# A2: Accessibility

Overview : accessiblity outside

Restrict to devolping: subsidiedies

Michelle Mello, June 2018, Professor of Law, Stanford Law School, and Professor of Health

Research and Policy, Department of Health Research and Policy, Stanford University School of

Medicine; Ph.D., University of North Carolina at Chapel Hill; J.D., Yale Law School; M.Phil.,

University of Oxford; A.B., Stanford University., Minnesota Law Review, ARTICLE: What Makes

Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?,

http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello\_MLR.pdf

Another perplexing moral problem is that tradeoffs may exist between improving the affordability of prescription drugs for Americans and maintaining their affordability to patients in other countries. 53 **Branded drug prices in the United States are generally higher than in other countries because most foreign governments have adopted stronger mechanisms than the United States for controlling prices - for example, more consolidated price negotiations or direct price Control**

s. **Because we pay so much, pharmaceutical companies may be more willing or able  to grant price concessions elsewhere, including outright donation of critical medications to low- income countries. Actions we take to restrict price, therefore, could have unintended, but real, effects on drug affordability in less wealthy countries**. ...However, because the market for prescription drugs is global but is propped up by high prices in the United States, tamping down drug prices has a zero-sum-game quality that is unique. Squeezing one part of the drug-price balloon may cause it to bulge out in other areas

https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481

**Some drugs, such as for HIV and hepatitis, cost less in certain overseas markets because companies cut prices for poor countries.**

[**https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.0923**](https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.0923)

Aug 2011

**For patented drugs**, middle-income countries pay on average 52 percent of what industrialized countries pay, while **developing countries pay 27 percent of the prices charged in industrialized countries**. For drugs that are no longer patented, middle-income countries pay 71 percent and developing countries 41 percent of what industrialized countries pay, while **for** products on the **World Health Organization’s list of essential drugs,** the figures are 28 percent and **6 percent**. Thus, the average prices charged in developing countries for all three categories of drugs are much lower than those charged elsewhere.

Restrict to devolped: increase erp

4. Companies are more likely to withdraw or increase prices on developing markets under ERP instead of developing new drugs (MR)

[Mzoughi et al 2015 University of Aix-Mairselle](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802694/)

Although ERP aims to achieve a better control of prices and faster price erosion, it might also induce a vicious effect, such as leading pharmaceutical companies to increase the target price in order to avoid both negative impact on the company's revenues of ERP and parallel trade (1, 2, 5). Carone et al. (15) noted that pharmaceutical prices reported to local purchasing power remain higher in countries with lower absolute price levels of pharmaceuticals (e.g., Poland, Romania, Bulgaria) versus countries with higher absolute price levels (e.g., Germany, Denmark, Ireland, and Italy), thus impacting country's affordability (2). For example, it was reported during the stakeholder consultation that **ERP might lead to product shortage in countries referencing the lowest price, due to discontinuations and parallel export, as illustrated with Bulgaria where about 200 products (strengths, pack sizes, and chemical entities) were withdrawn from the market in 2012.**

## 1. The increase in cost comes from rising insurance deductibles, not the pharmaceutical industry. Price controls won’t do anything. (BW)

[LTAC 2017](https://www.letstalkaboutcost.org/)

New therapies are transforming care for patients fighting debilitating diseases like cancer, hepatitis C, high cholesterol and more. In the midst of all this progress, **[pharmaceutical industry] spending on medicines grew just 0.6 percent in 2017**. And according to the nation’s largest pharmacy benefit manager, spending on medicines grew just 1.1 percent for their clients in the first half of 2018.**Unfortunately, it doesn't feel this way for patients. Insurers are increasingly using high deductibles, which result in patients paying the full list price for their medicines, even if their insurers receive significant discounts.**And middlemen, like pharmacy benefit managers and insurers, have been shifting more of the costs of health care to patients for years – **with deductibles increasing 350 percent since 2006.**

### 1.5 It’s other healthcare spending that’s the cost. The percent of total healthcare spending spent on drugs is far less than the average for other devolped countries

[Winegarden 2017](https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#c3467c463a68)

It is also important to note that generic medicines are significantly cheaper in the U.S. compared to the other major industrialized countries. In fact, [total pharmaceutical spending as a percentage of total health care spending](http://www.pacificresearch.org/u-s-pharmaceutical-spending-is-below-average/) is lower in the U.S. (12.2 percent) than the average for the 30 nations that comprise the Organization for Economic Cooperation and Development, or OECD, (16.9 percent). This is due to, in part, the prevalence of generic medicines that are more affordable here than in other OECD nations.

## 2. TURN/ Price Controls hurt margins and push companies out (risk too high), resulting in less companies selling to low income areas. This has been seen consistently across multiple countries

<https://blogs.wsj.com/pharmalot/2015/07/20/price-controls-for-drugs-in-india-fail-to-improve-access-for-patients-report/> (Says the same thing)

IMS Study, July 15, 2015

http://www.pharmabiz.com/NewsDetails.aspx?aid=89417&sid=2

**Price control** has **increase**d **margin pressures for small and mid-sized companies, limiting** both **employment and investment opportunities** in the sector. Price controls negatively impact internal capability-building and expertise-building initiatives, discourage local talent and undermine the government’s 'Make in India’ initiative.

Some key findings of the study are primary **beneficiaries of** the DPCO 2013 **price controls** **have been high income patient populations**,

rather than the low-income targets; **the consumption of price-controlled drugs in rural areas has decreased by 7%** over the past two years, **while that of non-price controlled products has risen by 5**%; and the DPCO 2013 has resulted in an increase in market concentration (fewer brands are now listed) and a decrease in competitive intensity (the average number of new brands has gone down since 2013).  
 These conclusions are corroborated by similar outcomes **in China, the Philippines and South Korea,** where **price controls have consistently failed to improve overall access to medicines**.  “Price control has limited impact on improving patient access and, furthermore, is not aligned with the requirements of a vibrant economy like India,” said Nitin Goel, general manager, IMS Health South Asia. “Government’s priority should be on strengthening India’s healthcare infrastructure and extending universal insurance coverage.”

## 3. Most drugs are generic, affordable drugs anyways -- the scope is super low

[Winegarden 2017](https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#c3467c463a68) (JW)

To start, the price controls would be irrelevant for most patients. **Nearly** [**90 percent**](http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021#form) **of all drugs dispensed in the U.S. in 2016 were generic medicines, according to IMS Health. Therefore, any price control scheme would not apply to the majority of patients who are using inexpensive generics, not more expensive patented products.**

### 3.5. Pharma Companies are undergoing a massive ‘patent cliff’ right now - that nonuniques their impact (BW)

[Keith Speights June 2018 The Motley Fool](https://www.fool.com/investing/2018/06/17/big-pharma-stock-investors-beware-another-250-bill.aspx)

Market research firm EvaluatePharma projects that **more than $250 billion in sales are at risk between 2018 and 2024 for drugs that will lose patent exclusivity.**Four companies could especially feel the sting from these losses: AbbVie (NYSE:ABBV), Celgene (NASDAQ:CELG), Johnson & Johnson (NYSE:JNJ), and Novo Nordisk (NYSE:NVO). Should investors beware of these big pharma stocks?

https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/

The upshot is simple. Forcing drug prices down would surely shave a few percentage points off what

we spend on healthcare today**. By 2032, drug prices could be half of what they are today, as every drug**

**would be a generic**. But our ability to treat or cure the many serious diseases that still afflict us will

have been crippled and squandered. In my view that is terrible policy.

[**https://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134441.htm**](https://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134441.htm)

**2004**

If you think all drugs from Canada are cheaper than U.S. drugs, think again. In the United States, generic drugs--roughly half of all prescriptions--are often cheaper than both Canadian brand-name drugs and Canadian generic drugs, according to a study by the Food and Drug Administration.

## 4. Innovation Short Circuit: Even those these drugs are expensive, the alternatives are worse--this means that a lack of innovation would be more costly in the long run

[Winegarden 2017](https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#c3467c463a68) (JW)

For example, in December 2013 and October 2014, the FDA approved two new medications to treat Hepatitis C. **These medicines were expensive, but they were also cures for a disease that was previously incurable. Of course, by curing the disease, more expensive (and more invasive) surgeries can now be avoided, which will reduce health care expenditures in the long-run** even as pharmaceutical expenditures as a share of total health expenditures increased in the short-run. Price controls risk such benefits in the future.

### 5. Shortages Turn: Black markets devolved bc of shortages spike prices higher than squo, even more unaffordable

[John Goodman Health Affairs 2012](https://jamanetwork.com/journals/jama/fullarticle/2612912)

Economics teaches that when prices are kept artificially low, shortages develop. People cannot get all of the care they try to obtain at the existing rate.  Also, regardless of the apparently multiple causes of the shortages, certain patterns tend to emerge. People **respond to** persistent **shortages** by doing things that invariably make the problem worse.

Black Markets. Another thing that happens **is the [shortages lead to the] development of black** (or gray) **markets, where price gougers buy up [all the remaining] quantity of a drug in short supply and sell it for a much higher price — even higher than would have been charged if the government had simply left the market alone**. For example, in their 2005 letter to Secretary Leavitt, hospitals complained that shortages were exacerbated by drug distributors who filled their more lucrative commercial orders instead. (The federal government, incidentally, claims this is illegal.)

# A2: Innovation

## A2: Justification for High Prices

### Not even high risk rn: 1. Many projects offset risk 2. They don’t even do the risky dev, that’s public research 3. They cut losses early for seemingly non-profitable drugs

[Donald Light](https://ethics.harvard.edu/blog/new-prescription-drugs-major-health-risk-few-offsetting-advantages) (Harvard), 2014 (DS)

Risk for the major companies is much less than claimed for several reasons. **First, they spread risk over many projects**. **Second, once inflators and public subsidies are taken out, net research costs are a fraction of the $1 billion to $5 billion per new drug claimed, and big companies largely invest after the public and others have paid for the high risks of research to discover new drugs.** As new drugs enter clinical trials, their risks are just 1 in 5. **Third, companies cut losses by stopping development of drugs whose profit potential is not as high as they want.** We never will know how many beneficial drugs never get approved because companies estimated they would not be profitable enough.

### Even if high risk, so assoc. with dru2gs price and R&D Costs. but instead the maximum amount people will pay. (BW)

[Aaron Kesselheim 16](https://jamanetwork.com/journals/jama/fullarticle/2545691)

The contention that high prescription drug spending in the United States is required to spur domestic innovation has not been borne out in several analyses.92 A more relevant policy opportunity would be to address the stringency of congressional funding for the National Institutes of Health, such that its budget has barely kept up with inflation for most of the last decade. Given the evidence of the central role played by publicly funded research in generating discoveries that lead to new therapeutic approaches, this is one obvious area of potential intervention to address concerns about threats to innovation in drug discovery. Thus, **there is little evidence of an association between research and development costs and drug prices93; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear.**This explanation also helps to account for several high-profile case studies, including high-priced new branded products94 and exorbitantly priced generic drugs described above.95 In preparation for recent hearings on this topic, the US House Committee on Oversight and Government Reform subpoenaed internal correspondence from Turing and Valeant Pharmaceuticals, which had sharply increased the prices of older drugs the companies had acquired. The investigation revealed, for example, that Turing received “no pushback from payors” when it increased “Chenodal price 5x... [Thiola] price 21x... [and Daraprim] price 43x.”96 Similarly, Gilead spent $11 billion to purchase sofosbuvir from Pharmasset, a small biotechnology firm that developed the drug, based in part on federally funded research led by an investigator at Emory University.97 Gilead recouped almost all of this cost in the first year that sofosbuvir was on the market, recording sales of $10.3 billion in 2014.98 In December 2015, the US Senate Committee on Finance released a detailed report based on its access to internal company documents on Gilead [pharmaceuticals] strategized to maximize the prices it could charge for both that drug and its planned successor, which the company also owned

Findings  Per capita prescription drug spending in the United States exceeds that in all other countries, largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the consumer price index. In 2013, per capita spending on prescription drugs was $858 compared with an average of $400 for 19 other industrialized nations. In the United States, prescription medications now comprise an estimated 17% of overall personal health care services. The most important factor that allows manufacturers to set high drug prices is market exclusivity, protected by monopoly rights awarded upon Food and Drug Administration approval and by patents. The availability of generic drugs after this exclusivity period is the main means of reducing prices in the United States, but access to them may be delayed by numerous business and legal strategies. The primary counterweight against excessive pricing during market exclusivity is the negotiating power of the payer, which is currently constrained by several factors, including the requirement that most government drug payment plans cover nearly all products. Another key contributor to drug spending is physician prescribing choices when comparable alternatives are available at different costs. **Although prices are often justified by the high cost of drug development, there is no evidence of an association between research and development costs and prices; rather, prescription drugs are priced in the United States primarily on the basis of what the market will bear.**

### 1. NU/High profit margins are used for stock buybacks right now, not for increased innovation. There is room to cut.

[William Lazonick 17 University of Massachusetts](https://www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf)

It is a compelling argument—until one looks at how major US pharmaceutical companies actually use the profits that high drug prices generate.**In the name of “maximizing shareholder value”** (MSV), **pharmaceutical companies allocate profits generated by high drug prices to massive** repurchases, or **buybacks, of their own corporate stock for the sole purpose of giving manipulative boosts to their stock prices.** Incentivizing these buybacks is stock-based compensation**that rewards senior executives for increases in their companies’ stock prices** (Lazonick 2014b; Lazonick 2014c; Lazonick 2015b; Hopkins and Lazonick 2016).

### Profits are 2x as high S&P 500, def something wrong

Neera [**Tanden**](https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/encourage-drug-research-over-profiteering-29) notes in the **New York Times** that in 2014,

"pharmaceutical costs grew 13.6 percent – faster than any other part of the healthcare industry – and pharmaceutical company profits were nearly 20 percent in 2012, double the average profit margin for the S&P 500 ”

## A2: Will Cut R&D

Double Bind

1. R/D opportunities would create new, unique solutions, then they will priotize monopolies and cut from other areas
2. R/D opportunities unlikely, then wouldn’t do it regardless

### 2. Delink: Barely any money goes to R&D anyways - mostly marketing/profit (BW)

[Joel Lexchin 05 York University](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1261198/)

Whether domestic revenues recover a given country's research and development costs is also irrelevant. If this were not the case the industry would have shut down operations in Switzerland long ago because of its small market size. If revenues are inadequate, it would make more sense to conclude they do not cover all marketing costs rather than research costs. Research is central to the industry, and costs associated with it should be deducted first. **Pharmaceutical companies report that they invest around three times more in the combination of marketing, advertising, and administration than in research, leaving ample room to cut costs**

[Ray Drasga 14](http://ascopubs.org/doi/full/10.1200/JOP.2013.001160) University of Illinois

Drugs and Medical Devices The cost of medications in the United States is higher than in any other developed country. The consulting firm McKinsey estimated that **pharma**ceutical **prices** in the United States **are 50% higher than in Europe for the same medications**, **and****118% higher****because of the more expensive US mix of drugs**.51 **Although drug companies**claim their high US prices are needed to cover their research costs, they only **spend 13% of their revenues on research** and development **compared with a much higher 31% on marketing and 20% on profit**.52 **Lower drug prices would not jeopardize drug innovation. Most true innovations in therapeutics** (**as opposed to** so-called me-too drugs that are slightly different versions of existing drugs) **stem from public**ly financed **research.**53

### 4. Even if they prove a connection to r/d, the r/d that will be cut will be the extra, superfluous testing that they do to try to make one drug look different than another.

[Santerre from the University of Connecticut](https://www.researchgate.net/publication/252205055_DRUG_PRICES_AND_RD_INVESTMENT_BEHAVIOR_IN_THE_PHARMACEUTICAL_INDUSTRY) 2018 \*\*\*dates are important!!!

First, **large pharmaceutical companies may spend beyond the efficient level on R&D because a substantial amount of testing not required by the FDA may be done for marketing purposes to distinguish one drug from other substitutes.** If price-cost margins of large pharmaceutical companies were thinner, a **as result of a drug price control, less of this optional or socially superfluous testing would be done**

### 3. Look to other countries. Other countries with PC have still contributed to innovation; high us prices haven’t been associated with more than expected innovation

[Wang from Yale University School of Medicine 2010](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866602/)

**Many countries with significant price regulation were important innovators of pharmaceuticals; therefore, our data suggest that country-specific pricing policies probably do not affect country-specific innovation**. For example, although prices in the United Kingdom are much less than are prices in the United States, the industry continues to be very profitable and innovative.11 In Canada, income from domestic sales of brand name companies is, on average, about 10 times greater than is research and development costs, even in the face of prices that are approximately 40% lower than in the United States.11 In addition, companies in the United Kingdom invest proportionately more revenue from domestic sales into research and development activity than do their US counterparts.11 Despite the above average profitability of US-based companies,26 **the higher prices paid by US consumers are not rewarded by more than expected domestic innovation.** US consumers pay disproportionately higher prices for brand name drugs,6 but the United States is not disproportionately innovative

1. TURN: things that decrease profits have historically resulted in increased public sector funding

<http://www.medicaldevicedaily.com/servlet/com.accumedia.web.Dispatcher?next=bioWorldHeadlines_article&forceid=98986&fbclid=IwAR388xOxhn8rDx3Vn2okORbNwSpNna7gXNd7G_3Hf1tpdYH8wXJJpzwJZ6Q>

**McCarthy Aug 27, 2018**

**The U.S. Senate passed a spending bill that would provide the National Institutes of Health with roughly $39 billion in the coming fiscal year, but the legislation also provides funding for development of drug pricing regulations.** While the Senate must reconcile its bill with the House of Representatives, the Trump administration has frequently promoted the idea of pharmaceutical price transparency, suggesting this provision has only to get past the House of Representatives to become law.

"The Senate version of H.R. 6157 emerged from the Senate floor with a resounding 85-7 vote in favor of passage, and a number of amendments arose on the last day of debate. **Working in the shadow of predictions that Alzheimer's disease will cost the U.S. economy more than** [**$1**](https://www.messenger.com/t/1851677944901164) **trillion by mid-century, the Senate provided an additional** [**$425**](https://www.messenger.com/t/1851677944901164) **million in spending on research into Alzheimer's disease**, a boost that would bring funding for this disease to roughly [$2](https://www.messenger.com/t/1851677944901164) billion in fiscal 2019."

<https://www.nejm.org/doi/full/10.1056/NEJMsa1008268>

Stevens Feb 10, 2011

We identified the distribution of the 153 products among four broad categories of therapeutic products (Table 1 in the [Supplementary Appendix](https://www.nejm.org/doi/suppl/10.1056/NEJMsa1008268/suppl_file/nejmsa1008268_appendix.pdf)). Particularly noteworthy was the large number of vaccines. **Virtually all the important, innovative vaccines that have been introduced during the past 25 years have been created by PSRIs.**

**https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0917**

**Bhaven Sampat Feb 2011**

The **nineteen HIV/AIDS drugs** we studied were exceptional in terms of all our indicators of direct or indirect government influence ( [Exhibit 3](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0917#EX3) ). Nearly a third of these drugs had a public-sector patent, and close to **95 percent cited government-funded research**.

## A2 R/D from Pharma actually matters

Zaitchik June 28, 2018 https://newrepublic.com/article/149438/big-pharma-captured-one-percent

In truth, the pharmaceutical industry in the United States is largely socialized, especially upstream in the drug development process, when basic research cuts the first pathways to medical breakthroughs**. Of the 210 medicines approved for market by the FDA between 2010 and 2016, every one originated in research conducted in government laboratories or in university labs funded in large part by the National Institutes of Health. Since 1938, the government has spent more than** [**$1**](https://www.messenger.com/t/brandonw.001) **trillion on biomedical research,** and at least since the 1980s, a growing proportion of the primary beneficiaries have been industry executives and major shareholders. Between 2006 and 2015, these two groups received 99 percent of the profits, totaling more than [$500](https://www.messenger.com/t/brandonw.001) billion, generated by 18 of the largest drug companies. This is not a “business” functioning in some imaginary free market. It’s a system built by and for Wall Street, resting on a foundation of [$33](https://www.messenger.com/t/brandonw.001) billion in annual taxpayer-funded research.

<https://www.washingtonpost.com/news/theworldpost/wp/2018/10/17/pharmaceutical/?utm_term=.c1f926d5752b>

By Mariana Mazzucato October 17

Sofosbuvir is not an exception. **The U.S. taxpayer has funded research for every single one of the 210 new drugs that the FDA approved between 2010-16.** Yet the companies that have access to this research are increasingly viewing pharmaceuticals in the same way that banks view their financial product — opportunities for short-term returns.

Hagop **Kantarjian 16**, (), "The Harm of High Drug Prices," US News &amp; World Report, 12-12-2016, https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-high-drug-prices-to-americans-a-continuing-saga, 10-31-2018 (cut by SA)

Under criticism, the drug industry repeats the same arguments: 1) high cost of research and development; 2) benefit justifies price; 3) market forces; and 4) regulating prices stifles innovation. But all four arguments lack validity. The cost of research and development is only 10 percent of the $1-2.6 billion figure that is claimed in industry-supported studies. **More than 50 percent of important discoveries are made in independent academic centers, funded by taxpayers, and 85 percent of basic research is conducted in academic centers. The drug industry spends 1.3 percent of its budget on basic research, but 20-40 percent on advertisements and related activities.** Some **studies show no relationship between drug benefits and price**. Drug companies enjoy monopoly-like conditions that discourage competition based on price. Finally, **innovation is driven by independent investigators who will continue to conduct research even if drug prices fall.**

### 1. Most innovation done by public research. The r/d done by pharma is just me-too drugs that slightly different versions of existing drugs so they can sell more drugs. Public research creates new drugs, pharma just markets them

[Ray Drasga 14](http://ascopubs.org/doi/full/10.1200/JOP.2013.001160) University of Illinois

Drugs and Medical Devices The cost of medications in the United States is higher than in any other developed country. The consulting firm McKinsey estimated that pharmaceutical prices in the United States are 50% higher than in Europe for the same medications, and 118% higher because of the more expensive US mix of drugs.51 Although drug companies claim their high US prices are needed to cover their research costs, they only spend 13% of their revenues on research and development compared with a much higher 31% on marketing and 20% on profit.52 **Lower drug prices would not jeopardize drug innovation. Most true innovations in therapeutics** **(as opposed to so-called me-too drugs that are slightly different versions of existing drugs**) **stem from public**ly financed **research.**53

[**Thomas 16**](https://sciencebasedmedicine.org/rd-and-the-high-cost-of-drugs/) (NA)

First, **important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health. A recent analysis of the most transformative drugs of the last 25 years found that more than half of the 26 products or product classes identified had their origins in publicly funded research in such nonprofit centers.** Other analyses have highlighted the importance of small companies, many funded by venture capital. These biotech startups frequently take early-stage drug development research that may have its origins in academic laboratories and continue it until the product and the company can be acquired by a large manufacturer, as occurred with sofosbuvir. Arguments in defense of maintaining high drug prices to protect the strength of the drug industry misstate its vulnerability. The biotechnology and pharmaceutical sectors have for years been among the very best-performing sectors in the US economy. The proportion of revenue of large pharmaceutical companies that is invested in research and development is just 10% to 20% (Table 4); if only innovative product development is considered, that proportion is considerably lower. The contention that high prescription drug spending in the United States is required to spur domestic innovation has not been borne out in several analyses . A more relevant policy opportunity would be to address the stringency of congressional funding for the National Institutes of Health, such that its budget has barely kept up with inflation for most of the last decade. Given the evidence of the central role played by publicly funded research in generating discoveries that lead to new therapeutic approaches, this is one obvious area of potential intervention to address concerns about threats to innovation in drug discovery.

Americans invest over $32 billion annually in medical research through the National Institutes of Health (NIH) alone. To put that in perspective Pfizer’s entire 2014 R&D budget was about $7.2 billion. But even this doesn’t tell the whole story because R&D means research and development. **While NIH funding is almost entirely for** basic research, the sort of fundamental **research that** fuels new understandings, opens new avenues and **leads to new drugs** and therapies**,** Big Pharma spends most of its R&D money on the development end – clinical trials.

So of Pfizer’s $7.2 billion R&D budget, perhaps 1.5 billion goes to basic research. Even there much of pharmaceutical companies’ R&D feeds on publicly-funded research. In a study published in Health Affairs, Kesselheim et al. note:

Perhaps the most common pattern of interaction involved academic scientists’ conceptualizing a therapeutic approach based on basic research about disease mechanisms and then demonstrating the proof of concept for a given molecule. Industry collaborators then developed the product for more extensive clinical testing.

The point here is that **pharmaceutical companies are increasingly in the busines s of running clinical trials and marketing drugs rather than** plowing the hard ground for **new discoveries**. In this sense the basic research costs are socialized while the profits, increasingly breathtaking profits, are privatized.

### 2. TURN/ Incentivize companies to develop new drugs since only new, unique drugs represent new areas of proft.

[Kirkwood 16](https://digital.law.washington.edu/dspace-law/bitstream/handle/1773.1/1573/91WLR0253.pdf?sequence=1&isAllowed=y) (NA)

In fact, **because federal negotiation would increase the relative profitability of new, unique drugs, it may actually heighten the incentive to develop them**.85 Finally, the companies are aided in their search for the next breakthrough drug by the federal government’s extensive support of basic scientific research.86 In short, it appears that federal negotiation of Medicare prescription drug prices is unlikely to cause a large decline in new drug development, particularly of drugs that constitute a major therapeutic advance. At the same time, the prices of those important new drugs are likely to remain high and, so long as they are on patent, to increase significantly each year. Since the government has little power to reduce these prices through negotiation alone, it may be appropriate, if fiscal pressures become acute, to turn to compulsory arbitration.Mergers and acquisitions thump---devastates innovation

Feldman, Robin, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256. Available at SSRN: <https://ssrn.com/abstract=3061567> or [http://dx.doi.org/10.2139/ssrn.3061567](https://dx.doi.org/10.2139/ssrn.3061567)

This study examines all drugs on the market between 2005 and 2015, identifying and analyzing every instance in which the company added new patents or exclusivities. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Key results include: 1) Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones**. On average, 78% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs**; 2) Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once; 3) Once a company starts down this road, there is a tendency to keep returning to the well. Looking at the full group, 80% of those who added protections added more than one, with some becoming serial offenders; 4) The problem is growing across time.

<https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.5.w969>

Donald Light, Oct 2009

It is widely believed that the United States has eclipsed Europe in pharmaceutical research productivity. Some leading analysts claim that although fewer drugs have been discovered worldwide over the past decade, most are therapeutically important. **Yet a comprehensive data set of all new chemical entities approved between 1982 and 2003 shows that the United States never overtook Europe in research productivity, and that Europe in fact is pulling ahead of U.S. productivity**. Other large studies show that most new drugs add few if any clinical benefits over previously discovered drugs. I discuss ways in which Congress, employers, and insurers can increase the value of drugs and revitalize the U.S. pharmaceutical industry.

How did the United States, Europe, and Japan perform for global and first-in-class new chemical entities? In global NCEs, European research productivity was about the same as U.S. productivity in the first period but increased by 30 percent in the second period (1993–2003), while U.S. research productivity declined 26 percent (Exhibit 3 ). **In first-in-class drugs, European relative innovativeness moved from well behind the United States in the first period to well ahead in the second. These are the most commercially and therapeutically important types of new chemical entities.**

## A2 Innovation Decrease

### 11. NUQ: Innovation is shifting to other countries (BW)

[Dr. Scott Atlas Stanford University 2014](https://www.hoover.org/research/obamacares-anti-innovation-effect-0)

But that environment is changing. According to R&D Magazine and the research firm Battelle, **growth of R&D spending in the U.S. from 2012 to 2014 averaged just 2.1%, down from** an average of **6%** over the previous 15 years. In that same 15-year period, **Malaysia, Thailand, Singapore, South Korea, India and the European Union saw faster R&D spending growth than the U.S. China's grew on average 22% per year.**

**3 warrants (original text below):**

1. **New taxes under ObamaCare [have made] healthcare technology companies [move] R&D centers and jobs overseas.**
2. **The FDA bureaucracy is slowing down the drug development process.**
3. **Brain Drain: Many students who came to the US to study STEM are returning to their home countries because of a lack of visas.**

The recent slowdown in R&D spending in the U.S. is in part caused by weak economic growth since the 2008 financial crisis. But the economy's weakness itself has been exacerbated by the negative impact of **new taxes** and regulations **under ObamaCare**. According to Congressional Budget Office estimates, the new health-care law will levy more than $500 billion in new taxes over its first 10 years to help pay for insurance subsidies and Medicaid expansion. These new taxes include significant levies on key health-care industries, such as manufacturers of medical devices and drugs, and their investors. As a result, small and large U.S. **[have made] health-care** technology **companies [move] R&D centers and jobs overseas.**

**The bureaucrats at the Food and Drug Administration are also hindering medical-technology and drug development.** According to a 2010 survey of more than 200 medical-device companies by medical professor and entrepreneur Josh Makower and his colleagues at Stanford University, delays of approvals for new medical devices are now far longer in the U.S. than in many other developed countries. In the European Union—not exactly known for cutting through red tape—it takes on average seven months to gain approval for low- to moderate-risk devices. In the U.S., FDA approval for similar devices takes on average 31 months.

**Meanwhile, many of the best and brightest who come to the U.S. to study science, technology, engineering and math—the STEM subjects that are so crucial to innovation—are choosing to return to their home countries upon graduation.** In 2008, a survey conducted by Vivek Wadhwa and his team of researchers at Duke, Harvard and the University of California found that only 6% of Indian, 10% of Chinese and 15% of European students expected to make America their permanent home. Much of this is Congress's fault. Lawmakers have been slow to increase limits on H-1B visas for high-skill foreign workers. Pressure has been brought to bear on Congress to take action, but it may be too late for an increase in the visas to have much effect in health care, given the decline in R&D spending that would make use of their talents.

### 2. Turn: Less US innovation stop international freeriding and increase innovation elsewhere. (BW)

[Mark Thoma 6 University of Oregon](http://economistsview.typepad.com/economistsview/2006/10/singlepayer_hea.html)

Given that **European countries can free ride on [US] research,** comparing the amount spent in the two countries may not accurately reflect European willingness to fund health care research since the two figures may not be independent. **If the U.S. spent less, European countries might be induced to spend more.**

# A2: Shortages

## A2: Cause of shortages

**1. TURN/Companies collude to pretend there are shortages in the squo to spike prices; pc solve**

B[elk](https://www.huffingtonpost.com/entry/collusion-or-coincidence-the-making-of-a-drug-shortage_us_5995eba9e4b03b5e472cedcf) 17 HuffPo

There’s also a rather dishonest reason six **pharmaceutical companies might simultaneously “run out” of the same drug**. **They might do this to give them an excuse for increasing the price of that drug** (to increase profits). This strategy wouldn’t work if only one or two companies stopped making a drug but, if (hypothetically) all six companies agreed to simultaneously limit supply, they could use this shortage as a pretext to drive the price up substantially.  Such agreements, while profitable, are also highly illegal. Again, I can’t be sure this is happening here, but I can tell you that **collusion between major corporations is apparently quite common. The reason collusion of this sort is so common (even though it’s illegal) is that it’s hard to prove conclusively and, when used properly, it can earn the colluding companies a lot of extra money.** For example: last December the Attorneys General of 20 different states filled charges accusing six generic pharmaceutical companies of colluding to fix the prices of at least two (and possibly many more) generic drugs in the past. The six companies in this case are: Mylan and Teva (again), Citron Pharma, Heritage Pharmaceuticals, Aurobindo Pharmaceuticals and Mayne Pharmaceuticals.

**2. NU/The FDA is working to alleviate shortages, 170 stopped in 2013**

[**McKesson**](https://www.mckesson.com/blog/preparing-for-drug-shortages/) **(JL)**

**The Food and Drug Administration (FDA) has implemented several initiatives, including the FDA Safety and Innovation Act and Strategic Plan for Preventing and Mitigating Drug Shortages, to help reduce drug shortages over the long term. According to the FDA, these efforts helped prevent 170 new shortages in 2013**.8 In addition, the pharmaceutical industry has launched its own initiatives to better prevent and forecast shortages.

## A2: Market Withdrawals

1. **Companies prioritize production regardless of low sales and low margins in order to limit shortages**

[**Synder 2017**](https://www.pewtrusts.org/-/media/assets/2017/01/drug_shortages.pdf) **(NA)**

Nine companies said patient impact (influenced by the number of replacements on the market) was a major factor they considered before exiting a market or deciding not to invest in additional facilities and/or equipment. The **companies** said that investments made to prevent drug shortages were not exclusive to high-margin products and that they would evaluate investments to help protect low-margin products from shortages, especially for drugs that had only limited replacements on the market. But they said that if a product had multiple replacements, meaning that patients’ needs could be met by other manufacturers, they would limit investments and potentially withdraw a product from the market. All the companies noted that **they prioritize the production of legacy products that have no replacements on the market, even when products had low margins and low sales volumes, since continuing to produce the legacy product would limit the potential impact on patients and also protect the company’s brand.**

1. **Room to shut down**

[Keeling 10, McKinsey](https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/operations/pdfs/outlook_on_pharma_operations.ashx)

**Pharma could shut down three out of four plants today and still meet demand**

## A2: Quality Assurances

1. **Failure to meet FDA regulations can lead to a recall. Theres no reason why companies would cut and risk that**

[FDA](https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm)

Pharmaceutical Quality affects every American. **The Food and Drug Administration (FDA) regulates the quality of pharmaceuticals very carefully. The main regulatory standard for** ensuring pharmaceutical quality is the Current Good Manufacturing Practice (CGMPs) regulation for human pharmaceuticals. Consumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective. Most people, however, are not aware of CGMPs, or how FDA assures that drug manufacturing processes meet these basic objectives. Recently, FDA has announced a number of regulatory actions taken against drug manufacturers based on the lack of CGMPs. This paper discusses some facts that may be helpful in understanding how CGMPs establish the foundation for drug product quality. FDA inspects pharmaceutical manufacturing facilities worldwide, including facilities that manufacture active ingredients and the finished product. Inspections follow a standard approach and are conducted by highly trained FDA staff. FDA also relies upon reports of potentially defective drug products from the public and the industry. FDA will often use these reports to identify sites for which an inspection or investigation is needed. **Most companies that are inspected are found to be fully compliant with the CGMP regulations.If the failure to meet CGMPs results in the distribution of a drug that does not offer the benefit as labeled because, for example, it has too little active ingredient, the company may subsequently recall that product.**This protects the public from further harm by removing these drugs from the market. While FDA cannot force a company to recall a drug, companies usually will recall voluntarily or at FDA’s request. If a company refuses to recall a drug, FDA can warn the public and can seize the drug.

1. **Delink: The majority of bad drugs come from the internet or developing countries where there is little regulation**

[Baggaley 17](https://www.popsci.com/what-can-we-do-to-stop-fake-medicines)

Stopping the influx of these faux medications isn't a simple prospect. In the United States, “The majority come from purchases on the Internet, which is an unregulated and unsecure supply chain,” says FDA Special Agent Daniel Burke, senior operations manager in the organization’s Cybercrimes Investigations Unit. And antimicrobial drugs aren't typically on the menu. “Antibiotics aren’t generally all that expensive; why would I counterfeit or make a substandard version of tetracycline when I can make a ton of money by selling [the hepatitis C treatments] Sovaldi or Harvoni?” Burke says. In developing nations, it's another story entirely. Antibiotics and antimalarial medicines are among the drugs most commonly affected and reported to the WHO**. Fake and poor quality medicines thrive in countries that lack strong regulations or oversight from organizations like the U.S. Food and Drug Administration.** In these areas, it’s also more common for people to be unable to find or afford the medicines they need. “If you desperately need a life-saving medication, and you can’t find it in your secure and reliable sources…you might procure it from unreliable sources,” Bourdillon Esteve says.

## A2: Impacts

**1. Turn: short-term shortages cause companies to overcompensate in the long term, leading to long term improvements that solve back**

**Kim from** [**Yale 2015**](http://faculty.som.yale.edu/sangkim/DrugShortage.pdf) **(Timeframe: neg shortages are solved back by the increase in capacity, these improvements say with the firm forever) {NO}**

We Önd that disruption probability and availability are nontrivially linked. Namely, the Örmsí equilibrium choices of spare capacities reverse the usual relationship between the two variables: a higher chance of disruptions [shortages] leads to higher availability**. Clearly, an immediate impact of increased [shortage] disruption probability is lower product availability and reduced sales**. **This direct effect, however, is countered by an indirect effect - firms’ capacity expansions to mitigate sales losses - which pushes availability in the opposite direction.** Interestingly, **the indirect effect dominates the direct effect, hence the reversal.** Our analysis reveals that this **overcompensation** arises because the shortage risk has a greater impact on the ÖrmsíproÖtability than it does on the consumersíchance of obtaining the product

# A2: Superbugs

## General Non-Unique

1. **Already free/discounted in many states**

[Li 2015,](http://sci-hub.tw/https:/onlinelibrary.wiley.com/doi/pdf/10.1002/hec.3008)

**Many national and local retail chains are now offering free or discounted antibiotics to their customers. Although the** main **stated intent of these programs is to help families reduce medical costs**, many worry that **these programs could lead to unintended consequences of antibiotic overuse and increased drug resistance.** This analysis presents a first step to examine this concern. Our finding that these programs indeed **[by] increase antibiotic usage** suggests that further research in this regard is warranted. One possible research design is to examine the effect of the program during the flu season, when inappropriate usage is more common.

[Outterson 15](https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2014.1003)

**Antibiotics** were the original wonder drugs, but they **have never been very expensive**. In community settings, **some US pharmacies offer generic antibiotics free (or nearly so)to drive traffic to their stores** In US hospitals, antibiotics are generally included within a bundled payment, giving hospitals strong financial incentives to limit the introduction of more expensive drugs unless clinically necessary. In both settings, new antibiotics compete against an array of low-cost generics that remain effective enough to suppress pricing for the vast majority of clinical applications. As a result, antibiotics accounted for 6.4 percent of all US prescriptions in 2013 but only 2.6 percent by value.

## A2: Aff general

1. **Mitigation: Antibiotic use is mainly growing in developing countries. DEve {NO}**

[**Klein 2018,**](http://www.pnas.org/content/early/2018/03/20/1717295115)

In HICs, although the total amount of antibiotics consumed increased 6% **between 2000 and 2015**, from 9.7 to 10.3 billion DDDs, **the antibiotic consumption rate decreased by** a modest **4% [in developed countries]**, from 26.8 to 25.7 DDDs per 1,000 inhabitants per day ([Fig. 2*A*](http://www.pnas.org/content/early/2018/03/20/1717295115#F2)). **In [developing countries], antibiotic consumption increased 114%**, from 11.4 to 24.5 billion DDDs, and the antibiotic consumption rate increased 77%, from 7.6 to 13.5 DDDs per 1,000 inhabitants per day. Low- and lower-middle-income countries (LMICs-LM) accounted for a greater share of this increase than upper-middle-income countries (LMICs-UM): total antibiotic consumption in LMICs-LM increased 117%, from 8.1 to 17.5 billion DDDs, while, in LMICs-UM, antibiotic consumption increased 110%, from 3.3 to 6.9 billion DDDs

1. **Accessible and cheap drugs promote overuse**

[Ventola 2015](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/)

“An analysis of the IMS Health Midas database, which estimates antibiotic consumption based on the volume of antibiotics sold in retail and hospital pharmacies, indicated that in 2010, 22.0 standard units (a unit equaling one dose, i.e., one pill, capsule, or ampoule) of antibiotics were prescribed per person in the U.S.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/#b17-ptj4004277) The number of antibiotic prescriptions varies by state, with the most written in states running from the Great Lakes down to the Gulf Coast, whereas the West Coast has the lowest use. In some states, the number of prescribed courses of treatment with antibiotics per year exceed the population, amounting to more than one treatment per person per year.[12 In many other countries, antibiotics are unregulated and available over the counter without a prescription.](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/#b12-ptj4004277)[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/#b10-ptj4004277)[,](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/#b12-ptj4004277)[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/#b15-ptj4004277) [This lack of regulation results in **antibiotics that are easily accessible, plentiful, and cheap,** which **promotes overuse.**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/#b12-ptj4004277)[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378521/#b15-ptj4004277) The ability to purchase such products online has also made them accessible in countries where antibiotics *are* regulated...The overuse of antibiotics**[which] clearly drives the evolution of resistance”**

## A2: Lack of adherence causes it

1. **NU: underuse doesn’t cause it, overuse does**

[**Llewelyn 17**](https://www.bmj.com/content/358/bmj.j3418.full)

**However, the idea that stopping antibiotic treatment early encourages antibiotic resistance is not supported by evidence, while taking antibiotics for longer than necessary increases the risk of resistance.**

## A2: Neg

1. **Already free/discounted in many states -> overuse/drug resistance**

[Li 2015,](http://sci-hub.tw/https:/onlinelibrary.wiley.com/doi/pdf/10.1002/hec.3008)

**Many national and local retail chains are now offering free or discounted antibiotics to their customers. Although the** main **stated intent of these programs is to help families reduce medical costs**, many worry that **these programs could lead to unintended consequences of antibiotic overuse and increased drug resistance.** This analysis presents a first step to examine this concern. Our finding that these programs indeed **[by] increase antibiotic usage** suggests that further research in this regard is warranted. One possible research design is to examine the effect of the program during the flu season, when inappropriate usage is more common.

# A2: Developing Countries (aff)

## A2: Parallel Trade – U.S.

1. **Literally illegal**

<https://assets.aarp.org/www.aarp.org_/articles/international/ReimportationQA.pdf>

It is against current U.S. law to re-import prescription drugs (the legal exceptions are that drugs manufactured in the U.S. may be re-imported by the original manufacturer or if the drug is required for “emergency medical care”). It is also illegal to advertise or otherwise promote re-imported drugs.

[**https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143561.htm**](https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143561.htm)

**march 1, 2018**

**The FD&C Act also states that prescription drugs made in the United States and exported to a foreign country can only be re-imported by the drug's original manufacturer**. Even when original manufacturers re-import drugs, the drugs must be real, properly handled, and relabeled for sale in the United States if necessary.

[**https://drugsafetynews.com/2018/04/25/u-s-law-against-drug-reimportation-originally-it-was-a-good-idea-but-has-outlived-its-purpose/**](https://drugsafetynews.com/2018/04/25/u-s-law-against-drug-reimportation-originally-it-was-a-good-idea-but-has-outlived-its-purpose/)

**April 25, 2018**

**Since then, however, the law has expanded to include any and all prescription drugs from outside the U.S.** Oddly, the [FDA website](https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194904.htm) says the reason is “because drugs from other countries that are available for purchase by individuals often have not been approved by FDA for use and sale in the United States,” even though in the vast majority of cases, those drugs are the same. There are **a few exceptions** to the FDA regulation; drugs that are used for serious conditions for which there are no treatments in the U.S. and are “not considered to represent an unreasonable risk” **are permitted, providing that the patient certifies in writing that it is for his or her own personal use or is for the continuation of a treatment started overseas. Patients must also provide the name of their physicians and are limited to purchasing a three month supply.**

**https://www.washingtonpost.com/news/to-your-health/wp/2018/07/19/trump-administration-to-explore-drug-imports-to-counter-price-hikes/?utm\_term=.6757c60b7eee**

**McGinley July 19th, 2018**

**Generally, the importation of drugs from other countries is illegal**. But the FDA doesn't enforce the ban against individuals bringing in small amounts of  drugs for personal use. And it occasionally allows the importation of foreign-approved drugs to ease supply shortages, such as those resulting from last year's hurricane in Puerto Rico.

1. Pc means no demand (also that’s the link to their case)

<https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.0923>

**Additionally, when profit margins are fixed,there is little demand for parallel imports that offer a lower price for an existing product.** The Netherlands and the United Kingdom use “clawback” mechanisms, in which any savings from the use of parallel imports are shared by the pharmacist and the government health authority.3

1. Not a threat, solve easily

**The available evidence on parallel trade suggests that its impact on manufacturers’ revenue and price differentials is relatively modest**. Because countries and manufacturers have ways to limit the trade’s effects, **it is not a major impediment to setting lower pharmaceutical prices in less-developed countries**

1. TURN/ High prices lead to subsidies rn, encourage selling

**Michelle Mello, June 2018**, <http://www.minnesotalawreview.org/wp-content/uploads/2018/07/Mello_MLR.pdf>

s. **Because we pay so much, pharmaceutical companies may be more willing or able  to grant price concessions elsewhere, including outright donation of critical medications to low- income countries. Actions we take to restrict price, therefore, could have unintended, but real, effects on drug affordability in less wealthy countries**. ...However, because the market for prescription drugs is global but is propped up by high prices in the United States, tamping down drug prices has a zero-sum-game quality that is unique. Squeezing one part of the drug-price balloon may cause it to bulge out in other areas

## A2: Parallel Trade – Other

[Jena from the Hill (JW)](https://thehill.com/opinion/healthcare/369727-us-drug-prices-higher-than-in-the-rest-of-the-world-heres-why)

One answer is that[**nearly all countries except the U.S.**](https://www.trade.gov/td/health/drugpricingstudy.pdf) **have** [**policies**](http://www.sciencedirect.com/science/article/pii/S0167629614000472?via%3Dihub) **to** [**lower drug prices**](http://www.sciencedirect.com/science/article/pii/S0167629614000472?via%3Dihub)**, including** [**price controls**](http://gabi-journal.net/the-impact-of-pharmaceutical-pricing-and-reimbursement-policies-on-generics-uptake-implementation-of-policy-options-on-generics-in-29-european-countries%E2%94%80an-overview.html)**, regulations that limit the profitability of drugs, reference pricing, and cost-effectiveness thresholds** (e.g., in the U.K., the National Health Service is the main purchaser of drugs and [frequently](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3109977/) does not cover therapies whose cost per "quality-adjusted" life year gained exceeds [$50,000 per year](http://www.tandfonline.com/doi/abs/10.1586/14737167.8.2.165?journalCode=ierp20)).

https://2016.trade.gov/td/health/DrugPricingStudy.pdf

**The study examined the drug price regulatory systems of 11 OECD countries and found that all rely on some form of price controls to limit spending on pharmaceuticals**

## A2: Donations

1. **Other reasons:**

[**http://www.cptech.org/ip/health/econ/taxcode.html**](http://www.cptech.org/ip/health/econ/taxcode.html)

**1. Tax deductions 2. Get rid of excess stock without having to pay for cost of destruction**

[**Pinheiro 2008 WHO**](http://www.who.int/bulletin/volumes/86/8/07-048546/en/)

**Drug donations provide benefits such as tax deductions and are a very convenient way for industries to get rid of stagnant stocks without having to pay for their controlled and expensive destruction in their country of origin**.[5](http://www.who.int/bulletin/volumes/86/8/07-048546/en/#R5) Some entities seem to find it legitimate to send unusable drugs to nations which are not prepared to dispose of them safely and properly. The recipients receive the drugs as donations and instead are obliged to manage them as waste. Lamentably, there is no international convention to regulate the transfer of non-requested pharmaceutical products and surpluses across borders. Once received into a country, the donations cannot be returned to donors, as recommended by the guidelines, because they are considered hazardous cargo and their shipment must respect the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.[6](http://www.who.int/bulletin/volumes/86/8/07-048546/en/#R6) This legal demand involves the existence of consented protocols between exporters and importers, and time-consuming procedures that severely compromise its feasibility.

**Nwabueze 05** – Professor of Law @ University of Ottawa [Remigius N. Nwabueze, “WHAT CAN GENOMICS AND HEALTH BIOTECHNOLOGY DO FOR DEVELOPING COUNTRIES?,” Albany Law Journal of Science & Technology, 2005, 15 Alb. L.J. Sci. & Tech. 369]edlee

Biotechnology R&D is an expensive enterprise, and only wealthy countries and corporations can afford the necessary investment. 88 Though the public sector in some developed countries is actively involved in biotechnology research, 89 the sector is dominated by private corporations, as shown in a recent survey by the Stanford-in-Washington Program. 90 The concentration of biotechnology R &D in the North has important implications for research priorities, which are strongly driven by market and profit incentives. 91 Accordingly, since developing countries constitute only 20% of the global pharmaceutical market, 92 and Africa only 1.1% of that market, 93 it would appear that **diseases prevalent in such countries are largely neglected in the research agendas of Western biotech and pharmaceutical industries. 94 Biotech industries concentrate on diseases prevalent in developed countries, where there is effective market for their products and consumers whose demands are backed by effective purchasing power**. 95 It is [\*389] therefore not surprising that out "of the 1233 new drugs marketed between 1975 and 1999, only 13" were for diseases suffered in developing countries. 96 Worse still, only 4 out of the 13 tropical disease drugs resulted from the research and development during this period. Two of the remaining 9 came from improvements on earlier drugs, and 7 were the products of military and veterinary research. 97

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/

At first glance it might be a simple index like thousands of other scientific measures. However, looking closer at the **index one can notice that it is effectively encouraging big pharma to increase the access to their products in their own way** and without any legislative obligation. Hogerzeil et al. showed that average score of these big pharmaceutical companies increased since 2010 to 2012 and we can be hopeful about continue of this increasing trend [[24](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/#CR24)**]. The reasons that may explain this positive effect, first is the attempts of companies to improve their image in the public opinion, which might be a promotion for their products and attract direct costumers. And second, the effect of improving public image on share values and convincing more shareholders to invest on the company**. However, this encouraging effect is still a theory and not proven yet, particularly in long term. By looking at the index for 2014 we can see a decreasing trend for most of the companies since 2012. It seems that even if it is effective, it cannot be a guarantee for improvement of access to medicine overtime.

**3. PR bc compete to get higher on Access to Medicines Index**

https://www.nytimes.com/2017/10/07/health/africa-cancer-drugs.html?\_r=0

**Companies compete to rise higher on the**[**Access to Medicines Index**](https://www.nytimes.com/2014/12/02/science/glaxosmithkline-leads-in-getting-drugs-to-poor.html?module=inline), which ranks them on how well they do at getting their products to the world’s poor.

John Young, president of Pfizer’s essential health group, said the **price-cut deal differs from Pfizer’s charitable donations, like the 500 million antibiotics doses** it provided to help [eliminat](http://www.pfizer.com/news/featured_stories/featured_stories_detail/we_refuse_to_turn_a_blind_eye_to_trachoma)e[the eye disease trachoma](http://www.pfizer.com/news/featured_stories/featured_stories_detail/we_refuse_to_turn_a_blind_eye_to_trachoma).

**Now nearly all companies offer a combination of donations and “tiered pricing,” under which they**[**charge poor countries a small fraction**](https://www.nytimes.com/2015/12/16/health/hepatitis-c-treatment-egypt.html?module=inline)**of what they charge rich ones — but impose safeguards to prevent smuggling of their products into wealthy markets.**

To help prepare the new guidelines, WHO did a systematic review of drug donations during 1998 to 2008. It found that only 56% of donations were appropriate given the characteristics of the event and what the recipient needed, **and only 12.5% of drugs requested by recipient countries were received. Up to 80% of appropriate donations were surplus to requirement**. “**The ensuing cost of drug destruction, where documented, was significant,”** says Dr Moller, one of the authors of the review

## BC of this, doing it right now:

[**https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.0923**](https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.0923)

Aug 2011

**For patented drugs**, middle-income countries pay on average 52 percent of what industrialized countries pay, while **developing countries pay 27 percent of the prices charged in industrialized countries**. For drugs that are no longer patented, middle-income countries pay 71 percent and developing countries 41 percent of what industrialized countries pay, while **for** products on the **World Health Organization’s list of essential drugs,** the figures are 28 percent and **6 percent**. Thus, the average prices charged in developing countries for all three categories of drugs are much lower than those charged elsewhere.

and drugs that the **World Health Organization classifies as “essential”—that is, those drugs that satisfy the top-priority health care needs of a given population,** based on disease prevalence, evidence about the safety and efficacy of the drugs, and comparative cost-effectiveness.15 Products in this final group are typically older than those in either of the other two categories.

<https://outline.com/srZbum>

http://online.wsj.com/article/SB124691259063602065.html

With a handful of other drug makers, including the U.K.'s [GlaxoSmithKline](http://quotes.wsj.com/gsk) PLC, Switzerland's [Novartis](http://quotes.wsj.com/nvs) AG and France's Sanofi-Aventis SA, Pfizer is making a big push into the developing world. **In addition to Venezuela, the company is expanding in China, India, Brazil, Russia and Turkey. Pfizer brought in $1.4 billion in sales from emerging markets in the first quarter of this year**. That's a fraction of its $10.8 billion in overall sales in the same quarter, but a slice Pfizer says it's determined to expand.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/

The best known- and probably most effective- project in this area is “Access to Medicine Index”. This index was innovated and introduced in 2008 by Bill & Melinda Gates Foundation and measures the amount of activities of biggest pharmaceutical manufacturers in means of increasing access to essential medicine all around the world [[21](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/#CR21)]. In this index 7 fields of activities have been considered with different weights: “Pricing, manufacturing and distributing” with 25 %, “research and development” with 20 %, “Patent and licencing” with 15 % and “general access to medicine management”, “market influence”, “capacity building”, “product donations” each with 10 % share of scores. Each of these fields are assessed based on 4 main criteria: commitment, transparency, performance and innovation. **As an instance, Gilead Science Inc. had the highest score in the two fields of “pricing” and “patents” in recent years. This is probably because of increasing access to its new anti-viral medicine sofosbovir (Sovaldi) which has been provided 99 % off price for developing countries [**[**22**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/#CR22)**].** Although this medicine is provided with about $1200 per pill in US [[23](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/#CR23)], Gilead allowed generic licencing in developing countries so that the medicine can be accessible in very low price and save lives of millions of people with **hepatitis C,** as well as its benefit from the market. Other examples also can be seen in the index report which clearly shows the improvements and lacks of the companies’ policies.

## A2: Political Complaining

<https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2015/11/STAT-Harvard-Poll-Nov-2015-Controversy-Over-Rising-Drug-Prices.pdf>

nov 2015

**About three-fourths (76%) of the public believes that brand-name prescription drug prices are unreasonably high today**. This contrasts with the much lower 26% that believe generic prescription drug prices are unreasonable. **A majority of both Democrats (80%) and Republicans (70%) believe brand-name prescription drug prices are unreasonable**. This view was also found among both the 20% who reported that paying the costs of prescription drugs was a major problem for themselves and their families and the 80% who did not report that it was major problem.

## A2: India china countries

https://www.nytimes.com/2017/10/07/health/africa-cancer-drugs.html?\_r=0

**Now nearly all companies offer a combination of donations and “tiered pricing,” under which they**[**charge poor countries a small fraction**](https://www.nytimes.com/2015/12/16/health/hepatitis-c-treatment-egypt.html?module=inline)**of what they charge rich ones — but impose safeguards to prevent smuggling of their products into wealthy markets.**

**Companies compete to rise higher on the**[**Access to Medicines Index**](https://www.nytimes.com/2014/12/02/science/glaxosmithkline-leads-in-getting-drugs-to-poor.html?module=inline), which ranks them on how well they do at getting their products to the world’s poor.

John Young, president of Pfizer’s essential health group, said the **price-cut deal differs from Pfizer’s charitable donations, like the 500 million antibiotics doses** it provided to help [eliminat](http://www.pfizer.com/news/featured_stories/featured_stories_detail/we_refuse_to_turn_a_blind_eye_to_trachoma)e[the eye disease trachoma](http://www.pfizer.com/news/featured_stories/featured_stories_detail/we_refuse_to_turn_a_blind_eye_to_trachoma).

<http://fortune.com/2015/08/14/drug-companies-pharmerging-countries/>

By LAURA LORENZETTI August 14, 2015

These sweeping trends have grabbed drugmakers’ attention, and many of them are already cashing in on this growth. **Novartis** [(NVS, -1.10%)](http://fortune.com/2015/08/14/drug-companies-pharmerging-countries/), **Sanofi** [(SNY, +0.40%)](http://fortune.com/2015/08/14/drug-companies-pharmerging-countries/) **and AstraZeneca** [(AZN, -0.19%)](http://fortune.com/2015/08/14/drug-companies-pharmerging-countries/) **all derive a quarter or more of their sales from emerging markets**, according to [an analysis by Bernstein & Co](http://www.fiercepharma.com/story/emerging-markets-still-beat-elsewhere-big-pharma-growth-astrazeneca-lead/2015-06-23).

Twenty-one countries are considered by IMS to be “emerging” within the pharmaceutical world. This category is defined as countries that are expected to see more than $1 billion in absolute spending growth from 2014 to 2018 and which currently have GDP per capita of less than $25,000. **The biggest of these is China, followed by Brazil, India and Russia**; after them comes the “Tier 3” group of smaller emerging markets, including Mexico, Turkey, Venezuela, Poland and 13 others.

**Drug spending in these nations will be boosted by a combination of rapid population growth–a result of falling infant mortality rates–and longer life spans.** Many of these countries have also been [making large investments in healthcare](http://www.bakermckenzie.com/news/pharmerging-markets-report-dealing-with-uncertainty-03-05-2015/), said Jane Hobson, head of law firm Baker & McKenzie’s global life sciences group.

## A2: Africa and super poor

https://www.pharmamanufacturing.com/industrynews/2017/pfizer-cipla-to-slash-cancer-drug-prices-in-africa/

The two market access agreements with NY-based Pfizer and Mumbai-based Cipla promise to expand access **to sixteen essential cancer treatment medications, including chemotherapies, in Ethiopia, Nigeria, Kenya, Uganda, Rwanda and Tanzania.**

The agreements will set competitive prices on the meds, allowing African governments to realize substantial savings while improving the quality of available treatment. **As**[**reported by the NY Times,**](https://www.nytimes.com/2017/10/07/health/africa-cancer-drugs.html?_r=0)**Pfizer will set prices just above its own manufacturing costs.** Cipla said it would sell some pills for 50 cents and some infusions for $10.

# **A2: Mergers and Acquisitions Bad**

#### Innovation through acquisitions

<https://www.businessinsider.com/innovation-through-acquisition-2012-10>

2012

**A critical component of the entrepreneurial ecosystem in the U.S. is the mergers and acquisitions marke**t. I’ve sifted through a number of studies and estimates, and it’s safe to say that the vast majority (over 90 percent) of the successful private company exits in 2011 and 2012 have been through company sale or M&amp;A. (IPOs may represent a higher percentage of VC-backed company exits, but remember that only a minuscule proportion of all startups – even successful ones – are funded by VCs.) What makes the M&amp;A “engine” run, in a real sense, is the creative and innovative people on the big-company side of the fence who are constantly scanning the market for promising startups. Don’t roll your eyes. It’s what you might think of as a conscious innovation-thought- acquisition strategy. Probably the prime imperative for Fortune 500 managers is to find areas for revenue and profit growth. But the challenge is to do so without endangering the existing franchise. Too often, the dilemma from the helm looks like this: You know you need to get into a promising new space, but it’s quite unproven and you suspect running two or three concurrent experiments might bleed cash for years. So in a real sense, you can’t afford – on a quarter-to- quarter income statement basis – to run too many such risky projects. But if you let **entrepreneurial startups run the experiments with their energy, time and capital – and let them ring out the technology risk and the market risk – then once a winner appears, you can buy that winner with capital** off your balance sheet. The key is often to watch and wait until markets sort out, and business models are proven. Then success acquisitions are often the ones subjected to the most careful and sober-minded competitive and market analysis prior to pulling the trigger. **Innovation-through- acquisition can be a great growth catalyst and has become a crucial complement to internal, organic innovation in a growing number of industries** . Let’s look a handful of examples

1. M&A foster growth of startup; more breakthroughs

<https://www.statnews.com/2017/11/29/startups-growth-pharmaceutical-companies/>

It’s no surprise, then, that dynamic biotech startups are nipping at the heels of big pharmaceutical companies. In fact, 45 percent of the big companies’[total forecast revenue in 2016](https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-measuring-the-return-pharma-report-2016.pdf)came from external sources. The bottom line? **Big pharmaceutical companies need these upstarts, and industry players must do more to foster the growth of the startups they have come to rely on and improve collaboration with them.**

To understand why startups are so important to big pharmaceutical companies, look at how innovation has changed. Today, the business of discovering new targets and developing diagnostic tests and medicines is far more complex than it was in the 1980s, when bigger breakthroughs were more common. The key now is collaboration between multidisciplinary teams, some of which do not even belong to “your” organization. This requires a high degree of trust and closer working relationships than we are used to. Further, as we learn more about the precise genomic and molecular stratification of patient groups, and even the need to create individual drugs for individual patients, **research and development complexity is deepening and big breakthroughs are becoming less frequent. The blockbuster has given way to the nichebuster.**

#### Increased employment from in short and long run from mergers/acq from 1978 to 2008

Upadhaya 2011, University of New Haven

This article studies the employment effects of mergers and acquisitions in the manufacturing, financial and service sectors of the US economy using annual time series data from 1978 to 2008. An empirical model is developed in which average wages per hour and the total value of mergers and acquisitions are the explanatory variables, with the number of people employed as the dependent variable. Before estimating the model, the time series properties of the data are diagnosed. The estimated results suggest that mergers and acquisitions have helped to increase employment in both the short-run as well as in the long-run in all three sectors of the economy. To ensure the robustness of the finding, a panel data set is created and the model is re-estimated using the fixed effects estimator. The finding is consistent with the sectoral results.

1. Pharma investment increase amount and diversity of drugs produced, and are better able to provide infa for startups to grow the greater the size

https://www.forbes.com/sites/stanfleming/2018/09/11/how-to-fix-pharmas-innovation-crisis-part-2/#33c3feab1784

Large companies cannot efficiently oversee 100 or more startups. **By sponsoring early-stage venture funds that include outside investors, they can increase**, not only **the numbers of drugs produced**, but their diversity, **including projects that might regarded as too “far-out” for internal development.** **The process is scalable, because**, unlike in a company, overhead for each additional project does not grow as the number increases. **Startups depend on external infrastructure--service providers, CROs, specialized consultants—a community that becomes more efficient with size.**

# A2: M & A Good

# A2: Delays

Mitigate: only 11% innovationo

**1. Turn – high prices increase prior authorization requirements, causing a delay anytime anyone wants drug at any point, creating a permantely lasting delay vs a 1 time**

Gary Price, MD, 2018, February 28, https://www.forbes.com/sites/physiciansfoundation/2018/02/28/sky-high-drug-prices-can-be-

controlled-heres-how/#6cc0f34c2cdc

All this said, in balancing drug prices, we can͛t ignore the fact that other health care priorities

may suffer**. To control costs, insurance companies might implement ever-more burdensome**

**prior authorizations that require physicians to justify a patient͛s need for certain drugs**

Thomas Beaton, May 19, 2018, Health Payer Intelligence,https://healthpayerintelligence.com/news/prior-authorization-issues-contribute-to-92-of-care-

delays

**Prior authorization issues are associated with 92 percent of care delays** and may contribute to

patient safety concerns as well as administrative inefficiencies, according to a new survey from

AMA.

https://www.wto.org/english/news\_e/pres03\_e/pr350\_e.htm

Flexibilities such as “compulsory licensing” are written into the TRIPS Agreement — **governments can issue compulsory licenses to allow other companies to make a patented product or use a patented process under licence without the consent of the patent owner**, but only under certain conditions aimed at safeguarding the legitimate interests of the patent holder.

They underscored countries’ ability to use the flexibilities that are built into the TRIPS Agreement, including compulsory licensing and parallel importing.

This 30 August 2003 agreement allows any member country to export pharmaceutical products made under compulsory licences within the terms set out in the decision (text below). **All WTO member countries are eligible to import under this decision,** but 23 developed countries are listed in the decision as announcing voluntarily that they will not use the system to import.

[Erin Fox 2017 Harvard Business Review](https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive)

**One of the ways branded drug manufacturers prevent competition is simple: cash. In so-called “pay for delay” agreements, a brand drug company simply pays a generic company not to launch a version of a drug.** The Federal Trade Commission estimates these pacts **cost U.S. consumers and taxpayers $3.5 billion in higher drug costs each year**.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/

**Khuman July 27, 2016**

Two global events and the drug donation challenges that were identified in their aftermath are discussed.

### Conflict relief: Bosnia and Herzegovina

During the war in Bosnia and Herzegovina between 1992 and 1996, it is estimated that approximately 27,800 to 34,800 tons of medical supplies were donated to the region.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr6-1715163516660575) Of these supplies, 13,200 tons were medication-containing hospital packs that met the WHO’s drug donation guidelines.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr6-1715163516660575) Only 5% of these hospital packs were deemed unsuitable for the needs of the local population.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr6-1715163516660575) In contrast, 90% of donations that were classified as miscellaneous were deemed inappropriate for the disease states being treated in the region and often arrived unsorted or expired.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr6-1715163516660575) Near the end of the conflict in 1996, field researchers estimated that 17,000 tons of useless medications were stored in warehouses throughout the region.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr6-1715163516660575)

### Disaster relief: Mozambique

Floods affected Mozambique in 2000, with 500,000 people being displaced.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr2-1715163516660575) The government of Mozambique created 3 lists of medications, containing a total of 33 drugs, to request from the international community and aid groups.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr2-1715163516660575) The weight of the requested drugs should have totaled approximately 1393 tons.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr2-1715163516660575) On the whole, however, the international community donated only 37% of the weight that was requested.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr2-1715163516660575) Despite only 33 drugs being requested based on Mozambique’s national formulary, they received more than 400 different agents, only 19 of which corresponded to the requested list.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr2-1715163516660575) Moreover, only 5 of the 19 requested agents were donated in the appropriate quantities.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089330/#bibr2-1715163516660575)

# Lobbying

1. Public sentimetn outeweighs

<https://www.cnbc.com/2016/10/28/a-warning-for-big-pharma-lobbying-wont-work-anymore-commentary.html>

Novak

Several reports say the the Big Pharma lobbying group known as PhRMA is looking to spend as much as $300 million and pull out lots of other stops in order to defend higher prescription drug costs. But here's the problem: **this is a battle the drug giants can't win. Public and political sentiment against expensive medicines and he companies that charge those prices is at a fever pitch**

The question is: Why do the drug companies think they can lobby or donate their way out of this situation, even with the $300 million war chest PhRMA is building**? Politicians do love campaign donations, but all the money in the world can't overcome the kind of bad publicity that comes from supporting industries when they are in such a negative spotlight and doing things that anger so many people.**

<http://law.emory.edu/ecgar/_documents/volumes/5/2/sekerka-benishek.pdf>

Lauren Benishek 2018

This has left much of the remaining discovery work to small, “pre-revenue” companies with no products on the market and limited budgets and R&D capacity.

.

# A2: Neg Dev Countries

## Alt Cause

**1. Tax deductions 2. Get rid of excess stock without having to pay for cost of destruction**

[**Pinheiro 2008 WHO**](http://www.who.int/bulletin/volumes/86/8/07-048546/en/)

**Drug donations provide benefits such as tax deductions and are a very convenient way for industries to get rid of stagnant stocks without having to pay for their controlled and expensive destruction in their country of origin**.[5](http://www.who.int/bulletin/volumes/86/8/07-048546/en/#R5) Some entities seem to find it legitimate to send unusable drugs to nations which are not prepared to dispose of them safely and properly. The recipients receive the drugs as donations and instead are obliged to manage them as waste. Lamentably, there is no international convention to regulate the transfer of non-requested pharmaceutical products and surpluses across borders. Once received into a country, the donations cannot be returned to donors, as recommended by the guidelines, because they are considered hazardous cargo and their shipment must respect the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal.[6](http://www.who.int/bulletin/volumes/86/8/07-048546/en/#R6) This legal demand involves the existence of consented protocols between exporters and importers, and time-consuming procedures that severely compromise its feasibility.

3. pr access to medicine index

https://www.nytimes.com/2017/10/07/health/africa-cancer-drugs.html?\_r=0

**Companies compete to rise higher on the**[**Access to Medicines Index**](https://www.nytimes.com/2014/12/02/science/glaxosmithkline-leads-in-getting-drugs-to-poor.html?module=inline), which ranks them on how well they do at getting their products to the world’s poor.

John Young, president of Pfizer’s essential health group, said the **price-cut deal differs from Pfizer’s charitable donations, like the 500 million antibiotics doses** it provided to help [eliminat](http://www.pfizer.com/news/featured_stories/featured_stories_detail/we_refuse_to_turn_a_blind_eye_to_trachoma)e[the eye disease trachoma](http://www.pfizer.com/news/featured_stories/featured_stories_detail/we_refuse_to_turn_a_blind_eye_to_trachoma).

**Now nearly all companies offer a combination of donations and “tiered pricing,” under which they**[**charge poor countries a small fraction**](https://www.nytimes.com/2015/12/16/health/hepatitis-c-treatment-egypt.html?module=inline)**of what they charge rich ones — but impose safeguards to prevent smuggling of their products into wealthy markets.**

https://www.washingtonpost.com/news/theworldpost/wp/2018/10/17/pharmaceutical/?utm\_term=.c1f926d5752b

 From 2000 to 2011, only 4 percent of newly-approved products globally were designed to treat neglected diseases that affect lower- and middle-income countries

<https://www.fda.gov/forindustry/importprogram/ucm173751.htm>

9/2015

The United States Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Thus, the importation of drugs that lack FDA approval, whether for personal use or otherwise, violates the Act. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval.

https://www.statnews.com/pharmalot/2016/11/07/supreme-court-pay-delay-glaxo-teva/

Silverman nov 2016

The case focused on a so-called pay-to-delay deal between Teva Pharmaceuticals and GlaxoSmithKline. In these arrangements, a brand-name drug maker reaches a settlement with a generic rival in exchange for ending patent litigation and an agreement for launching a copycat medicine at a future date. **The Federal Trade Commission has argued the deals are anti-competitive and cost Americans about $3.5 billion annually in higher health care costs.**

**A 2012** [**decision**](https://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf) **by the Supreme Court, however, left open to interpretation** whether a cash payment was the only sort of arrangement that generated antitrust concern. Drug makers have argued the ruling limited the decision to only cash payments. But the FTC and insurers have maintained that cash is not the only form of payment that has value and warrants antitrust review. The US Solicitor General agreed in a [brief](http://www.scotusblog.com/wp-content/uploads/2016/10/15-1055-US-Amicus.pdf) filed last month.

# A2 gen

<https://www.marketwatch.com/story/big-pharma-games-the-system-to-make-generic-drugs-more-expensive-2018-07-27>

court aug 2018

Most generic drugs, when they first hit the market, are priced at around 60% of the brand price, Allen Goldberg, vice president of communications at the Association of Accessible Medications, said in a statement. As competitors enter the market, prices decrease even further, to about 20% of the brand price, he said.

Innnovation fl

https://www.theatlantic.com/business/archive/2010/11/where-drugs-come-from/66311/

geenrics cheapr

<https://www.gao.gov/assets/680/679022.pdf>

# Frontline: Inno

[C. Lee Ventola, MS 2011 P&T Journal](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/)

**Informs, educates, and empowers patients**. Proponents claim that DTCPA educates patients and allows them to take charge of their health.5 In the U.S., it is thought that informing consumers will benefit the drive for health care reform.19 Consumers can also benefit from having access to multiple information sources about drugs and other treatment options rather than relying solely on health care providers.19 The Internet, including online DTC ads, has become an increasingly popular source of medical information for consumers. The results of a 2005 study of more than 6,000 adults indicated that although the physician was still the most trusted source of information, 48.6% of the subjects went online first and then consulted their physician, whereas only 10.9% talked to their physician first.31 Online DTCPA or other pharmaceutical company–sponsored Web sites can also be used to inform patients by communicating safety risks and public health information, public and private health warnings about topics such as online drug purchasing, and adverse reactions.15 Encourages patients to contact a clinician. A common claim is that DTCPA prompts patients to consult a health care provider to seek medical advice.17 A 2004 FDA consumer survey found that exposure to DTCPA prompted 27% of Americans to make an appointment with their doctor to talk about a condition they had not previously discussed.32 Another study found that the small print in a drug ad was strongly associated with patients contacting their health care providers.17 The effect of DTCPA in increasing patient contact with health care providers could also be beneficial by promoting dialogue about lifestyle changes that improve patients’ health, whether or not a drug is prescribed.17 Promotes patient dialogue with health care providers. Most health care professionals seem to agree that DTCPA is beneficial because it promotes dialogue with patients.32 In the 2004 FDA survey, 53% of physicians said DTCPA led to better discussion with patients and 73% believed that consumer drug advertising helped patients ask more thoughtful questions.32 In addition, in a survey of 221 American oncology nurse practitioners (ONPs), 63% of participants felt that DTCPA promoted dialogue with patients.4 DTCPA may also benefit patients by promoting heightened awareness and detection of adverse reactions, which also may lead to a discussion with a health care provider.19 Exposure to DTCPA prompted 27% of Americans to make an appointment with their doctor to talk about a condition they had not previously discussed.There is evidence that dialogue inspired by DTCPA doesn’t always benefit the manufacturer of the advertised drug, because physicians do not usually prescribe a medication simply because it is requested by a patient.34 In a November 2006 report from the GAO, only 2% to 7% of patients who requested a drug in response to DTCPA ultimately received a prescription for it.12,33,34 In another study, DTCPA increased the likelihood that a patient would initiate a dialogue with a physician to request an advertised drug.35 However, in this study, doctors usually prescribed requested drugs only for patients who had been advised by other health care providers, such as pharmacists and other physicians, not by the mass media.35 Data also show that patients who discuss a prescription medication with their doctor after seeing DTCPA often receive a different recommendation or treatment.31 According to a 2006 survey conducted by Prevention Magazine, of the patients who had a discussion with their doctors after seeing DTCPA, 77% reported that their doctors suggested health and lifestyle changes instead; 55% said they were prescribed a generic prescription; and 51% said their doctor suggested nonprescription treatments, such as over-the-counter medicines.31Strengthens a patient’s relationship with a clinician. Studies generally agree that participation of an informed patient in clinical decision-making benefits the patient–clinician relationship.19 One research study of print DTCPA suggested that DTC ads reinforced the patient–clinician relationship: 83% of the ads focused on physician–patient communication, 76% explicitly promoted dialogue with health care providers, and 54% clearly placed the doctor in control.31 Another study showed that the small print in DTCPA encouraged patients to seek the advice of their doctor, whom they described as their most preferred and trusted source of information.15 Encourages patient compliance. The data consistently show that small, but statistically significant, improvements in adherence occur among patients exposed to DTCPA.1 This increased compliance is believed to be due to drug ads serving as a reminder about a patient’s medical conditions and prescriptions.18 DTCPA is also thought to reinforce physician recommendations and make patients more likely to follow treatment instructions.7The beneficial effect of DTCPA on patient adherence has been detected in several research studies.31 In the 2004 FDA study, 33% of physicians reported that DTCPA increased patient adherence.32 In another study by Harvard University/Massachusetts General Hospital and Harris Interactive, **46% of physicians said that they felt DTCPA increased patient compliance.3**1 In addition, a study utilizing the Rx Remedy database (which follows drug utilization by 25,000 monthly diary panel participants) found that patients who requested a prescription after seeing DTCPA were the most compliant of any group tested.31 **Reduces underdiagnosis and undertreatment of conditions.** DTCPA has been credited with decreasing the under-diagnosis and undertreatment of medical conditions.18 Drug ads enhance patient perceptions about conditions

## A2: Focus on better/me-too

**1. Biochemical small changes has results/will result in unexpected novel breakthrough since small changes can have a big diff**

**Huber ’06** (Peter W. Huber – JD @ Harvard University, PhD in Engineering @ MIT, former associate professor at MIT, has clerked on the D.C. Circuit Court of Appeals for Ruth Bader Ginsburg and on the U.S. Supreme Court for Sandra Day O’Connor, partner at the Washington, D.C., law firm Kellogg, Huber, Hansen and Todd, “Of Pills and Profits: In Defense of Big Pharma,” 1 July 2006, https://www.commentarymagazine.com/articles/of-pills-and-profits-in-defense-of-big-pharma/)

**Biochemical tweaking is good for us, too. People and their diseases vary, often in small ways. Biochemical effects are hard to predict. Even trivial changes can make big differences,** and medical progress often depends on trial and error. **Developed for insomniacs, thalidomide now treats leprosy**. First revealed in the human womb, the drug's extraordinary power to halt cell division also holds promise in the treatment of brain and breast cancer, macular degeneration in the eye, and immune-system diseases. AIDS patients organized buyers' clubs to bootleg the drug from Brazil because of its powerful effect on the immune system. Drugs and drug cocktails are now being matched to genotype. Stem-cell scientists are moving beyond chickens and mice to cultivate genetically customized therapies from human ovaries.¶ Over the last decade, extraordinary advances in bioengineering have transformed pharmacology. **Sooner or later, the industry and its pilot fish will surely find drugs that can halt colon, breast, and lung cancers, that can curb obesity and thus heart disease, and that will not merely suppress the HIV virus but purge it from the body completel**y. A new pharmacology of the brain may cure depression and stop the onset of Alzheimer's. These and other once inscrutable scourges are now—essentially—becoming problems in diligent engineering.

**1. TURN/ small changes are good: a. less side effects make it more accessible b. more compliance (easier/less needed to take) c. incremental innovation provides the revenue to dev risky, new, blockbuster drugs. Policies (like pc) that curb these small changes will lead hinder the creation of genuinely novel drugs.**

[Albert I. Wertheimer 05 Temple University](http://www.who.int/intellectualproperty/submissions/en/Pharmacoevolution.pdf)

Incremental improvements to medicines are fundamental to enhancing the overall quality of health care. Many of the resulting medicines are inevitably very similar to existing treatments, treating the same ailment(s) in a similar way. Some have claimed that investment in the development of such drugs is wasteful. **However, these drugs often have subtle pharmacological differences which make them more appropriate for specific groups of patients. Some have fewer side effects with certain patients, which confers all manner of advantages, including better compliance and consequently reduced resistance. Others are more efficacious for particular patients.**

**Furthermore, pharmaceutical companies depend on incremental innovations to provide the revenue that will support the development of more risky “block-buster” drugs.**

**Policies that aim to curb incremental innovation will ultimately lead to a reduction in the overall quality of medicines in existing classes of drugs, and may ultimately hinder the creation of genuinely novel drugs.**

## A2: Public

**Moses et al 15** (Hamilton Moses III, MD; David H. M. Matheson, JD, MBA; Sarah Cairns-Smith, PhD; et al Benjamin P. George, MD, MPH4; Chase Palisch, MPhi,; E. Ray Dorsey, MD, MBA, The Anatomy of Medical Research: US and International Comparisons, JAMA. 2015;313(2):174-189, DOA: 8-11-2017)

In 1994, the National Institutes of Health (NIH) budget totaled $17.6 billion and in 2004 reached a peak of $35.6 billion (Figure 3). Following a decade of remarkable public sponsorship of medical research with growth exceeding 7% per year in the1990s, funding from the NIH declined nearly 2% per year in real terms (Figure 3) after the mid-2000s. This decrease represents a 13% decrease in NIH purchasing power (after inflation adjustment) since 2004 (eFigure 2 in the Supplement), which may be more severe when considering NIH appropriations through 2013.5 Other sources of US investment were not immune to slowed growth. Funding from major sources of investment either slowed or declined over the past 10 years, with the exception of other federal support, which includes organizations such as the Agency for Healthcare Research and Quality (AHRQ). From 1994 to 2004, the medical device, biotechnology, and pharmaceutical industries had annual growth rates greater than 6% per year (Figure 3), with biotechnology demonstrating the largest increases. The share of US medical research funding from industry accounted for 46% in 1994 and grew to 58% in 2012. Although much of the growth in medical research funding over the past 20 years can be attributed to industry, investment still slowed (medical device, 6.6% to 6.2% in 1994-2004 vs 2004-2012; biotechnology, 14.1% to 4.6% in 1994-2004 vs 2004-2012), or declined (pharmaceutical firms, 6.8% to −0.6% in 1994-2004 vs 2004-2012). Research Funding Biomedical Research The distribution of investments across the types of medical research changed from 2004 to 2011. Pharmaceutical companies shifted funding to late-phase clinical trials and away from discovery activity such as target identification and validation. The share of pharmaceutical industry funding (including that by US companies outside of the United States) spent on phase 3 trials increased by 36% (5%/year growth rate) from 2004 to 2011 (Figure 4), and the share of investment in prehuman/preclinical activities decreased by 4% (2%/year average decline). This shift toward clinical research and development reflects the increasing costs, complexity, and length of clinical trials but may also reflect a deemphasis of early discovery efforts by the US pharmaceutical industry. While industry has shifted funding to clinical trials, the share of NIH contributions dedicated to basic science and clinical research was unchanged (eTable 2 in the Supplement), with the majority of funds still focused on **basic research**. These data may not accurately reflect the true division of NIH investment for basic science vs disease-focused research, as a growing proportion of NIH expenditures is for projects having potential clinical application in many diseases or organ systems.7

Cintra Oct 2012

[**Clinical Trials are 60% of the total cost and are only done by pharma companies**](https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_New_Frontiers_Biopharma_Innovation_2012_Web.pdf)

**Clinical trials are the lengthiest and costliest investments**, accounting for more than half of the total R&D expenditures. **The clinical phase may take up to six years and cost nearly 60% of the total R&D investment**.23 Both length and costs are related to regulatory requirements aimed at ensuring scientific integrity, efficacy, safety, and quality of medicines. However, regulatory authorities must strike a balance; regulations should minimize costs by removing unnecessary burdens and bureaucracy, while ensuring a high threshold of quality.]

80% of vc funding goes to new research – pref helping startups (easton 64%), their stuff is about big pharma

**Booth, 15**-- Bruce Booth, Contributor, Forbes, Where Does All That Biotech Venture Capital Go?, FEB 9, 2015, http://www.forbes.com/sites/brucebooth/2015/02/09/where-does-all-that-biotech-venture-capital-go/#1d9a1f594455

First, **over the past decade, nearly 80% of venture capital for therapeutics went toward** **“novel drug R&D” rather than improvements on** **existing drugs** (e.g., new formulations, repurposing, drug delivery, etc…). **New chemical or biological entities have become the primary interest of venture capital investors,** and **this has** modestly **increased over time**. This trend is in contrast to the rise of “low technical risk” spec pharma investment model of the 2001-2007 period. The chart below captures the trend in both types of venture funding

## A2: Mergers and Acquisitions

1. Pharma investment increase amount and diversity of drugs produced, and are better able to provide infa for startups to grow the greater the size

<https://www.forbes.com/sites/stanfleming/2018/09/11/how-to-fix-pharmas-innovation-crisis-part-2/#33c3feab1784>

Fleming September 2018

Large companies cannot efficiently oversee 100 or more startups. **By sponsoring early-stage venture funds that include outside investors, they can increase**, not only **the numbers of drugs produced**, but their diversity, **including projects that might regarded as too “far-out” for internal development.** **The process is scalable, because**, unlike in a company, overhead for each additional project does not grow as the number increases. **Startups depend on external infrastructure--service providers, CROs, specialized consultants—a community that becomes more efficient with size.**