

Price Compression in the US Pharmaceutical Market: Options for Manufacturers, Payers, & Policymakers

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Overview

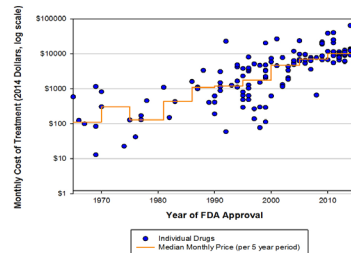


- Compression of drug prices and margins
- Options for manufacturers: value-based access
- Options for payers: the German framework
- Options for policymakers: sustaining innovation

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%
Exelbri (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	-2.8%
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	-38.4%

* 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

© REUTERS

Drug Pricing in the Good Old Days

Consider the lobster roll

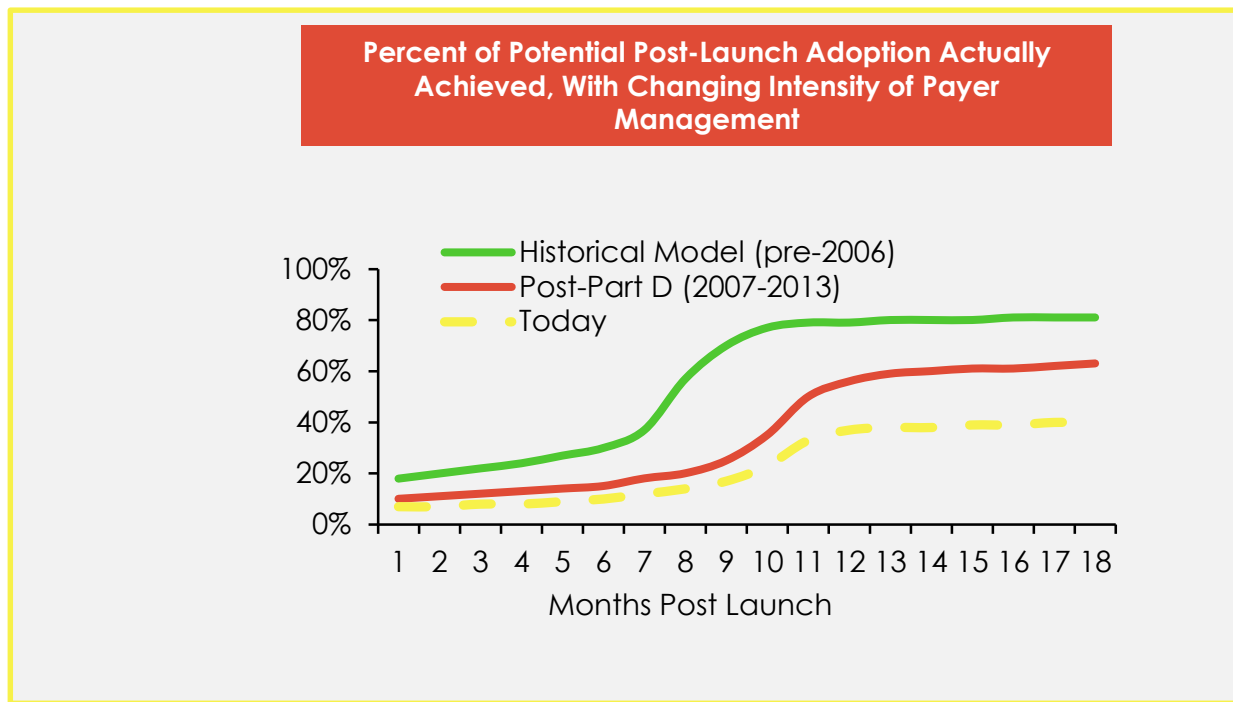
Why Americans pay more for lunch than Britons do

Even when they are buying the same sandwich



Source: The Economist, September 7, 2019

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

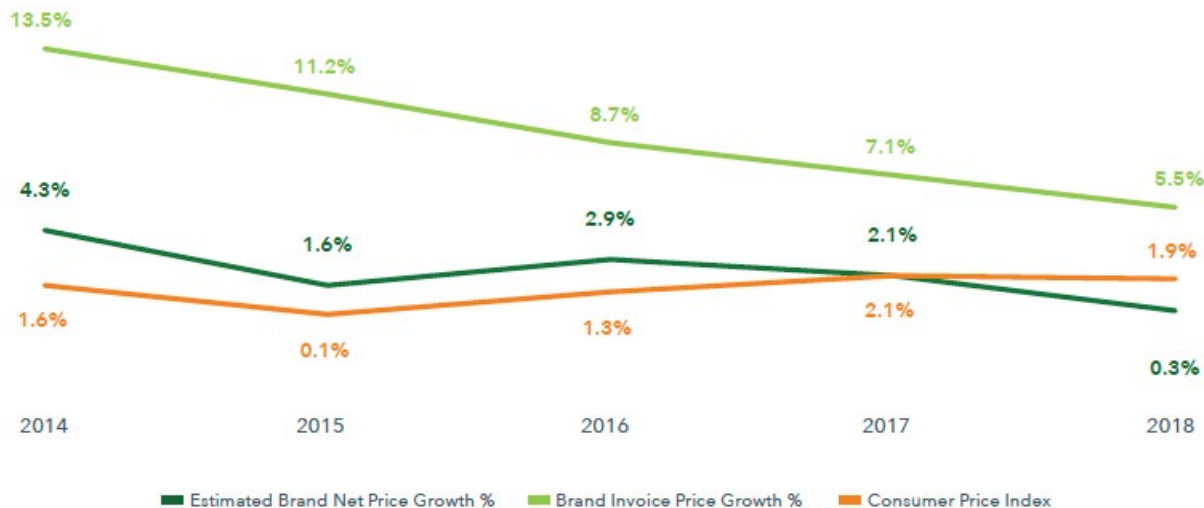


‡ Source: QuintilesIMS, Payer and Managed Care Insights

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 %

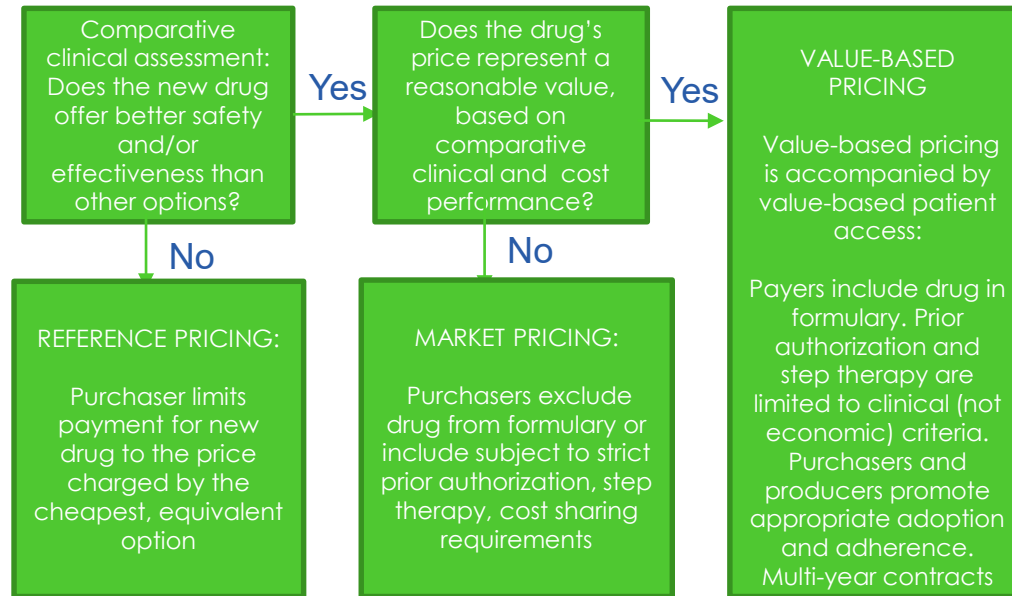


Options for Manufacturers: Value-based patient access



- Manufacturers are under severe pressure to accept lower ‘value-based’ prices. What could and should they demand in exchange?
- Current market negotiations impose severe burdens on physicians (prior authorization) and on patients (cost sharing), which are based largely on financial rather than clinical considerations
- Manufacturers should negotiate value-based access in exchange for value-based prices

The Emerging Logic of Value-Based Pricing and Patient Access



Further Reading

JAMA, June 5, 2018

VIEWPOINT

Value-Based Pricing and Patient Access for Specialty Drugs

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Insurers, employers, and pharmacy benefit managers (PBMs) bemoan high prices for specialty drugs and respond by closely managing patient access to drugs through prior authorization, step therapy, and consumer cost sharing. Pharmaceutical firms are concerned when the use and sale of specific drugs fall short of projections. High prices and access barriers compound each other. Pharmaceutical firms help physicians to navigate utilization management and patients to cover their financial obligations, but then must consider the costs of these programs in subsequent prices. Payers respond to price increases by intensifying access management. Physicians and patients are caught between payers and manufacturers, facing ever-higher administrative and financial obstacles.

The list prices charged for specialty drugs have been rising rapidly in the past decade, both at the time of initial market launch and through post-launch increases.¹ Between 2005 and 2013, for example, the launch price of new oncology drugs increased 12% per year without commensurate increases in efficacy, implying that the price per life-year gained increased from \$139 000 to

been interrupted. When poorly designed and implemented, step therapy programs may also make it difficult for physicians and patients to avoid having to start again with therapies that patients have already “tried and failed” before (eg, when enrolled in a different health plan). Some health insurance plans feature annual deductibles and percentage co-insurance instead of dollar co-payments. These have created meaningful financial barriers to specialty drug access. In 2016, 23% of individuals with employment-based insurance had an annual deductible of \$2000 or more⁵ and 48% of Medicare Part D enrollees were subject to percentage co-insurance for specialty drugs.⁶

The concerns of insurers, manufacturers, physicians, and patients highlight the failure of the current model of drug pricing and access in the United States. Innovative purchasers and manufacturers are potentially interested in closer and longer-term relationships that support the need of the purchasers for affordability and the need of the manufacturers for patient access and net revenue. This requires a new framework for linking price negotiations with improved patient access.

Options for Payers: Learning from the German System of Price Determination



- The US is negotiating price (rebates) in exchange for better patient access, but in a very inefficient and contentious manner
- Germany is very similar to US (similar income/person, private multi-payer insurance) yet has developed system of drug assessment and pricing that has gained broad (if grudging) support among all stakeholders
- How do they do it? Can the US learn anything here?

The German System of Drug Assessment & Price Negotiation



Germany at a Glance

Population = 82 million
Regionalized = 16 states
Rank of economy = #1 Europe

No public insurer
150 competing private insurers

Culture of patient access
Insurers must cover all drugs
approved by EMA (FDA)
Insurers cannot impose prior
authorization on physicians
Insurers cannot impose high
cost sharing on patients

Who Assesses Clinical Value?

- The German system uses a centralized assessment process, managed by the GBA (which is governed by associations of physicians, insurers, hospitals, & patient advocates)
- The process is public and transparent: analytic methods used, hearings conducted, documents used, final assessments
- Technical aspects of the assessments are delegated by the GBA to the independent IQWiG institute
- Participation is encouraged by manufacturers through early consultations, dossier preparation, public hearings
- Participation is encouraged by patient advocates, with insights into patient experience of disease and treatment
- Participation is encouraged by physician associations, to ensure GBA does not abrogate professional authority
- Participation is encouraged by insurers (Sickness Funds) to obtain insights into patterns of utilization and spending

Why Do Negotiating Parties Come to Agreement on Prices?

- A large, attractive market for drug manufacturers: prosperous economy, patient demand for access, strong physician authority over prescription, high visibility in other EU nations
- Highly structured negotiations : 4 sessions in tight timeframe
- Mandatory arbitration: If negotiators are not success, drug price is determined by Arbitration Board. Board does not 'split the difference' between final payer and manufacturer offers, but conducts own assessment and makes its own price decision
- Repeated game: Aggressive price demands by manufacturers for drugs without substitutes could lead to aggressive insurer demands for rebates for drugs with substitutes
- Manufacturers are not allowed to unilaterally increase prices. Drug prices can only change subsequent to new assessment by GBA and new negotiations with insurers

How Does the System Support Physician Prescription and Patient Access?

- Immediate insurance coverage of all drugs after EMA authorization; insurers cannot create their own formularies except for generics and biosimilars
- Negotiations consider prices in other EU nations but Germany is willing to pay higher prices to ensure fastest market access
- A risk adjustment system protects insurers who enroll patients needing very expensive drugs, and all insurers pay same prices
- No insurer can impose prior authorization restrictions on physicians
- Cost sharing is limited by statute to minimal levels (10 Euro per prescription). There are no deductibles.

Further Reading

STAT, June 27, 2019

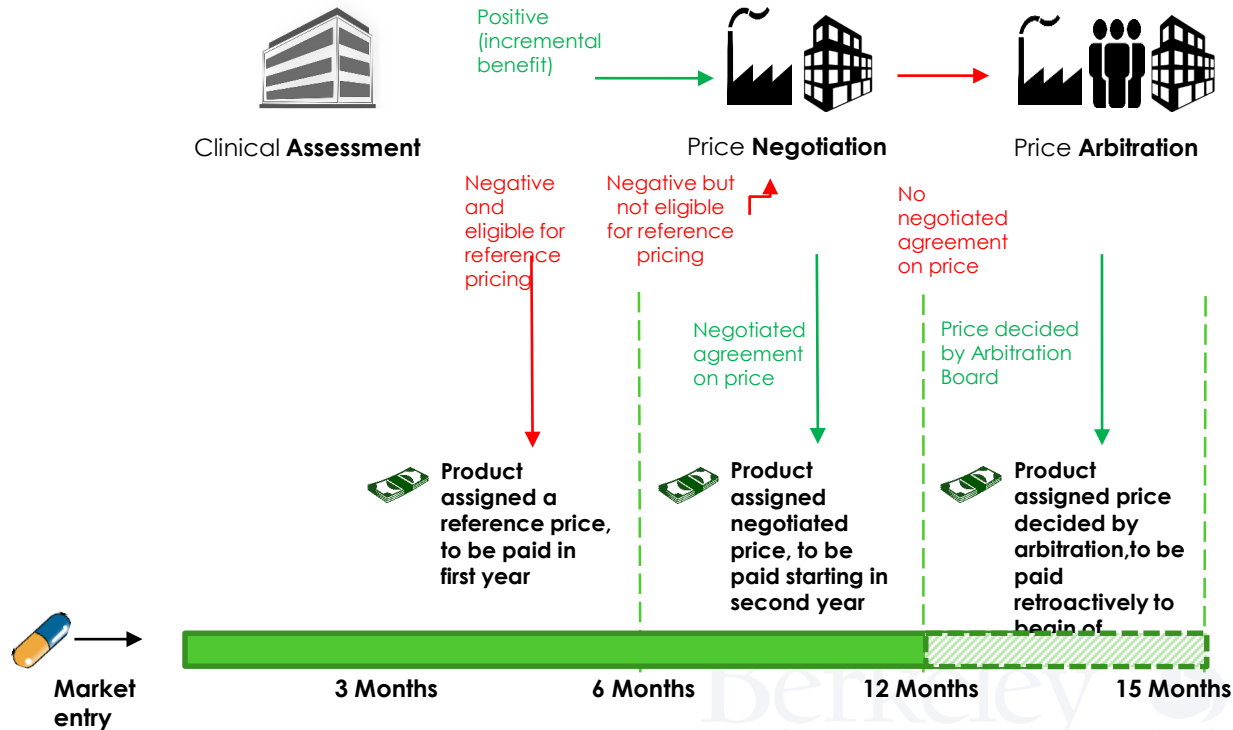
Negotiating drug prices without restricting patient access: lessons from Germany

By James C. Robinson, Dimitra Panteli, *and* Patricia Ex

June 27, 2019



The Joint Federal Committee Evaluates New Drugs; the Insurer Association Negotiates Prices based on these Evaluations; Failure to Agree Leads to Binding Arbitration

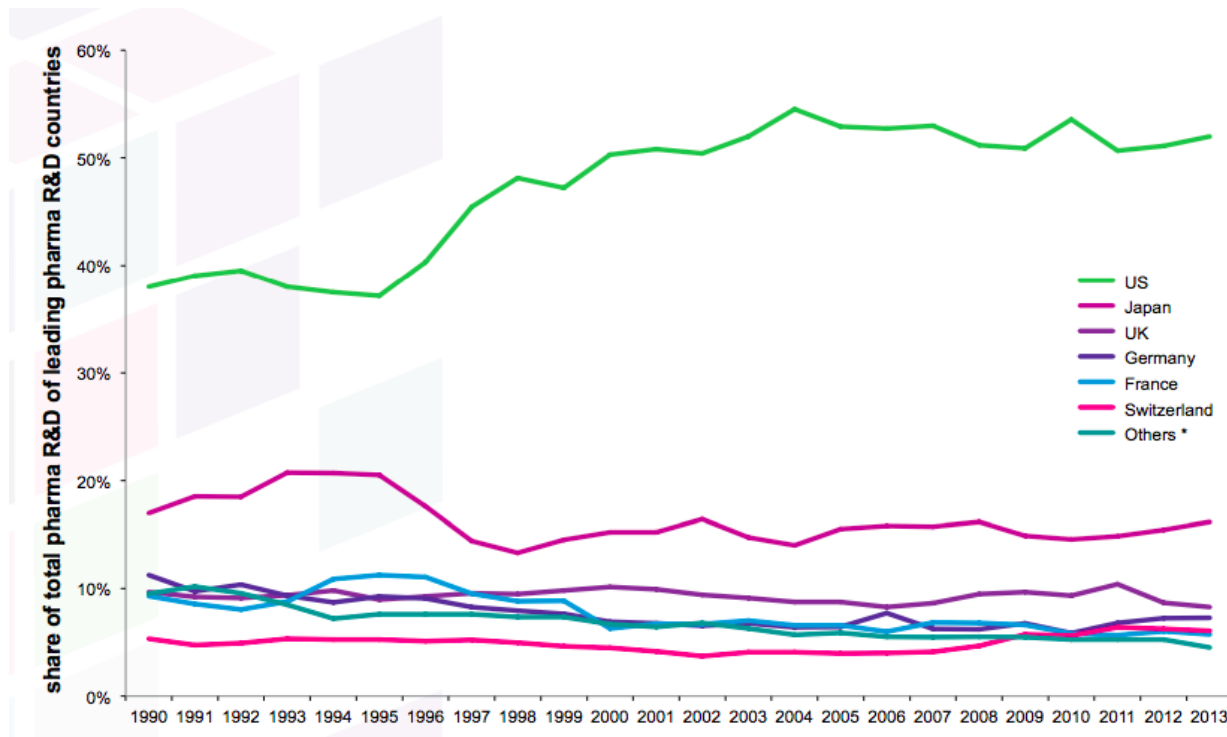


Options for Policymakers: How to Sustain Innovation and the Life Sciences Industry?



- 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

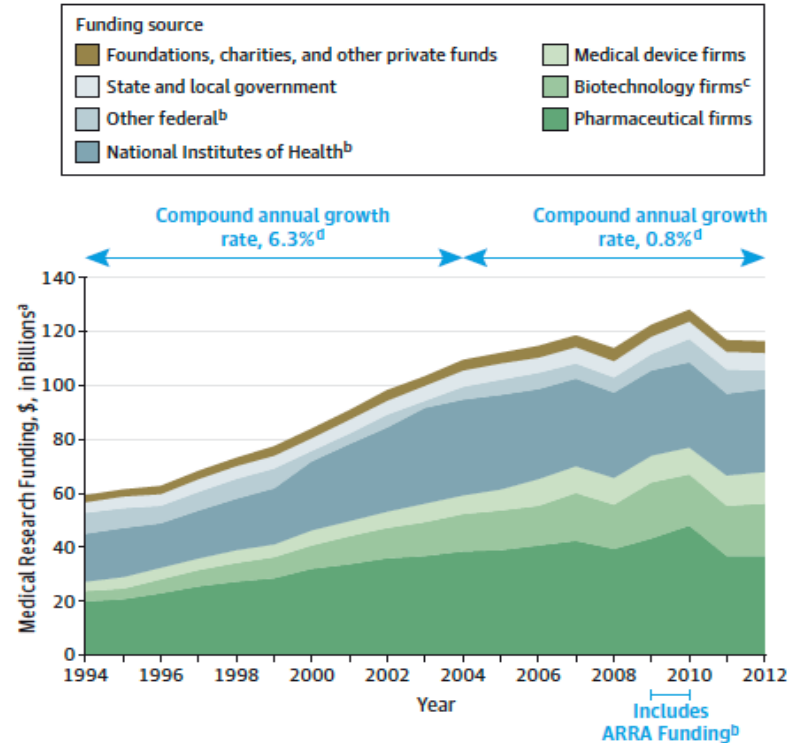


https://www.abpi.org.uk/media/11119/investing_innovation.pdf

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?

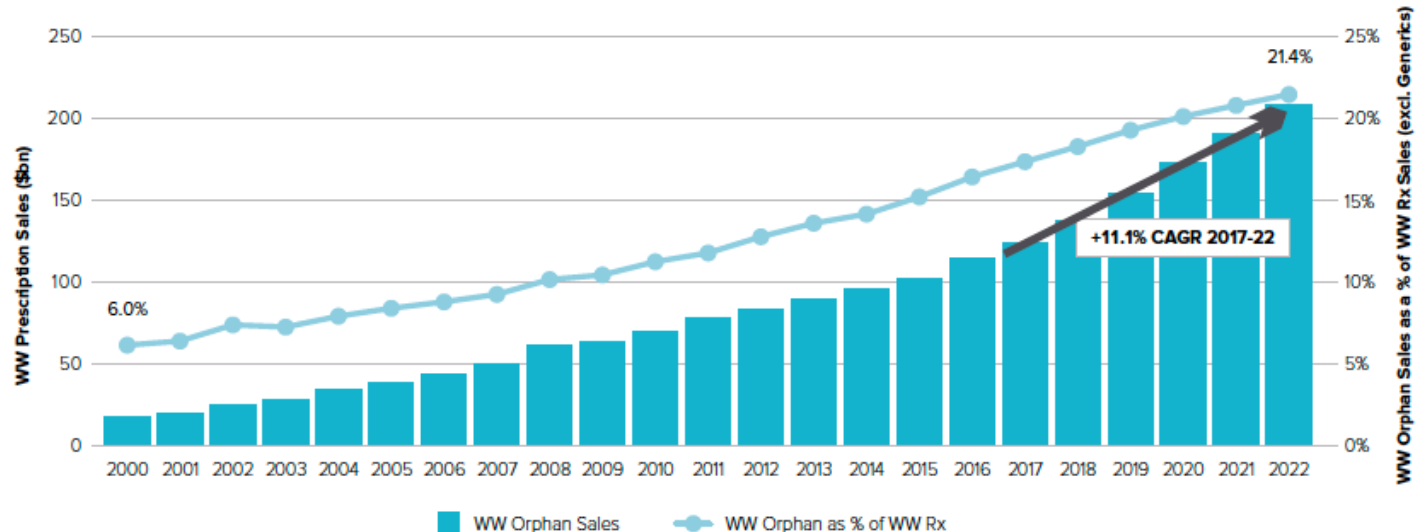
- Expanded tax-based support for basic science, through NIH and other entities
- Expanded tax-based support for translational science and product development, through NIH and other entities
- Expanded tax credits for R&D, with especially generous credits for investments in areas of especially high need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