

Price regulation and innovation in the pharmaceutical industry

Vicente Ortún



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Price regulation and innovation in the pharmaceutical industry

- I. Price regulation and innovation: reconciling health policy with economic/industrial policy
- II. If you were a Big Pharma CEO: Where would you locate your R&D?
- III. In a Galaxy far, far away (or at least in a peripheral country such Spain): how to attract and how to foster R&D?

I.- Price regulation and innovation

Reconciling health policy with
economic/industrial policy

Health & Economic Policies

- Health Policy, because of market failures, trying to achieve the most efficient production of health
- Economic/Industrial Policy, because of market failures, trying to facilitate the improvement in firm's competitiveness

Health Policy

- Benefits of health care (pharmaceutical) innovation greater than costs of health care pharmaceutical innovation

Benefits of pharmaceutical care

1. Value of improved health to those affected
2. Impact of health changes on the finance of others
3. Impact of health changes on the health of others

Costs of pharma innovation

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The price of innovation: new estimates of drug development costs

Joseph A. DiMasi^{a,*}, Ronald W. Hansen^b, Henry G. Grabowski^c

^a *Tufts Center for the Study of Drug Development, Tufts University, 192 South Street, Suite 550, Boston, MA 02111, USA*

^b *William E. Simon Graduate School of Business Administration, University of Rochester, Rochester, NY, USA*

^c *Department of Economics, Duke University, Durham, NC, USA*

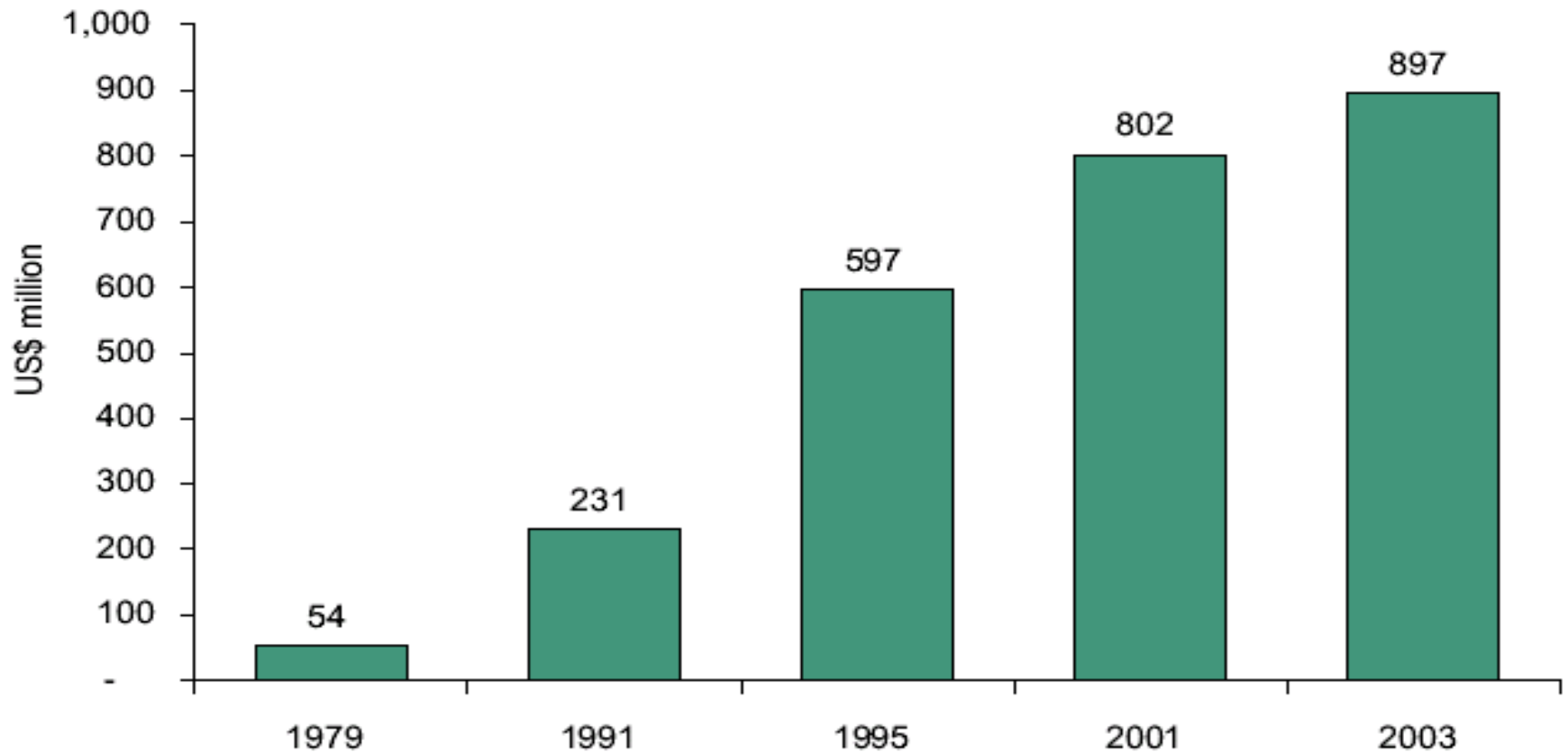
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Abstract

The research and development costs of 68 randomly selected new drugs were obtained from a survey of 10 pharmaceutical firms. These data were used to estimate the average pre-tax cost of new drug development. The costs of compounds abandoned during testing were linked to the costs of compounds that obtained marketing approval. The estimated average out-of-pocket cost per new drug is US\$ 403 million (2000 dollars). Capitalizing out-of-pocket costs to the point of marketing approval at a real discount rate of 11% yields a total pre-approval cost estimate of US\$ 802 million (2000 dollars). When compared to the results of an earlier study with a similar methodology, total capitalized costs were shown to have increased at an annual rate of 7.4% above general price inflation.

Costs of pharma innovation

Estimated cost of developing a new medicine



...and its distribution

- European free-riding?
 - Differences in prices are narrowing
 - Public financing boosts volume
 - Less drug innovation
 - Loss patent value
 - Loss of corporate research centers
 - Fewer high-value added jobs
 - ...all with its spillovers and multiplier effects

Health Policy

- Benefits of health care (pharmaceutical) innovation greater than costs of health care pharmaceutical innovation
- Always efficient?
 - Bicycle better than ‘stent’ in stable coronary artery disease Hambrecht R et al, Circulation 2004
 - “Bicycle” better than drugs acting on impaired glucose tolerance preventing type 2 Diabetes Mellitus Tuomilehto J et al, NEJM 2001; Diabetes prevention program research group, NEJM 2002.

Economic/industrial policy

- Because of market failures
 - R&D social benefits outweigh the private rewards
 - From the point of view of ‘peripheral’ countries: not enough participation in strategic sectors such as biomedicine
 - Financial market failures (unless self-financing or highly developed risk capital)
 - Increasing returns (minimum scale)
- ...and rent-seekers

Improving National Health Increasing National Wealth

1. Build a mutually advantageous collaboration between the industry and the NHS for patient benefit thru the National Clinical Trials Agency
2. Create a public and regulatory environment supportive of innovation
3. Invest in the bridge between idea generation and commercial financing

Improving National Health Increasing National Wealth

4. Build a strong bioprocessing sub-sector
5. Develop, attract and retain a high quality scientific and managerial talent base
6. Leadership by Government and industry working together

We are talking about the United Kingdom

www.bioindustry.org/bigtreport

...and we continue with the United Kingdom



House of Commons
Health Committee

The Influence of the Pharmaceutical Industry

Fourth Report of Session 2004–05

Pharmaceutical Industry Influence

- Interests of companies and those of the public, patients and NHS overlap but they are not identical
- An effective regulatory regime to ensure that the industry works in the public interest is essential

Pharmaceutical Industry Influence

- Pharm Industry affects every level of healthcare provision: discovery, development, promotion, prescription, compilation of clinical guidelines...
- Lax oversight has led to suppression of trial results, selective trial design and publication strategies, ghost-writing, distortion of medical practice, unsafe use of drugs...

Pharmaceutical Industry Influence

- Regulators, prescribers, industry... all have some blame to share
- Pharm Companies will continue to be the dominant influence in deciding what research is undertaken and conducting that research, publishing it and providing info to prescribers
- ...but important changes are required

Improving National Health Increasing National Wealth

- Health Policy for the *NHS*
- Industrial Policy for the *Industry and Trade Department*, including the responsibility for representing the interests of the pharmaceutical industry
- Talking each other since substantial trade-offs should be achieved in the pharmaceutical sector

Innovation and price regulation

- Aim of price regulation: Contribute to improvement in welfare taking into account conflict between moderate price level and delay in technical progress
- In practice, striking a constant balance between health, industrial, employment and public spending objectives

(Un)justification of price regulation

1. Price regulation in the markets of OTC and drugs whose patent has expired lacks justification (there's competition)
2. Instead of taking for granted the absence of competition, try to increase it by:
 - appropriate prescriber incentives
 - better info: cost-effectiveness awareness
 - cost sharing

(Un)justification of price regulation

3. Due consideration to the costs of intervention:
transaction (corruption included), distortions in incentives from the regulation itself, less generic market share...
4. Neither pharmaceutical expenditure nor drug utilization appropriateness are lower in countries with lower price levels
5. Product-price intervention seem inefficient.
Regulation shall give the company flexibility of pricing and exclude products subject to competition
Flexible, transparent systems work better than product-price interventions

Innovation and price regulation: way forward

- Strong role for the State:
 - Stop lax oversight of the industry
 - Promote competition
 - Implement efficient health policies
 - Separate price regulation and control systems (for the country as a whole) from public reimbursement policies for pharmaceuticals

Innovation and price regulation: way forward

- Strong role for the State: Public reimbursement policies:
 - Prices for different drugs shall reflect their relative effectiveness
 - The right signal both for R&D decisions and drug utilization
 - EURICE could help
 - Two-tiered co-payments for users: avoidable and inversely related with the incremental effectiveness of the drug

Innovation and price regulation: way forward

- Strong role for the State: Public reimbursement policies: Prices reflecting relative effectiveness
 - OHE –*The many faces of innovation*- rightly argues that innovation should not be described as binary (me-too or break-through)
 - ...true: it's incremental or detrimental
 - And evaluation can establish incremental effectiveness with a pro-industry bias... since, at launching, much more is known about drug benefits than about drug risks

Innovation and price regulation: way forward

- Strong role for the State: Public reimbursent policies: Two-tiered co-payments:
 - First tier: small, compulsory, with exceptions and ceilings
 - Second tier: almost avoidable and inversely related with drug effectiveness
 - Reference pricing in therapeutic groups where RP indicates public willingness to pay health improvements
 - Different co-payments depending on incremental effectiveness

II.- If you were to decide on
R&D location:

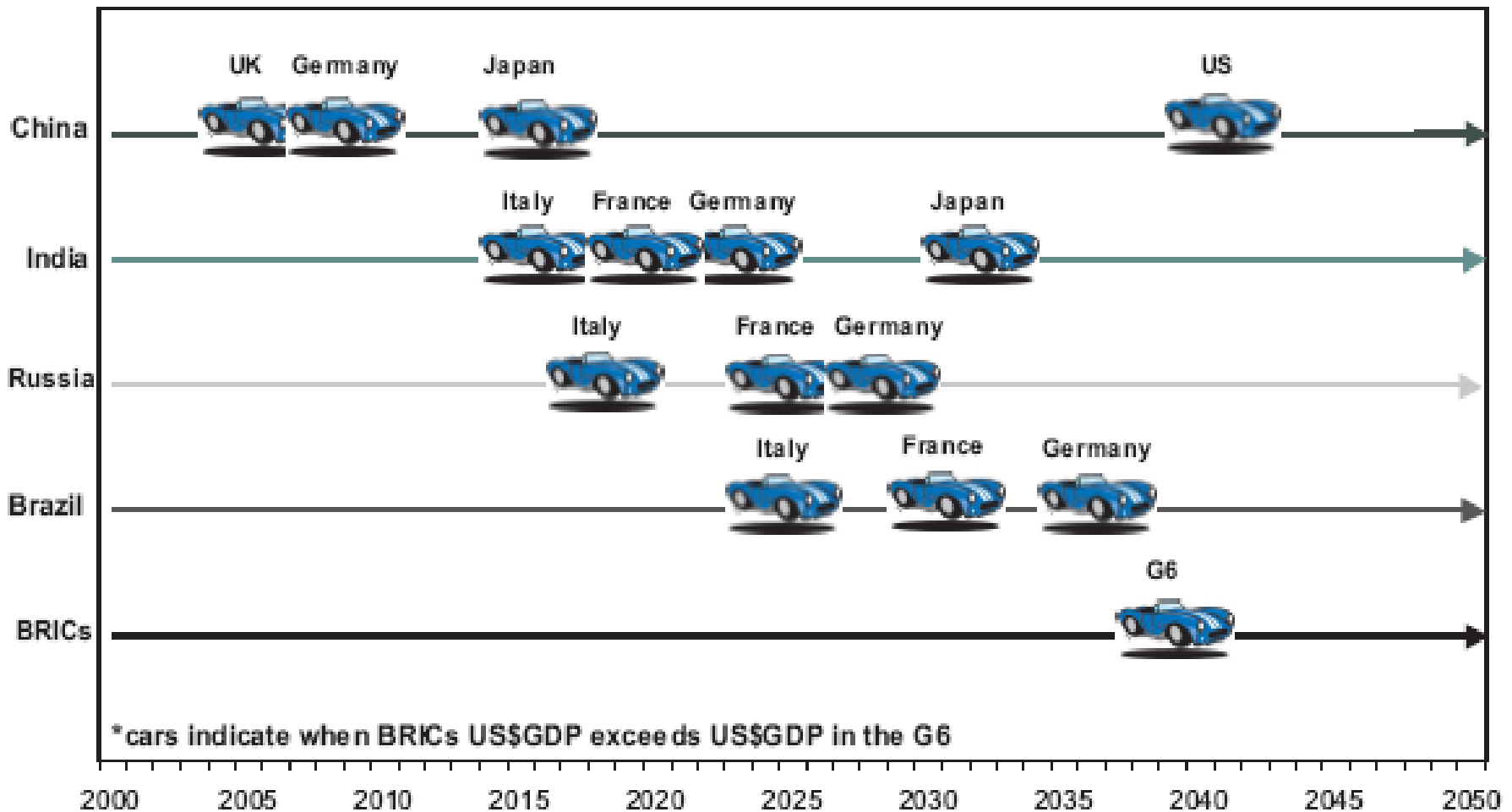
What would you do?

Emerging economies

- High technological level (India in biomedicine)
- Low costs

BRIC countries

Overtaking the G6: When BRICs' US\$GDP Would Exceed G6



Example Offshoring: Key Locations in R&D

Ilustrativo

Czech/Hungary/Poland

- Development: helpdesk (clinical operations)
- IT Infrastructure: helpdesk, distributed computing, WAN/network, enterprise operations
- Research: annotation of scientific/medical information

China

- Research: natural products supply/ isolation
- Development**: pre-clinical (bioanalytics / pharmacokinetics, antibody toxicology, slide reading)

Increase in execution of clinical trials in China results in synergies with other development activities

Decisions based on :

- Talent availability
- Cost savings potential (labor cost of structure)
- Business environment (infrastructure, political, physical)
- Vendor capabilities (landscape and track record)
- Country risk (political economic stability)

Israel

- Research: Functional Genomics (excl. bioinformatics)

India

- Finance and accounting
- IT application development
- Development**: clinical (e.g., data management and statistical analysis, narrative writing), technical R&D, regulatory affairs, safety/epidemiology
- Research: chemical synthesis, software development (CMM), prelab separations, bioinformatics
- Sales and Marketing

WITHIN INDIA, THE SELECTION OF THE RIGHT CITY IS IMPORTANT



Factors affecting location selection in example regions

NCR (Delhi)

- Well-developed infrastructure
- Excellent international flight accessibility

Mumbai

- Financial capital of India
- More expensive than other locations
- Emerging hub for customer care
- Highest university enrollment/literacy rates
- Excellent international flight accessibility

Hyderabad

- Strong state government support
- Limited international flight accessibility

Bangalore

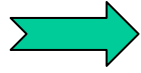
- IT capital of India (software)
- Strong state government support
- Emerging hub for customer care

Chennai

- Emerging hub for transaction processing
- Good telecom connectivity

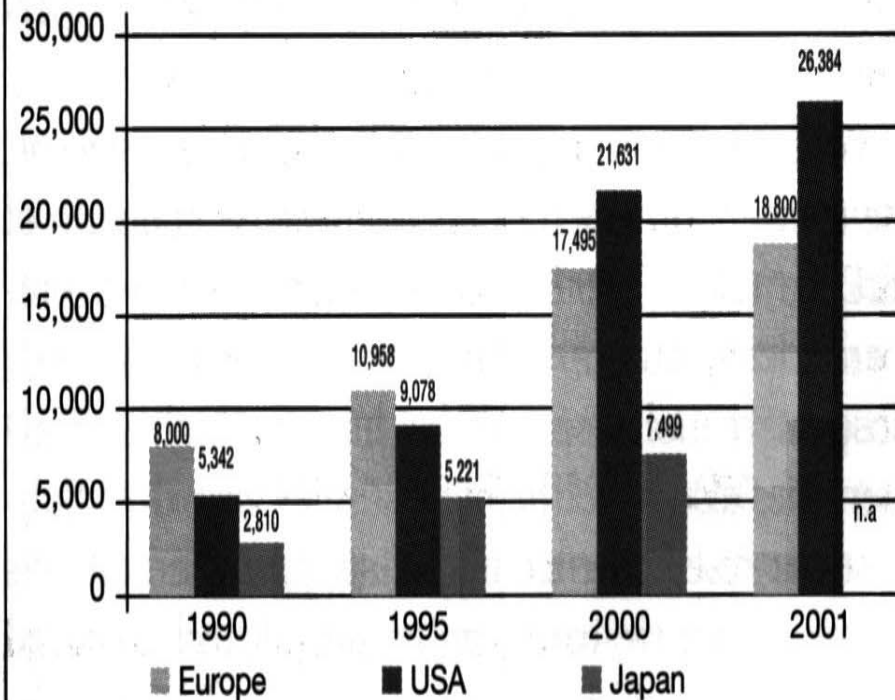
III.- How to attract R&D?

How to attract R&D?

- R&D, main engine of productivity growth
- Social benefits of R&D, either in house or external, tend to be localized  R&D activity better at home than abroad
- Location decisions with location criteria, regardless of price regulation

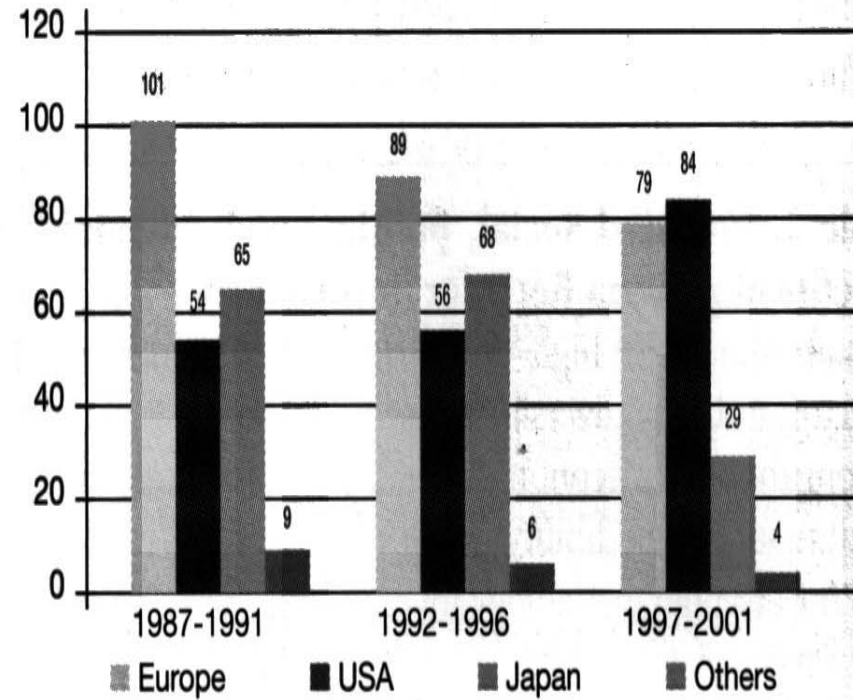
R&D European hemorrhagia

Figure 2. Pharmaceutical R&D expenditure in Europe, USA and Japan, 1990-2001, € million



Source: EFPIA member associations, PhRMA, JPMA. 2001 figures are estimates

Figure 3. New Molecular Entities 1987-2001



Source: SCRIP Publications – EFPIA calculations (based on nationality of parent company)

R&D European hemorrhagia

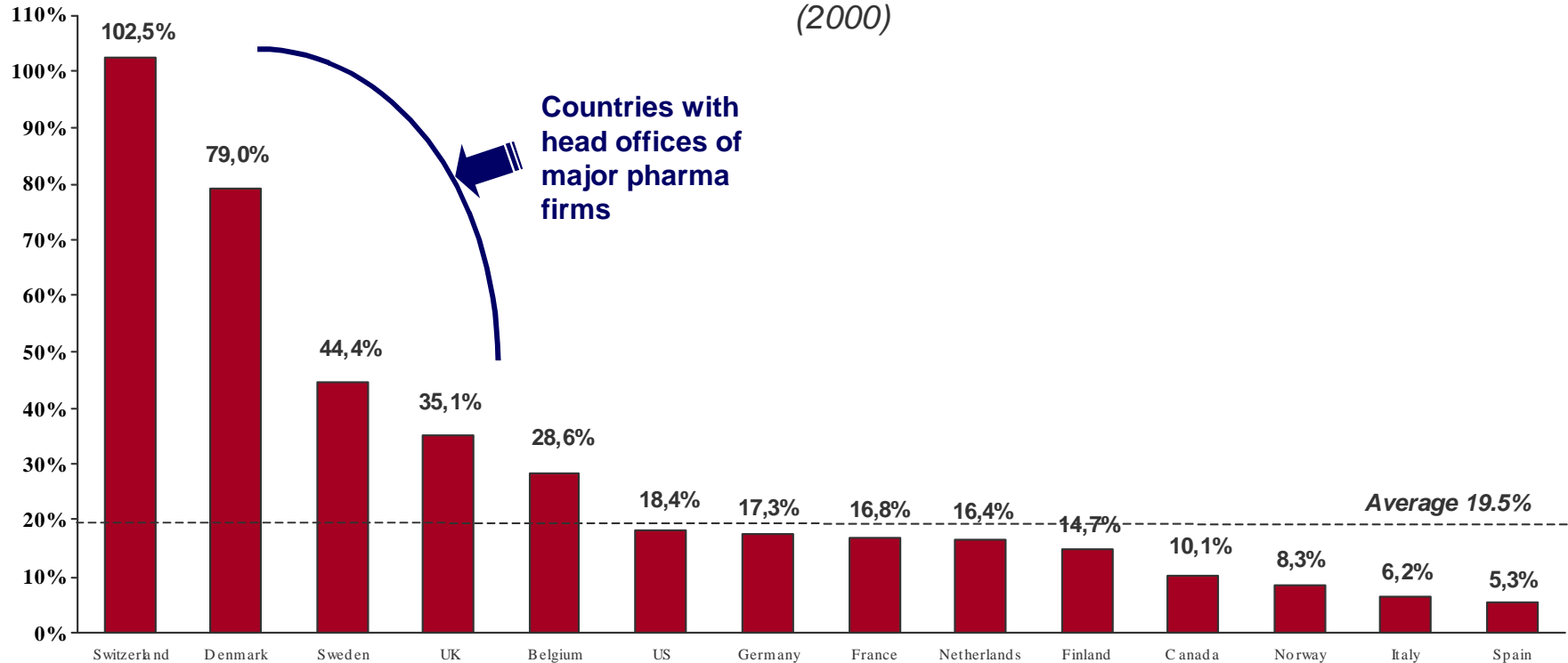
- Novartis to Massachusetts
- GSK to Philadelphia
- Organon to New Jersey
- ...

European Federation of Pharmaceutical Industries and Associations: irrefutable drift because of hostile European market characterized by heavy regulation and cost-containment measures

Bio-Pharmaceuticals in Peripheral Countries With Below-Average Research Intensity

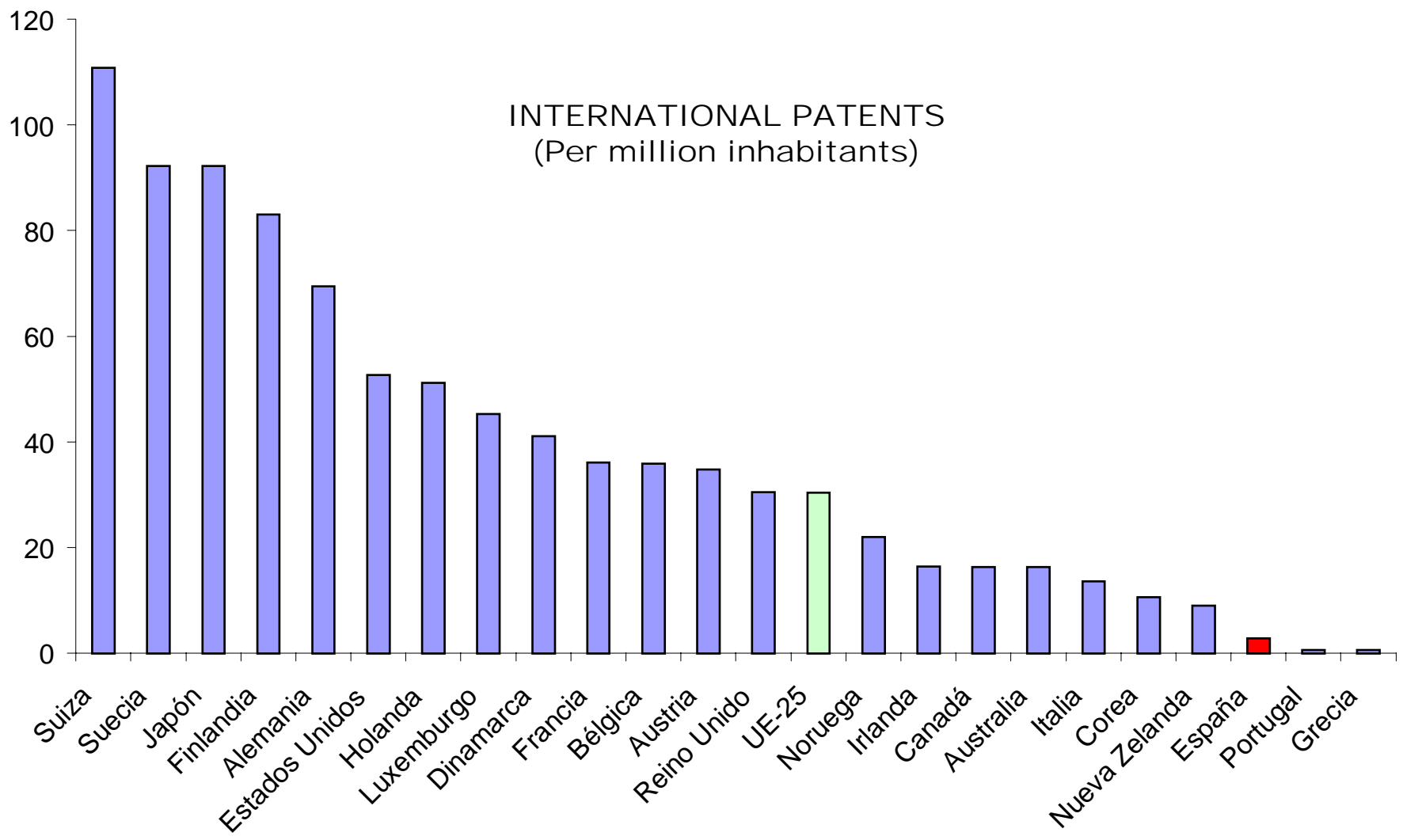
e.g. Spain accounts for two percent of the global pharmaceutical market, it captures only 0.5% of world R&D expenditures

A Comparison of R&D to Sales for Different Countries
(2000)



Source: PMPRB, *A Comparison of Pharmaceutical Research and Development Spending*, S-0217, December 2002 * Based on a voluntary survey of R&D expenditures for Rx&D members

INTERNATIONAL PATENTS
(Per million inhabitants)



e.g. Spain: less than 1% of UE patents with more than 8% of GDP

R&D European hemorrhagia

- EU Commission response to the G-10 High Level Group on innovation and provision of medicines
 - Enhance transparency, consistency across mutual recognition, and the speed of the pricing and reimbursement procedures
 - Faster market access for breakthrough treatments
 - Streamlining regulatory process and refocusing EMEA
 - Strengthening the EU science base
 -

R&D location factors

- Quality of common innovation infrastructure
- Environment for innovation in nation's industrial clusters, degree of competition-based innovation...
- Quality of science-industry knowledge transfer channels

– *Furman J et al. Research Policy 2002*

Maintaining Support for Innovation Is Essential

Key Objective of Peripheral Countries; to Enhance its Global Competitive Position.

Innovation Index		
1980	1995	2005 (forecast)
1. Switzerland	1. US	1. Japan
2. US	2. Switzerland	2. Finland
3. Germany	3. Japan	3. Switzerland
4. Japan	4. Sweden	4. Germany
5. Sweden	5. Germany	5. Sweden
6. Canada	6. Finland	6. US
7. France	7. Denmark	7. Denmark
8. Netherlands	8. France	8. France
9. Finland	9. Canada	9. Norway
10. UK	10. Norway	10. Canada
11. Norway	11. Netherlands	11. Australia
12. Denmark	12. Australia	12. Austria
13. Austria	13. Austria	13. Netherland
14. Australia	14. UK	14. UK
15. Italy	15. New Zealand	15. New Zealand
16. New Zealand	16. Italy	16. SPAIN
17. SPAIN	17. SPAIN	17. Italy

Source: Council on Competitiveness, "The New Challenge to America's Prosperity: Findings from the Innovation Index, March 1999

But we need to improve our Innovation Index...

- ← An Index developed by Michael Porter and Scott Stern, benchmarking how a nation's innovation system has performed relative to other nations and to itself over time
- ← Ten components: total R&D spending, total R&D personnel, the percentage of R&D funded by private industry, the percentage of R&D performed by the university sector, spending on higher education, the level of intellectual property protection, openness to international competition, per capita GDP, access to capital and the strength of a country's anti-trust policies
- ← Statistical modeling is used to examine how these measures affect innovative output across countries and over time
- ← The Index expresses innovative capacity on a per capita basis, allowing for a more meaningful comparison among economies of different size

Concluding remarks

1. Two different Departments (Health/ Trade & Industry) with two different and, sometimes, contradictory responsibilities... talking each other to strike the changing balance between industrial, employment, health and public spending objectives

Concluding remarks

2. Improved health, important part of welfare
 - ➡ Efficiency in the production of health required
 - ➡ Prices reflecting relative effectiveness (role for economic evaluation)
3. Benefits (depending on \mathbf{p} and \mathbf{q}) drive R&D... but not R&D location

Concluding remarks

4. There is no intrinsic contradiction between high productivity and a consolidated National Health Service (welfare state) as the European Nordic Countries tell us every day

Lindert P. Growing Public. Cambridge Univ Press, 2004