Why Life-Science Innovation Is Politically Purple

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Why Life-Sciences Innovation Is Politically “Purple”—and How Partisans Get It Wrong

BY ROBERT D. ATKINSON • FEBRUARY 2016

The United States has long had the world’s most effective and competitive system for discovering and developing new drugs—and for more than a half century, there has been a bipartisan consensus that there are two reasons for that success: First, the federal government provides robust funding for scientific research, mostly through the National Institutes of Health (NIH). Second, the U.S. system encourages vigorous innovation in the private sector by providing strong intellectual property protections and a drug reimbursement system that together allow companies to earn sufficient revenues to reinvest in highly risky research and development. But today that consensus is fraying as populists on the left and libertarians on the right question both the policy means and the end result. If the center cannot hold and the longstanding bipartisan policy framework falls apart, then the future of U.S. biomedical innovation will be in peril.

INTRODUCTION

Many on the left have long voiced concerns about drug prices, but most of them have acknowledged that the U.S. system for discovering and developing drugs has worked well and that America has benefited by constantly improving drugs and fielding a globally competitive biopharmaceutical industry (biopharma). Now that view is under attack from an ascendant camp that may be fairly described as “drug populists.” These left-wing advocates complain that biopharma companies charge too much for drugs and that government should impose price controls, weaken patent protections, and shorten the term of intellectual property protection for the clinical trial data related to new biologic drugs (known as “data exclusivity”). This is part and parcel of a larger policy agenda for the federal government to assume a significantly increased role in drug development, and the biopharma industry to be significantly hemmed in. These populists embrace the view that health care is a fundamental human right, and they deeply distrust the private sector, which

Source: ITIF, Why Life-Sciences Innovation Is Politically “Purple”— and How Partisans Get It Wrong
## U.S. World Leader in Life-Sciences Innovation

### Table 2: New chemical entities
By headquarter country of inventing firm

<table>
<thead>
<tr>
<th>Country</th>
<th>1971-1980</th>
<th></th>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>NCEs % total</td>
<td>NCEs % total</td>
<td>NCEs % total</td>
<td>NCEs % total</td>
<td>NCEs % total</td>
</tr>
<tr>
<td>U.S.</td>
<td>157 31</td>
<td>145 32</td>
<td>75 42</td>
<td>111 57</td>
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<tr>
<td>France</td>
<td>98 19</td>
<td>37 8</td>
<td>10 6</td>
<td>11 6</td>
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</tr>
<tr>
<td>Germany</td>
<td>96 20</td>
<td>67 15</td>
<td>24 13</td>
<td>12 6</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>75 15</td>
<td>130 29</td>
<td>16 9</td>
<td>18 9</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>53 10</td>
<td>48 11</td>
<td>26 14</td>
<td>26 13</td>
<td></td>
</tr>
<tr>
<td>U.K.</td>
<td>29 6</td>
<td>29 6</td>
<td>29 16</td>
<td>16 8</td>
<td></td>
</tr>
<tr>
<td>Total NCEs</td>
<td>508</td>
<td>456</td>
<td>180</td>
<td>194</td>
<td></td>
</tr>
</tbody>
</table>

Source: DeVol, Bedroussian, Benjamin Yeo, *The Global Biomedical Industry: Preserving U.S. Leadership*
Winning Formula

Bipartisan policy framework with two pillars:

1. Robust federal investment
   - @$30B annually in scientific research funding through NIH.

2. Vigorous private-sector innovation
   - >$50B per year for drug R&D.
   - Robust IP protections and a drug pricing reimbursement system allow companies to earn sufficient revenues.
U.S. System Under Threat on Both Fronts

1. “Drug libertarians” distrust public investment
   - Assert that government investment in scientific research is inefficient and wasteful.
   - Want to limit government-supported life-sciences research in order to shrink government and redistribute $$ to taxpayers.
   - Think private sector would invest enough in basic research.

2. “Drug populists” distrust private innovation
   - Assert that biopharma companies charge too much for drugs.
   - Want government to take leading role in drug development.
   - Advocate for price controls, weaker patent protections, and shorter data-exclusivity periods.
What Such Arguments Fundamentally Miss

1. Significant complementarities between public and private sector investment in life-sciences research.

2. Reality that a sufficient level of profits is vital for reinvestment in life-sciences R&D and perpetuating a virtuous cycle of innovation.

3. Favor the interests of present over future generations.
Public and Private Sector Investments Are Complements

1. Each $1 of NIH funding boosts the size of the bioscience industry by at least $1.70; each $1 of NIH research increases private medical research expenditures by at least 32 cents.

2. Federally funded biomedical research has been a key input both to new drugs and biologics, as well as entirely new companies.
   - NIH funding led to the discovery of monoclonal antibodies, which have given rise to numerous anti-cancer drugs (e.g., Avastin).
   - Federally funded NIH or university research has spawned scores of life-sciences startup companies.

Source: Ehrlich, An Economic Engine: NIH Research, Employment, and the Future of the Medical Innovation Sector
Select Biotech Companies With Origins in Federal Research Funding

<table>
<thead>
<tr>
<th>Adenosine Therapeutics</th>
<th>GeoVax Labs</th>
<th>PolyMedix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advaxis</td>
<td>HealthMeda</td>
<td>Paxis Biologics</td>
</tr>
<tr>
<td>Agensys</td>
<td>iCardiac Techs.</td>
<td>Protea Bioscience</td>
</tr>
<tr>
<td>Amgen</td>
<td>ImmuneWorks</td>
<td>Response Genetics</td>
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<tr>
<td>Aursos</td>
<td>Integrated Genomics</td>
<td>Saneron-CCEL</td>
</tr>
<tr>
<td>Avid Radiopharma</td>
<td>Kinex Pharma</td>
<td>TetraLogic Pharma</td>
</tr>
<tr>
<td>AzERx</td>
<td>Maroon Biotech</td>
<td>Therametric Techs</td>
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<tr>
<td>BioMarck Pharma</td>
<td>MicroMRI</td>
<td>TomoTherpay</td>
</tr>
<tr>
<td>BioNanomatrix</td>
<td>Momenta Pharma</td>
<td>Transgenex Nanobio</td>
</tr>
<tr>
<td>Cerluean Pharma</td>
<td>Nanopharma Techs</td>
<td>Triangle Pharma</td>
</tr>
<tr>
<td>CS-Keys</td>
<td>Natura Therapeutics</td>
<td>Vaccinex</td>
</tr>
<tr>
<td>Fast Diagnostics</td>
<td>ONY</td>
<td>VGX Pharma</td>
</tr>
<tr>
<td>FluGen</td>
<td>Pacific Biosciences</td>
<td>Xenogen</td>
</tr>
<tr>
<td>Genentech</td>
<td>Pharmasset</td>
<td>Ximerex</td>
</tr>
</tbody>
</table>

Source: The Science Coalition, *Sparking Economic Growth*
Reasonable Profits Are Vital for Life-Sciences R&D

- OECD: “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.”
- Drug populists don’t acknowledge trade off between lower drug prices and reduced innovation.

Source: OECD, *Pharmaceutical Pricing Policies in a Global Market*
Reasonable Profits Are Vital for Life-Sciences R&D

1. If US had used EU drug pricing system from 1986-2004, would have resulted in:
   - 117 fewer new medicine compounds.
   - 4,400 fewer research jobs.

2. Civan estimates a 50% drop in U.S. drug prices would result in the number of drugs in the development pipeline dropping up to 24%.

Source: Golec and Vernon, *Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms*
Policy Recommendations

1. Increase federal investment in life-sciences research.
   - Since 2004, NIH purchasing power has decreased 13% in real (inflation-adjusted) terms.
   - From 2004 to 2012, the total U.S. (public plus private) share of global research funding declined from 57% to 44%.

2. Congress should make the tax code more supportive of high-risk R&D, including by expanding the R&D tax credit and instituting an innovation box.

3. NIH grant funding should support more higher-risk, often inter-disciplinary research, especially from younger researchers.
Thank You

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