

Drug regulation, public funding and healthcare payments

Most Favored Nation (MFN) pricing
and regulatory reliance

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Most Favored Nation pricing may change foreign funding decisions

- On May 12, 2025, the U.S. announced Most Favored Nation (MFN) drug pricing.
- The May 20 target linked U.S. prices to the lowest price in an OECD country with GDP per person at least 60% of the U.S. level ([U.S. Department of Health and Human Services, 2025](#)).
- A manufacturer accepting a low foreign funding price could gain foreign sales while putting U.S. revenue at risk.

Question: Did new foreign public-funding entries slow more for medicines with greater prior U.S. spending?



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MFN literature: Entry is well studied, foreign funding less so

Literature	What it establishes
Prices and launch	Expected prices and price controls affect international introduction (Danzon et al., 2005; Kyle, 2007).
Reference pricing	Linking prices across countries can deter entry in low-price markets (Maini and Pammolli, 2023).
Pricing reforms	Medicaid procurement and German reimbursement rules change incentives and market outcomes (Feng et al., 2023; Büssgen and Stargardt, 2023).

Gap: How does a U.S. pricing announcement relate to foreign public funding, and does the response vary with U.S. spending exposure?



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What we do

- **A difference-in-differences (DiD) design:** Compare changes in new public-funding entries before and after the May 2025 announcement.
- **Reference versus comparison markets:** Australia, Switzerland and Britain versus Brazil, Hong Kong and Singapore.
- **An exposure test:** Ask whether the relative decline is larger for medicines with higher pre-announcement U.S. spending.

The DiD compares changes over time across the two market groups.



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A fixed cohort supports the six-market comparison

Common medicine cohort	Six observed markets
589 FDA-approved single-ingredient medicines, 2010–April 2025	OECD: Australia, Switzerland, Britain.
361 linked to positive 2023 Part D spending	Non-OECD: Brazil, Hong Kong, Singapore.
181 higher-spending and 180 lower-spending medicines	Markets chosen for verifiable funding histories and common identifiers.
Median spending: \$28.1 million	Income screen uses revised 2024 GDP data.

Count each medicine once per market at its earliest documented funded access.



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The design compares changes across countries and spending groups



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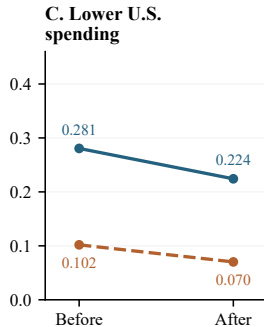
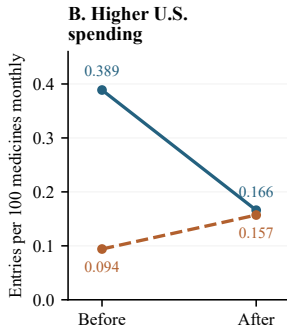
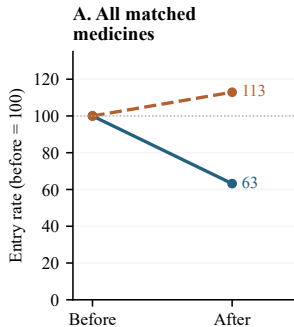
Outcome 1: New funding entries per country-month.

Outcome 2: Higher-minus-lower spending entry rates per 100 medicines.

$$\hat{\beta} = (\text{after} - \text{before})_{\text{reference}} - (\text{after} - \text{before})_{\text{comparison}}.$$

For outcome 2, a negative estimate means higher-spending medicines lose more ground in reference markets.

OECD funding entry slows most for higher-spending medicines



—●— OECD - - - ● - - - Non-OECD comparison

This provides evidence of slower OECD funding entry, with the largest relative decline among higher-spending medicines.



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Higher-U.S.-spending medicines show the larger relative decline

FDA-age-balanced entry rates	Higher spending	Lower spending
Reference-minus-comparison change	−0.286	−0.025

Difference between spending groups = $-0.286 - (-0.025) = -0.261$.

- Units: Entries per 100 medicines per month.
- Approximate 95% interval: $[-0.605, 0.083]$.

The larger decline concerns medicines with more U.S. spending at stake. This provides evidence consistent with the proposed MFN incentive.



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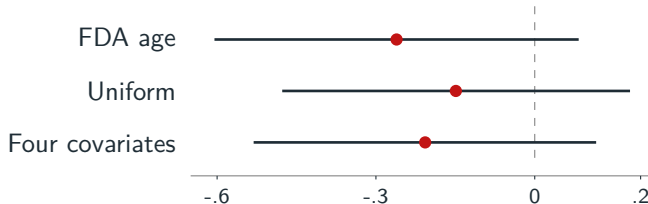
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Alternative medicine weights preserve the estimated direction



- Estimated declines range from 0.149 to 0.261 entries per 100 medicines per month.
- In a wider sensitivity exercise, 288 of 300 distinct designs retaining the original age-balanced exposure comparison are negative.

This provides evidence that the negative exposure association persists across medicine weights.



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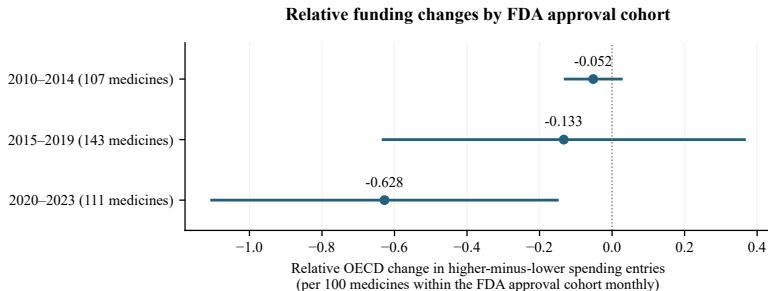
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The estimated decline is largest for newer medicines



The 2020–2023 cohort accounts for about 74% of the pooled decline. This provides evidence that newer medicines drive the estimated exposure pattern.



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What we find

- **What we find:** Higher-spending medicines show a larger relative decline in recorded funding entry after the announcement.
- **What is new:** Evidence on foreign public funding differentiated by prior U.S. spending exposure.
- **Substantive meaning:** The relative slowdown is concentrated among medicines with greater prior U.S. spending.

This provides evidence that foreign public-funding responses vary with medicines' prior U.S. spending.



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Reliance lets domestic authorities use foreign assessments

- A medicine approved abroad may still need a domestic authorization.
- Reliance allows a domestic authority to use another regulator's work while retaining responsibility for its decision ([World Health Organization, 2021](#)).
- Complete scientific reports, sharing permission and product matching may determine which procedures are available.

Question: How do these arrangements relate to medicine purchases and the allocation of healthcare payments?



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Reliance literature links rules, information and payment

Literature	What it contributes
Entry and regulation	Standardized legal comparisons and pharmaceutical entry barriers (Djankov et al., 2002; Kyle, 2007; Wang et al., 2023).
Reliance practice	Foreign reports, matching applications and documentary variation (Keyter et al., 2020; Poulard et al., 2025).
Text and information	Legal wording and the expertise needed to use external knowledge (Gentzkow et al., 2019; Cohen and Levinthal, 1990).
Healthcare financing	Insurance, reimbursement and pricing shape purchases and payment incentives (Duggan and Scott Morton, 2010; Yapar et al., 2025).

Gap: Connect the precise information a reliance route permits with spending and who pays for care.



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What we do

New evidence

What it lets us examine

250 countries and areas searched, 2000–2025

Historical coverage, with 444 national passages from 134 jurisdictions.

89 pathway texts and 65 language texts

Required reports, permissions, matching and domestic review.

The same medicine in 94 countries

How procedures change when reports, permissions or approvals change.

Dated routes linked to trade and healthcare accounts

Imported-medicine purchases and healthcare financing.

New contribution: Make usable foreign information an observable part of regulatory integration.



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The model links usable procedures to profitable applications

Input	Role in the manufacturer's decision
Reports and permissions	Determine usable information and which approval procedures are available.
Costs, delays and approval chances	Determine the expected net return from an available procedure.
Purchasing opportunities	Higher operating returns can expand applications. Responses may differ for first ingredient families and additional options.
Domestic expertise	Determines how effectively a regulator uses foreign reports.

We adapt the market-size logic of [Acemoglu and Linn \(2004\)](#) to medicines already available abroad.

A usable approval route matters when its expected sales justify the cost and delay of applying.



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The financing model asks who pays for additional treatment

Public payers choose coverage and purchases subject to treatment value and a budget.

Source of additional financing	Implication for healthcare payments
Government finances added treatment	The government share can rise when additions are more publicly financed than existing care.
Households or external programmes finance additions	The domestic-government share can fall even if more treatment becomes available.
Public coverage takes over an existing household bill	Household spending can fall without an increase in total expenditure.

The financing response depends on the marginal purchaser and coverage decisions.



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The reliance design compares earlier and later arrangements

- For an arrangement in year g , compare the average of $g + 1$ to $g + 3$ with $g - 1$. Omit the event year.
- Comparisons qualify for arrangements after $g + 3$ (Callaway and Sant'Anna, 2021).
- Measure prior medicine imports relative to GDP over $g - 4$ to $g - 2$.

$$\Delta Y = \alpha_g + \beta T + \theta(T \times Z) + \pi Z + X'\delta + u.$$

Read θ : The additional response associated with a one-standard-deviation difference in prior import exposure.

One exposure standard deviation represents roughly 2.25 times the prior import-to-GDP ratio.



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Latest estimates link import exposure to more public financing

Comparison	Estimate	95% interval
Broader arrangements, 62 treated, GDP weights	2.46	[0.17, 4.75]
Same sample, capped GDP weights	2.31	[0.50, 4.13]
National routes, 23 treated, GDP weights	4.50	[1.44, 7.56]

Units: Percentage points of government healthcare financing per exposure standard deviation.

More import-dependent countries show a larger shift toward government financing.

This provides evidence that national reliance arrangements are associated with larger public-financing gains in more import-dependent countries.



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The financing pattern concerns who pays for healthcare

Same 62 treated jurisdictions and pre-reform GDP weights

Payer	Spending change	Share change (pp)
Government	+8.1%	+2.46
Households	-2.5%	-0.96
Other payers	—	-1.50
Total healthcare	+2.7%	—

Government spending grows faster than total spending, shifting a larger share of healthcare costs toward public payers.

This provides evidence of a shift toward public financing in more import-dependent countries.



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Household surveys add separate evidence on financial strain

Exposure-related change	Estimate	Treated / countries
Findex medical borrowing, national routes	-5.23	10 / 16
WHO hardship, collaborative registration	-5.61	12 / 22
WHO impoverishing spending, same comparison	-5.69	12 / 22

- Units: Percentage points per prior import-exposure standard deviation.
- Findex adjusts for pandemic overlap. WHO adjusts for prior external health financing.

This provides evidence that greater prior import dependence is associated with larger reductions in household financial strain.



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The same medicine reveals the role of reports and permissions

Case	Prior approvals	What changes
A	FDA + European	Public summaries only, complete reports unavailable.
B	FDA + European	Complete reports and all required permissions.
C / D	FDA + European	Applicant consent or regulator-sharing permission unavailable.
E	FDA only	Complete FDA reports and permissions, European approval removed.

- Reports and permissions satisfy an applicable complete-report condition in **9 of 94** country cases.
- Ten cases involve multiple-approval requirements. Six also have a one-approval alternative.



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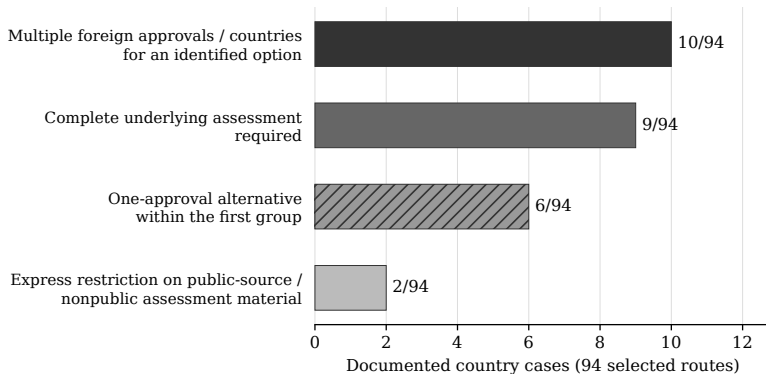
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The same medicine faces different documentary requirements



This provides evidence that foreign approvals and usable reports determine an applicant's procedural options.



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Two contributions connect international rules to payment decisions

	MFN pricing	Regulatory reliance
Gap	Foreign public funding after a U.S. pricing announcement.	Usable foreign assessments and healthcare payments.
What we do	Link funding dates to prior U.S. spending in six markets.	Combine legal texts, a fixed-medicine exercise and financing comparisons.
What we find	Higher-spending medicines lose more ground in recorded funding entry.	More import-dependent countries show larger public-financing responses in the latest GDP-weighted comparison.

This provides evidence that international policy connections matter for foreign funding entry and healthcare financing.



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