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Value-Based Pricing and Market Allocative Efficiency: How Should Cost-Effectiveness Thresholds be Set to “Optimally” Distribute Value between Payers and Developers?

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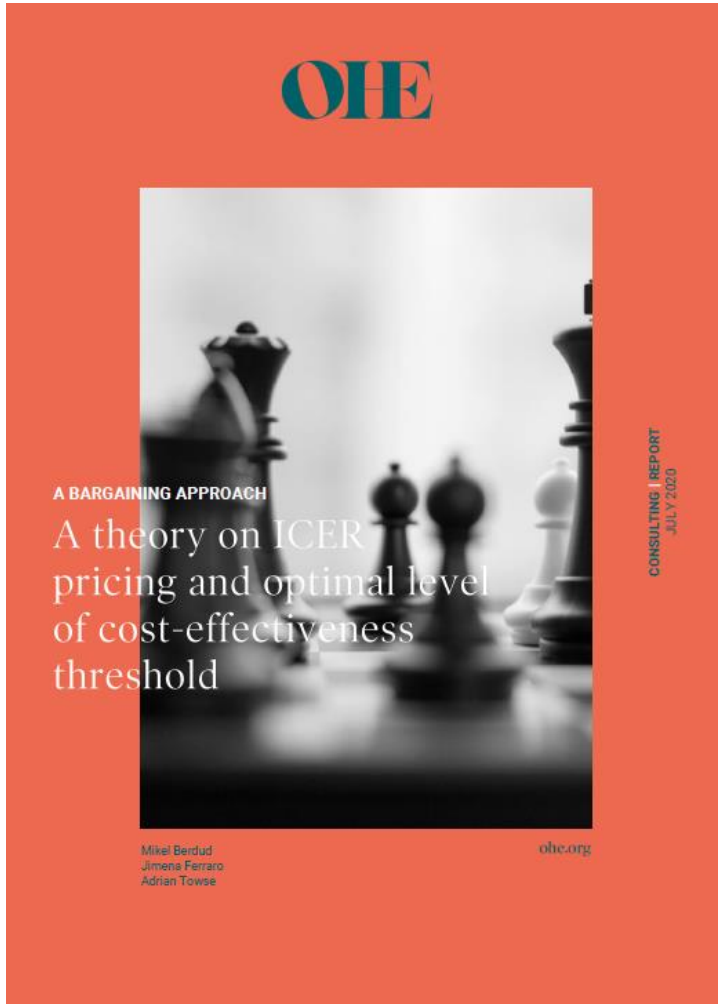
Conflicts of interest

This presentation content is based on results from a research conducted by authors from the Office of Health Economics and the Universidad de Buenos Aires, that was commissioned and funded by Hoffmann La Roche.

Any views expressed here are those of the authors.



A theory on ICER pricing and optimal level of cost-effectiveness thresholds

Dr. Mikel Berdud (OHE), Dr. Jimena Ferraro (UBA), Prof. Adrian Towse (OHE)

Context

- Incremental Cost Effectiveness Ratios help guide policymakers with resource allocations decisions to assess the health gains offered by an intervention relative to its additional costs
- However, currently there is not an agreed way on how the CET should be set as there are various approaches such as:
  - *Demand-Side approaches*: the level of the CET reflects society's monetary valuation of incremental health gain.
  - *Supply-Side* approaches: determines the level of the threshold as the health system opportunity cost
- In order to reflect the opportunity cost of resources allocated for a particular intervention, Cost Effectiveness Thresholds are used alongside ICER as a references of value and to inform Value based pricing decisions

Introduction

- A “Supply and Demand” model is presented, based on a novel model by Pandey et al. (2018) – some assumptions are relaxed and new ones applied
- The model allows the payer to set the CET and price negotiations to happen after the new medicine is given reimbursement status within the ICER-CET pricing framework
- The model incorporates a **bargaining process** to analyse the impact of different degrees of consumers’ and developers’ bargaining power on the distribution of the health and economic value of new medicines between the two parties
- The model incorporates the **R&D ‘sunk’ cost** as a key determinant of the **reserve ICER developers** – the minimum ICER developers will be willing to accept for new medicines
- The model also discusses the impact of: (i) non-uniform distributions of developers’ reserve ICERs and (ii) mid- / long-term flexible budgets

Timing of the Model: "static" vs "dynamic" model

- The timing of players' (i.e. the payer and the developers) decisions and outcomes is separated in six different stages
  - "Static" (short-run):

  - "Dynamic" (long-run):

Nash Bargaining Solution: the developer

- In the short run, the **developer** determines minimum price of medicine by equating it to its marginal cost of production: $p \geq c$
- At this price, the developer does not recoup R&D costs – hence sunk costs.
- In the long run however, the developer only has incentives to keep investing in R&D and producing new medicines if the price is charged such that both marginal cost and R&D costs are recouped:

$$p \geq c + \frac{R_i}{q}$$

- Also defining an outside option: whereby a price is not successfully reached, leaves the developer with a negative profit equal to the R&D cost

$$\Theta_d = -R_i$$

Nash Bargaining Solution: the payer

- Developers gross payoff is a function of total value of health gains obtained by patients treated with medicine minus total system treatment cost (direct and individual total health costs)

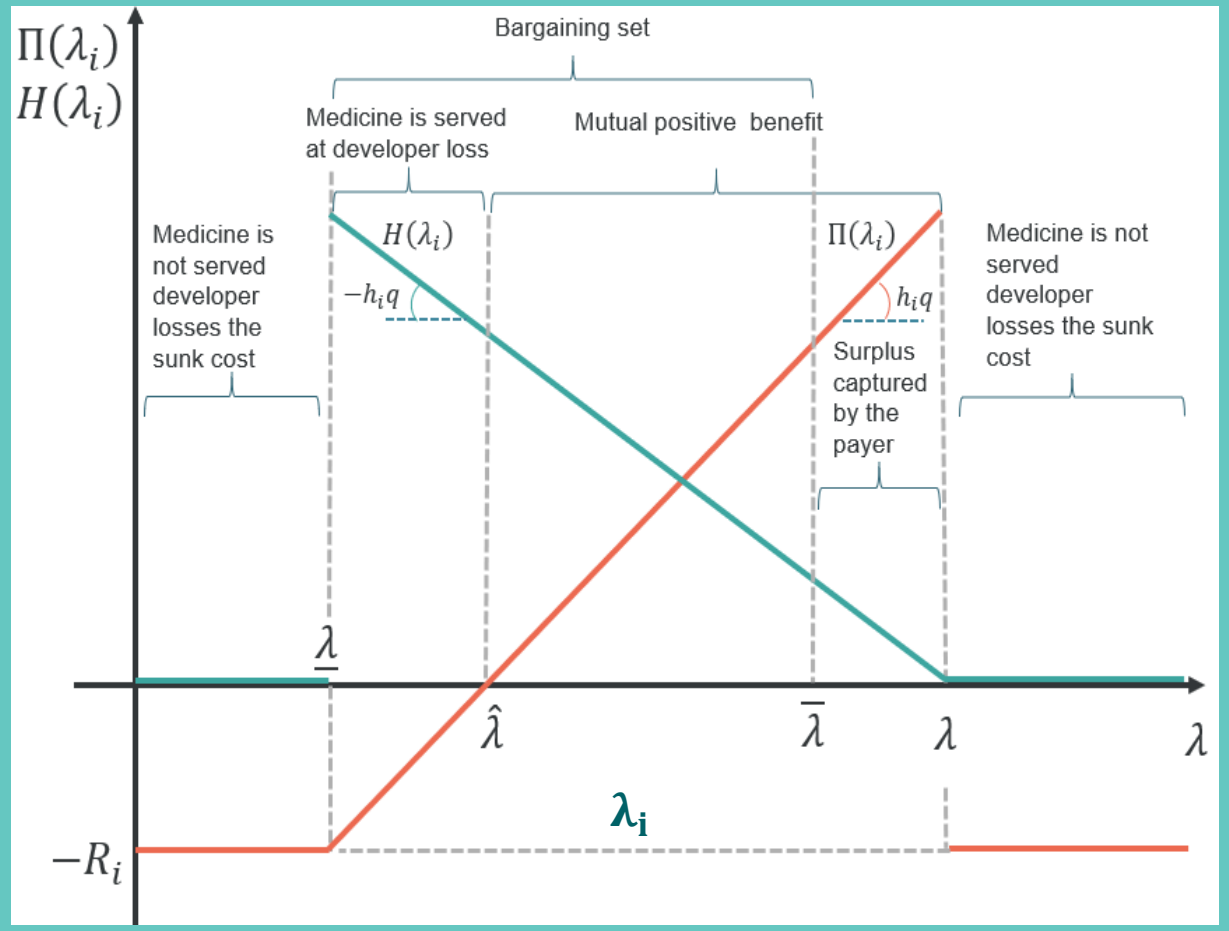
$$B_i(p_i) = \lambda h_i q_i - \left(p_i q_i + T_i(q_i)\right)$$

- Considering the outside option, that is when the new medicine (i) is not reimbursed because is not value for money and the system keeps using the comparator intervention (j), the system will only adopt new medicine whenever

$$H_i(q_i) = B_i(p_i) - B_j\left(p_j\right) \geq 0$$

- That is - **when the monetary value of the incremental health benefit exceeds the incremental cost, or alternatively the ICER is below (or equal) to the health system's maximum WTP** i.e. the opportunity cost or the supply-side cost-effectiveness threshold λ

Nash Bargaining Solution



The light blue line represents the payoff to the **payer** $H(\lambda_i)$
Orange line represents the payoff to the **developer** $\Pi(\lambda_i)$

- $\underline{\lambda}$ is the reserve ICER of the developer
- $\overline{\lambda}$ is the CET
- λ is the max WTP (i.e. health system's OC)
- The set of possible agreements on the ICER $\lambda_i \in [\underline{\lambda}, \overline{\lambda}]$

Nash Bargaining solution:

$$argMax_{\lambda_i} (\lambda_i - \underline{\lambda})^{\beta} (\overline{\lambda} - \lambda_i)^{(1-\beta)}$$

- $\beta \in [0, 1]$ is the developer's bargaining power $(1 - \beta)$ is the payer's bargaining power
- For values of λ_i between the dynamic reserve ICER of developers $\hat{\lambda}$ and $\overline{\lambda}$, both players obtain positive surplus
- In the short-run, if $\lambda_i \in [\underline{\lambda}, \hat{\lambda})$ the developer markets the medicine and sells it at a loss

Macro Level Implications

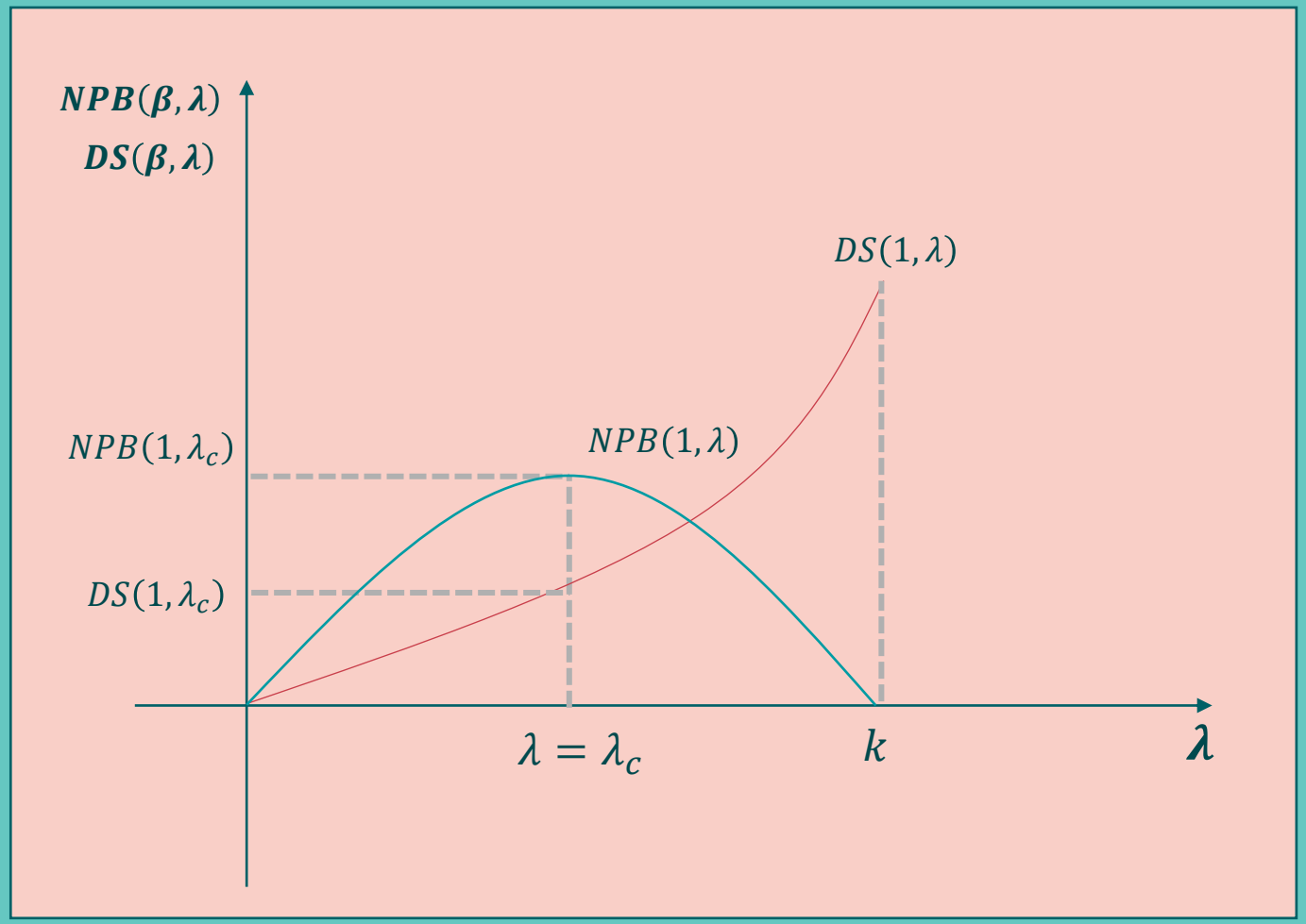
- To perform a welfare analysis of pharmaceutical markets regulated through a CET and ICER pricing requires additional analysis of the following:

I. Aggregate demand: how payers behave when using the whole health budget to provide health care to taxpayers, especially to what extent they are concerned about providing access to new medicines

II. Aggregate supply: how the health industry (i.e. all developers together) responds to a pricing and reimbursement environment based on ICERs and the CET

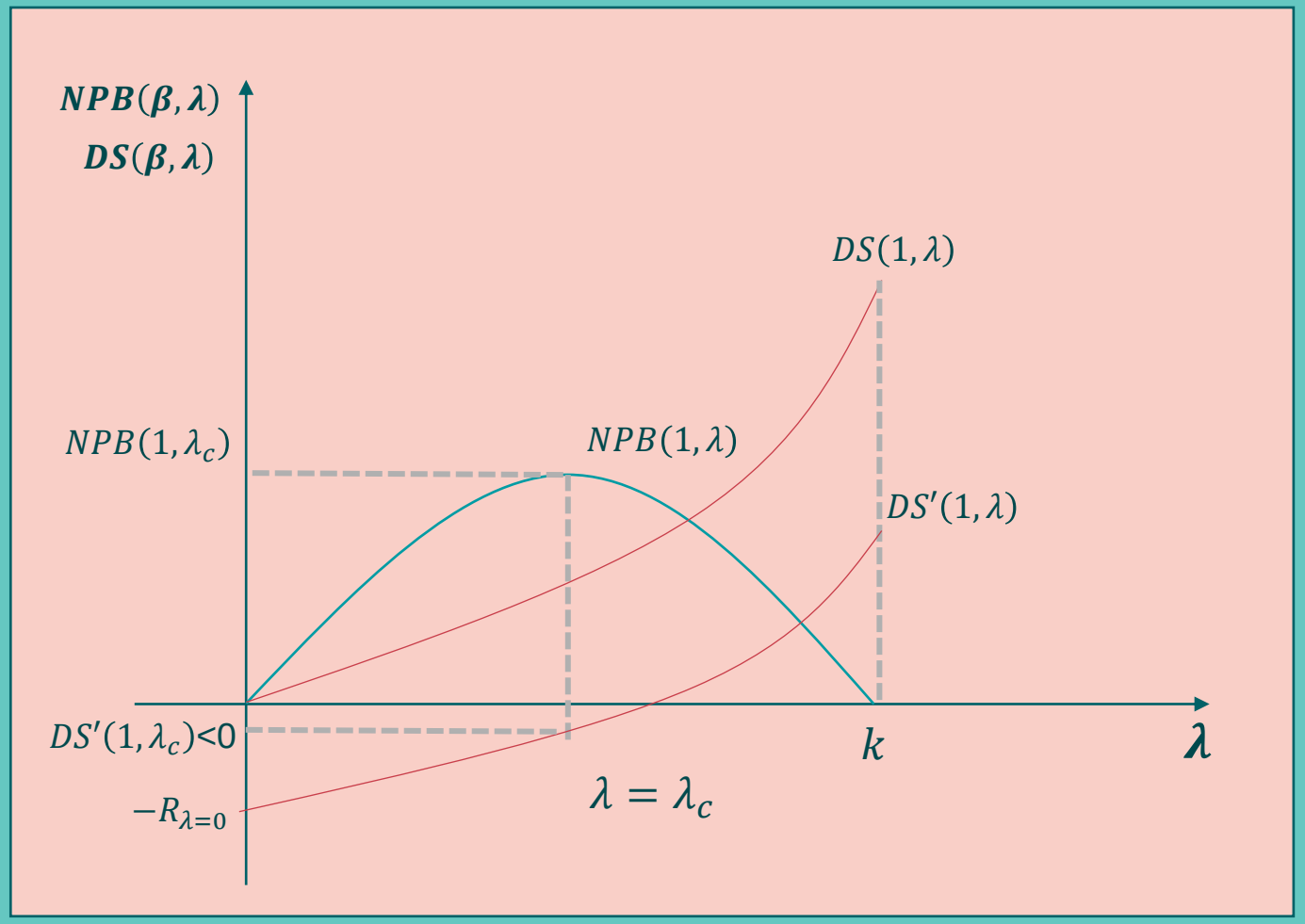
III. Final equilibrium: how the final price (i.e. effective ICER) resulting from ICER pricing at the reimbursement decision stage and the bargaining process of medicine at the commercial procurement stage affect the final distribution of the surplus between the payer and the industry

NPB Maximising payer and no R&D cost consideration



- All bargaining power is for the developer: $\beta = 1$
- The social optimum – max. sum of NPB and DS – is always at $\lambda^* = k$
- The payer maximises NPB at $\lambda = \lambda_c$ and gets $NPB(1, \lambda_c)$
- The developer gets $DS(1, \lambda_c) > 0$

R&D cost incorporated



- When the R&D cost ('sunk') is incorporated to $DS(1,\lambda)$, the curve translates downwards by amount R to $DS'(1,\lambda)$
- The payer maximises NPB at $\lambda = \lambda_c$ and gets $NPB(1,\lambda_c)$
- The developer gets $DS(1,\lambda_c) < 0$

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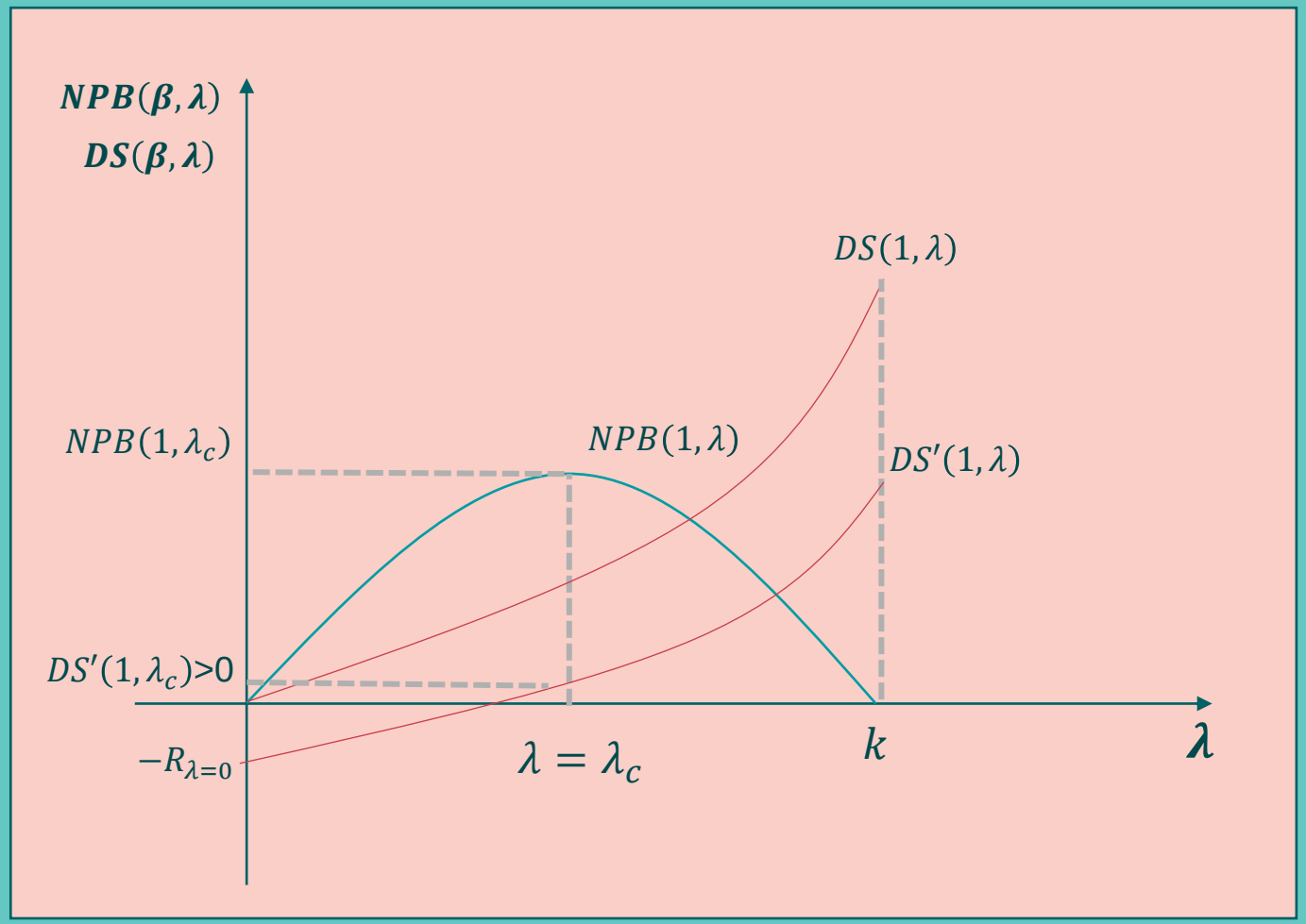

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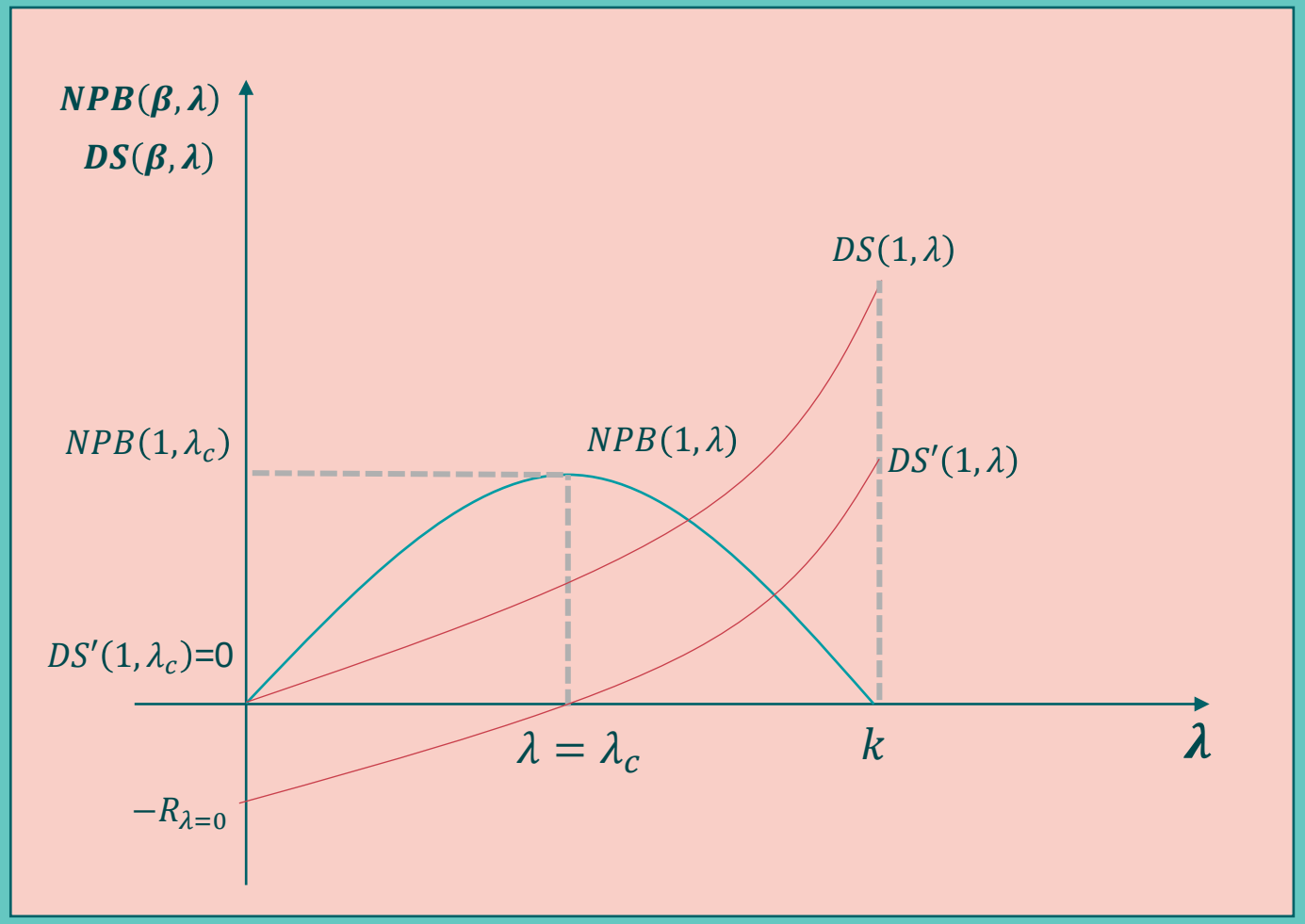
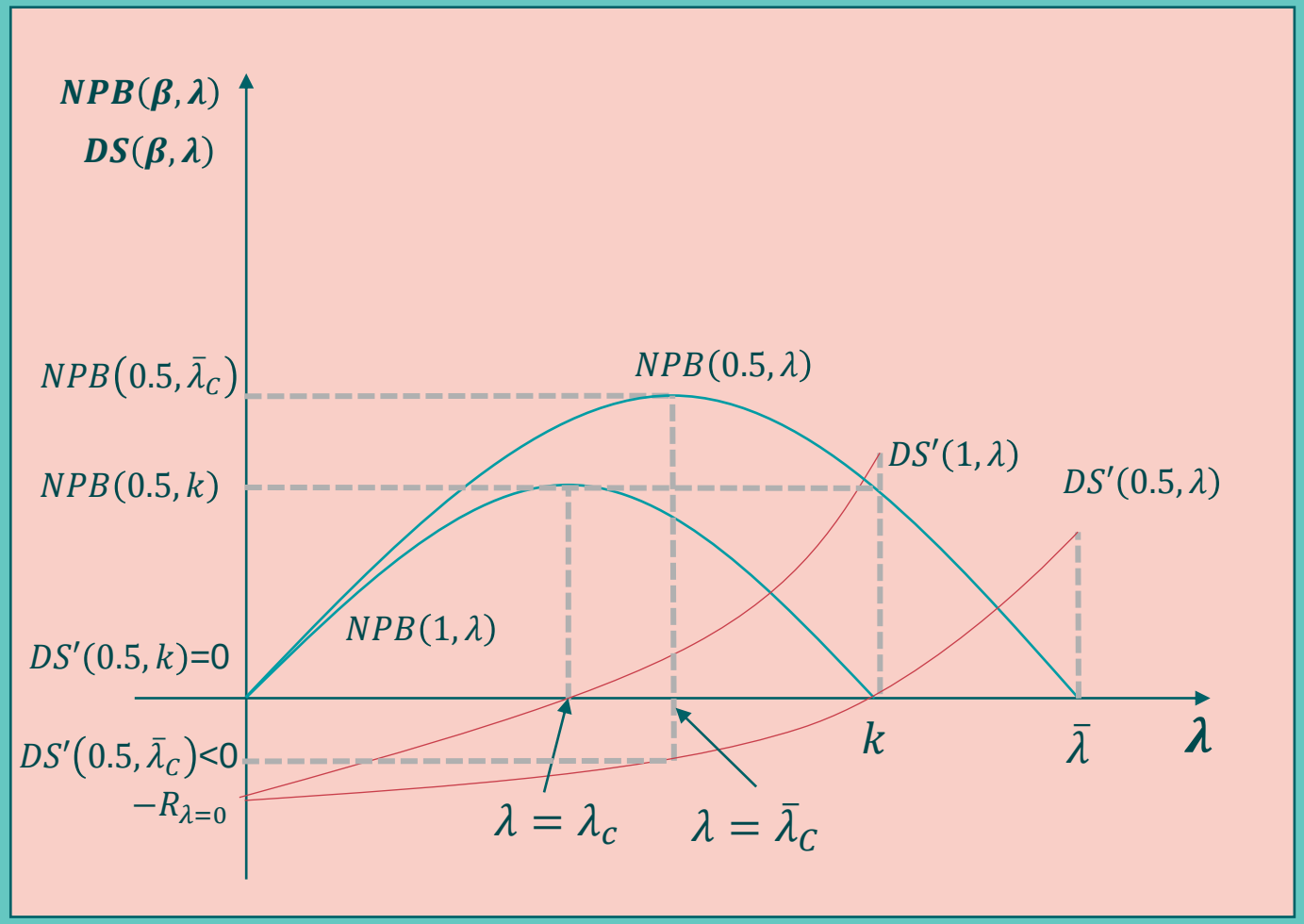


- When the R&D cost ('sunk') is incorporated to $DS(1,\lambda)$, the curve translates downwards by amount R to $DS'(1,\lambda)$
- The payer maximises NPB at $\lambda = \lambda_c$ and gets $NPB(1,\lambda_c)$
- The developer gets $DS(1,\lambda_c) = 0$
- The payer will still be able to maximise NPB without disincentivising long-term R&D investment (i.e. the industry is at the break-even point)

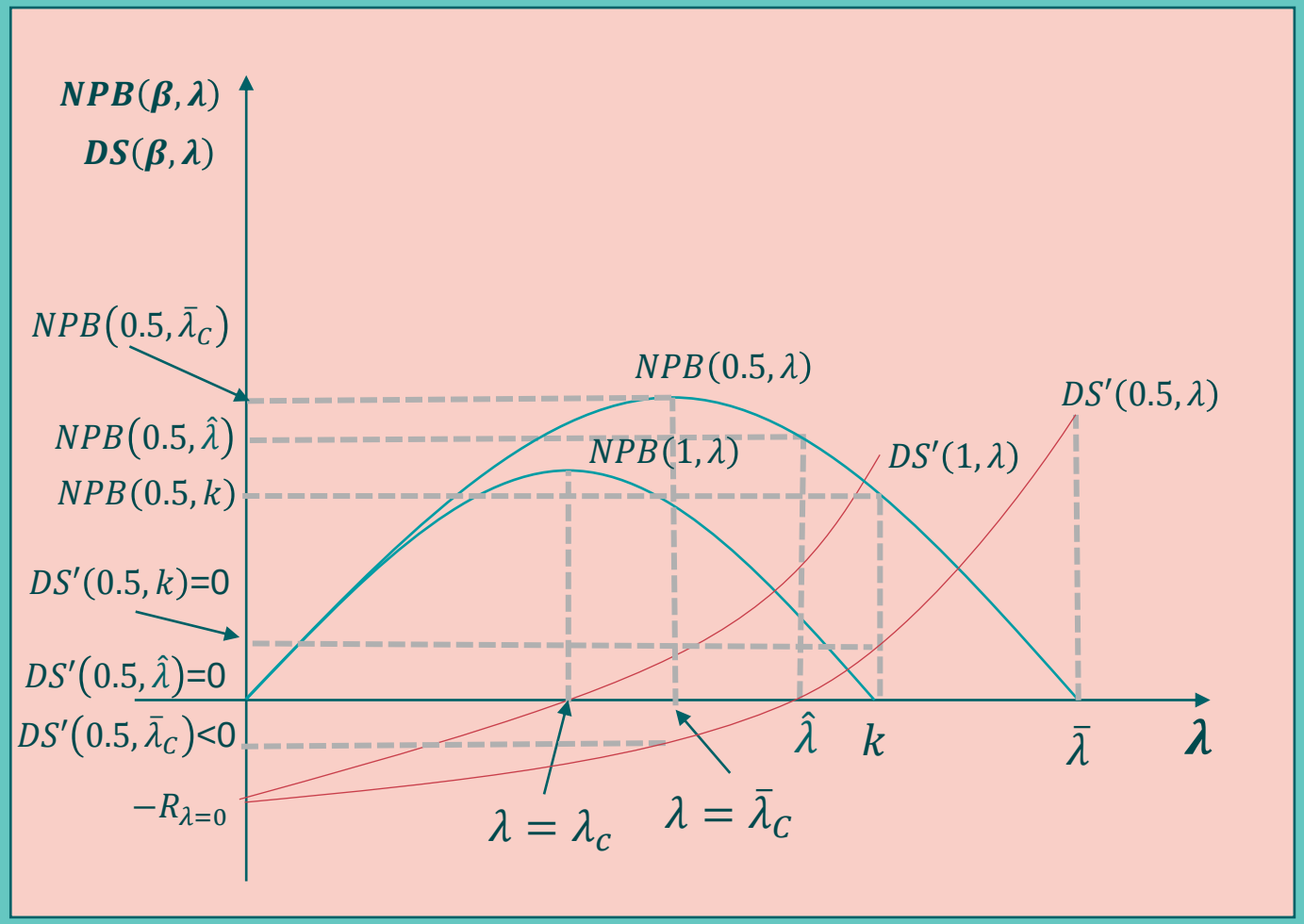
Bargaining and prices: surplus allocation, incentives and the dynamics



- The social optimum is always reached at $\lambda^* = k$
- For a NPB maximising payer with $\beta = 0.5$ bargaining power, the level of the CET is $\lambda = \bar{\lambda}_C$ (>λ_c) and $NPB(0.5,\bar{\lambda}_C)$
- At that $\lambda = \bar{\lambda}_C$ developers get $DS'(0.5,\bar{\lambda}_C)<0$
- At the social optimum developers would get $DS'(0.5,k) = 0$

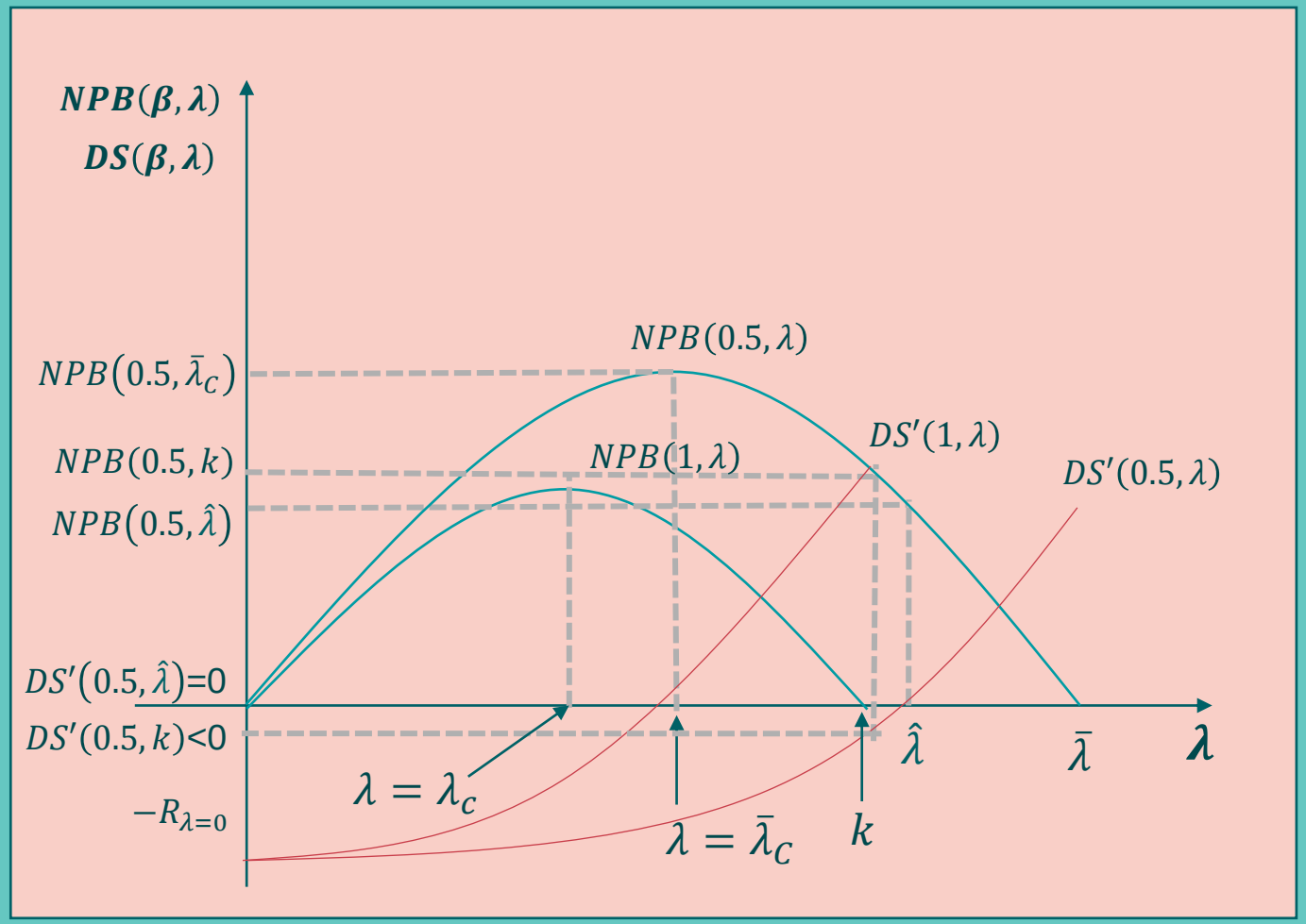
The social optimum generates sufficient economic value for the two parties

Bargaining and prices: dynamic efficiency



- Let $\hat{\lambda}$ the dynamic reserve ICER of the developers –cut point between DS and x-axis
- At NPB maximisation CET developers' surplus is negative
- At social optimum $\lambda^* = k$ both, payer's and developers' surpluses are positive – and the sum is the maximum achievable
- Moving from k to $\hat{\lambda}$, the payer would increase NPB without developers making any loss

Bargaining and prices: dynamic efficiency



- At social optimum $\lambda^* = k$, payer's surplus is positive and developers' surplus negative – developers will keep selling the medicines at loss in the short-run
- Moving from k to $\hat{\lambda}$, the payer would decrease NPB to make developers not making any loss – restore the market signal that investment have enough returns while NPB is still positive
- Under some circumstances involving more balanced bargaining power between players, the CET could be set above the OC

Conclusion

- We proposed a general theoretical model of CET and ICER pricing where the **key element of the bargaining** is added through a **Nash Bargaining Solution** approach to the baseline model as found in Pandey et al. (2018)
  - The main implication is that a payer with higher bargaining power has the ability to negotiate a lower final price per QALY gained than the price that would correspond to the CET – this means that the final short-term net population benefit is higher
  - Under some circumstances if the bargaining power over the final price of new medicines is split between the payer and developers, a CET above the OC will still generate NPB to payers (positive surplus)
- Other relevant question to consider:
  - If CETs are not adjusted to reflect bargaining power, there could be medicines that are denied access because they are considered not cost effective, even though they still produce net health gains after their net prices are agreed.

Conclusion II

Other elements have been added (or become central) to this revised framework :

- The incorporation of sunk R&D costs shifts the developers' surplus curve downwards
  - In the short-run, developers will still supply already-developed new medicines at a loss because the size of this loss is smaller than the sunk R&D costs
  - In the long-run however, it is not dynamically efficient as the signal of negative returns will disincentivise investors, who will respond by reducing the amount of resource devoted to pharmaceutical R&D – an increase of the CET would be needed to avoid that situation but, how much? which are the effects in the long-run? what would be the optimal increase?
- Other aspects explored also affecting the "optimal" level of the CET are: (i) the distribution of developers' reserve ICERs along the value of the CET and (ii) the effect of mid- / long-term flexibility on health budgets
- Further research: the dynamic model of bargaining with implications and empirical analysis of both, (i) international CETs and access decisions, and (ii) distribution of reserve ICERs i.e. by assessing R&D cost differences across therapy areas, medicine archetypes and/or disease characteristics

Response to other speakers' questions and areas for future research

Berdud et al. (2020) response to Paulden, M. criticism

1. Relevance of the **'pre-bargaining' policy threshold** for real-world price negotiation

- **Pre- / Post-bargaining stages incorporated, reflect important features of the market functioning** such as on- / off-patent competition, regulations, cost-containment measures, tendering, etc. – VPAS and therapeutic tendering in the UK are good examples
- **The effective ICER** i.e. the one corresponding to the post-bargaining stage, **is always equal or below k** in Berdud et al. (2020)

Berdud et al. (2020) response to Paulden, M. criticism

2. Appropriateness of the assumption that **R&D costs are sunk** and producer surplus may be **negative**

- Short-term negative surplus for developers has dynamic implications: **if less innovation is supplied** (*"less efficient firms exit")* at the same level of threshold, **less patient health is produced**. It is not a *"short-term consideration only"*.
- ***"Less efficient firms will exit"***: it is not about the efficiency of the same project, but which projects are pursued? **Developing highly innovative, breakthrough technologies is likely to be riskier and more scientifically challenging with higher failure rates pushing up costs.** Is the intention to signal no future benefit for investing in these **highly costly but still cost-effective (at health system opportunity cost) new medicines**?

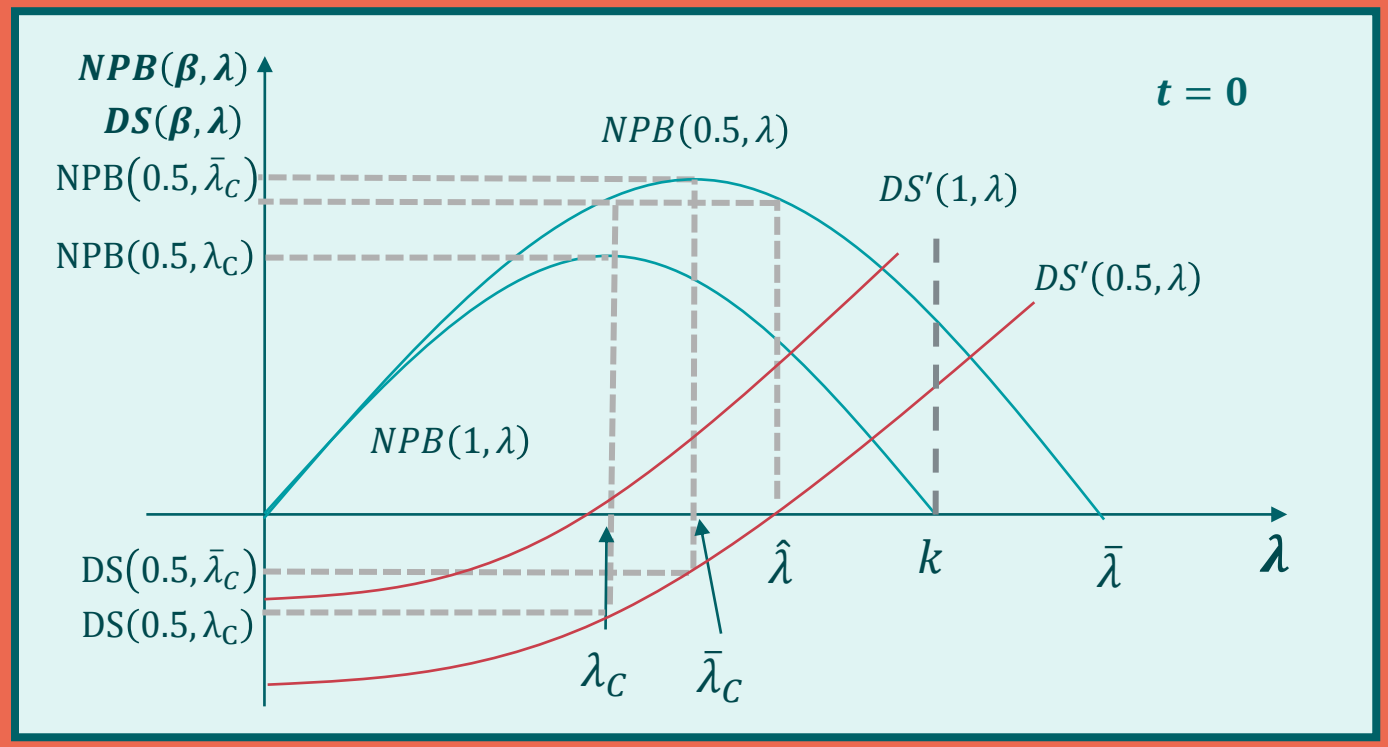
Berdud et al. (2020) response to Paulden, M. criticism

3. Specifying an **'optimal' policy threshold**

- **Optimising the social surplus – *"the social optimum is always reached at $\lambda^* = k$"* – is not normative. It results from maximising the sum of both, consumer and producer surplus.**
- **Policy objectives are normative**: for example, to maximise patients' health λ_C or the equal allocation of the total surplus.
- For any normative perspective implemented through policy, **it is crucial for policy makers to better understand all relevant factors driving the pharmaceutical market** including, bargaining (i.e. competition, regulation), R&D cost and dynamic efficiency and short- vs long-term trade-offs: **this is the aim of Berdud et al. (2020).**

Dynamic model: incentives and social surplus in the long-run

- If ex-post market bargaining environment is considered ex-ante, moving from λ_C to $\bar{\lambda}_C$ generates mutual gains
- This is short term perspective!

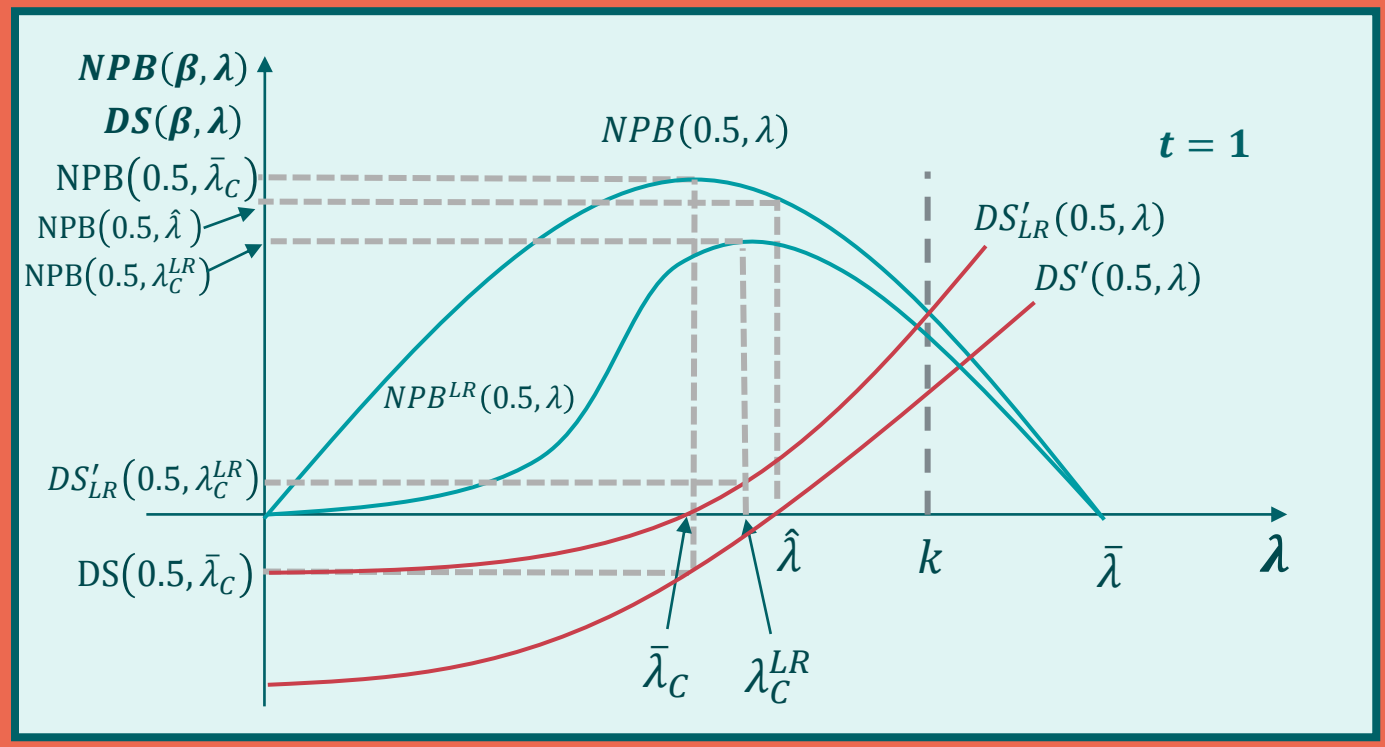


Dynamic model: incentives and social surplus in the long-run

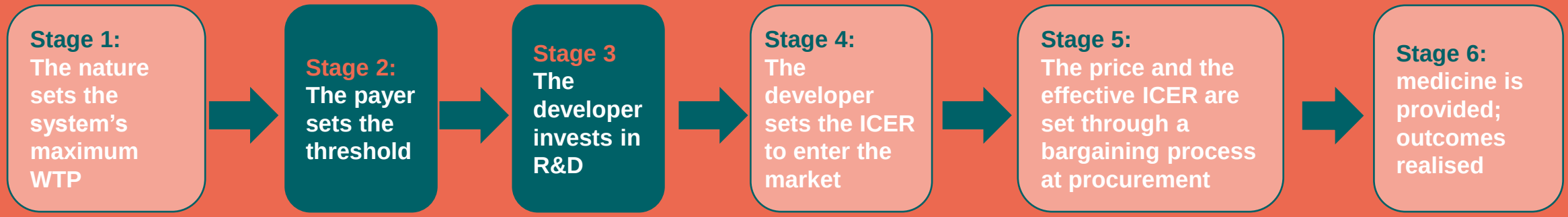
- If ex-post market bargaining environment is considered ex-ante, moving from λ_C to $\bar{\lambda}_C$ generates mutual gains
- The example shows "negative surplus" for developers yet: what happens in the long term?
- In t=1 (future) "less efficient" manufacturers – those producing cost-effective but costly medicines – will exit the market (no neg DS)
- Do other things remain constant?
  - What's the true trade-off?
  - How to optimise dynamically?
  - It's bargaining more relevant in the long-term?

Dynamics & strategic behaviour with:

Stage 2: The payer sets the threshold → **Stage 3** The developer invests in R&D



Future research (1): Dynamic model



- Understand the trade-off between static and dynamic efficiency and the long-term equilibrium:
  - Health maximisation in the long run: what, when and how?
  - The life-cycle approach of supply/demand and the policy/bargaining environment
  - Distribution of reserve ICERs and supply/demand responses to economic incentives
  - Distribution of reserve ICERs and type of innovation i.e. breakthrough, radical, incremental

Future research (1): Dynamic model

- It is necessary to understand how supply respond to incentives inn the long run: the “less efficient” leaving, the “most-risky” leaving, the “most challenging/costly” leaving and their health effects
- The health effects: how the NPB respond in the long-term to the change in the amount of innovation
- Formalisation and endogenisation
- *The effective ICER<K: always keep in mind!*

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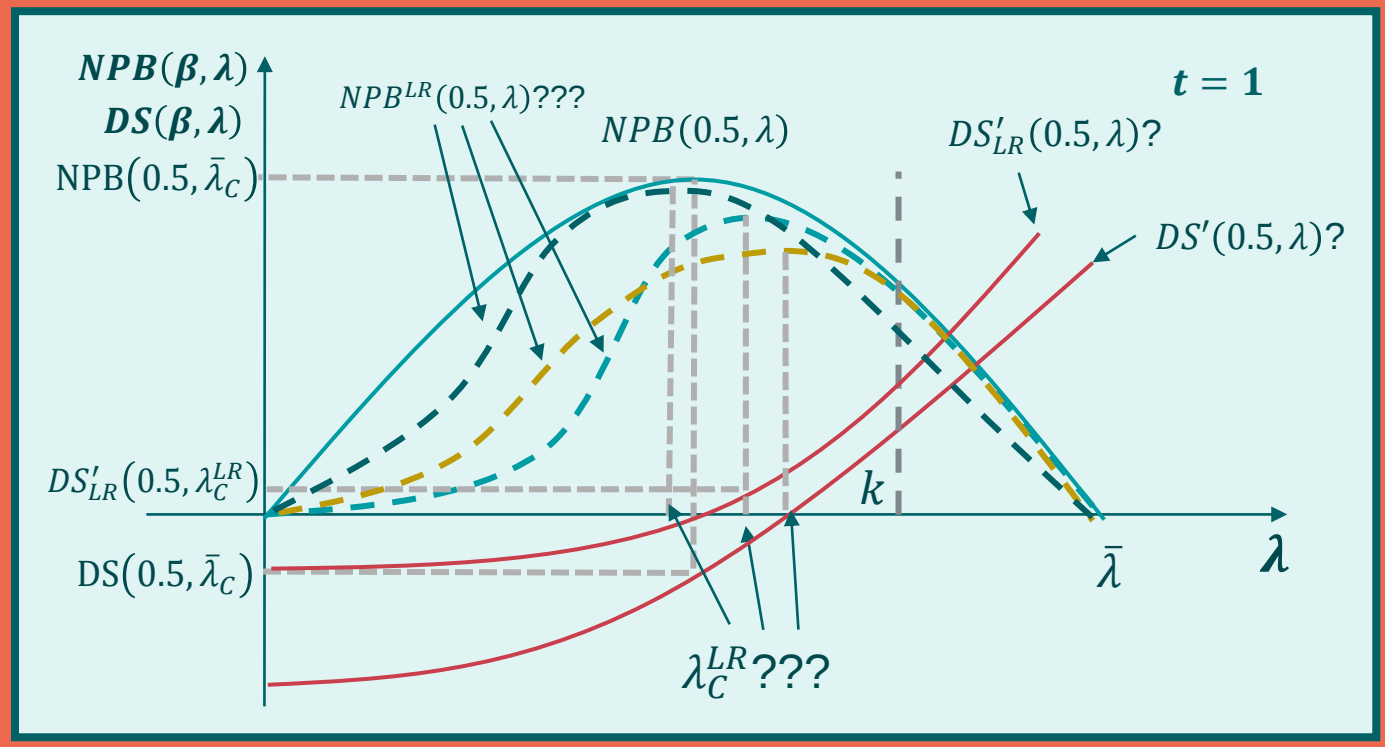

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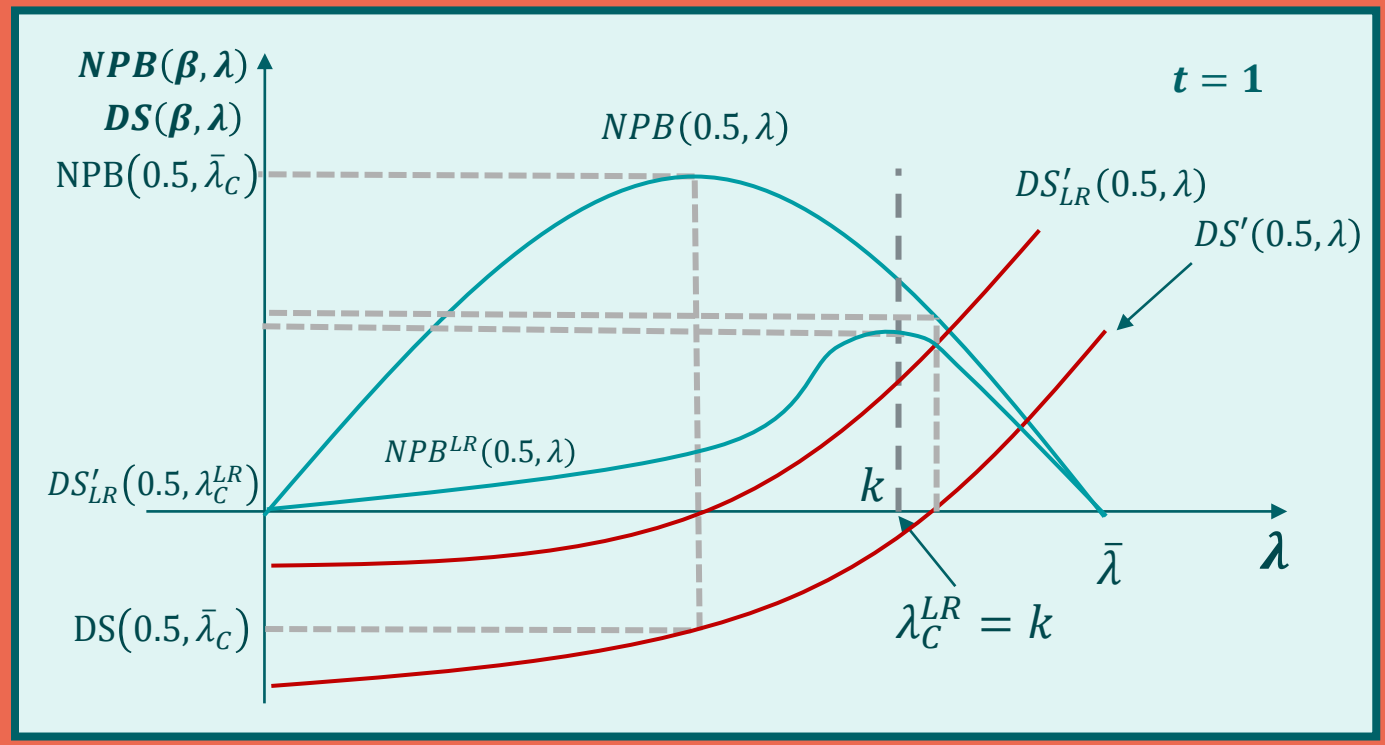

Future research (1): Dynamic model

- Formalisation and endogenization
- Where is the dynamic equilibrium $\lambda_1^{LR}, \lambda_2^{LR}, \lambda_3^{LR} \ldots$?
- And, when T=1,2,3,…,n?
- How the (sum of all periods) surplus created with those iterations compares with increasing the threshold to the dynamic reserve ICER at t=0?
- *The effective ICER<K: always keep in mind!*

Dynamics & strategic behaviour with:

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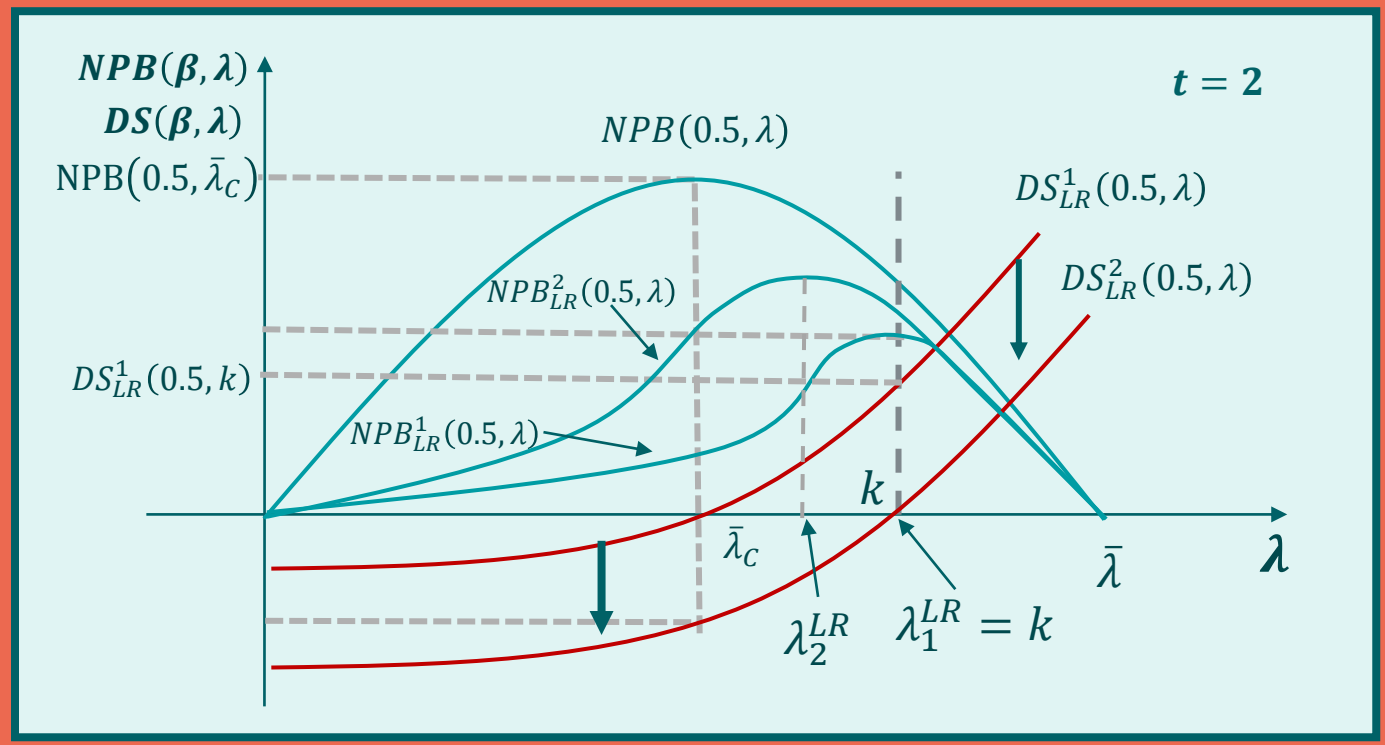
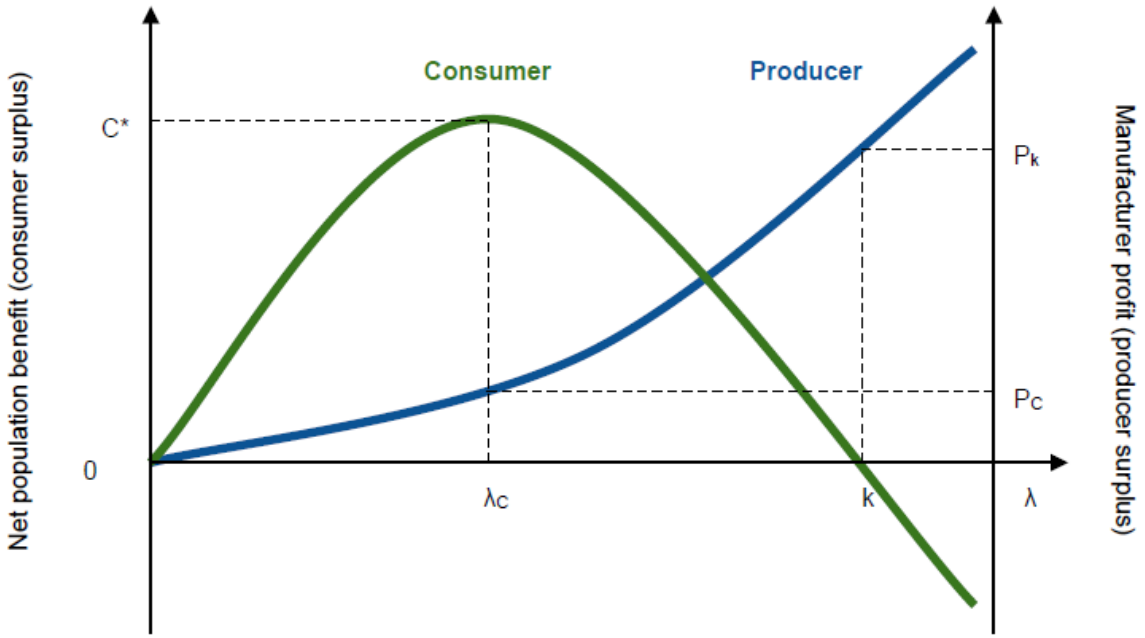


Future research (2): Demand/supply and reserve ICERs, formalisation of endogeneity

FIGURE 2: Consumer and producer threshold curves, reflecting the relationship between the threshold (λ), net population benefit (consumer surplus), and manufacturer profit (producer surplus)



Source: Pandey, H. (2018). *Theoretical models of the cost-effectiveness threshold, value assessment, and health care system sustainability*. Institute of Health Economics.

- What is behind the 'Laffer curve'?
  - The gross health curve?
- How does the distribution of the reserve ICERs $F(\lambda)$ affect this function?
  - And the NPB in the short and long-run?
  - And policy / non-policy thresholds i.e. $\lambda_C, \lambda_C^{LR}, \hat{\lambda}$?
- Are different distributions by therapy area, type of disease, risk, technologies possible?
- Endogenisation of demand and supply is crucial **to understand short- vs long-run trade-offs and policy making**

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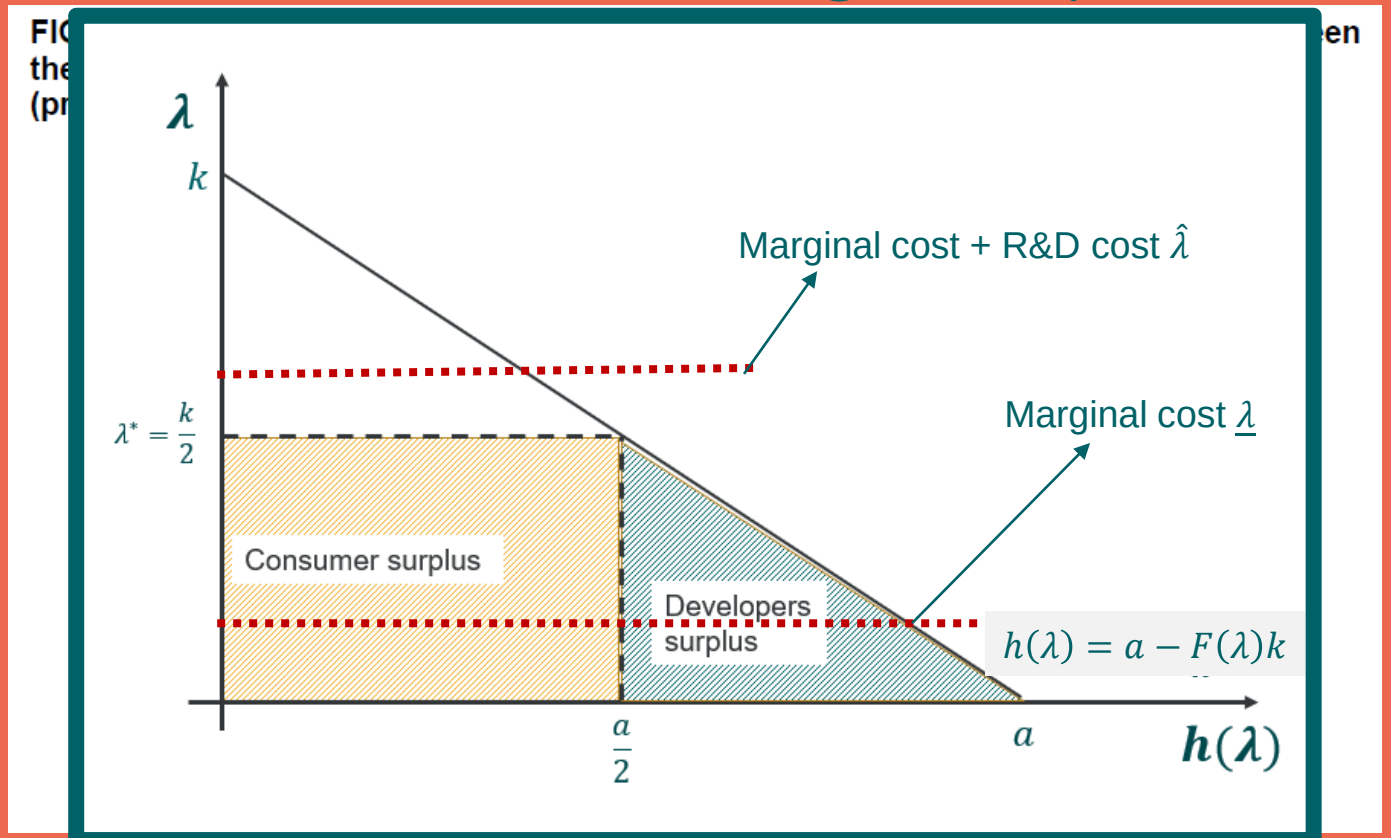

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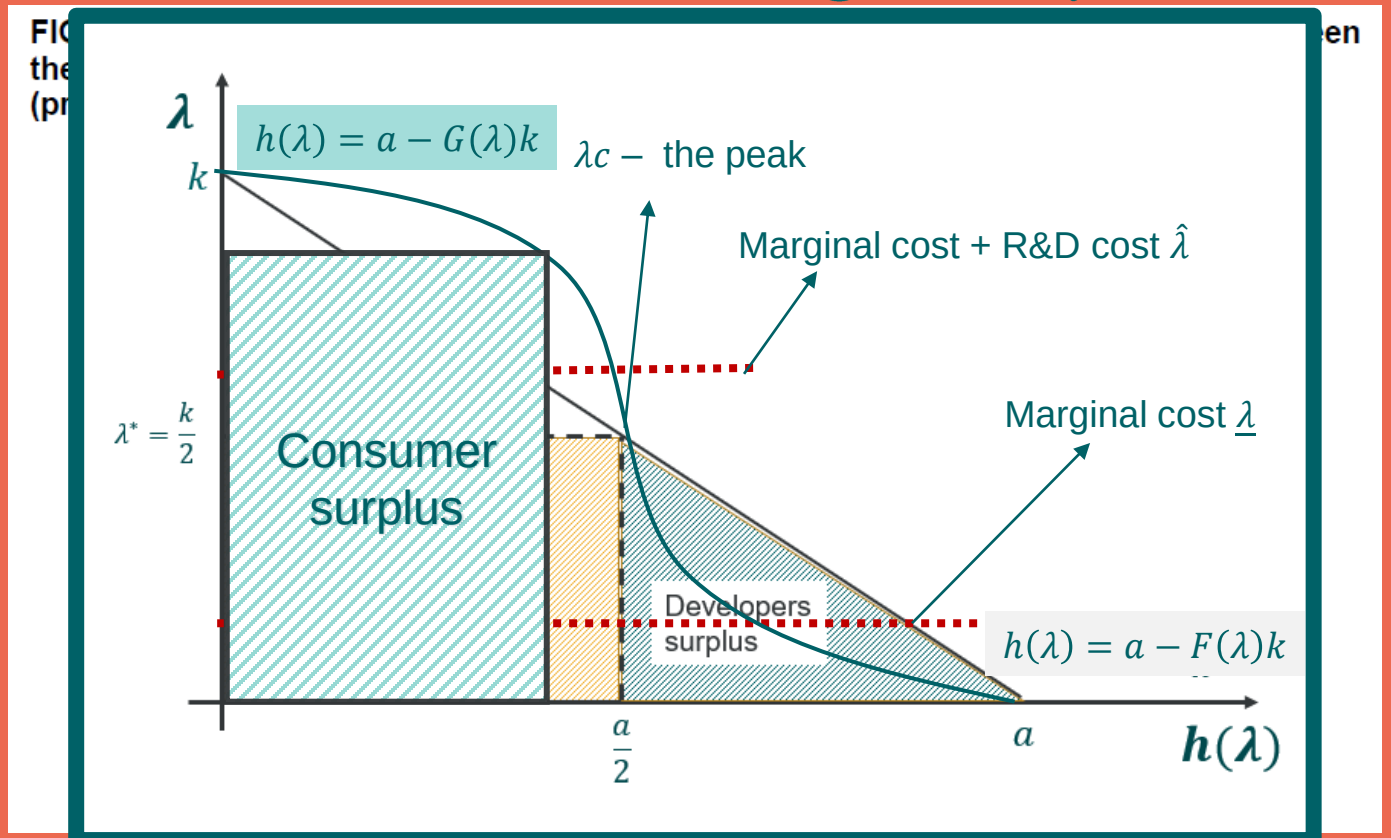

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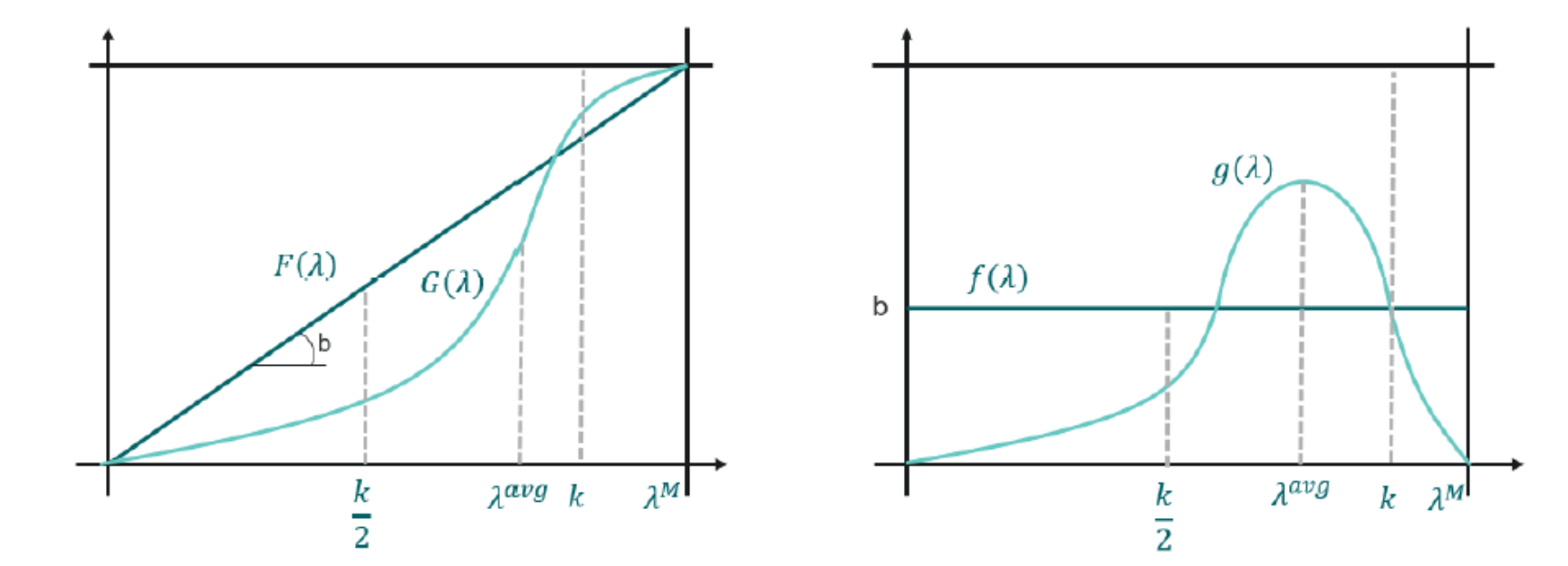

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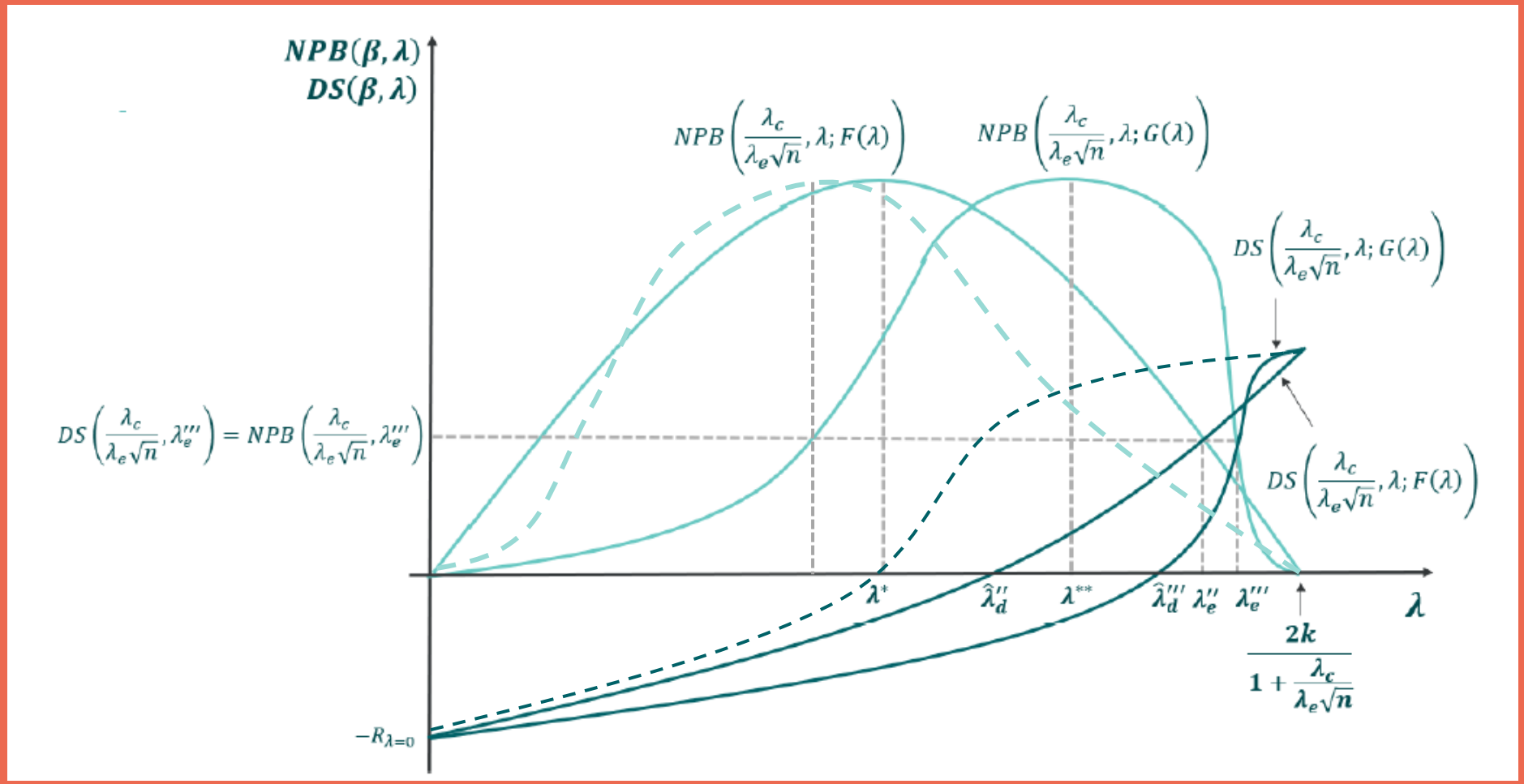

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