Barriers to Competition in the US pharmaceutical industry

Fiona Scott Morton
Lysle Boller
Yale University School of Management

May 2017
• Expenditures on pharmaceuticals are high and rising; there are too many examples of prices unrelated to value
• Regulation is really hard to get right when innovation is important, innovation costs are sunk, and marginal costs are low

⇒ Competition between drugs in well-functioning markets can bring down prices and also generate innovation that people value

• Exactly because competition is so effective, manufacturers attempt to avoid it –
  – Use influence with regulators to get regulations that dampen competition
  – Use influence with legislators to prevent pro-competitive legislation
  – Utilize creativity in complex markets to reduce rivalry
Motivation

• This paper argues that enabling vigorous competition should be the first response to the problem of high pharma spending
• Remove barriers to competition
  – Some created by manufacturers
  – Some created by science
  – Some created by regulators
• If regulators pay attention to competition, enhance and enable it, may get lower prices, innovation, and no need to regulate
• Caveat: Paper does not address unique patented valuable treatments (see early paper by Richard Frank)
Price growth: specialty / biologic versus small-molecule drugs
Stylized price paths:

- biologics (top line)
- small-molecule drugs with generic entry (bottom line)
1) **Biosimilar entry needed**

*FDA*

quick entry and approve interchangeable biosimilars

---

Europe has had biosimilars since 2006. More than 20 on the market today generating significantly lower prices.

The United States has 2 biosimilars for sale.

FDA has approved a grand total of 5 biosimilars to date (disputes over patents or regulatory procedure are blocking the sale of 3)
Impact of second filgrastim brand (granix)

Impact of first 6 months of generic entrant (zarxio)
Biologics

1) **Biosimilar entry needed**
   - Agency: FDA
   - Action: quick entry and approve interchangeable biosimilars

2) Biosimilar naming
   - Agency: FDA
   - Action: one scientific name

3) Procurement
   - Agency: CMS
   - Action: redesign j codes

4) Orphan drugs
   - Agency: Leg
   - Action: reform

---

**Yale School of Management**
Generics

- Pay for delay
- REMS
- Product hopping
- Small market monopoly
- Approval delays
- Complex product
- Shortages

FTC antitrust enforcement
FTC antitrust enforcement
FTC antitrust enforcement
Leg importation
FDA quicker approvals
FDA clearer guidelines
FDA keep inspecting
Demand side

• Ther subst Part D CMS relax formularies
• Ther subst Part B CMS/Leg reference pricing
• PBM competition FTC 6(b) study
• PBM incentives FTC/Leg rebates flow directly

Confidential rebates promote price competition.
If 100% of rebates flow back to plan sponsor, can then negotiate PBM compensation from position of full information = > may intensify competition

Yale School of Management
Demand side

- Ther subst Part D: CMS, relax formularies
- Ther subst Part B: CMS/Leg, reference pricing
- PBM competition: FTC, 6(b) study
- PBM incentives: FTC/Leg, rebates flow directly
- Patient kickbacks:
  - Coupons: OIG, States, ban
  - PAPs: IRS, CMS, limit, make unprofitable
  - Patient benefits: OIG, CMS, limit, ban
<table>
<thead>
<tr>
<th>Rank</th>
<th>Foundation</th>
<th>Total Giving</th>
<th>PAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>$3,439,671,894</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Silicon Valley Community Foundation</td>
<td>$956,834,000</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>The Abbvie Patient Assistance Foundation</td>
<td>$853,356,401</td>
<td>✓</td>
</tr>
<tr>
<td>4</td>
<td>The Bristol-Myers Squibb Patient Assistance Foundation, Inc.</td>
<td>$811,433,684</td>
<td>✓</td>
</tr>
<tr>
<td>5</td>
<td>Johnson &amp; Johnson Patient Assistance Foundation, Inc.</td>
<td>$711,632,110</td>
<td>✓</td>
</tr>
<tr>
<td>6</td>
<td>Merck Patient Assistance Program, Inc.</td>
<td>$686,800,564</td>
<td>✓</td>
</tr>
<tr>
<td>7</td>
<td>Genentech Access To Care Foundation</td>
<td>$680,278,040</td>
<td>✓</td>
</tr>
<tr>
<td>8</td>
<td>Pfizer Patient Assistance Foundation, Inc.</td>
<td>$668,050,404</td>
<td>✓</td>
</tr>
<tr>
<td>9</td>
<td>GlaxoSmithKline Patient Access Programs Foundation</td>
<td>$625,427,284</td>
<td>✓</td>
</tr>
<tr>
<td>10</td>
<td>The Atlantic Philanthropies</td>
<td>$521,711,000</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Ford Foundation</td>
<td>$518,380,000</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Lilly Cares Foundation, Inc.</td>
<td>$503,299,479</td>
<td>✓</td>
</tr>
<tr>
<td>13</td>
<td>Sanofi Foundation for North America</td>
<td>$485,359,572</td>
<td>✓</td>
</tr>
<tr>
<td>14</td>
<td>Novartis Patient Assistance Foundation, Inc.</td>
<td>$456,825,176</td>
<td>✓</td>
</tr>
<tr>
<td>15</td>
<td>The Susan Thompson Buffett Foundation</td>
<td>$416,440,853</td>
<td></td>
</tr>
</tbody>
</table>

Largest US foundations.

PAPs accept tax-free donations of medicine and then give them away as free samples.
Example in trade press to illustrate the profits gained from a $10 million contribution to a Patient Assistance Program

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Charitable Contribution</td>
<td>$10,000,000</td>
</tr>
<tr>
<td>2</td>
<td>Charity Overhead</td>
<td>20%</td>
</tr>
<tr>
<td>3</td>
<td>Net Contribution</td>
<td>$8,000,000</td>
</tr>
<tr>
<td>4</td>
<td>Market Share</td>
<td>25%</td>
</tr>
<tr>
<td>5</td>
<td>Subsidized Patient Revenue</td>
<td>$2,000,000</td>
</tr>
<tr>
<td>6</td>
<td>Insurer Cost Share</td>
<td>88%</td>
</tr>
<tr>
<td>7</td>
<td>Revenue</td>
<td>$16,000,000</td>
</tr>
</tbody>
</table>

8 Charitable Margin 60%

Note the role of the contributor’s market share (25%). Then $2m in “patient” co-payment generates $16m in insurer payments.

The $16m in incremental revenue is greater than the $10m contribution. Moreover, the contribution is subsidized by the taxpayer, as it is tax deductible.