Sustaining Innovation in the US Pharmaceutical Market

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Payer and Policymaker Arousal

- Payers, policymakers, and the public are very aroused on drug prices; the industry is demonized

- Why? The timing seems difficult to explain:
  - The pipeline of innovation is remarkable. Breakthrough therapies are benefiting rare, intractable conditions and large public health conditions: orphan illnesses, gene therapies, HCV, auto-immune, oncology

- Reason: per-patient prices are rising rapidly at launch and in post-launch increases, and are being passed on thru premiums and cost sharing
## Pharmaceuticals: the Least Loved Industry

### Americans' Views of U.S. Business Industry Sectors, 2019

For each of the following business sectors in the United States, please say whether your overall view of it is very positive, somewhat positive, neutral, somewhat negative or very negative.

<table>
<thead>
<tr>
<th>Industry</th>
<th>Total Positive</th>
<th>Neutral</th>
<th>Total Negative</th>
<th>Net Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restaurant industry</td>
<td>66</td>
<td>25</td>
<td>8</td>
<td>+58</td>
</tr>
<tr>
<td>Computer industry</td>
<td>61</td>
<td>28</td>
<td>11</td>
<td>+50</td>
</tr>
<tr>
<td>Grocery industry</td>
<td>58</td>
<td>27</td>
<td>15</td>
<td>+43</td>
</tr>
<tr>
<td>Farming and agriculture</td>
<td>58</td>
<td>24</td>
<td>17</td>
<td>+41</td>
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<tr>
<td>Travel industry</td>
<td>52</td>
<td>35</td>
<td>13</td>
<td>+39</td>
</tr>
<tr>
<td>Accounting</td>
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<td>45</td>
<td>9</td>
<td>+36</td>
</tr>
<tr>
<td>Automobile industry</td>
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<td>29</td>
<td>18</td>
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<tr>
<td>Retail industry</td>
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<td>28</td>
<td>19</td>
<td>+31</td>
</tr>
<tr>
<td>Real estate industry</td>
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<td>31</td>
<td>19</td>
<td>+30</td>
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<tr>
<td>Banking</td>
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<td>25</td>
<td>+25</td>
</tr>
<tr>
<td>Electric and gas utilities</td>
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<td>28</td>
<td>24</td>
<td>+23</td>
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<tr>
<td>Sports industry</td>
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<td>25</td>
<td>+20</td>
</tr>
<tr>
<td>Airline industry</td>
<td>42</td>
<td>32</td>
<td>23</td>
<td>+19</td>
</tr>
</tbody>
</table>

### Data Source

GALLUP, AUG. 1-14, 2019
Responses by private insurer and public programs

- Private insurers take the lead, with public payers benefitting from average or lowest net prices negotiated by private payers.
- The strategy pursued by private insurers is to limit physician prescription and patient access to specialty drugs, with the offer to partially relax restrictions in exchange for price rebates.
- These access barriers, including prior authorization and consumer cost sharing, are rapidly becoming more intense, sparking a backlash from physicians and patients.
- Both insurers and manufacturers face strong adverse publicity.
- The strategies have been effective in reducing the growth, and in some cases the level, of net prices.
Intense Prior Authorization and Cost Sharing Are Slowing Drug Adoption, Relative to Projections

Percent of Potential Post-Launch Adoption Actually Achieved, With Changing Intensity of Payer Management

‡ Source: QuintilesIMS, Payer and Managed Care Insights
Price Negotiations Now Are Reducing Growth in Net Prices, in Some Case to Negative

Protected brand net price increases moderated to 0.3% on average in 2018 as invoice price growth continued to fall.

Source: IQVIA

List vs. Net Price Growth for Brand-Name Drugs, 2014 to 2019

Source: SSR Health

Published on Drug Channels (www.drugchannels.net) on January 5, 2020.
Possible Futures: Increased public regulation of prices

- Congressional Democrats and President Trump are promoting very aggressive legislation to support price negotiations and regulation.
- Congressional Republicans traditionally have opposed regulation, but face strong public pressure to cooperate.
- All need to ‘do something’ but neither the Democrats nor the Trump administration want to give the other a perceived policy victory.
- Chances for cooperation and successful legislation are limited.
- Legislation will depend on the outcome of 2020 elections, which cover the presidency, all Congressional seats, and 1/3 of Senate seats.
- A victory by Democrats would almost certainly result in stringent new drug price negotiations and regulations.
Congressional Democrats Focus on Launch Price “Negotiations” with Heavy Regulation

- Government would negotiate prices for Medicare, which would apply to private payers
- Upper limit on prices would be 120% of prices for other wealthy nations (reference pricing)
- If manufacturers refuse to price below benchmarks, they face 75% tax on sales

STAT+

Pelosi’s drug pricing plan is more aggressive than expected

By Nicholas Florko@NicholasFlorko and Lev Facher@levfacher

September 9, 2019
Bipartisan Senate Committee and Trump Emphasize Limits on Price Increases

- Manufacturers must rebate to Medicare any price increases faster than inflation
- Limits on consumer cost sharing, requiring private insurers to pay greater share of total costs
- No controls on launch prices, which will continue to be negotiated by private insurers
Overlap between Senate (G-W), House (Pelosi), Trump proposals
Implementation limitations of policy proposals

- The political debate ignores the challenges facing any centralized process for assessing value and negotiating/regulating prices.

- How to assess value? Private ICER is favored by Democrats, opposed by Republicans. No public HTA entity exists.

- Which process for Medicare negotiations? The stringent limits on outcomes (limited by global reference prices, US price inflation, compulsory licensing, and/or mandatory arbitration) make this more a process of regulation than negotiation.

- How would Medicare prices affect private insurers? Will private insurers be allowed to limit payments to Medicare levels, or will manufacturers be able to increase prices to private payers to offset reduced prices to public payers?
Options for Policymakers:  
How to Sustain Innovation and the Life Sciences Industry?

- The US market accounts for 46% of sales revenues and 78% of profits across all OECD nations
- Compression of prices and profits will reduce potential funding for investments in R&D
- What other funding sources are potentially available?
- Do we have examples of successful policy initiatives to stimulate investment and innovation?
The US has been Supplying a Large and Growing Portion of Global Drug R&D

https://www.abpi.org.uk/media/1119/investing_innovation.pdf
Industry has funded 60% of total R&D in the US, rising over time as governmental funding has eroded in inflation-adjusted terms. This now is at risk.
Which Sources of R&D Funding Can Be Used to Supplement Industry Revenues?

• Expanded tax-based support for basic science, through NIH and other entities
• Expanded tax-based support for translational science and product development, through NIH and other entities
• Expanded tax credits for R&D, with especially generous credits for investments in areas of especially high need
• Expanded direct public grants to support product commercialization, including the SBIR and related programs for technology-based startups
• Expanded innovation prizes that reward developmental milestones as well as new product launch
• Targeted tax reductions on profits obtained from patent-protected and other innovation-intensive products
Do we Have Examples of Successful Policy Initiatives to Expand Investment and Innovation? The Orphan Drug Act of 1984
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