

Impact of Biosimilar Entry

FDA/FTC Workshop on a Competitive Marketplace for Biosimilars
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Disclosures

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Financial Disclosures: None



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- Trends in Prices and Discounts for Originator Biologics Facing Biosimilar Competition:
 - How did list prices of originator biologics change with biosimilar entry?
 - What about net prices after accounting for discounts?
 - Did these changes start before the biosimilar hit the market?
- Uptake of Basaglar in Medicaid: Impact of Rebates
 - How does the uptake of biosimilars differ between fee-for-service Medicaid and Medicaid managed care organizations?



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Study sample: originator biologics that faced biosimilar (or within-molecule*) competition by December 2018:

– Filgrastim:

- *Tbo-filgrastim (Granix, Nov 2013)
- Filgrastim-sndz (Zarxio, Sep 2015)
- Filgrastim-aafi (Nivestym, Oct 2018)

– Pegfilgrastim

- Pegfilgrastim-jmdb (Fulphila, Jul 2018)

– Infliximab

- Infliximab-dyyb (Inflectra, Nov 2016)
- Infliximab-abda (Renflexis, Jul 2017)

– Insulin glargine

- *Basaglar (Dec 2016)

Objective: To describe changes in list price, net price, and discounts before and after commercialization of competitors



List vs Net Prices

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- **List price** = Wholesale acquisition cost =WAC
 - Represent manufacturer's price to wholesalers
 - Do not account for manufacturer rebates or other discounts

- **Net price** = **List price** – **Discounts**

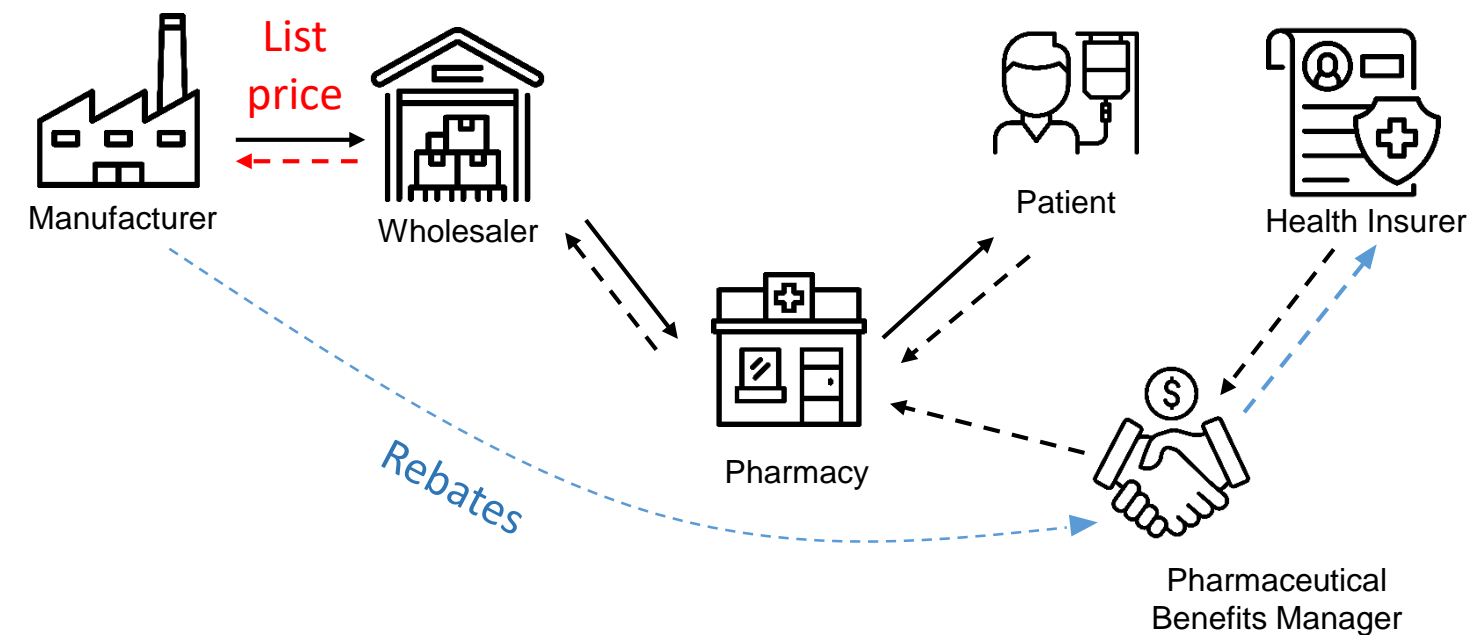
- Discounts (and thus net prices) are proprietary information
- Indirect estimations are only data source available (SSR Health)
- Net per unit = sales / number of units sold



- Net represents average revenue per unit of product
- Net captures all manufacturer discounts, not only rebates!

- **Discounts** = $(\text{List price} - \text{Net price}) / \text{List price}$

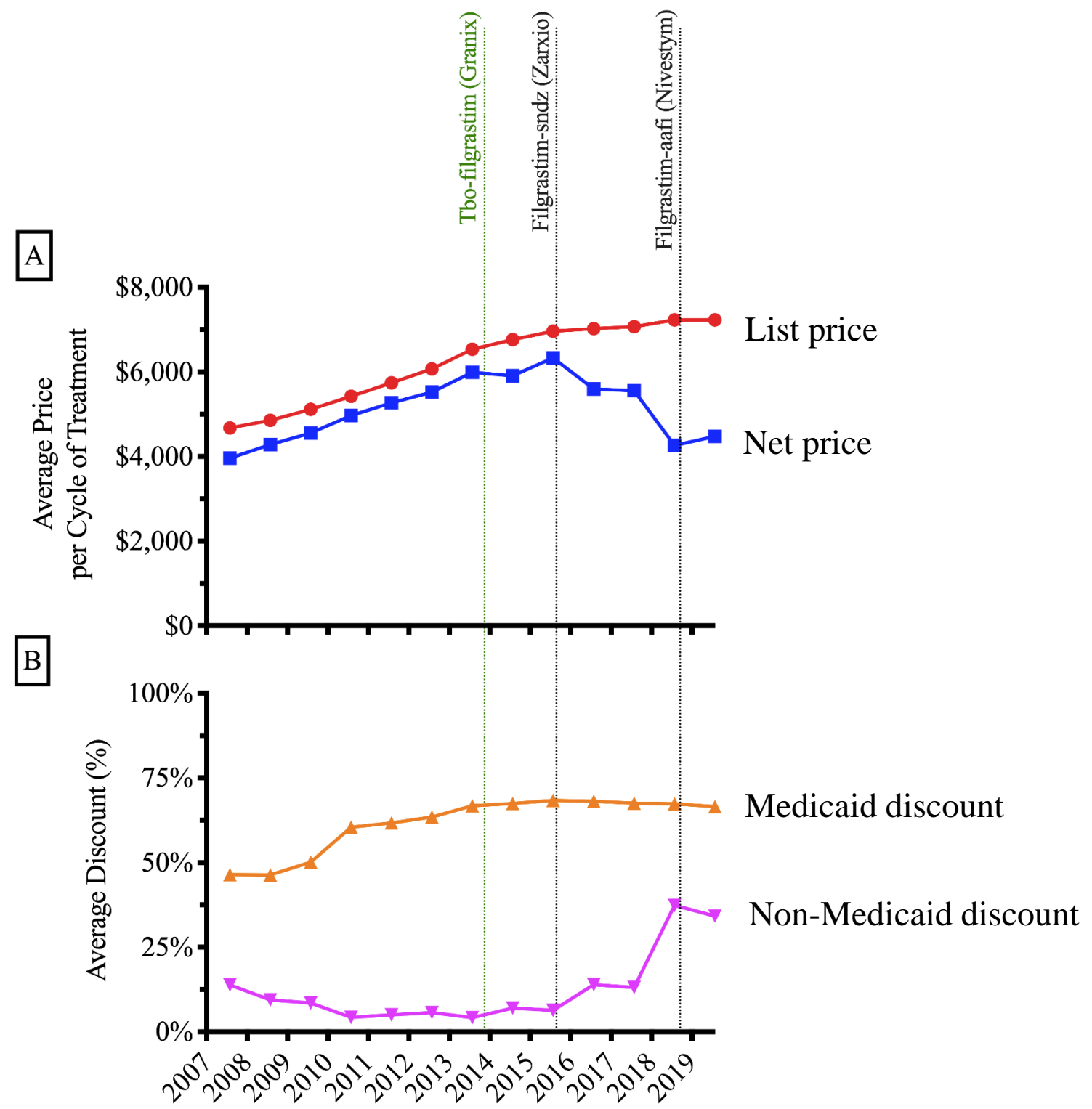
- Separately estimated for Medicaid and other payers





Results: Filgrastim

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- ✓ List and net prices increased in parallel until 2013
- ✓ Net prices started to decrease in 2015, when Zarxio reached the market
- ✓ This was driven by increasing discounts in payers other than Medicaid



Results: Peg-filgrastim

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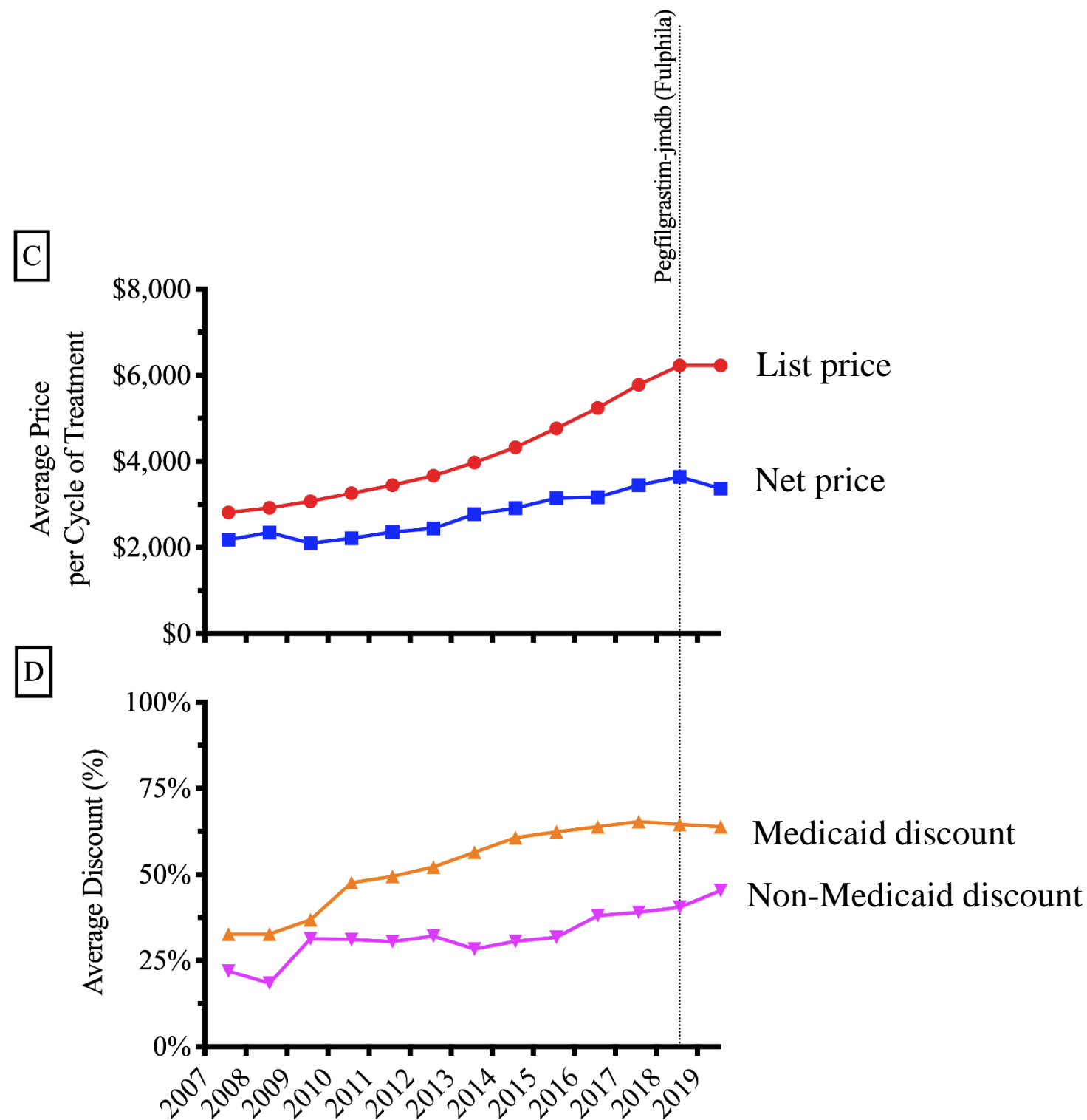
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- ✓ List and net prices increased until 2018
- ✓ After biosimilar entry, list prices stagnated and net prices started to decrease
- ✓ This was driven by increasing discounts in payers other than Medicaid



Results: Infliximab

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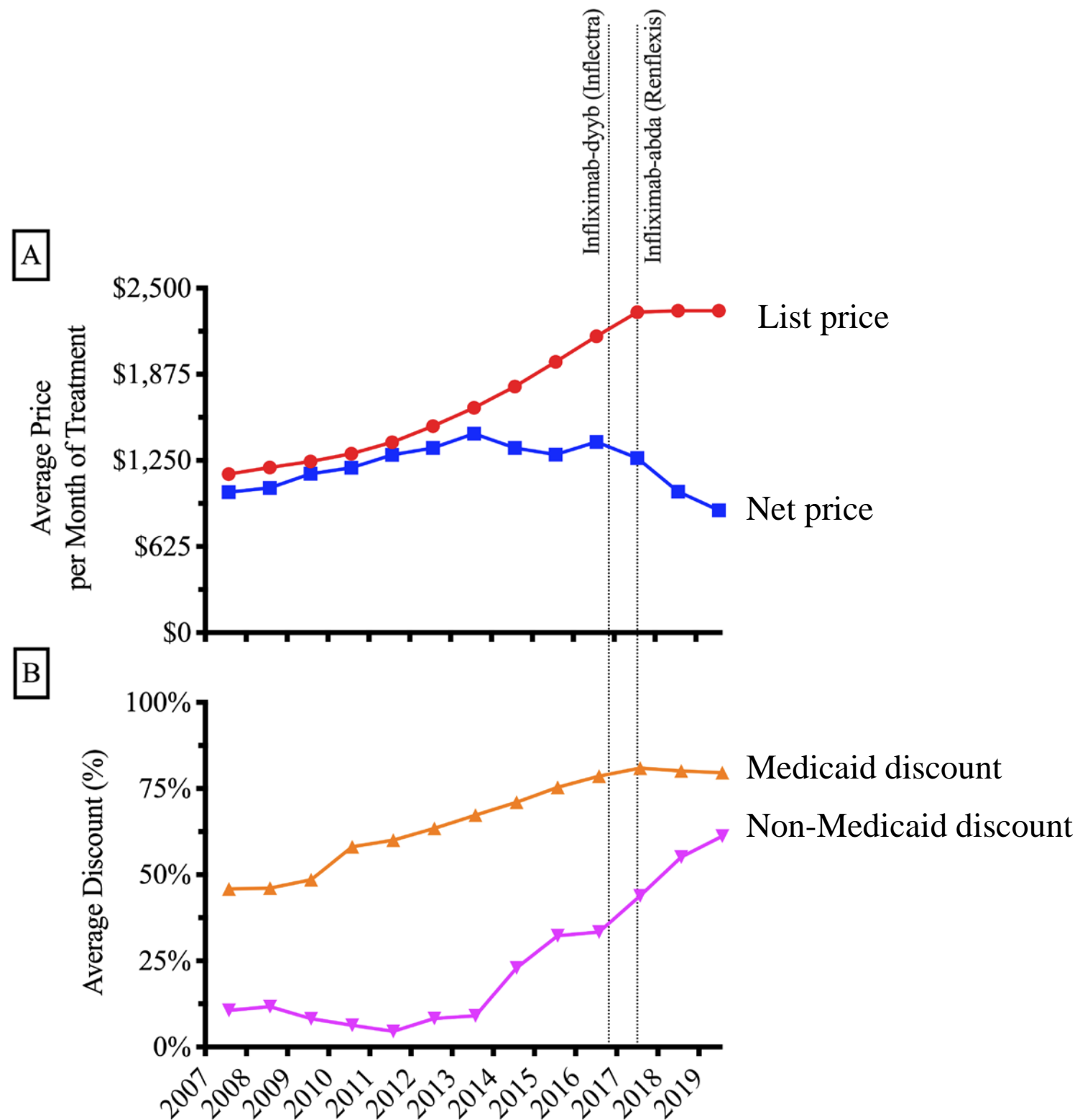
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- ✓ List and net prices increased in parallel until 2013
- ✓ Net prices started to decrease in 2013
 - ✓ IV golimumab (Simponi Aria) approved in 2013
- ✓ List prices stagnated after biosimilar entry, net prices continued to decrease
- ✓ Decreases in net prices were driven by discounts in payers other than Medicaid



Results: Insulin Glargine

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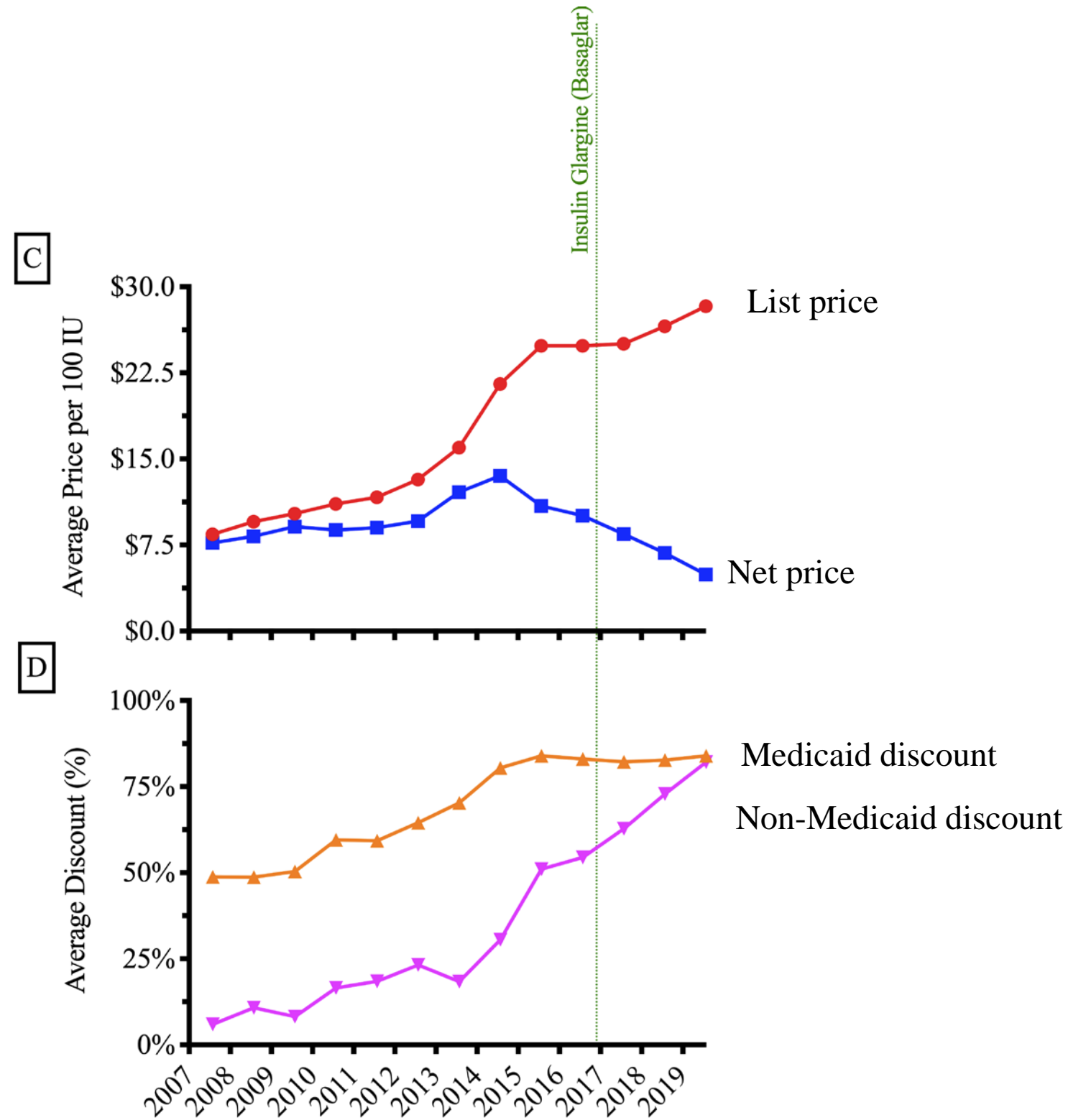
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- ✓ List and net prices increased until 2014
- ✓ Net prices started to decrease in 2014
 - ✓ Tresiba and Toujeo approved in 2015
- ✓ Net prices continued to decrease after Basaglar approval



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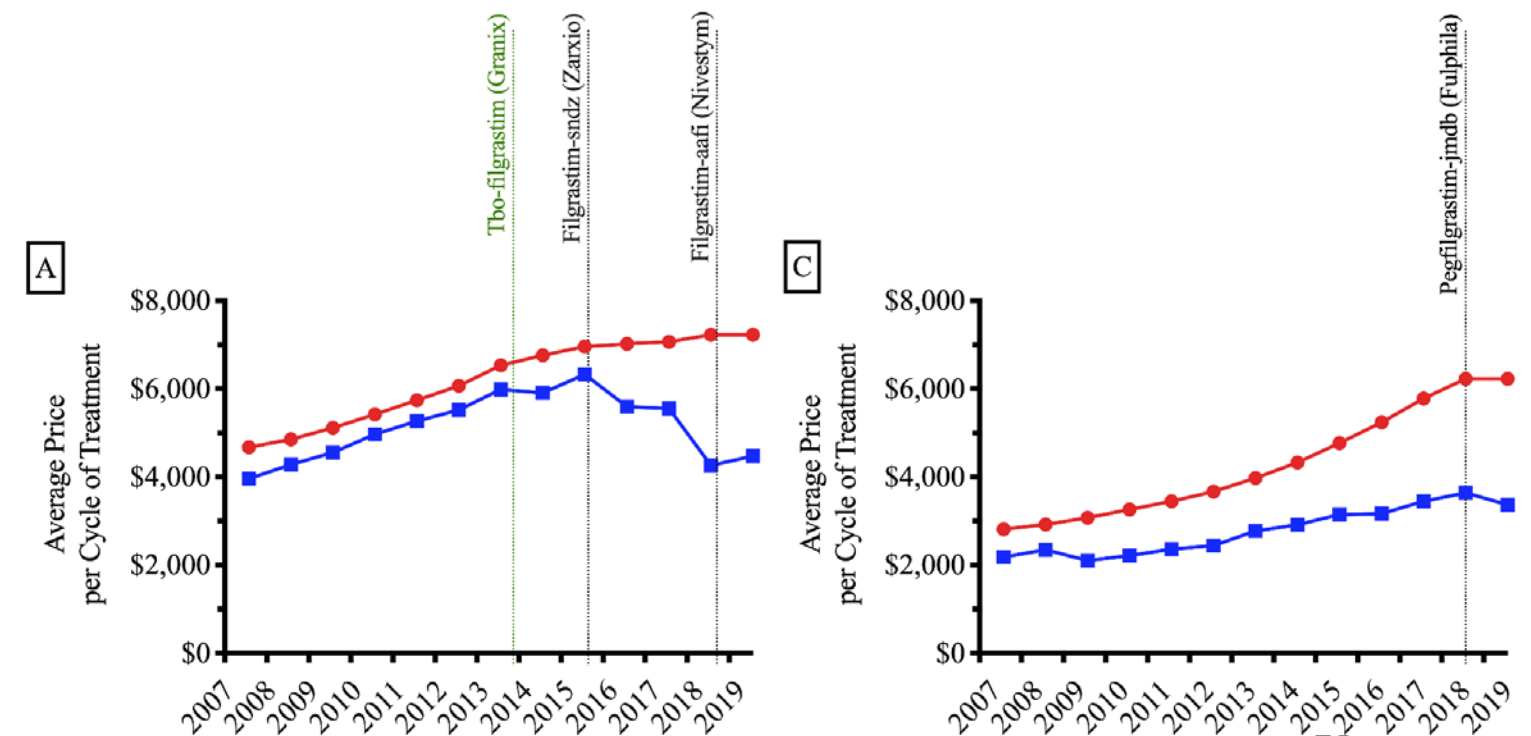
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- Following biosimilar entry:
 - List prices of originator biologics stagnated but did not decrease
 - Net prices decreased
 - This was driven by increases in discounts in payers other than Medicaid
- For infliximab and insulin glargine, decreases in net prices preceded biosimilar entry
 - But they faced within-class competition!
- Unclear whether decreases are related to number of biosimilars or simply to number of years post-biosimilar entry observed





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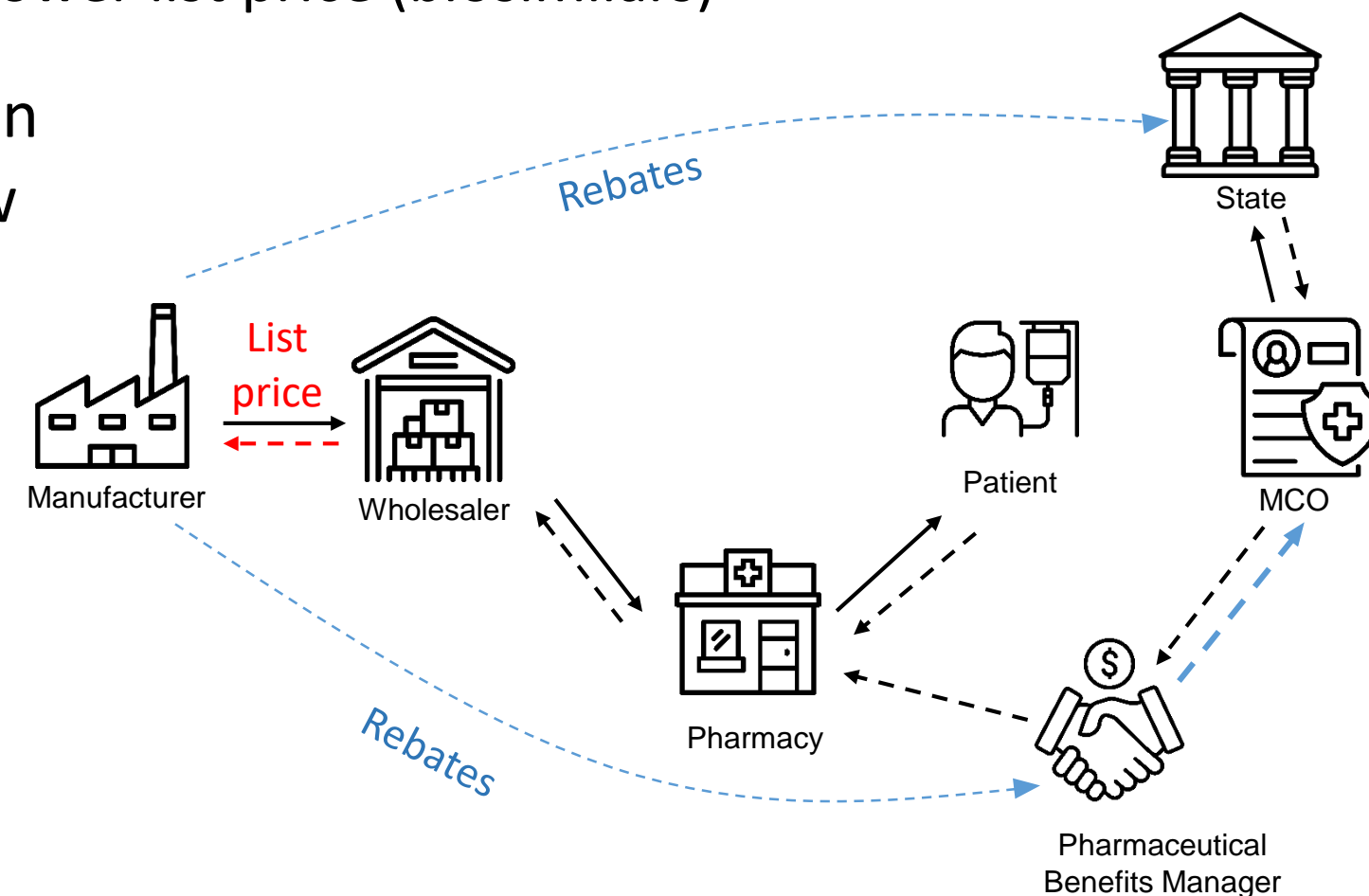
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- Since the passage of the Affordable Care Act, states collect rebates for drugs covered under Medicaid managed care organizations (MCOs)
- This creates differential incentives:
 - States are incentivized to use high list price originator drugs that, after discounts, have lower net prices than biosimilars
 - MCOs are incentivized to use drugs with lower list price (biosimilars)
- To promote the use of branded products in MCOs, some states require them to follow statewide preferred drug lists





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- Objective: To compare utilization of Basaglar in Q1-Q3 2018 between:
 - States with only FFS Medicaid
 - States with MCOs where drug benefits have been carved out into FFS
 - States with MCOs not subject to preferred drug lists for insulin glargine
 - States with MCOs subject to preferred drug lists for insulin glargine

State	Insulin Glargine
Arizona	Lantus preferred
Delaware	Lantus preferred
Florida	Lantus preferred
Iowa	Lantus preferred
Kansas	Lantus preferred
Massachusetts	Therapeutic class not included in PDL
Minnesota	Therapeutic class not included in PDL
Mississippi	Lantus preferred
North Dakota	Lantus preferred
Nebraska	Lantus preferred
Oregon	Therapeutic class not included in PDL
Texas	Lantus preferred
Washington	Lantus preferred

✓ All states that included insulin glargine in preferred drug lists favored Lantus (originator brand-name)

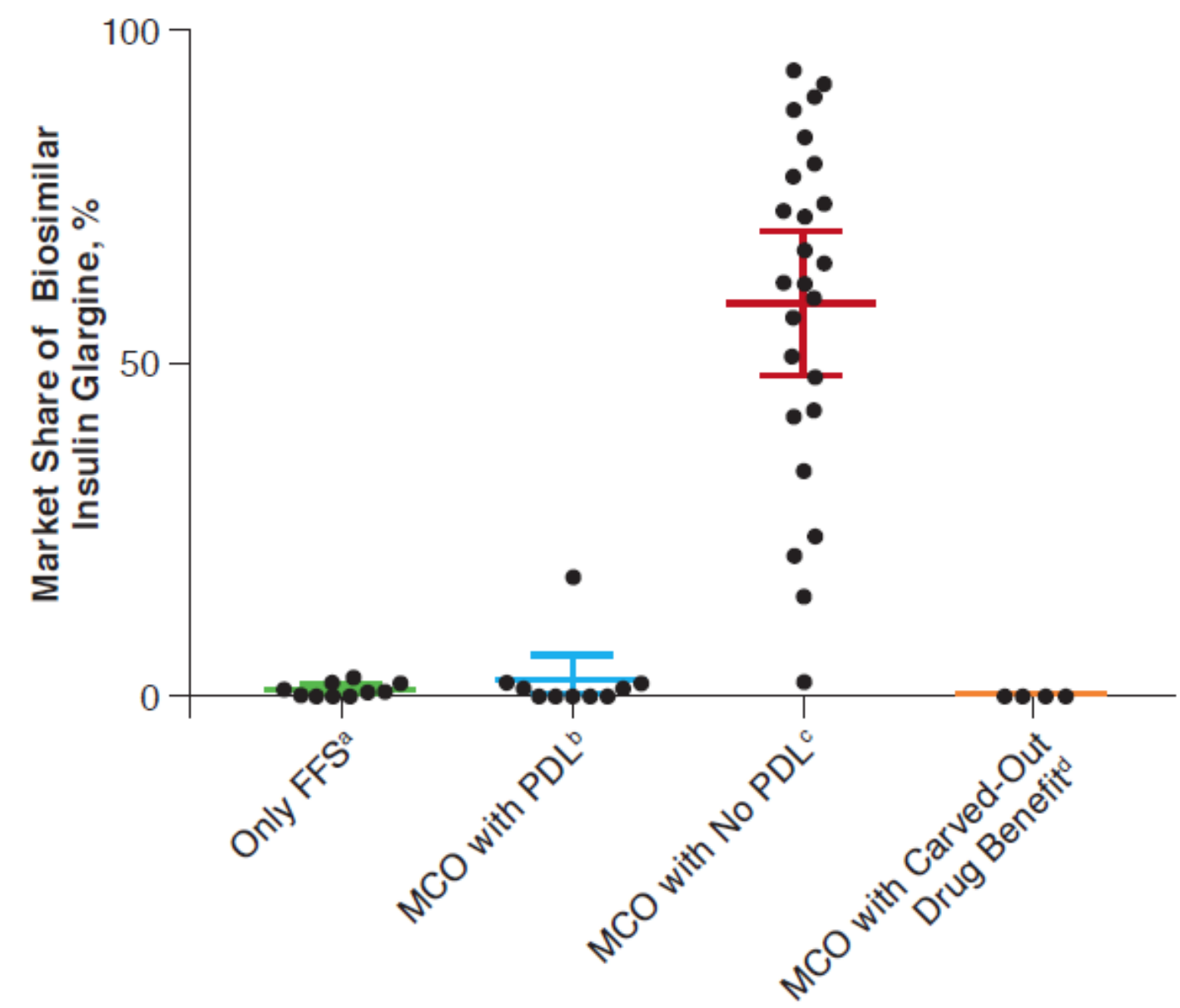
- Data source: Medicaid drug state utilization data
- Outcome: Proportion of international insulin units reimbursed for insulin glargine that were accounted by Basaglar



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Market Share of Basaglar At the State Level





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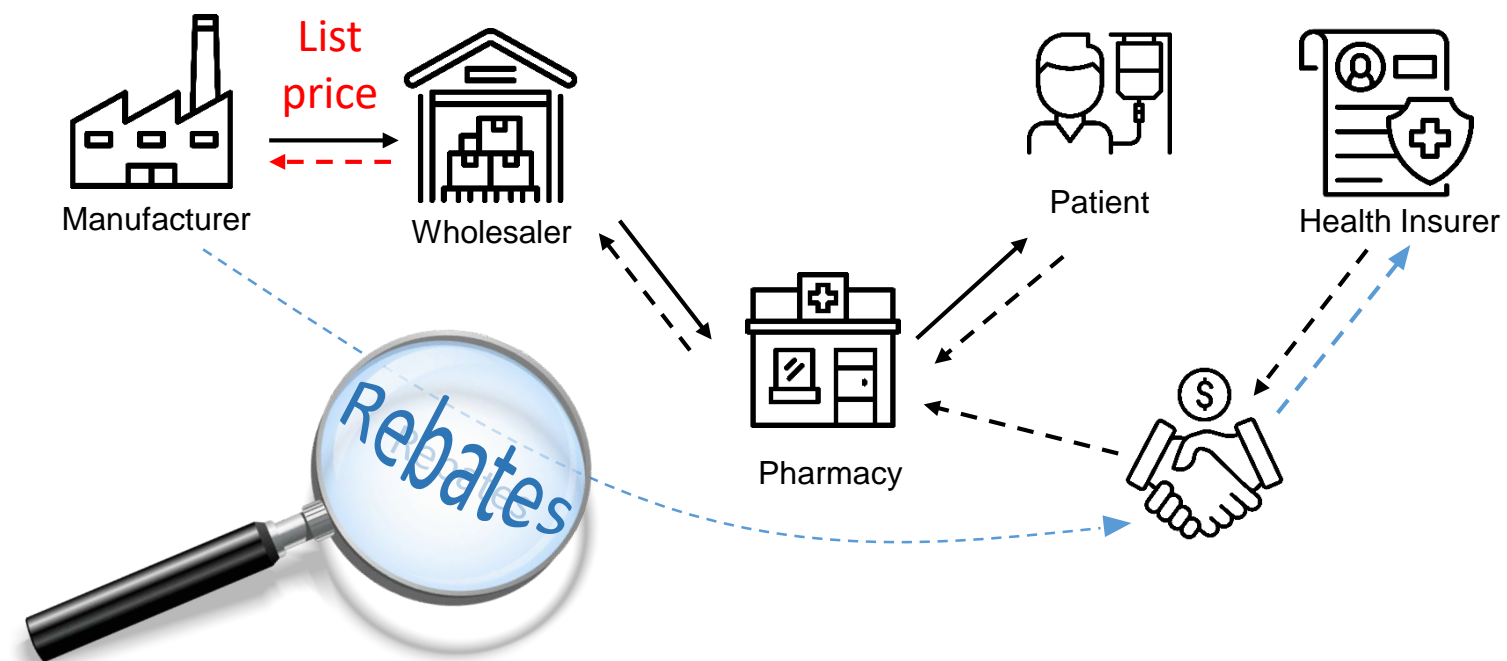
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- Only substantial uptake of Basaglar in states with MCOs not subject to preferred-drug lists
- PDLs prevented uptake of Basaglar by listing it as non-preferred
- Results reflect the strong financial incentives of rebates
- Timely! More states implementing preferred-drug lists (MN, PA)

- Biosimilars exert competition, but competition happens in the discount space, not in the list price space
- Unclear whether discounts will get passed on to patients
- Need to account for discounts in statutorily defined prices





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Questions?



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