The Supply of Prescription Drugs in the COVID19 Era

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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.

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

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.

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

Transparency needed to improve supply and demand:

- Identity of manufacturer
- Identity of drug name, formulation

Who Makes This Drug? Disclosing The Identity Of Generic Drug Manufacturers

Rena M. Conti, Ernst R. Berndt

OCTOBER 16, 2015

10.1377/hblog20151016.051268
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.fda.gov/media/131130/download
- https://www.csis.org/analysis/world-crisis-will-buying-american-help-or-hurt
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● 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.