ULTOMIRIS	AstraZeneca	Immunosuppressants	2018	NA	426
DOVATO	ViiV	Antivirals	2019	NA	244
NURTEC	Pfizer	Analgesics	2020	105	229
ODEFSEY	Gilead	Antivirals	2016	125	212
QULIPTA	AbbVie	Analgesics	2021	NA	170
JULUCA	ViiV	Antivirals	2017	130	111
IMJUDO	AstraZeneca	Antineoplastic agents	2022	NA	53
AJOVY	Teva	Analgesics	2018	150	48
MAYZENT	Novartis	Immunosuppressants	2019	125	43
PRALUENT	Sanofi/Regeneron	Lipid modifying agents	2015	68	41
SOLIQUA	Sanofi	Diabetes & obesity drugs	2016	245	24
BEOVU	Novartis	Ophthalmologicals	2019	130	11
MEDIAN			-	130	212
MEAN			-	163	531

Source: Authors' analysis using data from the FDA, IQVIA, and public reports. Notes: Using data from 2014 to 2025, but forecasting beyond 2025. Values are in millions of U.S. dollars. "Price" is the price paid for the voucher. "NA" indicates that the voucher was used internally or that the sale price was not disclosed.

Supplementary Table 2. Forgone value of vouchers for drugs that did not use vouchers

Drug	Manufacturer	Class	FDA Approval	Value (MM$)
OZEMPIC	Novo Nordisk	Diabetes & obesity drugs	2017	1,962
JARDIANCE	Boehringer Ingelheim	Diabetes & obesity drugs	2014	911
STELARA	Johnson & Johnson	Immunosuppressants	2009	654
TRULICITY	Eli Lilly	Diabetes & obesity drugs	2014	567
IMFINZI	AstraZeneca	Antineoplastic agents	2017	473
XARELTO	Bayer	Antithrombotic agents	2011	408
GENVOYA	Gilead	Antivirals	2015	415
TECENTRIQ	Roche	Antineoplastic agents	2016	343
VICTOZA	Novo Nordisk	Diabetes & obesity drugs	2010	268
FORXIGA	AstraZeneca	Diabetes & obesity drugs	2014	187
MEDIAN			-	444
MEAN			-	619

Source: Authors' analysis using data from the FDA, IQVIA, and public reports. Notes: Using data for 2014 to 2025, but forecasting beyond 2025. Values are in millions of US dollars.

Supplementary Table 3. Parameter assumptions and sensitivity

Notation	Description	Baseline Source	Baseline	Reduces Value	Increases Value
κ	Corporate tax rate (%)	U.S. rate	21%	25%	17%
c	Cost of goods sold share (%)	[7]	25%	30%	20%
s_t	Annual net sales in year *t*	IQVIA		Varies	
r	Annual discount rate (%)	[9]	10.5%	13%	8%
ρ	Probability of approval (%)	[9]	95%	90%	100%
Δm	Market share gain per quarter (%)	[8]	0.9%	0.7%	1.1%
m_0	Baseline market share (%)	Authors	50%	60%	40%
T	Exclusivity (years)	[6]	13	10	16
τ^{hold}	Time holding the voucher (years)	Authors	1	1.20	0.80
τ^{std}	Standard review time (years)	[11]	0.825	0.66	0.99
τ^{pri}	Priority review time (years)	[11]	0.5	0.60	0.40
$\Delta\tau$	Extra exclusivity (years)	Authors	0.325	-	-

Baseline values are used in the main analysis. Changing assumptions by 20% decreases or increases the net present value.

Supplementary Table 4. Annual growth rates

Year	Share of Peak	Implied Annual Growth
1	11%	—
2	31%	182%
3	58%	87%
4	76%	31%
5	89%	17%
6	100%	12%

Source: Authors' estimates using the median growth rate from previous studies [5].

Supplementary Table 5. Estimated voucher value and 18% of peak net sales, with voucher status

Drug	Used voucher	Estimated voucher value (in millions USD)	18% of peak net sales (in millions USD)
AJOVY	Yes	48	53
BEOVU	Yes	11	26
BIKTARVY	Yes	1952	2064
DOVATO	Yes	244	260
IMJUDO	Yes	53	54
JULUCA	Yes	111	115
MAYZENT	Yes	43	39
MOUNJARO	Yes	3120	3233
NURTEC	Yes	229	238
ODEFSEY	Yes	212	220
PRALUENT	Yes	41	49
QULIPTA	Yes	170	183
RINVOQ	Yes	518	767
SOLIQUA	Yes	24	24
TREMFYA	Yes	613	928
ULTOMIRIS	Yes	426	480
VABYSMO	Yes	1214	1230
FORXIGA	No	187	261
GENVOYA	No	415	650
IMFINZI	No	473	632
JARDIANCE	No	911	1480
OZEMPIC	No	1962	2505
STELARA	No	654	1254
TECENTRIQ	No	343	386
TRULICITY	No	567	1020
VICTOZA	No	268	505
XARELTO	No	408	450

Source: Authors' analysis using data from the FDA, IQVIA, and public reports. Notes: Drugs using vouchers appear at the top and those not using vouchers appear at the bottom. Estimated voucher values are the same as reported in Supplementary Tables 1 and 2. These estimates are compared to 18% of the product's peak annual net sales.

Supplementary Figure 1

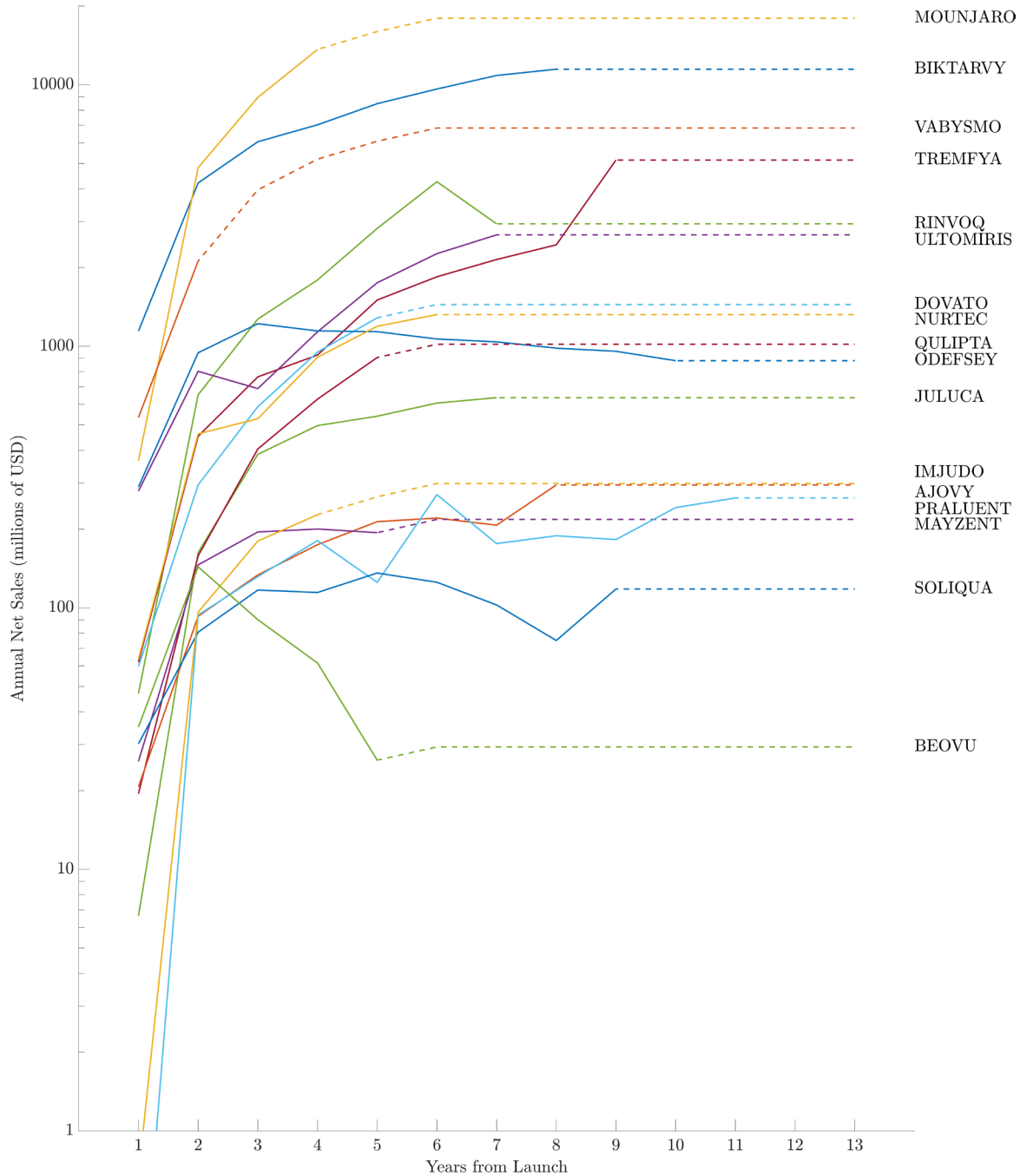


Figure 3. Annual net sales for drugs that used vouchers. Source: Authors' analysis using IQVIA data, 2014–2023, and company reports, 2024–2025. Notes: Annual net-of-rebate sales (log scale), measured in millions of USD. Dashed lines indicate estimated values.

Supplementary Figure 2

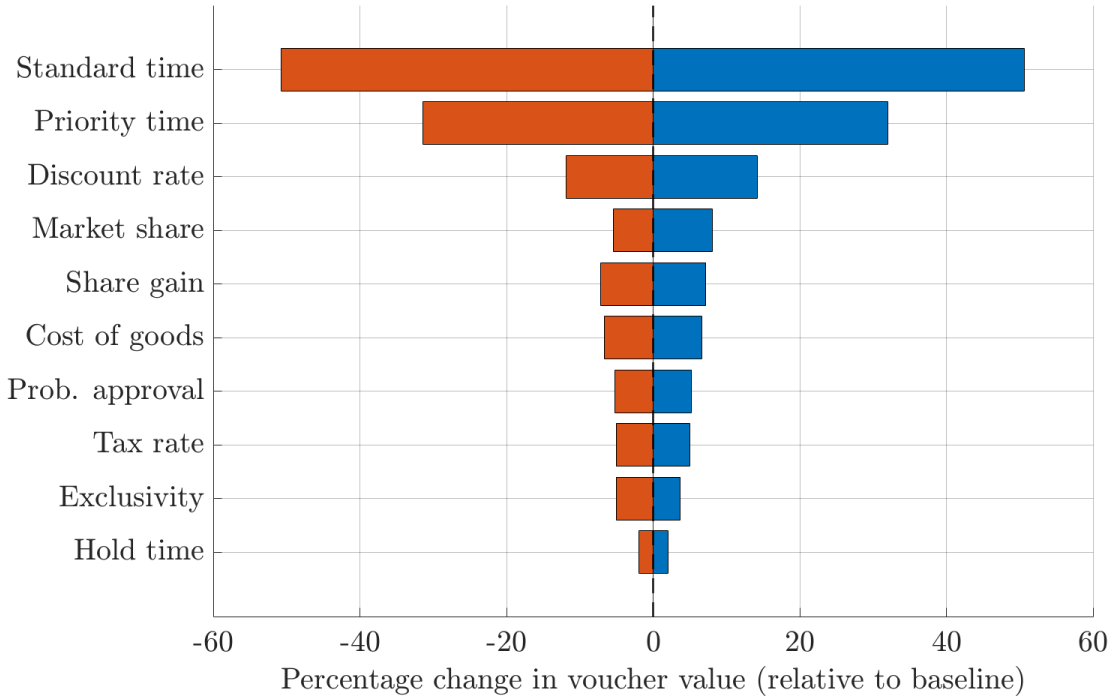


Figure 4. Net present value of the drug with annual sales from [5] as parameter values decrease or increase by 20%.

Supplementary Figure 3

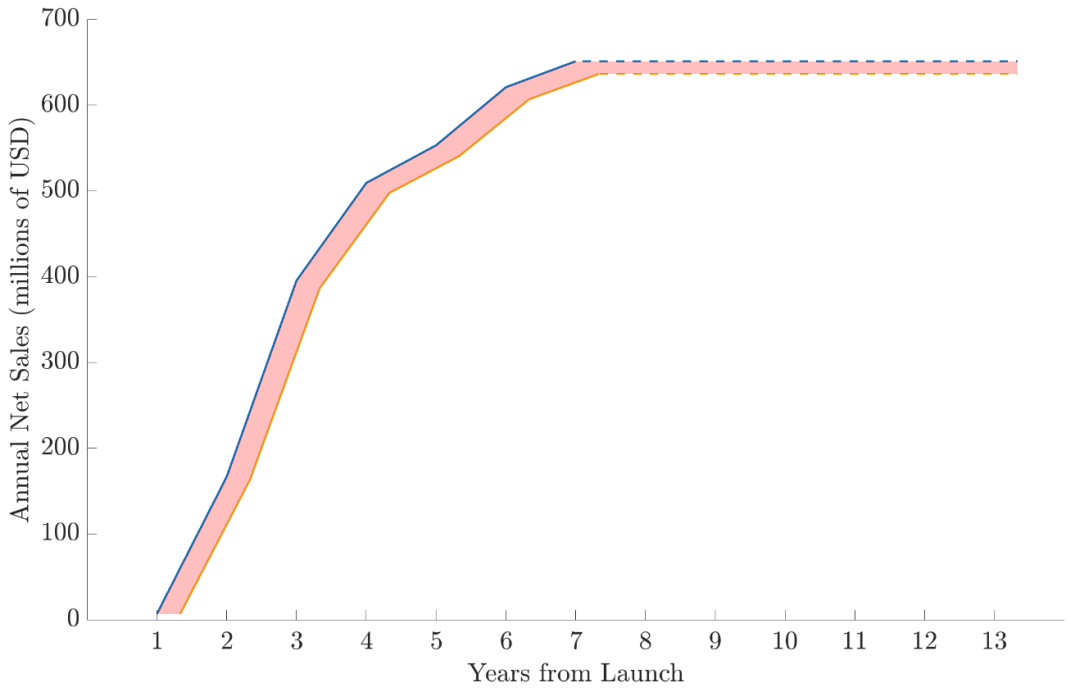


Figure 5. Priority review shifts sales forward and early-mover advantage shifts sales up. The voucher value is the net present value of the area between the curves. The dashed lines indicates estimated values. Source: Authors' analysis of Juluca.

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