

Flexible Pricing Mechanisms Are the European Systems Ready for Them? Focusing on Oncology

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European Pharmaceutical Pricing & Reimbursement
6th October, London

The Elephant in the Room



Comments from Oncologists...

“The good news is that effective new cancer therapies are being developed by pharmaceutical and biotechnology companies at a faster rate than ever before. More than 900 new drugs are under development, many for rare cancers. Drug companies should be rewarded with reasonable profits for these efforts. The unfortunate news, also acknowledged by some of the pharmaceutical leadership, is that the current pricing system is unsustainable and not affordable for many patients.”

A. Tefferi et al (more than 100 US based oncologists); Mayo Clinic Proceedings, 2015

“There has been no shortage of media coverage concerning the performance and pricing of existing therapeutics, which the biopharma industry insists are justified and necessary to cover their R&D expenses and inevitable failures. While potential solutions have been proposed, we are at best at a crossroads, at worse, parked at a fever pitch of a stalemate”

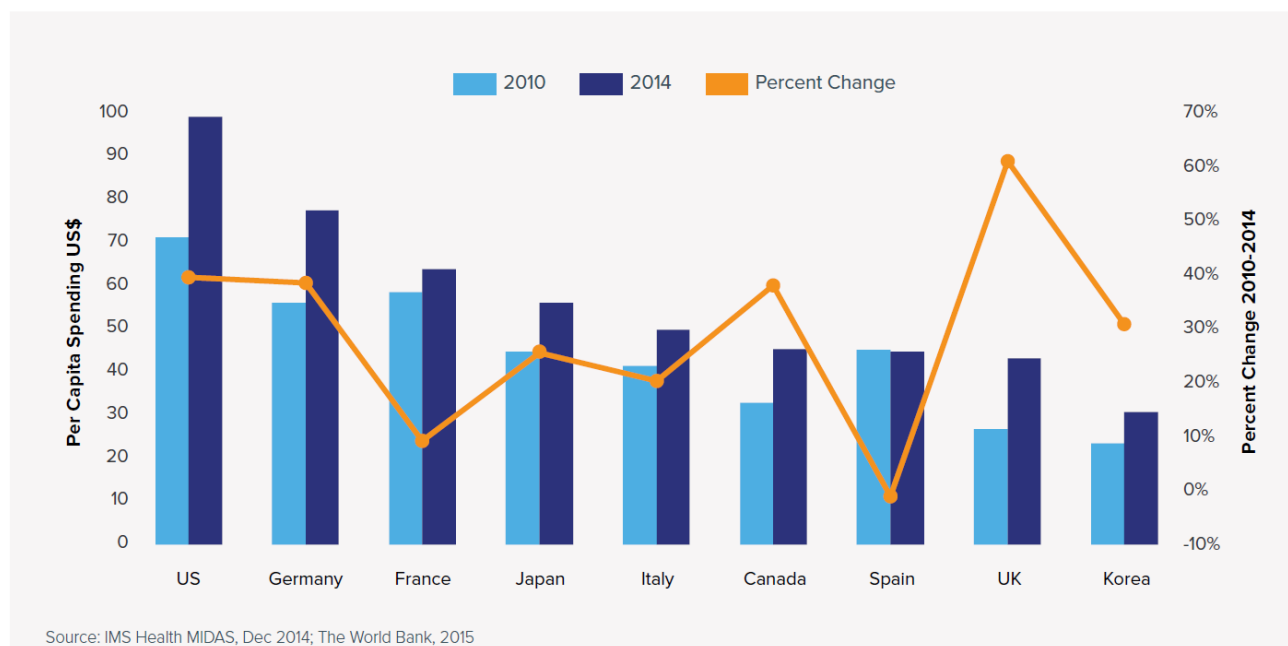
J. Tabernero on behalf of ESMO Executive Committee; Annals of Oncology, 2015, vol 26: 1529-1531

Spending on Oncology Drugs

Oncology Drug Spend Per Capita

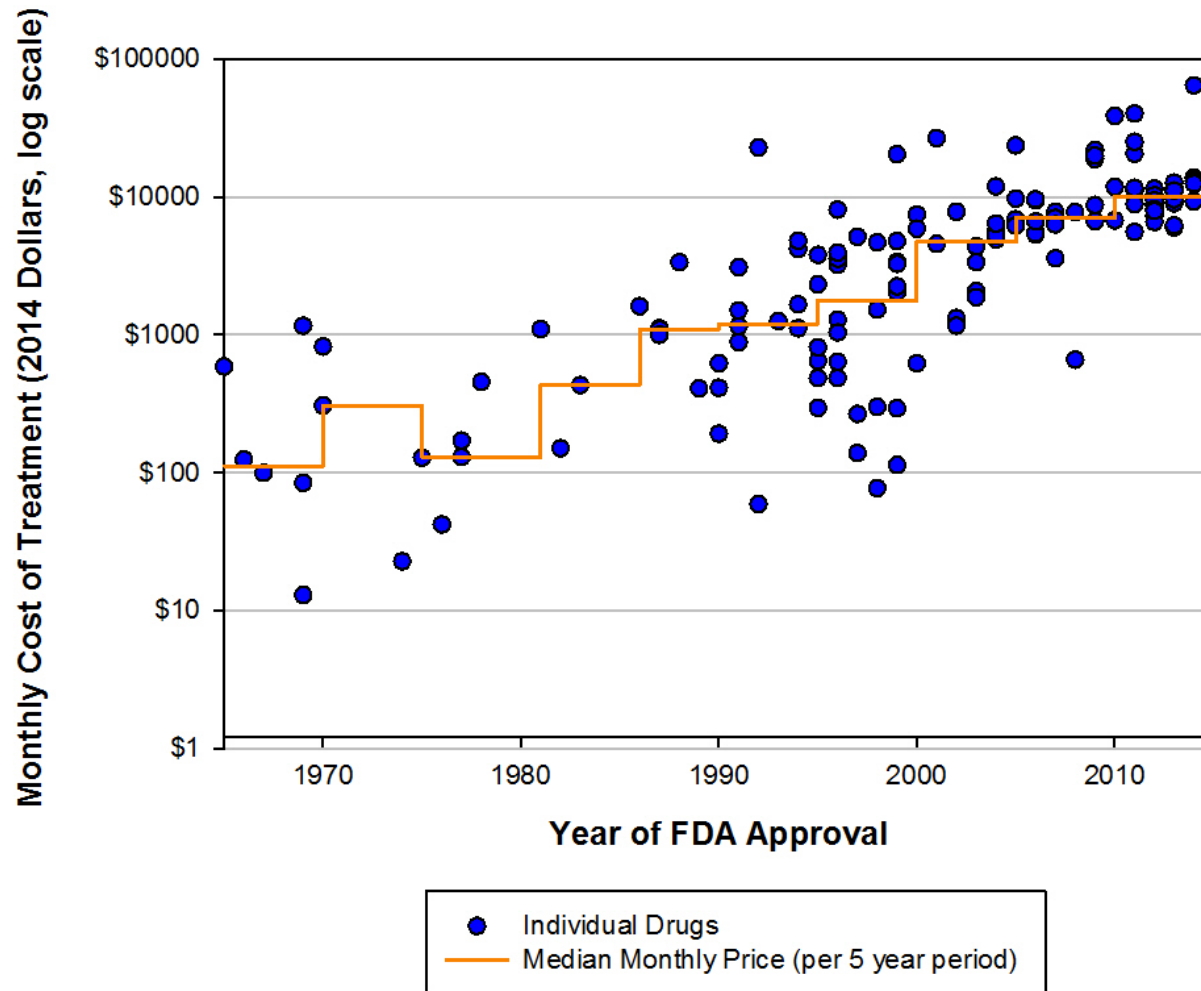
Spending increase coinciding with the introduction of new biologics and targeted agents

Therapeutic Oncology Drug Spend Per Capita 2010-14



IMS Developments in Cancer Treatments, Market Dynamics, Patient Access and Value: Global Oncology Trend Report 2015

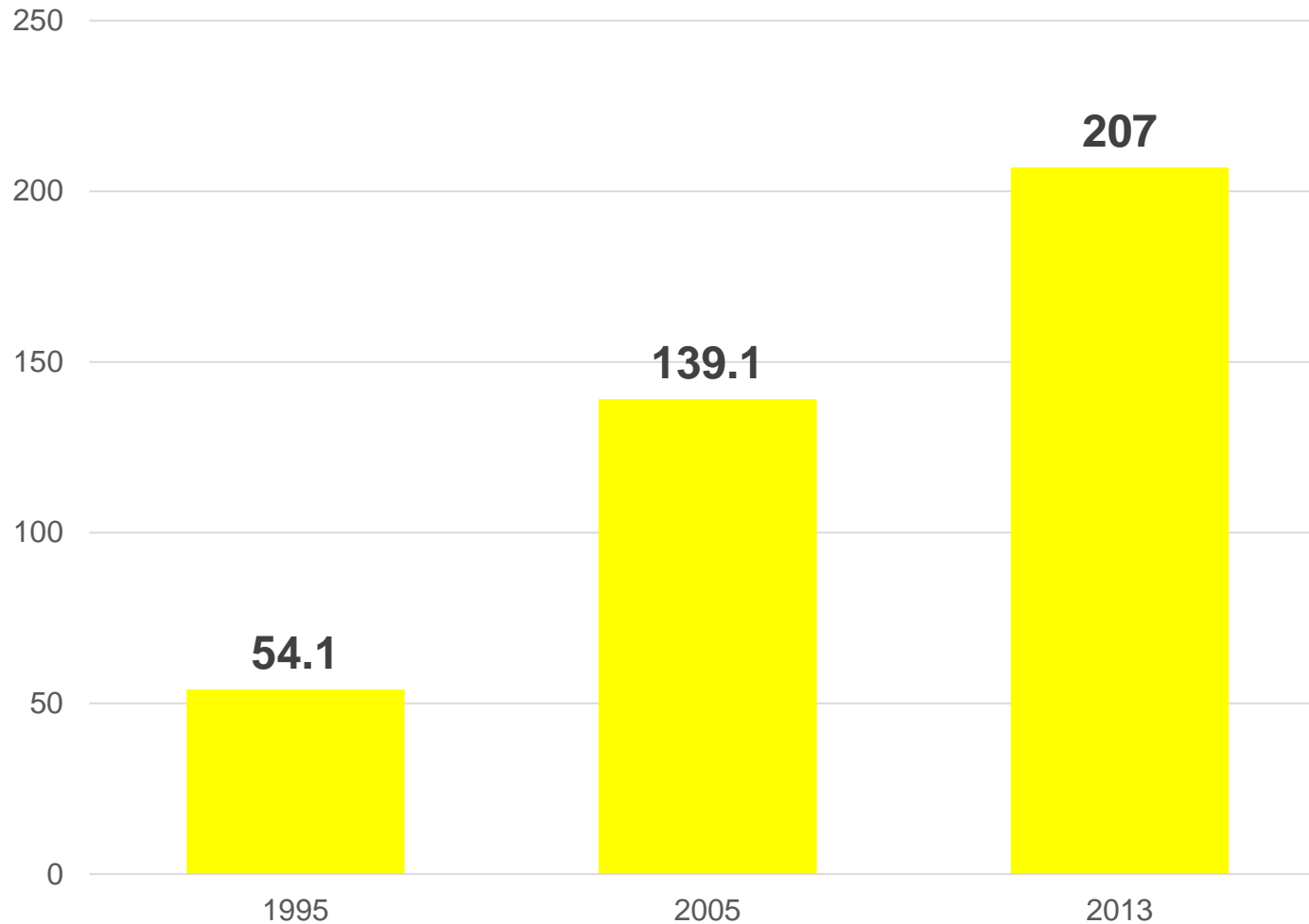
Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval - 1965-2015



Source: Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center

Average Cost for an Oncology Product for One Life Year Saved (2013 Prices)

\$1000/life year saved



Source: Howard et al, 2015

Factors Explaining Variation in Pricing of Oncology Products

Between products (Howard et al, 2015; US data)

- Life year gained
- Year of launch – about 10% increase per year (fixed prices) when controlling for outcome
- Reference price benchmarking versus previously launched oncology products

Between countries in Europe

- HTA – value based (UK, Nordics, Netherlands etc); Innovation classification and price negotiation (Germany, France, etc.)
- Price discrimination between countries – gross to net
- Ability to contract, e.g., risk-sharing, price/volume, PAS

Conclusion

- **Total expenses for cancer drugs gone up:**
 - Total cost/capita
 - Per newly introduced drug
 - Per Life Year Gained
- **Pricing system is by many key stakeholders broken**
 - What are the alternatives and still supporting a profitable R&D industry?

Payers' Response

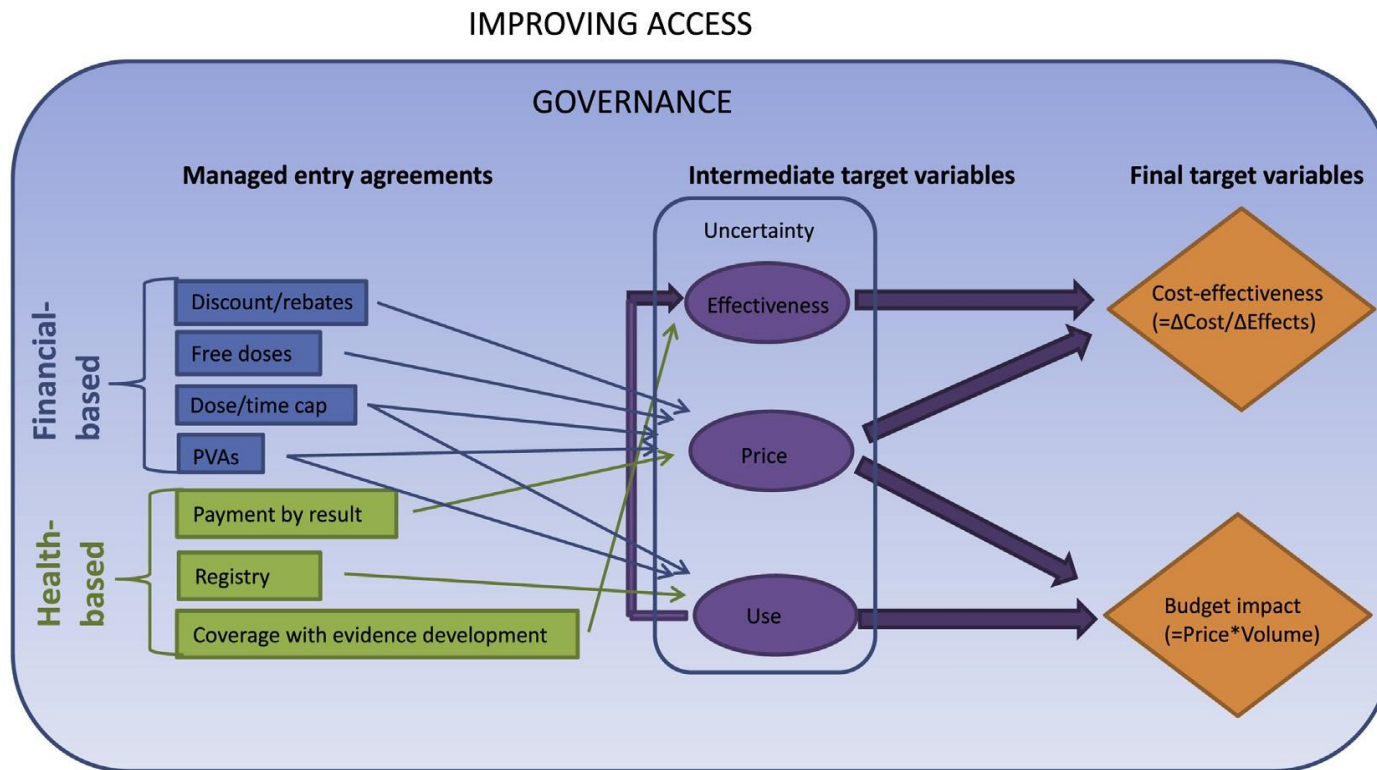
Payers' Objectives for New Medicines

1. Ensure patient access to adequate medicines
2. Operate within agreed budget
3. Only fund products that provide value for money
4. Simple payment schedules
5. Consistent response to manufacturers

Payers' Objectives for New Medicines - Responses

1. Ensure patient access to adequate medicines
Managed Entry
2. Operate within agreed budget
Manage budget uncertainties via contracts and rebates
3. Fund only products that provide value for money
Risk sharing or pay for performance
4. Simple payment schedules
Avoiding too complex tracking and follow up
5. Consistent response to manufacturers
Transparency around decision making

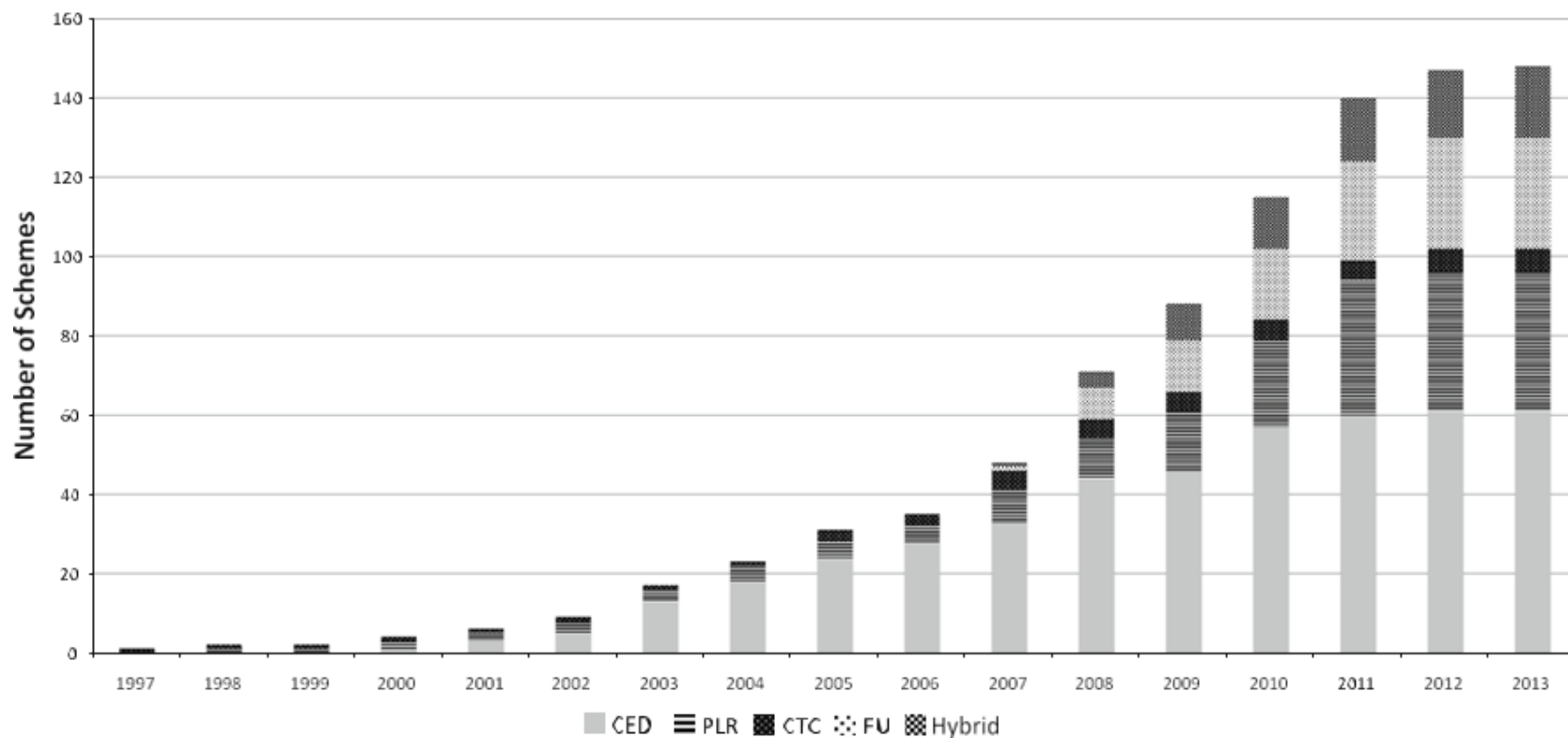
Addressing Payer Uncertainty



Source: Ferrario and Kanavos, 2015

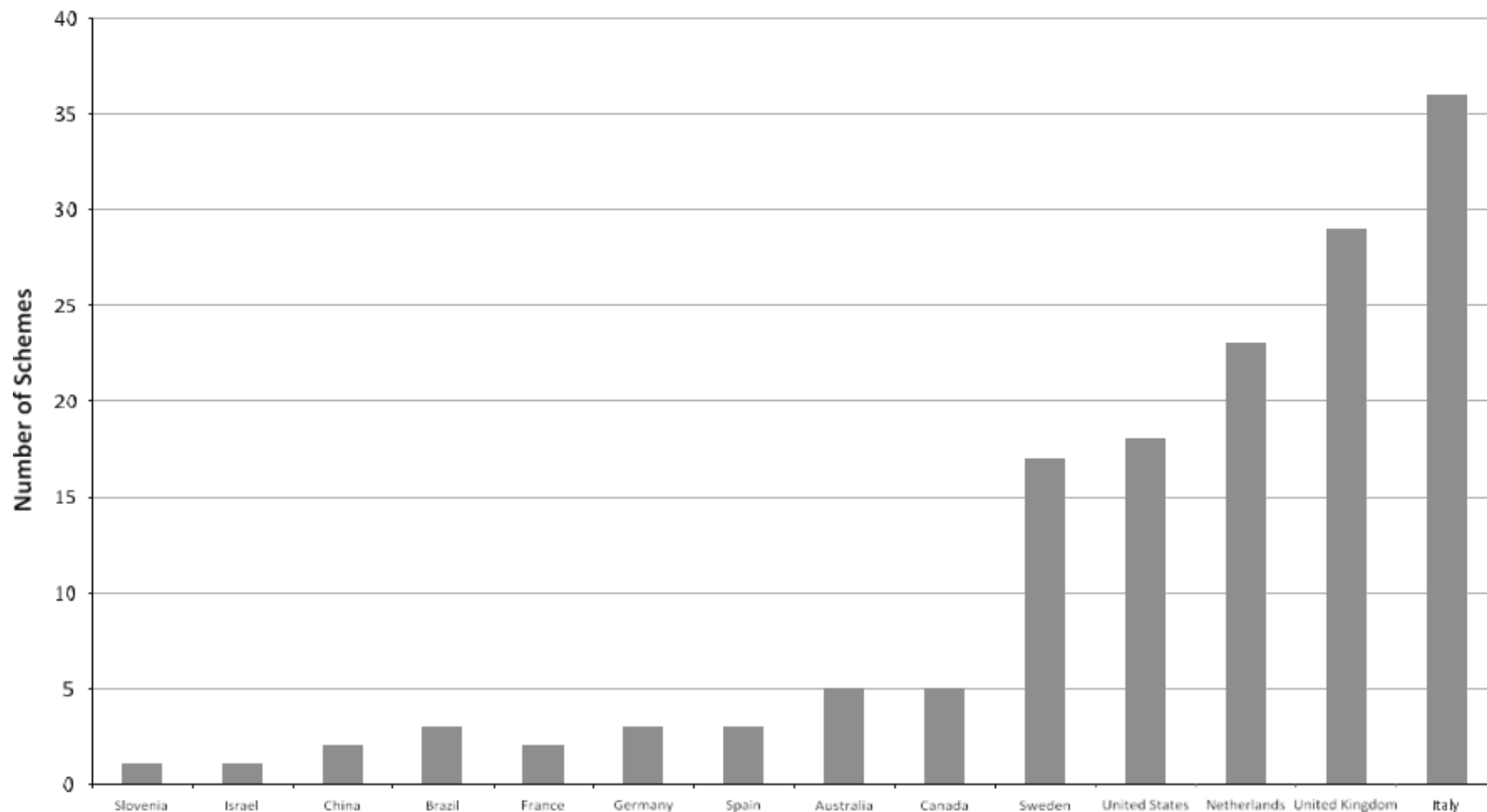
Novel Pricing I: Health Based Performance-based Schemes

Performance-based Schemes by Year



Source: Carlson, Gries et al. 2014

Performance-based Schemes by Country



Source: Carlson, Gries et al. 2014

Some Reasons Why Performance-based Pricing Schemes Only Have Had Moderate Success

- Definition of outcome many times difficult
- Complex management and tracking
- Payment/re-payment outline may be unclear
- Easier with flat discount!
- Incentive structures
- ...

Novel Pricing II: Financially Based Price Differentiation/Discrimination

Issues with Price per Unit Schemes

- High price per patient treated
- Challenges in providing different prices for different indications
- Patients that benefit from therapy but value lower than price may not get therapy
- Very high stacked prices as a result of high priced mono therapies that also can be used in combinations

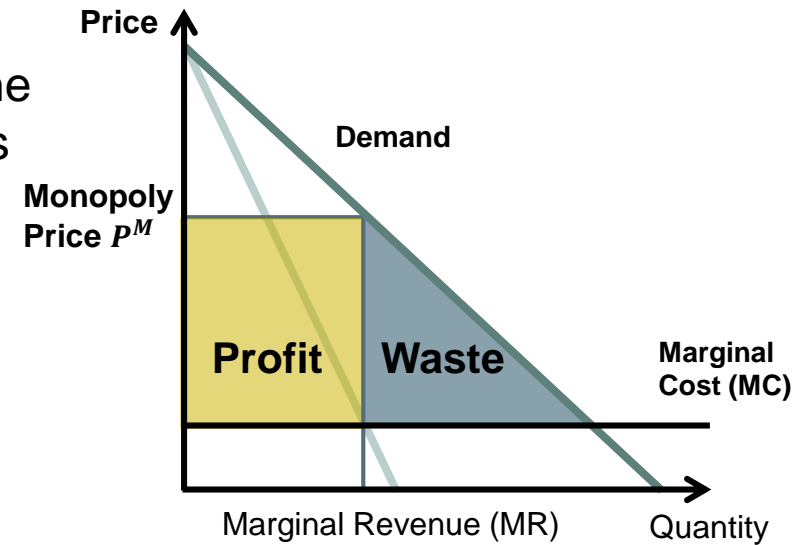
AND

- The marginal cost to manufacture one extra treatment for a patient is normally small; maybe only 10-20% of list price

What is Economic Theory Telling Us About Pricing When Monopoly?

Under price per unit, the monopoly sets the price at P^M , causing market inefficiencies

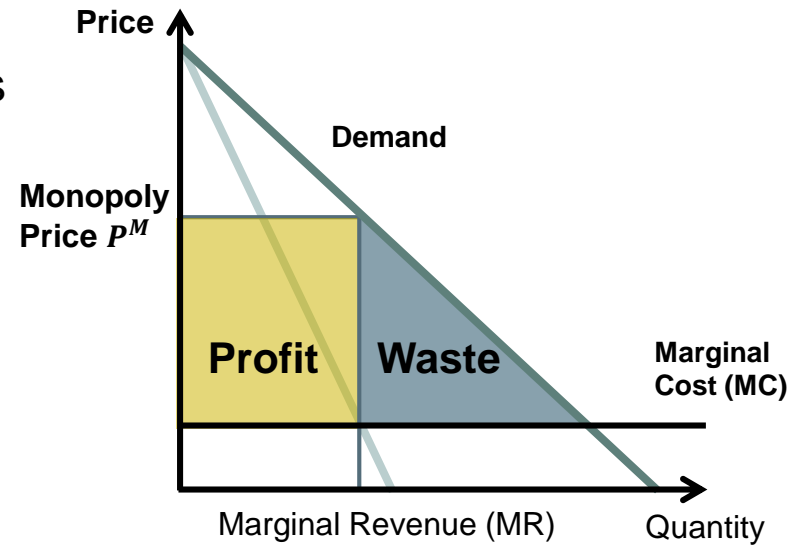
Potential to increase use



Price per Unit vs. Two-part Pricing in Theory

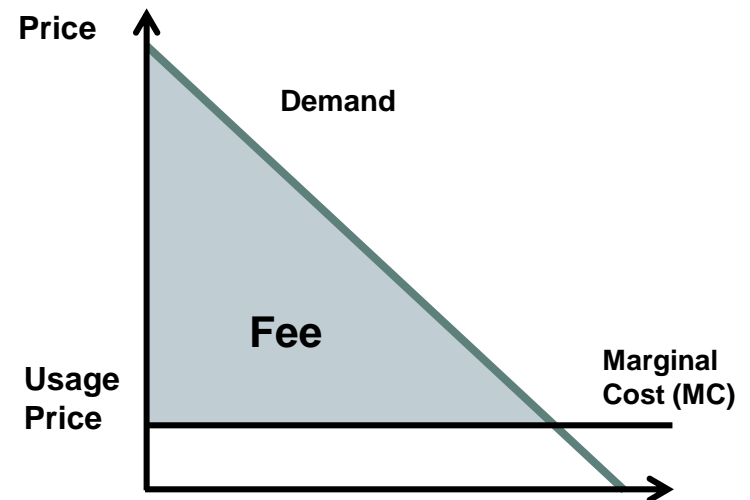
Under uniform pricing, the monopoly sets the price per unit P^M , causing market inefficiencies

Potential to increase use



Under two-part pricing, the monopoly charges the users a fee for their entire surplus, while setting a usage price equal to marginal costs

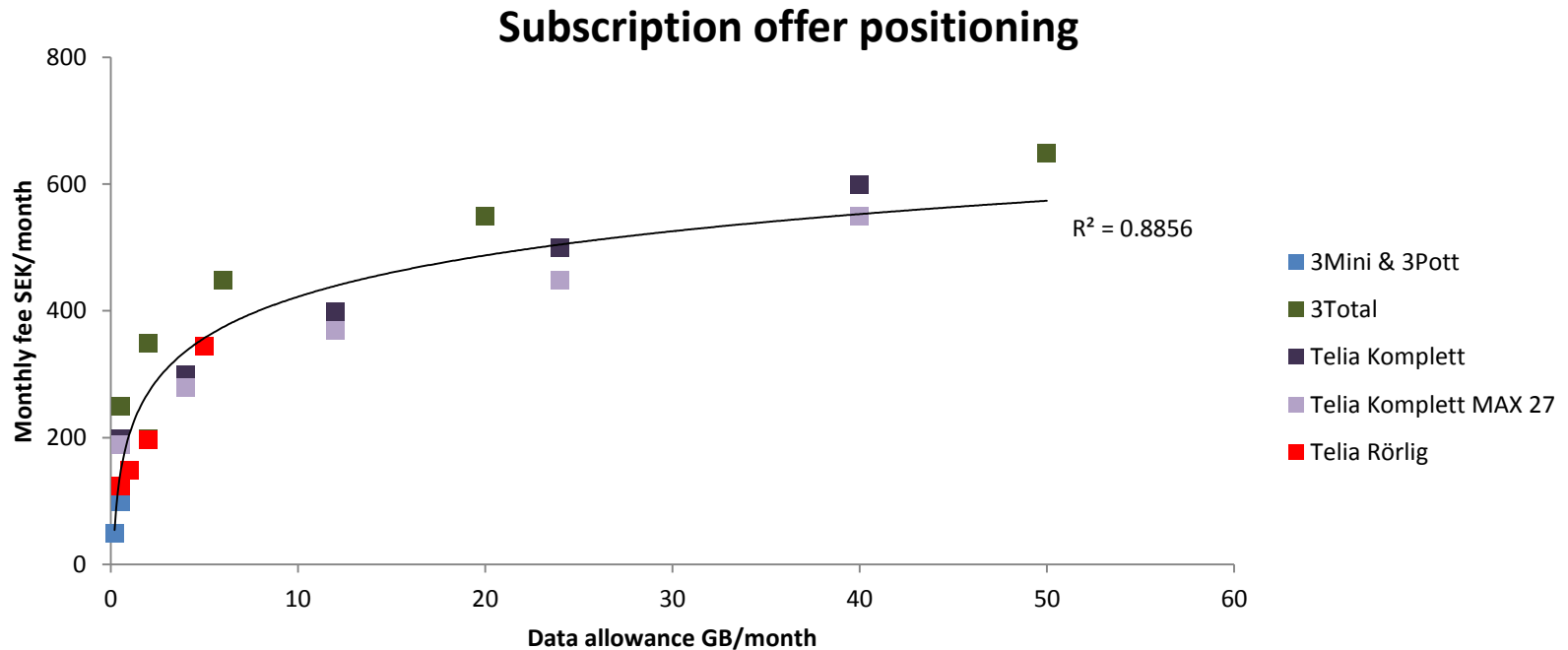
Profits are maximized



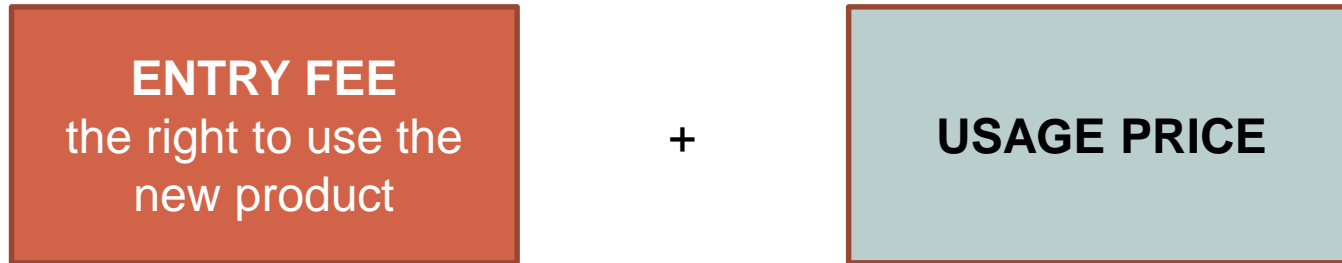
Example: Mobile communication and Software industries operate with various forms of pricing schemes, in particular price discrimination models

Pricing structure	Price per Unit	Two-part Pricing	Three part Pricing	Flat rate
Usage price(s)	X	X	X	
Access fee		X	X	X
Free allowance			X	X
Price discriminating		X	X	X

Example: Mobile phone offerings



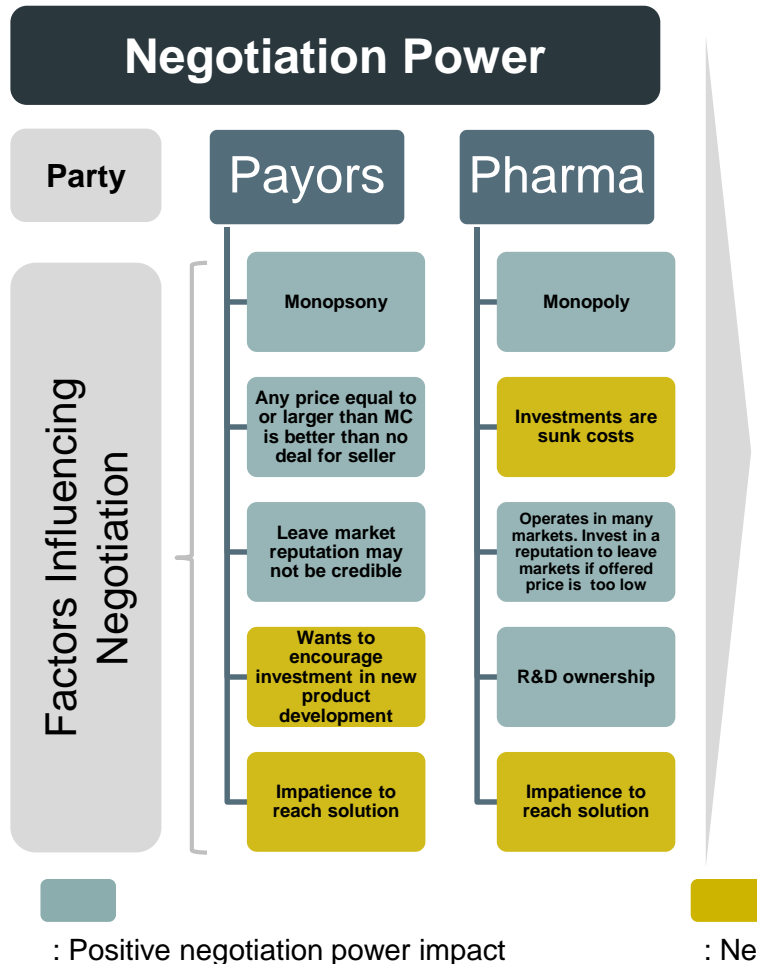
Two-part Pricing Construct



The Entry Fee is calculated on the expected value of all products/services expected to be bought, minus the Usage Price

The Fee Bargaining Process: A Monopoly-Monopsony Market

The outcome of the market structure will depend on a **bargaining process** and the outcome of the bargaining process will depend on the parties' **negotiation power**.



Outcomes

Game theoretic perspectives

From a game theoretic point of view, the bargaining outcome is uncertain, but it will likely be more efficient than in a strict monopoly market. The parties' impatience in servicing the market is fundamental in understanding the pricing outcome.

Behavioural Perspectives

Empirical evidence suggest that buyers will offer prices above marginal cost and that sellers are willing to leave markets if they consider the price to be unfairly low.

Payers' Objectives for New Medicines – What does Two-Part Pricing provide?

1. Ensure patient access to adequate medicines:
Broad access as limited economic restrictions as Usage Price is low
2. Operate within agreed budget:
Uncertainty on budget significantly reduced - core impact comes from Entry Fee
3. Only fund products that provide value for money:
Entry Fee based on number of patients and value
4. Simple payment schedules:
Less complex than Performance-based Payment; But need to control for arbitrage
5. Consistent response to manufacturers:
Open for all; similar approach as Tendering if more products in the space

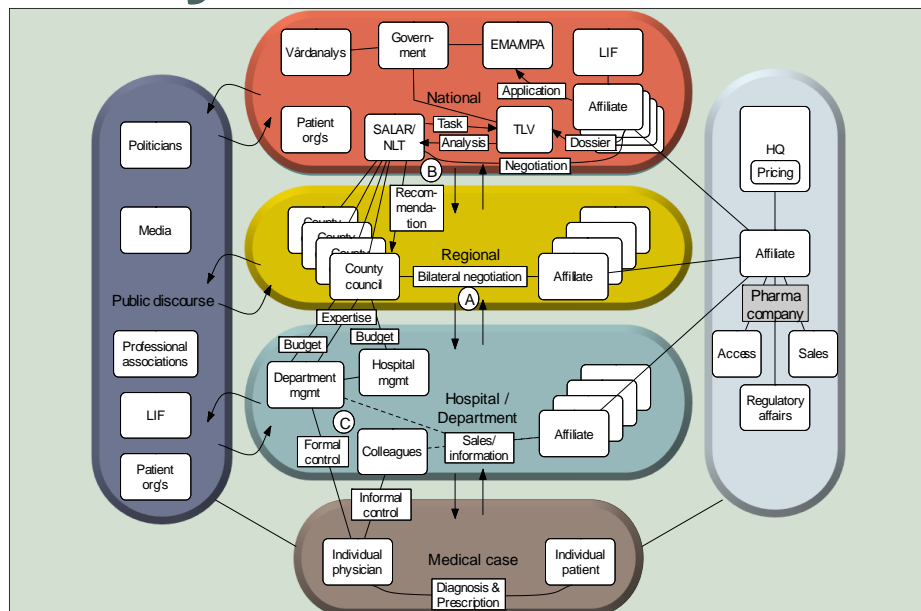
Conclusions

- Major frustration on current pricing approach from all stakeholders
- Issues on “value for money”, “budget impact” and “equity”
- “Performance-Based Pricing” is one pricing scheme option but often complex to manage
- “Two-Part Pricing” has the ability to provide improvements for patients, prescribers, payors and manufacturer
- BUT: Is the industry ready? Are the payors ready?

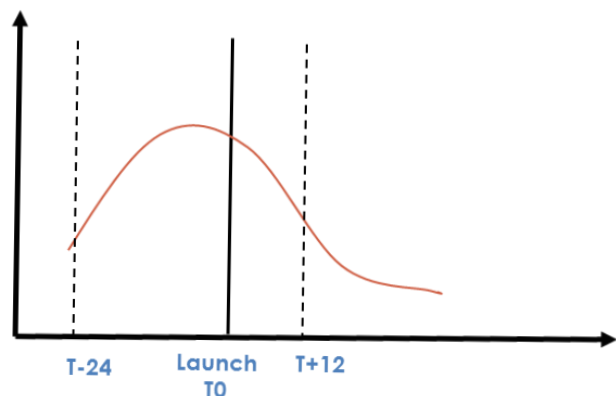
HEALTH | **ACCESS**
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Key Considerations

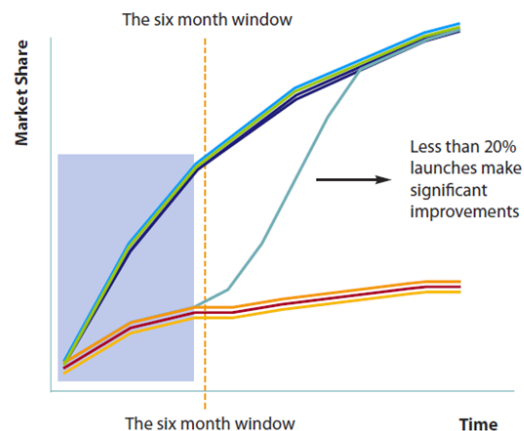
1. Integration of expertise to manage the complex access work



2. The bulk of the access work is done over a concentrated time period around launch



3. Access approval timelines critical for long-term success!



Health Access Agency

Business Objective:

Work with biopharma/biotech companies to minimize time for patients to get access to new medicines

We are

a group of **highly experienced** partners and associates throughout Europe and North America with broad access competencies.

Local Country Level, e.g. direct payer negotiations, reimbursement applications, HTA and value dossier submissions, government interactions.

Functional Level, e.g. HTA, Health Economics, Health Technology Assessment, Pricing, Value Dossier, Government Affairs.

We will

Evaluate market access opportunities
Develop market access strategies and plans;
Implement market access related activities, including brand team participation, HTA submissions, as well as direct external negotiations.

Our ambition is to be a **FULL SERVICE PROVIDER**. We all have substantial **hands-on experience** managing launches of new products – at both local country and international levels