Issues in Prescription Drug Costs: Level, Growth, Innovation, and Perspectives on Policy Options

Len M. Nichols, Ph.D.
National Association of Attorneys General
Presidential Initiative Summit
New York, NY
April 27, 2017
Drug Spend as percentage of NHE

- 1960: [VALUE]
- 1980: [VALUE]
- 2015: [VALUE]
Drug $ as percent of total spend, by payer (2015)
Chart 1: Total Spending on Medicines US$Bn

Source: IMS Health, National Sales Perspectives, Jan 2016; U.S. Census Bureau; U.S. Bureau of Economic Analysis
Chart 2: Spending Growth and Drivers US$Bn

Source: IMS Health, National Sales Perspectives, Jan 2016
Chart 8: Spending on Specialty Medicines US$Bn

- **Oncology**
- **Autoimmune**
- **Viral Hepatitis**
- **Multiple Sclerosis**
- **HIV Antivirals**
- **Other Specialty**

<table>
<thead>
<tr>
<th>Year</th>
<th>Oncology</th>
<th>Autoimmune</th>
<th>Viral Hepatitis</th>
<th>Multiple Sclerosis</th>
<th>HIV Antivirals</th>
<th>Other Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>24.8</td>
<td>10.1</td>
<td>7.8</td>
<td>13.1</td>
<td>10.1</td>
<td>24.1</td>
</tr>
<tr>
<td>2012</td>
<td>24.1</td>
<td>11.1</td>
<td>9.1</td>
<td>15.2</td>
<td>11.9</td>
<td>25.6</td>
</tr>
<tr>
<td>2013</td>
<td>24.9</td>
<td>12.2</td>
<td>11.9</td>
<td>18.3</td>
<td>14.0</td>
<td>28.1</td>
</tr>
<tr>
<td>2014</td>
<td>26.3</td>
<td>14.0</td>
<td>15.0</td>
<td>23.5</td>
<td>12.2</td>
<td>33.1</td>
</tr>
<tr>
<td>2015</td>
<td>28.9</td>
<td>16.2</td>
<td>17.7</td>
<td>18.8</td>
<td>16.2</td>
<td>39.1</td>
</tr>
</tbody>
</table>

Source: IMS Health, National Sales Perspectives, Jan 2016
EXHIBIT 1

Annual Cost Of Oncologic Drugs Approved By The Food And Drug Administration In 2012

- Afinitor (everolimus)
- Bosulif (bosutinib)
- Cometriq (cabozaatinib)
- Erivedge (vismodegib)
- Iclusig (ponatinib)
- Inlyta (axitinib)
- Kyprolis (carfilzomib)
- Perjenta (pertuzumab)
- Stivarga (regorafenib)
- Votrient (pazopanib)
- Xtandi (enzalutamide)
- Zaltrap (ziv-aflibercept)

Annual drug cost ($)
AVERAGE COST OF CANCER DRUGS TO DELIVER A “LIFE YEAR” (IN 2013 DOLLARS)

Chart 14: New Active Substances (NAS) by Therapy Area Launched in the U.S. 2006–2015

Source: U.S. FDA, Drugs@FDA, Dec 2015, IMS Health, IMS Institute for Healthcare Informatics, Mar 2016
August 2016

GENERIC DRUGS UNDER MEDICARE

Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases
Figure 3: The Number of Established Drugs under Medicare Part D That Experienced an Extraordinary Price Increase, First Quarter 2010 to First Quarter 2015

Number of generic drugs

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>45</td>
<td>59</td>
<td>53</td>
<td>91</td>
<td>103</td>
</tr>
</tbody>
</table>

Source: GAO analysis of Medicare Part D prescription drug event data | GAO-15-706

Note: A price increase of at least 100 percent from the first quarter of one year to the first quarter of the next is considered an extraordinary price increase. To be considered an established drug, a drug had to be in the Medicare Part D claims data for each quarter from the first quarter of 2009 through the second quarter of 2015 and meet certain other data reliability standards. A total of 1,441 drugs met these criteria.
Chart 32: Late Phase R&D Pipeline by Top Therapy Areas

43-49 NAS/Year Expected by 2020

- **Oncology**: 51% (Phase 2: 430, Phase 3: 591, Pre-reg/Registered: 591)
- **Neurological**: 25% (Phase 2: 150, Phase 3: 350, Pre-reg/Registered: 350)
- **Dermatology**: 15% (Phase 2: 70, Phase 3: 115, Pre-reg/Registered: 115)
- **Vaccines**: 4% (Phase 2: 15, Phase 3: 22, Pre-reg/Registered: 22)
- **All Others**: 5% (Phase 2: 25, Phase 3: 38, Pre-reg/Registered: 38)

Competition/Affordability

Innovation

ACA

Hatch-Waxman

NIH FUNDED RESEARCH

Protection from Re-importation

Pricing freedom

Exclusivity

Patent