

Market for Pharmaceuticals

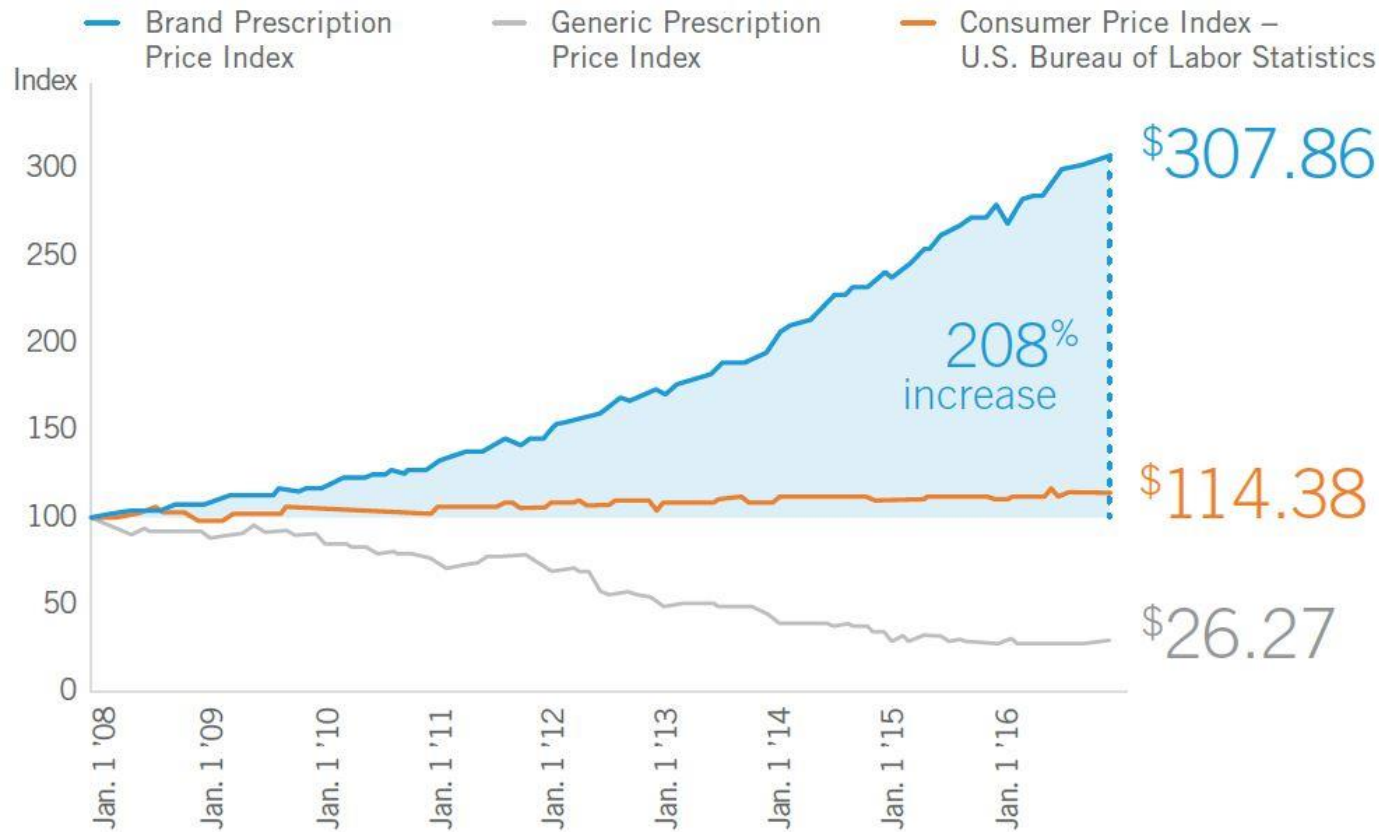
Pharmaceuticals

- Biopharma will be key component of the specialized modules we will do a bit later. So this set of pharma-related slides in particular are helpful as broader context
- First set of slides provide some data and informational items
- Miscellaneous details in the last set of slides

Pharmaceuticals – Price Index

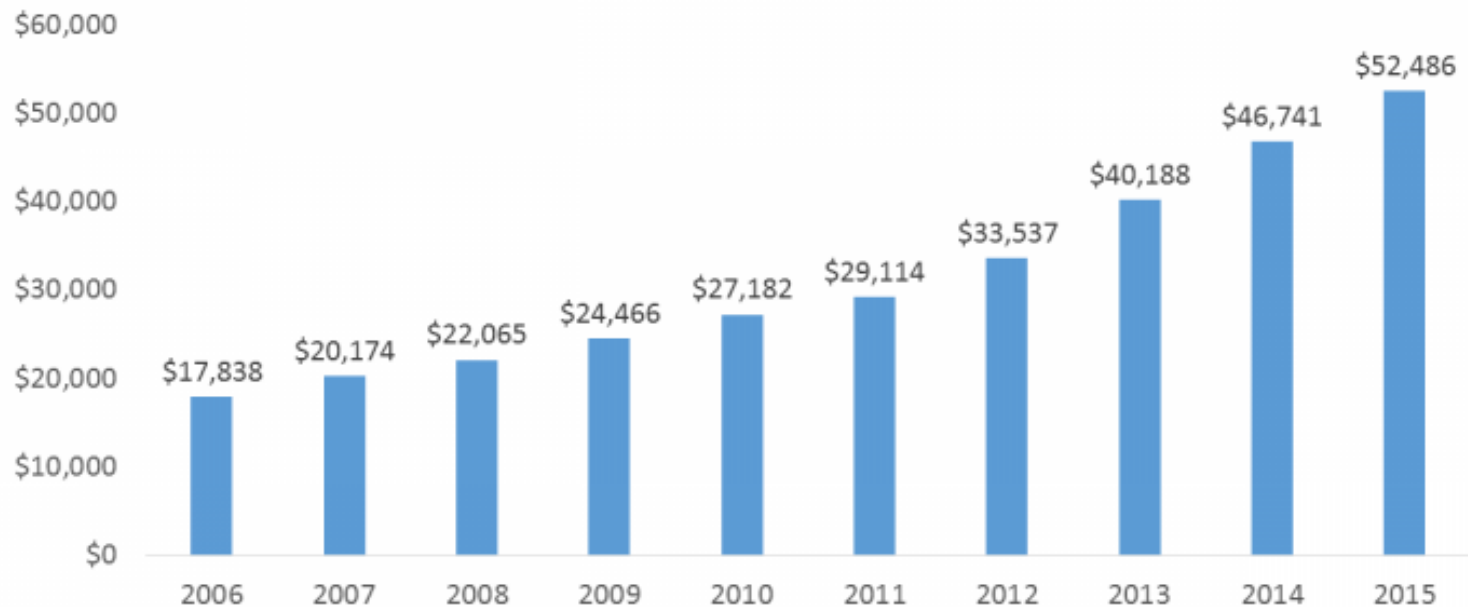
EXPRESS SCRIPTS PRESCRIPTION PRICE INDEX

2016



Pharmaceuticals – Prices

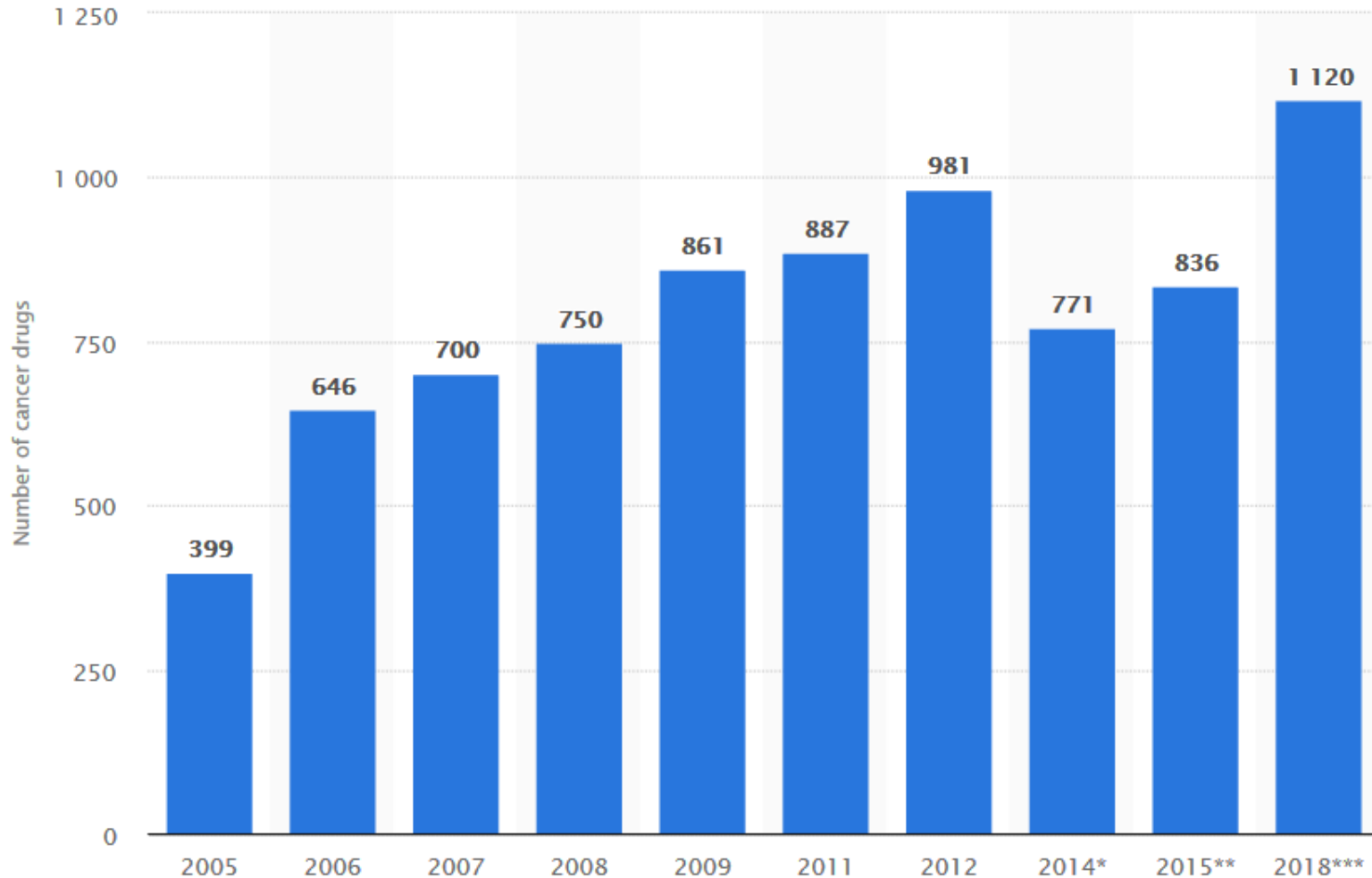
The Average Annual Price of Specialty Drugs Tripled
Between 2006 and 2015



Source: Rx Price Watch Report – Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2015, AARP, September 2017

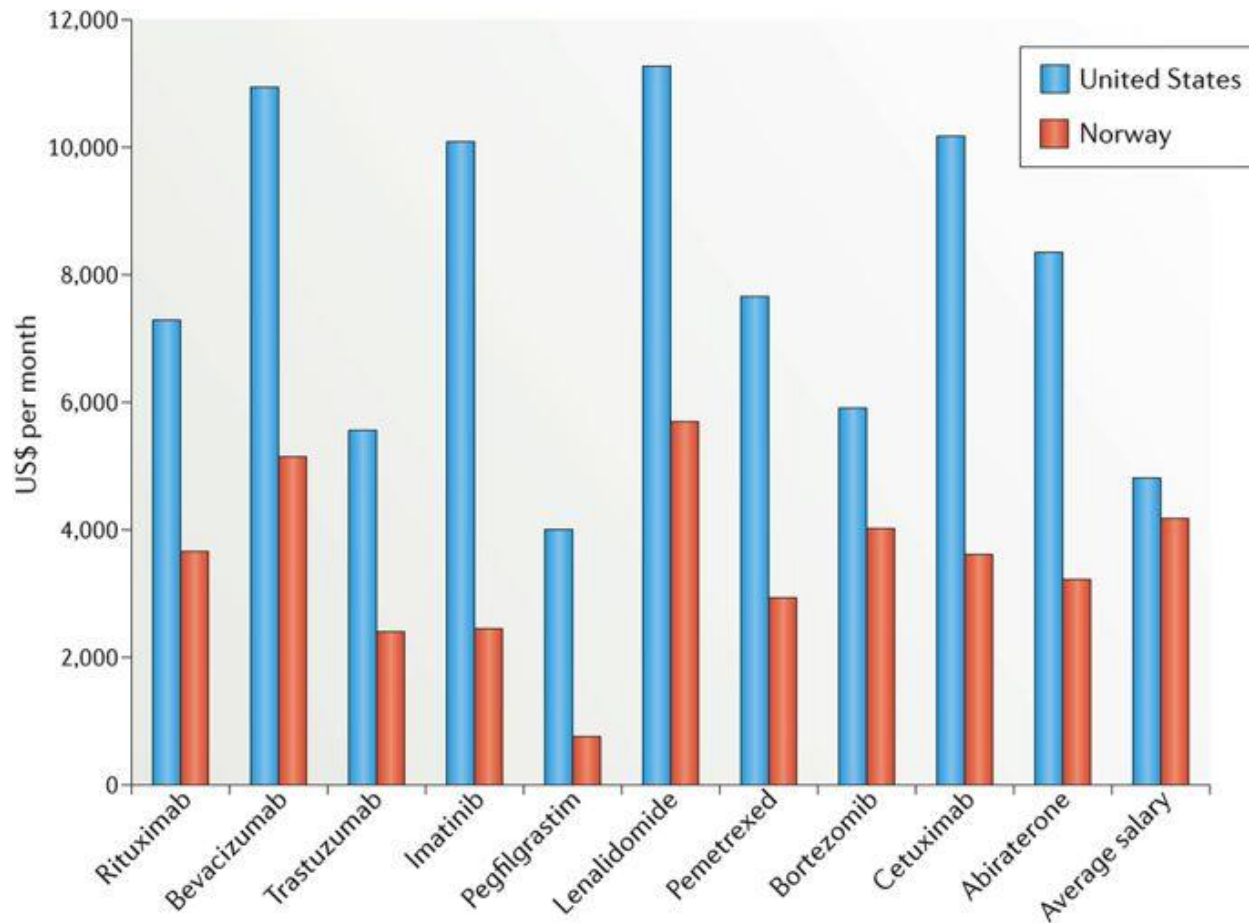
<https://www.healthpopuli.com/2017/09/14/americans-prescription-drugs-cost-misuse-self-rationing/>

Pharmaceuticals – Oncology



<https://www.statista.com/statistics/268805/number-of-cancer-drugs-in-development-since-2005/>

Pharmaceuticals – Oncology

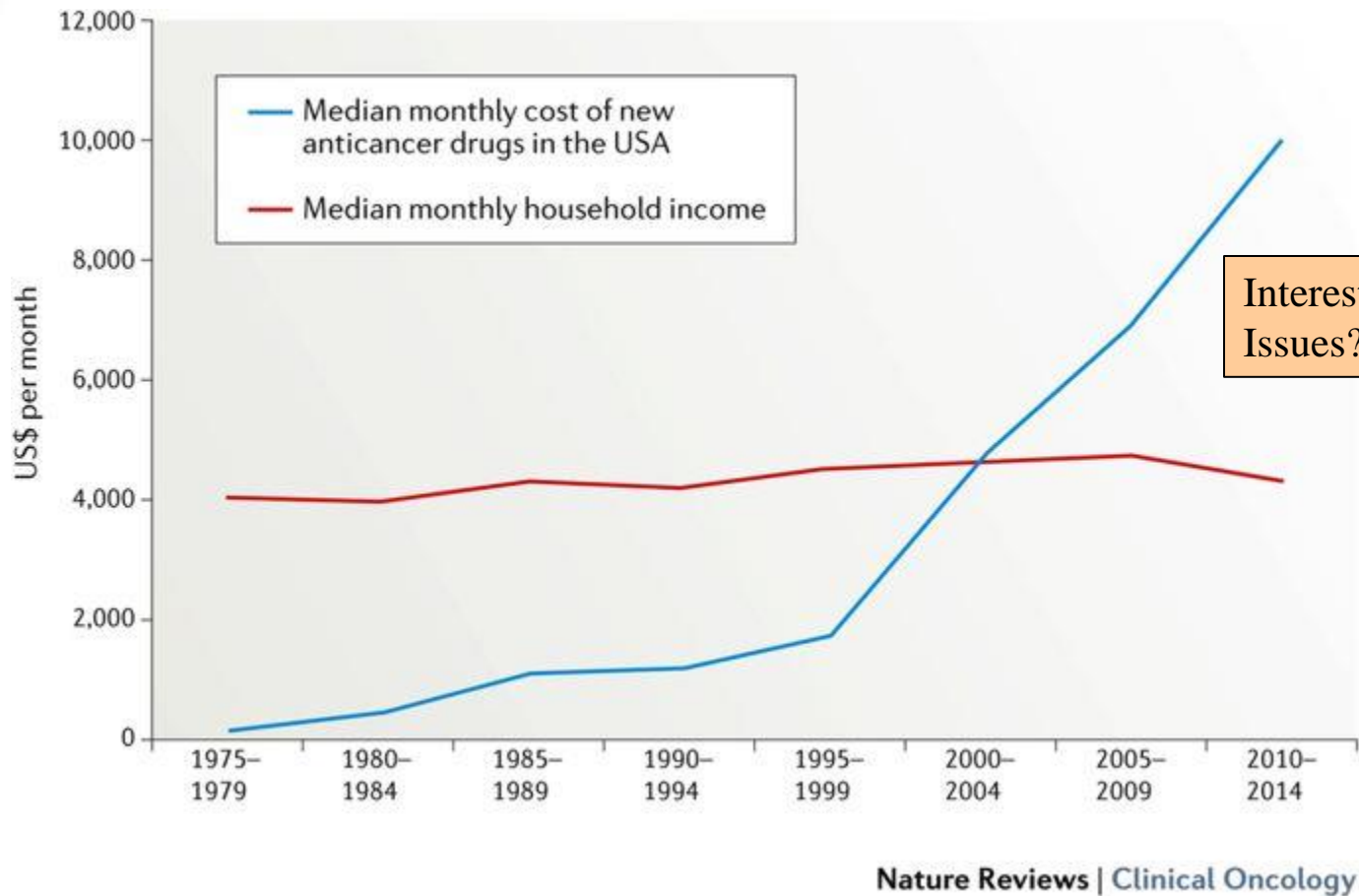


Nature Reviews | Clinical Oncology

Cost of one month of treatment.

<https://www.nature.com/articles/nrclinonc.2017.31>

Pharmaceuticals – Oncology

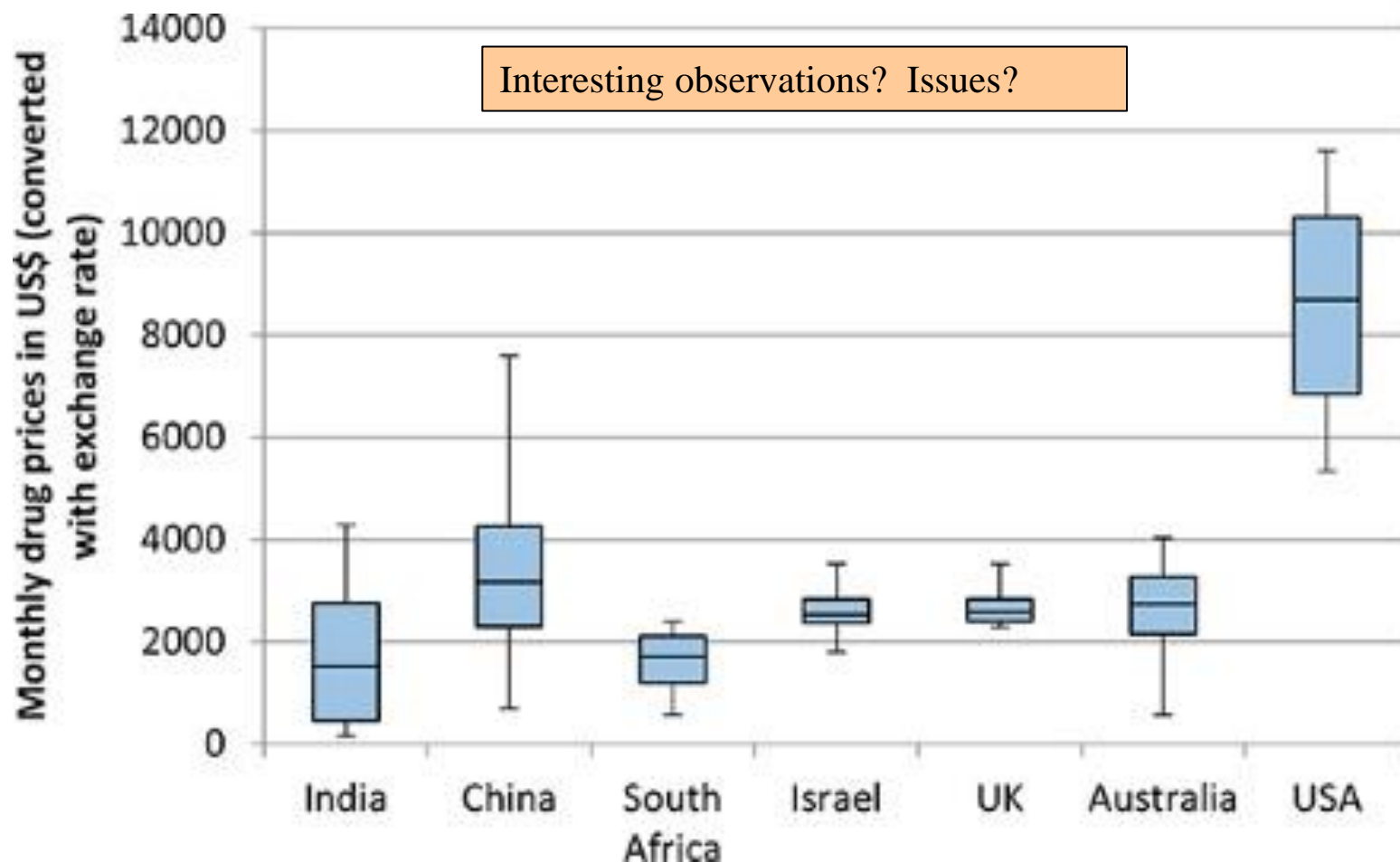


Interesting observations?
Issues?

<https://www.nature.com/articles/nrclinonc.2017.31>

Pharmaceuticals – Oncology

Monthly price of 8 patented cancer pharma in 7 countries.



Source: <https://www.oncotarget.com/article/17742/text/>

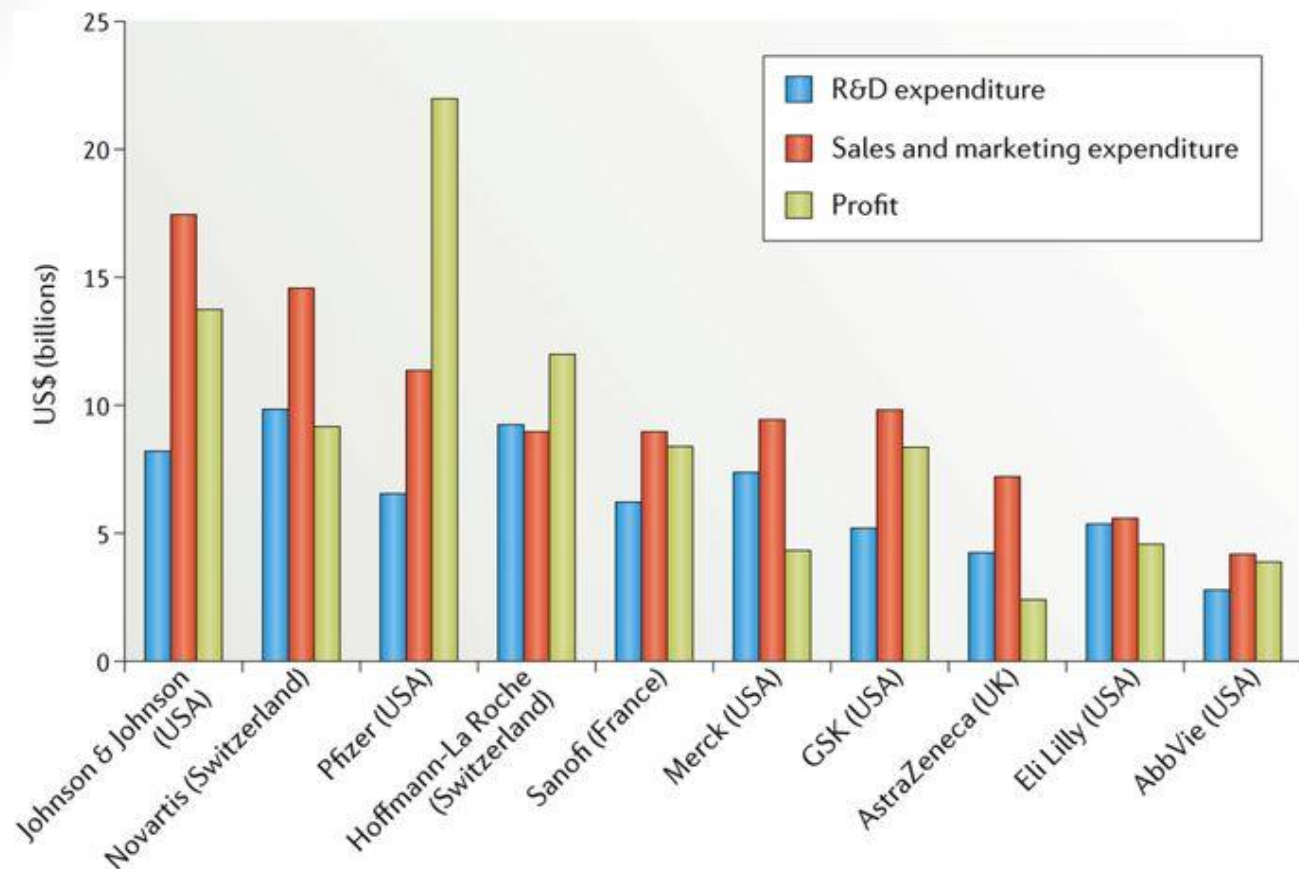
This link contains other interesting facts you can check out.

Pharmaceuticals – Oncology

Table Monthly Cost of 15 Generic and 8 Proprietary Cancer Drugs by Country

[illegible]

Pharmaceuticals – R&D and Profits



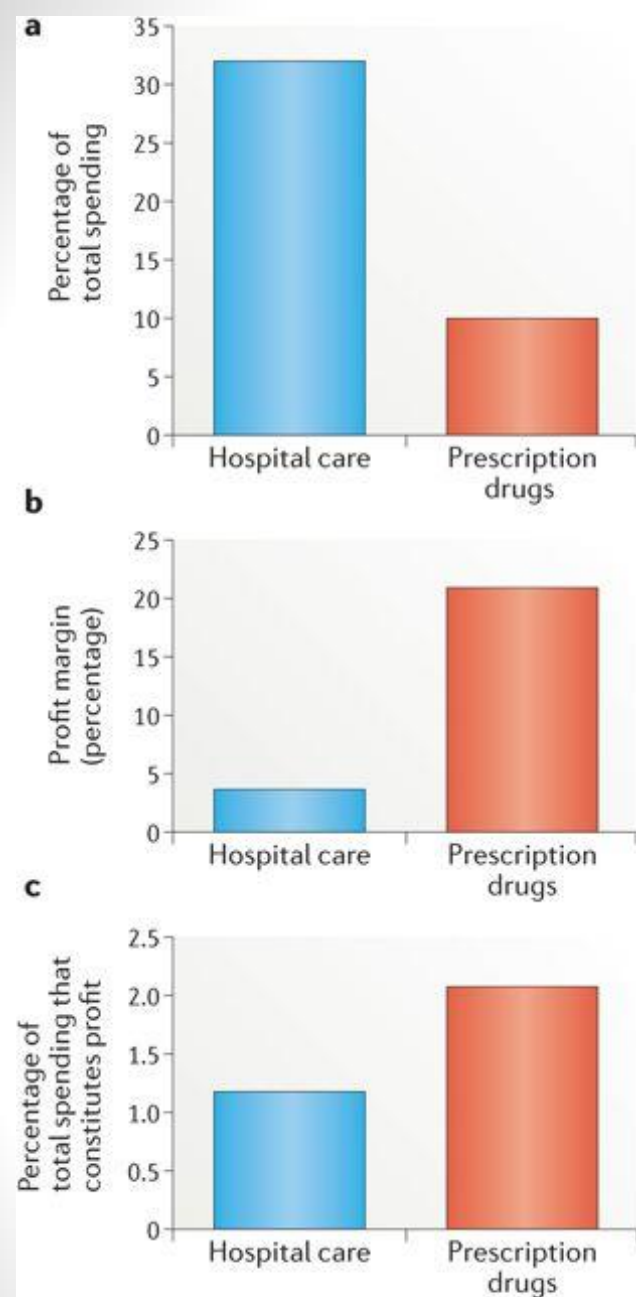
Nature Reviews | Clinical Oncology

Annual profits, and annual expenditure on research and development (R&D) and marketing for the 10 largest pharmaceutical companies in 2013.

<https://www.nature.com/articles/nrclinonc.2017.31>

Pharmaceuticals v. Hospitals

<https://www.nature.com/articles/nrclinonc.2017.31>



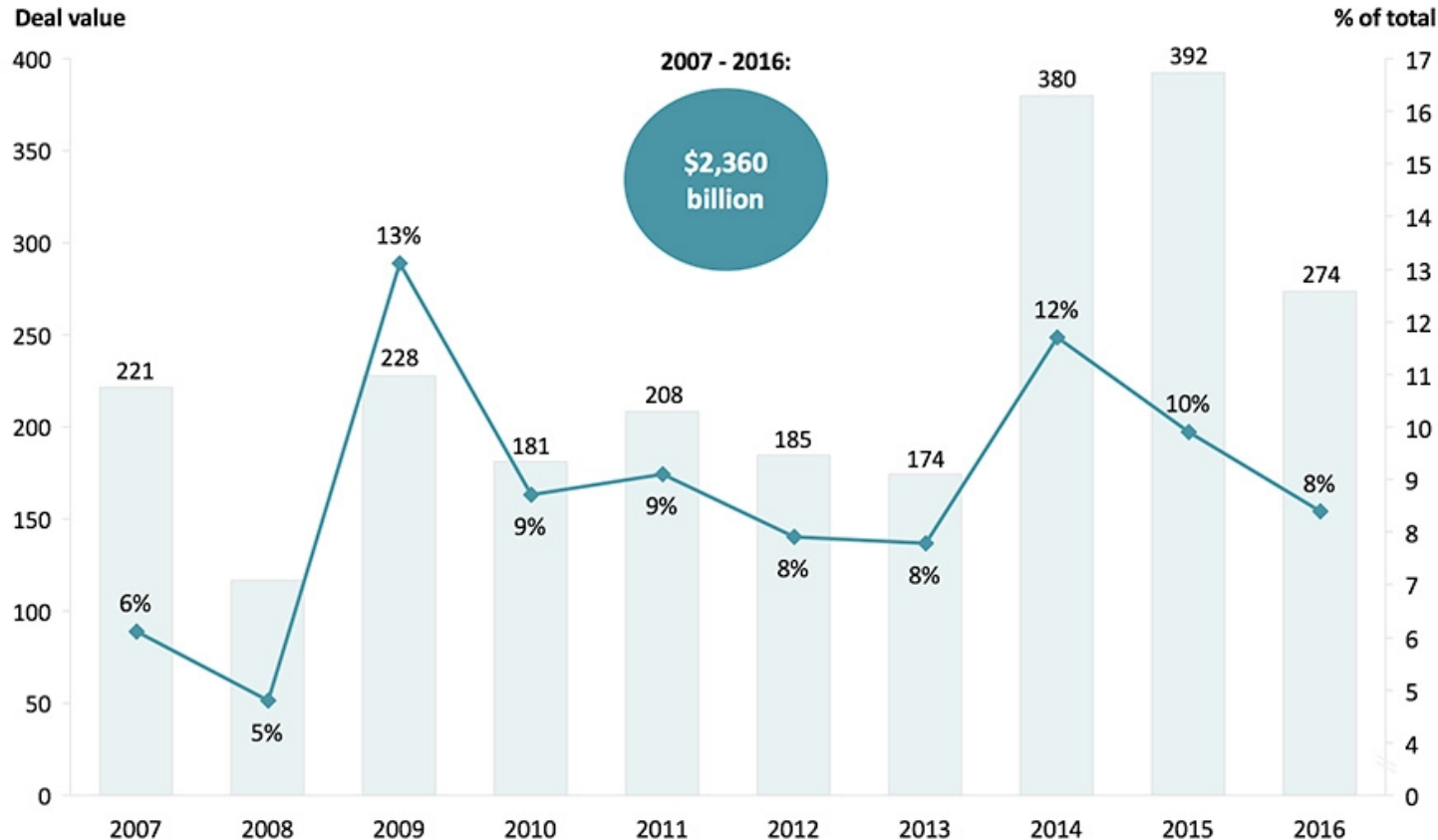
Pharmaceuticals – Price, Revenue, R&D

Company	International price/US price	US premium price percent	US sales (2015, \$mm)	Revenue from US premium (\$mm)	Revenues from US premium as percent of global research and development
AbbVie	48%	52%	\$13,561	\$7,092	166%
Amgen	43%	57%	\$16,523	\$9,355	239%
AstraZeneca	36%	64%	\$9,474	\$6,078	101%
Biogen	25%	75%	\$6,546	\$4,934	245%
Bristol-Myers Squibb	45%	55%	\$8,188	\$4,516	76%
Celgene	45%	55%	\$5,525	\$3,020	148%
Roche (Pharma Div)	45%	55%	\$1,7782	\$9,759	119%
Gilead	75%	25%	\$21,200	\$5,200	173%
GlaxoSmithKline (ex consumer)	48%	52%	\$10,188	\$5,300	114%
JNJ (just pharma division)	39%	61%	\$18,300	\$11,127	163%
Merck	39%	61%	\$17,519	\$10,649	159%
Novartis	52%	48%	\$18,079	\$8,678	97%
Pfizer (ex Consumer)	21%	79%	\$19,906	\$15,735	219%
Sanofi	28%	72%	\$12,625	\$9,123	163%
Teva (specialty meds)	22%	78%	\$6,442	\$5,018	263%
Average	41%				163%

Interesting observations?
Issues?

Pharmaceuticals – M&As

Value of M&A in the global pharma industry (\$ / billion)

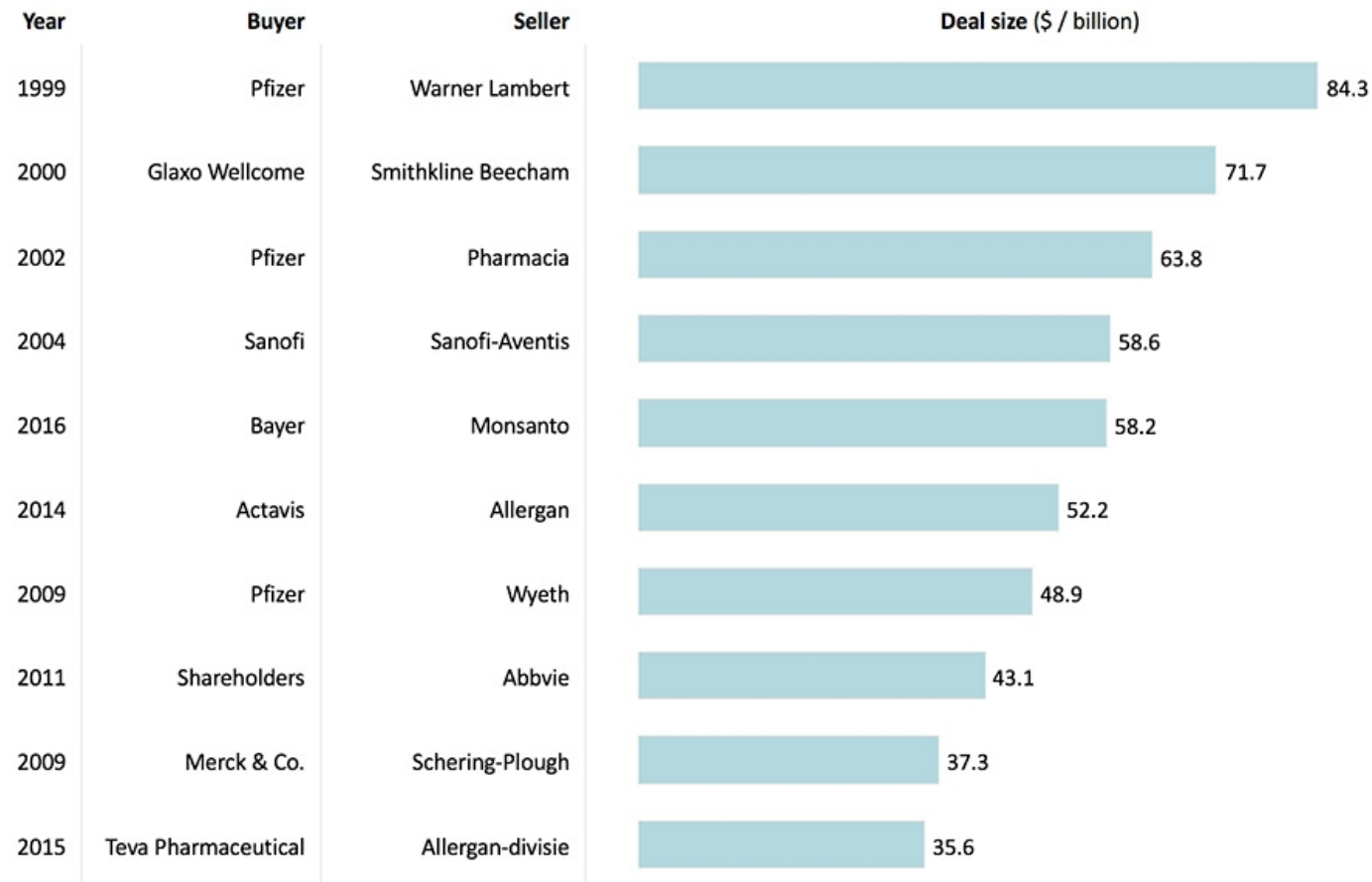


Source: Consultancy.uk analysis, Mergermarket data

<https://www.consultancy.uk/news/13046/ten-year-deal-activity-in-pharmaceuticals-industry-stands-at-24-trillion>

Pharmaceuticals – M&As

The 10 largest transactions in the pharma industry

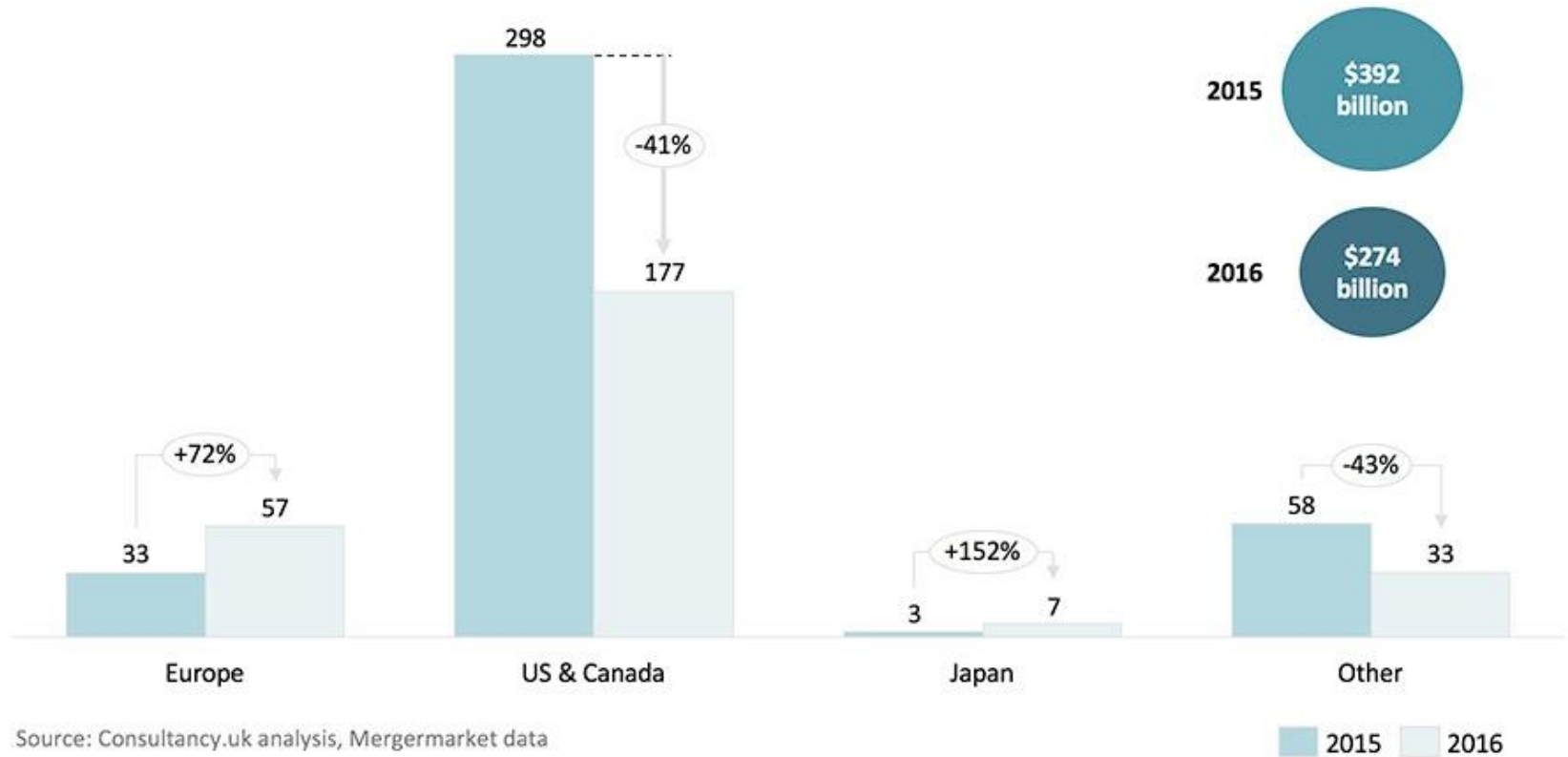


Source: Consultancy.uk analysis, Bloomberg data

<https://www.consultancy.uk/news/13046/ten-year-deal-activity-in-pharmaceuticals-industry-stands-at-24-trillion>

Pharmaceuticals – M&As

Value of M&A in the global pharma industry (by region)



<https://www.consultancy.uk/news/13046/ten-year-deal-activity-in-pharmaceuticals-industry-stands-at-24-trillion>

Pharmaceuticals: Patents, R&D, Strategy

- **This slide onwards contains some background materials. Take a look for perspective.**

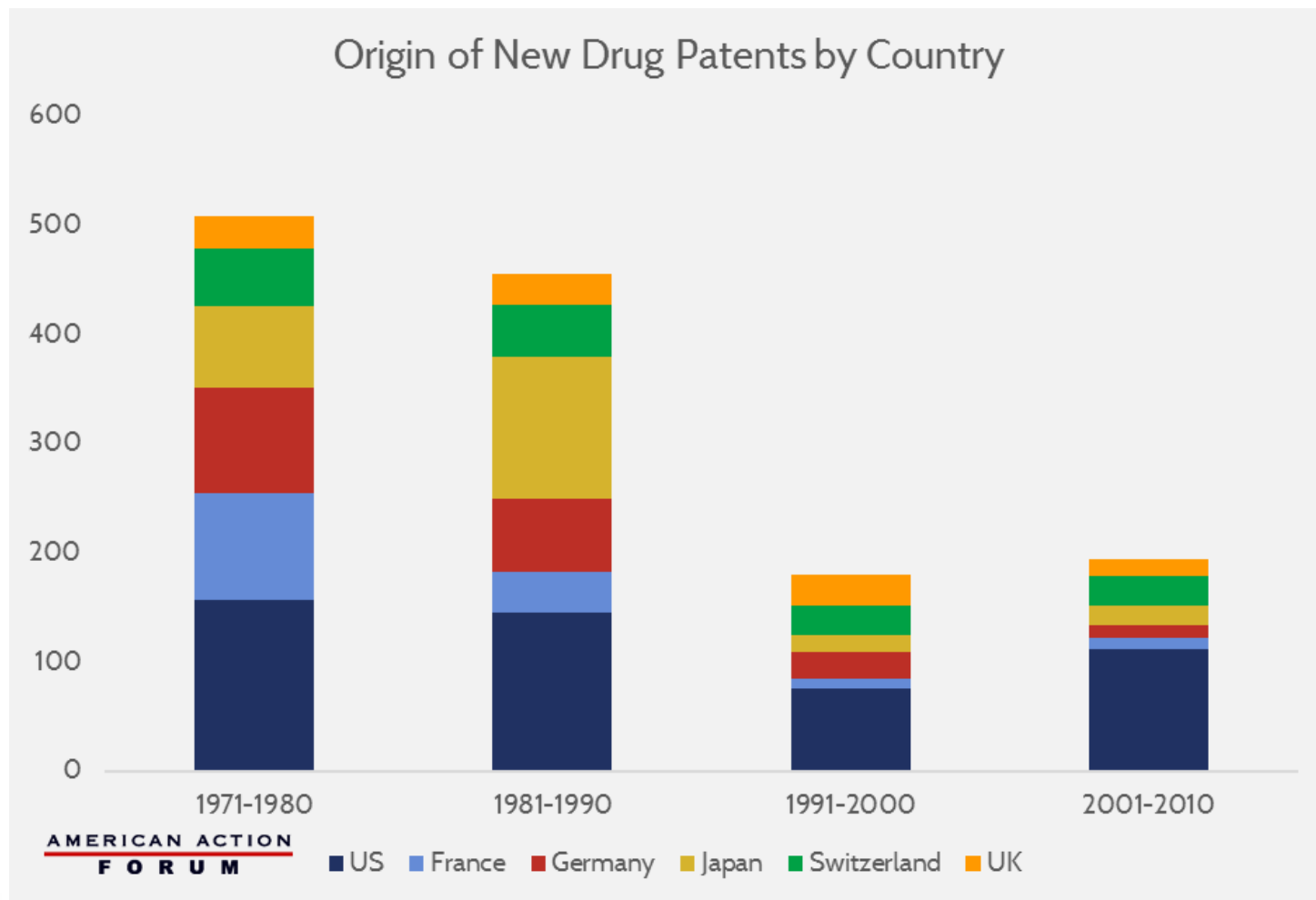
Patents, and Research & Development

- The U.S. has relied on private sector initiative and market mechanisms for the direction of research & development
- In the pharmaceutical industry, government, private philanthropy and academia intimately involved in new product development
- Government sponsors relatively little *applied research*, towards commercialization of a product
- Government & private philanthropy directly fund *basic research*, to advance knowledge

Patents, and Research & Development

- Patents are necessary to protect innovators
 - Given high \$R&D and lengthy pharma product development, no or weak patents will result in somewhat limited incentives to innovate
- Over 65% of the world's total R&D spending in pharma is based in U.S.
- Introduction of new drugs is a major determinant in profitability
 - The longer a drug is on the market, its profitability and sales fall

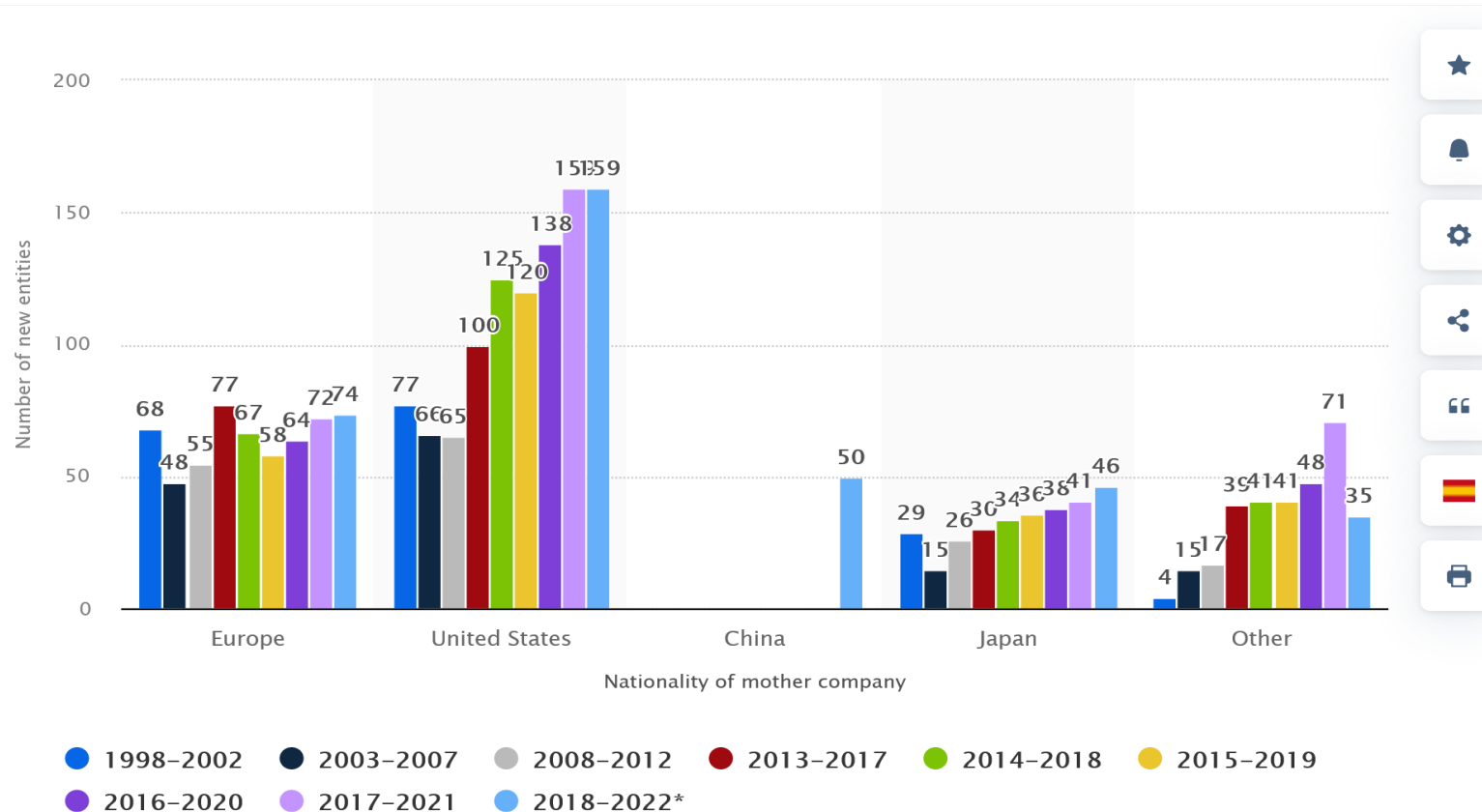
Patents, and Research & Development



Source: milkeninstitute.org

Patents, and Research & Development

Number of new chemical or biological entities developed between 1998 and 2022, by region of origin

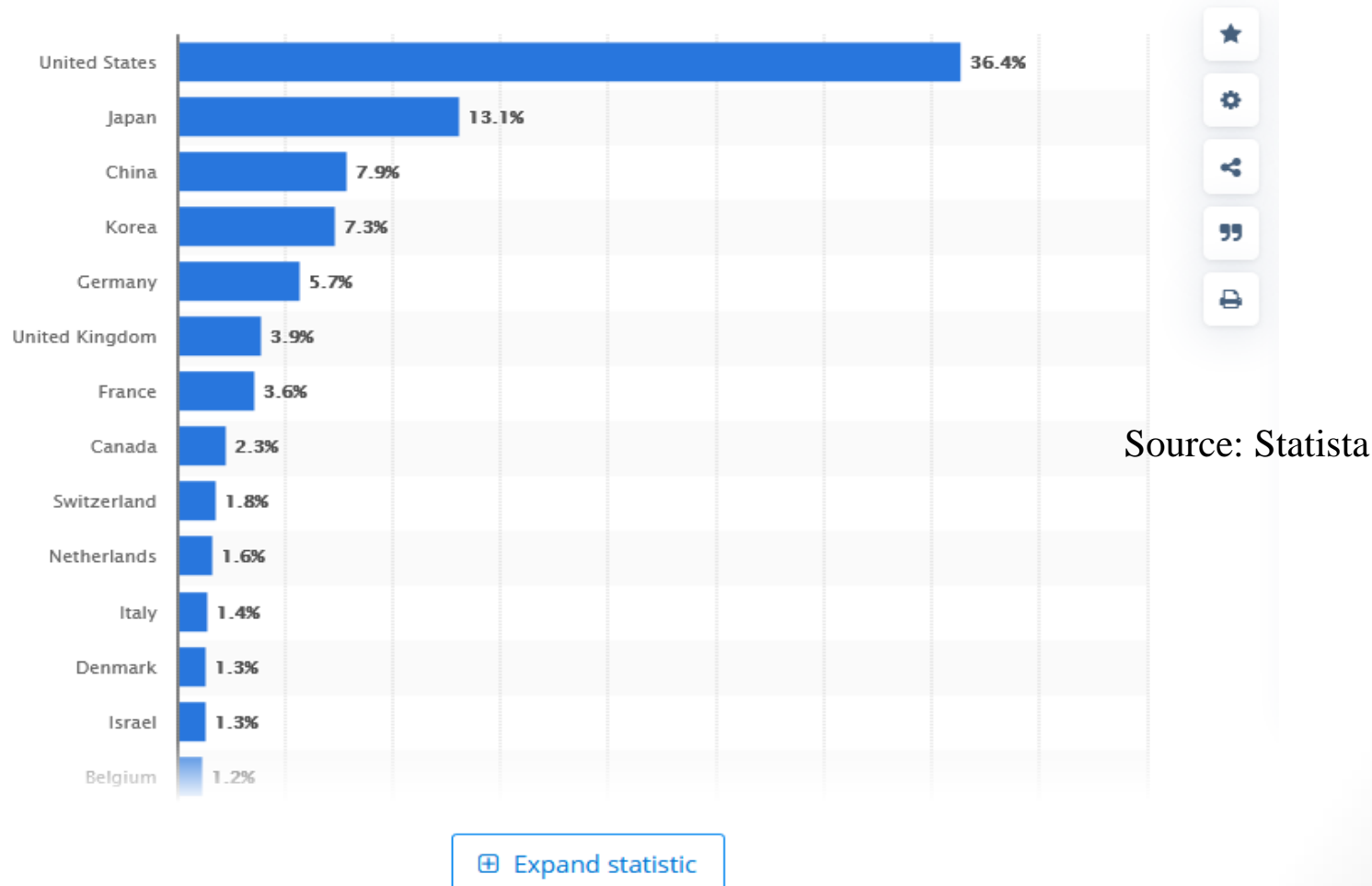


Details: Worldwide

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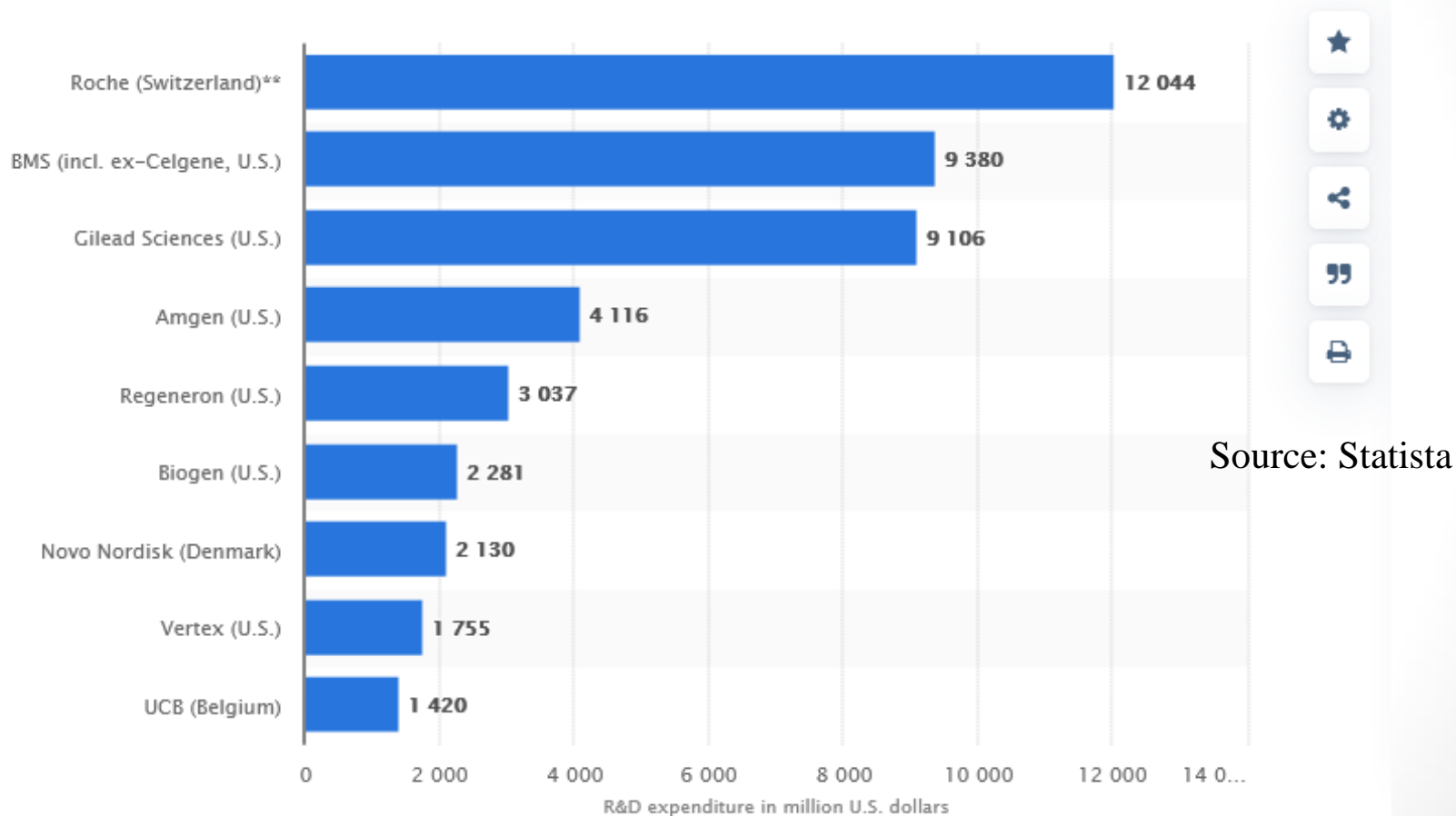
Patents, and Research & Development

Distribution of biotechnology patents filed in 2018 by select country



Patents, and Research & Development

Select leading global biotechnology company R&D expenditures in 2019 (\$million)



Details: Worldwide; Various sources (company data); Pharmaceutical Executive; Statista

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Patents, and Research & Development

Orphan Drugs

- Pharma protects its products through patents, which provide exclusive rights to production of the drug, usually for 20 years
- But the long development period for many drugs, often 12-15 years, means the effective market benefit of the drug is much less
- Exception: when firms pursue **orphan drugs**, those used to treat rare diseases but which have limited commercial value; firm receives the exclusive right to manufacture

Pharmaceuticals – R&D Process

TABLE 10.1 STEPS IN THE PHARMACEUTICAL R&D PROCESS

Testing Phase	Mean Phase Length (Years)	2011 Spending (billions) ¹	Percentage Share
Discovery–Preclinical	6.5	\$10.5	21.5
Clinical Trials			
Phase 1	1.5	4.2	8.7
Phase 2	2.0	6.1	12.5
Phase 3	3.5	17.4	35.8
FDA Review and Approval	1.5	4.0	8.3
Post-Marketing Testing—Phase 4 ²	-	4.8	9.8
Uncategorized	-	1.7	3.5
Total R&D	15.0	\$48.6	100.0

Source: *Pharmaceutical Industry Profile*, 2013, Washington, DC:PhRMA, 2013.

¹PhRMA member companies only

²Additional testing required by the FDA

Impact of Patents on Prices

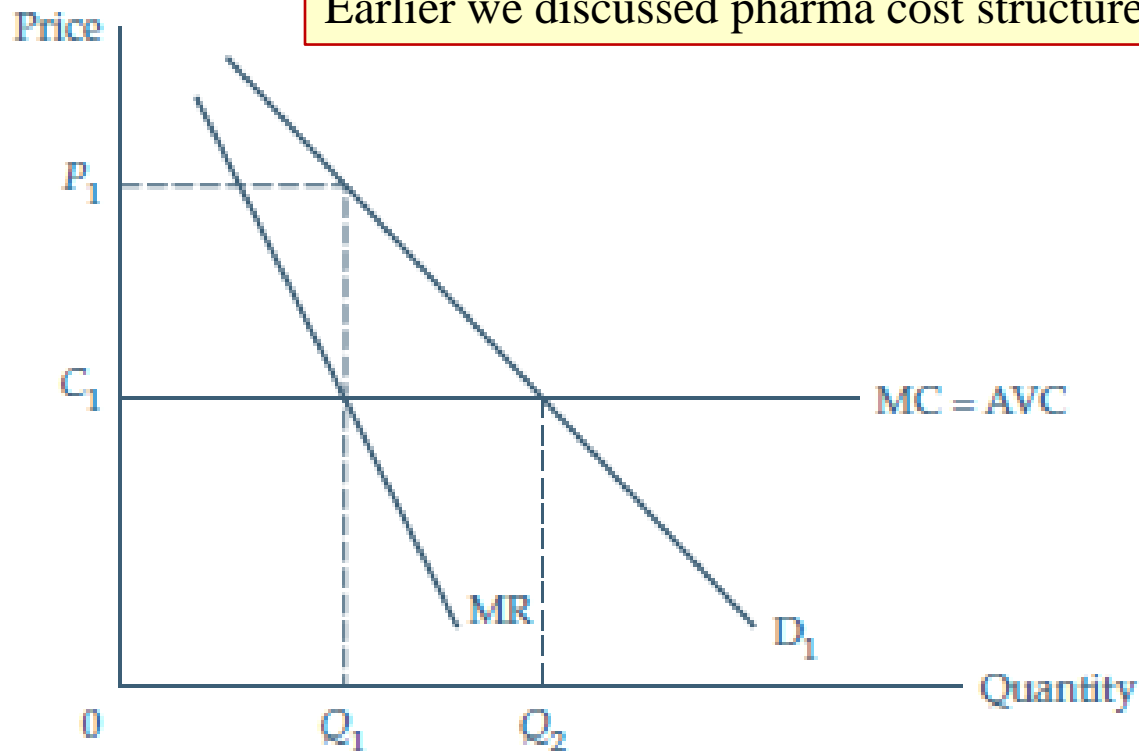
- Patent provides innovator with monopoly power: to limit availability and set prices above marginal cost of production
 - See BM1 slides and problems for monopoly solutions
- Patents can distort pharma prices, limit treatment options for individuals who do not have the means to pay (uninsured or under-insured), and increase medical costs
- Prices are lower for brand-name drugs in Europe and Canada
 - Reason for lower prices? We did this earlier: *Monopsony* model of decision-making and pharma pricing in variants of single-payer healthcare systems (prevalent in Europe and Canada)
 - But vast majority of these countries produce very few, if any, new cutting-edge pharma products

Pharmaceutical Pricing

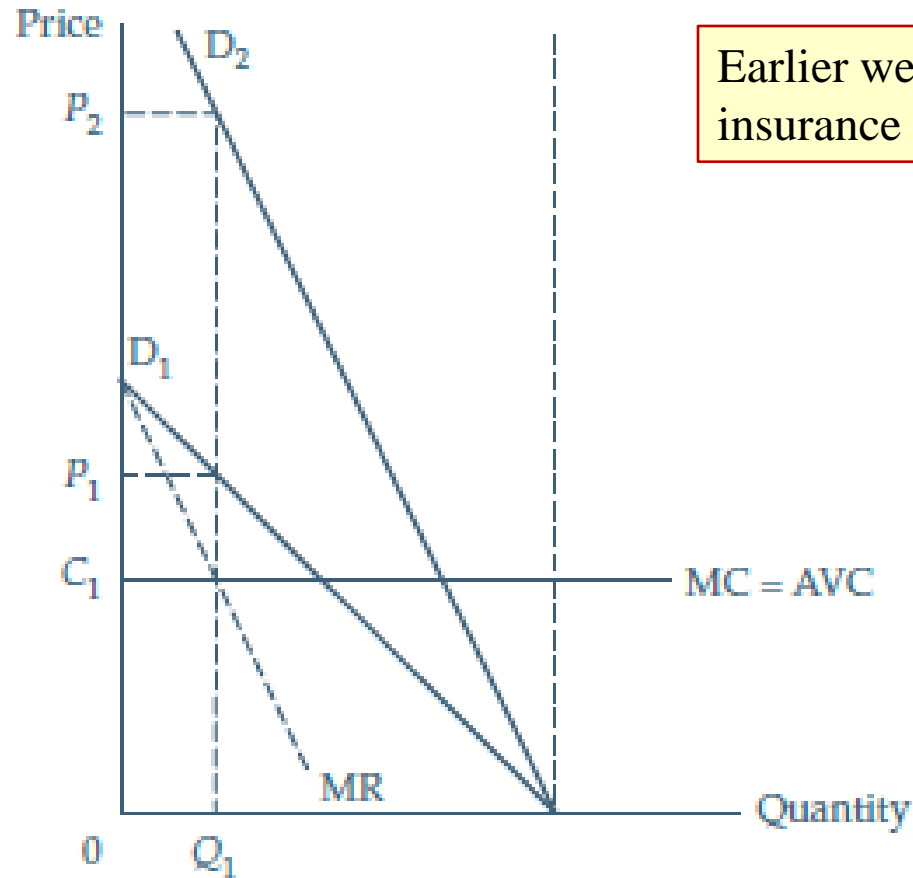
- Structure of demand and costs
- Bit later we will discuss in more detail pharmaceuticals pricing, nature of competition, etc. All of those discussions and readings are relevant here
- We discussed models of Bertrand differentiated-products price competition. Materials in BM2 will be relevant here
- *Between-patent* competition: when multiple patented pharma compete in the same treatment category (e.g., lung cancer)
- *Within-patent* competition: when generics/biosimilars enter and there is competition in the same molecular structure

Pricing a Patented Drug: Monopoly

Earlier we discussed pharma cost structure and pricing



Pricing a Patented Drug: Monopoly and Insurance



Earlier we discussed effects of insurance on demand and prices

Pricing a Patented Drug: Complex Issues

- Cost of producing a modern drug is high, because of high expenditures on R&D and clinical trials
- Are new drugs worth the high cost?
 - If drug therapy reduces need for expensive treatments such as surgery
 - If drug therapy can prevent or slow the progression of certain diseases, increase longevity, and quality of life (we will discuss Quality-adjusted-life-years, QALY, later in the semester)
- The insurance system (private, mix of private and Government, or some version of single-payer) presents a complex tradeoff
- Vast majority of countries do not innovate to produce new frontline drugs. They are just consumers of these products

Pharmaceuticals: Advertising & Promotion

- Pharma firms can spend twice, or more, on administration & marketing compared to what they spend on R&D
 - Are these necessary expenditures?
 - Later we will examine specific advt and marketing complexities
- New drugs may sell at 3-6 times (or much higher multiple) than their MC of production
 - But what about R&D and bringing these products to market?
 - How long can a firm enjoy monopoly status?
- Most sales efforts directed at providers, but increasingly, direct to consumer (DTC) ads
 - Complex role of advertising in this industry

Role of FDA

- The FDA has been criticized as too cautious in the regulatory processing, causing delays in approval of new drugs, worried about:
 - Type I error: mistakenly allowing a harmful drug onto the market before fully tested (ex: thalidomide, kept out of U.S. market, but allowed in Europe, causing birth deformities)
 - Type II error: delaying a drug from market until its safety and efficacy are fully understood (reduces competition, raises costs)
 - Type I highly visible; Type II not
- In our specialized modules we will examine the complexities FDA confronts when undertaking drug approvals
 - We will also take a brief look at COVID vaccine development and FDA approvals

Some Issues for the Industry

- Pharma firms widely criticized for high markups, high profits margins, & high and rising prices on most popular products
- Price controls on prescription drugs in Canada, for example, have resulted in substantially lower prices
 - About 25% at wholesale level
 - However, since Canadian price controls were adopted, hardly any new frontline pharma products developed there
 - Vast majority of countries have no new product development
- Supporting pharma R&D perhaps requires incentives that reach globally
 - Pharma R&D spending creates a cost-allocation problem. How much is attributable to one specific country?