Federal Policy Opportunities to Address High Prescription Drug Prices

Waxman Strategies

September2019

Waxman

Understanding cost drivers in the pharmaceutical market

Waxman

Drivers

Major Federal Legislation Shaped Today's Pharmaceutical Market

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

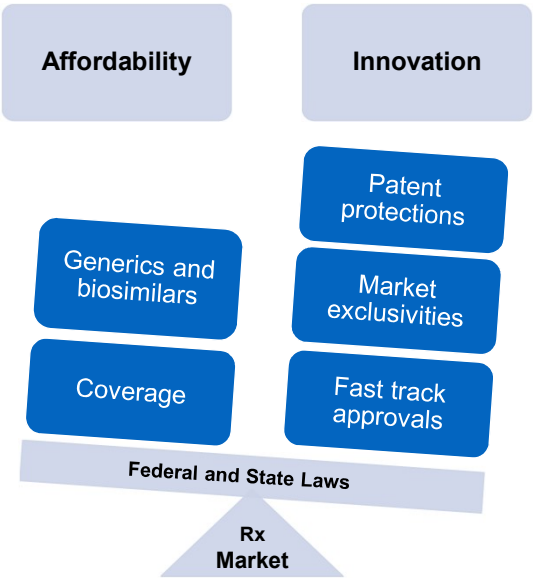
- Generic drug competition,
- Coverage of prescription drugs, and
- Incentives for innovation.

1983	1984	1990	2003	2010	2016
Orphan Drug Act – provided incentives to develop drugs for rare diseases	Drug Price Competition and Patent Term Restoration Act — commonly referred to as the Hatch-Waxman Act – created market protections for brand-name prescriptions drugs and abbreviated approval pathway for generic drugs	Omnibus Drug Reconciliation Act – authorized the Medicaid Drug Rebate Program and expanded retail prescription drug coverage for low-income patients	Medicare Prescription Drug, Improvement, and Modernization Act – authorized the Medicare Part D program and expanded retail prescription drug coverage for seniors	Affordable Care Act and Biologics Price Competition and Innovation Act – expanded private insurance coverage for retail prescription drugs and created the biosimilar pathway and exclusivity for biologics	21st Century Cures Act – facilitated development and approval of genetically targeted and variant protein targeted drugs for rare diseases as well as accelerate the FDA approval process for new drugs and biologics
Created 7-year market exclusivity for FDA-approved orphan drugs	Created 5-year market exclusivity for new drugs and 3-year market exclusivity for new clinical investigations of on-market drugs Provided patent restoration to manufacturers who lose patent time during the FDA review and approval process	Expanded market for drug manufacturers by guaranteeing coverage in Medicaid	Expanded market for drug manufacturers by guaranteeing coverage in Medicare	Created 12-year market exclusivity for new biologic drugs Expanded market for drug manufacturers by Guaranteeing coverage in most private insurance	Modified drug approval pathways that support patient-focused drug development as well as streamlined pathways for orphan drugs and other products

3

Drivers

Federal Policy Goals Have Sought Market Balance – New Targeted Reforms Are Needed



4

Policy in Play for Prescription Drugs

Waxman

Policy

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 –** Includesd proposals that align with some bipartisan Congressional proposals - strongest signal yet that President would support federal legislation to tackle high drug prices.

6

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

7

Policy

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

8

Policy

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

9

Waxman
1900 M Street, NW 3rd Floor
Washington, DC 20036
202.810.9166
info@waxmanstrategies.com
waxmanstrategies.com