Comments on "Regulating the Innovators: Approval Costs and Innovation in Medical Technologies"

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Summary of Empirical Results

Class III → Class II events ("down-regulation")

- Patent flow up 15/year (base 8/year), w/ much from new firms. Mean citations/patent value rise.
- Flow of new devices up 2.3/year (base 0.5/year), with roughly 30% from new entrants
- Prices of procedures that use devices little changed
- Mixed signs, somewhat noisy

Class II → Class I events ("deregulation")

- Patent flow up 7/year (base 19/year), albeit noisy, w/ much from new firms. Mean citations/value rise.
- Prices of procedures that use devices fall
- Deaths/hospitalizations decline sharply

Agenda

1) A quirk in the FDA adverse event data
2) Interpretation of the results
   - Welfare
   - Generalizability
3) What should device regulators take away?

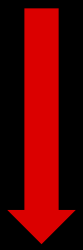
Hypothesis: Changes in MAUDE Coverage

More types of reports reflected in MAUDE over time:

- User facilities (i.e., providers): 1991
- Distributors: 1993
- Voluntary reports: 1993
- Manufacturers: 1996

Source: Ensign and Cohen (2017)

Large number of II → I events



Source: Ensign and Cohen (2017)

Implications for Adverse Event Results

Reporting change raises two concerns:

1. Pre-period treatment/control differences may be a poor proxy for counterfactual post-period differences if reporting regimes are very different
2. Pre-period common trends likely less informative than it seems since scale of pre-period outcomes is low

Potential solutions:

- Obtain preely leea58 0 Td (in)3.7p (d)-00.7 (c)4.6 (o)-[p)-0.6

How Did These Events Affect Welfare?

Unpacking the fi ł fi ef ect

What Should Device Regulators Take Away?

Important lesson: Classification decisions (esp. III → II) can have big effects on patent activity/entry

- Broadly consistent w/ US-Europe comparisons for class III devices (Grennan and Town 2020)
- Valuable to have within-US evidence for "marginal" device types (and evidence beyond class III)

But important caveats too:

- Welfare effects murky (for now at least) given quirks in adverse event data, challenges in estimating producer surplus, and various unquantified effects
- For class III → II, effects likely not readily generalizable. Some reason to worry on class II → I also.