Reference Pricing as a Deterrent to Entry
Evidence from the European Pharmaceutical Market

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Price regulation can affect access to drugs

Drug prices are strictly regulated in most countries

- US: prices are benchmarked to private market
- UK: prices tied to therapeutic value
- EU: gov’t negotiates using external reference pricing (ERP)
  - Set price using prices of the same drug abroad as reference
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ERP affects access in potentially unexpected ways

- Linking prices across countries limits price-discrimination
- Firm may respond by delaying entry in low-income countries
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How does ERP affect access to newly approved drugs?
This paper quantifies the impact of ERP in Europe

Overview of today’s presentation

1. Launch delays in Europe: what models (don’t) justify them?

2. ERP as a deterrent to entry: theory

3. Estimation of the impact of ERP in three parts:
   - Do countries actually follow ERP guidelines?
   - Are firms better off with delays?
   - How much would delays fall if ERP were removed?
Launch delays in Europe: what models (don’t) justify them?
Drug diffusion across Europe: 1 year after approval
Drug diffusion across Europe: 2 years after approval

- **85 - 100%**
- **75 - 85%**
- **65 - 75%**
- **50 - 65%**
- **0 - 50%**
Drug diffusion across Europe: 3 years after approval
Drug diffusion across Europe: 4 years after approval
Drug diffusion across Europe: 5 years after approval
Many models predict delays...

1. Limited number of entry applications at the same time
   - Prioritize highest revenue, not highest price
   - Price inversely correlated with delays, controlling for revenue

2. Fixed costs of entry

3. Capacity constraints
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3. Capacity constraints
   ▶ No more entry once firm hits full capacity
   ▶ > 10% of launches occur after the firm has reached peak output
ERP as a deterrent to entry: theory
ERP generates delays by limiting price discrimination

Toy model: 1 firm, 2 countries, 2 periods

At the end of each period countries adjust prices to match minimum available price.

Period 1: price $p_j$
quantity $q_j$

Period 2: price $\min_{k \in \{1,2\}} (p_k)$
quantity $q_j$
ERP generates delays by limiting price discrimination

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Period 1:  price $p_1$
  quantity $q_1$

Period 2:

Two possible strategies:

1. Wait until period 2 to launch in country 2
ERP generates delays by limiting price discrimination

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**Period 1:** price $p_1$
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**Period 2:** prices $(p_1, p_2)$
- quantities $(q_1, q_2)$

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2. Launch everywhere right away
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- **Period 1**: prices $(p_1, p_2)$
  - quantities $(q_1, q_2)$
- **Period 2**: prices $(p_2, p_2)$
  - quantities $(q_1, q_2)$

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quantities \((q_1, q_2)\)

Optimal solution: delay if

\[(p_1 - p_2) \times q_1 > p_2 \times q_2\]
We estimate an extended version of this toy model

Model components

1. Demand
   - Data: *quantity* sold for each drug \( i \), year \( t \), country \( j \)
   - Goal: predict *quantity* in years prior to entry

2. Price
   - Data: average yearly drug *prices, reference pricing functions*
   - Goal: predict *prices* under alternative entry sequences
   - Parameter \( \mu_j \in [0, 1] \) allows partial adherence to ERP
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3. Firm dynamic entry decision model
   - Firms apply for entry, but may experience stochastic delays
   - Goal: link 1. & 2. to compute revenue of any entry sequence
Stage I: Firm choose where to send entry applications

Strategic delays:
firm only sends applications to some countries
Stage II: delay shocks are realized

Idiosyncratic delays: some applications are randomly delayed
Stage III: prices are set

FIRM

\[ P_{FR}, P_{DE} \]
Stage IV: products are sold and profits realized

$P_{FR}$

$P_{DE}$
Estimation of the impact of ERP in three parts
What we need to estimate

1. Do countries actually follow ERP guidelines?
   - $\mu_j$ needs to be close to 1 for at least some countries
Do countries actually follow ERP guidelines?

Estimates of $\mu_j$
What we need to estimate

1. Do countries actually follow ERP guidelines?
   ▶ $\mu_j$ needs to be close to 1 for at least some countries
   ▶ Spain and Italy follow ERP, their prices are affected by EU10

2. Are firms better off with delays?
   ▶ Firms should earn more if entry is delayed
Are firms better off with delays?

% of drugs for which delaying entry in country X only is optimal

- more than 50%
- 20 - 50%
- 10 - 20%
- 0 - 10%
- 0%

Map showing distribution across Europe.
What we need to estimate

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   ▶ Spain and Italy follow ERP, their prices are affected by EU10

2. Are firms better off with delays?
   ▶ Firms should earn more if entry is delayed
   ▶ Most firms earn more when delaying entry in EU10

3. How much would delays fall if ERP were removed?
   ▶ If we get rid of ERP, there should be faster entry
How much would delays fall if ERP were removed?

**Empirical problem:** find $\psi_j$ (prob. of random delay in country $j$)

- Ideally: solve model, match observed entry to predicted entry
- In practice: model is too complicated to solve

Solution:

- Lower bound: lower $\psi_j$ is better for the firm with low $\psi_j$, can find strategies that earn more than firm did
- Find these strategies $\rightarrow$ reject low values of $\psi_j$

- Upper bound: worst case scenario: all delays are idiosyncratic

Output:

- Western Europe: assume away strategic delays
- Eastern Europe: estimate interval $\psi_{EU10} \in [0.416, 0.669]$
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Simulated delays w/out ERP: only idiosyncratic delays remain

Upper bound $\psi$: all delays idiosyncratic
How much would delays fall if ERP were removed?

Simulated delays w/out ERP: only idiosyncratic delays remain

Lower bound $\psi$: delays reduced by 63% (14.5 mos)
What we need to estimate

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3. How much would delays fall if ERP were removed?
   - If we get rid of ERP, there should be faster entry
   - Up to 14.5 months earlier entry in EU10
Conclusion: the bigger picture

Main takeaway:

▶ A framework to formally uncover policy-driven entry delays
Conclusion: the bigger picture

Main takeaway:
- A framework to formally uncover policy-driven entry delays

General implication: price-linked regulation causes spillovers
- Medicare/Medicaid reimbursement rules affect private prices
- Medicare Part B reform would introduce ERP to US
  - US prices are well above highest prices in Europe
  - US market is roughly 3x size of entire EU market

What we still don't know
- Without ERP would prices rise in West. EU or fall in East. EU?
- Would ERP reduce US prices or raise foreign prices?
Conclusion: the bigger picture

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- A framework to formally uncover policy-driven entry delays

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thank you