Negative Product Disclosure and Innovation

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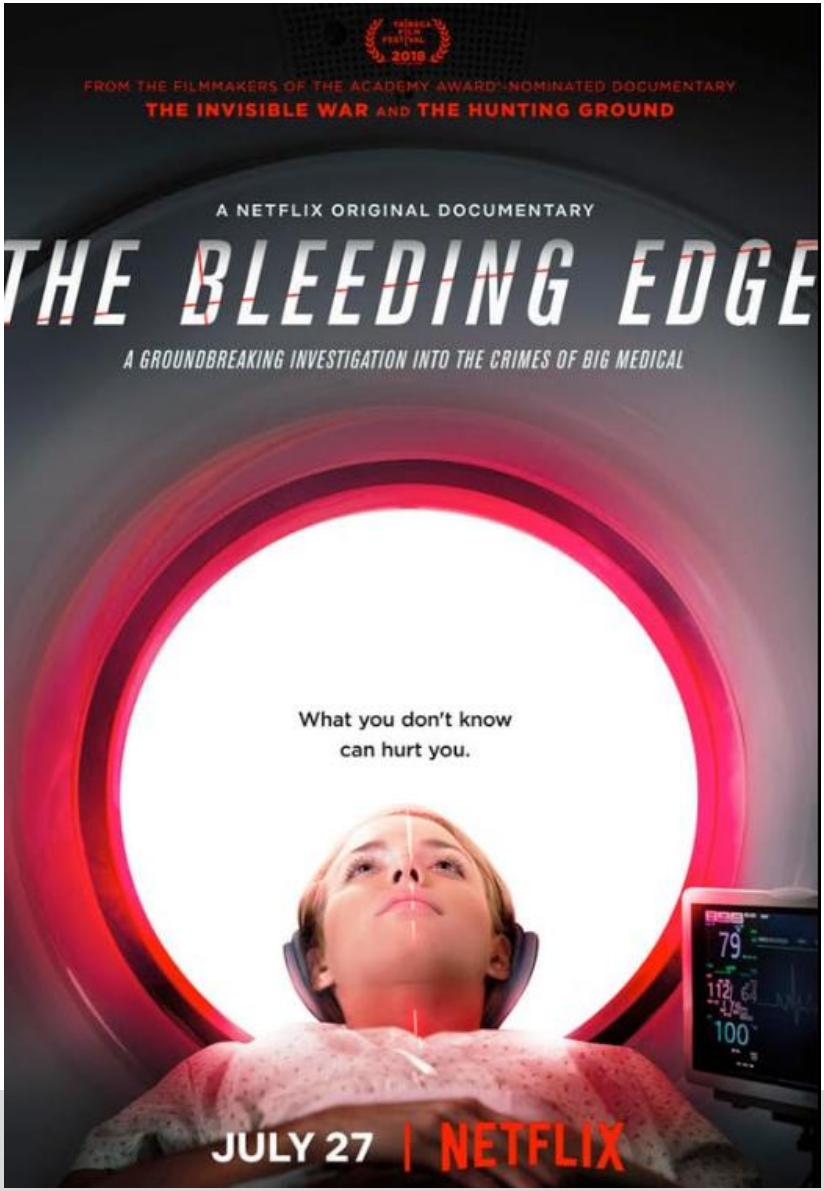
Main message and contribution

- Research question: How does a large-scale negative product info disclosure affect the rate, direction, and quality of innovation?
- Approach: diff-in-diff exploits the 2019 termination of ASR prog.
  - examining both the 2019 info release and the 2017 wind down phase
- Results: 17% drop in new device application in affected markets
  - Mainly driven by information effects, rather than withholding
  - Firms develop safter, higher-quality (in patent citations), but less novel (refer to older predicate) devices, reallocate R&D away, and more exit
- Contributes to several strands of literature on disclosure (post-market, forced) and innovation, with novel data and measures

The hidden dangers in medical devices

- Less strict regulation than drugs
- Only class III (high risk) devices requires clinical/lab evidence from premarket approvals (PMA)
  - Ex. pacemakers, breast implants, deep brain stimulators, high-risk SaMD
- Class II (med risk) 510(k) pathway relies on references (i.e., predicate)
  - Ex. Da Vinci Surgical robot
- De Novo clearance: low/med risk, no predicate, avoid PMA
  - Ex. Apple Watch's health features (ECG, IRN)



2018 documentary ->

Institutional setting: info/risk class nuances

- 1: What info does ASR reveal: new types of problems or higher intensity
  - Why ASR came into place and how the gradual addition of prod market work?
  - **Ideas**: 1) compare ASR vs non-ASR AEs on the distribution differences, on severity (death *v.* injuries *v.* malfunction); 2) do firm/market react differently to info on extensive vs intensive margins (current HighExposure = ever-exposed); 3) clarify which % of markets are high exposure (2%), market-year or firm-level

- 2: Firms increase safer (text measure), higher-quality (2-year patent fwd citation), yet less novel (older predicate) devices: quality vs novelty?
  - Quality is more critical for class III devices, but class II devices drive the results
  - **Ideas**: 1) are some of the released injuries suggest going though PMA or de novo pathway rather than 510(k)? Are some of the ASRs in categories encountered med device regulations (III->II)? 2) are there market-based measures of "quality" in terms of safe, effective (link w trials), and low recalls?

Decompose mechanisms: D/S, (partial) info

- 3: Firms react to info primary to update tech beliefs or expected risks?
  - learning on (supply-side) *technical feasibility/safety of product markets*, or
  - learning on (demand-side) *downstream user/investor shifts and liability risks*
  - spillover results -> tech info; substitutability results -> demand. Policy implications differ – if mainly via D, nega info can kill viable tech. **Ideas**: (1) whether effects differ for physician-driven vs consumer-facing devices, (2) whether innovation drops more when ASR reveals new types of issues.

- 4: Therapeutic (diff tech) v. technological (similar tech, diff use) substitutes
  - Already very information in the fine product-codes level analyses
  - **Ideas**: would we see more muted reactions in med conditions with limited therapeutic substitutes? Can potentially tie this with PMA subsample.

- 5: Overall welfare implications: net of "lower quantity, but higher quality"
  - Is there post-market safety improvement in health outcomes (fewer AEs)?

Minor suggestions/future extensions

- Current specification uses log(Y+1) as Dept Var., worth robustness
  - With highly skewed data (lots of 0s), check w/ levels (Y) or count data models
- Framing of diff types of innovation: device application vs patents
  - Device application is more market-facing (R&D output) vs patents (upstream)
- Welfare nuances on short-run market exit and entry deterrence
  - #firms drop by incumbent exit can be efficient-enhancing if "bad" firms leave
- Heterogeneity by firm size or scope: does market structure matter?
  - Subsample analysis or a brief discussion would be informative
- Potential robustness at a more aggregated product market level
  - ASR covered 12 -> 102 product markets, is it too fine for users? Maybe clarify.

Final thoughts

- Very interesting topic, lots of food for thought
- Key takeaway: a large, historical disclosure of negative information reduces market-facing innovation, and shifted R&D effort into more safter, high-quality (yet less novel) areas
- Main thoughts: would be nice to explore mechanism decomp. & overall welfare using the already v rich institutional details
- Very cool topic. Looking forward to a new version!