

# Drug Importation: Economic Impact

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# Effects of Drug Importation are Highly Uncertain

- US legislative proposals differ
  - Countries
  - Pre-conditions
  - Enforcement
- Manufacturer response
- US and exporting countries' response
- Least bad vs. worst case scenario

# Status Quo

- Importation into the US is illegal
  - In practice, individual own use is permitted
  - Health plan/payer initiatives cooled by FDA warning
- US\$650-700m. imported from Canada in 2003 (IMS estimate) of over \$200b. US sales
- Safety concerns are a major issue
  - Authorized countries could become conduits
- Political pressure
  - Consumers, payers and Medicare face rising drug costs
  - Higher US prices viewed as “unfair”

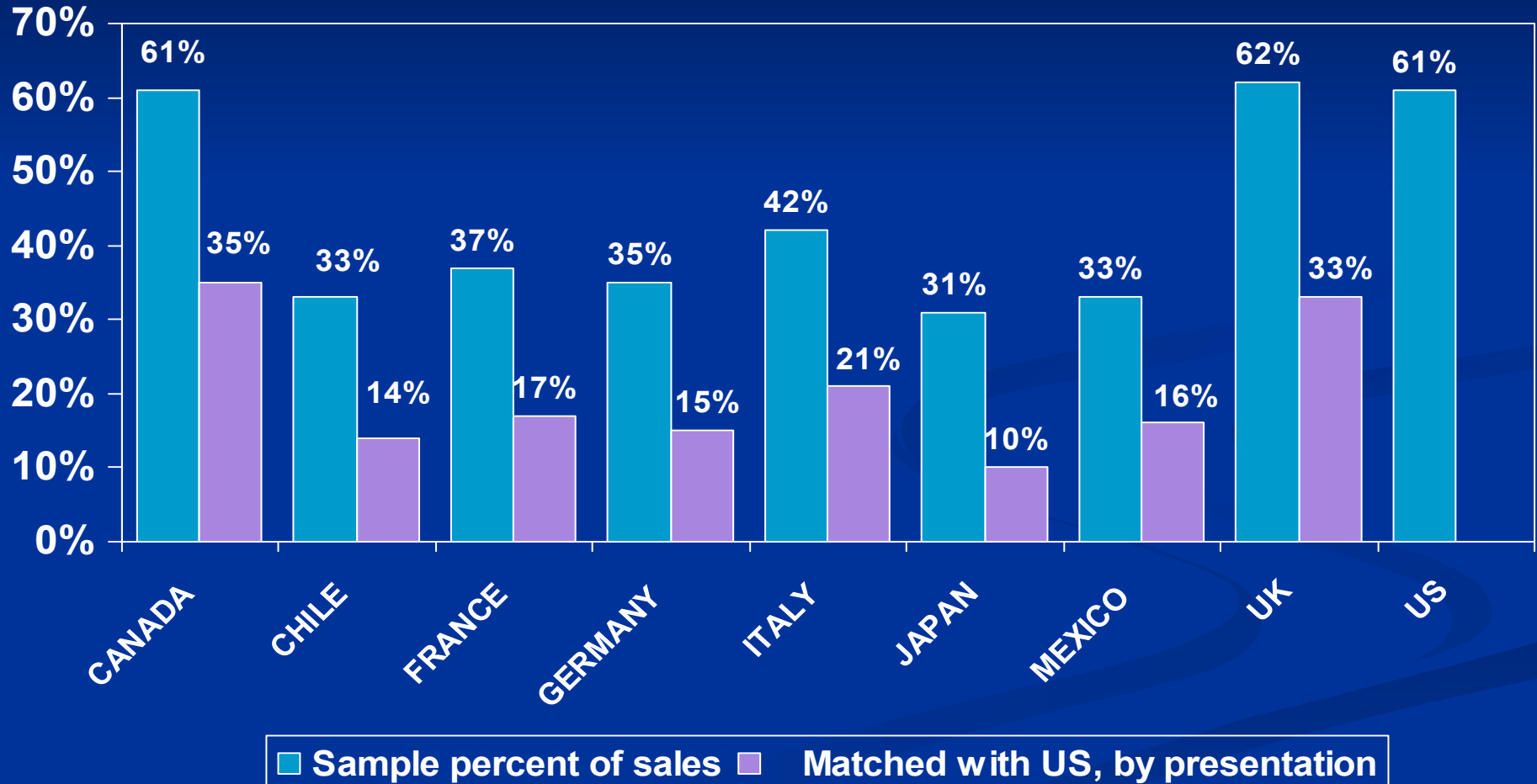
# Importation from Canada, EU, Japan:

## 1. Least Bad Scenario

- Aggregate savings to US consumers is 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 some of the savings

## a. Mismatch of products

Matching on formulation/strength reduces matching sample by roughly 50%



# Different formulations may limit importation

Country	Strength	PackSize	E/Pack	Strngth	Pack	E/Pack
United Kingdom	37.5	56	33.01	75	56	55.05
Germany	37.5	50	34.33	75	50	60.39
France	25	30	6.57	50	30	9.87
Italy	37.5	28	13.3	75	14	11.61
Spain	37.5	60	25.9	75	60	42.2
Netherland	37.5	60	25.85	75	60	43.09
Austria	37.5	60	31.69	75	60	58.14
Portugal	37.5	60	30.69	75	60	50.93
Greece	37.5	28	11.27	75	28	19.53
Belgium	37.5	56	24.36	75	56	40.64

## b. Manufacturer Supply Restrictions of Launched Products

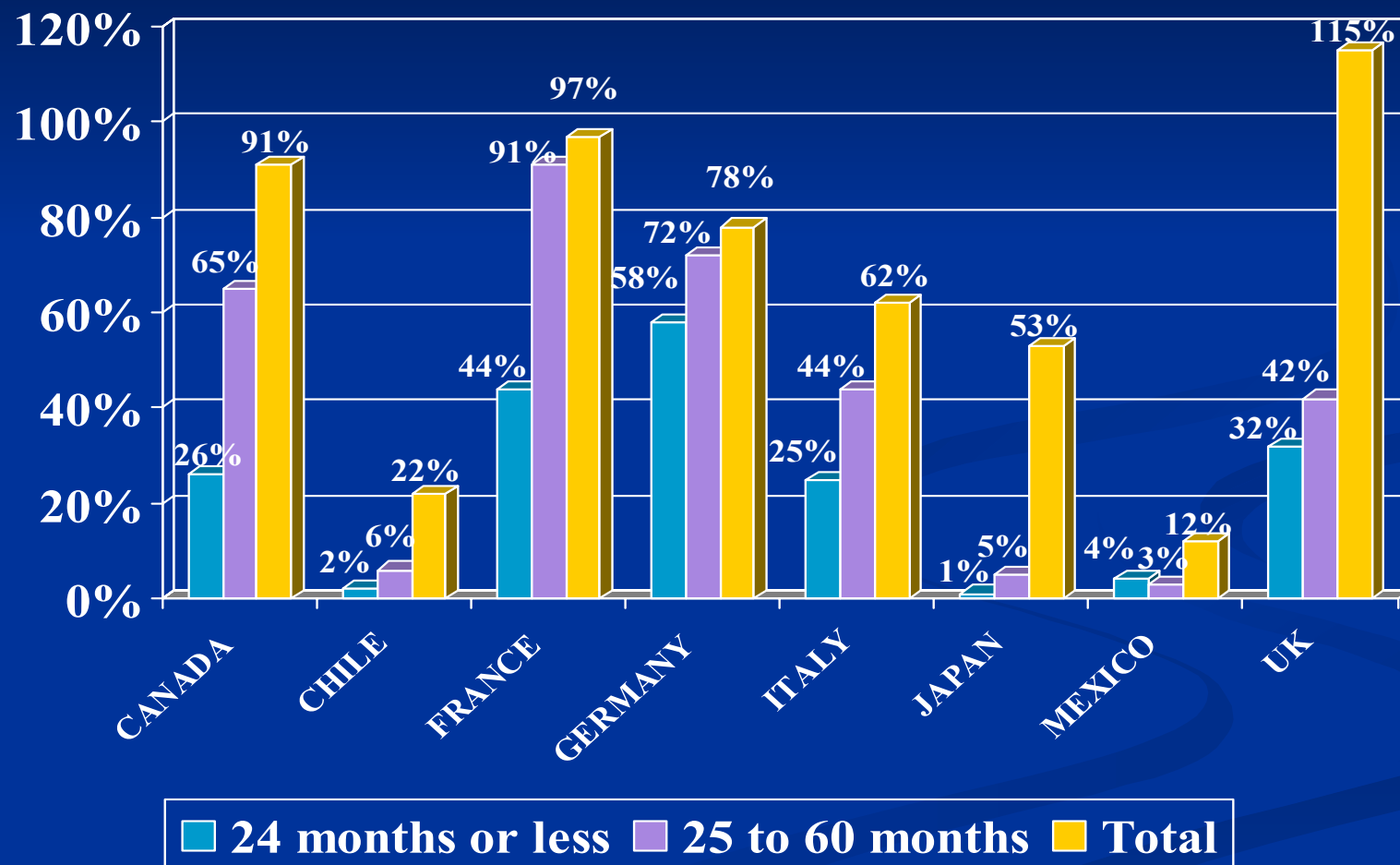
- Some manufacturer supply restrictions for Canadian pharmacies; common in EU
  - legal so far.....
- Will wholesalers/pharmacies forego profitable export opportunity?
  - Some shortages reported
- Even if 20% of EU + Canada volume is shipped to US, would only fill 20-30% of US volume
  - And only for matching drugs

# US Dominates Global Sales: Due to Volume and Price

	2003		% Growth Constant \$	
	<i>US\$ Bill</i>	<i>% Share</i>	<i>2003</i>	<i>CAGR 98-02</i>
World Audited Market				
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 Consumption, By Molecule Age, Relative to U.S. Consumption

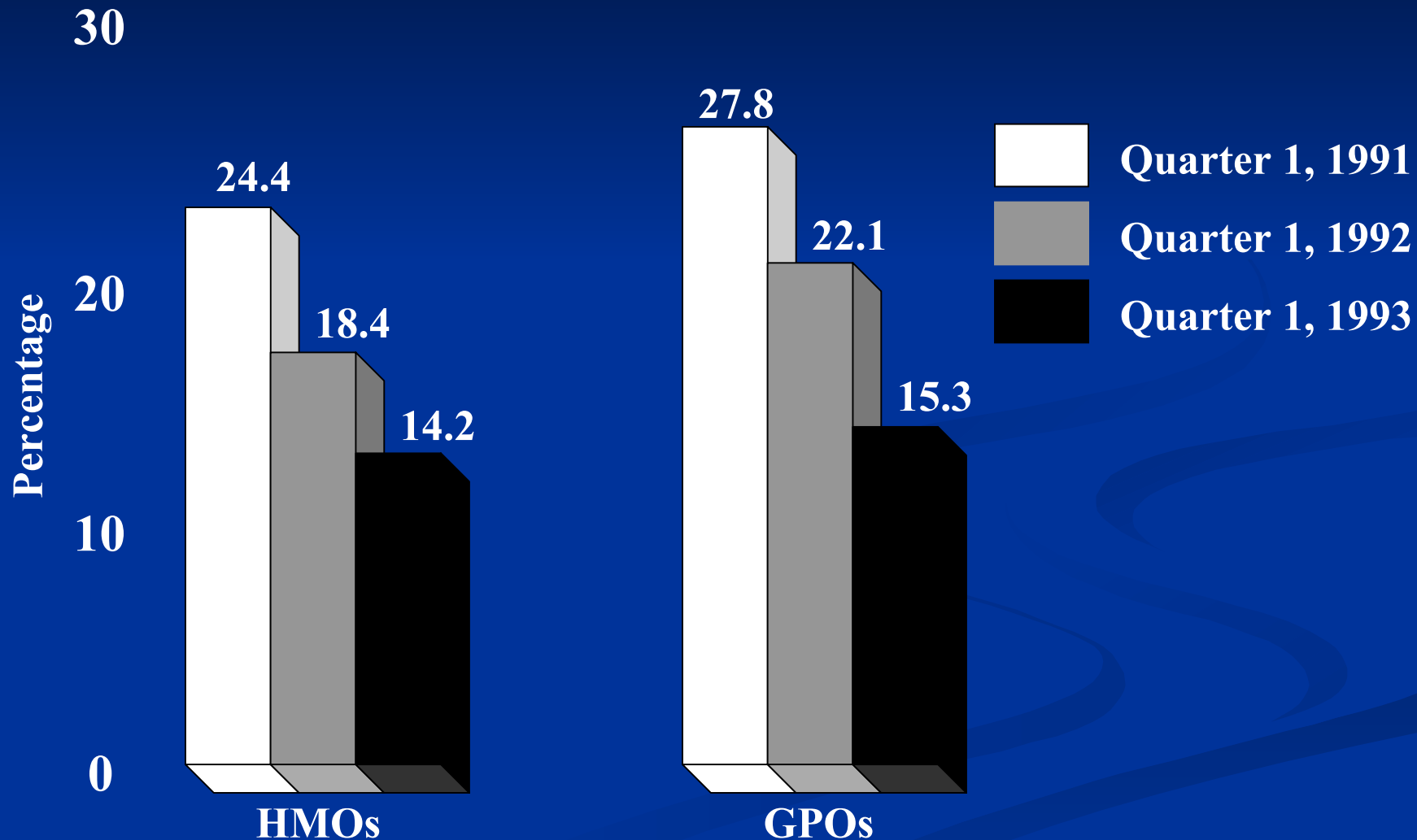


Note: United States equals 100%. Source: Danzon and Furukawa, *Health Affairs* Oct. 2003

## c. Decline in Foreign-US Price Differentials

- Manufacturers will be less willing to sell at low prices
  - Manufacturer control greatest for launch price
  - US market vs. loss of foreign sales
  - Feasible pricing band varies by product, importer costs etc.
- Countries that are unwilling/unable to pay higher prices may see fewer/delayed product launches
- => Loss of access abroad, lower manufacturer revenues but little gain for US consumers

# Decline in Median Best Price Discounts for HMOs and GPOs after OBRA 1990 "Best Price"



SOURCE: GAO: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals, Aug. 1994.

# Countries with Lower Prices Have Fewer Launches, Longer Launch delays

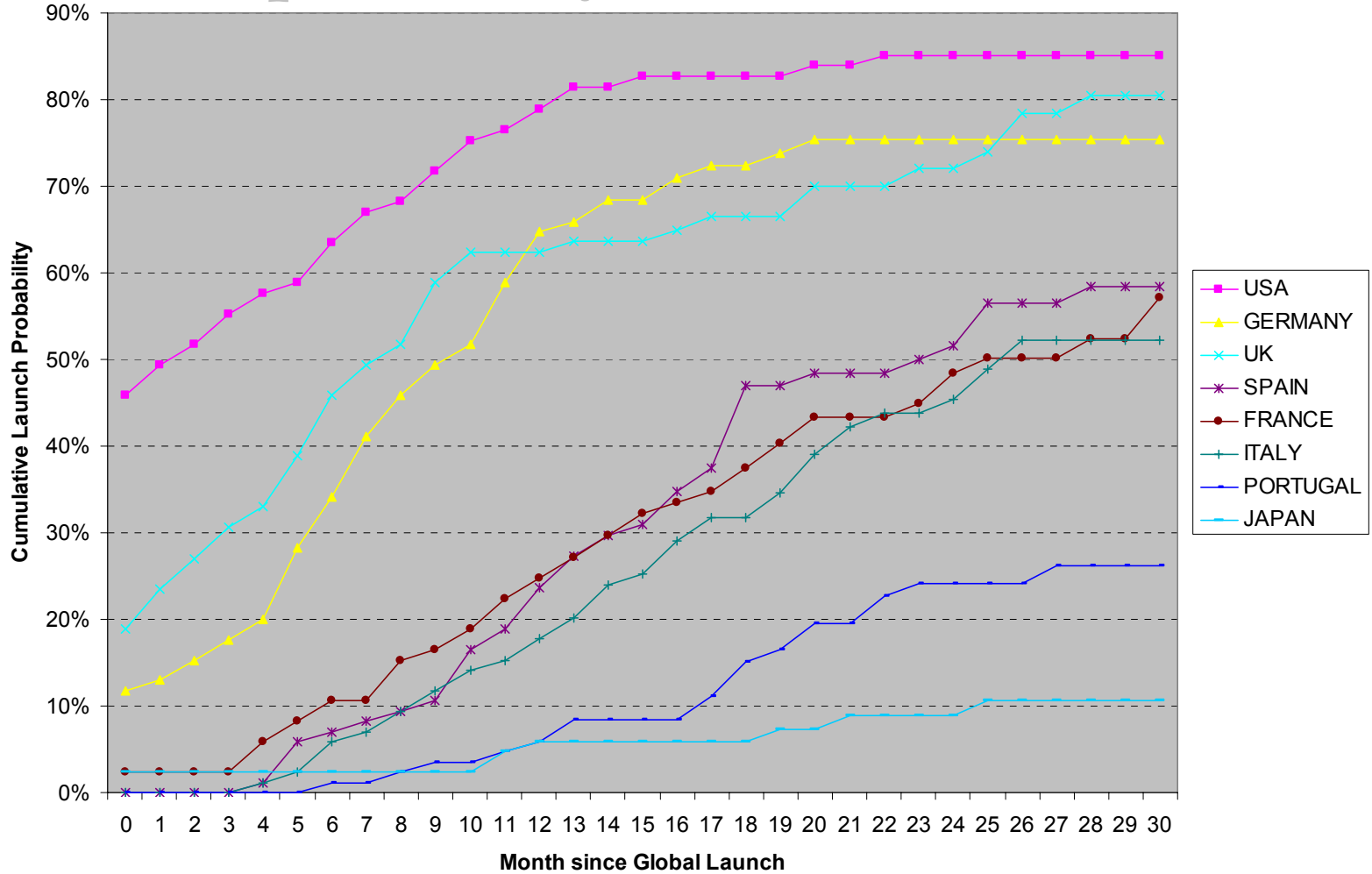
(Danzon, Wang and Wang 2003)

- We analyzed launch of 85 NCEs in 1994-1999
- 14 EU countries, plus Australia, Canada, Czech, Japan, Mexico, New Zealand, Norway, Poland, South Africa, Switzerland, USA
- 55% of the potential launches occurred
  - most in countries with unregulated prices
    - USA (73), Germany (66) and UK (64)
  - fewest in Japan (13), Portugal (26), New Zealand (28)

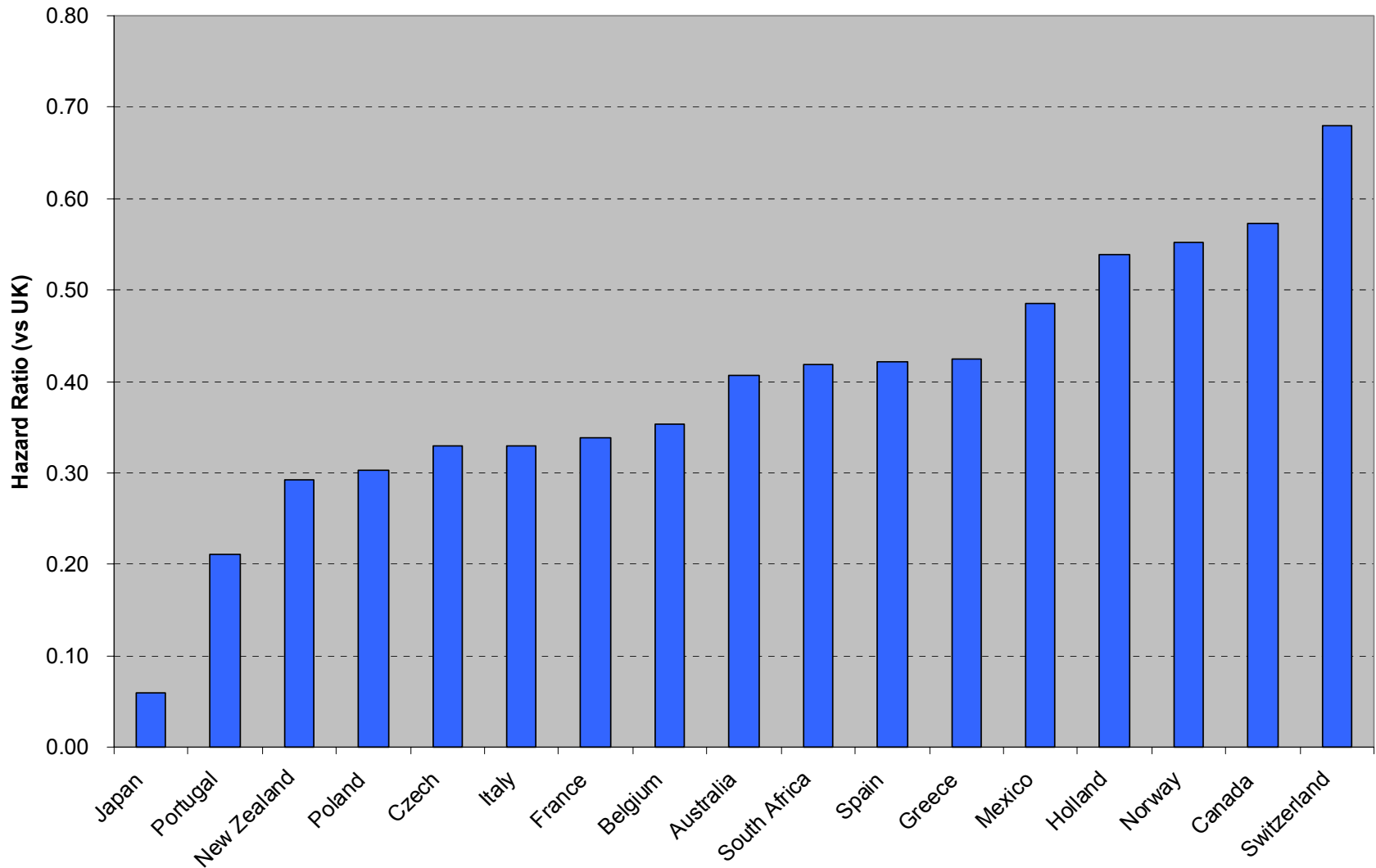
# Findings

- 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



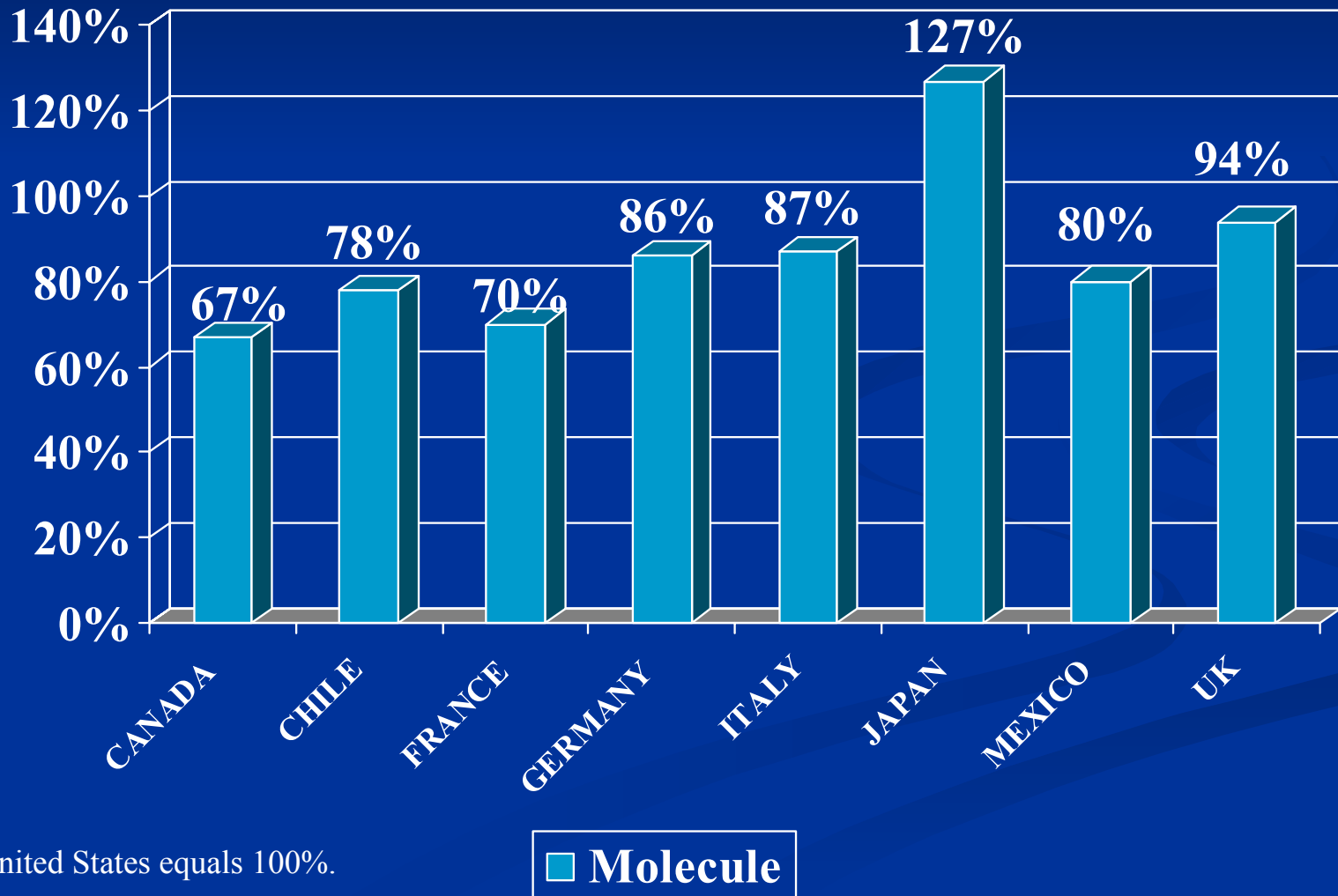
# Price Differentials with Other Countries

## Largely Reflect Income Differences

Danzon and Furukawa, Health Affairs (Oct, 2003)

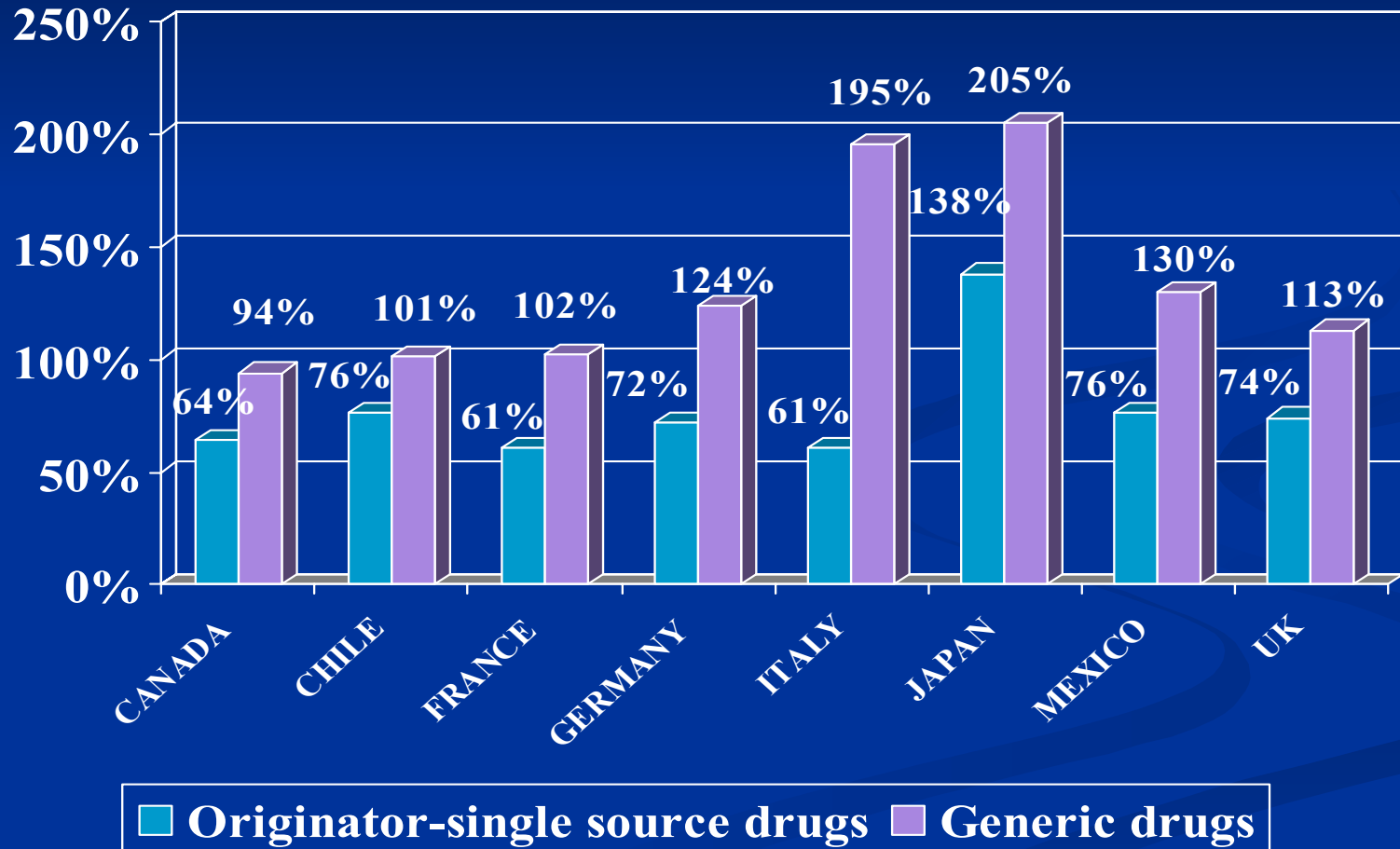
- Sample: 249 leading molecules in US 1999, by volume
  - 61% of US sales
- IMS data, all products in each molecule, 9 countries
  - Brands and generics, all forms
- Manufacturer-level prices
- We adjust for manufacturer discounts in US
  - reduces US prices by 8-10 percent on average
- US volume weights

# Price Indexes, Relative to the US: All Matching Products Exchange Rate Conversion



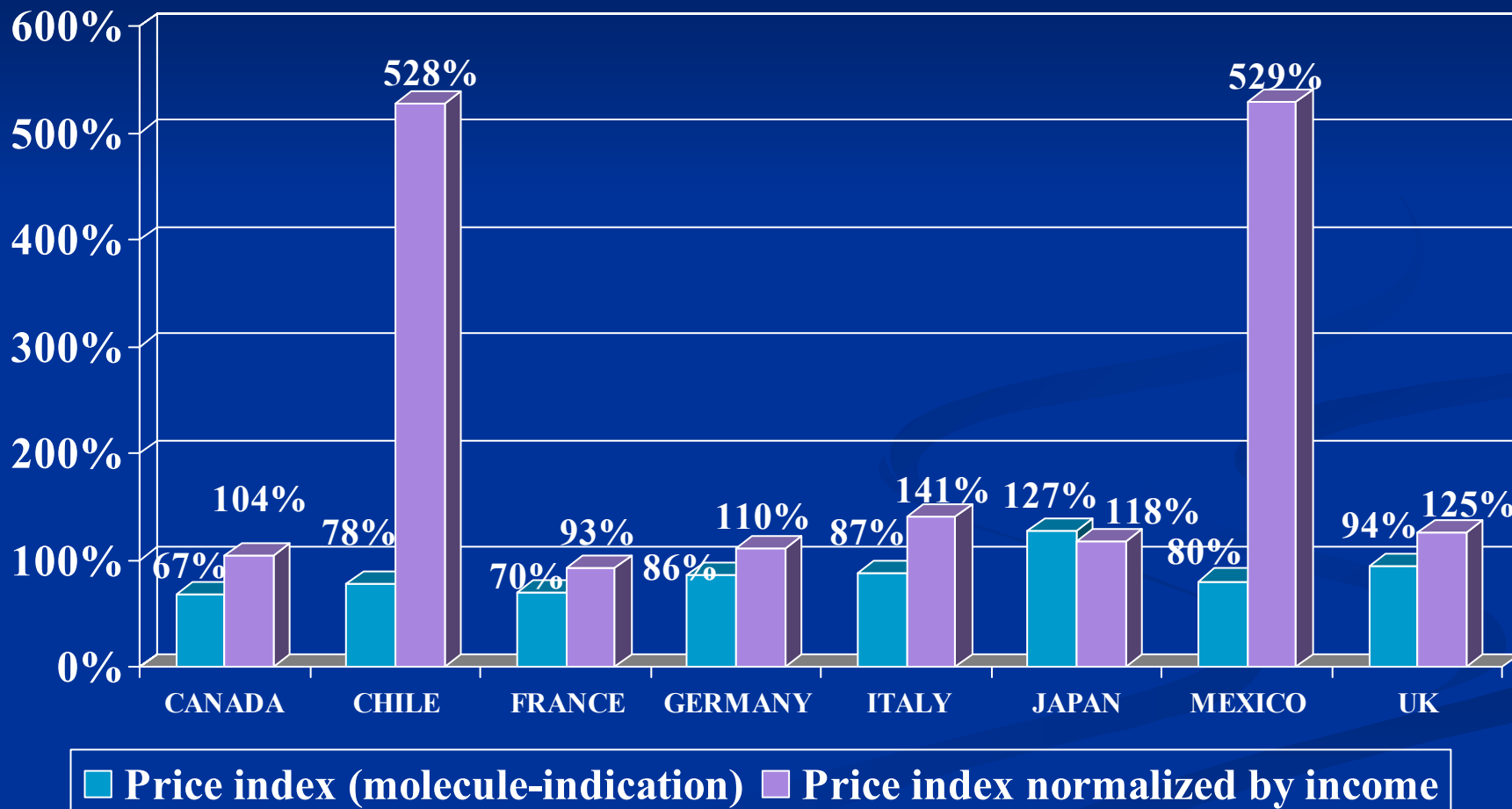
Note: United States equals 100%.

# Price Indexes: On-Patent Versus Generic Drugs



Note: United States equals 100%.

# Price Indexes Relative to Per Capita Income



Note: United States equals 100%.

# Conclusions on Average Price Differences

## US Market Basket, 1999 prices and exchange rates

- Most other countries' prices are 6-33% lower than the US, on average
- Price differentials are roughly reflect income differentials, except Mexico and Chile
- Foreign prices differentials are larger for other medical services than for drugs
- Foreign countries are unlikely to pay higher drug prices
- US has relatively high originator prices and high use of new drugs, relatively high generic volume and low generic prices, compared to countries that regulate prices

## d. Middlemen will Capture Some of Any Savings

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

## 2. The Worst Case Scenario

- US constrains supply limitations
  - Anti-trust
  - Legislation
- US requires registration of foreign formulations
- Foreign countries apply compulsory licensing if
  - high prices
  - Non-launch

# Policy Conclusions: Price Differentials for Drugs are Good, Not Bad

- Free trade and uniform prices cross-nationally are not appropriate policy for products with significant R&D costs
- Charging higher drug prices in high income countries is an efficient and equitable way to pay for R&D
  - R&D is a global joint cost
- Current price differentials roughly reflect income differentials, except for Mexico and Chile
- Importation would reduce access abroad, reduce manufacturer revenues and reduce R&D, with little or no gain to US consumers