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

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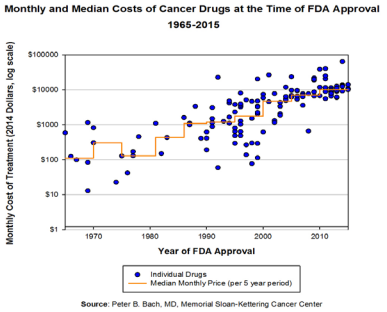
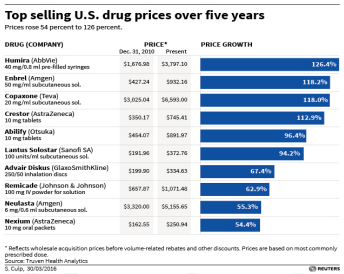
Payer and Policymaker Arousal

- 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



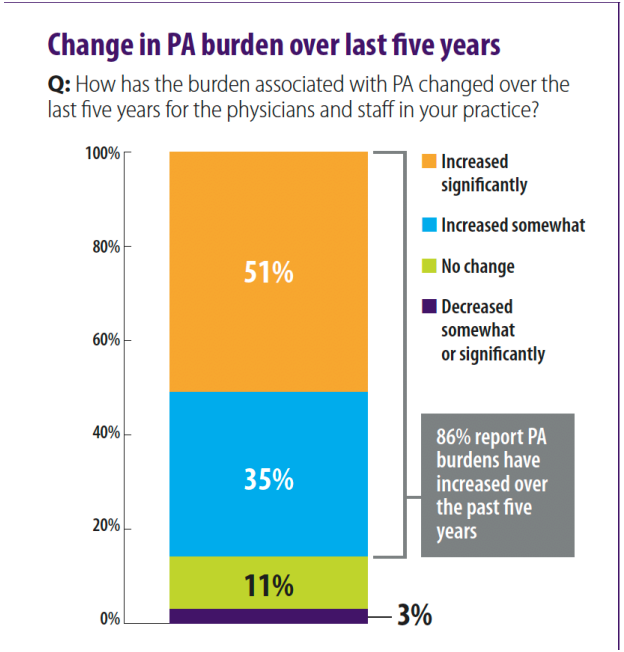


Payer Strategies

- 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

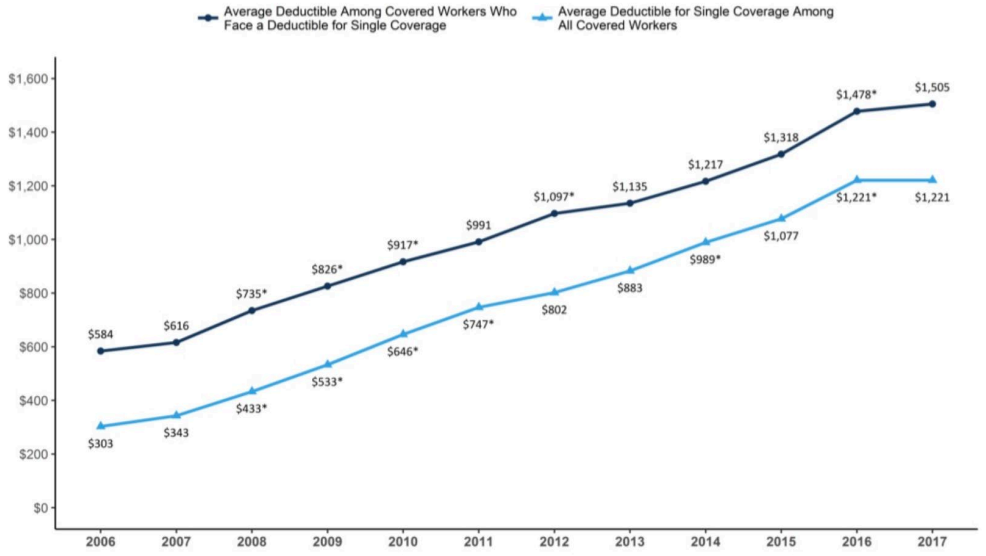


Source: 2017 AMA Prior Authorization Physician Survey

Employees and Patients Face Ever-Higher Cost Sharing

Figure 15

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



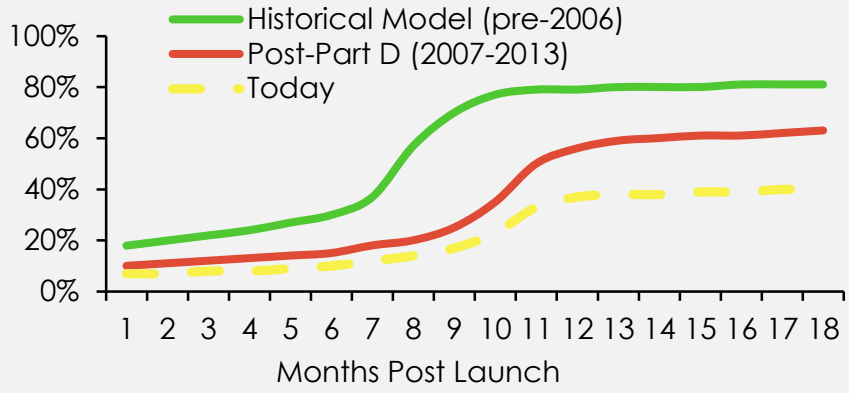
* Estimate is statistically different from estimate for the previous year shown ($p < .05$).

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.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2017

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

Percent of Potential Post-Launch Adoption Actually Achieved, With Changing Intensity of Payer Management

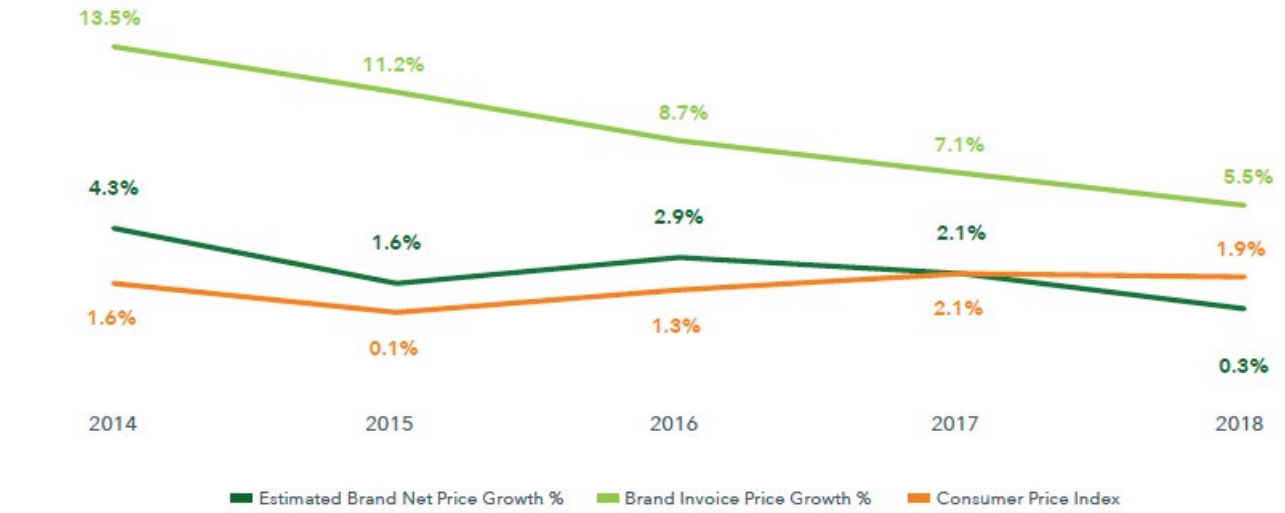


‡ *Source: QuintilesIMS,* Payer and Managed Care Insights

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

Exhibit 18: Protected Brand Invoice and Net Price Growth %



Source: IQVIA National Sales Perspectives, Jan 2019; IQVIA Institute, Apr 2019

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)

Blueprint Proposal Immediate Actions	Action Taken
Increase Medicare formulary flexibility	8/29/18
Eliminate cost-sharing on generic drugs for low-income beneficiaries	
Require Medicare Part D plans to apply rebates at the point-of-sale	1/31/19
Exclude manufacturer discounts from beneficiary OOP costs in the donut hole	
Establish a beneficiary out of pocket maximum in the catastrophic phase coverage	
Steps to prevent manufacturer gaming of regulatory processes such as REMS	5/17/18
Measures to promote innovation and competition for biologics	7/18/18
Leveraging the Competitive Acquisition Program in Part B	10/25/18
Prioritize FDA review where there is limited to no competition	8/8/18
FDA evaluation of requiring manufacturers to include list prices in advertising	8/23/18
Update Medicare's drug-pricing dashboard so price increases and generic competition is transparent	5/15/18
Pharmacy "gag" rule closes	10/10/18
Information on price increases and low cost alternatives in the Part D EOB	
Experimenting with value-based purchasing in federal programs contracting	
Report to the President on Medicare Part B negotiation for Part D	8/7/18
Assessing the problem of foreign free-riding protection	10/25/18
Proposals to stop Medicaid from raising prices in the private market	

Blueprint Proposal Further Opportunities	Action Taken
Requiring site neutrality in payment	
Additional efforts to promote the use of biosimilars	7/18/18
Considering fiduciary status for Pharmacy Benefit Managers (PBMs)	1/31/19
Restrict the use of rebates, incl. revisiting the AntiKickback statute	1/31/19
Reforms to the 340B Drug Discount Program	
Value-based purchasing in fed programs, incl. indication-based pricing and L-T financing	
Considering how to encourage sharing of samples needed for generic drug development	
Removing government impediments to value-based purchasing by private payers	
Evaluating the accuracy and usefulness of current national drug spending data	
Tools to address foreign government threats of compulsory licensing or IP theft	11/30/18
Incentives to discourage manufacturer price increases for drugs used in Part B and Part D	8/20/18
Reforms to the Medicaid Drug Rebate Program	8/20/18
Measures to inform Medicare Part B and D beneficiaries about lower-cost alternatives	
Providing better annual information on costs to Part D beneficiaries	
Considering changes to HHS regulations regarding drug copay discount cards	

Source: Nephron Research, 2019

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

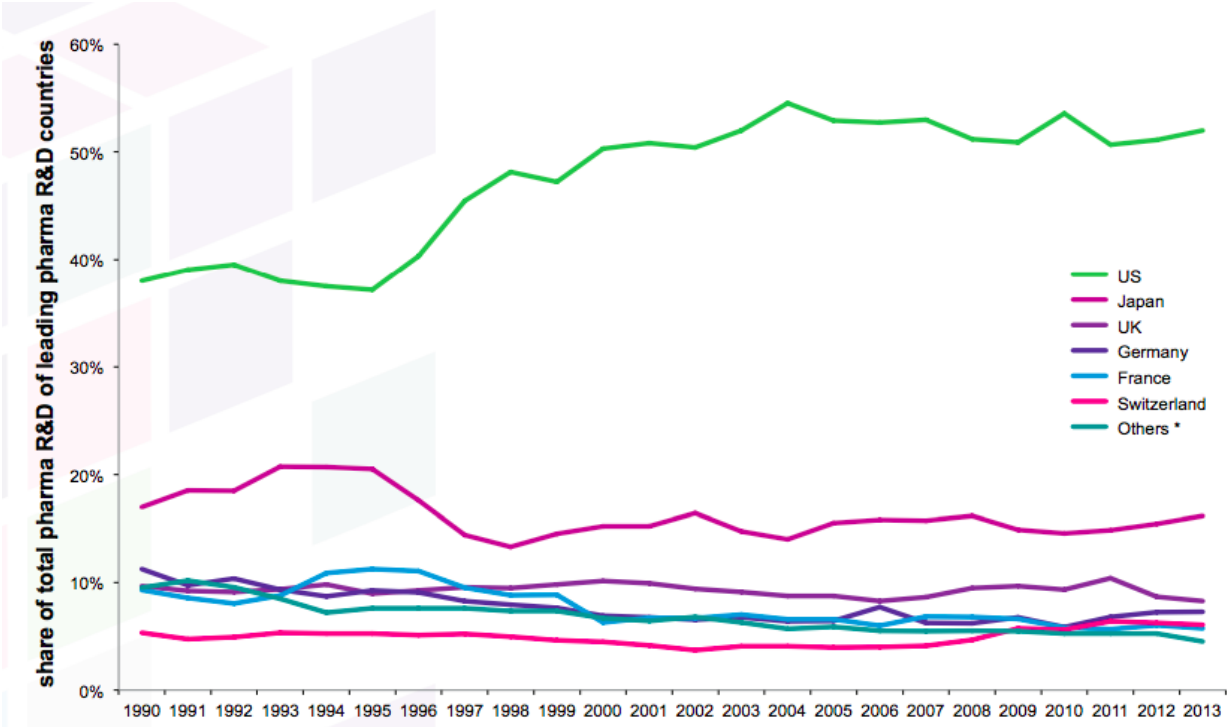
Energized Democrats

- 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

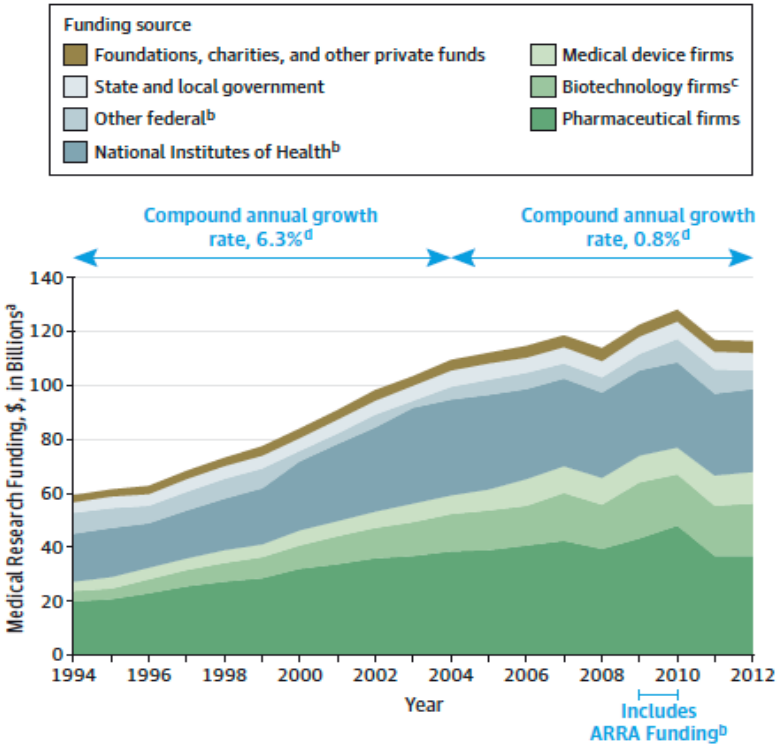


https://www.abpi.org.uk/media/1119/investing_innovation.pdf

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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