The Drug Importation Debate: An Economic Perspective

Patricia M. Danzon PhD
The Wharton School
University of Pennsylvania
http://hc.wharton.upenn.edu/danzon/index.htm

Effects of Legalizing Drug Importation are Highly Uncertain

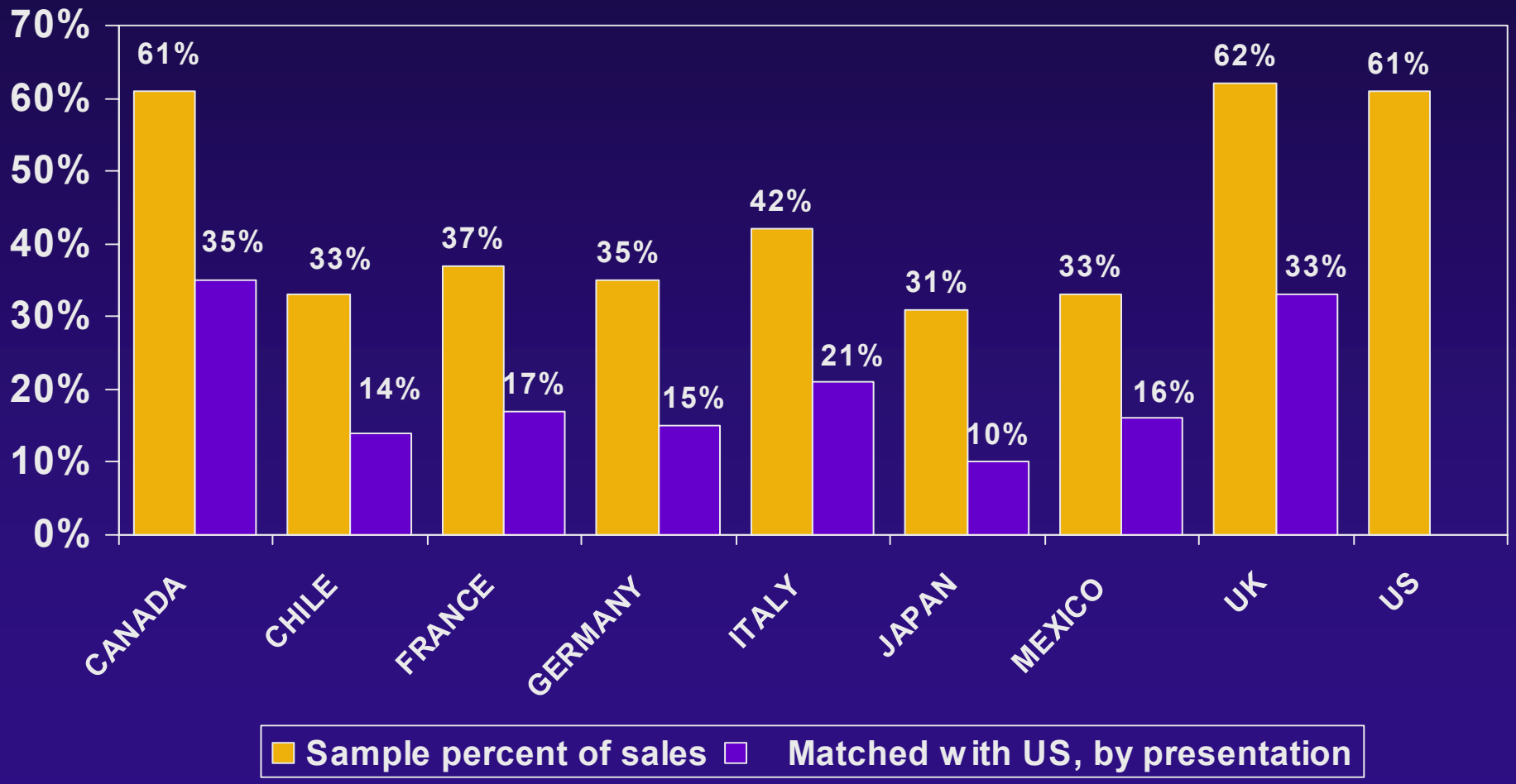
- US legislative proposals differ
  - Countries included, conditions
  - Enforcement measures
- Uncertain responses of
  - Manufacturers
  - Wholesalers
  - Governments in exporting countries
- What is clear: Legalizing importation => massive wholesaler involvement and system-wide adjustments
- Current savings to individual consumers on individual drugs overstate system-wide savings

Importation from Canada + EU, with No Radical New Enforcement Rules

- Focus here on economic effects, but safety issues are major
- Aggregate savings to US consumers will be smaller than revenue loss to manufacturers
- Key issues
  - Mismatch of products
  - Supply restrictions – launched products
  - Foreign price increases or non-launch - new products
  - Intermediaries capture much of the savings

1. Mismatch of Compounds and Presentations Reduces Potential for Importation

Sample = Top 249 molecules, by US Unit Volume



Source: Danzon and Furukawa, *Health Affairs,* Oct. 2003

2. Manufacturer Supply Restrictions to Exporting Countries

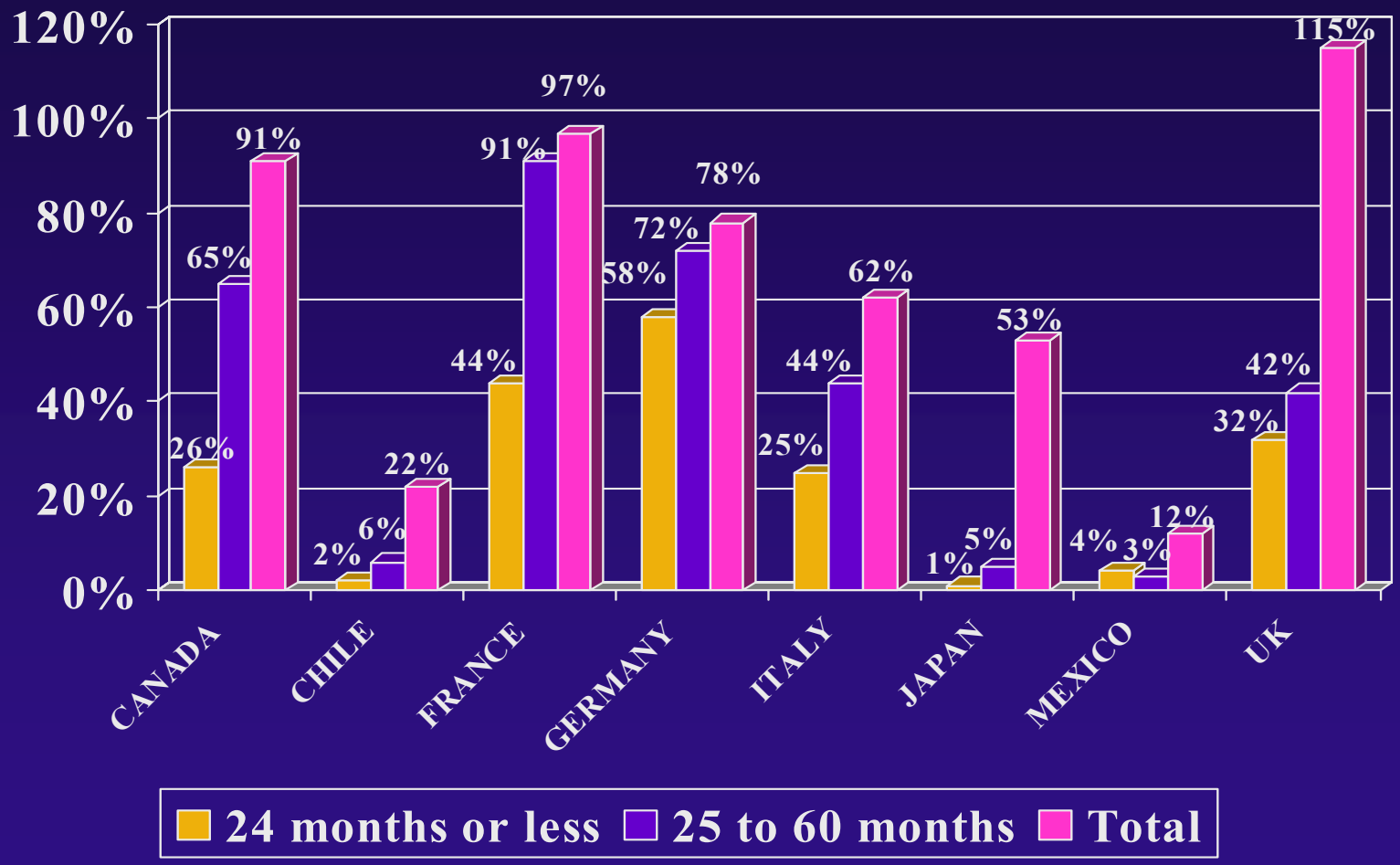
- Some manufacturers restrict supply to Canada to volume needed for Canada
  - Supply restrictions are common in EU, and legal so far
  - Provided manufacturer acts unilaterally and without market dominance (*Bayer Adalat* case)
- How much of limited supply will wholesalers/pharmacies export?
  - Some shortages reported in Canada
- Even if 20% of EU + Canada volume is shipped to US, would only fill 20-30% of US volume
  - And only for matching drugs
- Illegal sourcing from other countries, channeled through authorized export countries, could pose significant safety risk

US Dominates Global Sales: Due to Volume and Price

	2003		% Growth Constant $	
World Audited Market	*US$ Bill*	*% Share*	*2003*	*CAGR 98-02*
Latin America	$17.4	3.7%	+5.5	-2.8
Asia/Africa/Australia	$33.8	7.2%	+9.3	+11.0
Japan	$52.4	11.2%	+3.4	+4.0
Europe (All)	$134.5	28.8%	+9.4	+8.8
North America	$229.5	49.1%	+11.1	+15.2
Worldwide	$467.9	100.0%	+9.3	+10.4
10 Key Markets	$389.2	83.2%	+9.1	+11.3
EU (15)	$116.3	24.9%	+8.0	+8.4

Source: IMS Health Incorporated

Per Capita Unit Volume, By Molecule Age Since Global Launch. Relative to U.S. (US = 100)



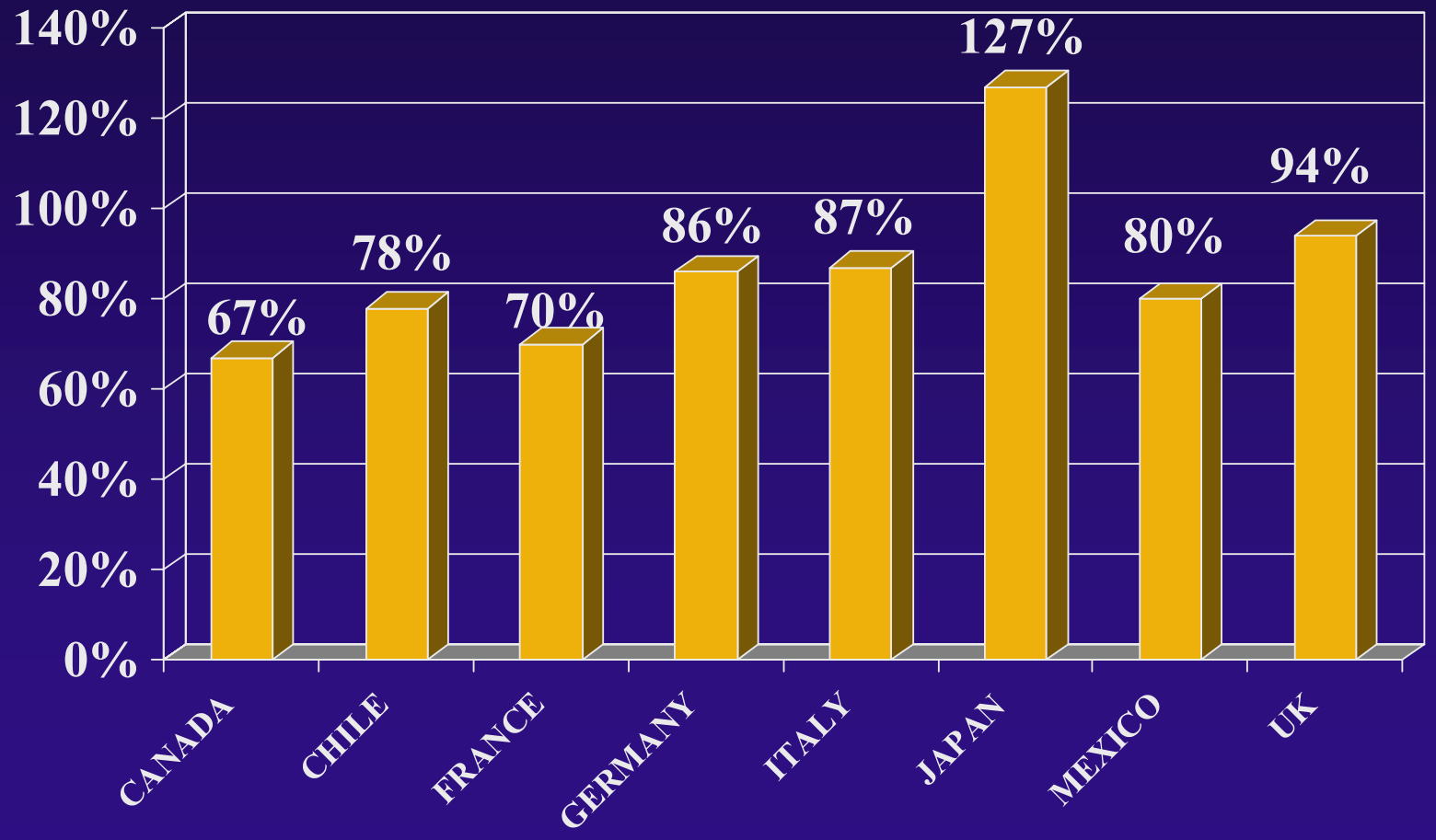
Source: Danzon and Furukawa, *Health Affairs* Oct. 2003.
Note: UK consumption upward biased by a few respiratory products.

3. Some Decline in Foreign-US Price Differentials: (a) Manufacturers May Try to Raise Foreign Prices ---But Resistance is Likely

- Health policy is social insurance and fiscal policy: designed to stabilize health spending and drug spending as a percent of GDP
  - Price/reimbursement controls built in to insurance systems

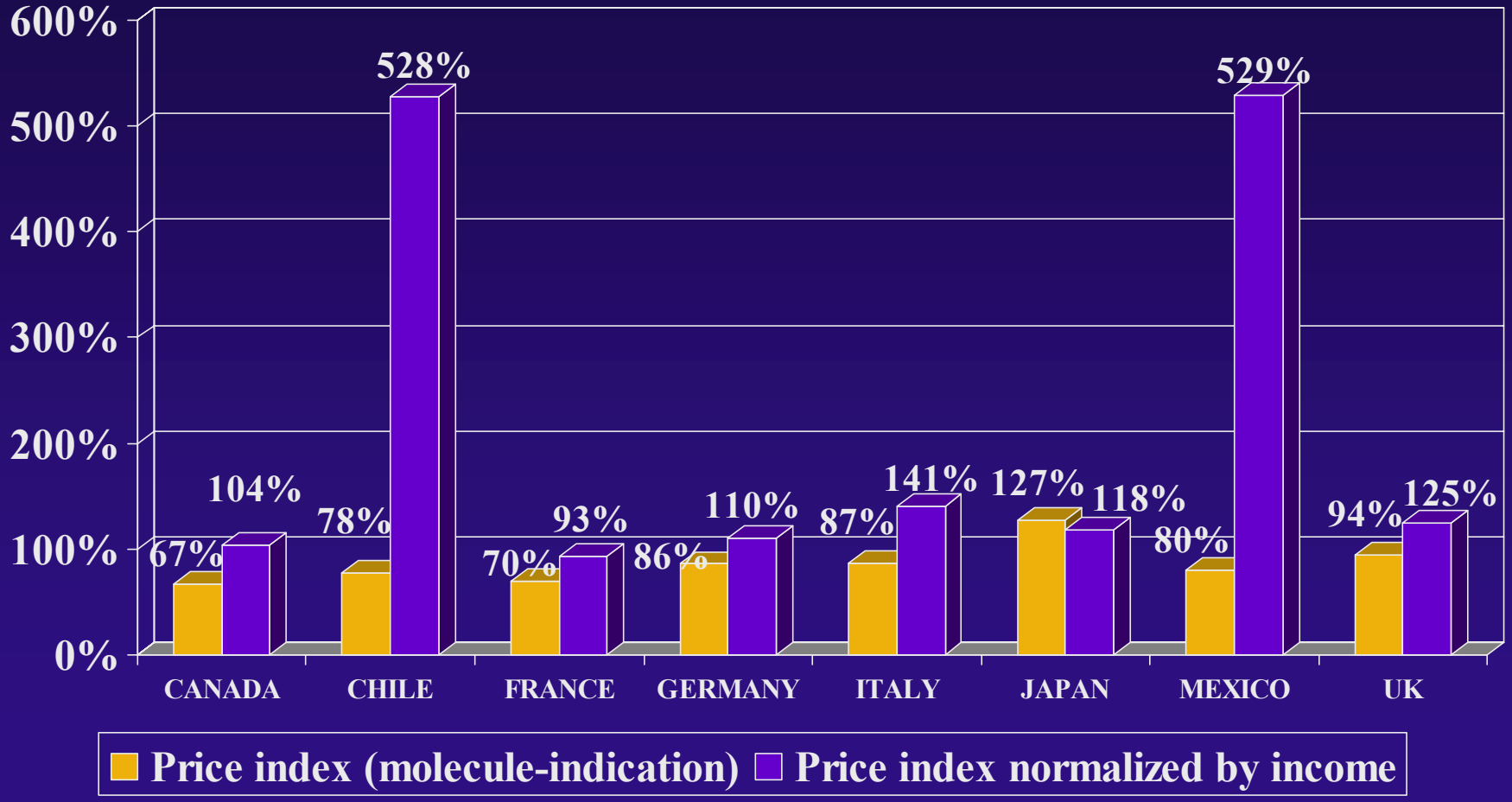
- Foreign drug prices already roughly in line with income in industrialized countries (Danzon and Furukawa, *HA* 2003)

Price Indexes for Comprehensive Sample: Leading 249 Compounds, by Volume, US 1999



Note: United States equals 100%.

Price Indexes Relative to Per Capita Income Differentials (1999)



Note: United States equals 100%.

Control Policies Ex-US Will Constrain Significant Price Increases Abroad

- Health expenditures (including pharmaceuticals) constrained to growth of GDP
- Controls on prices and volumes
- Increased consumer cost-sharing
- Generic and therapeutic referencing=> prices of old products constrain new product prices
- Cost-effectiveness review prior to reimbursement

(b) Delay and Non-launch of New Drugs ex-US if Low Prices

- Manufacturers will rationally weigh foreign revenues vs. loss of US revenues if must accept a lower price to launch abroad
- Price differential sufficient to induce importation will vary by product, potential sales volume, importer costs of repackaging etc.
- Countries that are unwilling/unable to pay prices close to US levels may see fewer/delayed new product launches
- Will non-launch lead to retaliation? compulsory licensing?

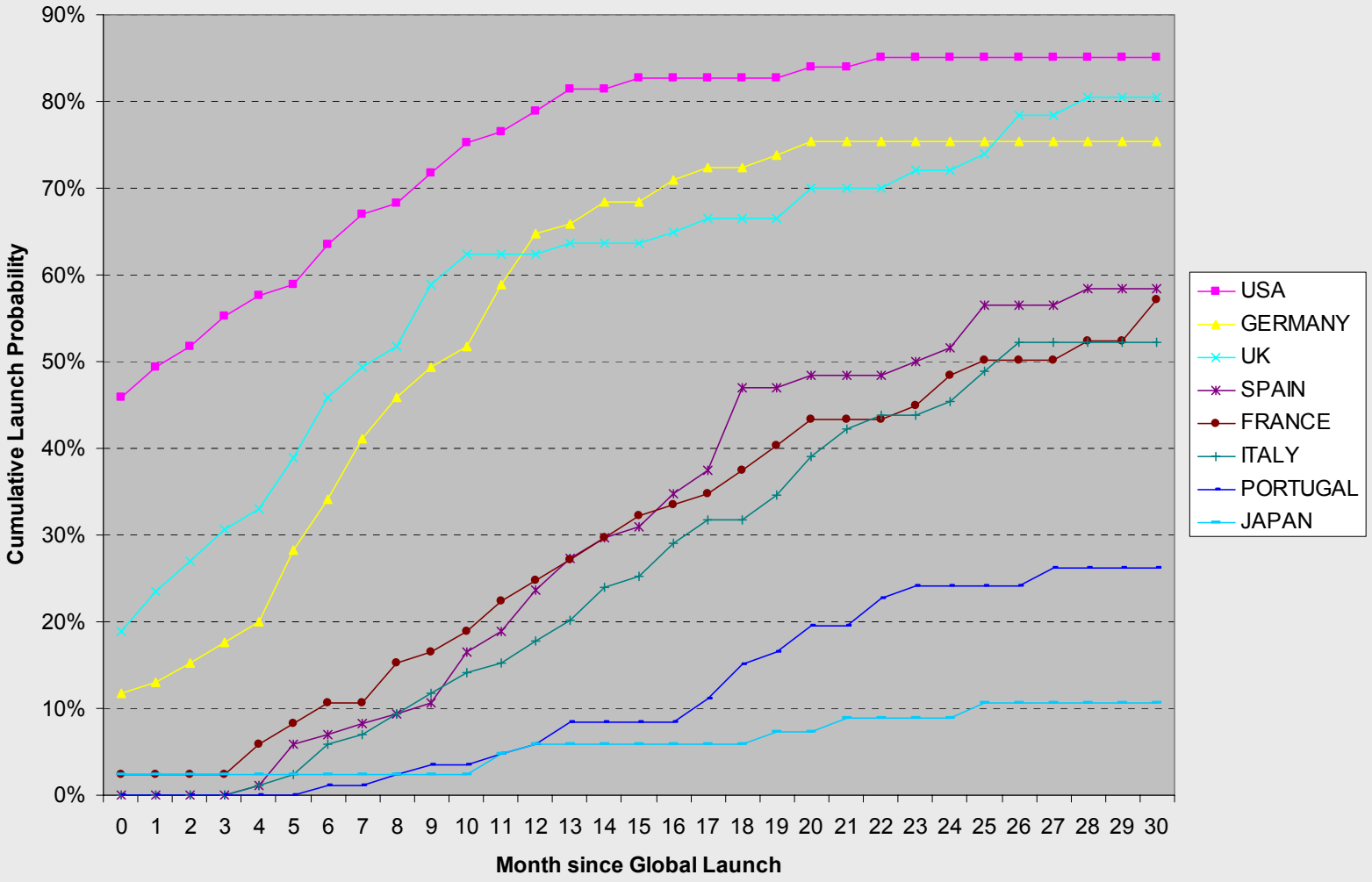
Countries with Lower Prices have Fewer Launches, Longer Launch Lags (Danzon, Wang and Wang, *Health Economics* 2005)

- We estimated the effects of expected price (lagged price of competitor products) on launch delay, controlling for market size , per capita income, etc.
- Sample: launch of 85 NCEs launched in 1994-1999
- 14 EU countries, plus Australia, Canada, Czech, Japan, Mexico, New Zealand, Norway, Poland, S. Africa, Switzerland, and USA
- IMS data on prices and volumes

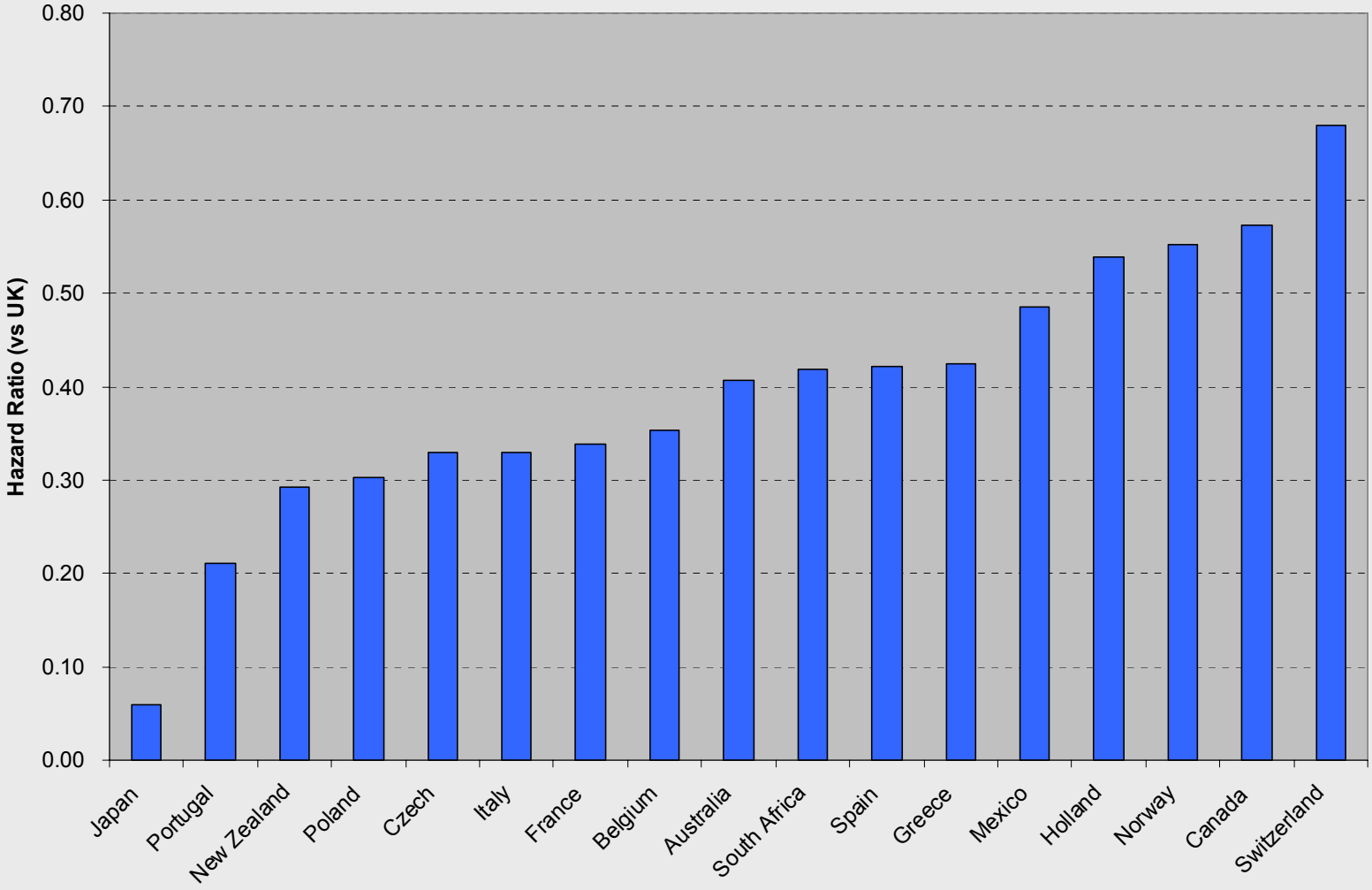
Findings

- Countries with lower prices have longer launch lags and fewer launches
- EU countries that are major PI exporters have longer delays, controlling for expected price and volume

Kaplan-Meier estimates of cumulative launch probability for selected countries



Countries with a significantly longer delays/fewer launches, relative to UK, controlling for price and volume



c. US Price Pressure from Medicare will Narrow Differentials

- Medicare Modernization Act (MMA) to deliver drug benefit through private prescription drug plans (PDPs)
- Each PDP must have at least 2 drugs in each class
  - Classes defined for Medicare by US Pharmacopeia
- Broad definition of classes => older drugs and generics compete with new, on-patent drugs
- Discounts for formulary access could be large in crowded therapeutic classes
- PDPs may demand same discounts for their private plans

4. Middlemen will Capture Some of Any Savings from Importation

- If only a fraction of US demand can be sourced abroad, who will capture the savings?
  - Pharmacy chains and GPOs that buy direct
  - PBMs may "clawback" average pharmacy savings
    - AWP – X% - z%
- Cash-paying customers are unlikely to benefit

- EU experience confirms that middlemen capture much of the savings from parallel trade

Pricing Options When Markets Are Linked by Importation and Regulatory Referencing

1. Uniform Pricing in Interconnected Markets

- Single price is a weighted average of "best" country-specific prices if prices could differ

- US market dominates determination of best single price

- Delay or non-launch in countries that cannot pay target price

Evidence

- 1990s Pricing within bands in EU + Non-launch in low-price countries

Single List Price with Confidential Discounts to Purchasers: The US PBM Model

- Selling to wholesalers at one price eliminates arbitrage potential of importation/parallel trade
- Rebates can be directed to payers, by-passing wholesalers/distributors, to achieve ex-post price differentials
- Regulatory referencing is not feasible if rebates/differentials are confidential
- Rebate recipients have strong incentives not to "leak"
- Rebates can target subgroups e.g. purchasers for poor in LDCs
  - Public hospitals and clinics, NGOs etc.

Implementing Confidential Rebates

- Examples
  - US PBMs negotiate confidential discounts in return for increased market share
    - High control formularies get bigger discounts, more elastic
  - Rebates to East Germany after reunification
  - UNICEF procurement of vaccines: supply prices are not published

- Confidentiality encourages competitive discounting, benefits consumers

Least Bad and Worst Case Importation Scenarios

Least Bad:

- Modest importation risk => price and launch strategies are more complex
- Some narrowing of price differentials due to Medicare pressure in US + attempts to raise prices ex-US
- Lags and non-launch => lower company revenues, loss of access abroad
- Minimal savings to US consumers

Worst Case:

- US constrains manufacturer ability to limit foreign supply
  - Anti-trust suits and/or legislation
- US requires registration of foreign formulations
- Foreign countries apply compulsory licensing if
  - High prices
  - Non-launch

The Global Social Welfare Perspective: Differential Pricing Increases Social Welfare, Compared to Uniform Pricing

1. Greater Use of Existing Drugs (Static Efficiency)
   - Low-income markets can only afford drugs at low prices

2. Efficient incentives for R&D (Dynamic Efficiency)

- Differential pricing is the most efficient, practical way to pay for R&D
- Lower revenue, less R&D with uniform pricing

3. Equity
- Pricing related to income is equitable, by most criteria

=> Importation that undermines differential pricing is bad public policy

Conclusions

- Likely increased pressure on prices: US and ex-US
  - Importation only one factor
- Drug importation in the US would likely reduce industry sales and profits, with little savings to US consumers
  - System-wide effects far less than drug-specific savings to individual consumers
- Costs of enforcing safety will further reduce potential savings
- Other measures to constrain drug prices could be more effective and less harmful to US consumers, foreign consumers and drug manufacturers