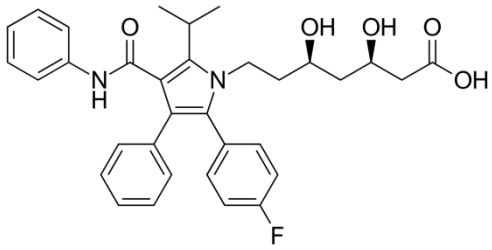
Biosimilar Entry and the Pricing of Biologic Drugs

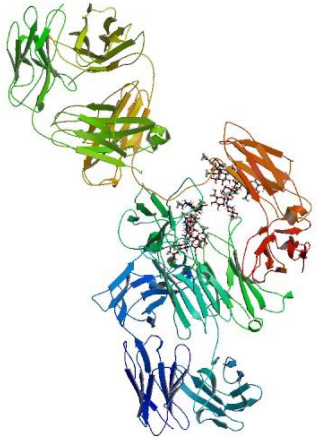
Luca Maini (UNC Chapel Hill)
Josh Feng (Utah Eccles)
Thomas Hwang (Harvard Medical School)
Jacob Klimek (UNC Chapel Hill)

Debate – How to Regulate Biologic Drugs Markets

- Drugs approved before 2000
  - Hatch-Waxman Act deals with regulation after loss of exclusivity (LOE)
  - Generic entry, 90%+ reduction in brand volume (policymakers generally happy)



- Many recent drugs: biologics (e.g., Humira)
  - 2% of prescriptions, 37% of net spending (IQVIA 2017)
  - BPCIA 2009 addresses regulation after LOE for biosimilars
  - Biologics seem to be maintaining volume and (list) prices are not going down after loss-of-exclusivity



- Potential alternatives
  - Cost-plus regulations?
  - Recent bipartisan legislation/proposals: information, formulary ratings

Research Questions

1. How do incumbent biologics manufacturers respond to the entry of biosimilars?
   - Previous work: analyses of list prices; net price evidence from individual markets (San-Juan-Rodriguez et al., 2019)
   - *Our paper*: analysis of net price and formulary data using diff-in-diff approach and all available data

2. Is there heterogeneity in incumbents' responses?
   - Variation in response can provide suggestive evidence on the factors driving incumbent response => point to future trends, responses to potential policies
   - *Our paper*: compare biosimilars approved through different mechanisms (suggestive evidence)

Empirical Approach

Core specification: two-way fixed-effects focusing on biologic drugs (including insulins) at the drug-year level

$$Y_{it} = \alpha_i + \delta_t + \beta \times EntryCounter_{it} + \epsilon_{it}$$

Other specifications:

- Time-varying effects
- Heterogeneous effects
- Different control groups
- No time FE

Econometrics issues:

- Specifications partly address econometrics issues (Sun and Abraham, 2021; Goodman-Bacon, 2021; many others).
- Generally less worried because # untreated (184) >> # treated (10)

Minimal List Price Response, Negative Response in Net Price, Noisy Volume Response

	Log(WAC)	Log(net price)	Log(units)
Biosimilar Entry Counter	0.0322	-0.173**	-0.0579
	(0.0489)	(0.0645)	(0.130)
Fixed Effects	Year	Year	Age
Observations	1438	1438	1438

Note: Standard errors are clustered at the product level

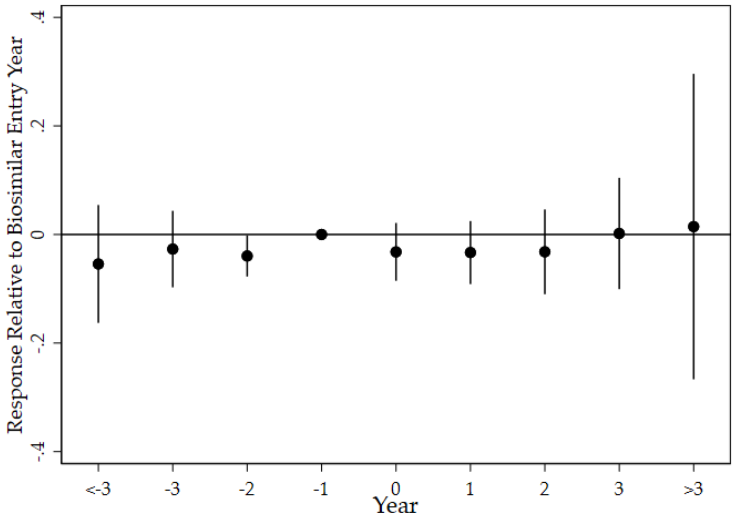
Minimal List Price Response, Negative Response in Net Price, Noisy Volume Response

	Log(WAC)	Log(net price)	Log(units)
Biosimilar Entry Counter	0.0322	-0.173**	-0.0579
	(0.0489)	(0.0645)	(0.130)
Fixed Effects	Year	Year	Age
Observations	1438	1438	1438

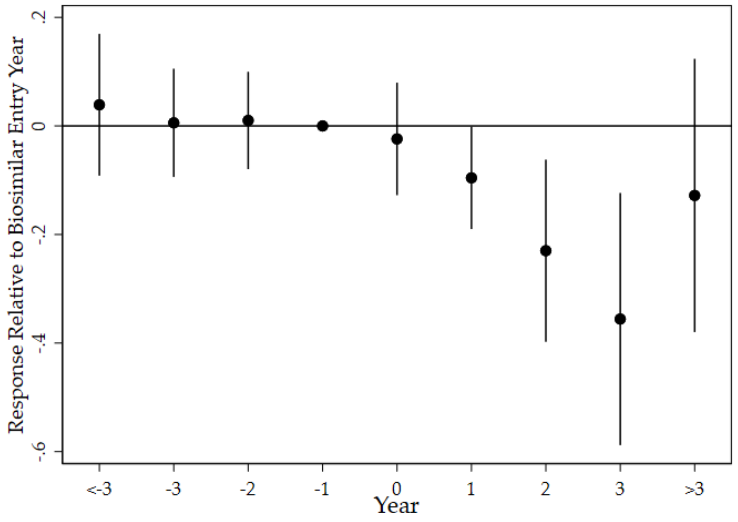
Note: Standard errors are clustered at the product level

Allowing for Time-Varying Responses

Log(WAC)



Log(net)



Slightly Worse Formulary Coverage for Incumbent Biologics

	Preferred	Unrestricted	Covered
Biosimilar Entry Counter	-0.0392**	-0.0227**	-0.0305
	(0.0112)	(0.0108)	(0.0194)
Fixed Effects	Year	Year	Year
Observations	552	552	552
Context	AVG: 0.2 SD: 0.17	AVG: 0.43 SD: 0.23	AVG: 0.86 SD: 0.11

Note: Standard errors are clustered at the product level

Discussion of Core Findings

- Robustness: raw descriptive evidence, different controls, ASP data
- Using price to deter entry?
  - Evidence: no clear price response by incumbents after FDA *approval* of competing biosimilar
  - Likely to be more focused on patent litigation as a deterrent
    - If patent channel is weakened through regulation, might see different price response to approval
- Big picture
  - Biosimilar competition is bringing down costs, just in a different way relative to generics:
    - Small molecule drugs: maintain price, lose 90%+ in volume
    - Formularies: generics automatically slotted into lowest copay tier
  - Results consistent with story of incumbents offering larger rebates to maintain formulary position
    - List price => no response

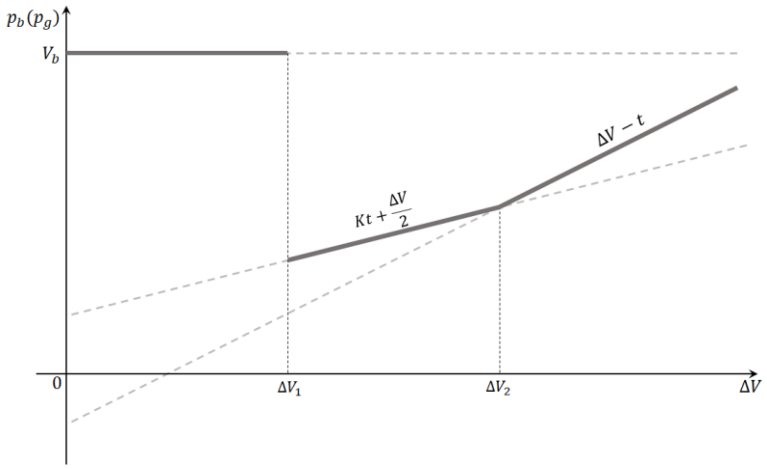
Heterogeneous Response Based on Entry Type?

- What might be driving the different response by biologic incumbents vs. small molecule?

- Difference is consistent with a model based on Frank and Salkever (1992)
  - FS: some loyal consumers
  - Incumbent response differs based on difference perceived by other consumers
  - Incumbents will choose to **not compete on prices** if the entrant is **perceived to be similar enough**

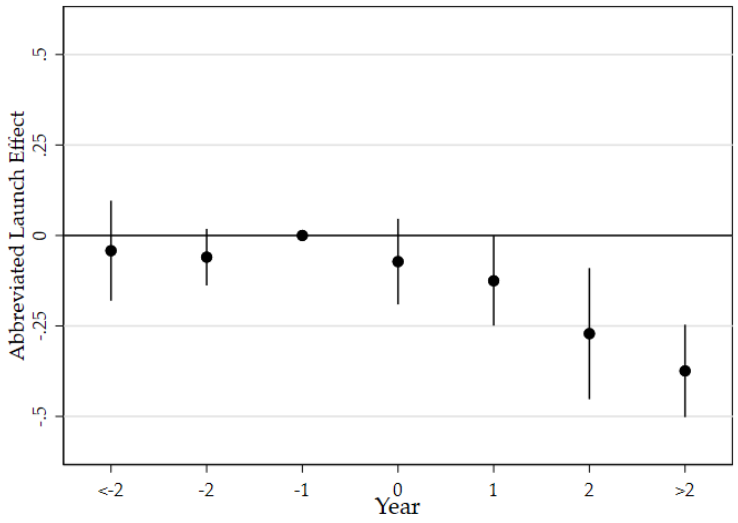
- Exploit regulatory quirks to test this hypothesis within biologics
  - A few biosimilars were approved through "regular" approval channel for approving branded drugs
  - Tested on a larger sample, go beyond showing "equivalence"
  - Potentially perceived to have higher quality

- *Note*: imperfect test

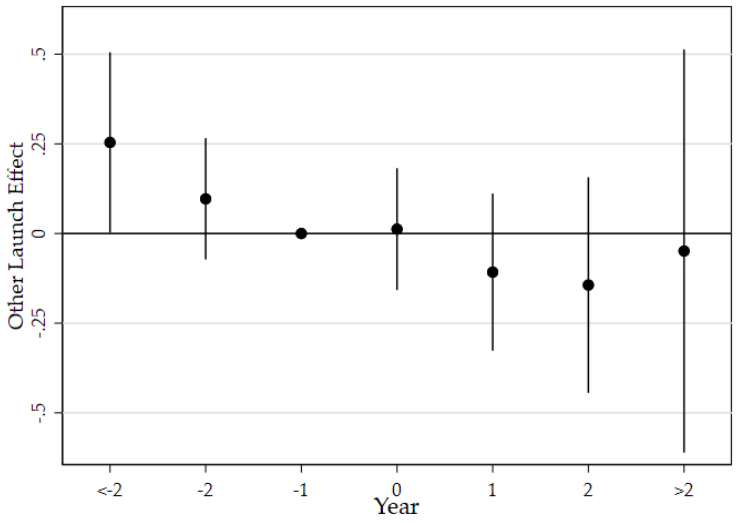


Suggestive Evidence – Net Prices

Abbreviated



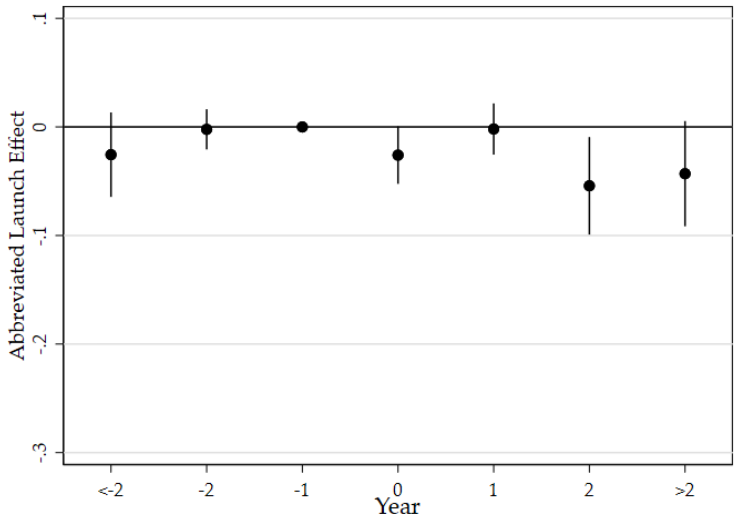
Other



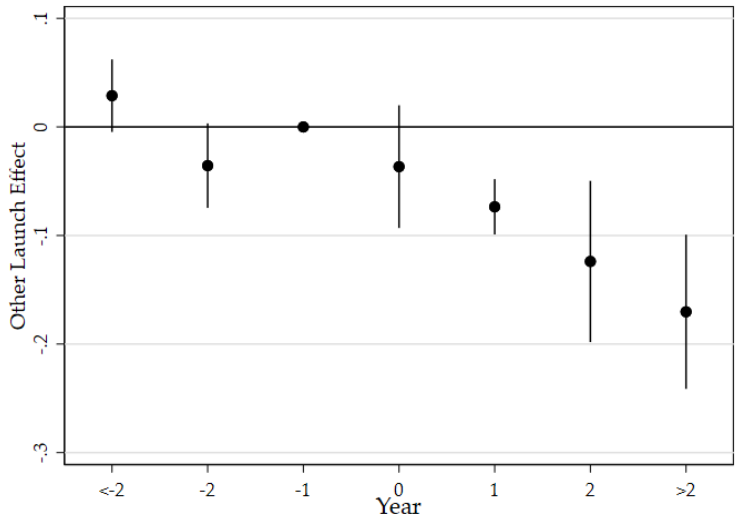
Very noisy zero effect for “other”, point estimates generally less than those for “abbreviated”

Suggestive Evidence – Formulary Coverage Rate

Abbreviated



Other (Noisy)



Noisy effect for other (again), but larger subsequent coverage decrease (point estimate) than for abbreviated (AVG: 0.86 SD: 0.11). Similar patterns for other coverage outcomes.

Summary

- Provided evidence on the nature of competition between biologics and biosimilars under the current regulatory regime
  - Biologics offer greater discounts to maintain formulary position
  - Some evidence of heterogeneity by approval process

- Implications
  - Biologics are currently competing on price
  - Potential policy implication of suggestive evidence
    - Greater consumer familiarity with biosimilars could move incumbent response towards those observed for small molecule incumbents
    - Advancing Education on Biosimilars Act (signed on 4/23/2021)