

# Drug Price Regulations

## Recent Trends and Neglected Issues

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## Lemma

*[El príncipe reformador] "tiene por enemigos activísimos a cuantos sacaron provecho de los estatutos antiguos, y aun los que puedan sacarlo de los recién establecidos, suelen defenderlos con tibieza suma"*

Maquiavelo, N. (1513) *El Príncipe*

# Outline of my presentation

1. Progress in price regulation literature
2. Well-known results
3. Open questions
4. Neglected issues
5. Some concluding remarks

# Countervailing forces in drug pricing

- ▶ Overpricing
  - ▶ Insurance creates inelastic demand and patents restrict competition
- ▶ Underpricing
  - ▶ Government /Insurer power leads to classical hold-up problem

# Two regulatory/procurement traditions

- ▶ Direct price regulations
  - ▶ Extensive product-by-product upstream marginal-pricing
  - ▶ Regulated downstream markups
- ▶ Government/Insurer procurement schemes
  - ▶ Company level revenue/profits controls
  - ▶ Incentive based reimbursement schemes and remuneration fees
  - ▶ Demand management

# Price regulation/procurement today

- ▶ Cost-based price regulations
  - ▶ Auditing and cross-country (external) reference pricing
- ▶ Incentive-based price regulations (in-patent, branded unique drugs)
  - ▶ Price negotiations, cost-effectiveness evaluations, revenue agreements, profit controls, incentives to providers, and demand management
- ▶ Competition-based price regulations (out-of-patent brands and generics)
  - ▶ Mandated substitution, formulary policies, and reference pricing

# Trends in 19 OCDE countries 1992-2004

(Sood N. et al 2009 Health Affairs)

	1992	2004
Direct price controls	13	16
Incentive-based regulations		
Cost-effectiveness evaluations	2	10
Degressive pharmacy fee	5	10
Global budget controls	1	6
Profit controls	1	3
Prescribing budgets	0	2
Competition-based regulations		
Generic substitution	3	14
Generics reference pricing	2	7
Therapeutic reference pricing	3	6
Generic prescribing incentives	2	5

## Well-known results

- ▶ Regulation decreases revenues but not prices (Sood N. et al 2009 & Cabrales & Jiménez 2007). How?
  - ▶ Constraining insured demand
  - ▶ Managing demand towards generics and older drugs
  - ▶ Shaping the choice set: launch delays, limits availability of some type of new drugs, and encourages brand proliferation (Danzon et al 2005 and Kyle 2007)

# Cost-based price regulations

1. Imperfect auditing leads to price negotiations (strong impact on revenues) and external referencing
2. Brand proliferation
3. Delays in having new effective treatments
4. Usually combined with local licencing
5. Paralel trading

# Incentive-based price regulation

- ▶ Profit controls do not bite
  - ▶ Encourage investments, and diversification
- ▶ Global and physical budgets do bite revenues
- ▶ Decreasing returns from additional regulations

# Competition-based price regulation

- ▶ Strong impact of using formularies and managed demand for pricing non-unique drugs (Elzinga & Mills 1997; Dugan & Scott Morton 2008)
- ▶ Impact of generics on pricing depends strongly on substitution and reimbursement rules
  - ▶ Reference pricing has much more impact in countries with less direct price regulation
- ▶ Reference pricing slows down entry of further generics:
  - ▶ Lower prices with less competitors (Moreno, Puig & Borrell 2009)

# Open questions

- ▶ The weakness of cost-effectiveness: bargaining
  - ▶ Frank & Newhouse (2009) arbitration procedure
- ▶ Increasing awareness of governments of the effect of local pricing on global R&D
  - ▶ In this case, parallel trading is not so bad (Sauri 2009), it constrains the bargaining power of governments

# Neglected issues

## Downstream competition

- ▶ Discounts from pharma firms to pharmacists
- ▶ Clawback mechanisms
  - ▶ the case of the UK and the Netherlands
  - ▶ the case of Spain

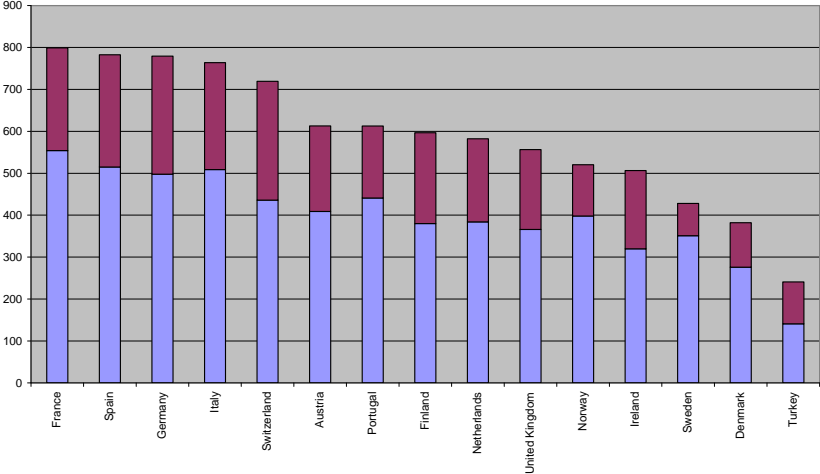
# Neglected issues

## Downstream regulations in the EU

	Number	out of	
Ownership restricted	16	27	59%
Pharmacist-owned only	15	27	56%
State-owned only	1	27	4%
State-owned pharmacies	9	27	33%
Entry restricted	20	27	74%
Distances regulated	6	27	22%
NHS contracts restricted	3	27	11%
Margins regulated	25	25	100%
Fixed or degressive margins	18	25	72%
Maximum margins	7	25	28%

# Neglected issues

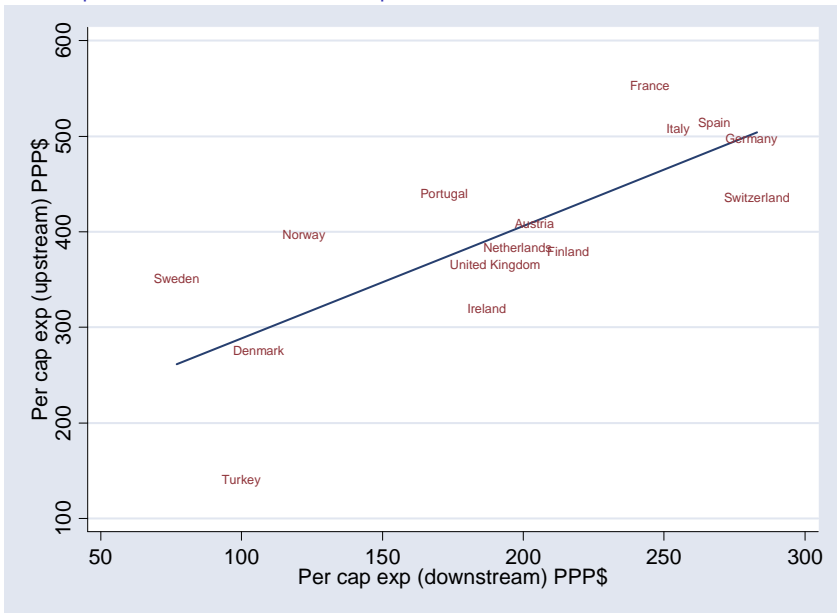
## Correlation Upstream and Downstream Expenditures



■ Per capita spending on pharmaceuticals USD PPP 2005 ex factory ■ Per capita spending in downstream USD PPP 2005

# Neglected issues

## Correlation Upstream and Downstream Expenditures



# Neglected issues

## Competition restrains in Spain

Table 1. Entry restriction impact on the number of pharmacies: counterfactuals

	Euskadi	A
A.- # pharmacies: entry restricted best prediction	210	
B.- # new pharmacies with entry deregulation	72	
C.- # new pharmacies with entry and distance deregulation	28	
$(A+B+C)=D$ .- # pharmacies with entry and distance deregulation	310	
B/D: entry restriction relative impact	23%	
A/D: distance restriction relative impact	9%	

Source: Computed using counterfactuals from Borrell, JR and Fernandez-Villadangos (2009)

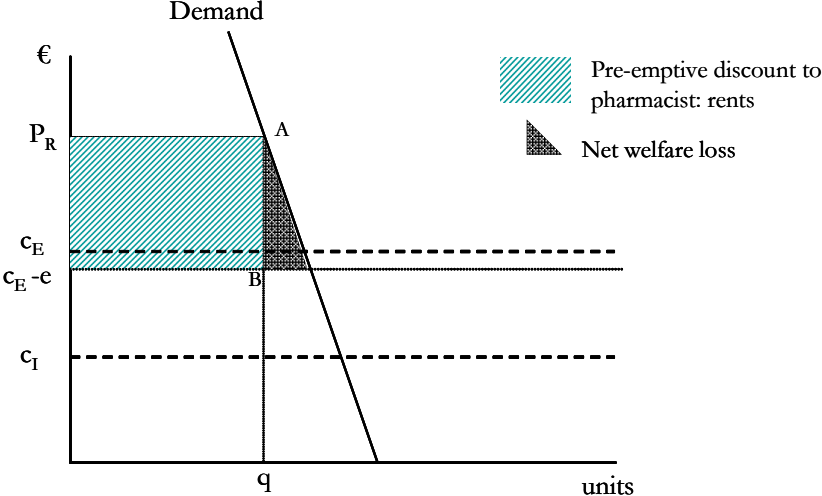
# Neglected issues

## Discounts to pharmacists

Principio activo (# EFGs)	Octubre 2003	Julio 2004	Agosto 2004	Septiembre 2004	Octubre 2004	Noviembre 2004	Enero 2005	Descuento medio
Azitromicina (18)		30%		33%	32%	32%	37%	33%
Captopril (16)	37%	33%	33%	34%	36%	33%	32%	34%
Ciprofloxacino (33)	40%	30%	22%	30%	35%	38%	37%	33%
Clarithromicina (18)	31%	31%		34%	37%	37%	38%	34%
Diclofenaco (5)	21%	17%	17%	17%	17%	17%	17%	17%
Diltiazem (2)	33%	30%		30%	33%	33%	33%	31%
Doxazosina (6)	33%	30%		35%	42%	42%	46%	36%
Enalapril (21)	41%	36%	29%	38%	36%	36%	37%	37%
Fluoxetina (26)	44%	35%	25%	36%	34%	34%	33%	35%
Ibuprofeno (4)	33%	29%		28%	29%	29%	28%	29%
Omeprazol (41)	37%	32%	28%	32%	32%	31%	32%	32%
Paracetamol (4)	34%	22%		27%	38%	38%	33%	29%
Paroxetina (6)		25%		41%	25%	25%	50%	35%
Ranitidina (37)	40%	38%	33%	38%	39%	38%	40%	38%
Simvastatina (19)	42%	36%		35%	36%	33%	36%	36%
Triflusal (5)		48%		48%	42%	33%	38%	44%
<b>Total</b>	38%	33%	26%	34%	35%	35%	36%	34%

Font: elaboración propia a partir de los datos de descuentos y bonificaciones.

# Discounts to pharmacists



# Concluding remarks

- ▶ The need for a full test for upstream and downstream price/margin regulations:
  - ▶ Necessity
  - ▶ Adequacy
  - ▶ Proportionality
  - ▶ Non-discrimination
- ▶ From extensive cost-based regulations to intensive incentive/competition-based procurement schemes