Wharton
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Innovation in Medical Devices

Policy Lessons from the EU

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The New York Times
Fundamental tension in medical innovation: **Access vs. Risk**
First, a Vaccine Approval. Then 'Chaos and Confusion.'
Come spring, Americans may have their choice of several so-so coronavirus vaccines — with no way of knowing which one is best.

Medical Devices from Idea to Implant

TESTING:

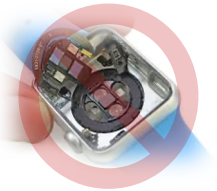
- Bench, animal, human
- Voluntary and required

ADOPTION:

- Physicians (specialists) choose
- Insurers and hospitals pay

Key features of devices:

1. (Expert specialists) use devices in procedures



2. Large variation in evidence generated/required
   (US: PMA vs. 510k, depending on risk; US vs. EU for high risk)

EU vs. US and High Risk Devices (Pre-EUMDR)

- Class III regulatory requirements much lower in EU
  - US (PMA from FDA) safety and efficacy
  - EU (CE Mark from Notified Body) safety and "performance"
- Ex: Grennan & Town (AER 2020) coronary stents

PANEL A. EUROPEAN UNION VERSUS UNITED STATES: CLINICAL AND MARKET DATA

	US	EU
Clinical trial data		
Pct products with published trials pre-entry	85.7	20.1
Median number of trials	2	1
Median total trial size (patients)	1,313	280
Median total trial time (months)	28	19
Market structure data		
Mean manufacturers in market	4 (3)	21 (5)
Mean products in market	11 (5)	39 (8)
Total products in market, 2004–2013	21 (11)	109 (22)
Mean months EU to US entry	10	—
Mean months EU to US entry (DES)	17	—

Note: Usage within hospital in parentheses.

Lessons from EU Stents 2004-13

Grennan and Town (AER 2020) compares EU physician usage patterns after entry for stents that undergo extra US testing vs. don't

- Evidence suggests EU physicians *learn from* US testing outcomes

Estimate model capturing risk vs. access tradeoff, and consider different testing regulatory requirements

- EU testing prevents "chaos and confusion" and market shut down
- US testing requirements close to optimal
- More post-market surveillance could improve welfare >20%

Does this generalize?

- Value of more pre-market testing and post-market surveillance robust across most scenarios and parameter values

Early Lessons from EU 2017 MDR Reform

New products now face much higher scrutiny to obtain CE Mark

- Sometimes higher than FDA standards now

Old and New products face rigorous “post-market surveillance” requirements

- Costs of data collection falling on firms, leading to some exit by smaller brands

Takeaways for Medical Innovation Policy

1. Need some pre-market testing, and understanding of results, to avoid "chaos and confusion"
   - *Understanding* for consumer-facing devices?
2. Post-market surveillance makes a lot of sense
3. Be careful of raising costs of compliance
   - Lots of small, niche products in devices
   - High fixed costs could increase concentration even more, and exacerbate challenges for innovative new entrants