The Impact of the Most-Favoured-Nation (MFN) Policy on the Pharmaceutical Market and on R&D

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Disclosures

- Member of CAPF
- No conflicts of interest

Introduction:
What is the Most Favoured Nation (MFN) policy?

- Dual objective: To lower prices in the US and increase prices abroad.
- Mechanism: Linking US prices for Medicare and Medicaid programs to the lowest prices paid in other high-income countries.
  - “International Reference Prices” (IRP): a tool for regulating prices
- Background: From 2003 until MFN, Medicare was not allowed to negotiate prices with industry

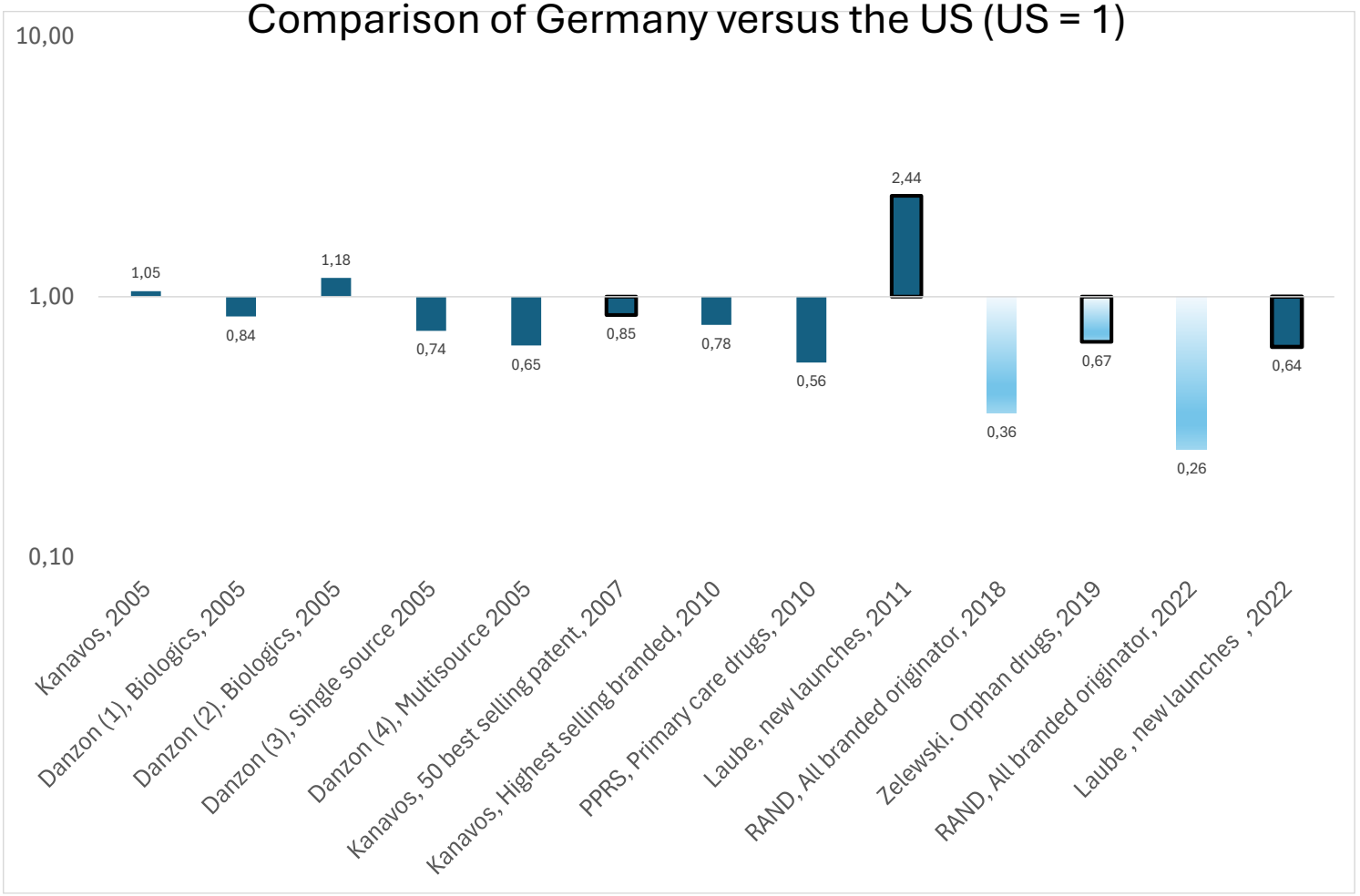
Study methodology

- Review of **empirical** literature
- EconLit, PubMed, grey literature + Elicit AI
- 3 interrelated study questions
  1. Comparison of brand-name drug prices between the US and other high-income countries: “List prices” and “net prices”
     a) “Cross-sectional” studies and b) “longitudinal” studies
  2. Impact of international reference pricing (IRP) policies on prices
  3. Impact of IRP on R&D and innovation
     a) MFN -> lower pharma industry revenues?
     b) lower pharma industry revenues -> les R&D investment?
     c) MFN -> pharma industry relocation to US?

- 49 selected publications.

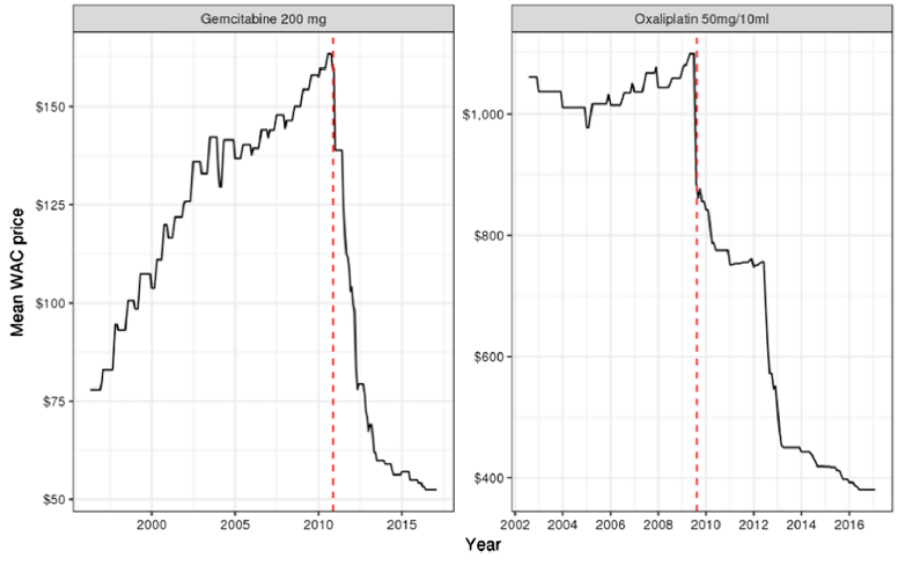
1.a. Price comparison: *cross-sectional studies*

- Before 2010: Data on whether **net prices** in the US were higher are inconclusive
- Last two decades: **Studies** on net prices **are lacking**



1.b. Price comparison: *longitudinal studies*

- Prices in the US rise after the launch date



Note: Price time-series for oxaliplatin based on 50mg vial prior to May 2005 and the 50mg/10ml vial thereafter. WAC = wholesale acquisition cost.

Stephens 2020, Savage 2017

Table 2. Analysis of Price Changes for 10 Top-Selling Oncology Drugs Between Year of Initial Drug Launch and 2015

		Total and Annual Average Price Increase (%)*	
Drug	Year Introduced	United Kingdom	United States
Rituximab	1998	−4.5 (−0.26)	133.7 (7.9)
Trastuzumab	2001	0	75.8 (5.4)
Imatinib	2002	10.7 (0.8)	313.4 (24.1)
Pegfilgrastim	2003	−10.7 (−0.9)	99.9 (8.3)
Bortezomib	2004	0	76.5 (7.0)
Cetuximab	2004	30.5 (2.8)	15.5 (1.4)
Pemetrexed	2004	0	52.6 (4.8)
Bevacuzimab	2005	0	19.7 (1.9)
Lenalidomide	2008	0	53.7 (7.7)
Abiraterone	2012	0	59.9 (19.9)

*Overall total changes, with annual equivalent changes shown in parentheses.

2. The impact of IRP on the pharmaceutical market

- Empirical evidence suggests that IRP policies such as MFN can reduce the prices of **some** medicines in the US.
- And a ‘spillover’ effect: price increases in reference countries as a response from the industry.
  - MFN obliges pharmaceutical companies to match the discount in the US to other countries. A “credible threat” that increases the pharmaceutical company’s bargaining power in its trade agreements with the reference country.
- Evidence of delays in the launch of some new medicines in international markets.

3. The impact of MFN on global R&D

1. MFN -> lower global revenues for pharmaceutical companies?
2. Lower revenues -> less R&D?
3. Relocation of pharmaceutical companies from the EU to the US?

3.1 MFN -> lower global revenues for pharmaceutical companies?

- The literature and evidence on IRP suggests that policies such as IRP
  - may reduce the net prices of some medicines in the US
  - and increase them in reference countries
- The net effect on the overall revenue of pharmaceutical companies is uncertain

3.2 Lower revenue -> less R&D?

- Some studies suggest that R&D expenditure depends on the historical cash flows of the largest pharmaceutical companies (Golec & Vernon 2006, Giaccotto 2005)
  - Global revenues of the ‘top 16’ pharmaceutical companies grew by 6% per year between 2000 and 2020, and R&D investment grew proportionally
- But… if the capital market is efficient, investment (*venture funds, biotech* start-ups…) will depend on expectations of future revenue, not past revenue
  - Acemoglu & Linn 2004, Blume-Kohout (2012) demonstrate that investment in pharmaceutical R&D is determined by the demographic and economic trends of patients in the US

3.3 Will EU pharmaceutical companies relocate to the US?

- European governments are quite concerned
- Several authors argue that companies prefer to set up in the US (a country that historically has not had price regulation) rather than in European countries with greater price regulation: Golec (2006), Kyle (2007), Golec (2010), Eger (2014)
- Meanwhile, Koenig (2011) found that the effect is limited to companies' administrative and marketing activities

Part of R&D is limited to adapting existing products for the US market (Duggan & Morton 2006)

Conclusions

- Cross sectional studies do not show significantly greater net prices of branded drugs in the US before 2010. There have been almost no studies of net prices since then.
- However, net prices increase much more rapidly post launch in the US than in other high-income countries
- MFN is likely to reduce the prices of some medicines in the US and increase them in the reference countries
- The aggregate impact on the sector's profitability is difficult to predict, but could be negative
- The aggregate impact on global pharmaceutical R&D is uncertain, but is likely to be negative
- Many companies have announced that they will relocate to the US, but this is likely due to other factors (tariffs, threats) rather than MFN or price regulation in Europe.