INTERNATIONAL PRICING INDEX The Impact on Patients, Outcomes, and Innovation

GLOBAL INN



A Study by Vital Transformation

The International Pricing Index

The Department of Health and Human Services (HHS) has proposed reimbursing certain drugs under Medicare Part B based on an international benchmark that effectively imports foreign government price controls into the United States.

The Study

Together with industry partners, GIPC commissioned international consultancy Vital Transformation (VT) to model the likely real effects of the IPI proposal on private sector R&D.

VT used HHS's own IPI model to calculate the balance sheet impact to those companies with affected products under Medicare Part B's revised pricing.

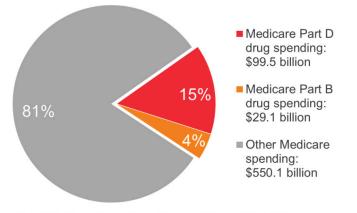
The HHS IPI model targets medications where the price is above the calculated 1.26 (126%) threshold (i.e., 20 products).

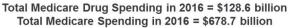
IPI's targeting of Medicare Part B spending (4% of total Medicare spending) will skew R&D away from physician-administered cancer therapies, a major focus of Part B, as companies try to avoid this classification.

VT analyzes those medications targeted by IPI to run three scenarios:

- 1) the impact of the 50% Medicare IPI implementation at year 5,
- 2) a 100% Medicare IPI implementation at year 5, and
- 3) a Medicare IPI scenario that impacts all U.S. pricing.

IPI only focuses on 4% of total Medicare spending:





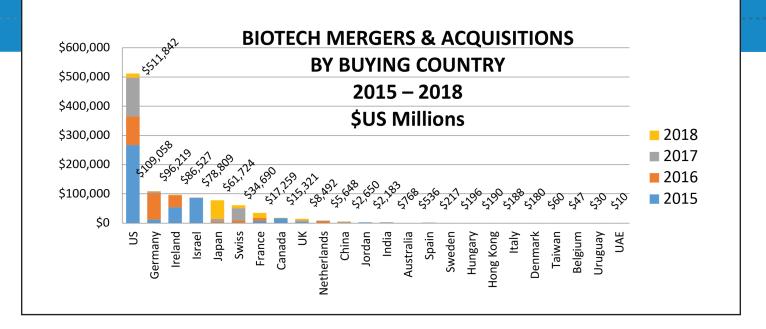
SOURCE: MedPAC, June 2018 Data Book (Part B drug spending) and 2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, Tables III D1 and V.B.



KEY TAKEAWAYS

- IPI penalizes innovation. It targets the companies with the most advanced, newest products.
- Bringing European pricing models to the U.S. imports problems, not solutions. If broadly applied, IPI will drive down R&D by 25% a year on average. (Much higher than the 1% reduction assumed by HHS).
- Prior to the introduction of reference pricing, in 1986 Europe invested 24% more in R&D than the United States; after introducing reference pricing, in 2018 Europe invested 40% less.
- As well as large cuts to R&D, IPI is likely to contribute to excessive industry consolidation, radically reducing the amount of liquidity available to support diverse, small-scale projects throughout the innovation ecosystem for medicines. This innovative environment centered around various U.S. hubs has been enormously beneficial to the longterm well-being of Americanshaving a world leading ecosystem with large R&D investments has led to more high-paying jobs and a stronger economy.

Since the vast majority of global bio-pharma investment happens in the United States, reduced R&D budgets here mean fewer bio-tech start-ups, less research, and fewer new medicines overall.



The U.S. is at the center of the global biotech ecosystem, with the largest investments in R&D. The U.S. system enables the development of the most innovative drugs and treatments, providing Americans with access to life-saving cures.

A Deeper Dive

- For affected firms, the total reduction in net revenue from IPI is likely as much as 25% per annum, roughly \$15 billion in net income for the sector. This is an order of magnitude higher than the 1% of R&D, \$700 million in total revenue impact quoted by HHS.
- The effect will be felt most directly in next generation oncology products such as monoclonal antibodies, since the IPI directly hits physician-administered oncology therapies funded under Medicare Part B.
- The IPI proposal assumes companies will be able to raise prices in Europe; this is highly unlikely, and could lead to retaliatory action (e.g., compulsory licenses) against U.S. products and companies choosing not to release products in the EU.
- The IPI proposal assumes that Medicare Part B prices will not erode the commercial market prices for medicines, which is unrealistic and ignores market economics.

Reducing Medicare Part B Revenue Decreases Likelihood of Successful New Medicines

Oncology (cancer)	Current	50% Medicare (-\$15.5 Bil)	100% Medicare (-\$31.1 Bil)
Total Investment	\$21 billion	\$13.74 billion	\$6.49 billion
Hematology (blood diseases)	Current	50% Medicare (-\$15.5 Bil)	100% Medicare (-\$31.1 Bil)
Total Investment	\$11.6 billion	\$7.59 billion	\$3.58 billion
Central Nervous System Disorders	Current	50% Medicare (-\$15.5 Bil)	100% Medicare (-\$31.1 Bil)
Total Investment	\$5.19 billion	\$3.4 billion	\$1.6 billion