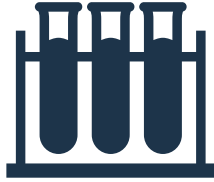


Turning Japan's Innovation Crisis into a National Growth Engine

Policy Proposals to Eliminate Drug Loss and Attract Investment

APRIL 17, 2026

The Global Biopharmaceutical Industry Is Vital to Japan's Health, Security and Economic Growth



1,200+

Medicines in Clinical Development in Japan

74%

Potential First-In-Class Treatments



436 Million

COVID-19 Vaccine Doses Administered in Japan

81%

Cancer Patients Returning To Work Within a Year of Diagnosis



140,000+

Direct Biopharmaceutical Sector Jobs in Japan

¥14 Trillion

Japan R&D Investment in the Last Decade

Foreign-Headquartered Biopharmaceutical Companies Are Major R&D Investors in Japan

Medicines Pipeline



Foreign companies are responsible for **73%** of new medicines in clinical development in Japan

Clinical Trials



Foreign companies are responsible for **78%** of clinical trials in Japan

Medicines Launched



Foreign companies are responsible for **79%** of innovative medicines launched in Japan

Japan Has Right Elements To Be a Life Sciences Leader, But Harmful Policies Stand in the Way

Strengths of Japan's Ecosystem



Strong basic science capabilities, including academic institutions and Nobel Prizes



World-class regulator (PMDA) that ensures safety, efficacy and quality



Biopharmaceutical research companies



Rapid access to medicines for all citizens through National Health Insurance

Pricing Policies Threaten Progress



Launch prices in Japan are lower and falling relative to other major markets



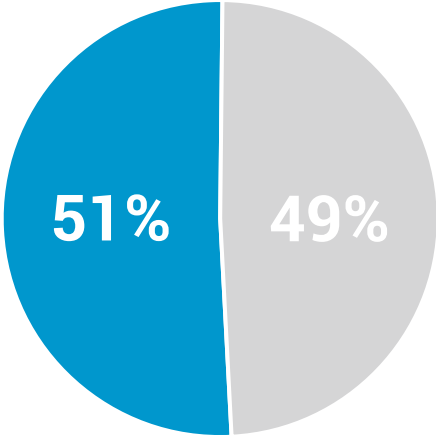
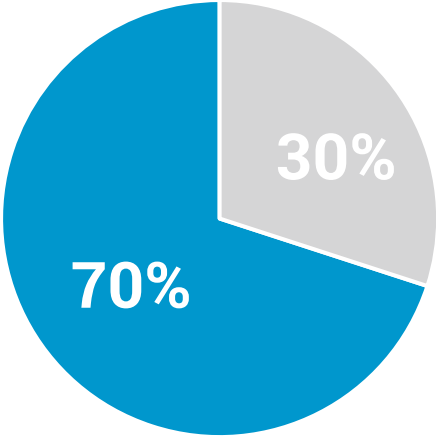
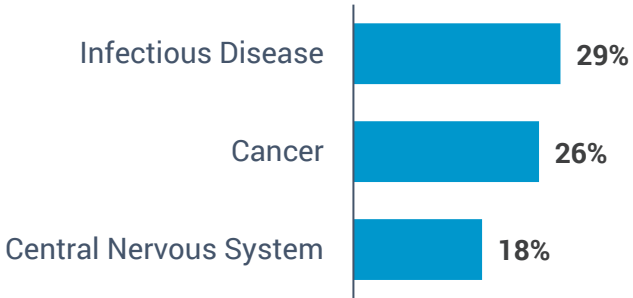
Japan then cuts prices repeatedly during the patent period



Current government proposals are not on track to reverse course

Japan's Drug Loss Is Projected to Worsen

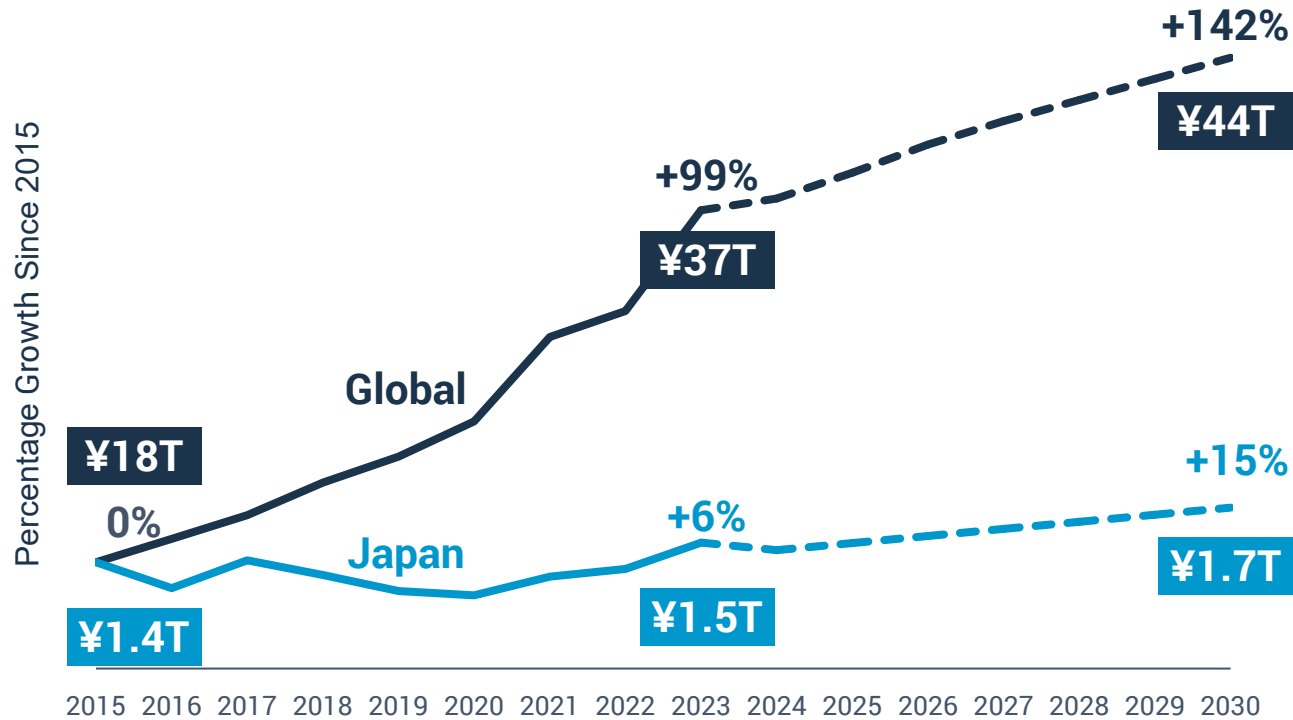
70% of late-stage new medicines in the US or Europe are not yet developed in Japan

Current Drug Loss	Future Drug Loss	
<p>! 245 new medicines launched in United States or Europe but not Japan from 2014 to end of 2023</p>	<p>! 601 future medicines are currently in Phase 3 clinical trials in United States or Europe</p>	<p>! 404 future medicines not in development in Japan target major areas of unmet medical need</p>
<p>Of these 245 new medicines, 124 (51%) have not begun development in Japan</p> 	<p>Of these future medicines, 404 (70%) have not begun development in Japan</p> 	<p>Top 3 therapy areas of new medicines not in development in Japan</p> 

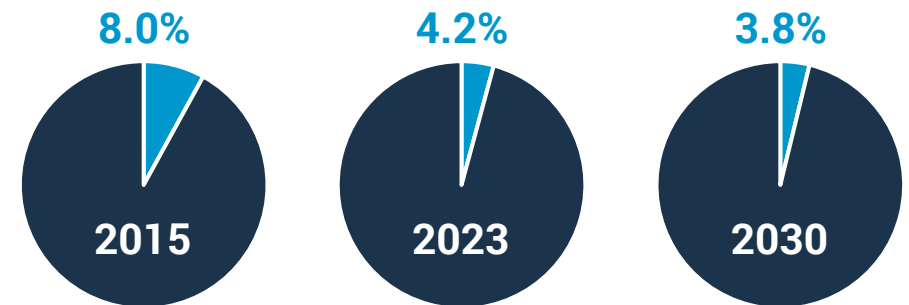
Japan's R&D Investment Gap Projected to Worsen

Japan struggles to attract global biopharmaceutical R&D investment

Percentage Growth in Biopharmaceutical Industry R&D Investment in Japan vs. Global



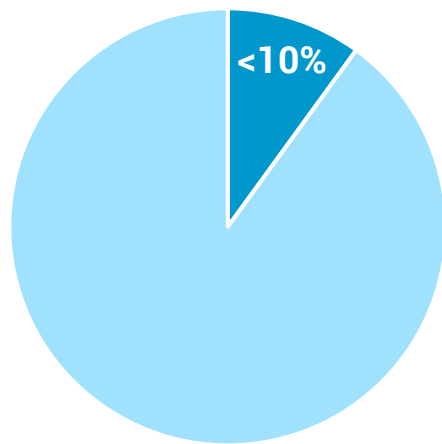
Japan Share of Global Biopharmaceutical Industry R&D Investment



Japan Has Become Overly Dependent on Drug Price Cuts to Control Overall Social Security Budget

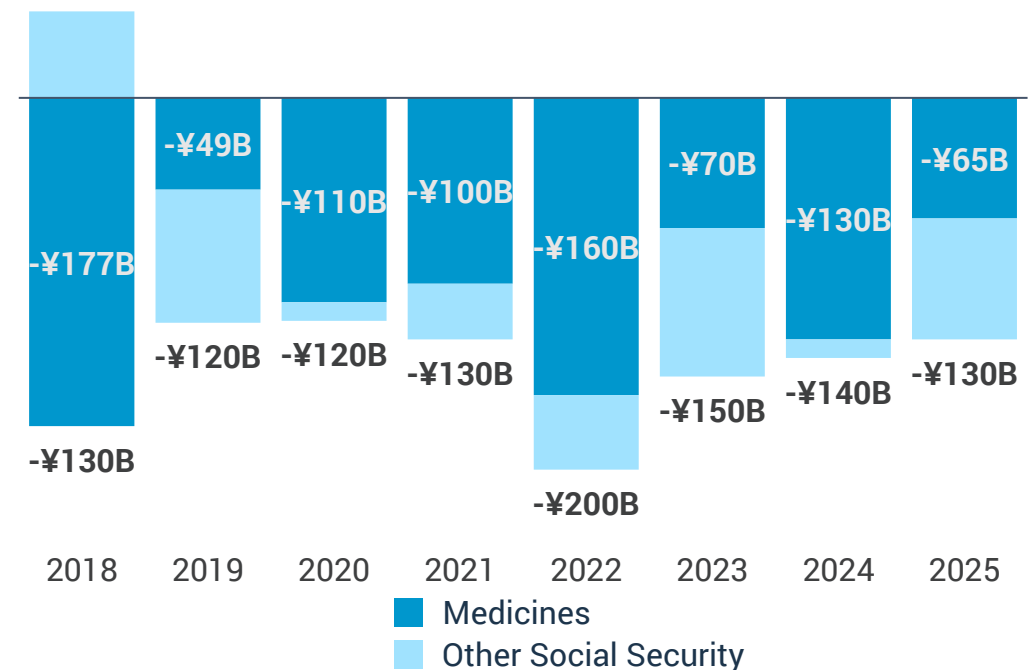
Share of Social Security Budget Spent on Medicines

Less than 10% of the budget is spent on medicines



Share of Social Security Budget Reductions from Medicines vs. Other Sectors

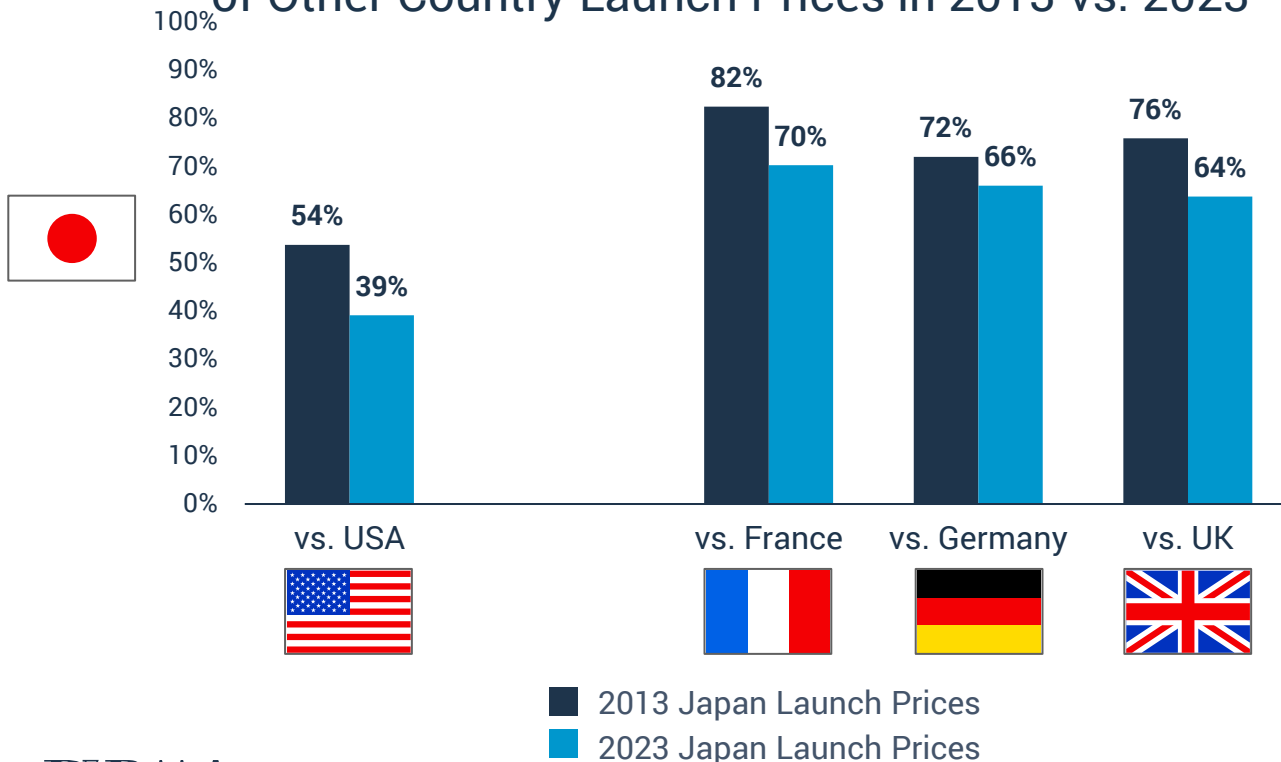
But 70% of budget reductions are from drug price cuts



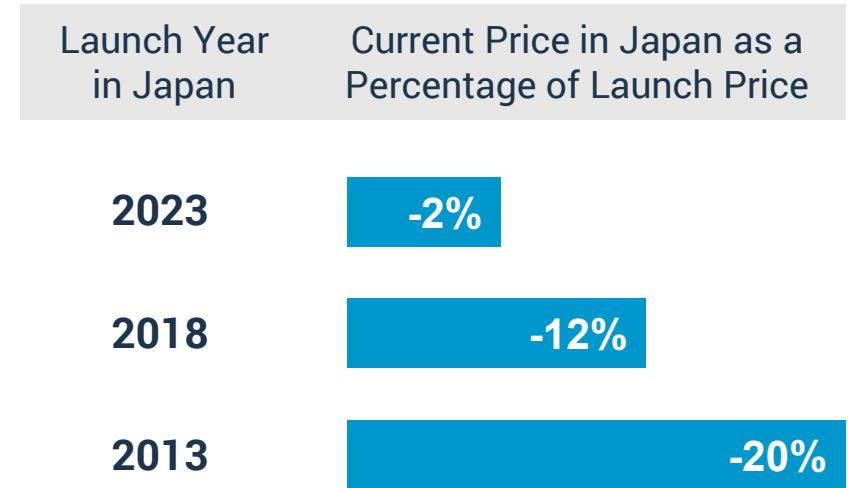
Japan's Drug Pricing Has Worsened Significantly

Launch prices in Japan have fallen vs. all major markets, and these price differentials are then exacerbated by repeated price cuts during the patent period

New Medicine Launch Prices in Japan as a Percentage of Other Country Launch Prices in 2013 vs. 2023



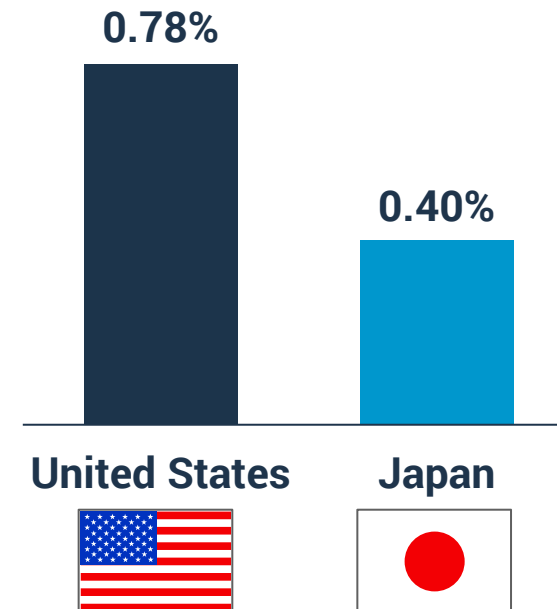
Average Price Erosion in Japan Since Product Launch



U.S. Most Favored Nation Policy Increases Urgency for Action on Longstanding Challenges in Japan



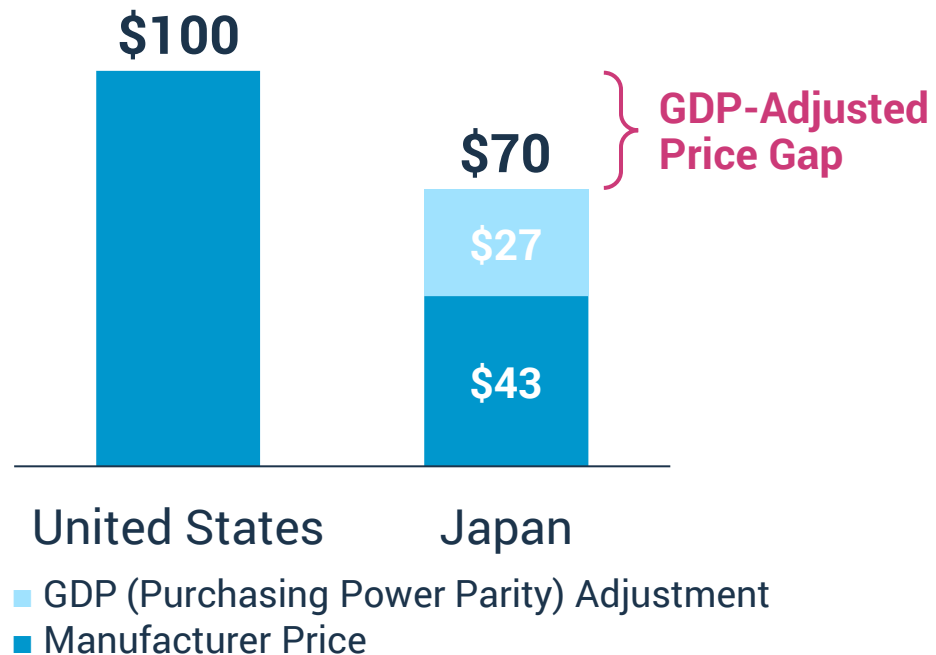
Percentage of GDP Spent on New Innovative Medicines



Relative Net Prices and Revenues in U.S. vs. Japan

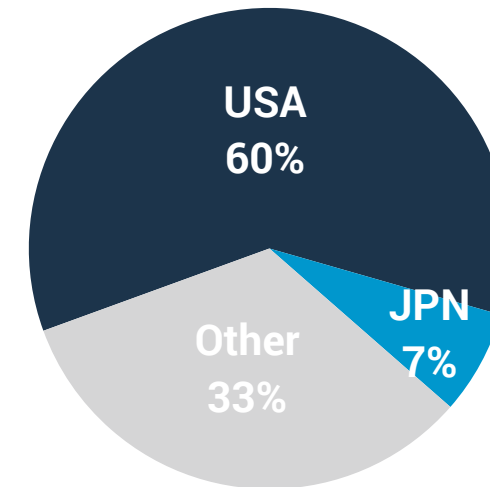
**Median PPP-Adjusted Prices in Japan
Are 30% Lower than U.S. Net Prices**

Median Price in Japan
Relative to U.S. Net Price



**Net Revenues from United States
Are Over 8x Larger than from Japan**

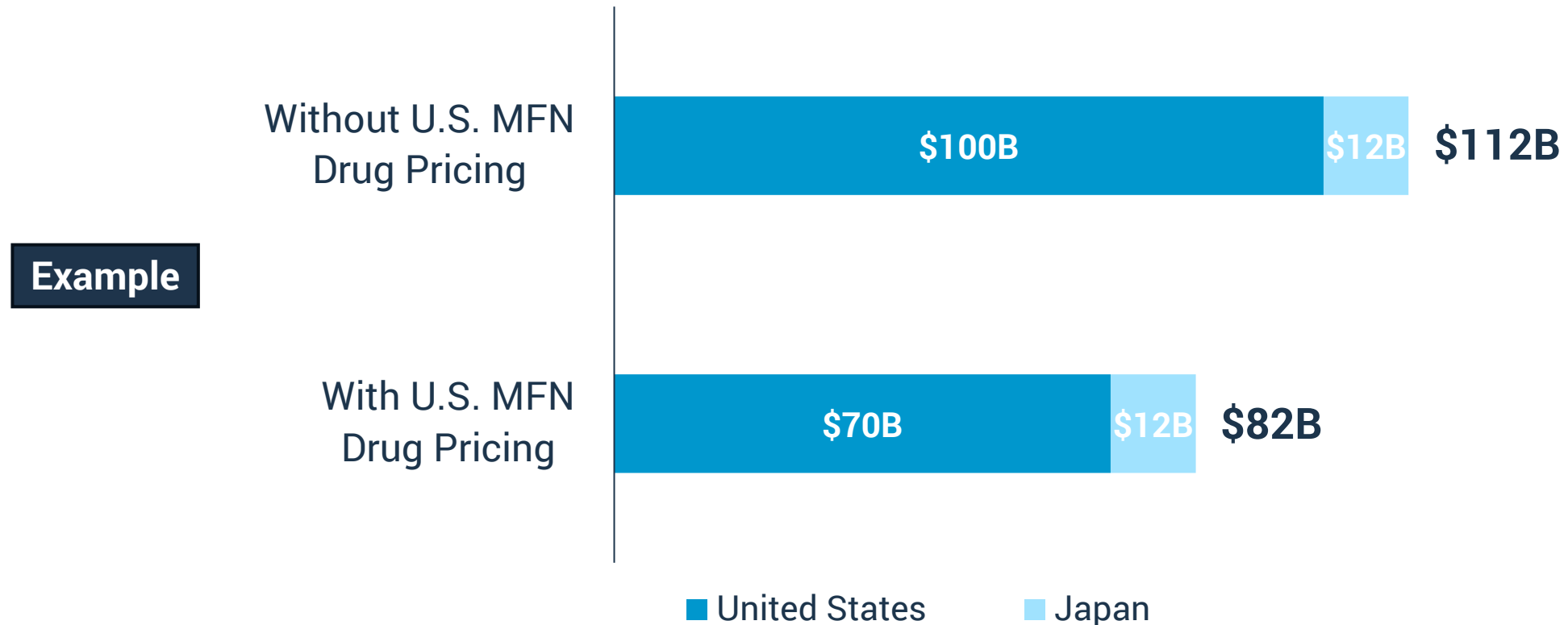
Share of Revenues from
New Innovative Medicines



Launching in Japan Could Decrease Total Revenues

Access to Japan's smaller market does not offset revenue losses in the larger U.S. market

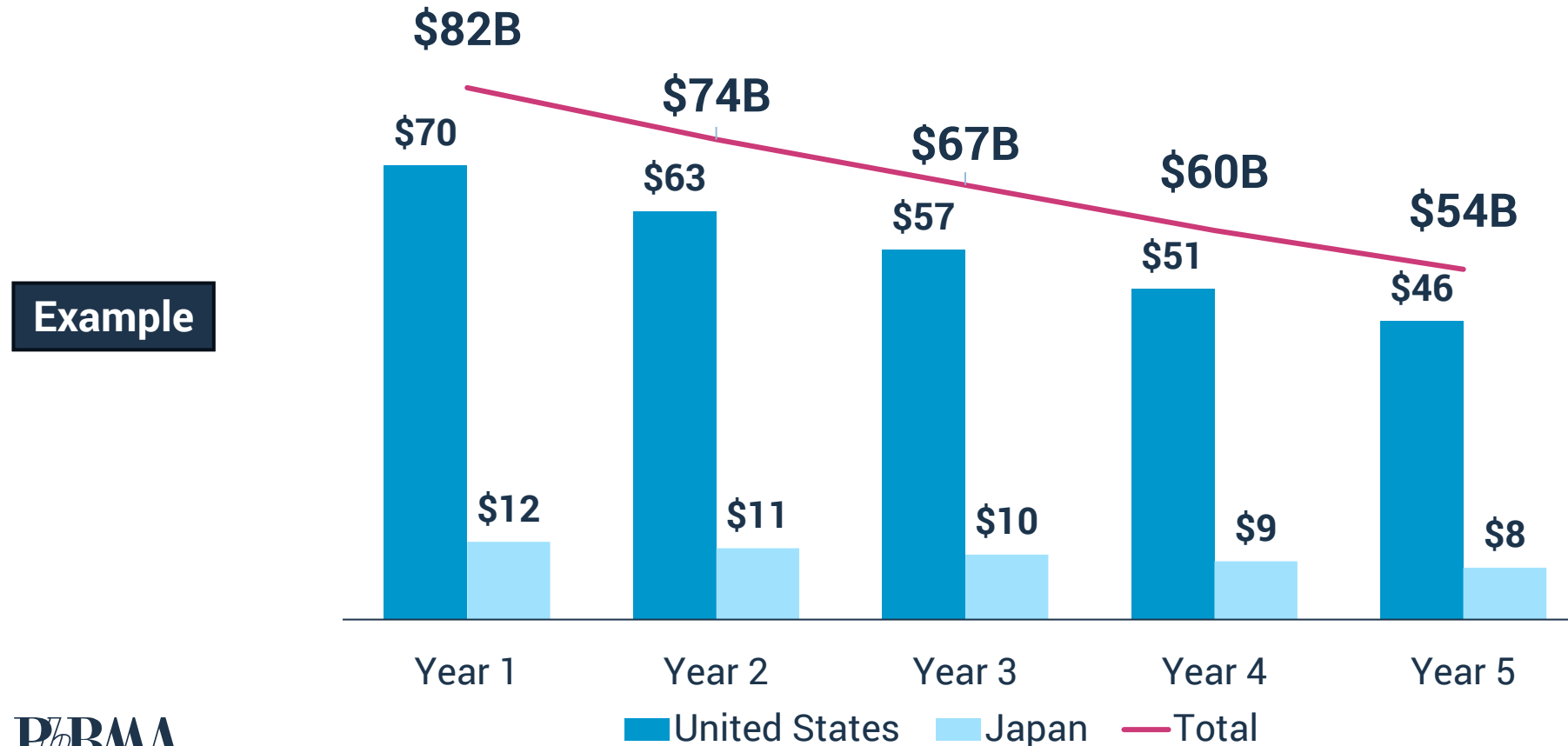
Total Revenues From Launching a \$100B Revenue U.S. Product in Japan



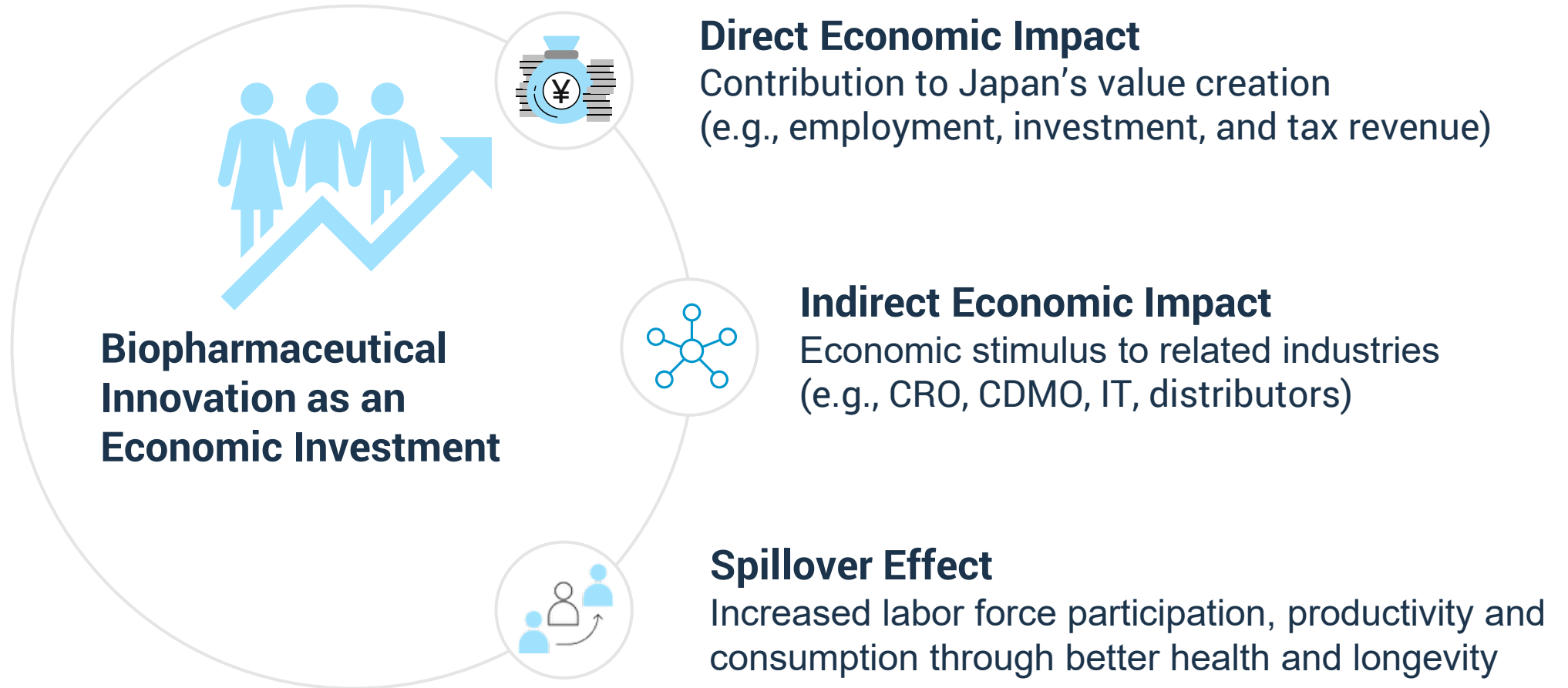
Price Cuts in Japan Could Further Reduce U.S. Price

Japan's price cuts could trigger MFN price cuts and revenue losses in U.S. market each year

Total Revenues With U.S. MFN Pricing and 10% Annual Price Cuts in Japan



Paradigm Shift: Unlocking Japan's GDP Growth through Biopharmaceutical Innovation



NHI Drug Pricing System Reform Is Urgently Needed to Address MFN and Attract Investment

Improve Initial Price Setting and Recognition of Value

- **Reform initial NHI pricing rules** so that prices are in line with global benchmarks
- **Improve rules to value new modalities** (e.g., regenerative medicine)

Maintain Prices During the Patent Period

- **Exclude patented medicines from annual repricing**
- **Abolish or cap price cuts from market expansion repricing** and related rules (e.g., HSR)
- **Stop expansion of cost effectiveness assessment** and ensure objective verification

Drive Economic Growth and NHI Sustainability

- **Help recapture 1% of global biopharmaceutical R&D** and yield ¥370B in new investment by ending ¥250B in price cuts to patented medicines annually
- **Reallocate budget savings to innovation** by optimizing spending on off-patent drugs

Japan Needs a Bold Strategy with Key Actions

Addressing market stagnation and MFN-reshaped incentives requires urgent strategy development and execution of Public Private Council recommendations

Set Goal and Policy Reform Direction Work Group for Drug Discovery and Advanced Medicines



Goal

- Achieve growth in Japan's patented medicine market in line with other major developed countries

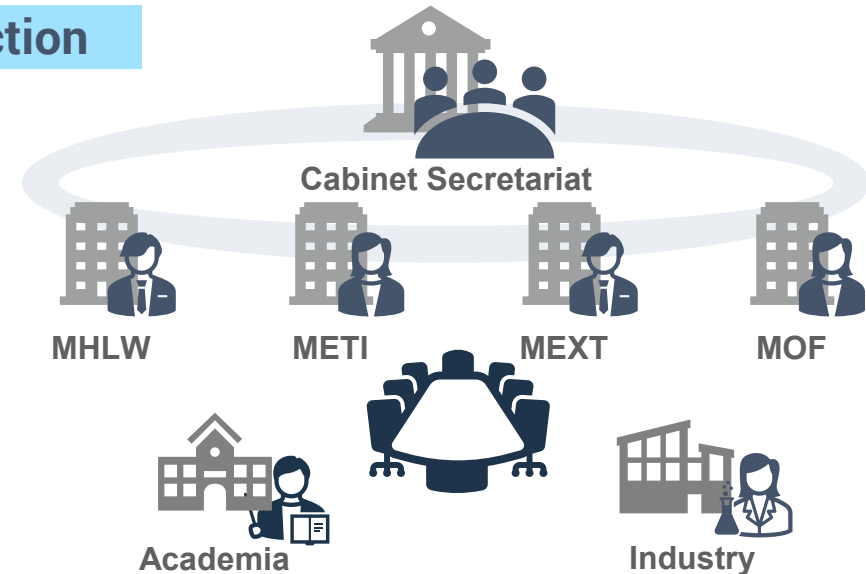


Direction

- Promote a transparent and pro-innovation drug pricing system
- Strengthen the environment for R&D and biotech start-ups
- Improve and harmonize Japan's regulatory environment

Identify and Recommend Needed Actions Public Private Council for Enhancing Drug Discovery

Action



- Hold action-oriented discussions on concrete policy reforms needed to drive innovation and sustain the universal health insurance system

PhRMA
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