The Supply of Prescription Drugs in the COVID19 Era

Rena M. Conti, PhD
Associate Professor
Questrom School of Business
Boston University
rconti@bu.edu
@contirena1

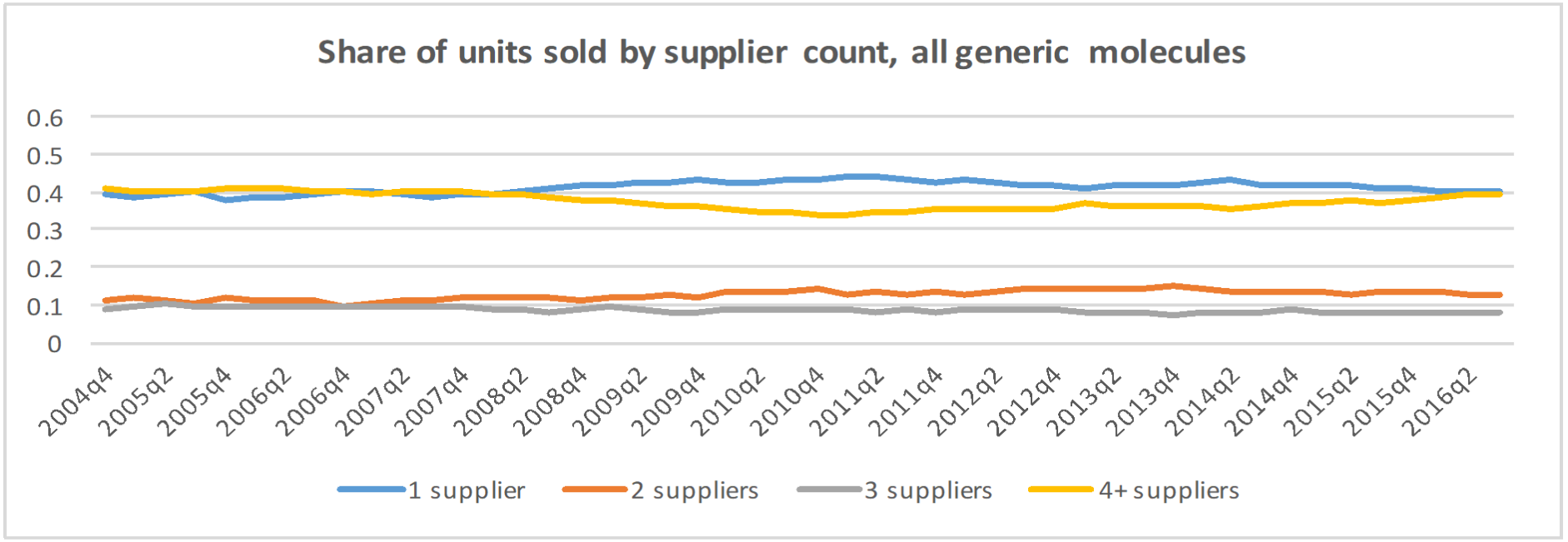
BU Questrom School of Business

Creating Value for the World®

Dr. Janet Woodcock
@DrWoodcockFDA

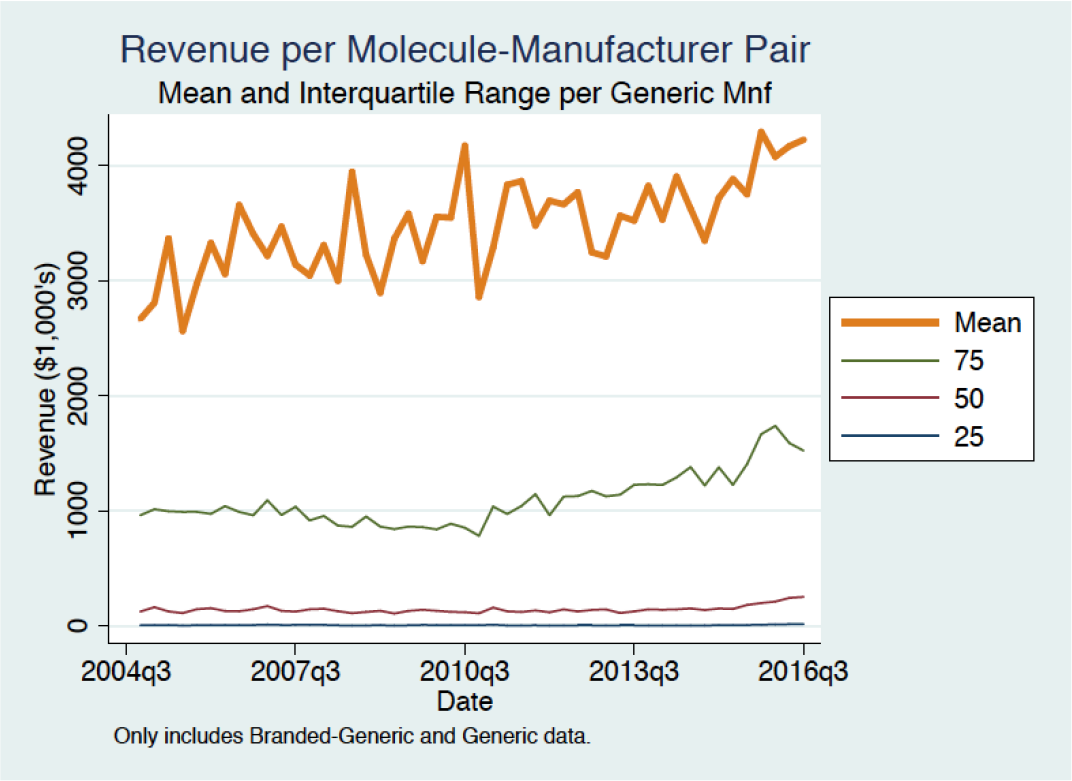
While we focus on development of new agents to treat #COVID19, we have an equally large effort on the supply chain which is totally stressed by the demand for critical care products to treat hospitalized patients.

In steady state, competition is quite limited



"Four facts concerning U.S. supplier competition and market performance in prescription drugs that have undergone loss of patent exclusivity 2009-2012" NBER 2019 (Published 2019)

Median generic drug generates very limited revenue



"Four facts concerning U.S. supplier competition and market performance in prescription drugs that have undergone loss of patent exclusivity 2009-2012" NBER 2019 (Published 2019)

What is a drug ‘manufacturer’?

Manufacturing drugs typically entails several actions:

- Initial set of steps involves making essential biochemical ingredients – called “raw”, “bulk” or “starting” materials, and using these to create “intermediates”
- Second step is to combine the bulk or intermediate materials into a form that is biologically active but not readily consumable by patients (active pharmaceutical ingredients, or “APIs”)
- In the final step, the API is converted into consumable formulations (final dosage forms, “FDFs”, e.g., tablets, capsules, ointments, topicals, also called “drug products”)

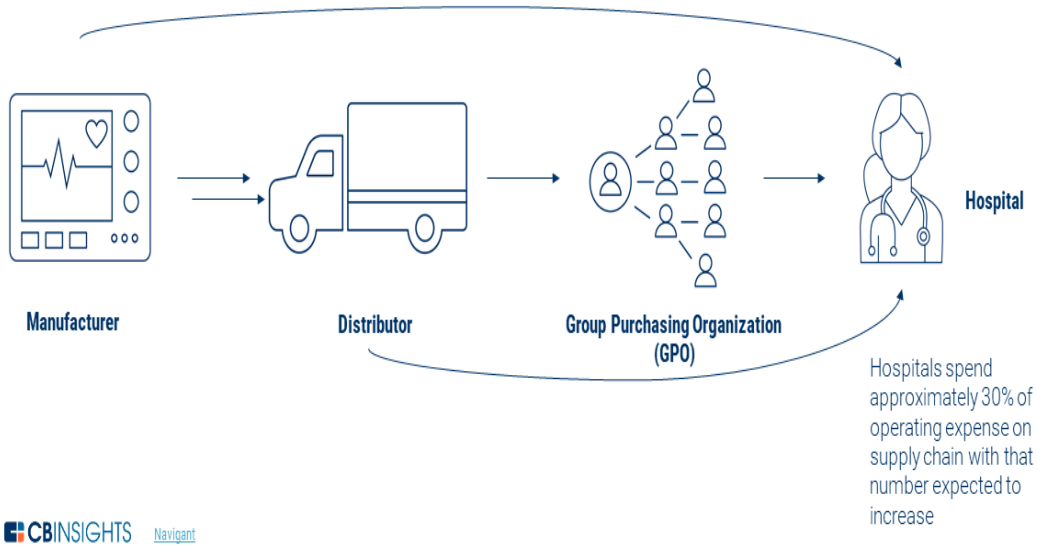
EXHIBIT 1: The Number and Share of API and FDF Generic Drug Facility Sites by Global Region in 2019.

	API		FDF	
	numbers	shares	numbers	Shares
US	118	13%	288	40%
Non-US Americas	33	4%	30	4%
Europe	264	30%	136	19%
IND	249	28%	163	23%
CHN	148	17%	59	8%
Other Asia	68	8%	45	6%
Total US	118	13%	288	40%
Total Ex-US	762	87%	433	60%
TOTAL	880		721	

Source: We are indebted to Dr. Andreas Schick and Qiyu Liu at the US Food and Drug Administration for making this data available to us in Excel files.

"The Geography of Prescription Pharmaceuticals Supplied to the U.S.: Levels, Trends and Implications" https://www.nber.org/papers/w26524;
"We still don't know who makes this drug" Health Affairs blog January 2020. https://www.healthaffairs.org/do/10.1377/hblog20200203.83247/full/

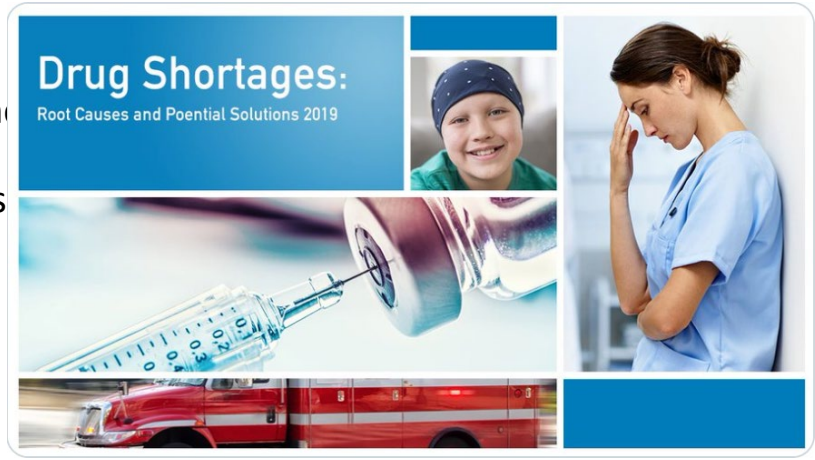
Medical Product Supply Chain 101: Hospitals ‘go it alone’



CBINSIGHTS Navigant

Current Drug Procurement System Widens Disparities between Hospitals, Contributes to 'Shortages'

- Low/bundled reimbursement
- Just in time orders, limited supply reserves
- Larger, better financed hospitals get supply preferen
- No pricing guarantees, only state price gouging rules
- No GPO accountability, failure to supply clauses
- No quality guarantees, only FDA oversight



Policy Responses Rooted in Federalism

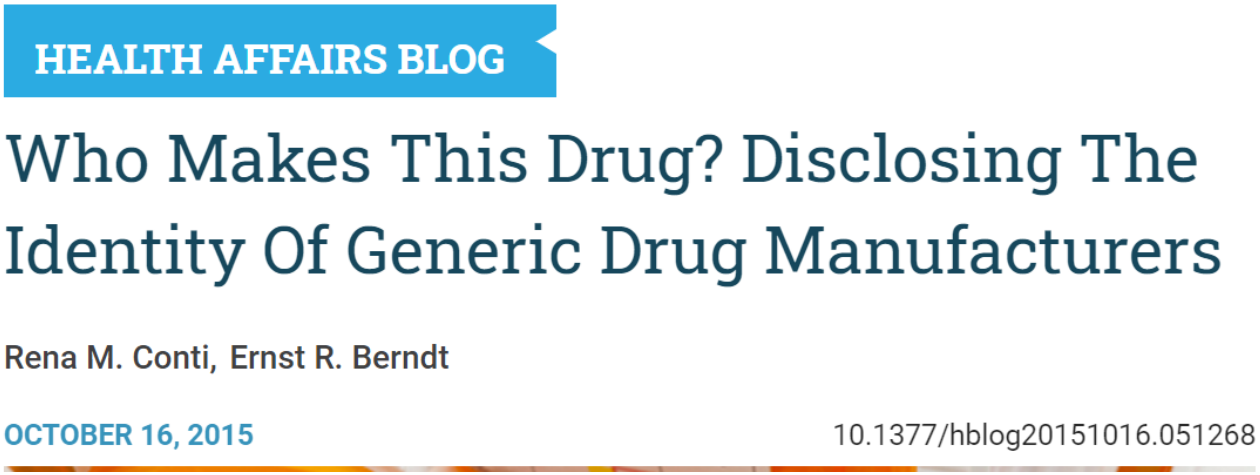
- CARES Act improves hospital finances, but $$ not distributed based on need
- 'Buy American' is largely non-actionable for many drugs, will generate increased costs
- Increased FDA oversight, reduction in barriers to entry

https://www.whitehouse.gov/presidential-actions/presidential-executive-order-buy-american-hire-american/

Transparency needed to improve supply and demand:

✓Identity of manufacturer

✓Identity of drug name, formulation



Takeaways

- Generic drugs are important consumer goods
  - Prices paid for generic drugs are low, generate savings for payers
  - Low prices are determined by competition & facilitated by regulation
- Limited suppliers, reliance on foreign suppliers entails vulnerabilities
  - Yet measurement of supply adequacy is challenging
- Current policy responses are inadequate to address challenges, I suggest three reforms:
  1. Significant increases in transparency of drug supply chains
  2. Targeted improvement in supply, increased requirements for hospitals to hold supply ‘reserves’
  3. Consider additional reimbursement rules

Further reading

- https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/
- https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023
- https://www.iqvia.com/insights/the-iqvia-institute/reports/global-oncology-trends-2019
- https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity-pricing-and-treated-populations.pdf?_=1583248482598
- https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf
- https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf
- https://www.aarp.org/content/dam/aarp/ppi/2019/09/price-growth-for-brand-name-and-specialty-drugs-more-than-offset-price-decreases-for-generic-drugs.doi.10.26419-2Fppi.00073.004.pdf
- https://www.aarp.org/content/dam/aarp/ppi/2019/04/trends-in-retail-prices-of-generic-prescription-drugs-widely-used-by-older-americans.pdf
- https://www.aarp.org/content/dam/aarp/ppi/2017/08/trends-in-retail-prices-of-generic-prescription-drugs-widely-used-by-older-americans.pdf
- https://www.fda.gov/media/131130/download
- US Government Accountability Office, Dec. 10, 2019 Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, Statement of Mary Denigan-Macauley, Director, Health Care, *"DRUG SAFETY: Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections"*, GAO-20-262T
- December 10, 2019, testimony of Janet Woodcock, M.D., Director, CDER, FDA, DHHS, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, "*Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program*"
- FDA Websites: https://www.fda.gov/ICECI/Inspections/ucm346077.htm, https://www.fda.gov/iceci/inspections/ucm250720.htm, and an Excel file https://www.fda.gov/downloads/ICECI/Inspections/UCM576541.xlsx
- Ernst R Berndt & Rena M Conti & Stephen J Murphy, 2018. "The generic drug user fee amendments: an economic perspective," Journal of Law and the Biosciences, vol 5(1), pages 103-141. https://www.nber.org/papers/w23642
- Rena Conti & Ernst Berndt. "We still don't know who makes this drug" Health affairs blog January 2020. https://www.healthaffairs.org/do/10.1377/hblog20200203.83247/full/
- https://www.healthaffairs.org/do/10.1377/hblog20200311.912049/full/
- https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions
- https://www.csis.org/analysis/world-crisis-will-buying-american-help-or-hurt

Acknowledgements

- Professor Conti acknowledges research support from The Commonwealth Fund, the American Cancer Society and Arnold Ventures
- Professor Berndt acknowledges research support from the National Institutes of Health (NIH), National Institute on Aging (NIA), Grant R01AG043560 to the National Bureau of Economic Research (NBER)
- Dr. Conti and Berndt are both special economic advisors to the U.S.FDA's Office of Generic Drugs
- We have benefited from discussions on FDA regulatory and user fee payment file matters with Dr. Randall Lutter, Dr. Andreas Schick and Mr. Qiyu Liu of the US Food and Drug Administration, data sources identified by Dr. Chris Stomberg of National Economic Research Associates, and access to manufacturing facility geographic data provided by the US FDA
- Any opinions and findings expressed here are those of the authors, and are not necessarily those of the research sponsors, the institutions with whom they are affiliated.