

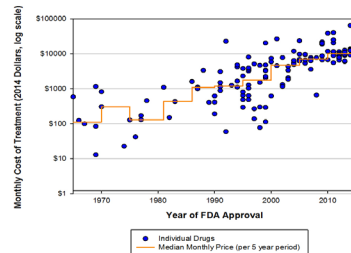
Sustaining Innovation in the US Pharmaceutical Market

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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

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval
1965-2015



Source: Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center

Top selling U.S. drug prices over five years

Prices rose 34 percent to 126 percent.

DRUG (COMPANY)	Dec. 31, 2010	Present	PRICE GROWTH
Humira (Abbott) 40 mg/0.4 ml pre-filled syringe	\$1,678.98	\$3,787.10	126.4%
Exelun (Amgen) 50 mg/ml subcutaneous sol.	\$427.24	\$932.18	118.0%
Copaxone (Teva) 20 mg/ml subcutaneous sol.	\$3,023.04	\$6,593.00	118.0%
Crestor (AstraZeneca) 40 mg tablets	\$590.17	\$745.41	112.9%
Abilify (Otsuka) 10 mg tablets	\$454.07	\$901.97	95.4%
Lantus Solostar (Sanofi SA) 100 units/ml subcutaneous sol.	\$381.96	\$372.76	-2.4%
Advair Diskus (GlaxoSmithKline) 250/10 inhalation disc	\$199.90	\$194.43	-2.7%
Brevelin (Johnson & Johnson) 100 mg IV powder for solution	\$687.87	\$1,071.40	62.3%
Neulasta (Amgen) 6 mg/0.4 ml subcutaneous sol.	\$3,320.00	\$5,195.65	55.3%
Neutrogena (AstraZeneca) 10 mg and patches	\$162.65	\$100.94	-37.4%

* Reflects wholesale acquisition prices before volume-related rebates and other discounts. Prices are based on most commonly reported dose.
Source: Tufts Health Analytics
5. Culp, 30/09/2018

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Pharmaceuticals: the Least Loved Industry

Americans' Views of U.S. Business Industry Sectors, 2019

For each of the following business sectors in the United States, please say whether your overall view of it is very positive, somewhat positive, neutral, somewhat negative or very negative.

	Total positive	Neutral	Total Negative	Net positive
	%	%	%	
Restaurant industry	66	25	8	+58
Computer industry	61	28	11	+50
Grocery industry	58	27	15	+43
Farming and agriculture	58	24	17	+41
Travel industry	52	35	13	+39
Accounting	45	45	9	+36
Automobile industry	53	29	18	+35
Retail industry	50	28	19	+31
Real estate industry	49	31	19	+30
Banking	50	25	25	+25
Electric and gas utilities	47	28	24	+23
Sports industry	45	29	25	+20
Airline industry	42	32	23	+19

Telephone industry	42	32	26	+16
Publishing industry	39	36	24	+15
Internet industry	43	26	30	+13
Movie industry	41	31	28	+13
Education	45	18	35	+10
Television and radio industry	40	27	32	+8
The legal field	35	34	30	+5
Oil and gas industry	39	25	36	+3
Advertising and public relations industry	33	32	34	-1
Healthcare industry	38	14	48	-10
The federal government	25	23	52	-27
Pharmaceutical industry	27	15	58	-31

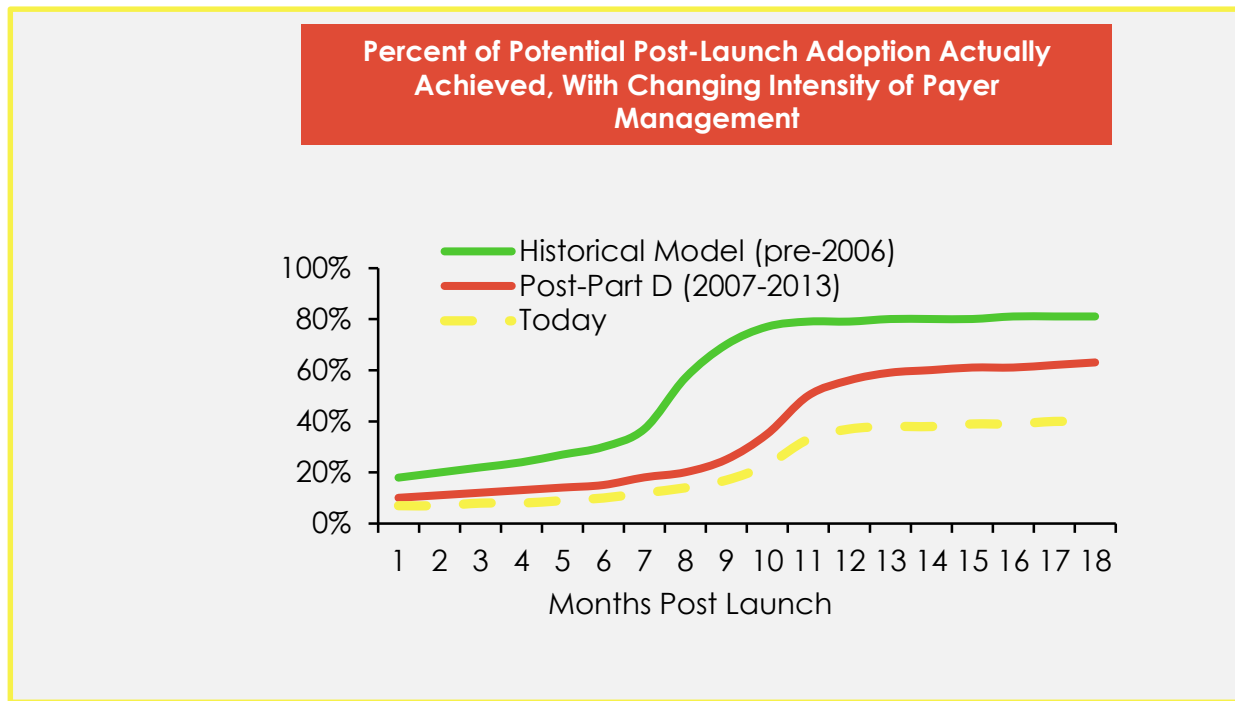
GALLUP, AUG. 1-14, 2019

Responses by private insurer and public programs



- Private insurers take the lead, with public payers benefitting from average or lowest net prices negotiated by private payers
- The strategy pursued by private insurers is to limit physician prescription and patient access to specialty drugs, with the offer to partially relax restrictions in exchange for price rebates
- These access barriers, including prior authorization and consumer cost sharing, are rapidly becoming more intense, sparking a backlash from physicians and patients
- Both insurers and manufacturers face strong adverse publicity
- The strategies have been effective in reducing the growth, and in some cases the level, of net prices

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

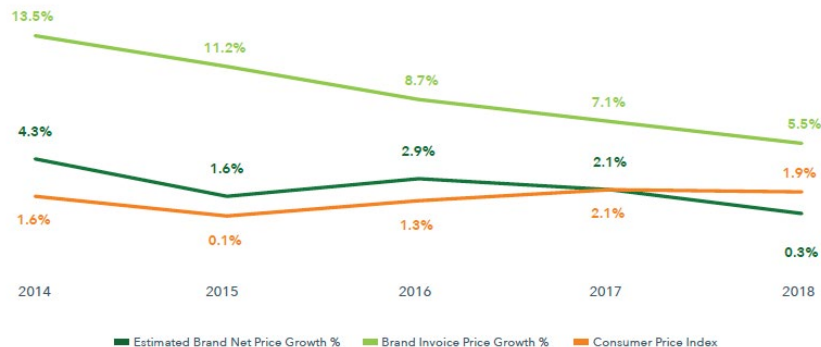


‡ Source: QuintilesIMS, Payer and Managed Care Insights

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

Exhibit 18: Protected Brand Invoice and Net Price Growth %



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

Source: IQVIA

List vs. Net Price Growth for Brand-Name Drugs, 2014 to 2019



Source: Drug Channels Institute analysis of SSR Health data. List and estimated net pricing figures are based on data for approximately 1,000 brand-name drugs with disclosed U.S. product-level sales from approximately 100 currently or previously publicly traded firms. The products and companies account for more than 90% of U.S. branded prescription net sales. Net prices equal list price minus off-invoice rebates and such other reductions as distribution fees, product returns, chargeback discounts to hospitals, price reductions from the 340B Drug Pricing Program, and other purchase discounts. Data for 2019 reflect first three quarters only.

Published on Drug Channels www.drugchannels.net on January 9, 2019.

Source: SSR Health

Possible Futures: Increased public regulation of prices



- Congressional Democrats and President Trump are promoting very aggressive legislation to support price negotiations and regulation
- Congressional Republicans traditionally have opposed regulation, but face strong public pressure to cooperate
- All need to 'do something' but neither the Democrats nor the Trump administration want to give the other a perceived policy victory
- Chances for cooperation and successful legislation are limited
- Legislation will depend on the outcome of 2020 elections, which cover the presidency, all Congressional seats, and 1/3 of Senate seats
- A victory by Democrats would almost certainly result in stringent new drug price negotiations and regulations

Congressional Democrats Focus on Launch Price “Negotiations” with Heavy Regulation

- Government would negotiate prices for Medicare, which would apply to private payers
- Upper limit on prices would be 120% of prices for other wealthy nations (reference pricing)
- If manufacturers refuse to price below benchmarks, they face 75% tax on sales

STAT⁺₂

Pelosi's drug pricing plan is more aggressive than expected

By [Nicholas Florko](#)³ [@NicholasFlorko](#)⁴ and [Lev Facher](#)⁵ [@levfacher](#)⁶

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Bipartisan Senate Committee and Trump Emphasize Limits on Price Increases

- Manufacturers must rebate to Medicare any price increases faster than inflation
- Limits on consumer cost sharing, requiring private insurers to pay greater share of total costs
- No controls on launch prices, which will continue to be negotiated by private insurers

HEALTH AFFAIRS BLOG

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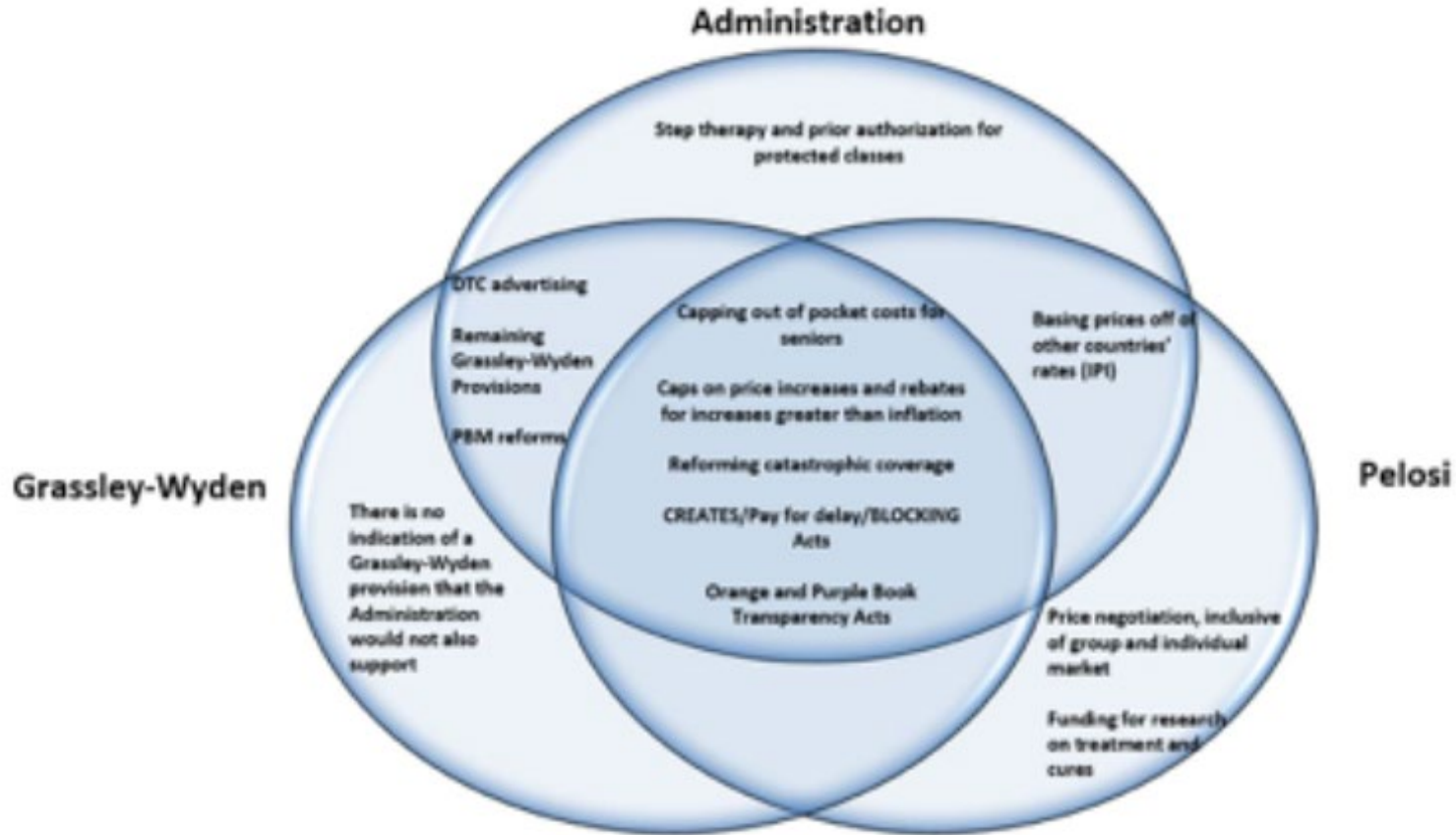
Understanding The Senate Finance Committee's Drug Pricing Package

Rachel Sachs

JULY 26, 2019 DOI: 10.1377/hblog20190726.817822



Overlap between Senate (G-W), House (Pelosi), Trump proposals



Implementation limitations of policy proposals

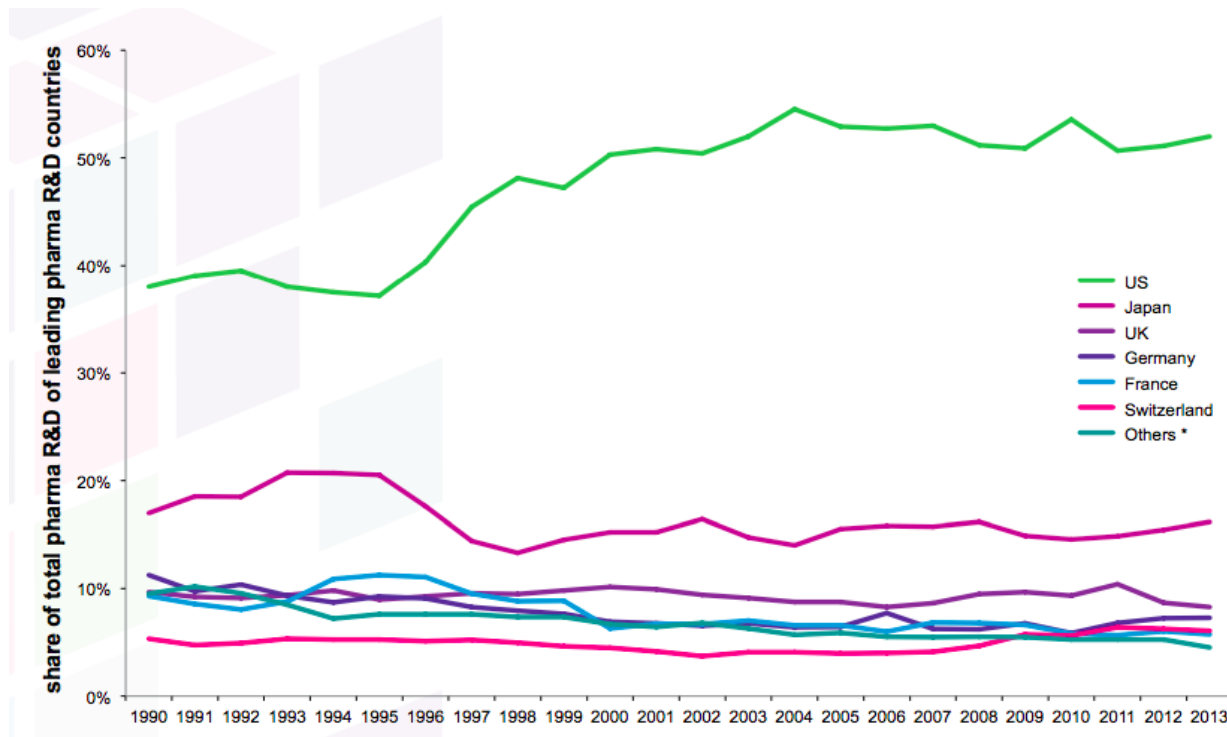
- The political debate ignores the challenges facing any centralized process for assessing value and negotiating/regulating prices
- How to assess value? Private ICER is favored by Democrats, opposed by Republicans. No public HTA entity exists
- Which process for Medicare negotiations? The stringent limits on outcomes (limited by global reference prices, US price inflation, compulsory licensing, and/or mandatory arbitration) make this more a process of regulation than negotiation
- How would Medicare prices affect private insurers? Will private insurers be allowed to limit payments to Medicare levels, or will manufacturers be able to increase prices to private payers to offset reduced prices to public payers?

Options for Policymakers: 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

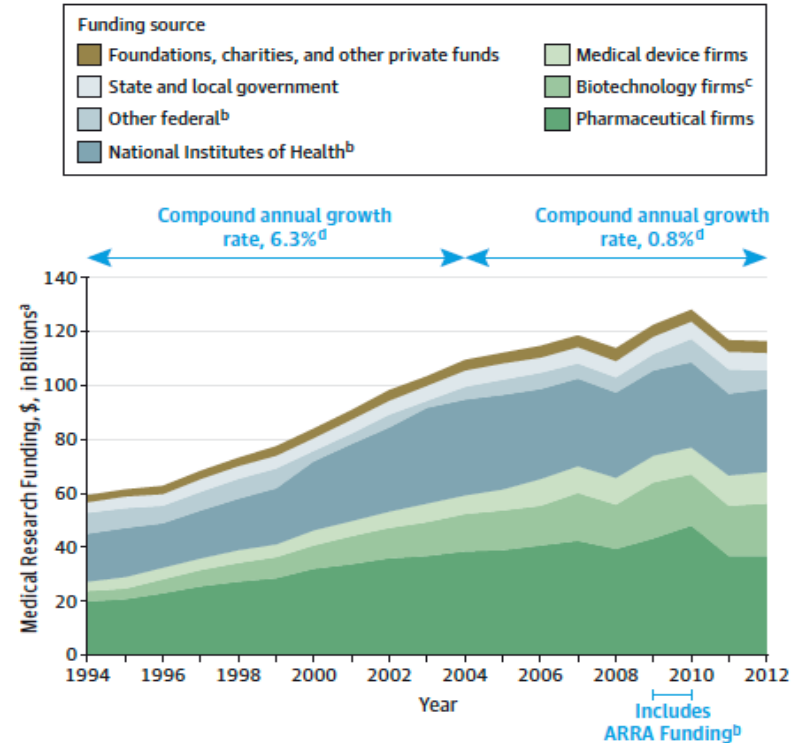


https://www.abpi.org.uk/media/11119/investing_innovation.pdf

US Industry and Governmental Funding for Pharmaceutical R&D

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



Which Sources of R&D Funding Can Be Used to Supplement Industry Revenues?

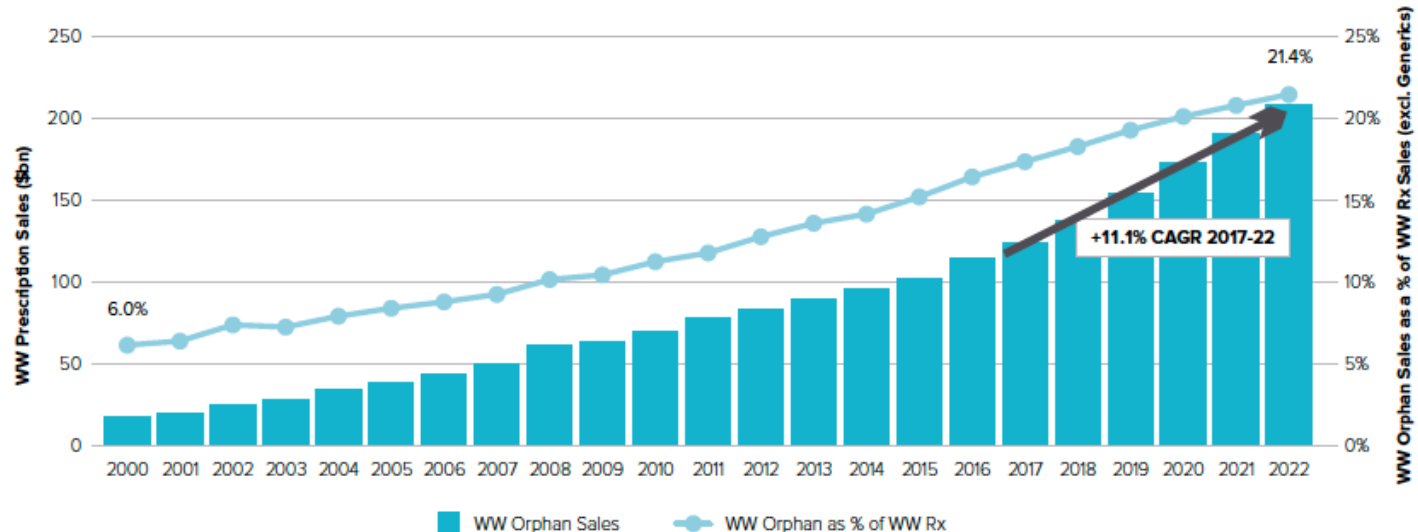
- Expanded tax-based support for basic science, through NIH and other entities
- Expanded tax-based support for translational science and product development, through NIH and other entities
- Expanded tax credits for R&D, with especially generous credits for investments in areas of especially high need
- 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

Do we Have Examples of Successful Policy Initiatives to Expand Investment and Innovation?

The Orphan Drug Act of 1984

Worldwide Orphan Drug Sales & Share of Prescription Drug Market (2000-2022)

Source: EvaluatePharma® February 2017





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