Federal Policy Opportunities to Address High Prescription Drug Prices

Waxman Strategies
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Understanding cost drivers in the pharmaceutical market
Major Federal Legislation Shaped Today’s Pharmaceutical Market

Congress has passed major laws to support a viable, affordable pharmaceutical market place, that includes:

- Generic drug competition,
- Coverage of prescription drugs, and
- Incentives for innovation.

<table>
<thead>
<tr>
<th>Year</th>
<th>Legislation</th>
<th>Description</th>
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<tr>
<td>1983</td>
<td>Orphan Drug Act</td>
<td>Provided incentives to develop drugs for rare diseases</td>
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<td>1984</td>
<td>Drug Price Competition and Patent Term Restoration Act</td>
<td>Commonly referred to as the Hatch-Waxman Act – created market protections for brand-name prescriptions drugs and abbreviated approval pathway for generic drugs</td>
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<td>1990</td>
<td>Omnibus Drug Reconciliation Act</td>
<td>Authorized the Medicaid Drug Rebate Program and expanded retail prescription drug coverage for low-income patients</td>
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<td>2003</td>
<td>Medicare Prescription Drug, Improvement, and Modernization Act</td>
<td>Authorized the Medicare Part D program and expanded retail prescription drug coverage for seniors</td>
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<td>2010</td>
<td>Affordable Care Act and Biologics Price Competition and Innovation Act</td>
<td>Expanded private insurance coverage for brand-name prescription drugs and created the biosimilar pathway and exclusivity for biologics</td>
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<td>2016</td>
<td>21st Century Cures Act</td>
<td>Facilitated development and approval of genetically targeted and variants protein targeted drugs for rare diseases as well as accelerated the FDA approval process for new drugs and biologics</td>
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Federal Policy Goals Have Sought Market Balance – New Targeted Reforms Are Needed

Drivers

- Affordability
- Innovation

Unpacking Policy Options to Promote Prescription Drug Affordability
Policy in Play for Prescription Drugs

Recap of Administration’s Actions to Date

- **FDA** – Steps or announced actions in sole-source markets, generics, biosimilars, anticompetitive behaviors, and drug importation.
- **HHS** – Blueprint solicited public input on competition, better negotiations in Medicare for PDPs, incentives for lower list prices, and lowering out-of-pocket costs.
- **CMS** – Proposed regulations for international reference pricing in Medicare Part B.
- **FY 2020 President’s Budget** – Included proposals that align with some bipartisan Congressional proposals - strongest signal yet that President would support federal legislation to tackle high drug prices.
Policy

Potential Areas for Bipartisan Reform in 116th Congress

1. Stop industry abuses that delay price competition
2. Streamline biosimilar and generic approval process
3. Encourage appropriate state policy innovation
4. Provide federal programs with better tools to purchase
5. Reform incentives in the supply chain and increase price transparency
6. Rethink government-funded drug development
7. Reform monopoly protections

House Bills in Play

- **House E&C and W&M Committees bipartisan legislation** – Stopping anti-competitive behaviors and improve transparency
  - H.R. 1781 (Carter) – Payment Commission Data Act of 2019
  - H.R. 938 (Schrader) – BLOCKING Act of 2019
  - H.R. 1520 (Eshoo) – Purple Book Continuity Act of 2019
  - H.R. 1503 (Kelly) – Orange Book Transparency Act of 2019
  - H.R. 1499 (Rush) – Protecting Consumer Access to Generic Drugs Act of 2019
  - H.R. 965 (Cicilline) – CREATES Act of 2019
  - H.R. 2113 (Neal) – The STAR ACT - bundles 4 previous bills related to drug price transparency: justify price increases, require PBM reporting on rebates, improve ASP reporting

- **House leadership/tri-Committee legislation (H.R. 3)** – Allowing the federal government to negotiate drug prices for high-priced drugs with little or no competition, addressing price increases in Part B and Part D, improving Medicare Part D, increasing federal funding for R&D, and improving the Medicare program broadly
Senate Bills in Play

- **Senate Judiciary Committee bipartisan package** – Stopping anti-competitive behaviors and improve transparency
  - S. 1227 (Grassley) – Prescription Pricing for the People Act of 2019
  - S. 440 (Cotton) – PACED Act of 2019
  - S. 1224 (Klobuchar/Grassley) – Stop STALLING Act
  - S. 1416 (Cornyn/Blumenthal) – Affordable Prescriptions for Patient Act of 2019
- **Lower Health Care Costs Act (S. 1895)** – Stopping anti-competitive behaviors, improve transparency, and enhance PBM reporting for group health plans
- **Prescription Drug Pricing Reduction Act (S. xx)** – Modernizing Medicare Part D and increasing transparency and accountability in Medicaid