US Payer Strategies for Managing Drug Prices, and Implications for Sustaining Research and Innovation

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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
Payer Strategies

- FDA is accelerating authorization based on limited evidence, creating payer uncertainty on value
- Payers are pushing back on utilization and access:
  - Formulary exclusions
  - Prior authorization and step therapy for prescription
  - Physician payment incentives to select cheaper option
  - Rising consumer cost sharing
- These strategies target reductions in volumes (prescription/adherence) and reductions in price
- Competition is fierce in large specialty classes:
  - HCV, multiple sclerosis, auto-immune biologics, diabetes, some cancers, cardiovascular
- Greater reliance on HTA, with some explicit agreements to accept ‘value-base’ prices in exchange for enhanced access
Increased Payer Resistance to Prescription of Expensive Treatments

- Tighter and more stringent criteria for prior authorization
- Criteria increasingly linked to disease severity, going ‘inside the FDA label’
- Requirement for documentation, not merely MD attestation
- More stringent step therapy, with more patients required to ‘try and fail’ drugs

Source: 2017 AMA Prior Authorization Physician Survey
Employees and Patients Face Ever-Higher Cost Sharing

Figure 15
Average General Annual Health Plan Deductibles for Single Coverage, 2006-2017

* Estimate is statistically different from estimate for the previous year shown (p < .05).

NOTE: Average general annual deductible is among all covered workers. Workers in plans without a general annual deductible for in-network services are assigned a value of zero.

Intense Prior Authorization and Cost Sharing Are Slowing Drug Adoption, Relative to Projections

† 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
Policy Developments

- Political and policy context
- Trump administration proposals
- Democrat proposals
Political Context

- All eyes on the 2020 national elections
  - Trump seeks to rally populist base by bashing pharma prices; traditional Republicans are pro-industry
  - Democrats seek to rally liberal base by bashing pharma prices; moderate Dems seek non-radical changes

- Pharma is relentless criticized, required to justify prices, R&D spending, marketing etc. before Congress
- Payers (PBM) also are relentlessly criticized. Politicians cannot decide whether they are the problem, the solution, or both
Energized Trump Administration

Trump Administration has proposed a wide range of potentially radical proposals, though it is not clear how much political capital they will spend (don’t want to collaborate with Dems and give them a victory).

Most (if any) of these never will be enacted, but they contribute to an atmosphere of siege of the industry.

Source: Nephon Research, 2019
Energized Democrats

- Democrats in Congress, as well as Democratic candidates for president, also have proposed a wide range of radical proposals
  - Expand Medicare (single payer), which will lead to administered pricing and HTA for drugs
  - Even without expansion, permit Medicare Part D plans to negotiate prices collectively with pharma
  - Some states seek to impose ceiling on annual prices increases; some seek to impose ceiling on price levels
  - Some favor direct regulation of prices for biologics, arguing that reliance on biosimilars has failed
  - Some would weaken patent protections
    - Prohibit patent extension strategies by pharma
    - Enforce ‘march in rights’ to establish lower prices
    - Greater reliance on government grants to fund R&D
    - Price regulation based on public utility model
  - None of this has been approved. None may be approved due to opposition from Republicans. It is not clear that Trump would collaborate, as he would not want to give the Dems a policy victory
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 and Governmental Funding for Pharmaceutical R&D in the United States

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.

H Moses et al. JAMA 2015;313(2):174-189
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 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
Innovation Prizes To Support Cell And Gene Therapy

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