# Nocember A/2: CON

## Overviews

### Affordability vs Innovation

1. Three reasons as to why voting for affordability always outweighs innovation.
   1. **Prerequisite**. We don’t need new drugs; we need to make the drugs we currently have cheaper, especially as **Light of Rowan University** finds that 90% of new drugs don’t provide any benefits over drugs we have now. It doesn’t matter how many new drugs are created if they remain unaffordable for million.
   2. **Timeframe. Easton of STAT News**[[1]](#footnote-1) reports that any research funding loss wouldn’t materialize until 2023. However, the minute you affirm, prices are lowered, immediately increasing affordability for millions.
   3. **Clarity of impact**. We don’t know exactly what type of and how many drugs or how many lives we would lose by affirming, but we do know that “x” amount of lives are being lost annually in the status quo from a lack of medication adherence because of high drug costs.

### Action First

As an overview, realize that the status quo is an unstable world with prices way to high. The only way to change the upward trend of drug prices is by taking some sort of action. aff advocates for action whereas the neg remains in the unstable status quo. If the AFF can prove even minimally that we can solve, prefer taking action and solving the problem over doing nothing. With that in mind, lets go down their case.

### Innovation

According to **Canoy**[[2]](#footnote-2), member of the Dutch Health Care Institute, if companies gain more than the benefit of the drug to society, we show that this creates two inefficiencies in innovation. First, companies invest too many resources in projects where they expect to be able to gain more than the drug is worth to society. Second, pharmaceutical companies invest too few resources in other valuable drug development projects. As a result, high drug prices lead to crowding out of valuable drug development projects. In these instances, enforcing lower prices does not harm innovation but improves it, because as a result of lowering those prices future investments will be geared towards projects that are more desirable for society.

### Rural hospitals come first

1. Urgency: Medicines are given for long term conditions, where patients are able to get help from other places in other ways. However, hospitals exist for immediate care, there are no other alternatives
2. **Ellison[[3]](#footnote-3)** explains that in the last 8 years, over 85 hospitals have closed in rural areas
3. this is problematic as **Pink of the university of North Carolina[[4]](#footnote-4)** explains that the trend of closing rural hospitals is only rising

only affirming solves

1. Probability: Hospitals are closing in the status quo because of high costs, its 100% probability our impact occurs, any increase in profit would save them from closing. However, the impact of innovation is unknown, you don’t know what will come as a result
2. Prereq: Hospitals in rural areas are how rural ppl get prescriptions, w/o hospitals rural ppl wouldnt be able to access any medicine,
3. Irreversbility- lives will be lost as a result of hospitals closing. Unfortunately, **Nicholl[[5]](#footnote-5)** in 2007 finds that a 10-km increase in distance is associated with 1% increase in mortality and hurts minorities and low-income the worst:

## A2- Status Quo Good

### A2: Drug Prices are Cheap

1. Mitigate- According to a study by **Bloomberg**[[6]](#footnote-6) that even after discounts, we pay more in the U.S. for common medicines than almost every other country in the study.
2. Turn- According to **the commonwealth fund**[[7]](#footnote-7) in 2014 35 million U.S. citizens did not get their prescriptions because they could not afford it, if they lowered the price then they would open up the market for poorer individuals
3. Mitigation- According to **money magazine**[[8]](#footnote-8) from may 2015 to may 2016 the average cost for medication increase 10% while overall inflation only increase 1%, meaning prices are outpacing inflation rates.

### A2: drug prices no problem

1. **Yale School of Public Health**[[9]](#footnote-9) contends that 25% of Americans experience difficulty affording drugs that results in ⅛ of the family members start skipping doses due to the cost.
2. **Agustine**[[10]](#footnote-10) explains that ⅔ of U.S. Personal Bankruptcies are because of drug costs and individual’s inability to pay for them.
3. **The US senate Committee on Homeland Security**[[11]](#footnote-11) explains that Drug costs are increasing at 10x the rate of inflation.

### A2: Drugs account for little of healthcare spending

1. TURN - Prescription drug spending is high and increasing in the status quo. According to a study conducted by the **Centers for Medicare and Medicaid Services in 2018**[[12]](#footnote-12), spending growth is projected to be fastest for prescription drugs, averaging an increase of 6.3 percent by 2026. This study postdates all of their evidence, so you give their argument to us.

### A2: Insurance Companies Pay for Drugs

1. **Delink - Chan from Boston University in 2016[[13]](#footnote-13)** found that as the cost of medication increases, health insurers look to shift the burden of expenses onto patients through higher deductibles or premiums. This is confirmed by the **Healthline Board in 2018[[14]](#footnote-14)** when they find that an increase in drug prices greatly outpace healthcare inflation costs, which have been comparatively low in the past few years. These price increases increase insurance premiums
2. **Delink -** This argument completely isolates low income individuals. **The Kaiser Family Foundation in 2017[[15]](#footnote-15)** found that 45% of uninsured adults said that they remained uninsured because the cost of coverage was too high. Many people do not have access to coverage through a job, and some people remain ineligible for financial assistance for coverage. These are the patients that matter, by affirming these patients gain the access to drugs that their insurance blatantly denies them.

## A/2: Innovation Links

### A/2: R&D General

#### Uniqueness

1. **Lammatina of Forbes[[16]](#footnote-16) continues** that R&D dropped in fund allocation from 10% of profits in 2010 to only 3.6% in 2017. **Bolden concludes[[17]](#footnote-17)** that R&D effectiveness has been decreased by 50% every 9 years for the past 50 years. Do not let them claim all the lives R&D has saved because it never will in the future. Instead evaluate the harms of overpricing in the status quo and its permanent damage to society. If anything, price controls are a better option as,  **Chaip of The World Health Organization** [[18]](#footnote-18)explains that even though Europe had strict price controls, there has been a threefold rise in R&D there in the last few decades.

#### Delink

1. **Mazzucato ’13 of New Scientists[[19]](#footnote-19)** notes that the US National Institutes of Health spends around $30 billion every year on pharmaceutical and biotechnology research and is responsible for 75 per cent of the most innovative new drugs annually.
2. **Bernstein ’15 of the NY Times[[20]](#footnote-20)** furthers, that the private sector cannot be relied on for innovation, because the medicines they seek out are the ones that would be most profitable, which ARE NOT the drugs that have social benefits. **Light** [[21]](#footnote-21)cites studies showing that in the last 40 years, only about 11 to 15 percent of new drugs provided significant clinical improvement over existing ones, while the remaining 85 to 89 percent include what are called "me-too" drugs, clones of existing drugs, marketed as the latest breakthrough.
3. **De-link:** Empirically, high pricing has not been used for innovation. Rather, once companies develop a profitable drug, they stop funding research and just jack up prices. This way, they bring in huge revenues without shelling out billions to develop new products. **David Belk[[22]](#footnote-22)** further writes that as early as 1990, the pharmaceutical industry had made enough effective products to generate billions of dollars for years, and thus they stopped funding foundational research and just kept pushing what they already had. **Belk** concludes that almost no new important therapies have been created in over 15 years, while pharmaceutical profits have skyrocketed.

#### No Impact

1. **Reuters reports[[23]](#footnote-23)** in a study that out of the 984 new drugs developed since 2001, only 17 were deemed as real advancements in medicine. That means that even if innovation does go down, the you lose little to nothing.

### A2 – Loss of Funding

1. **Mitigate on scope -** Sure companies have a lot of money, but they don’t tell you what this money is actually going toward. **Goldacre of The Guardian[[24]](#footnote-24)** reports that pharmaceuticals spend twice as much on advertising than R and D. Indeed, **University of New Jersey[[25]](#footnote-25)** writes that these companies devote a net of only 1.3% of sales to innovation. This has two implications**:**
   1. A loss of funding has literally zero impact on innovation.
   2. Their narrative about needing high prices to sustain investment incentive is broken if 99% of funds are wasted in the squo. That’s why **Vivian 16 of US News[[26]](#footnote-26)** reports that drug development actually only costs a tenth of what they say it does.
2. Even if you buy that they lose this profit, it still doesn’t matter. Realize pharmaceutical companies are so profitable that **Emanuel of UPenn[[27]](#footnote-27)** finds that even if profits were cut by 50%, there would still be plenty of incentive to assume the risks of drug development. In fact, you can actually
   1. That’s why you can **TURN** it. **Hopkins of the FGC[[28]](#footnote-28)** reminds us that none of their funding loss studies take into account government subsidies, but the **IMF[[29]](#footnote-29)** reports that price controls would automatically be accompanied by government subsidy revenue. Prefer subsidies over blank profits because while profits can and are spent on less useful things like advertising, with only 1.3% going to actual innovation research, 100% of subsidies have to go directly towards the core research. That’s why **Shang 18 of the MDPI[[30]](#footnote-30)** finds that every 1% increase in subsidies increases private R and D investment 58%.

### A2 Venture Capital Firms Innovation

1. **Non-Unique:** When prices are higher, by my opponent’s logic investors would increase investment. However, drug prices are at an all-time high and the opposite is true. According to **Andrew Low of Fortune[[31]](#footnote-31)**, because the development process has become extremely tedious, the general trend over the last decade is that venture capitalism has decreased in the pharmaceutical industry.
2. **De-link:** The risk of having less profit doesn’t apply to venture capitalists. **Jacob Bell of Biopharma Dive in 2017[[32]](#footnote-32)** writes that when venture capitalists make investments, it is typically in the later stages of development. This means that they can assure that they are investing in drugs that are already set to turn a profit.
3. [**Ambele from the University of Geneva**](https://books.google.com/books?id=yOE-DgAAQBAJ&pg=PA39&lpg=PA39&dq=venture+capital+pharmaceutical+companies+unsustainable&source=bl&ots=o3hweQZ2Ww&sig=LaXGhZ-XeQgBUUsAJoYxHnu-OBw&hl=en&sa=X&ved=2ahUKEwjKg9DyrKTeAhXIxYMKHXTNDdcQ6AEwCHoECAYQAQ#v=one) finds that companies funded by investment become more concerned w economic standing and thus are very focused on short term, which leads a push to create drugs very fast, which often fails, having a 90% failure rate.
4. **PubHealth[[33]](#footnote-33)** reports that the drug industry’s investment return averages 3x higher than industries represented in the Fortune 500. Investment will still be high, especially considering the gov does most of the risky research

### A/2: Profits

1. **Uniqueness overwhelms the link –** even if we do reduce profits by a lot (which we don’t), the incentive to innovate is still incredibly high. **Emanuel of the New York Times writes in 2015[[34]](#footnote-34)** that drug companies are making so much money – up to 20-30% profit – that even with half the profits, they’d continue innovating.
2. Mitigate. Companies have a lot of money, but they don’t tell you what this money is actually going toward. **Goldacre of The Guardian**[[35]](#footnote-35) reports that pharmaceuticals spend twice as much on advertising than R&D. Indeed**, University of New Jersey[[36]](#footnote-36)** writes that these companies devote a net of only 1.3% of sales to innovation. This has two implications:
   1. A loss of funding has literally zero impact on innovation.
   2. Their narrative about needing high prices to sustain investment incentive is broken if 99% of funds are wasted. That’s why **Vivian of US News[[37]](#footnote-37)** reports that drug development actually only costs a tenth drug company reports.

#### Turn

**Edmunds of The Houston Chronicle[[38]](#footnote-38)** explains that selling at lower prices increases sales volume, by making up for decreased profit per unit by creating bigger gross profits. For example, **Anderson of BBC[[39]](#footnote-39)** reports that in the UK, a country with strict price controls, profits for companies have still doubled.

### A/2: Innovation

1. Recognize that even if innovation occurs, if it is not affordable innovation, it has no impact on the general public. This is why **Bernstein of the New York Times[[40]](#footnote-40)** notes that the private sector cannot be relied on for innovation, because the medicines they seek out are the ones that would be most profitable, which are not the drugs that have social benefits.
2. Pharmaceutical innovation is extremely unlikely. 2 reasons.
   1. Probability. **The Medicine Net [[41]](#footnote-41)** reports that the chance for a new drug to hit the market is 1 in 5000, due to regulations and research boundaries.
   2. Efficiency. **Paul of Nature Reviews [[42]](#footnote-42)**writes that there has been a decline of R&D productivity in the past two decades, which is why it takes 12 years to bring a medicine from the lab to shelf. **Leaf of Fortune[[43]](#footnote-43)** confirms that pharmaceutical companies only get one-tenth of their revenue from drugs released in the past 5 years- they aren’t effective.

#### Large Pharma Innovation

1. Non-Unique: When prices are higher, by my opponent’s logic investors would increase investment. However, drug prices are at an all time high and the opposite is true. **John Lamattina of Forbes[[44]](#footnote-44)** in June of this year writes that because the industry is running out of the easiest innovations, investment in the industry are projected to go down by 4 percent over the next few years.
2. Mitigate: Research is actually only a small percentage of pharmaceutical expenses, so reductions in price controls will be offset by other areas of budgeting. Indeed, **David Belk[[45]](#footnote-45)** analyzes the 13 biggest pharmaceutical companies and finds that marketing cost 60% more than R&D, totaling $895 billion. Moreover, R&D budgets are made up of numerous costs other than actual research, such as more marketing, corporate takeovers, and repeated attempts to approve old drugs.
3. Mitigate: Even if companies lose profit, they will still receive critical funding from the US government. **Gilman of the New England Journal of Medicine writes in 2017[[46]](#footnote-46)** that the U.S. government substantially subsidizes basic research and the provision of health care for the pharmaceutical industry. Indeed,

#### Small company innovation

* + - 1. **The Street[[47]](#footnote-47) writes** that large pharmaceutical companies rely on the small companies for new research and products. That means that if small business were hurt, large pharmaceuticals would also be hurt.

## AT: innovation impacts

### A/2: Superbugs

1. Status quo solves. **Hu of Business Insider [[48]](#footnote-48)** gives two reasons as to why the problem is being tackled.
   1. The FDA is already researching a model to stop multi-drug resistant infections.
   2. The CDC has a strategic plan and solution initiative to fight superbugs.
2. Delink. **Hu** [[49]](#footnote-49)continues that most pharmaceutical companies are pulling out from antiviral research against superbugs because of a lack of profit- there are literally 3 companies left researching, and only 12 antibiotics have been approved in the last 2 decades.

### A2: Vaccine (Research and Access Loss)

* + - 1. DL. Private sector development is not where vaccines are researched and developed. There are two main sources of vaccine research
         1. **Caceres[[50]](#footnote-50)** in 2018 finds that the majority of vaccine research is done in universities like Harvard, UCLA, and the University of Washington.
         2. A study **by Hinman from Clinical Infectious Disease[[51]](#footnote-51)** in 2004 found that 57% of immunizations do not come from the private sector. Make them uniquely prove why the private sector will start providing more immunizations when they are not doing it in the status quo,
      2. NU. **Tate from the Healthcare Institute of New Jersey[[52]](#footnote-52)** in 2002 found that vaccine prices already have price regulations and have been stagnant since 1994. This has been an issue for over 20 years, voting for them on this reason literally does nothing.
      3. Turn**, Rosenthal ‘14[[53]](#footnote-53)** explains that because of high drug prices, doctors lose money on every vaccination and thus reserve shots for just a few patients. In fact, 1 in 3 doctors give up an immunization because of the cost. We directly lower drug prices, increasing accessibility to these vaccines.

### AT: X molecules developed

1. **Lexchin ‘18**[[54]](#footnote-54) explains that only 1 in 10,000 molecules actually results in a new drug

### AT: Cancer research

* + - 1. **Cavallo[[55]](#footnote-55)** ‘16 of ASCO reports that federal grants for cancer-based research total $60 billion, outpacing private industry research 15 fold - private research is a drop in the bucket
      2. Affordability prereq, **Durell**[[56]](#footnote-56) ‘17 of NPR explains that cancer medication tends to be extremely expensive, with ¼ cancer patients not filling their prescription because of cost

### A2 Rare/Orphan Diseases

* 1. DL. The Orphan Drug Act has made substantial progress to making breakthroughs in rare orphan diseases. **The National Organization for Rare Disorders[[57]](#footnote-57)** found that as of 2017, the FDA has approved 600 orphan drugs. These advancements are not related to the private sector but are rather coming from federal organization funding.
  2. DL. The **FDA[[58]](#footnote-58)** decides what orphan drugs are approved and what rate they are licensed at. In fact, under Section 529 to the FD&C Act, the FDA awards priority review to rare orphan diseases. Under this program, a drug sponsor who receives priority approval may qualify to receive a priority review, expediting the licensing procedure and making it top priority. This means that the private sector has nothing to do with how these drugs get to the people
  3. [**Smith 17 of the Harvard Business School**](https://hbr.org/2017/04/the-cost-of-drugs-for-rare-diseases-is-threatening-the-u-s-health-care-system)  explains that the high cost of orphan drugs is becoming impossible to bear for patients; all this innovation doesn’t matter if literally no one can afford it. Only through price controls can these drugs become accessible to more people.
  4. [**Lo of MIT**](https://www.the-scientist.com/features/how-orphan-drugs-became-a-highly-profitable-industry-64278) writes thatcompanies are shifting away from orphan drug investment because public funded scientists have become primary researchers; not companies
  5. Federal funding incentives for orphan diseases will always cause investment
     1. **Radcliffe ‘17**[[59]](#footnote-59) explains that the government gives tax credits for R&D on orphan drugs. Which the **NORD**[[60]](#footnote-60) finds has already increased orphan drug investment by 33%
     2. **Section 529**[[61]](#footnote-61) of the FDA Act puts orphan drugs on a fast-track through the approval system, reducing risk of waiting periods

### AT: drug quality goes down

**The Catalyst[[62]](#footnote-62) reports** that the FDA has already been seen assisting generic versions of the drugs they talk about that produce the same benefits at a lower price.

**Their argument doesn’t make a lot of sense as Pharmaceutical Technologies[[63]](#footnote-63) reports** that if the FDA rules your products to be low in quality, they can recall it from store shelves. There’s no incentive for companies to decrease the quality of their drugs.

**That’s why the center for Drug Research and Manufacturing concludes[[64]](#footnote-64)** that drug quality will never decrease to a point where it harms consumers because the FDA will always be there to step in and prevent the sale of the drug.

## A/2: Economy

### A/2: Jobs

1. Non unique. Two reasons.
   1. Current losses. **Paavlova of The Hospital Review** [[65]](#footnote-65) explains that the healthcare sector has increased the jobs it is cutting by 124 percent per year- all jobs will be cut.
   2. Automation. **Medioros of The RD Magazine** [[66]](#footnote-66)writes that automation adoption in the pharmaceutical industry is at its highest peak ever. In fact, **Wilkins of The Engineer** [[67]](#footnote-67)finds that robots will handle one third of pharmaceutical operations by the end of the year.
2. Make them give you a terminal impact to unemployment- workers can just switch to other industries.

### A/2: Investment

1. Cross apply mitigation on profits.
2. Investment increase in status quo unlikely. **Root of The Independent**[[68]](#footnote-68) writes that pharmaceuticals have been volatile and tend to lag the market- people don’t invest as they look for value in the economy, not defensive growth areas.
3. Turn. More exposure means more investment; examples empirically prove.
   1. Investors don’t leave. **Thomson of The APBI** [[69]](#footnote-69) writes that even with strict price controls, the pharmaceutical industry in the UK saw a 10 percent increase in investments relating to R&D. **Miller of BMJ Journals** [[70]](#footnote-70) corroborates that amidst Canadian price controls, venture capital in Canada doubled.
   2. More accessibility means more sales. **Beattie of Investopedia** [[71]](#footnote-71)writes that when Viagra surged into consumer’s bedrooms, its stock saw a sudden rise.

### A/2: Shortages

1. This is extremely illogical- just because prices go down, consumer need does not increase. For example, a discount on Tylenol does not mean you go and buy 6- you still buy only as many as necessary.
2. Delink**- Devi[[72]](#footnote-72) ‘12** explains that a 2011 executive order requires drug companies to report to a federal agency when supplies are threatened. Concluding that in one month alone, the FDA has intervened to stop shortages, saving thousands of patients.
3. **Frank from Brookings[[73]](#footnote-73)** ‘17 finds that the cost of producing drugs is “pennies a pill” - increased demand will just cause more production.
4. No clarity- Price controls have empirically happened in other countries and shortages have never occurred. Make them prove to you that the companies will not keep up with demand.
5. **Elvidge[[74]](#footnote-74)** ‘17 finds that the FDA created a new task force designed to minimize the impacts of drug shortages on patients and create long-term solutions
6. Uniqueness, **Elvidge** [[75]](#footnote-75)‘17 furthers that drug shortages have reached an all time high because of lack of control in the generic market - still occur at a high propensity in their world
7. Even if a shortage happens, **Ferrari[[76]](#footnote-76)** ‘18 explains that the FDA
   1. Quickly increases approval of necessary drug materials
   2. Allows temporary imports of foreign drugs to offset losses
8. Just because innovation may be stifled doesn’t mean basic drugs are stopped in production.

#### DL. Harvard Medical School in 2012 found that the FDA often addresses and solves drug shortages in 2 ways:

#### The FDA can ramp up production of hard-to-get drugs by expediting approval of materials that have already gone through licensing procedures.

#### The FDA can look for international sources for specific drugs. They review the safety of such supplies and allows temporary imports to ensure that critical patient needs are met

#### A/2 examples

(US) and food(Venezuela) example-

* 1. Oil was in the 1970s
  2. This is imported and not necessarily produced.
  3. This is a limited resource rather than pills which are produced at a much faster rate in the modern day

### A/2: Big Pharma

1. Historically untrue- Europe has passed price controls without loopholes and America has passed things like Medicare and the Affordable Care Act without hurting the policies.
2. Make them give specific policies or its unclear.
3. Delink. Big Pharma is getting weaker. Three warrants.
   1. Public backlash. **Jones of The Hill[[77]](#footnote-77)** writes that Big Pharma’s polling numbers remain low as no amount of money can change the fact that drug makers have set high prices. Jones thus concludes that despite lobbying and financial power, drug makers are still losing and have been singled out by both parties.
   2. Legislation. **Bowmer for The Center for American Progress** [[78]](#footnote-78)writes that there is legislation to ban members from lobbying permanently.
   3. Executive power. **Ferry of Wired News** [[79]](#footnote-79) reports that Trump will facilitate negotiations with drug companies over prices and has refused their funding.

### A2: Competition

1. **New York Times reports in 2018[[80]](#footnote-80)** that companies do “sticky pricing” which is when they just decide not to compete and set the prices of their drugs at unbelievably high prices.
2. **The University of OSLO writes[[81]](#footnote-81)** that after analyzing 30 different drugs that were all subject to competition because their patents had expired, the mean drug price decline was only 4.5%. This means if you were to pay 20 dollars for a drug without competition, you would still be paying 19 dollars for it with competitors.
3. **In addition, the Source[[82]](#footnote-82)** finds that medications used to treat arthritis and diabetes have increased as much as 500% since their introduction to the market, despite emerging competition. They give four reasons why this happens
   1. **The principal-agent problem**- doctors, the ones that prescribe the treatment, either don’t know or don’t discus the treatment cost with the patients
   2. **Lack of transparency**- without additional information provided by pharmaceutical companies, it becomes unbelievably difficult for doctors and patients to determine the costs of their treatments
   3. **Prescription drug formularies**- the managers that provide the drug to these doctors usually never give the cheapest option due to agreements with drug manufacturers
   4. **Coupon programs**- manufactures offer coupons that appear to decrease prices, but in reality they only steer consumers from cheaper options and only decreases prices for a short while
4. You’re going to prefer us when it comes to increasing competition anyway**.** **Nocerca ’17 of Bloomberg**[[83]](#footnote-83) finds that the main way companies prevent competition, is by using their patent monopolies to crowd out generic drugs. Since we solve for that patent crowding out, you affirm.
5. **Amin ’18 of CNBC**[[84]](#footnote-84) furthers that companies extend their patents through ‘evergreening’ where they add on a new patent claiming that a drug does something new, thus extending is exclusivity period. Negotiations solve because part of negotiations is that US agencies get to analyze how beneficial a drug is compared to previous iterations.

## A/2: Global Health

1. Make them show you specific examples, lives it has saved, or policies- otherwise, there’s no probability that this truly occurs.
2. **Their logic is incorrect.** It’s not that high profits incentivize US pharmaceutical companies to produce more drugs to sell to other countries. In fact, the **Financial Times reports[[85]](#footnote-85)** that it’s because companies can’t make large profits in any other countries because of their price controls that force them to have such high profit margins in the United States to try to compensate. If anything, other countries freeloading off us because they have price controls hurts us in two ways
   1. **Incentivizing Monopolies- Community Catalyst[[86]](#footnote-86) reports** that high drug prices allow for the promotion of monopolies, which in turn harms innovation because single drug companies have the power to run smaller companies out of business
   2. **Decreasing Accessibility**- **Patient Engagement[[87]](#footnote-87)** reports that rising out of pocket costs hinder patient’s access to treatments, making it hard for citizens in American to access the treatment they need.

#### Non-Unique.

1. American foreign aid. **Kaiser of the KFF[[88]](#footnote-88)** explains that American government foreign aid efforts improve the health of people in countries while addressing diseases with almost 11 billion dollars in funding this year.
2. Foreign price controls**. The Council of Economic Advisers [[89]](#footnote-89)** posits that foreign governments already force drug manufacturers to comply with pricing rules to gain market access and set drug prices lower- meaning distribution will be cheap either way.
3. Non-unique, other firms fill void of U.S, **Workman** ‘18 explains that the U.S is only the fifth biggest net exporter of drugs, with countries like Germany, Switz, Belgium, and France ahead

#### Delink

1. **The Economist ’01[[90]](#footnote-90)** explains that companies historically have faced backlash whenever they try to increase prices in other places, and as a result end up dropping them.
2. De-link, **Industry Week[[91]](#footnote-91)** reports in ‘18 that drug donations to the developing world are strictly profit-motivated to develop future markets - companies pursue regardless
3. De-link, **The Guardian[[92]](#footnote-92)** reports in ‘12 that drugs are cheaper in developing nations only because they are sold in bulk - at a discount - not because of subsidization
4. They never tell you that companies are operating at their max. limit in other nations, there’s no reason to believe that the first place they go to increase is those places. In fact, **Pear ’18 of the NYT[[93]](#footnote-93)** explains that right now, the first place that the US is looking to increase prices in is DEVELOPED NATIONS, meaning developing countries wouldn’t be harmed
5. African dependence is decreasing,[**Holt 15 of the McKinsey Institute**](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/africa-a-continent-of-opportunity-for-pharma-and-patients) writes that Africa’s pharmaceutical industry has quintupled over the past decade, and is projected to grow by over 12 times by 2020.

#### Turn

1. **The Economist[[94]](#footnote-94)** reports that pharma firms often sell their patented drugs cheap in developing nations to prevent domestic manufacturing of generic medicine, establishing monopolistic control over the market
2. **Turn. MacDonald of The Western Journal of Medicine[[95]](#footnote-95)** gives three reasons as to why the pharma’s distribution is a bad thing.
   * 1. Companies test their products on the developing world which they see as free trial subjects.
     2. Drugs are refused when they will not reap corporate rewards, which takes away the possibility of cures in the area.
     3. Companies stop poorer countries from manufacturing the generic, much cheaper versions of essential medicines when they move into the area.
3. Turn, **Kelly ‘13[[96]](#footnote-96)** finds that pharmaceutical companies test drugs on people in the developing countries, so that they can discover side effects. Kelly furthers that just one testing trial killed 438 people alone
4. **Cox ‘13[[97]](#footnote-97)** finds that U.S companies are lobbying in India to shut out domestic drug markets, which are actually comparatively cheaper than U.S drugs. When the drug companies no longer have an incentive to sell in India, they will stop lobbying.

## AT: politics

### AT: Medicare

* 1. **CNN reports[[98]](#footnote-98)** that in the status quo, the Medicare prices are souring 10 times the rate of inflation. It clearly isn’t a good enough solution for the status quo.

### lobbying

#### Gutchecks

1. Lobbyists do not get any unique incentive to lobby in the pro world. Right now, it is well known that both sides of the political spectrum are seeking to deal with drug prices. At that point, in their world government backlash still occurs
2. Any impacts that lobbyists have occur before a law is passed (ex. Gutting the bill and removing enforcement). Since you give us fiat into controls being passed, I would say there really isn’t an impact to what they are talking about

#### Delink

1. According to **John Jones of the Hill in 2018[[99]](#footnote-99),** no amount of money can change the fact that both republicans and democrats know that drugprices are too high, drug makers alone set the prices.
2. According to **Novak of CNBC[[100]](#footnote-100)**, the lobbying techniques that big pharma uses in the status quo are old fashioned and won’t worked anymore, Congress has become increasingly aggressive against them
3. **American progress[[101]](#footnote-101) writes** that proposals have already reached congress which would ban lobbying as a whole, crippling the ability for drug companies to shape U.S. policies.
4. **Reason.com[[102]](#footnote-102) writes** that most companies would not backlash to price controls because the money it takes them to produce each new additional pill is unbelievably low. This means that price controls would produce little to no effect on their costs.

#### Turns

1. **Turn the argument as Chron News reports[[103]](#footnote-103)** that lower prices would spike sales, making companies happier because as more people can now afford the drug.

#### Loopholes

* + - 1. Historically untrue, Europe passed successful price controls and Medicare and ACA passed without any loopholes
      2. No contextualization, make them give specific loopholes and their effect
      3. Big pharma getting weaker. three warrants
  1. Public backlash. **Jones of The Hill[[104]](#footnote-104)** writes that Big Pharma’s polling numbers remain low as no amount of money can change the fact that drug makers have set high prices. Jones thus concludes that despite lobbying and financial power, drug makers are still losing and have been singled out by both parties.
  2. Legislation. **Bowmer for The Center for American Progress** [[105]](#footnote-105)writes that there is legislation to ban members from lobbying permanently.
  3. Executive power. **Ferry of Wired News** [[106]](#footnote-106) reports that Trump will facilitate negotiations with drug companies over prices and has refused their funding.

### AT: conservative backlash

1. **Hancock ‘17[[107]](#footnote-107)** finds that both sides of political spectrum want to decrease drug prices, political win
2. **Jopson ‘16[[108]](#footnote-108)** explains that congress has been deadlocked for years, backlash doesn’t change policy
3. FIAT bill is successfully passed through congress
4. Abusive, inherently take away aff ground by saying the physical implementation of the policy is flawed from the get-go
5. Conservatives wouldn’t risk losing so much political capital over a price control, if anything they champion the measure as their own in order to appeal to their voter base, many of which rely on gov. sponsored healthcare.

## A2 Rebates

1. Turn- increasing transparency kills rebates. **Watson in 2017[[109]](#footnote-109)** explains that PBMs use their leverage to negotiate w/ manufacturers and increase rebates to consumers, because they also receive a portion of these rebates, and that making all negotiations transparent would end this leverage and decrease discounts that would be passed on to consumers, increasing costs and decreasing accessibility
2. **The American Health Association[[110]](#footnote-110) writes** that the discounts companies offer are a “bait and switch” technique used to scheme patients out of paying for lower generic costs. This is because in the short-term patients pay less. However, in the long term, when the discount runs out, the price of the drug returns back normal where it is too high.
3. **Turn-CNN reports[[111]](#footnote-111)** that by reducing out of pocket payments, pharmaceutical companies have a greater incentive to increase the prices of their products because they know that the government, not the consumers, will be paying for them.

### A2 Rebates Most Probable

Before you vote on rebates, they need to win that rebates are the most probable form of price controls to happen in the united states. We tell you with the **Berman** evidence in case that the most comprehensive type of price control to happen in the US would be a fair value negotiation method. Prefer our evidence because first, it analyzes what is actually being proposed in congress and it is not a hypothetical action they are suggesting, and second, **Sanders** tells you that most advanced economies have price controls in the form of negotiations. Onto their warrants,

### A2 European Countries

1. Rebates exist now. So the fact that they exist under price controls doesn’t matter if the effect of rebates is less in a world with price controls. All of their impact evidence explaining why rebates are bad is evidence of rebates in the status quo doing damage without price controls. Their argument is entirely nonunique.

### A2 Trump

* 1. The Trump administration is moving away from rebates. **CNBC[[112]](#footnote-112)** reports that in outlining Trump’s Health policy the head of Health and Human Services Azar suggested getting RID of rebates.

### A2 Rebates Raise Prices

* 1. Their argument is 100% reverse causal. Rebates are implemented in order to reduce drug costs, they do not increase costs. The reason why rebates are a problem is because companies are able to set high list prices for their drugs, then bargain for high rebates to offset that cost. This leads to an unending cycle where pharmaceutical companies increase prices exponentially and then ask for more rebates. In a world WITH price controls, companies are not able to raise prices and then ask for more rebates, short-circuiting their impact.

## A2: Misc

### A2: BioTerrorism

#### Non-Unique. There are so many alternate causes of bioterror happening. According to the U.S. International Trade Commission in 2007[[113]](#footnote-113), countries like India and China are also major pharmaceutical giants. By my opponent’s, logic they could trigger these same impacts, worldwide. At best we should prioritize happiness right now for American people.

### A2: PBMs

* + - 1. There is historical evidence for the PBM threat. **Sheperd ’18[[114]](#footnote-114) of the Emory School of Law** finds that from 2012-2016, the PBM industry pushed drug companies to increase the prices, such that their profits increased by more than 100%

### A2: Failed Product Compensation

1. NU. This argument is making the assumption that every drug that is ever developed is going to be successful. Unless they can prove to you that voting CON means that every drug they develop without price controls will be a success then they lose uniqueness
2. T. Drug companies are exploiting consumers to compensate themselves. This is inherently immoral because the **New York Times**[[115]](#footnote-115) finds in 2017 that a result of skipping medication due to high costs has resulted in a 10% increase in hospitalization. If you agree with the idea that we should overcharge and kill patients that need lifesaving medication just to compensate a drug company then by all means, negate the resolution. We reject these inherently corrupt and blatantly immoral standards at which consumers must be exploited for the mistakes of companies.

### A2: Generics

1. The pharmaceutical industry is inherently fluctuating in cost **Winnegarden[[116]](#endnote-1) of Forbes explains in 2016 that** the pharmaceutical market historically fluctuates in 2008 there was a 36% drop and in 2014 there was a 32% increase in 2014 followed by just a 1% increase in 2015, the drug market is always switching so it’s impossible to know that generic prices are always going to be enough.
2. Empirically generic drugs aren’t as effective **Sherman[[117]](#endnote-2) of CBS news explains in 2013** that in some cases the generic drugs are not equivalent to the result of the original because the generic companies are not required to release the active ingredients.
3. **Turn** this as relying upon generic drugs is problematic as the prices have been increasing **Forbes[[118]](#endnote-3) finds in 2015** through a meta-analysis of more than 4 thousand drugs 200 of them have seen a 100% increase in prices within a year while 17 of which have seen a 1 thousand percent increase in the same time frame.
4. A main flaw with generics is the system of patenting. **Keshavan writes[[119]](#endnote-4)** that EpiPen technology of injection has maintained and will maintain its superiority in the market above every other company.

### AT: opiods

1. The issue is being solved right now in 4 ways
   1. Federal Legislation- **Sotomayor of NBC[[120]](#footnote-116)** writes that the 2018 Senate opioid crisis act has increased funding to federal agencies to deal with the prevention, treatment and recovery process of the opioid crisis.
   2. State legislation- **The NCSL[[121]](#footnote-117)** finds that since the first introduction of opioid limiting legislation in 2016, 28 states have worked to pass state level restrictions on the access of opioids and that over 130 bills have been introduced in more than 30 states to try to combat the opioid epidemic.
   3. Executive Action- **Tolbert of the NFF** explains that just 2 weeks ago, President Trump signed the SUPPORT Act which expands Medicaid’s role in helping states provide coverage and services to people who need substance use disorder (SUD) treatment, particularly those needing opioid use disorder (OUD) treatment.
   4. Quality control- **Hellman of the hill[[122]](#footnote-118)** highlights that in the following year, the DEA will enforce a 10% reduction in the production in the most abused opioids.

### AT: External reference pricing

1. According to **H.A.I[[123]](#footnote-119)**. in 2015, based on information from 100 countries, historically, low prices offered by pharmaceutical companies to low-income countries would ***not*** result in reduced prices in high-income countries as a consequence of current in ERP practices.
2. **H.A.I[[124]](#footnote-120)** furthers that ERP requires requires substantial human and institutional resources, and accurate information, to implement effectively

### A2 – Delays

1. The Pharma industry cares about the profits that they make especially when price controls are introduced which means that the US isn’t going to want to mess up their profit margins because a new drug stays off the market.

2. Europe is a terrible example – In Europe you have to negotiate with every single country but the FDA who sets price controls is a lot more streamlined because it is just one body that is directly negotiating

3. Delays only apply on new drugs, which we don’t even know will be helpful (read 1/5000 evidence). Accessibility is on every single drug in the market.

### A2- Generics

1. Cross app 448% evidence

2. Many doctors tend to prescribe brand name medication because large companies give them handouts. According to **NPR in 2013[[125]](#footnote-121)**, doctors who were surveyed said that they would prescribe brand name drugs even when generics were available. The NPR analysis furthers that these doctor’s willingness was associated to their acceptance of free commodities or samples of brand name drugs from the same companies that were influencing their decision to prescribe expensive medication. This makes monopolies so much more important

3. Generics are poor quality as observed in 2 instances.

a.) **Harvard Medical School[[126]](#footnote-122)** found in 2018, that the utilization of generics in emergency room visits resulted in an increase in future hospitalization. Harvard furthers that this is because generics are manufactured with different inactive ingredients and have variations in chemical formula that cause people to react differently

b.) According to the **Harvard Business Review[[127]](#footnote-123)** in 2017. Over 260 generic drugs were recalled for being poor quality.

## Indicts

### 40-50% Lower Price = Cut 60% R&D

1. Study referring to another study analyzing effects of **U.S re-legalizing Canadian drug imports[[128]](#footnote-124)**, not about price controls at all

### I2: $2.6 Bil per Drug (Tufts)

1. At bottom of study says funded by pharmaceutical industry
2. **Harris ‘17 of NPR[[129]](#footnote-125)** explains the study doesn’t disclose which drugs it uses, why **Vivian ‘16[[130]](#footnote-126)** of U.S News explains that it’s very exaggerated, only costs 1/10th of that

### Lakdawalla

1. **Scherer of Harvard[[131]](#footnote-127)** find that Lakdawalla exaggerates effects of innovation, doesn’t look at most therapeutically innovative drugs, and doesn’t examine drugs that would be most affected by price controls
2. Every number is 22% - literally random

### Easton

#### The author is biased due to owning multiple pharmaceutical firms.

#### Leads multiple pharma firms

http://bionest.com/company/team/robert-j-easton/

Robert J. Easton Senior Advisor New York **Bob has been recognized as a thought leader in medical business strategy for almost forty years.** Bob was formerly co-chairman of Bionest Partners. Prior to that, he built and led two other consulting firms, The Wilkerson Group and Easton Associates. **Bob has led strategy development and supervised opportunity assessments for** hundreds of clients on four continents, including **large and specialty pharmaceutical companies, early-stage through publicly-traded biopharmaceutical companies, and diagnostics businesses.** He is past chairman of the New York Biotechnology Association and **has served on ten medical company boards.** He also serves as past chairman of Gilda’s Club of New York City. Bob holds degrees in chemical engineering from Rice University and an MBA from the Harvard Business School.

### Indict R&D Studies (Lakdawalla, Soor)

#### Scherer of Harvard contends in 2009 that studies on how price controls decrease research and development projects are statistically flawed for using an exaggerated baseline, skewing the results. Additionally, it samples drugs that aren’t even innovative in the first place. In fact, we don’t know if it is a hundred drugs less or just one drug less; the study just gives hypothetical percentages.

Scherer, F.M. [Professor emeritus of public policy and corporate management at the John F. Kennedy School of Government, Harvard University, in Cambridge, Massachuses]. “Price Controls And Global Pharmaceutical Progress”. Health Aﬀairs, 2009. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaﬀ.28.1.w161

This Perspective reviews critically the work on price control impacts by Darius Lakdawalla and colleagues. It argues that **the innovation elasticity of 3.0 emphasized by the authors is too high, exaggerating the long-run costs of price controls**. It argues, too, that **the drugs chosen for the authors’ analysis are neither the most therapeutically innovative candidates nor those whose development is most likely to be discouraged by price controls.**

### Indict- Tufts study overestimates & receives industry funding

**Richard Harris (NPR) “R&D Costs For Cancer Drugs Are Likely Much Less Than Industry Claims, Study Finds” September 11, 2017**

[**https://www.npr.org/sections/health-shots/2017/09/11/550135932/r-d-costs-for-cancer-drugs-are-likely-much-less-than-industry-claims-study-finds**](https://www.npr.org/sections/health-shots/2017/09/11/550135932/r-d-costs-for-cancer-drugs-are-likely-much-less-than-industry-claims-study-finds)

**The analysis, published in the current issue of JAMA Internal Medicine, concludes that it costs, on average, $650 million to develop a new cancer drug.** The authors add in another $100 million or so to account for income those companies could have had if that money had been invested in the stock market instead of in new products.

**That total is far lower than the $2.7 billion figure that the drug industry frequently points to when it justifies the soaring cost of medicine**. (It's far higher than $320 million — an inflation-adjusted figure from a 2001 study by the consumer group Public Citizen).

To arrive at this new figure, cancer physicians Vinay Prasad, at Oregon Health and Science University, and Sham Mailankody, at the Memorial Sloan Kettering Cancer Center, took a novel approach. They identified 10 companies that each had a single cancer drug on the market. They looked up the companies' research and development costs, as reported in their federal stock reporting paperwork, to come up with the average figure of $650 million.

**The companies reaped substantial rewards. On average, the study found each product produced seven times as much revenue as it cost in research and development — and the drugs will yield profits for years to come.** "I think these results would suggest that pharmaceutical drug development is extremely lucrative and the current drug prices are not necessarily justified by the R & D [research and development] spending on these drugs," Mailankody says.

It's hard to compare their findings directly with the industry's benchmark figure of$2.7 billion ($2.6 billion in 2015 dollars). T**hat figure comes from an analysis by the Tufts University Center for the Study of Drug Development Research. The analysis is based on about 100 new drugs; not just those used to treat cancer. The center, which receives industry funding, doesn't disclose which drugs it uses in its analysis and isn't transparent about its methods, Mailankody says.**

### Think Tanks General

**First: Think Tanks are bought out by politics**

Bartlett of Forbes found that think tanks, like ***(Insert Think tank)*** accept massive donations from extreme partisan sources, creating pressure to conform to the party line. This led to self censorship with many staffers careful not to criticize the party their organization aligned with. The influence got so bad in fact that he reports that every think tank has congressional liaisons on their staff.

Bruce Bartlett, 4-16-2010, "The End Of The Think Tank," Forbes, <https://www.forbes.com/2010/04/15/think-tanks-david-frum-politics-opinions-columnists-bruce-bartlett>

It's one thing to promise a donor some research that would be produced and distributed much faster than could be done by a university professor, the traditional producers of serious policy research--but it was quite another to promise the sort of immediate impact on legislation that a congressman or senator could offer. The result was even more pressure on think tanks to work with congressional offices and coordinate their activities. Now every Washington think tank has congressional liaisons on their staff.

At the same time, congressmen and senators were under pressure to dispense with costly policy analysts and replace them with PR people and Webmasters to manage their growing Internet and e-mail operations, which have allowed them to communicate with voters and constituents much more easily and directly. Congressional offices found that think tanks were more than willing to fill the gap and produce research to order.

As the think tanks became more political and donations from extreme partisans became a bigger source of revenue there was increased pressure on their staff to conform to the party line. Usually this took the form of self-censorship, as a former Heritage staffer recently told me. He understood that the organization was closely aligned with the Republican Party so he just avoided ever saying anything publicly critical of Republicans. No one needed to tell him to do so; it was part of the corporate culture that was simply understood.

Bender from the Boston Globe finds that think tanks have grown so political that, to avoid losing their tax status as charitable organizations, they have established separate operations dedicated to lobbying. He coins this the “think tank industrial complex”. He explains that without the money from party politics, it is difficult to survive as a non-partisan think tank.

We need to prefer all sources from non think tanks, like ours.

Bryan Bender, 8-11-2013, "Many D.C. think tanks now players in partisan wars," BostonGlobe, <https://www.bostonglobe.com/news/nation/2013/08/10/brain-trust-for-sale-the-growing-footprint-washington-think-tank-industrial-complex/7ZifHfrLPlbz0bSeVOZHdI/story.html>

Some say Washington’s once-heralded “ideas industry” steadily looks like a “think tank-industrial complex.”

“They have evolved into what looks like a business,” said Alan Dye, a Washington attorney who has represented think tanks, including Heritage, for three decades. “A brain trust for sale.”

Some thinks tanks on the left and the right of the ideological spectrum have grown so political that, to avoid losing their tax status as charitable organizations, they have established separate operations dedicated to lobbying and other advocacy work.

The Heritage town hall tour, one of the most high-profile examples of merging scholarship with political salesmanship, is being organized by Heritage Action for America, the lobbying arm Heritage launched three years ago under the same roof.

The aggressive politicking is making even some of the think tank’s own scholars uncomfortable, according to a number of insiders who declined to be identified for fear of reprisal.

### Manhattan Institute

#### I2: About Drug $ in US (10%) Less Than Europe

“The **Manhattan Institute** (MI) is a [right-wing](https://www.sourcewatch.org/index.php/Right-wing) [501(c)(3)](https://www.sourcewatch.org/index.php/501(c)(3)) non-profit [think tank](https://www.sourcewatch.org/index.php/Think_tank) founded in 1978 by [William J. Casey](https://www.sourcewatch.org/index.php/William_J._Casey_(CIA_Director)), who later became President [Ronald Reagan](https://www.sourcewatch.org/index.php/Ronald_Reagan)'s [CIA](https://www.sourcewatch.org/index.php/CIA) director.[[1]](https://www.sourcewatch.org/index.php/Manhattan_Institute_for_Policy_Research#cite_note-Nimmo-1) It is an associate member of the [State Policy Network](https://www.sourcewatch.org/index.php/State_Policy_Network).

It is actually the direct successor to the [International Center for Economic Policy Studies](https://www.sourcewatch.org/index.php?title=International_Center_for_Economic_Policy_Studies&action=edit&redlink=1) (ICEPS) which was founded by the english chicken-king, Sir [Antony Fisher](https://www.sourcewatch.org/index.php/Antony_Fisher), in 1977. He had previously set up the [Institute for Economic Affairs](https://www.sourcewatch.org/index.php/Institute_for_Economic_Affairs) (IEA) in London, and before moving to the USA he had become a principle advisor to Prime Minister Margaret Thatcher.”

Sourcewatch.com

<https://www.sourcewatch.org/index.php/Manhattan_Institute_for_Policy_Research>

#### Marcel Canoy and Jan Tichem

These Authors are from the Netherlands and their article talks about Netherlands. Realize that the Netherlands and the US have vastly different economic systems.

### Cato Institute

**Cato Institute is republican**

Ames 12’ mentions the large political linking between the Cato Institute and the Republican Party. The Republican Party houses a large amount of Cato Institute alumni and the Republican Party has relied on lobbying by top Cato officials. The vast majority of Cato’s staff has been people affiliated with the Republican Party. It’s only obvious from these political ties that the Cato Institute will support any form of tax cuts no matter the harms.

Mark Ames, 4-20-2012, "Independent and Principled? Behind the Cato Myth," Nation, <https://www.thenation.com/article/independent-and-principled-behind-cato-myth/>

Fact: In reality, the Cato Institute has been one of the leading Republican Party policy and propaganda factories since at least the early 1990s. In 1995, the LA Times described the Cato Institute as the Republican revolution’s favorite hangout, “the hottest think tank in town. On any given day, House Majority Whip Tom DeLay of Texas might be visiting for lunch. Or Cato staffers might be plotting strategy with House Majority Leader Dick Armey, another Texan, and his staff. Cato’s constitutional law briefs cross the desks of conservative Supreme Court justices and their clerks.” In 2005, a Washington Post article observed, “Nowadays, Cato alumni are everywhere in the Bush administration.” Among Cato figures in the Bush administration named in the article: Andrew Biggs, Derrick Max, Charles Blahous, Leanne Abdnor and Carolyn Weaver, who helped launch Cato’s war on Social Security back in 1979. President Bush’s high-priority Social Security privatization plan was all thanks to lobbying by Cato president Ed Crane and Cato executive José Piñera, a former Pinochet official who heads Cato’s Social Security privatization project. Cato Claim #3: The Kochs are staging an unprecedented GOP takeover of the Cato Institute by staffing it with Republican Party operatives and backers (here and here). Fact: The Cato Institute’s board of directors and staff have always been stacked with Republican Party supporters, donors and operatives. Rupert Murdoch was a Cato board member, serving at least through the early 2000s. When Murdoch first joined Cato’s board, Ed Crane hailed the News Corp chief as “a strong advocate of the free market and a committed civil libertarian.” So was Murdoch’s longtime US partner, John C. Malone of Liberty Media, whom Al Gore once reportedly called the Darth Vader of cable. Malone is a major GOP donor and the largest private landowner in the United States. Stephen Moore, longtime Dick Armey sidekick and author of the 2004 hagiography Bullish on Bush: How George W. Bush’s Ownership Society Will Make America Stronger, was director of Cato’s Fiscal Policy Studies and remains a senior fellow. Other major GOP sponsors on the Cato board before the Kochs’ recent “coup” include K. Tucker Andersen, Howard Rich (funder of the term-limits movement) and Ethelmae C. Humphreys, who along with her son has “doled out hundreds of thousands of dollars to Republican candidates.” Republican operatives in Cato are numerous and include former Phil Gramm staffer and Bush HUD deputy assistant secretary Mark Calabria, director of Cato’s Financial Regulation Studies; and former Senate Republican Policy Committee analyst Michael Cannon, director of Cato’s health policy studies and adviser to Florida Republican Governor Rick Scott. Cannon’s “independent scholarship” includes his famous November 2008 Cato blog post: Blocking Obama’s Health Plan Is Key to the GOP’s Survival. That’s before Obama took office. Cato Claim #4: Cato’s employees are “independent” scholars free from the corrupting influence of “special interests.” Fact: The Cato Institute is one of the leading manufacturers of toxic corporate propaganda, cynically undermining science and scholarship to serve the interests of tobacco companies, oil and gas, chemicals, health insurance, financial industry and other Cato donors. Cato chairman Robert Levy, who today accuses the Kochs of turning Cato into “a mouthpiece of special interests,” once faithfully served the tobacco industry as a leading tobacco-death denialist. In his article, “Lies, Damn Lies & 400,000 Smoking-Related Deaths”, Levy claimed, “children do not die of tobacco-related diseases” and “there is no credible evidence that 400,000 deaths per year—or any number remotely close to 400,000—are caused by tobacco.” (In fact, tobacco use kills more than 5 million people a year worldwide.) Greenpeace labeled Cato a “Koch Industries climate denial front group” that is “focused on disputing the science behind global warming and questioning the rationale for taking action.” Among Cato’s anti-science propagandists: Patrick J. Michaels, called “a serial deleter of inconvenient facts” by ThinkProgress and Steven Milloy, a onetime Cato adjunct scholar on the payroll of Philip Morris, oil companies and others. Philip Morris listed Cato VP David Boaz as one of its “National Allies;&rdquo in a 2000 memo. In 2001, a British-American Tobacco executive sent a thank-you letter to Levy and the Cato Institute, noting: “I was also pleased to learn after our meeting that our subsidiary company, Brown & Williamson, provided the Cato Institute with funding in 2000.” So there you have it: a brief look at the Cato Institute’s factual record, which reads nothing at all like the heroic fairytales spun by Cato and its allies about its principled opposition to the Bush Administration’s imperial presidency, or its opposition to the Republican Party, or whatever else Cato’s minions tell us to win our hearts rather than our minds. In fact, it’s hard to know what, if anything, to believe about Cato—PR and spin are so ingrained in their thinking and their breathing, one wonders if Cato’s own flaks can tell the difference themselves between reality and spin. Lately, they seem to have a hard time keeping track of their numerous and rather careless flip-flops, particularly when it comes to how they characterize their longtime benefactors, the brothers Koch. Most of the same libertarians who attacked the Kochs as unprincipled GOP usurpers of the Cato Institute only yesterday defended the same Kochs as principled patrons of purist libertarian scholarship. Last October, David Boaz, Ed Crane’s number two in Cato, defended the Koch brothers as principled libertarians under attack for “opposing a president who supports fiscal irresponsibility, the Patriot Act, the war on drugs, and secret wars.” Five months later, Boaz darkly warned that the very same Koch brothers posed a “direct threat to the independence, nonpartisanship and libertarianism of the Cato Institute.”

### Adam Smith Institute

There are 2 things wrong with this source

**First: Transparency**

According to WhoFundsYou?, an organization committed to rating the transparency of certain think tanks, the Adam Smith Institute ranks the lowest giving absolutely no data on where their funding comes from or where it goes.

"The UK campaign for think tank transparency," Who Funds You?, http://whofundsyou.org/

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Organisation** | **Income** | **Displays funding details on website** | **Names funders** | **Declares amounts given** | **Rating** |
| [**Adam Smith Institute**](http://whofundsyou.org/org/adam-smith-institute) | Not disclosed | No | No | No | **E** |

**Second: History of bias**

Transparify 17’ tells you that the Adam Smith Institute has before received undisclosed donations from certain companies and then proceeded to release research supporting those companies. This nullifies any trust you should put in their source.

Dustin Gilbreath, 12-5-2017, "Home," Transparify, http://www.transparify.org/

A closer look at the highly opaque institutions on our list confirmed our hypothesis that think tanks that hide their donors usually have something to hide. For example, according to research compiled by TobaccoTactics, the Adam Smith Institute, the Centre for Policy Studies, and the Institute for Economic Affairs have all previously received undisclosed funding from tobacco companies, and all have produced research that was then used to lobby against stronger anti-smoking regulations. We found that the Adam Smith Institute has created a structure so opaque that it concealed not only who gave money, but also who took it, leaving us unable to determine where close to one million pounds given by American donors had ended up. Meanwhile, Policy Exchange has previously used evidence that appears to have been fabricated; the resulting report led to fake news headlines in several media outlets that had naively trusted “research” conducted by an opaque think tank.

### A2: Fox News

Funding

Fox cherry picks examples to support the conservative GOP. Ackerman of Fair in \*find date\* tells you that Fox News is always supporting conservatives.

When it comes to Fox News Channel, conservatives don’t feel the need to “work the ref.” The ref is already on their side. Since its 1996 launch, Fox has become a central hub of the conservative movement’s well-oiled media machine. Together with the GOP organization and its satellite think tanks and advocacy groups, this network of fiercely partisan outlets–such as the Washington Times, the Wall Street Journal editorial page and conservative talk-radio shows like Rush Limbaugh’s–forms a highly effective right-wing echo chamber where GOP-friendly news stories can be promoted, repeated and amplified. Fox knows how to play this game better than anyone.

The reason is that Fox News was made to be a propaganda arm of the republican party. The co founder

In February 1996, after former U.S. Republican Party political strategist and NBC executive Roger Ailes left cable television channel America's Talking (now MSNBC), Murdoch asked him to start Fox News Channel

1. Robert J. Easton, 1-22-2018, "Price controls would stifle innovation in the pharmaceutical industry," STAT, <https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/> [↑](#footnote-ref-1)
2. Marcel Canoy and Jan Tichem 2018 The authors work for the Netherlands Authority for Consumers & Markets. Canoy is also member of the Advisory Commission Basic Package (ACP) of the Dutch Health Care Institute. https://editorialexpress.com/cgi-bin/conference/download.cgi?db\_name=EARIE45&paper\_id=550

   However, if companies gain more than the benefit of the drug to society, we show that this creates two inefficiencies in innovation. First, companies invest too many resources in projects where they expect to be able to gain more than the drug is worth to society. Second, pharmaceutical companies invest too few resources in other valuable drug development projects. As a result, high drug prices lead to crowding out of valuable drug development projects. In these instances, enforcing lower prices does not harm innovation but improves it, because as a result of lowering those prices future investments will be geared towards projects that are more desirable for society. [↑](#footnote-ref-2)
3. <https://www.beckershospitalreview.com/finance/state-by-state-breakdown-of-85-rural-hospital-closures.html>

   Of the 26 states that have seen at least one rural hospital close since 2010, those with the most closures are located in the South, according to [research](http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/) from the North Carolina Rural Health Research Program.

   Fourteen hospitals in Texas have closed since 2010, the most of any state. Tennessee has seen the second-most closures, with eight hospitals closing since 2010. In third place is Georgia with six closures, followed by Alabama, Mississippi and North Carolina, which have each seen five hospitals close over the past eight years.

   Listed below are the 85 rural hospitals that closed between January 2010 and July 2018, as tracked by the NCRHRP. For the purposes of its analysis, the NCRHRP defined a hospital closure as the cessation in the provision of inpatient services. As of July 3, 2018, all of the facilities listed below had stopped providing inpatient care. However, some of them still offered other services, including outpatient care, emergency care, urgent care or primary care. [↑](#footnote-ref-3)
4. <https://www.hrsa.gov/enews/past-issues/2017/october-19/hospitals-closing-increase.html>

   TREND IS RISING [↑](#footnote-ref-4)
5. <https://sci-hub.tw/10.1136/emj.2007.047654> [↑](#footnote-ref-5)
6. Fielding 16 of US news and world report fielding, Jonathan. “We Can Make Medicine Affordable.” U.S. News & World Report, U.S. News & World Report, 5 Oct. 2016, [www.usnews.com/opinion/articles/2016-10-05/the-us-can-make-prescription-drugs-more-affordable](http://www.usnews.com/opinion/articles/2016-10-05/the-us-can-make-prescription-drugs-more-affordable).

   Whenever I am outside, I carry two EpiPens. If a bee stings me, the pens could save my life. I was recently stung, but not by a bee. **The sting came from Mylan pharmaceuticals when it raised the retail price of a two pack of EpiPens from about $100 to more than $600 dollars over nine years. According to** [**Money**](http://time.com/money/4481786/how-much-epipen-costs-to-make/) **magazine, each EpiPen costs about $30 to produce.** I am lucky because my health insurance pays most of the cost of my EpiPens. But millions of Americans, both young and old, cannot benefit from this drug or others when the initial price or rapid price increase make them unaffordable. Even those with insurance coverage who do not use costly drugs still pay for them through rising premiums and co-pays. List prices for all medicines are subject to various discounts and rebates often negotiated by insurance companies and pharmacy benefit managers, and the actual cost can be lower**. But a study by** [**Bloomberg**](http://www.bloomberg.com/graphics/2015-drug-prices/) **found that even after discounts, we pay more in the U.S. for common medicines like Crestor (high cholesterol), Lantus (insulin), Advair (asthma), Januvia (diabetes), Humira (rheumatoid arthritis) and Herceptin (breast cancer) than in most other countries in the study, including Australia, Canada, Japan, Saudi Arabia, China, Brazil, India, Russia, Morocco and several European countries.** The role of intermediaries like insurance companies and pharmacy benefit managers in our health care system makes it very difficult for doctors and patients to know the true price of medicine. [↑](#footnote-ref-6)
7. Prescription justice 17 Prescription Justice, 2-6-2017, "45 Million Americans Forego Medications Due to Costs, New Analysis Shows – 9 Times the Rate of the UK," <https://prescriptionjustice.org/press_release/45-million-americans-forego-medications-due-to-costs-new-analysis-shows-9-times-the-rate-of-the-uk/>

   But it is not hard to know the public health implications. In 2014, **35 million Americans did not fill a doctor's prescription because they could not afford it, according to a study released by** [**The Commonwealth Fund**](http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2015/jan/1800_collins_biennial_survey_brief.pdf). In addition, the [Centers for Disease Control](http://www.cdc.gov/nchs/data/databriefs/db184.htm) and Prevention reports that Americans use a variety of other strategies to trim medication costs, including reducing the dosage to make a supply last longer, buying medicines from foreign countries and substituting alternative therapies. [WebMD reports](http://www.webmd.com/healthy-aging/features/letter-and-spirit-of-drug-import-laws) that medicines sold in Canada can cost 55 percent less than an identical medicine in the U.S. According to the [American Heart Association](http://www.heart.org/HEARTORG/Conditions/More/ConsumerHealthCare/Medication-Adherence---Taking-Your-Meds-as-Directed_UCM_453329_Article.jsp#.V9gTuU1TE5t), failure to take a prescribed medicine or reducing the amount costs $300 billion in extra medical expenses and contributes to 125,000 deaths a year. As a standalone category, nonadherence would be a leading [cause of death](http://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm) in the U.S., ahead of Alzheimer's, diabetes, influenza, pneumonia and kidney disease. [↑](#footnote-ref-7)
8. **Brady 16 of WP** Brady Dennis, 1-11-2016, "Prescription drug prices jumped more than 10 percent in 2015, analysis finds," Washington Post, <https://www.washingtonpost.com/news/to-your-health/wp/2016/01/11/prescription-drug-prices-jumped-more-than-10-percent-in-2015/?utm_term=.28b53dfc7d49>

   Second, Congress should authorize the U.S. Food and Drug Administration, the agency that must approve new prescription drugs for the market, to consider a drug's value and price in addition to its safety and efficacy in that process. Shouldn't the price of a new drug reflect how its safety and efficacy compare to drugs already on the market? How does the requested price compare with existing products with similar indications for use? And shouldn't there be federal guidelines on prescription drug price increases? Is it fair that pharmaceutical companies, who have been granted a monopoly for many of their drugs in the form of a patent, are allowed to raise prices as much and as often as they want? We should not be surprised that the price of many prescription drugs is increasing at several times the rate of most other goods and services**.** [**Money**](http://time.com/money/4406167/prescription-drug-prices-increase-why/) **magazine reports from May 2015 to May 2016, medicine prices increased 10 percent. Overall inflation was just 1 percent**. Finally, the FDA should aggressively implement the biosimilars provisions of the Affordable Health Care Act. Biosimilars are lower-cost, interchangeable versions of biologic drugs. The law was designed to bring biosimilars to market sooner, creating competition for medicines like Humira, Remicade, Embrel and the cancer drugs Herceptin and Avastin. Biosimilar medicines are widely used in Europe. To date only three biosimilar medicines have been approved by the FDA, two in the last three months. These changes will be controversial. Pharmaceutical companies will strongly oppose them, arguing that they need high profits to continue to invest and innovate. But without these changes, the high price of prescription medicines will only worsen this crisis for patients and make our health care system less and less affordable. [↑](#footnote-ref-8)
9. **Aaron Berman (Yale School of Public Health) ‘Curbing Unfair Drug Prices” August 2017**

   [**https://law.yale.edu/system/files/area/center/ghjp/documents/curbing\_unfair\_drug\_prices-policy\_paper-080717.pdf**](https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf)

   Research shows that prescription drug spending is growing faster than any other part of the health care dollar.5 In 2015, prescription drug spending reached $457 billion, accounting for roughly 17 percent of total health care costs.6 Patients are increasingly feeling the effects of these rising costs: **More than one in four Americans currently taking prescription medications report difficulty affording them.7 One in eight report that they or a family member have cut pills in half or skipped doses due to high drug costs.**8 Nearly two-thirds of Americans – regardless of political affiliation – believe that lowering the cost of prescription drugs should be a top policy priority.9 ● 86% of Americans support actions requiring drug companies to release information to the public on the process of setting drug prices.10 Nearly 80% of Americans want government to limit what companies charge for high-cost drugs for illnesses like cancer or hepatitis.11 [↑](#footnote-ref-9)
10. Norman R. Augustine, Chair, National Academies of Science, Engineering, & Medicine study on drug costs, Testimony before the Senate Committee on Health, Education, Labor and Pensions, 12—12—17, [www.help.senate.gov/imo/media/doc/Augustine.pdf](http://www.help.senate.gov/imo/media/doc/Augustine.pdf)

    Yet, while few argue that the current situation is acceptable, virtually each newly proposed potential corrective measure has confronted strong opposition from one or more quarters. This is in part because an overarching moral issue remains unresolved in the United States: is access to health care—including prescription drugs—a fundamental human right? And if it is not, who is to decide, and based on what criteria, which individuals are to be denied access to the drugs and the care that they need? But if health care is a right, who is to pay its costs? And is this cost affordable not only to the individual but also to society as a whole, and does it represent the most appropriate allocation of the nation’s resources? The burden of high-priced drugs often falls disproportionately on vulnerable elements of the population in spite of government, industry and charitable efforts to alleviate its impact. For example, the Kaiser Family Foundation reports that in 2015, about 20 percent of Americans did not fill at least one prescription due to affordability considerations, while others rationed the drugs that they did acquire. **Two-thirds of personal bankruptcies in the United States have been attributed in part or entirely to the overall cost of medical care, including drugs.**  [↑](#footnote-ref-10)
11. NO AUTHOR (U.S. Senate Committee on Homeland Security) “BREAKING: Brand-Name Drugs Increasing at 10X Cost of Inflation, McCaskill Report Finds” March 26, 2018 <https://www.hsgac.senate.gov/media/minority-media/breaking-brand-name-drugs-increasing-at-10x-cost-of-inflation-mccaskill-report-finds>

    U.S. Senator Claire McCaskill, the top-ranking Democrat on the Senate Homeland Security and Governmental Affairs Committee, today released a report as part of her years-long effort to investigate dramatic prescription drug price increases, showing that **the prices of many of the most popular brand-name drugs increased at nearly ten times the cost of inflation from 2012 to 2017.** [↑](#footnote-ref-11)
12. #### Centers for Medicare and Medicaid Services

    “Press Release CMS Office of the Actuary Releases 2017-2026 Projections of National Health Expenditures.” CMS Office of the Actuary Releases 2017-2026 Projections of National Health Expenditures | CMS, 14 Feb. 2018, [www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-2026-projections-national-health-expenditures](http://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-2026-projections-national-health-expenditures).

    Personal healthcare spending: Over 2017-2026, growth in personal healthcare spending is projected to average 5.5 percent. Among the factors, personal healthcare price growth is anticipated to be the largest factor at 2.5 percentage points, growth in the use and intensity of goods and services is expected to contribute 1.7 percentage points of total growth, and population growth (0.9 percentage point) and changing demographics (0.5 percentage point) account for the remaining growth. Prescription drug spending: **Among the major sectors of healthcare, spending growth is projected to be fastest for prescription drugs, averaging 6.3 percent for 2017-2026.** This is due in part to faster projected drug price growth, particularly by the end of the period, influenced by trends in relatively costlier specialty drugs. Insured share of the population: The proportion of the population with health insurance is projected to decrease from 91.1 percent in 2016 to 89.3 percent in 2026, due in part to the elimination of the penalty payments associated with the individual mandate and also to a continuation of a downward trend in the offering and take-up of employer-sponsored health insurance.

    [↑](#footnote-ref-12)
13. #### Chan

    Chan, Kelvin. “Why We’re All Talking about Drug Prices Inaccurately: The EpiPen Controversey.” Medium, 26 Sept. 2016, https://medium.com/unraveling- healthcare/why-were-all-talking-about-drug-prices-inaccurately-the-epipen- controversey-2d061689b904.

    **Drugs feel more expensive when health insurers cover less of a drug. And as healthcare costs rise, health insurers look to shift the burden of expenses onto its patients through higher deductibles or premiums.** Deductibles refer to the amount you have to pay before coverage kicks in. And since 2010, average deductibles have increased over 67%. As more Americans enroll in High-Deductible Health Plans (HDHP), so does the feeling of cost. Under an HDHP, EpiPen, which may have been previously covered by a health insurer for a $50 co-pay, now costs $600 until the deductible is met. Premiums or the monthly payments one makes to be covered are rising too, and have increased by about 27%. **What’s ultimately driving this feeling of “cost” boils down to rising healthcare costs and insurers counteracting those costs by covering less of it.**  [↑](#footnote-ref-13)
14. #### Healthline Board

    Healthline Board. “Drug Price Increases and Your Health.” Healthline, 18 July 2018, <https://www.healthline.com/health-news/rising-drug-prices-risk-to-your-health>.

    **Drug price increases also greatly outpace healthcare inflation costs, which have been comparatively low in the past few years. These price increases affect insurance premiums and out of pocket expenses,** but it’s hard to say exactly how much**.** However, Jonathan Gruber, a professor of economics at the Massachusetts Institute of Technology and president of the American Society of Health Economists, says the overall direction is clear. **“Higher drug prices translate to higher health insurance costs for all of us,” he says**. He notes the convoluted system of rebates and discounts between pharmaceutical companies, pharmacy benefit managers, and insurance companies makes things even more murky. “Obviously, if they raise the price, that’s going to pass through to some extent to consumers. Whether PBMs are helping or hurting is still unclear, it all depends on how these rebates play through,” says Gruber. “We just don’t know yet. When they raise the price, how much of that is actually making its way to consumers?” [↑](#footnote-ref-14)
15. #### Kaiser Family Foundation

    Kaiser, Henry. Nov 29, Updated:, et al. “Key Facts about the Uninsured Population.” The Henry J. Kaiser Family Foundation, 19 Sept. 2017, https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured- population/.

    **Even under the ACA, many uninsured people cite the high cost of insurance as the main reason they lack coverage. In 2016, 45% of uninsured adults said that they remained uninsured because the cost of coverage was too high. Many people do not have access to coverage through a job, and some people, particularly poor adults in states that did not expand Medicaid, remain ineligible for financial assistance for coverage.** Some people who are eligible for financial assistance under the ACA may not know they can get help, and undocumented immigrants are ineligible for Medicaid or Marketplace coverage. **Most uninsured people are in low-income families and have at least one worker in the family.** Reflecting the more limited availability of public coverage in some states, adults are more likely to be uninsured than children. People of color are at higher risk of being uninsured than non-Hispanic Whites. [↑](#footnote-ref-15)
16. John **Lamattina**, 1-24-**2018**, "About Those Soaring Pharma Profits," **Forbes**, <https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaring-pharma-profits/#3569ced63f9d>

    That’s a pretty good speech, but in an era of fake news, how accurate are Read’s comments? Actually, available data\* are pretty supportive. The average return on equity for key industries from 2014 – 2016 shows that biopharma’s profits stand at 16.2%, significantly lower than Computer Sciences (31.6%), Beverages (27.4%), Aerospace/Defense (23.0%), and Trucking (19.1%) while modestly higher than Software System/Applications (15.2%) and Healthcare Support Services (14.4%). Another measure, Internal Rate of Return (IRR) is even more telling. IRR calculates the sales/cash flows resulting from R&D investments, ties R&D and the returns it generates together, and is a more appropriate metric for biopharma productivity. **Deloitte reports that the IRR for biopharma [biopharma is a collection of the biggest pharma companies] R&D has been steadily falling from 10.1% in 2010 to 3.2% in 2017. Even Wall Street hasn’t bought into the “pharma soaring profits” view.** Since February 1, 2014, while the Dow has risen 63%, the stock prices of a number of major pharma companies have been muted with Pfizer and Bristol-Myers each growing by about 15%, and Merck and AstraZeneca by roughly 6.5%. Even Lilly’s growth of 43% still lags the Dow. The drug pricing debate that has been underway is certainly warranted. One can even argue that it has led to some positives, particularly with respect to greater transparency around the rationale for how new drugs are priced. In addition, companies are moderating annual price increases and pledging to raise prices only once a year. Furthermore, it is important to recognize that while a company may raise the price of a drug by 9.9%, that is the LIST price of the drug. The actual increase negotiated by insurance companies and other payers is a lot less. [↑](#footnote-ref-16)
17. Jack W. **Scannell**, Alex **Blanckley**, Helen **Boldon** and Brian **Warrington**, No Date, "To Lower Drug Prices, Innovate, Don't Regulate," **Semantic Scholar (Peer Reviewed Studies)**, https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate

    Abstract | The past 60 years have seen huge advances in many of the scientific, technological and managerial factors that should tend to raise the efficiency of commercial drug research and development (R&D). Yet **the number of new drugs approved per billion US dollars spent on R&D has halved roughly every 9 years since 1950, falling around 80‑fold in inflation-adjusted terms. There have been many proposed solutions to the problem of declining R&D efficiency. However, their apparent lack of impact so far and the contrast between improving inputs and declining output in terms of the number of new drugs make it sensible to ask whether the underlying problems have been correctly diagnosed**. Here, we discuss four factors that we consider to be primary causes, which we call the ‘better than the Beatles’ problem; the ‘cautious regulator’ problem; the ‘throw money at it’ tendency; and the ‘basic research–brute force’ bias. Our aim is to provoke a more systematic analysis of the causes of the decline in R&D efficiency. [↑](#footnote-ref-17)
18. **http://www.euro.who.int/en/media-centre/sections/press-releases/2013/07/pharmaceutical-innovation-must-align-with-patient-needs,-says-new-report**

    “Despite an **over three-fold rise in spending on pharmaceutical research and development in Europe since 1990**, there is an increasing mismatch between people’s real needs and pharmaceutical innovation. We must ensure that industry develops safe, effective, affordable and appropriate medicines to meet future health needs,” says Nina Sautenkova, Manager of Health Technologies and Pharmaceuticals at WHO/Europe. [↑](#footnote-ref-18)
19. Mariana Mazzucato, 8-1-2013, "State of innovation: Busting the private-sector myth," New Scientist, <https://www.newscientist.com/article/mg21929310-200-state-of-innovation-busting-the-private-sector-myth/>

    The examples don’t just come from the military arena, either. **The US National Institutes of Health spends around $30 billion every year on pharmaceutical and biotechnology research and is responsible for 75 per cent of the most innovative new drugs annually.** Even the algorithm behind Google benefited from US National Science Foundation (NSF) funding. [↑](#footnote-ref-19)
20. No Author, 6-29-2016, "Drug Price Controls Are Vital in a Market That's Not Free," No Publication, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free>

    The producers argue that this will stifle their incentive to innovate. But the evidence is increasingly clear that we cannot count on the private sector to make necessary medicines affordable. In fact, given the incentive structure, neither can we count on private drug companies to develop the drugs we most need versus the ones that will be most profitable. In health economics, maximizing social benefits is often at odds with private benefits. [↑](#footnote-ref-20)
21. **Stanford**

    "Researcher: Europe Surpasses United States In New Drug Discoveries | Stanford News Release". 2018. *News.Stanford.Edu*. Accessed October 4 2018. https://news.stanford.edu/pr/2009/pr-light-pharma-study-082109.html.

    Contrary to public opinion, the research productivity of U.S. pharmaceutical companies has fallen behind European competition, says Donald Light, visiting professor in human biology and international health policy at Stanford. Light's latest study on the topic, which will be published in Health Affairs, also shows that new drugs often lack clinical advantage over existing ones. "While it's widely believed that most new drugs are discovered and developed in the United States and that American researchers have far outstripped their European competitors, on a level playing field of dollar for dollar, European researchers actually have been more innovative since 1982," Light said. By analyzing clinical studies and papers on pharmaceutical discoveries, Light found that European companies discovered more drugs than U.S. companies from 1982 to 2003, overall and in proportion to funding. **Light also cites studies showing that in the last 40 years, only about 11 to 15 percent of new drugs provided significant clinical improvement over existing ones, while the remaining 85 to 89 percent include what are called "me-too" drugs, clones of existing drugs, marketed as the latest breakthrough.**  [↑](#footnote-ref-21)
22. **Belk, 18** – (David, “The Pharmaceutical Industry,” True Cost of Healthcare, 2018, http://truecostofhealthcare.org/the\_pharmaceutical\_industry/, CD - JO)

    **The “golden age of the pharmaceutical industry” was drawing to a close as early as 1990** when the pharmaceutical companies began to tire of new ideas. **New ideas are always expensive and risky.** Even the most brilliant sounding ideas often go nowhere when tested clinically.

    **By 1990 the pharmaceutical industry knew they already had a lot of very effective products that were making them lots of money each year.** They had patents that were generating billions of dollars a year and would continue to do so for many years to come. They also knew they could probably find a number of new uses for the classes of medications they already had. The most profitable course they saw at that point was to just coast; put no more funding into new foundational research and just keep pushing what was already working for them. That’s exactly what they did, and it worked!

    **The profits made by the pharmaceutical companies exploded over the last decade without them putting out any new products that were even remotely innovative.** But that strategy can only work for a little while. Two decades after they shut the door on actual innovation the revenue from the old ideas is starting to run dry.

    So, we in the US continue to overpay for brand name prescription medications, but **the pharmaceutical industry has given us almost no new important therapies in more than 15 years.** A somewhat unexpected result of this is that, total pharmaceutical revenue has been nearly flat since 2010. [↑](#footnote-ref-22)
23. https://www.reuters.com/article/health-drugs-effectiveness/new-drugs-trail-many-old-ones-in-effectiveness-against-disease-idUSL2N0EC1E720130603  
    The law established an independent research institute to compare the effectiveness of different treatments for the same condition. That way, patients as well as private insurers and government programs such as Medicare can stop paying for less effective therapies. If the new analysis is correct, then “comparative effectiveness research” could conclude that older drugs, which are more likely to be generics, are better than pricey new brand names that deliver the most profits for drugmakers. Fears of a crisis in drug innovation have grown over the years. When the healthcare journal Prescrire in 2011 ranked new drugs, only 17 of the 984 developed since 2001 were deemed “a real advance” or better. And a survey of 184 expert physicians in 15 specialties published last month in Nature Reviews Drug Discovery showed the doctors were more likely to rate drugs more than a decade old as “transformative.” [↑](#footnote-ref-23)
24. #### Goldacre

    Goldacre, Ben. [Writer for The Guardian]. “Evil ways of the drug companies”. The Guardian, 2007. <https://www.theguardian.com/science/2007/aug/04/sciencenews>

    In 2002, the 10 **US drug companies** on the Fortune 500 list had combined international sales of $217bn (£106.6bn). They **spent only 14% of that money on research and development, but 31% on marketing and administration**. They are very careful not to let anyone see how much goes on marketing and on administration. Whenever you hear the drug companies explaining why they have to charge so much for their products - perhaps as they are denying their lifesaving Aids drugs to the 20 million HIV-positive people in Africa - the plea is that they need money to develop new drugs. That’s not true if they spend twice as much on marketing as on research and development. This unhappy collision of facts makes them look very evil indeed. They also charge this money in slightly evil ways. Drugs have 10 years ”on patent.” Loratadine is an effective antihistamine drug that does not cause drowsiness. Before the patent ran out, the price of this drug, by Schering-Plough, was raised 13 times in the US in just five years, increasing by over 50%. This is not a price rise in keeping with inflation. This is evil. [↑](#footnote-ref-24)
25. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1261198/#!po=37.5000

    The Pharmaceutical Research and Manufacturers of America reports that companies invest on average about 18-19% of domestic sales into research.9 This figure is considerably higher than that produced by the US National Science Foundation.16 Its 1999 data show that drug companies invest 12.4% of gross domestic sales on research and development (10.5% in-house and 1.9% contracted out), but only 18% of the amount spent in-house went on basic research. Assuming that 18% of contracted out research is also spent on basic research (the actual figureis not reported) then only 2.2% (18%×12.4%) of revenue goes to basic research. The after tax cost of $1 of research and development expenditures in the US seems to be $0.53 to $0.61, owing to tax incentives to do research.17 Thus **US pharmaceutical companies devote a net of only about 1.3 cents** (2.4%×(0.53+0.61)/2) **of every dollar from sales to innovation.**

    #### Vivian

    [↑](#footnote-ref-25)
26. Ho, Vivian. [Reporter for US News]. “The Harm of High Drug Prices”. US News, 2016. <https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-highdrug-prices-to-americans-a-continuing-saga>

    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. [↑](#footnote-ref-26)
27. Emanuel, Ezekiel. [Oncologist and vice provost at the University of Pennsylvania]. “The Solution to Drug Prices”. New York Times, 2015. https://www.nytimes.com/2015/09/09/opinion/thesolution- to-drug-prices.html

    Almost all developed countries — including those run by very conservative governments — have an effective solution for drug prices, which is why these countries often pay less than half of what people in the United States pay for drugs. For instance, Australia’s more than 60-year-old Pharmaceutical Benefits Scheme has been the single purchaser of drugs for the country, making drugs available at fixed prices that are now listed online. If the United States were to consider such an approach, drug companies would immediately raise two objections: the high risks associated with drug development and, related, the high cost of research and development. But both of these arguments are fatuous. It is true that a vast majority of drugs fail. On average, only one in every 5,000 compounds that drug companies discover and put through preclinical testing becomes an approved drug. Of the drugs started in clinical trials on humans, only 10 percent secure F.D.A. approval. Regardless of the risks, **many drug companies are making huge profits**. Gilead, maker of Sovaldi, has profits of around 50 percent. Biogen, Amgen and other biotech firms have profits of around 30 percent. Merck and Pfizer are seeing profits of 18 percent or more. **Even if profits were cut by a** third or a **half, there would be sufficient incentive to assume the risks of drug development.** [↑](#footnote-ref-27)
28. #### Hopkins

    http://www.fgcasal.org/politicafarmaceutica/docs/Greg\_Hopkins.PDF

    I will present two case studies that deal with the effect of government regulation on innovation. Both opinions were that government regulation would have a significant negative effect on innovation. In the short run firms would have sustainable growth, but in the long run there would be no incentive to innovate and there would be a loss to the pharmaceutical market of new drugs. These views are consistent with economic views of how regulation effects innovation, but the pharmaceutical market may be an exception due to the unusual subsidization of the research and development. **In both case studies the amount of subsidization done by the government was not taken into account.** [↑](#footnote-ref-28)
29. #### IMF

    International Monetary Fund “Equity and Efficiency in the Reform of Price Subsidies - A Guide for Policymakers.” International Monetary Fund, 15 Dec. 2000, www.imf.org/external/pubs/ft/equity/index.htm#ref.

    A price subsidy reduces the consumer price of a good or service below what it would be in the absence of the subsidy (consumer subsidy) or increases the price received by a producer above its market level (producer subsidy). In practice, **consumer subsidies are always implemented with price controls**, resulting in shortages of the subsidized item. Producer subsidies, on the other hand, are often administered through producer support prices. When support prices are set too high, there is an oversupply of the subsidized item. 37. Explicit price subsidies are recorded in the government budget as expenditures, although not necessarily under the category “subsidies.”15 Explicit subsidies can take many forms. In the case of a consumer subsidy, a public agency can make direct payments to producers to compensate them for charging lower prices for their output. Alternatively, the government can directly provide goods and services free of charge or at below-market prices through a public distribution system. [↑](#footnote-ref-29)
30. #### Shang

    [file:///Users/jscmedley/Downloads/sustainability-10-02205-v2%20(2).pdf](about:blank)

    As Table 7 illustrates, **a 1% increase in government subsidies leads to a** 33.1% and **58.7% increase in private R&D investment** . Therefore, H1 and H4 are further supported. It is worth noting that the coefficient of Sub on ROA in SOEs (β1 = 0.245, t = 1.846) is greater than that in POEs (β1 = 0.128, t = 0.988). This means that the impact of government subsidies on firm performance in SOEs is stronger than in private enterprises. [↑](#footnote-ref-30)
31. Andrew W. Lo, 1-21-2014, "Wall Street's next bet: Cures for rare diseases," Fortune, http://fortune.com/2014/01/21/wall-streets-next-bet-cures-for-rare-diseases/, accessed 10-22-2018 Josh B.

    An orphan disease mega-fund is not only a potentially attractive investment; it’s also a potential lifesaver. **The drug development process has become expensive, lengthy, and risky — and not just for orphan diseases. The biotech and pharmaceutical sectors have performed miserably over the past decade, which has caused venture capital flows to wane.** At the same time, government funding — another important source of funding for biomedical research — has been declining. In other words, this is an area desperate for funding, and a mega-fund would bring much-needed resources to drug discovery. The fund also has appeal to philanthropists and patient advocacy groups because they can put their dollars to work in a new way — by providing financial guarantees to mega-fund securities. The impact of such guarantees is to reduce the risk of the mega-fund, greatly expanding their appeal to a broader audience of potential investors, giving philanthropists just what want: impact. Finance doesn’t have to be a zero-sum game. With sufficient scale and proper financial engineering, you can actually do well by doing good. [↑](#footnote-ref-31)
32. Jacob Bell, 9-26-2017, "What does venture capital look for when investing in biopharma?," BioPharma Dive, https://www.biopharmadive.com/news/what-does-venture-capital-look-for-when-investing-in-biopharma/505885/, accessed 10-22-2018 Josh B.

    **Venture capital is frequently a vital resource for fledgling drugmakers, but not all investments are made the same. A drug's therapeutic target, stage in development and potential to yield returns shape whether its manufacturer is worth backing — or whether money would be better spent elsewhere**. At least, that's according to a few prominent life science investors. During a Tuesday panel discussion at the BioPharm America conference in Boston, Todd Foley of MPM Capital Inc., Kevin Johnson of Medicxi and Nilesh Kumar of Novo Ventures explained what catches the eyes of biopharma-focused VCs. Particularly attractive are medicines ahead of the curve, aimed at diseases likely to move into the spotlight over the next few years. "We do react to trends and emerging trends and try to build what we think the pharma companies are going to want to buy," Foley said. The biopharma sector literally has a wealth of VC funding at its fingertips. Biotechs, for instance, received the second most venture funding of any industry in the first half of 2016 despite [overall declines in deal value and volume](https://www.biopharmadive.com/news/pwc-biotech-deal-values-and-volume-drop/428425/) across a number of industries, including the life sciences. Those investments come from companies like MPM, which has provided capital to 23andMe Inc., Radius Health Inc. and Valeritas Inc. MPM specializes in financing early-stage life sciences businesses, usually conducting pay rounds in the $40 million to $60 million range, according to Foley. Identifying promising preclinical assets, therefore, is key to MPM's strategy. "As early-stage investors, we're willing to take significant biology risk and early development risk," Foley said. While not every drug selected will be a winner, those that hit can offer huge returns because "you start to see the value is quite high after proof of concept," he said. Therapeutic areas come into play as well. Treatments for neurodegenerative diseases are on MPM's radar. So are immuno-oncology drugs — as is the case across many life science VC funds. Behind each target, investors are considering how the candidate fulfills patient needs, according to Medicxi's Johnson. **"The general rule we think works is if you put the patient at the center of it, you won't go far off. Even though the world may not know it needs a particular modality for a particular condition, if you can see how that's really going to make an impact," then a VC can reason out whether a therapy is worth investing in, he said**. With the backing of Novartis AG and Alphabet Inc., Medicxi in June [launched a $300 million fund](https://www.biopharmadive.com/news/novartis-verily-venture-medicxi-european-biotech/445084/) aimed at European biotechs in late-stage drug development. At the time, Medicxi said it would be funding companies that craft treatments for unmet medical needs, but didn't specify much further. Yet, according to Johnson, at the top of the investor wish list are products that are forward-thinking rather than currently fashionable. "You do sort of have to have the idea of what's going to be a must-have in five years or beyond. The chances are it's not what's hot now — and I think people want to be in a hot area because it feels like where complex and interesting dealmaking are," he said. **In any case, investments are more likely to pour in when a company's drug is supported by strong data, particularly evidence demonstrating its effectiveness both in animals and in the clinic.** "People come up to us with some great animal data. The problem is attrition rates in those things and translatability to man is huge, they're a very difficult thing to go into. And once you've got something [that can make that leap], it's a huge validation that this stands a chance of working," Johnson said. [↑](#footnote-ref-32)
33. PubHealth, Drug, 7-23-2001, "The Case Against The Drug Industry’s R&amp;D "Scare Card"," No Publication, <http://pubhealth.spb.ru/EBM/ebm2002/PCPharm.htm>

    * **Drug industry R&D does not appear to be as risky as companies claim. In every year since 1982, the drug industry has been the most profitable in the United States,** according to *Fortune* magazine’s rankings. During this time, **the drug industry’s returns on revenue (profit as a percent of sales) have averaged about three times the average for all other industries represented in the Fortune 500. It defies logic that R&D investments are highly risky if the industry is consistently so profitable and returns on investments are so high.** (See Section V)

    Drug companies stress how difficult it is to discover new drugs – particularly innovative life-saving dru**gs. But the evidence suggests it’s not all that risky because the federal government is doing much of the crucial re**search. The National Institutes of Health (NIH) budget reached $20.3 billion in fiscal year 2001 (a 14 percent increase over FY 2000) with much of that money going to research that ultimately helps with the discovery and development of pharmaceuticals – how much exactly is hard to say. The NIH admits it doesn’t track its spending on drug development. NIH officials claim it’s a tough task because so much NIH work is basic research into diseases that is converted years later – often through several other related discoveries that build on one another – into a marketed drug.[28](http://pubhealth.spb.ru/EBM/ebm2002/PCPharm.htm#28) [↑](#footnote-ref-33)
34. Ezekiel J. Emanuel, 9-9-2015, "Opinion", No Publication, https://www.nytimes.com/2015/09/09/opinion/the-solution-to-drug-prices.html?fbclid=IwAR1zwLd3jlbpEQnot\_\_qmf1649jR80MzKaU-kv1AMLstIzVtlBV2Js11Htg   
    Regardless of the risks, many drug companies are making huge profits. Gilead, maker of Sovaldi, has profits of around 50 percent. Biogen, Amgen and other biotech firms have profits of around 30 percent. Merck and Pfizer are seeing profits of 18 percent or more. Even if profits were cut by a third or a half, there would be sufficient incentive to assume the risks of drug development. What should be done? The United States government has created myriad special pricing arrangements that pervert incentives. For instance, Medicaid generally gets the lowest prices in the market. This discourages drug companies from experimenting with other payers on lower price arrangements, knowing that they will most likely have to give the same deal to Medicaid. Similarly, through the Orphan Drug Act of 1983 the United States created many incentives for developing drugs for orphan diseases — those with fewer than 200,000 patients nationwide. Through special tax credits and better deals on marketing exclusivity, the federal government is encouraging the companies to benefit thousands instead of millions. The result has been the development of more than 400 drugs and biologics. While it is important to find effective treatments for rare diseases, it is more important to target serious, common diseases such as stroke and antibiotic-resistant infections. Also, as outrageous as they are, prices are not the real issue. Value is. What really frustrates people are expensive drugs that do not provide a cure. For instance, Opdivo adds an average of 3.2 months of life to lung cancer patients and costs $150,000 per year for treatment. [↑](#footnote-ref-34)
35. #### Goldacre

    Goldacre, Ben. [Writer for The Guardian]. “Evil ways of the drug companies”. The Guardian, 2007. <https://www.theguardian.com/science/2007/aug/04/sciencenews>

    In 2002, the 10 **US drug companies** on the Fortune 500 list had combined international sales of $217bn (£106.6bn). They **spent only 14% of that money on research and development, but 31% on marketing and administration**. They are very careful not to let anyone see how much goes on marketing and on administration. Whenever you hear the drug companies explaining why they have to charge so much for their products - perhaps as they are denying their lifesaving Aids drugs to the 20 million HIV-positive people in Africa - the plea is that they need money to develop new drugs. That’s not true if they spend twice as much on marketing as on research and development. This unhappy collision of facts makes them look very evil indeed. They also charge this money in slightly evil ways. Drugs have 10 years ”on patent.” Loratadine is an effective antihistamine drug that does not cause drowsiness. Before the patent ran out, the price of this drug, by Schering-Plough, was raised 13 times in the US in just five years, increasing by over 50%. This is not a price rise in keeping with inflation. This is evil. [↑](#footnote-ref-35)
36. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1261198/#!po=37.5000

    The Pharmaceutical Research and Manufacturers of America reports that companies invest on average about 18-19% of domestic sales into research.9 This figure is considerably higher than that produced by the US National Science Foundation.16 Its 1999 data show that drug companies invest 12.4% of gross domestic sales on research and development (10.5% in-house and 1.9% contracted out), but only 18% of the amount spent in-house went on basic research. Assuming that 18% of contracted out research is also spent on basic research (the actual figureis not reported) then only 2.2% (18%×12.4%) of revenue goes to basic research. The after tax cost of $1 of research and development expenditures in the US seems to be $0.53 to $0.61, owing to tax incentives to do research.17 Thus **US pharmaceutical companies devote a net of only about 1.3 cents** (2.4%×(0.53+0.61)/2) **of every dollar from sales to innovation.**

    #### Vivian

    [↑](#footnote-ref-36)
37. Ho, Vivian. [Reporter for US News]. “The Harm of High Drug Prices”. US News, 2016. <https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-highdrug-prices-to-americans-a-continuing-saga>

    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. [↑](#footnote-ref-37)
38. **https://smallbusiness.chron.com/cutting-prices-good-marketing-strategy-61446.html**

    **Selling at a lower price often increases your sales volume,** hopefully **making up for your decreased profit per unit by returning bigger gross profits.** Raising your price might increase your profit margins, but often results in a decrease in sales volumes. In a best-case scenario, a price increase creates enough perceived value among consumers that you realize both increased profit margins and sales volumes. Test different prices in several geographic areas to learn the elasticity of the demand for your product and help you find the optimal selling price. [↑](#footnote-ref-38)
39. leaves a margin of 24%, still pretty spectacular by any standard. **In the UK, for example, there was widespread anger when the industry regulator predicted** energy **companies' profit margins would grow from 4% to 8% this year.** [↑](#footnote-ref-39)
40. No Author, 6-29-2016, "Drug Price Controls Are Vital in a Market That's Not Free," No Publication, <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-are-vital-in-a-market-thats-not-free>

    The producers argue that this will stifle their incentive to innovate. But the evidence is increasingly clear that we cannot count on the private sector to make necessary medicines affordable. In fact, given the incentive structure, neither can we count on private drug companies to develop the drugs we most need versus the ones that will be most profitable. In health economics, maximizing social benefits is often at odds with private benefits. [↑](#footnote-ref-40)
41. In the United States**, it takes an average of 12 years for an experimental drug to travel from the laboratory to your medicine cabinet**. That is, if it makes it. Only 5 in 5,000 drugs that enter preclinical testing progress to human testing. One of these 5 drugs that are tested in people is approved. **The chance for a new drug to actually make it to market is thus only 1 in 5,000. Not** very good odds. The process of drug approval is controlled in most countries by a governmental regulatory agency. In the U.S., the Food and Drug Administration (FDA) governs this process. The FDA requires the following sequence of events before approving a drug [↑](#footnote-ref-41)
42. Here, using a large database that contains information on R&D projects for more than 28,000 compounds investigated since 1990, we examine the **decline of R&D productivity in pharmaceuticals in the past two decades** and its determinants. We show that this decline is associated with **an increasing concentration of R&D investments in areas in which the risk of failure is high**, which correspond to unmet therapeutic needs and unexploited biological mechanisms. We also investigate the potential variations in productivity with regard to the regional location of companies and find that although companies based in the United States and Europe differ in the composition of their R&D portfolios, there is no evidence of any productivity gap [↑](#footnote-ref-42)
43. On average, the 30 large and small pharmaceutical and biotech companies IDEA **Pharma examined got just 11% of their 2017 revenue from drugs developed within the past five years**, says Mike Rea, the firm’s CEO and one of the most insightful people I’ve met—no exaggeration—when it comes to pinpointing innovation choke points in the drug industry. Take out Gilead and Biogen from the mix and the group average drops to 8.1%. Nineteen of these 30 **companies, meanwhile, got less than 7% of sales in the last calendar year from “new” products, says Rea**. Please read his LinkedIn essay on this for more context (and you might want to follow him on Twitter, too). [↑](#footnote-ref-43)
44. #### Large Pharma decreasing investment

    John Lamattina, June 12, 2018 "Pharma R&amp;D Investments Moderating, But Still High," Forbes, https://www.forbes.com/sites/johnlamattina/2018/06/12/pharma-rd-investments-moderating-but-still-high/#485a62876bc2, accessed 10-22-2018 Josh B.

    But what about Big Pharma’s internal investment in R&D? Traditionally, this has been relatively high, running at approximately 15% of top line revenues. Will this level of spend – higher than any other industry – be sustainable? A new analysis, “[World Preview 2018, Outlook to 2024”](http://info.evaluategroup.com/rs/607-YGS-364/images/WP2018.pdf) newly issued by *EvaluatePharma* provides guidance on this. Interestingly, *EvaluatePharma* is predicting accelerating sales for the pharmaceutical industry with annual compound growth of 6% between now and 2024. “The launch of novel therapies, including gene and cell therapies, as well as increased access to medicines globally should help fuel progress in the market. Total prescription sales are expected to be $1.2 trillion in 2024.” But, these higher sales are not expected to translate into higher R&D investments. “R&D spend is forecast to grow at a CAGR of 3.1% to 2024 lower than the CAGR of 3.6% between 2010 and 2017 signaling that companies will be improving R&D efficiencies or less revenue will be directed towards replenishing pipelines.” While disappointing, it is important to put these numbers into perspective. According to *EvaluatePharma*, in 2017 the top 20 pharmaceutical companies invested 20.9% of top line revenues into R&D - a very impressive number. This amounted to $97.2 billion in 2017. For comparison purposes, the NIH budget is $37 billion. In 2024, *EvaluatePharma* is projecting that the top 20 companies will be spending $116.4 billion on R&D, 16.9% of sales – still a very high percentage when compared to other industries. The 2024 leaders will be Roche at $11.7B, Johnson & Johnson at $10.0B and Novartis at $9B. These changes are probably not enough to allay Stott’s concerns. However, it is clear that the pharmaceutical industry is going to continue to invest in R&D at a pretty healthy rate for the foreseeable future. For all of our sakes, it is imperative that their efforts are successful. [↑](#footnote-ref-44)
45. **Virtually no innovation is happening now**

    **Belk, 18** – (David, “The Pharmaceutical Industry,” True Cost of Healthcare, 2018, http://truecostofhealthcare.org/the\_pharmaceutical\_industry/, CD - JO)

    **The “golden age of the pharmaceutical industry” was drawing to a close as early as 1990** when the pharmaceutical companies began to tire of new ideas. **New ideas are always expensive and risky.** Even the most brilliant sounding ideas often go nowhere when tested clinically.

    **By 1990 the pharmaceutical industry knew they already had a lot of very effective products that were making them lots of money each year.** They had patents that were generating billions of dollars a year and would continue to do so for many years to come. They also knew they could probably find a number of new uses for the classes of medications they already had. The most profitable course they saw at that point was to just coast; put no more funding into new foundational research and just keep pushing what was already working for them. That’s exactly what they did, and it worked!

    **The profits made by the pharmaceutical companies exploded over the last decade without them putting out any new products that were even remotely innovative.** But that strategy can only work for a little while. Two decades after they shut the door on actual innovation the revenue from the old ideas is starting to run dry.

    So, we in the US continue to overpay for brand name prescription medications, but **the pharmaceutical industry has given us almost no new important therapies in more than 15 years.** A somewhat unexpected result of this is that, total pharmaceutical revenue has been nearly flat since 2010. [↑](#footnote-ref-45)
46. **US government substantially subsidizes drug R&D**

    **Gilman, 17** – (David, “Is Value-Based Drug Pricing Compatible with Pharma Innovation?” New England Journal of Medicine, 20 November 2017, https://catalyst.nejm.org/is-value-based-drug-pricing-compatible-with-pharma-innovation/, CD - JO)

    This innovation has occurred within the context of an implicit social contract. **The U.S. government substantially subsidizes basic research and the provision of health care**, and it waives its ability to negotiate directly with manufacturers about prices. In return, the biomedical industry is allowed to attempt to recoup its R&D investments during a limited post-approval period defined by the Drug Price Competition and Patent Term Restoration Act of 1984 (often called the Hatch–Waxman Act), with the expectation that drug prices will be set at a point that ensures a reasonable level of population access. [↑](#footnote-ref-46)
47. https://www.thestreet.com/investing/stocks/why-investors-should-favor-smaller-biotech-companies-14645143  
    Large-cap companies have paid premiums for smaller firms to help supplement their pipelines with their products, experts say. Most of the time, it's a mutually beneficial relationship: larger companies get a product without having to devote its own capital to new research or weathering the risks associated with the development of a new drug, and smaller companies are compensated for their work. Tax reforms have also helped expedite the M&A movement in the biotech sphere in 2018. The new repatriation rule that lowered the taxation rate on overseas cash holdings to 15.5% freed up more capital for larger companies to use as they see fit, which in many cases have been in acquisitions [↑](#footnote-ref-47)
48. To encourage the costly development of new antibacterial drugs, **FDA Commissioner** Scott Gottlieb has mentioned the possibility **of a reimbursement model for antibiotics that met certain criteria, primarily their ability to target dangerous, multi-drug resistant infections.** **Both the CDC and the National Institute of Allergy and Infectious Diseases have developed strategic plans and solutions initiatives to fight antimicrobial resistance.** [↑](#footnote-ref-48)
49. Just two years after Novartis announced it would embrace the challenge of searching for cures for life-threatening infections known as superbugs, **the drugmaker said last week it would exit antibacterial and antiviral research. Novartis' retreat follows a growing trend of big pharmaceutical companies** — including AstraZeneca, Sanofi, and Allergan — that **are exiting from this type of research because of a lack of profit. That leaves Merck, Roche, GlaxoSmithKline, and Pfizer** as the remaining pharmaceutical companies with active antibiotic programs, according to Nature Biotechnology. Only 12 antibiotics have been approved since 2000. [↑](#footnote-ref-49)
50. #### Caceres

    Caceres, Marco. “Big Pharma Pays Universities for Most Medical Research in U.S. Today.” The Vaccine Reaction, 15 Apr. 2018, https://thevaccinereaction.org/2018/04/big-pharma-pays-universities-for-most- medical-research-in-u-s-today/.

    **In the past, collaboration between scientists in academia and pharmaceutical companies was relatively uncommon. However, lately there has been a growing interest in developing financial partnerships between these two sectors.** The drug industry’s funding patterns for academic research has shifted from handpicked projects on investigation of the biology of disease to large integrated programs, with an emphasis on the development of therapeutic drugs and vaccines. In the last few years, pharmaceutical companies have also formed “science hubs” in bigger academic institutions to promote biomedical innovation.1 **Some of these partnerships include GlaxoSmithKline at Harvard University, Pfizer at University of California, and AstraZeneca at University of Washington, etc.1 In fact, with the increasing financial ties between academia and the pharmaceutical industry, many drug companies have formed specialized divisions that are solely responsible for seeking research and development relationships with academic institutions**. [↑](#footnote-ref-50)
51. #### Hinman

    Hinman, Alan R., et al. “Financing Immunizations in the United States.” Clinical Infectious Diseases, vol. 38, no. 10, May 2004, pp. 1440–46. academic.oup.com, doi:10.1086/420748.

    **Children in the United States receive immunizations through both private and public sectors. The federal government has supported childhood immunization since 1963 through the Vaccination Assistance Act (Section 317 of the Public Health Service Act). Since 1994, the Vaccines for Children (VFC) program has provided additional support for childhood vaccines. In 2002, 41% of childhood vaccines were purchased through VFC, 11% through Section 317, 5% through state and/or local governments, and 43% through the private sector.** The recent introduction of more-expensive vaccines, such as pneumococcal conjugate vaccine, has highlighted weaknesses in the current system. Adult immunization is primarily performed in the private sector. Until 1981, there was no federal support for adult immunization. Since 1981, Medicare has reimbursed the cost of pneumococcal vaccine for its beneficiaries; influenza vaccine was added in 1993. [↑](#footnote-ref-51)
52. #### Tate

    Tate, Edward. Government Price Controls on Prescription Drugs May Be More than Patients Bargain For - HealthCare Institute of New Jersey. 7 Oct. 2002, http://hinj.org/government-price-controls-on-prescription-drugs-may-be-more- than-patients-bargain-for/.

    Consider the recent flu vaccine shortage. The largest purchaser of the vaccine is the federal Vaccines for Children Program. The program buys up nearly 70 percent of all childhood vaccines at government-set prices and then distributes them to states according to a federally-set formula. The end result is that vaccines have been distributed to states where there is no epidemic often leaving a shortage where it is needed. **Because the government controls the price, the vaccine makers are discouraged from producing more than what the government orders. Vaccine prices have remained stagnant since 1994. Thanks to these price controls, there now are only four developers of childhood vaccines. That’s down from 20 companies just a few years ago.** Even the U.S. Department of Health and Human Services recognizes the consequences to medical innovation if the federal government should choose to impose price controls. In a recent study the Department stated, **“There are potentially serious consequences to medical innovation with the implementation of government controls that are inevitably arbitrary and out of touch with the diversity of patients needs and consequences.**  [↑](#footnote-ref-52)
53. Rosenthal, Elisabeth. “The Price of Prevention: Vaccine Costs Are Soaring.” The New York Times, 2 July 2014. NYTimes.com, https://www.nytimes.com/2014/07/03/health/Vaccine-Costs-Soaring-Paying- Till-It-Hurts.html.

    **To deal with the rising prices,** some **doctors,** who say they **lose money on every vaccination, reserve their shots for longstanding patients**. A survey of family-practice doctors, who along with pediatricians are among the lowest-earning physicians, found that about **one-third were considering giving up immunizations because of the expense.** Another survey found that 40 percent do not offer at least some required childhood immunizations. That is why Breanna Farris, a San Antonio mother, had to call 10 pediatricians in April before she found Dr. Irvin to vaccinate her son, Traven, who is entering kindergarten this fall. The family’s usual doctors do not offer vaccinations, and referred Ms. Farris to local pharmacies (which do not vaccinate children) or the city health clinic (which would not take Traven’s insurance). [↑](#footnote-ref-53)
54. Joel Lexchin, Mar 1 2018. Monthly Review. “The Pharmaceutical Industry in Contemporary Capitalism” https://monthlyreview.org/2018/03/01/the-pharmaceutical-

    industry-in-contemporary-capitalism/

    The industry also justifies its high level of profits with the claim that drug development is inherently risky. To this end, **the pharmaceutical corporations maintain that only one in every 10,000 molecules actually results in a new drug .** Though this may be true, most of the molecules that fall by the wayside do so in the very early stages of development when costs are minimal. The $2.6 billion figure that is now cited as the cost to bring a new drug to market comes from data that are confidential, and the calculations are based on a set of assumptions that have been widely challenged. Were drug development such a risky proposition, then one would expect that from time to time the fortunes of corporations would vary. On the contrary, since 1980, all the large corporations have done well financially. As Stanley Finkelstein, a physician, and Peter Temin, an economist, both based at the Massachusetts Institute of Technology, point out, “No matter how many times industry analysts warn that a patent expiration is going to make this or that company vanish, it hasn’t happened.” [↑](#footnote-ref-54)
55. Cavallo

    http://www.ascopost.com/issues/november-25-2016/the-emergence-of-philanthropy-to-fund-high-risk-high-reward-cancer-research/

    Although there is no comprehensive tracking of the magnitude—or impact—of science philanthropy, a 2012 analysis by the National Bureau of Economic Research put **the combined donations from both individuals and private foundations at over $4 billion annually,1 a figure that pales in comparison to the $60 billion in scientific grants made by the federal government each year.**2 Still, while not a replacement for public dollars, private donations can fuel the kind of scientific innovation that is often not possible in more traditionally risk-averse government grants. [↑](#footnote-ref-55)
56. Durrell

    Robert Durell March 2017 https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments

    With new cancer drugs commonly priced at $100,000 a year or more, Krahne's story is becoming increasingly common. Hundreds of thousands of cancer patients are delaying care, cutting their pills in half or skipping drug treatment entirely, a Kaiser Health News examination shows. **One-quarter of all cancer patients chose not to fill a prescription due to cost, according to a 2013 study in The Oncologist**. And about 20 percent filled only part of a prescription or took less than the prescribed amount. Given that more than 1.6 million Americans are likely to be diagnosed with cancer this year, **that suggests** 168,000 to **405,000 ration their own prescription use**. "Patients are being harmed daily" by high treatment costs, says Dr. Hagop Kantarjian, a leukemia specialist and professor at Houston's MD Anderson Cancer Center. "It's causing more deaths than necessary." For instance, one-third of Medicare patients who were expected to use Gleevec — a lifesaving leukemia medication that costs up to $146,000 a year — failed to fill prescriptions within six months of diagnosis, according to a December study in the Journal of Clinical Oncology. Stopping drugs like Gleevec could be cutting years from some patients' lives. Instead of dying in five to seven years, patients with chronic myeloid leukemia who take Gleevec and similar drugs can survive nearly as long as people without cancer, and with a good quality of life, Kantarjian said. [↑](#footnote-ref-56)
57. #### National Organization for Rare Disorders

    National Organization for Rare Disorders , "Trends in Orphan Drug Costs and Expenditures Do Not Support Revisions in the Orphan Drug Act: Background and History", https://rarediseases.org/wp-content/uploads/2017/10/NORD-IMS- Report\_FNL.pdf

    **The success of the ODA in the U.S. has been widely recognized over the years and helped to encourage similar legislation in other parts of the world.** Japan adopted orphan drug legislation in 1993, Australia in 1998, and the European Union in 2000**. As of January 2017, FDA had approved almost 600 orphan drugs** and granted nearly 4,000 orphan drug designations since 1983. The orphan designation requests include new molecular entities, original biological products and new orphan uses of previously approved drugs and biologics.8 Over the years, the ODA has resulted in many treatments, such as zinc acetate for Wilson’s disease, that have provided valuable treatment for patients but which had little prospect of commercial return. It has also made possible treatments that have resulted in cost savings. For instance, a treatment for infant botulism developed by California Public Health officials and made possible by the ODA and the orphan grants program, used to date to treat more than 1,500 patients, has resulted in more than 90 years of avoided hospital stay and more than $130 million of avoided hospital costs.9 The need for safe, effective treatments for children has been widely documented, and a 10-year analysis of the ODA concluded that from 2000 through 2009 pediatric products increased from 17.5% to 30.8% of total orphan approvals. These products were for diseases on the rare end of the spectrum, with a median prevalence of 8,972.10 The ODA has been credited with helping drive innovation in cancer treatment,11 and it has resulted in life-saving enzyme replacement therapies for children and adults with metabolic diseases for which there was previously no treatment. From the patient perspective, the Orphan Drug Act has been extremely successful, encouraging research and development of products for diseases that would otherwise have no treatment. [↑](#footnote-ref-57)
58. #### FDA

    U.S. Food and Drug Administration, "Rare Pediatric Disease Priority Review Voucher Program", 11/02/17, https://www.fda.gov/forindustry/developingproductsforrar ediseasesconditions/rarepediatricdiseasepriorityvoucherprogram/default.htm

    Under Section 529 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), **FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. Under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product**. On September 30, 2016, the Advancing Hope Act of 2016 (Public Law No: 114-229) amended Section 529 of the FD&C Act. Among the changes, the term "rare pediatric disease" now means a disease that meets each of the following criteria: A. The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents. B. The disease is rare disease or conditions, within the meaning of Section 526. The Act changed the language of Subsection (A) from, "The disease primarily affects individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents." The full text of the Advancing Hope Act is available at: https://www.gpo.gov/fdsys/pkg/BILLS-114s1878enr/pdf/BILLS-114s1878enr.pdf Effective 90 days after the enactment of the Advancing Hope Act of 2016, the sponsor of a rare pediatric disease product application that intends to request a priority review voucher must submit such request in a cover letter to their NDA/BLA submission. [↑](#footnote-ref-58)
59. Radcliffe

    Shawn Radcliffe, The Huffington Post, "Why Are Drug Prices for Rare Diseases on the Rise?", 3/16/17,<https://www.huffingtonpost.com/entry/why-are-drug-pricesfor-rare-diseases-on-the-rise_us_58caf2fae4b0537abd956eff>

    According to the National Institutes of Health (NIH), there are around 7,000 rare diseases, which affect a total of 25 to 30 million Americans. **In exchange for investing in research and development of orphan drugs, companies receive a tax credit on research and development**, access to federal grants, and exclusive rights to sell the drug for that disease in the United States, even if the patent expires before then. [↑](#footnote-ref-59)
60. NORD

    National Organization for Rare Disorders , "Trends in Orphan Drug Costs and Expenditures Do Not Support Revisions in the Orphan Drug Act: Background and History", https://rarediseases.org/wp-content/uploads/2017/10/NORD-IMSReport\_ FNL.pdf

    From the patient perspective, the Orphan Drug Act has been extremely successful, encouraging research and development of products for diseases that would otherwise have no treatment. While the vast majority of the 7,000 diseases do not yet have an FDA-approved treatment, many patients and caregivers feel that the ODA offers hope that even those with the rarest of diseases may someday have a treatment, thereby eliminating or reducing the need for a lifetime of medical care. The three primary incentives of the ODA, along with waived user fees, have each contributed substantially to the success of the law. Credit is most often given to exclusivity, which has indeed proven a powerful incentive. However, **a 2015 study underscored the substantial importance of the orphan drug tax credit (ODTC). According to that study, investment in orphan drugs would be reduced by one-third without the ODTC.** [↑](#footnote-ref-60)
61. Section 529

    U.S. Food and Drug Administration, "Rare Pediatric Disease Priority Review Voucher Program", 11/02/17, https://www.fda.gov/forindustry/developingproductsforrar ediseasesconditions/rarepediatricdiseasepriorityvoucherprogram/default.htm

    **Under Section 529 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA will award priority review vouchers to sponsors of rare pediatric disease product** applications that meet certain criteria. **Under this program, a sponsor who receives an approval for a drug** or biologic **for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.** [↑](#footnote-ref-61)
62. https://catalyst.nejm.org/reframing-conversation-drug-pricing/. Accessed 7 Oct. 2018.  
    Efforts by the U.S. government to foster the generic pharmaceutical industry have been extraordinarily successful in bringing high-quality medicines to the American public at low cost. Branded drugs transition to generics very efficiently, often the day after patent expiration. These efforts continue: Scott Gottlieb, MD, the new FDA Commissioner, recently announced that the FDA will undertake efforts to reduce the backlog of generic drug applications to speed these less expensive drugs to market and enhance competition. The FDA regulates the generics industry, and the quality of generic drugs entering the U.S., with few exceptions, has been high. Generics stimulate innovation: because research-driven drug companies know years in advance when their patents will expire, they strive to replace those losses with new patent-protected drugs. Generally, they leave the generic market to manufacturers who specialize in that area [↑](#footnote-ref-62)
63. http://www.pharmtech.com/costs-failure-product-quality. Accessed 7 Oct. 2018. Poor quality in pharmaceuticals is often not visible or otherwise obvious to the consumer, so the quality control and quality assurance (QA) activities performed by the manufacturer are crucial. All products must be manufactured under strict cGMP guidelines and require extensive controls and testing prior to release of the product. Extensive testing is necessary to determine if a product is defective. When a quality issue is suspected at any time, there must be proper investigations, root-cause analyses, and action plans to address issues (1). In addition, if the products do not meet specifications, all affected lots of the drug products must be recalled from distribution after informing FDA and other regulatory agencies. Lots that have not been distributed should be quarantined to prevent distribution. [↑](#footnote-ref-63)
64. https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm2 78584.htm. Accessed 7 Oct. 2018.  
    The requirements of good manufacturing practice are underpinned by a central objective: to create a system of programs, policies, processes, and facilities that prevent errors and defects. Senior managers in the drug industry are responsible for the effectiveness of this system, which is known as the Pharmaceutical Quality System (PQS). A PQS is successful when it assures an ongoing state of control. In a healthy PQS, managers establish a vigilant quality culture in which timely action is taken to prevent risks to quality. Lifecycle adaptations are made to address manufacturing weaknesses and continually improve systems. An effective process performance and product quality monitoring program provides early warning of emerging quality issues. Systemic solutions are implemented rather than ineffective shortcuts. A firm will also habitually attend to the seemingly small problems that quality experts remind us later would accumulate into costly, complex problems. An effective PQS will ultimately support stable processes, and predictable quality and supply. FDA's routine surveillance inspections determine whether a site’s Quality System is operating in a state of control. Inspections cover multiple systems (see below compliance program). All inspections audit the overall quality assurance system to determine if it is functioning well. This aspect includes evaluating if responsible managers are notified of, and respond to, emerging quality problems, process control issues, or any new stresses on the system that may lead to defective medicines. [↑](#footnote-ref-64)
65. https://www.beckershospitalreview.com/human-capital-and-risk/job-cuts-in-healthcare-pharma-industries-soar-in-2017-3-things-to-know.html

    While job cuts across all U.S. industries decreased by 22 percent in 2017, both **pharmaceutical and healthcare sectors saw a stark increase in job cuts** in 2017, according to a recent report published by Challenger, Gray & Christmas, an outplacement and career transitioning firm. Here are three things to know. 1. **The healthcare sector announced 38,145 job cuts so far this year, which is a 123.9 percent increase** from the 17,030 dismissals announced through the same period a year prior. [↑](#footnote-ref-65)
66. **https://www.rdmag.com/article/2017/07/growing-role-automation-pharmaceutical-industry**

    Despite being an old concept, **automation and the extent of its adoption is at its highest peak in the industry.** Therefore, pharmaceutical organizations need a better understanding of its benefits and ensure they have a stringent automation strategy in place to guarantee they partner with the best technology provider that can deliver business efficiency without compromising security. [↑](#footnote-ref-66)
67. [**https://www.theengineer.co.uk/automating-pharmaceuticals/**](https://www.theengineer.co.uk/automating-pharmaceuticals/)

    A recent study by the Association for Packaging and Processing technologies (PMMI) has predicted that **robots will handle 34 per cent of primary pharmaceutical** packaging **operations in North America by 2018.** An increase in the use of robots is particularly significant in dispensing, sorting, kit assembly and light machine-tending. The advantages include greater speed and accuracy, more flexibility and more reliability. [↑](#footnote-ref-67)
68. https://www.independent.co.uk/news/business/investment-should-you-invest-in-pharmaceutical-companies-1090074.html

    Jeremy Batstone of NatWest Stockbrokers has a different focus." **Pharmaceuticals have been very volatile and the sector has tended to lag the market**," he says. "**People are looking more for value as the economy has improved, away from more defensive growth areas like pharmaceuticals."** Mark Mathias, head of investment funds at Rea Brothers Investment Management, agrees the sector's long-term growth potential is undisputed. Mathias, whose firm runs two specialist pharmaceutical funds, says: "There is the trend to ageing populations in the OECD countries, with the highest proportion of lifetime healthcare expenditure coming in the last two years of life, underpinned by the significant increase in healthcare research expenditure. At the same time, the OECD governments are trying to rein in the cost of government-subsidised healthcare and the way you do that is to spend more on drugs to keep people out of hospital." [↑](#footnote-ref-68)
69. Data published today by the ABPI shows that **the pharmaceutical industry continues to invest significantly in UK research** and development despite the future uncertainty of Brexit – working closely with healthcare professionals and organisations to improve patient care. The data published on Disclosure UK – the pharmaceutical industry’s database of payments and benefits in kind made to UK healthcare professionals (HCPs) and organisations (HCOs) – shows **industry spent £370.9 million on partnerships relating to research and development¹ activities in the UK during 2017. This is a 9.7% increase on 2016** (£338.1 million). Spending on research and development activities accounts for three quarters of the total spending disclosed on the database for working in partnership with leading UK health experts and organisations to improve patient care. [↑](#footnote-ref-69)
70. <https://innovations.bmj.com/content/2/3/111>

    In the past decades, North American and European countries actively sought to increase the size of their venture capital markets.6–10 **The levels of venture capital available to Canadian life sciences companies have more than doubled** from 2001 to 2010.11 In Europe, the UK enjoyed in 2009 the second largest venture capital market, accounting for 21% of all investments. In the same year, 20% of the UK £677 million of venture capital was invested in the health sector.4 [↑](#footnote-ref-70)
71. **When Viagra surged into consumers' bedrooms, Pfizer's stock enjoyed a sudden rise** - satisfying investors and consumers alike. Although Pfizer was far from an unknown company at the time, most of us did not hold stock. There are many reasons why an investor may not feel comfortable investing in pharmaceutical companies, but if you do want to get in on the next little blue pill there is still the obstacle of how to evaluate the industry. This article will explore some of the issues involved in pharmaceutical investing. [↑](#footnote-ref-71)
72. Sharmi Devi, “Maryland already sets hospitals’ prices. Now it wants to cap their spending.”, The Lancet, March 17, 2012,<https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60414-0/fulltext>, SP, October 19, 2018

    **The FDA is at the forefront of an increasingly complex battle to ensure the USA retains access to critical drugs.** President Barack Obama issued an executive order **in October, 2011, requiring drug companies to report to the federal agency when critical supplies were threatened. Meanwhile, new legislation that would make it mandatory for companies to notify the FDA of a wider range of supply problems and give it extra powers languishes in Congress.**

    **Last month, the FDA stepped in to resolve shortages of two cancer drugs that threatened thousands of patients**—methotrexate, used to combat lymphoblastic leukaemia, and doxorubicin, sold under the trade name Doxil, used to treat ovarian cancer, Kaposi's sarcoma related to HIV/AIDS, and multiple myeloma. [↑](#footnote-ref-72)
73. Richard **Frank** and Paul Ginsburg, 11-17-**2017**, "Pharmaceutical industry profits and research and development," **Brookings**, <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2017/11/17/pharmaceutical-industry-profits-and-research-and-development/>

    The pharmaceutical industry is what economists call a high-fixed low-cost marginal cost industry. This means that the cost of bringing a new drug to market is very high and the process is risky, while **the cost of producing an extra unit of a product that is on the market is frequently “pennies a pill”.** There is energetic disagreement about the exact cost of bringing a new drug to market, but there is widespread recognition that the costs run into at least many hundreds of millions of dollars per new drug product. [↑](#footnote-ref-73)
74. Suzanne Elvidge, “FDA creates task force to combat drug shortages”, BioPharma Drive, July 13, 2018,<https://www.biopharmadive.com/news/fda-creates-task-force-to-combat-drug-shortages/527734/>, SP, October 19, 2018

    New drug shortages in the U.S. have been steadily declining since a peak in 2011. **However, in 2017, The Food and Drug Administration** [**tracked more new drug shortages**](https://www.biopharmadive.com/news/new-drug-shortages-on-the-rise-in-2017-after-years-of-steady-declines/526246/) **than in either of the two previous years.** These disruptions followed issues at a Pfizer manufacturing plant in Kansas, and a damaging hurricane season wiping out facilities in Puerto Rico. While last year may be an aberration, the FDA [announced its commitment](https://www.biopharmadive.com/news/fda-working-to-mitigate-critical-drug-shortages/524779/) in June to mitigating existing issues and preventing new ones from occurring.

    **Food and Drug Administration head Scott Gottlieb has formed a new task force to try to minimize the impact of drug shortages on patients and physicians. This will focus on creating long-term solutions to the "underlying structural concerns that give rise to these recurring challenges."**

    **The task force, which will be led by Keagan Lenihan, the agency's associate commissioner for strategic initiatives, has been charged by Gottlieb to look into why some shortages remain an issue.** The task force will include senior leaders from the FDA, the Centers for Medicare and Medicaid Services and the Department of Veterans Affairs. The next step will be to engage with the public, and hold a meeting with stakeholders. [↑](#footnote-ref-74)
75. **As the** [**rolling waves of generic drug shortages**](http://www.nytimes.com/2013/09/03/opinion/how-a-cabal-keeps-generics-scarce.html) **and recent escalations in generic drug prices should remind us, both of these assumptions are questionable.** The market’s invisible hand works until it doesn’t, and then, as Adam Smith wrote in [The Wealth of Nations](http://www.amazon.com/dp/0553585975/?tag=slatmaga-20), we are left with conditions of market failure when supply doesn’t meet demand. **In the generic drug industry, market failure occurs when a crowd of different companies that once competed to sell a drug like doxycycline ditch it to pursue more profitable drugs, leaving just one generic supplier—or a** [**new gray-market monopoly**](http://democrats.oversight.house.gov/investigations/investigation-of-the-gray-market) **able to raise prices just like brand-name manufacturers. This happens in part because generic companies are drawn toward the market exclusivity of newer drugs when they come off patent, in part because of bottlenecks in the supply of precursor chemicals, and in part because of shrinking margins in the production of older generic drugs. The stampede leaves the supply of many older but essential medicines in the hands of just a few suppliers, whose production lines are unprepared to deal with surges in demand, leading to shortages of key pharmaceutical agents needed for the treatment of cancer, pneumonia, and** [**heart disease**](http://blogs.wsj.com/pharmalot/2014/11/10/justice-department-probes-generic-competition-after-price-hike-reports/)**, as well as for basic anesthesia**. Prices eventually recede—but by then, usually, other drugs are seeing similar cost surges. [↑](#footnote-ref-75)
76. Ferrari

    Ferrari, Nancy. “How Drug Shortages Happen.” Harvard Health Blog, Harvard Medical School, 23 Feb. 2012, www.health.harvard.edu/blog/how-drug-shortages-happen-201202174276.

    A drug shortage can occur because of increased demand. It can also happen when a pharmaceutical company discontinues a drug or takes a manufacturing facility offline—which companies can do at any time. What can be done? **The FDA can** sometimes **help ease a drug shortage**. When a drug is in short supply but the manufacturer has some in stock that has expired or is close to expiring, the FDA can review whether extending the expiration date is safe. If so, it can free those supplies to be used. **The FDA can also help ramp up production of hard-to-get drugs by expediting approval of new production lines or new materials that can be used to make the drug.** In some cases, **the FDA may look for overseas sources for specific drugs**. **It reviews the safety of such supplies and allows temporary import to ensure that critical patient needs are met.** Within the FDA, the Center for Drug Evaluation and Research maintains a Drug Shortage Action Plan. Its goal is to help prevent and address drug shortages. You can read the specifics of the plan here. [↑](#footnote-ref-76)
77. **Jones**, John. “Big Pharma's Lobbyists Are Losing despite Their 'Pass the Buck' Campaigns.” **TheHill**, 5 Mar. **2018**, thehill.com/opinion/healthcare/376699-big-pharmas-lobbyist-are-losing-despite-their-pass-the-buck-campaigns.

    However, **their polling numbers remain as low as before their advertising blitz began as Americans have overwhelmingly negative views of drugmakers** and the pricing schemes of “Pharma Bro" Martin Shkreli and others who increased drug prices simply because they found that they could. The response from the drugmaker lobby has been to rollout slick public relations slogans like “Share the Savings” and “Let's Talk About Cost” that use fancy infographics in an attempt to move the conversation away from those setting the price of the drug (drug companies) to everyone else who uses or pays for their products, like employers, hospitals, pharmacy benefit managers, insurers, and others. This isn’t surprising and certainly not unpredictable, but ignores the basic challenge facing drug companies: **no amount of money can change the fact that Republicans and Democrats know the problem is high drug prices and that drugmakers alone set those prices**. So **despite** all this overwhelming **lobbying and financial firepower, the question remains: Why are drugmakers losing? In the recent budget bill, drugmakers were singled out by both parties to pay billions more in discounts to help seniors** in the Medicare prescription drug benefit “donut hole [↑](#footnote-ref-77)
78. **Bowmer**, Rick. “Fighting Special Interest Lobbyist Power Over Public Policy.” **Center for American Progress**, 27 Sept. **2017**, https://www.americanprogress.org/issues/democracy/reports/2017/09/27/439 675/fighting-special-interest-lobbyist-power-public-policy/.

    **Some proposals would even ban members from lobbying permanently.** Extending the ban on lobbying would give lawmakers one less reason to elevate special interest concerns over the concerns of their constituents. Implementing effective policies to fight the corrupting influence of special interest lobbyists depends on an accurate and effective system of lobbyist registration. Unfortunately, the current definition is all too easily evaded and has resulted in many people engaged in lobbying activities deregistering or failing to register in the first place. Fortunately**, bills have been introduced** in both the House and Senate **that would institute a commonsense definition of lobbying that applies to anyone who makes more than one lobbying contact on behalf of a client over a two-year period.** In addition to enabling enforcement of the proposals above, expanding lobbying disclosure would also allow the public to better understand who is spending money to try to influence government—as well as how much money is being spent—so that representatives are held accountable. [↑](#footnote-ref-78)
79. **Ferry**, David. “The New War on (Overpriced) Pharmaceuticals.” **Wired**, Conde Nast, 8 Nov. **2017**, www.wired.com/story/fighting-high-drug-prices/.

    President Donald **Trump has said that the pharmaceutical industry is “getting away with murder” and that he wants to let Medicare negotiate with drug companies over the prices we pay—**something that was forbidden in 2003, part of a compromise with the politically potent industry to get the Medicare drug expansion plan passed. (Since 1998, Big Pharma has spent more on lobbying than any other industry.) [↑](#footnote-ref-79)
80. https://www.nytimes.com/2018/06/21/opinion/competition-drug-prices.html  
    When Gleevec came on the market, its list price was about $26,000 a year. Today, there are several highly effective drugs in the same family on the market (sometimes called “sons of Gleevec”). The list price for each is about $150,000 annually. (Notably, Dr. Brian Drucker, the researcher who demonstrated that the drug could cure cancers, never got a patent and never made money from it.) What happened is that each new entrant cost more than its predecessors, and their makers then increased their prices to match the newcomer’s. When the first generic version entered the market in 2016, its list price was only slightly less, about $140,000.This phenomenon, what economists call “sticky pricing,” is common in pharmaceuticals. It has raised the prices in the United States of drugs for serious conditions including multiple sclerosis and diabetes even when there are multiple competing drugs. The problem is that companies have decided it is not in their interest to compete. In situations where there can be only one winner, competing is a given. But a lot of life and a lot of business just isn’t like that, especially when a group of companies are all doing good business by selling a type of drug for a very high price. There’s cover in numbers. [↑](#footnote-ref-80)
81. <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwidyuOdqITfAhVLVK0KHQvTCKYQFjAAegQIChAC&url=https%3A%2F%2Fwww.frisch.uio.no%2Fpublikasjoner%2Fpdf%2FHERO2006_1.pdf&usg=AOvVaw2vBWS2xdC6sV1fMK2_S7UG>

    file:///C:/Users/craft/Downloads/HERO2006\_1.pdf  
    Frank and Salkever (1997) arrived at similar results when they looked at a sample of 32 drugs that lost patent protection during early to mid-1980s. More competition among generic drug producers is found to cause price reductions for those drugs. Increased competition from generic drugs, however, is not accompanied by lower prices on branded drugs. Their results suggest instead a small price increase on branded drugs. Caves et al. (1991) investigate the experience of 30 drugs that lost patent protection between 1976 and 1987. Their result differs from that of Frank and Salkever (1997). The branded drug price declines with the number of generic entrants, but the rate of decline is small. For the mean number of generic drugs, the brand name price declines by 4.5 percent only. At the same time, generic prices are much lower than the brand name prices. Their results suggest that average generic price is about 50 percent of the branded drug price when 3 generic producers have entered the market. [↑](#footnote-ref-81)
82. http://sourceonhealthcare.org/do-drugs-that-treat-the-same-indication-compete-with-each-other/   
    The pharmaceutical market, however, is far from a free-market and this kind of competition seems to be an exception rather than the rule when it comes to prescription drugs. A study by the Alliance of Community Health Plans found that drug costs for widely prescribed medications increased substantially for many therapeutic classes including rheumatoid arthritis (RA), multiple sclerosis (MS), and diabetes, even though there were multiple treatment options for each disease. More than a dozen treatment options exist for multiple sclerosis, for example, but even the first generation of drugs to treat MS (interferon (IFN)–β-1b) that originally cost $8,000-$11,000 per year can now cost more than $60,000 per year, and there are no treatments for MS that cost less than $50,000 annually (not accounting for manufacturer’s coupons).[5] A study by researchers at Oregon State University found that rather than driving down prices, manufacturers increased the price of existing drugs when a new treatment option became available for MS.[6] The authors say “the simplest explanation is that pharmaceutical companies raise prices of new and old [treatments for] MS in the United States to increase profits and our health care system puts no limits on these increases. Unlike most industrialized countries, the United States lacks a national health care system to negotiate prices directly with the pharmaceutical industry.”[7] A growing body of literature suggests that in many disease areas, the release of a new drug drives prices up rather than down, as drugs do not seem to compete on price.[8]The pharmaceutical market, however, is far from a free-market and this kind of competition seems to be an exception rather than the rule when it comes to prescription drugs. A study by the Alliance of Community Health Plans found that drug costs for widely prescribed medications increased substantially for many therapeutic classes including rheumatoid arthritis (RA), multiple sclerosis (MS), and diabetes, even though there were multiple treatment options for each disease. More than a dozen treatment options exist for multiple sclerosis, for example, but even the first generation of drugs to treat MS (interferon (IFN)–β-1b) that originally cost $8,000-$11,000 per year can now cost more than $60,000 per year, and there are no treatments for MS that cost less than $50,000 annually (not accounting for manufacturer’s coupons).[5] A study by researchers at Oregon State University found that rather than driving down prices, manufacturers increased the price of existing drugs when a new treatment option became available for MS.[6] The authors say “the simplest explanation is that pharmaceutical companies raise prices of new and old [treatments for] MS in the United States to increase profits and our health care system puts no limits on these increases. Unlike most industrialized countries, the United States lacks a national health care system to negotiate prices directly with the pharmaceutical industry.”[7] A growing body of literature suggests that in many disease areas, the release of a new drug drives prices up rather than down, as drugs do not seem to compete on price.[8] The principal-agent problem: A doctor, in consultation with the patient, chooses the treatment but does not pay for the treatment. Physicians are often unaware of treatment costs[11] and frequently don’t discuss cost as part of the treatment decision-making process with patients.[12] The insurer, Medicare, Medicaid, or the patient, if he or she does not have prescription drug coverage, pays for the treatment and has little or no impact on what treatment choice is made. If a patient has good drug coverage, he or she is insulated from considering the price of a treatment. Economists refer to situations like this as a principal-agent problem, where the agent (the physician) making decisions is not the one who bears the consequences or costs of that decision (the principal). Lack of Price Transparency: A comprehensive report from the Commonwealth Fund states that “a lack of price transparency and availability of information about the comparative value of similar therapeutic drugs makes the drug marketplace less efficient. It also undermines the goal of robust price competition to ensure patient access to the most important drugs.”[13] Without knowing the cost of a drug, specifically what the out-of-pocket costs will be for a patient, the doctor and patient cannot accurately assess whether to try a cheaper alternative treatment. Prescription drug formularies: Pharmacy benefit managers (PBMs) and insurers often institute a prescription formulary for beneficiaries of insurance plans. Pharmacy and therapeutics (P&T) committees ensure that formularies include enough drugs to satisfy health plan beneficiaries and give physicians a sufficient number of treatment options.[14] The formularies, however, are often a result of negotiations with drug manufacturers and don’t necessarily result in lower prices for patients. Because the negotiations about a formulary typically include all drugs made by that manufacturer as a package, the price of any one drug can be shielded from competition. In addition, drug manufacturers can negotiate terms that offer significant discounts for a particular product in exchange for keeping competitors off preferred tiers in a formulary. For example, Pfizer filed a lawsuit against Johnson & Johnson (J&J) alleging that J&J forced insurers to enter into “exclusionary contracts” that kept patients from using Inflectra, Pfizer’s biosimilar drug for J&J’s Remicade. Even though Inflectra cost 30% less than Remicade, less than 1% of patients used Inflectra because it was not included in most formularies.[15] In the end, formularies restrict patient choices and prevent competition between drugs that treat the same indication. Manufacturer Coupon Programs: Brand manufacturers can provide patients with coupons and other financial assistance to cover the cost of their prescription co-pays. Since insurers typically cover about 80% of the total price of a prescription, manufacturers can make more money by charging a higher price to insurers, even if they do not collect the 20% of the cost that the patient would pay. These incentives undo financial pressure that would otherwise steer demand to lower-priced alternatives. They prevent patients from choosing treatments with the lowest overall cost because the patient can get the expensive drug with minimal cost-sharing. Anti-kickback statues prevent Medicare and all beneficiaries of federal health care programs from using these coupons,[16] but the practice is still common for patients covered by private insurance. A study by Leemore Dafny, Christopher Ody, and Matt Schmitt estimated that coupons increased the total spending on pharmaceuticals by at least $700 million and perhaps as much as $2.7 billion between 2005 and 2010.[17] [↑](#footnote-ref-82)
83. Joe Nocera, 10-23-2017, "Here's how drug companies game the patent system," chicagotribune, <https://www.chicagotribune.com/news/opinion/commentary/ct-perspec-drugs-health-care-pharm-1024-20171023-story.html> [↑](#footnote-ref-83)
84. **Tahir Amin,&nbsp;Co-Founder Of Nonprofit I-Mak.Org, 6-27-2018, "The problem with high drug prices isn't 'foreign freeloading,' it's the patent system," CNBC, https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html** [↑](#footnote-ref-84)
85. https://www.ft.com/content/5ec2c642-54b0-11e8-b3ee-41e0209208ec  
    Mr Trump complained that foreign countries were paying “a tiny fraction of what the medicine costs in the USA” as his officials said overseas buyers were not contributing their fair share to research and development costs. “It’s unfair and it’s ridiculous and it’s not going to happen any longer,” Mr Trump said in a speech at the White House on Friday. “It’s time to end the global freeloading once and for all.” Healthcare stocks rallied following the speech on relief among investors that the plan did not contain radical measures likely to hurt profits in the US healthcare industry, although Mr Trump did chastise the industry for its prolific lobbying. [↑](#footnote-ref-85)
86. https://www.communitycatalyst.org/resources/publications/document/2018/CC-PrescripDrugPrices-Report-FINAL.pdf  
    The fundamental cause of high prescription drug prices in the U.S. is the failure to counterbalance the monopoly power of pharmaceutical manufacturers with a strong coordinated purchasing strategy. This monopoly power is conferred via federal patent laws as well as rules that diminish federal and state authority to negotiate drug prices or implement measures to lower drug costs [↑](#footnote-ref-86)
87. https://patientengagementhit.com/news/high-drug-costs-limit-patient-access-to-treatment-medication  
    Rising out-of-pocket patient costs are keeping patients from using two common heart medications, hindering patient access to treatment, according to an analysis from the Cleveland Clinic. Published as a letter to the editor in the most recent edition of the New England Journal of Medicine, the report claims that rising drug costs are keeping patients from accessing nitroprusside and isoproterenol. The former lowers blood pressure and helps treat critical hypertension and congestive heart failure, while the latter mostly treats bradycardia and heart block. Neither drug has an entirely comparable alternative treatment, highlighting the importance that patients be able to access them, according to the researchers. [↑](#footnote-ref-87)
88. \.S. government (**U.S.) global health efforts** aim to **help improve the health of people in low- and middle-income countries** while also contributing to broader U.S. global development goals, foreign policy priorities, and national security concerns. The U.S. has been engaged in international health activities for more than a century and today is the largest funder and implementer of global health programs worldwide. Many different U.S. government departments and agencies, congressional committees, and funding streams are involved in these efforts. Through both bilateral programs and multilateral engagement, the U.S. supports activities that address a range of global health challenges (including but not limited to HIV, malaria, family planning and reproductive health, and maternal and child health) in more than 70 countries. Total **U.S. global health funding was $10.8 billion in FY 2018**, up from $5.3 billion in FY 2006; the current Administration, however, has proposed significantly reducing global health funding for FY 2019. [↑](#footnote-ref-88)
89. This is because most **foreign governments, which are the primary buyers in their respective pharmaceutical markets, force drug manufacturers to comply with pricing rules to gain market access. Through this leverage, foreign governments are able to set drug prices below those that prevail in the United States** and erode the returns to innovation manufacturers might otherwise see from selling in their markets. Among members of the Organization for Economic Co-operation and Development (OECD), CEA estimates that Americans pay more than 70 percent of patented biopharmaceutical profits, despite the fact that the United States accounts for only 34 percent of OECD GDP at Purchasing Power Parity (PPP). [↑](#footnote-ref-89)
90. Apr 19th, xx-xx-xxxx, "The price of Africa's cheap drugs," Economist, https://www.economist.com/unknown/2001/04/19/the-price-of-africas-cheap-drugs [↑](#footnote-ref-90)
91. Industry Week, 2018 [**https://www.industryweek.com/companies-amp-executives/drug-companies-rx-bottom-line**](https://www.industryweek.com/companies-amp-executives/drug-companies-rx-bottom-line)

    **“By giving away drugs in developing countries with** the best **potential to become future markets, pharmaceutical manufacturers** can **gain expertise, contacts, and demand for their products that will propel sales. In** the Manhattan headquarters of **Pfizer Inc., the strategy is called "venture philanthropy."**

    [1] Apr 19th, xx-xx-xxxx, "The price of Africa's cheap drugs," The Economist 2001 https://www.economist.com/unknown/2001/04/19/the-price-of-africas-cheap-drugs

    [1] **First, drug companies are increasingly testing their new products** on people who will never benefit from them. Evidence exists that **companies see the developing world as a “virgin territory” with millions of potential trial subjects.** For example, CenterWatch, a clinical trials listing service, recently published an article called “Latin American fever,” in which it said that the continent “may offer a unique opportunity to reach much larger numbers of study subjects.”3 In 1994, Eli Lilly enrolled just 590 trial patients across Africa, the Middle East, and central and eastern Europe. This year, the company expects to enroll 7,309 subjects.4 It is cheaper to conduct trials in poor countries, which often have fewer regulatory controls, so the industry stands to benefit. But the trial subjects rarely do. Trials in poor countries are associated with local improvements in health care only while the trials are ongoing. **The improvements are rarely sustained after the trials end and the companies have withdrawn their treatments and patient monitoring.**5 Many drugs tested in the developing world are designed to treat conditions that largely affect industrialized, not developing, nations. And although in theory new treatments may be available to all who might benefit after being tested in poor countries, their inflated prices usually put them out of the reach of the study population. **The second way in which the poor lose out is that drug companies can refuse to market products that would save lives in the tropics but do not reap corporate rewards.** An illustration is the story of the drug eflornithine, which was originally developed—but found to be ineffective—as an anticancer agent. The drug is effective against African sleeping sickness,6 which claims thousands of lives annually in sub-Saharan Africa. It is the only known treatment for the resistant form of the disease, which has a prevalence of up to 20% in parts of Uganda.7 Hoechst Marion Roussel**, the company that developed it, stopped its production** in 1999, citing commercial failure. This decision **left thousands dying of a curable illness without treatment.** Would the US government stand by and allow a drug company to refuse to market a safe treatment for a disease that killed thousands of US citizens every year? We doubt it. And there is a distasteful twist in the story. Bristol-Myers Squibb and Gillette have just introduced Vaniqa, a facial cream containing eflornithine HCl, the “first and only prescription cream proven to slow the growth of unwanted facial hair in women” (www.vaniqa.com). The drug may indeed reach Africa, but only because its cosmetic properties make it profitable. **A third way in which the pharmaceutical industry stands to profit at the expense of others is in its attempts to prevent poor countries from manufacturing generic versions of essential medicines.**8 The industry fiercely guards its patents, and it has been aided by the World Trade Organization's agreements on intellectual property rights, which include the right to exclusively market a patented drug for at least 20 years. [↑](#footnote-ref-91)
92. The Guardian, 2012 <https://www.theguardian.com/global-development/2012/nov/28/big-pharma-drugs-poor-countries>

    “Although there has been improvement and a greater willingness among companies to change their business practices, it is not yet enough. More **companies are using tiered pricing – offering a discount for poorer countries – for a broader range of products,** "but it is unclear whether the price reductions are enough to meaningfully increase affordability", says the report.”

    **Tiered pricing is when companies offer discounts to developing countries for being in large quantities, whether or not U.S. is priced high doesn’t change whether or not developing countries have access to to drugs, the reason things like HIV medicine are cheap in developing countries is because of tiered pricing, not subsidization.** [↑](#footnote-ref-92)
93. Robert Pear, 5-9-2018, "To Lower Drug Costs at Home, Trump Wants Higher Prices Abroad," No Publication, https://www.nytimes.com/2018/05/09/us/politics/trump-prescription-drug-prices.html [↑](#footnote-ref-93)
94. The Scientist, 2000 <https://www.the-scientist.com/news-analysis/more-than-altruism-behind-donations-of-aids-drugs-to-africa-55279>

    According to Brian Ager, Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA), **patent infringement is a key concern. Donating patented HIV/AIDS drugs or offering them at greatly reduced prices could blunt competition from cheaper generic versions. This could reduce the influx of these generic drugs into the northern hemisphere** as well. For example, **Glaxo Wellcome opposes plans by Indian generic drugmaker Cipla to sell discounted versions of Glaxo's patented Combivir AIDS medicine in Ghana.** In addition, Cipla is selling nevirapine, a patented Boehringer Ingelheim drug (Viramune) under its own trade name, Nevimune. In India, Cipla is doing nothing illegal. It received clearance from the Drugs Controller General of India to manufacture and market nevirapine for AIDS. [↑](#footnote-ref-94)
95. **First, drug companies are increasingly testing their new products** on people who will never benefit from them. Evidence exists that **companies see the developing world as a “virgin territory” with millions of potential trial subjects.** For example, CenterWatch, a clinical trials listing service, recently published an article called “Latin American fever,” in which it said that the continent “may offer a unique opportunity to reach much larger numbers of study subjects.”3 In 1994, Eli Lilly enrolled just 590 trial patients across Africa, the Middle East, and central and eastern Europe. This year, the company expects to enroll 7,309 subjects.4 It is cheaper to conduct trials in poor countries, which often have fewer regulatory controls, so the industry stands to benefit. But the trial subjects rarely do. Trials in poor countries are associated with local improvements in health care only while the trials are ongoing. **The improvements are rarely sustained after the trials end and the companies have withdrawn their treatments and patient monitoring.**5 Many drugs tested in the developing world are designed to treat conditions that largely affect industrialized, not developing, nations. And although in theory new treatments may be available to all who might benefit after being tested in poor countries, their inflated prices usually put them out of the reach of the study population. **The second way in which the poor lose out is that drug companies can refuse to market products that would save lives in the tropics but do not reap corporate rewards.** An illustration is the story of the drug eflornithine, which was originally developed—but found to be ineffective—as an anticancer agent. The drug is effective against African sleeping sickness,6 which claims thousands of lives annually in sub-Saharan Africa. It is the only known treatment for the resistant form of the disease, which has a prevalence of up to 20% in parts of Uganda.7 Hoechst Marion Roussel**, the company that developed it, stopped its production** in 1999, citing commercial failure. This decision **left thousands dying of a curable illness without treatment.** Would the US government stand by and allow a drug company to refuse to market a safe treatment for a disease that killed thousands of US citizens every year? We doubt it. And there is a distasteful twist in the story. Bristol-Myers Squibb and Gillette have just introduced Vaniqa, a facial cream containing eflornithine HCl, the “first and only prescription cream proven to slow the growth of unwanted facial hair in women” (www.vaniqa.com). The drug may indeed reach Africa, but only because its cosmetic properties make it profitable. **A third way in which the pharmaceutical industry stands to profit at the expense of others is in its attempts to prevent poor countries from manufacturing generic versions of essential medicines.**8 The industry fiercely guards its patents, and it has been aided by the World Trade Organization's agreements on intellectual property rights, which include the right to exclusively market a patented drug for at least 20 years. [↑](#footnote-ref-95)
96. Stephanie Kelly, xx-xx-xxxx, "Testing Drugs on the Developing World," Atlantic, <https://www.theatlantic.com/health/archive/2013/02/testing-drugs-on-the-developing-world/273329/>

    **These clinical trials for new medications take place all over the world, but developing countries often serve as cost effective locations.**

    **These trials led to 438 deaths in 2011 alone.** This kind of misinformation will not show up in the data released by GSK.

    Not only that, but **drug trials do not last forever. Once the period of allotted time for testing ends, the researchers can pack up and head back to headquarters. What if the illness being cured involves lifelong treatment, such as for HIV/AIDS patients?** Indeed, what if the treatment being tested requires interrupting testing, just to see what happens? [↑](#footnote-ref-96)
97. Cox, News, 10-18-2013, "Surprise! Big Pharma Don't Want Developing Countries Having Access to Cheap Medicine," **Vice**, <https://www.vice.com/en_uk/article/8g344x/american-lobbyists-are-fighting-to-halt-the-availability-of-affordable-medicine-to-the-3rd-world>

    However, **aggressive lobbying from US pharmaceutical companies is set to change all that. America's pharmaceutical plutocrats are attempting to revise intellectual property laws in India, meaning that many people seeking treatment will be forced to buy expensive US imports instead of domestically produced replicas. Which obviously isn't great news for the** [**96.9 percent of citizens living with less than $5 (£3) a day**](http://povertydata.worldbank.org/poverty/country/IND)**.**  [↑](#footnote-ref-97)
98. https://www.cnn.com/2018/03/26/health/report-medicare-drug-prices-soaring/index.html  
    The prices of the 20 most commonly prescribed brand-name drugs for seniors have risen nearly 10 times more than the annual rate of inflation over the past five years, according to a congressional report released Monday. "Can you imagine if you went to an auto dealership and last year's exact model was being sold at a 20 percent mark-up, and then you went back the next year and it had happened again?" said Sen. Claire McCaskill, D-Missouri, who released the report as part of a years-long investigation into escalating drug prices. [↑](#footnote-ref-98)
99. Bipartisan agreement that drug prices are too high now, so lobbying is becoming ineffective.

    John Jones. The Hill. “Big Pharma's lobbyists are losing despite their 'pass the buck' campaigns”, March 5 2018,<https://thehill.com/opinion/healthcare/376699-bigpharmas-lobbyist-are-losing-despite-their-pass-the-buck-campaigns>

    “This isn’t surprising and certainly not unpredictable, but ignores the basic challenge facing drug companies: **no amount of money can change the fact that Republicans and Democrats know the problem is high drug prices and that drugmakers alone set those prices.** So **despite** all this overwhelming lobbying and financial firepower, the question remains: Why are **drugmakers [are] losing**? **In the recent budget bill, drugmakers were singled out by both parties to pay billions more in discounts to help seniors in the Medicare prescription drug benefit** “donut hole.” This comes as states across the country are taking a harder look at drugmaker pricing schemes and passing legislation in California and Nevada that faced significant pushback fr m drug companies (and their surrogates). Like the emperor who wore no clothes, drugmakers have confused politician’s fear of speaking out against them with support for their pricing practices. It appears that most politicians will tolerate, but not believe in the drug lobby's messages or goals. Drug manufacturers have a number of options to alter public perception of their pricing strategies. They can assert that their products are a great value at any price but there is definitely a level where that argument fails. They can also compete on price and refrain from automatic pricing increases that obviously impact healthcare affordability. Instead, they peddle distracting narratives and government mandates that undermine federal programs and result in huge industry profit windfalls.”  [↑](#footnote-ref-99)
100. https://www.cnbc.com/2016/10/28/a-warning-for-big-pharma-lobbying-wont-work-anymore-commentary.html  
     Let's be blunt. Corporate America is in delusional denial about how much the ground in Washington has shifted against it. The rise of Senators Bernie Sanders and Elizabeth Warren, both inside the halls of Congress and throughout the country, is more than just a passing fad. Just ask Wells Fargo CEO John Stumpf... oops, I mean former CEO John Stumpf, who stepped down in part thanks to Senator Warren's grilling during recent Senate hearings. Here's a warning and a wake up call to big business: If you try to use the same old lobbying and crony networks to get your way, it won't work. Not anymore. And here's a special warning call just for Big Pharma: You need to change your public relations and marketing strategies now, or die. The good news is, unlike so many other industries, the drug companies have a very effective way out of this mess [↑](#footnote-ref-100)
101. https://www.americanprogress.org/issues/democracy/reports/2017/09/27/439 675/fighting-special-interest-lobbyist-power-public-policy/.   
     Some proposals would even ban members from lobbying permanently. Extending the ban on lobbying would give lawmakers one less reason to elevate special interest concerns over the concerns of their constituents. Implementing effective policies to fight the corrupting influence of special interest lobbyists depends on an accurate and effective system of lobbyist registration. Unfortunately, the current definition is all too easily evaded and has resulted in many people engaged in lobbying activities deregistering or failing to register in the first place. Fortunately, bills have been introduced in both the House and Senate that would institute a commonsense definition of lobbying that applies to anyone who makes more than one lobbying contact on behalf of a client over a two-year period. In addition to enabling enforcement of the proposals above, expanding lobbying disclosure would also allow the public to better understand who is spending money to try to influence government—as well as how much money is being spent—so that representatives are held accountable [↑](#footnote-ref-101)
102. https://reason.com/archives/2017/03/10/president-trump-dont-resort-topharmaceu.   
     Trump was characteristically vague about just how he would lower pharmaceutical prices, but let's assume that Medicare was legally mandated to negotiate prices with drug companies. In this case, "negotiate" amounts to creating price controls since pharmaceutical manufacturers would largely have to take whatever price the government wanted to offer, much like what already occurs in the case of the Veterans Affairs Department. Most companies would likely agree to the government price controls because they would still make money from their existing drugs because marginal costs of each additional pill are so low. What would happen? A new study in Forum for Health Economics & Policy by a team of researchers led by Jeffrey Sullivan at the consultancy Precision Health Economics finds that price controls would indeed reduce the cost of drugs to Medicare Part D participants.\* But the unintended consequences to Americans' lives and health in the future would be substantial and bad. [↑](#footnote-ref-102)
103. https://smallbusiness.chron.com/cutting-prices-good-marketing-strategy61446.html.   
     The price you set for your product sends a message to consumers about your worth, creating a perceived value for your products or services. Selling your product at prices lower than the competition tells consumers who buy based on value and affordability that you are a bargain. Low prices can scare away high-end shoppers. High prices might send a message that you offer superior quality because of your product’s features, the customer service you offer or both. Selling at a lower price often increases your sales volume, hopefully making up for your decreased profit per unit by returning bigger gross profits. [↑](#footnote-ref-103)
104. **Jones**, John. “Big Pharma's Lobbyists Are Losing despite Their 'Pass the Buck' Campaigns.” **TheHill**, 5 Mar. **2018**, thehill.com/opinion/healthcare/376699-big-pharmas-lobbyist-are-losing-despite-their-pass-the-buck-campaigns.

     However, **their polling numbers remain as low as before their advertising blitz began as Americans have overwhelmingly negative views of drugmakers** and the pricing schemes of “Pharma Bro" Martin Shkreli and others who increased drug prices simply because they found that they could. The response from the drugmaker lobby has been to rollout slick public relations slogans like “Share the Savings” and “Let's Talk About Cost” that use fancy infographics in an attempt to move the conversation away from those setting the price of the drug (drug companies) to everyone else who uses or pays for their products, like employers, hospitals, pharmacy benefit managers, insurers, and others. This isn’t surprising and certainly not unpredictable, but ignores the basic challenge facing drug companies: **no amount of money can change the fact that Republicans and Democrats know the problem is high drug prices and that drugmakers alone set those prices**. So **despite** all this overwhelming **lobbying and financial firepower, the question remains: Why are drugmakers losing? In the recent budget bill, drugmakers were singled out by both parties to pay billions more in discounts to help seniors** in the Medicare prescription drug benefit “donut hole [↑](#footnote-ref-104)
105. **Bowmer**, Rick. “Fighting Special Interest Lobbyist Power Over Public Policy.” **Center for American Progress**, 27 Sept. **2017**, https://www.americanprogress.org/issues/democracy/reports/2017/09/27/439 675/fighting-special-interest-lobbyist-power-public-policy/.

     **Some proposals would even ban members from lobbying permanently.** Extending the ban on lobbying would give lawmakers one less reason to elevate special interest concerns over the concerns of their constituents. Implementing effective policies to fight the corrupting influence of special interest lobbyists depends on an accurate and effective system of lobbyist registration. Unfortunately, the current definition is all too easily evaded and has resulted in many people engaged in lobbying activities deregistering or failing to register in the first place. Fortunately**, bills have been introduced** in both the House and Senate **that would institute a commonsense definition of lobbying that applies to anyone who makes more than one lobbying contact on behalf of a client over a two-year period.** In addition to enabling enforcement of the proposals above, expanding lobbying disclosure would also allow the public to better understand who is spending money to try to influence government—as well as how much money is being spent—so that representatives are held accountable. [↑](#footnote-ref-105)
106. **Ferry**, David. “The New War on (Overpriced) Pharmaceuticals.” **Wired**, Conde Nast, 8 Nov. **2017**, www.wired.com/story/fighting-high-drug-prices/.

     President Donald **Trump has said that the pharmaceutical industry is “getting away with murder” and that he wants to let Medicare negotiate with drug companies over the prices we pay—**something that was forbidden in 2003, part of a compromise with the politically potent industry to get the Medicare drug expansion plan passed. (Since 1998, Big Pharma has spent more on lobbying than any other industry.) [↑](#footnote-ref-106)
107. 1] Hancock, Jay, 9-23-2017, “Everyone Wants To Reduce Drug Prices so Why Can’t We Do It?”<https://www.nytimes.com/2017/09/23/sunday-review/prescription-drugs-prices.html> New York Times.

     Of all the promises President Trump made for the early part of his term, controlling stinging drug prices might have seemed the easiest to achieve. An angry public overwhelmingly wants change in an easily vilified industry. The pharmaceutical industry’s recent publicity nightmare included 1,000 percent price increases and a smirking chief executive who said, “I liken myself to the robber barons.” Even **powerful members of Congress from both parties have said that drug prices are too high**.But any momentum to curtail prescription drug costs — a problem that a large number of Americans now believe government should solve — has been lost amid rancorous debates over replacing Obamacare and stalled amid roadblocks erected via lobbying and industry cash. [↑](#footnote-ref-107)
108. [2] Barney Jopson, 2016, The Financial Times “U.S. Election Winner Faces Deadlock on Capitol Hill”<https://www.ft.com/content/ada7f512-a1e6-11e6-aa83-bcb58d1d2193>

     **Deadlock has been endemic in the US Congress since Republicans seized the House of Representatives** in 2010, ending the full Democratic control that President Barack Obama enjoyed for two years. **In the six years since, the “do-nothing Congress” tag has stuck as the frustrations of businesses and others who want to see some lawmaking pile up.** Whether the next president is Donald Trump or Hillary Clinton, breaking the logjam on Capitol Hill is the only way the commander-in-chief will get close to fulfilling pledges made on the campaign trail. The best chance of a legislative surge would come from an electoral sweep that gave one party control of the White House, Senate and House. Yet the chances of that are remote. The battle for the Senate, currently under Republican control, is too close to call. But polls suggest the presidency is most likely to go to Mrs Clinton while Republicans keep hold of the House. That is not an encouraging prospect for the already frustrated. It would make the former secretary of state the first newly-elected Democratic president since the second world war to be sworn in knowing his or her party does not call all the shots on Capitol Hill. **Complicating matters further, both Republicans and Democrats are likely to face damaging internal battles between moderates and hardliners who have been emboldened by the populist tumult of the 2016 campaign.** [↑](#footnote-ref-108)
109. Taylor Watson 17, (), &quot;Indirect Pricing Controls Through PBM Regulation: If You Can’t Beat Them,

     Arrange to Have Them Beaten,&quot; CBPartners, 6-29-2017, http://cbpartners.com/blog/indirect-pricing-

     controls-through-pbm-regulation-if-you-cant-beat-them-arrange-to-have-them-beaten.html, 11-1-2018

     (cut by SA)

     Any kind of methodology or rebate disclosure could be hugely debilitating to PBMs, who rely on their

     confidentiality to establish negotiating leverage in both directions of their operation. Even requirements

     for PBMs to report directly to government agencies could be challenging. If disclosure is not sufficiently

     confidential, leaks or other unintended revelations could reveal to both manufacturers and the health

     plans they serve how a PBM is treating them relative to other stakeholders. Payers could demand

     greater rebates if they see others receiving more significant discounts, and manufacturers could push

     in the opposite direction to lessen their provided rebate. The net effect would likely be contrary to the

     bills’ intentions: freedom of information in this space hamstrings PBMs’ ability to negotiate for larger

     rebates, which thereby increases the net price. Any discount that would otherwise be passed along to

     the health plan customer or directly to patients via cost-sharing would be affected. [↑](#footnote-ref-109)
110. https://www.aha.org/2017-12-11-high-rising-drug-prices-myth-vs-fact  
     Drug manufacturers use discount cards to promote brand-name drugs even when lower cost generics are available. These are really a “bait and switch” scheme where discount cards reduce patients’ out-of-pocket spending in the short term until the discount runs out. This means the patient has to pay higher out-of-pocket costs in order to continue the drug regime for the long term. In addition, use of discount coupons does nothing to address the increasing drug costs for patients overall. [↑](#footnote-ref-110)
111. https://www.cnn.com/2018/03/21/opinions/the-overlooked-ingredient-to-lower-drug-prices-atlas/index.html  
     Some have proposed that Medicare provide even more coverage for drugs, but further reducing out-of-pocket payment would only prop up prices. It would eliminate incentives for patients to consider price and prevent the very competition necessary to lower prices while enhancing quality. [↑](#footnote-ref-111)
112. <https://www.cnbc.com/2018/06/12/hhs-secretary-azar-outlines-trump-administrations-drug-pricing-plan.html>

     President [Donald Trump](https://www.cnbc.com/donald-trump/) unveiled [his administration’s blueprint](https://www.cnbc.com/2018/05/11/president-trump-unveils-prescription-drug-price-plan.html) to lower drug prices last month. It includes rethinking rebates, or discounts that firms called pharmacy benefit managers negotiate with manufacturers. Azar expanded on the idea in a hearing with the Senate Committee on Health, Education, Labor and Pensions.

     Pharmaceutical companies set the advertised price, known as the list price. Pharmacy benefit managers, or PBMs, negotiate discounts, or rebates, down from this. Critics argue the practice inflates drug prices because it encourages manufacturers to set higher prices. [↑](#footnote-ref-112)
113. William, U.S. International Trade Commission, 2007 “The Emergence of India’s Pharmaceutical Industry and Implications for the U.S. Generic Drug Market”, [http://www.usitc.gov/publications/332/ working\_papers/EC200705A.pdf](http://www.usitc.gov/publications/332/%20working_papers/EC200705A.pdf))

     **There are approximately 34 foreign drug companies engaged in the Indian pharmaceutical market and among them are 15 of the world’s 20 largest pharmaceutical companies.** According to FICCI, although MNCs have not launched new products **they have invested in new production facilities and R&D centers and many are engaged in contract manufacturing, clinical trials, and other forms of outsourcing.**25 In 2005-06, MNCs invested more than $172 million in India’s pharmaceutical industry and FDI has grown by a compound annual growth rate (CAGR ) of 62 percent during 2002-06.26 However, many industry experts believe that the return of the world’s leading pharmaceutical companies will gradually erode India’s cost advantages. According to the Organization of Pharmaceutical Producers of India, multinational drug companies currently command 24 percent of the domestic Indian market, through their share could rise to 40 percent by 2010.27GSK-India, a 51 percent subsidiary of GSK Plc (UK), is the largest foreign company in India’s pharmaceutical market, its fourth largest pharmaceutical company, and leading prescription drug supplier**. GSK-India operates two Indian manufacturing plants and controls approximately 5.9 percent of the domestic Indian market.** GSK-India is among India’s leading suppliers of anti-infective, anti inflammatory, analgesic, gastroenterological, anti-allergic, and dermatological drugs**. GSK-India announced plans to extend its product line by launching several antibiotic, cancer, and cardiovascular products in India in the near term.** Likewise, MNCs dominate India’s OTC (over the counter) drug market, with Pfizer accounting for 5.1 percent of the market, Sanofi-Aventis for 5.0 percent, and Johnson & Johnson for 4.8 percent. These companies offer analgesics, cough and cold preparations, indigestion medicines, skin care products, and vitamins and minerals. Other foreign multinationals active in India’s pharmaceutical market include: Bristol-Myers Squibb, Eli Lilly, Boehringer, Bayer, Chiton Corp, Abbott, AstraZeneca, Janssen, and Roche. Recently, Teva Pharma (Israel), the world’s leading generic drug manufacturing company, acquired a bulk drug manufacturing and intermediate facility in the State of Uttar Pradesh, announced plans to add two more units, and more than triple the value of its exports from India by the end of 2007. Teva also opened an R&D facility in India and announced plans to register between 10 and 15 bulk drugs per year in the United States from its Indian facilities. Mergers, acquisitions, and other alliances: The last 3 years have seen a significant rise in the number of consolidations, mergers & acquisitions, and other types of alliances and tie-ins in the Indian pharmaceutical industry. **Most of the acquisitions involve Indian companies searching for ways to penetrate overseas markets and widen their global footprint, diversify and enhance their product portfolios, offer their customers a ‘nearshore-offshore’ option, improve their custom manufacturing, packing, and R&D capabilities, acquire existing brands, and gain access to the highly regulated markets of Western Europe and the United States. Indian companies without significant R&D capabilities for drug discovery are also purchasing Western drug discovery companies. In 2005-06, 18 Indian companies spent approximately $1.6 billion to acquire generic drug manufacturing firms in Europe, North America, and Mexico.29 These companies included Ranbaxy, Dr. Reddy’s Labs, Nicholas Piramal, Sun Pharmaceutical, and Jubilant Organosys** (table 5).30 Although eleven of these transactions were for medium-and-small sized companies valued between $5 million and $30 million, several have been significant acquisitions valued in excess of $500 million. To date, Dr. Reddy’s purchase of Betapharm Arzneimittel of Germany for $572 million is the industry’s largest overseas acquisition. [↑](#footnote-ref-113)
114. Pbm Rebate, 7-19-2018, "The Perverse Incentives Created by PBM Rebate Arrangements," Morning Consult, <https://morningconsult.com/opinions/perverse-incentives-created-pbm-rebate-arrangements/> [↑](#footnote-ref-114)
115. #### New York Times

     Brody, Jane E. “The Cost of Not Taking Your Medicine.” The New York Times, The New York Times, 17 Apr. 2017, [www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html](http://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html).

     The numbers are staggering. “Studies have consistently shown that **20 percent to 30 percent of medication prescriptions are never filled**, and that approximately 50 percent of medications for chronic disease are not taken as prescribed,” according to a review in Annals of Internal Medicine. People who do take prescription medications — whether it’s for a simple infection or a life-threatening condition — typically take only about half the prescribed doses. This **lack of adherence**, the Annals authors wrote, **is estimated to cause approximately 125,000 deaths and at least 10 percent of hospitalizations**, and to cost the American health care system between $100 billion and $289 billion a year. Former Surgeon General C. Everett Koop put it bluntly: “Drugs don’t work in patients who don’t take them.” This partly explains why new drugs that perform spectacularly well in studies, when patients are monitored to be sure they follow doctors’ orders, fail to measure up once the drug hits the commercial market. [↑](#footnote-ref-115)
116. **Winegarden 16**

     Winegarden Wayne. "How To Encourage Pharmaceutical Innovation And Why It Is Important." *www.forbes.com*, 15 Jul. 2016, <https://www.forbes.com/sites/econostats/2016/07/15/regulating-short-term-volatility-will-harm-pharmaceutical-innovation/> . Accessed 22 Oct. 2018.

     Between 2006 and 2015 the S&P 500 grew 7.25% per year on average–**if you had invested $100 in the stock market in the beginning of 2006 it would be worth nearly $188 by the end of 2015. Sounds great. But, any investor during that period would surely feel less confident. After all, following the 36% decline in stock prices in 2008, a nervous investor might inaccurately conclude that the future is grim and that stock prices will never grow again. Alternatively, following the over 32% price surge in 2014, an overly exuberant investor might feel that prices can now only go up–only to be disappointed by the meager 1% growth in 2015**. The lesson here is that **drawing long-term implications from short-term fluctuations will often lead to inaccurate answers. The same is true in the pharmaceutical market**. In misplaced attempts to address the problems with the U.S. healthcare industry, many analysts point to specific list price increases on specialty pharmaceutical drugs to claim that high drug prices are driving overall healthcare costs ever higher. Such proclamations misdiagnose the problem with the healthcare industry and risk future innovations that can address pressing healthcare needs. It is true that the average price of medicines grew faster than average over the past two years. Over these two years, there was also a significant increase in new medicines. In 2015, 73 new brand name drugs were introduced, 43 of which were novel therapies. This followed 74 new brand name drugs being introduced in 2014, 45 of which were novel therapies. [↑](#endnote-ref-1)
117. **Sherman 13**

     Sherman Erik. "Do generics work as well as name brands? Maybe not." *www.cbsnews.com*, 13 May. 2013, https://www.cbsnews.com/news/do-generics-work-as-well-as-name-brands-maybe-not/. Accessed 23 Oct. 2018.

     But, as the Ranbaxy case shows, there is no guarantee that what was licensed is what the consumer will always receive. For example, in 2008, the DOJ filed suit against Actavis Totowa LLC, and its parent, Actavis Inc., seeking a permanent injunction barring them from manufacturing or distributing generic drugs "until they demonstrate compliance with the Good Manufacturing Practice requirements of the Federal Food, Drug and Cosmetic Act (FDCA)." The problem was alleged adulterated and misbranded products. Repeated FDA inspections had allegedly turned up "numerous and recurring violations of Good Manufacturing Practice requirements" in the manufacture of oxycondone. The companies entered a consent decree with the FDA early in 2009. In 2012, the **FDA announced that some generic versions of the antidepressant Wellbutrin were "not therapeutically equivalent" to the original. The problem was that the generics failed to release the active ingredient "at the same rate and to the same extent." Some people found the differences to be debilitating.** A major issue is that many insurance plans require consumers to purchase the generic version of a given drug, if available. Complicating matters is that generics often look physically different from the originals, which can put patients off from taking the medicine if they notice a change. [↑](#endnote-ref-2)
118. **Forbes 15**

     Team Trefis. "Why Are Generic Drug Prices Shooting Up?." *www.forbes.com*, 27 Feb. 2015, https://www.forbes.com/sites/greatspeculations/2015/02/27/why-are-generic-drug-prices-shooting-up/. Accessed 22 Oct. 2018.

     However, **generic prices have been moving up** for some time now, which is leading to some serious concerns for the pharmacy retail industry in the form of reimbursement rate pressure (Here’s a detailed analysis of this issue**). The Rise Of Generic Prices According to a report by Elsevier, a drug product and pricing information provider, out of a research sample of 4421 drug groups, 222 drug groups increased in price by 100% or more (between Nov’13 and Nov’14). There are also some extreme cases (17 drug groups) where price increases of more than 1000% were seen. One such product is tetracycline, which is commonly prescribed for bacterial infections. During the same period (between Nov’13 and Nov’14), it’s per tablet price increased from $0.0345 to $2.3632. That is a 67-fold increase in one year**! But, why are generic drug prices increasing at such high rates? YOU MAY ALSO LIKE Factors That Contributed To The Price Rise Industry Consolidation In 2009, generic drug markets were saturated and projections looked dull. To avoid falling into losses, generic drug makers began to consolidate through mergers and acquisitions to achieve the scale needed to maintain profitability. Typically, when a branded drug loses patent protection, multiple generic manufacturers produce the drug and compete on price. But post-industry consolidation, fewer generic manufacturers are applying to the FDA for permission to produce those drugs. With substantially fewer manufacturers producing a particular generic drug (in some cases only 2 or 3 makers), generic prices have crept up with time. However, there are more influential factors than this. [↑](#endnote-ref-3)
119. But critics say Mylan has little incentive to improve EpiPens: “If you’re the monopolist, and you’ve got a product that expires every year, and it’s not super easy to carry around so the safest thing to do is have several tucked away in different places — I don’t see why there would be any pressure to innovate,” said Nicholson Price, an assistant professor at the University of Michigan Law School who studies health care regulation and patent law. “EpiPen’s flaws seem like features, not a bug,” Price said. **Competitors have tried to make runs at the EpiPen. And more are trying now that there’s such a spotlight on the product. But it’s unclear if anything can displace the familiar auto-injector with the bright orange cap. Here’s why: 1. Mylan has patent protection that lasts through 2025 Epinephrine, as a drug, was first synthesized more than a century ago**. It’s been used for various medical applications since then, and was first packaged in an auto-injector (to protect soldiers against chemical warfare) back in the 1970s. But Mylan has a lock on the particular EpiPen design that millions of patients, parents, and school nurses have come to trust. The company’s main innovation has been a bright orange cap that covers the needle, but releases automatically when a patient pushes an EpiPen against her thigh, so there’s no need to stop and unscrew the cover in the midst of an allergy attack. The very fact that the EpiPen has been dominant for so long makes it hard for challengers to come in with a radically different design. (Mylan is now pledging to make a generic version, which it says will be identical except for the label.) “If you’re a parent, and your child’s suffering from an allergic reaction, you have to give them an injection — and don’t want to read the instructions in that moment,” said Matthew Allen, head of drug delivery for Cambridge Consultants. “You just have to know how to use it.” Allen’s work at Cambridge Consultants centers around designing other forms of auto-injectors. He said the Food and Drug Administration has rules to standardize the way these life-saving devices work. Those rules keep consumers safe. But they also make it difficult to come up with design that can meet the standards — without infringing on Mylan’s patent. “It would not be very difficult to create an EpiPen product, in terms of engineering,” Allen said. “It’s not rocket science. It’s purely the patent that stops us.” Related: How the generic EpiPen could actually be more profitable for Mylan 2. There’s no room for error when you’re treating anaphylaxis Chris Stepanian is CEO of Windgap Medical, a Boston startup that’s been working on a next-generation epinephrine auto-injector for the past five years. Windgap’s device is meant to improve upon the EpiPen: It’s supposed to be smaller, about the size of a Bic lighter, with a much more stable formulation of epinephrine intended to survive in a pants pocket without getting overheated. But that’s proving easier said than done. Stepanian said he’s at least a few years away from bringing his newfangled auto-injector to market. Though EpiPen components look pretty basic, Mylan notes that it is made up of 26 parts and must be able to deliver the drug with a sterile needle within seconds. Stepanian agrees that it’s more complicated than it seems at first glance: “It’s really challenging to make a reliable auto-injector — and surprisingly hard to make a combination drug product,” he said. “It’s a tough thing to nail down the drug supply chain, the plastics and design, and then incorporate that all together, and put the drug inside it — and then regardless of how the user uses it, get the appropriate dose within the acceptable limits of the FDA,” Stepanian added. “At least Mylan and Pfizer have done a good job of making a pretty reliable one.” One EpiPen alternative that did make it to market: The Auvi-Q, an epinephrine auto-injector shaped like a bulky credit card. But Sanofi recalled the devices last year over concerns that patients weren’t getting the correct dose every time. It returned the commercial and marketing rights to Kaleo, from whom it licensed the auto-injector in 2009. A representative from Kaleo said that it’s “in the process of evaluating when and how” to bring the Auvi-Q back to the market — but Sanofi is no longer involved. Related: How the EpiPen drug price story went viral — and what may be next 3. It doesn’t take an auto-injector to get epinephrine into the body — but it sure helps In the wake of the recent outrage at Mylan, Los Angeles-based MannKind Corporation announced it’s developing an inhalable form of epinephrine. “We could make something very tiny, that you could carry on a keychain — much smaller than an EpiPen or auto-injector by far,” MannKind CEO Matthew Pfeffer said. MannKind already has an inhalable insulin product, called Afrezza, on the market, which gives diabetics an alternative to injections. But it’s proved exceedingly tough to get patients to switch from a format of insulin intake they’re familiar with to an inhaler. Sales have been far below expectations. The same problem could stymie an epinephrine inhaler, especially since one of the frightening features of an anaphylactic attack is that the airways constrict — which, in theory anyway, could make it hard for a patient to use the inhaler in a moment of crisis. 4. The regulatory process is slow and expensive A lot of the challenge lies in the regulatory system, said Mark Baum, CEO of San Diego-based Imprimis — a compound pharmaceutical company that’s working on a cheaper alternative to the EpiPen. It can take a long time, and a lot of money, to get FDA approval for a new product. “The only time it makes economic sense to take the risk of going through these clinical trials is when you have a situation like this,” Baum said. “But when the market was more normalized — when the EpiPen was only retailing around $100 — competitors questioned whether it was worth taking that risk.” Public anger at EpiPen is so high right now that Baum figures it is worth taking the risk. Imprimis has had its eyes on the epinephrine auto-injector market for about two years now; it’s finally going to go for it. “We’re just focused on being that competition,” he said. Related: Mylan may have violated antitrust law in its EpiPen sales to schools, legal experts say 5. The public hasn’t spoken (loud enough) Denise Clark, whose son has that peanut allergy, is a consultant with Boston MedTech Advisors. She helps medical device companies with design, market analysis, and regulatory strategy. But though she works in the field every day, she says she never even thought much about the flaws of the EpiPen design — or the lack of innovation — until the product started hitting headlines. “It’s something that’s always been irritating to me, but not to the point that I’ve looked at it closely — until I had to start paying all this money,” Clark said. Granted, the Federal Trade Commission has been fielding complaints about Mylan’s pricing for years, and complaints about the device’s clunkiness are no secret. But since the EpiPen is generally covered by insurance, many customers have simply gone with it. That means there’s been little pressure from the paying public for innovation. “I guess Mylan’s motto is, ‘If it ain’t broke, don’t fix it,’” Clark said. “They have such a monopoly, so why would they bother improving the EpiPen?” [↑](#endnote-ref-4)
120. Sotomayor, Marianna. “Senate Passes Sweeping Legislation to Combat Opioid Epidemic.” *NBCNews.com*, NBCUniversal News Group, 17 Sept. 2018, www.nbcnews.com/politics/politics-news/senate-passes-sweeping-legislation- combat-opioid-epidemic-n908901.

     Similar to the House package passed in June, **the** Senate's **Opioid Crisis Response Act of 2018** (OCRA) **directs funding to federal agencies to establish or expand programs dealing with prevention, treatment and recovery. Highlights from the 70 bills in the package include funding that requires the Food and Drug Administration to dole out prescription opioid pills in smaller quantities and money that offers an incentive to the National Institutes of Health to prioritize the development of non-addictive painkillers, two solutions medical experts believe could help decrease opioid addiction in the long run.** The package also includes Ohio Republican Sen. Rob Portman's Synthetics Trafficking and Overdose Prevention Act "STOP" Act, a bill endorsed by President Donald Trump because it establishes parameters to crack down on shipments of fentanyl, a synthetic opioid, from entering the U.S. [↑](#footnote-ref-116)
121. <http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx>

     State lawmakers are crafting innovative policies—engaging health, criminal justice, human services and other sectors—to address this public health crisis while also ensuring appropriate access to pain management. This report provides an overview of state legislation setting guidelines for, or limits on, opioid prescriptions. As of early April 2018, at least 28 states have enacted legislation related to opioid prescription limits.

     LOOK AT THE DAMN CHART IF YOU PULL IP THE LINK

     Legislation limiting opioid prescriptions debuted early in 2016, with Massachusetts passing the first law in the nation. Among other provisions in the comprehensive act, the state set a seven-day supply limit for initial (first-time) opioid prescriptions. Prior to Massachusetts’ law, some states had passed bills related to prescribing, such as Washington’s legislation directing five professional boards and commissions to adopt rules related to chronic, non-cancer pain management, but none had set such a short time limit in statute.

     By the end of 2016, seven states had passed legislation limiting opioid prescriptions, and the trend continued in 2017. More than 30 states considered at least 130 bills related to opioid prescribing in 2016 and 2017. According to NCSL’s tracking, 28 states had enacted legislation with some type of limit, guidance or requirement related to opioid prescribing by early April 2018. [↑](#footnote-ref-117)
122. Hellmann, Jessie. “Trump Administration Cracking down on Production of Prescription Opioids.” *TheHill*, The Hill, 16 Aug. 2018, thehill.com/policy/healthcare/402157- trump-administration-cracking-down-on-production-of-prescription-opioids.

     The Trump administration is using new powers to propose a significant decrease in how many opioids drug companies can manufacture in the U.S. in 2019. **The Justice Department and Drug Enforcement Administration (DEA) are proposing an average 10 percent decrease next year in the manufacturing quotas for six frequently misused opioids.** “We’ve lost too many lives to the opioid epidemic and families and communities suffer tragic consequences every day,” said acting DEA Administrator Uttam Dhillon.“This significant drop in prescriptions by doctors and DEA’s production quota adjustment will continue to reduce the amount of drugs available for illicit diversion and abuse while ensuring that patients will continue to have access to proper medicine.” [↑](#footnote-ref-118)
123. <http://haiweb.org/wp-content/uploads/2015/10/ERP-Working-Paper.pdf> **Based on information from 100 countries, we found no examples of high-income countries referencing low-income countries as defined by the World Bank. On the basis of this finding, low prices offered by pharmaceutical companies to low-income countries would not result in reduced prices in high-income countries as a consequence of current, formal ERP practices.** Moreover, the practical difficulties of identifying prices in low-income countries, especially actual prices (net of discounts, rebates, etc.) as opposed to official prices, **makes the possibility of high-income countries referencing prices in low-income countries very unlikely**. A key secondary finding of this study is that ERP is not a “simple” system to operate and requires substantial human and institutional resources, and accurate information, to implement effectively. Low-income countries which do not at present use ERP should consider these substantial resource requirements before they decide to attempt to implement such a system. [↑](#footnote-ref-119)
124. <http://haiweb.org/wp-content/uploads/2015/10/ERP-Working-Paper.pdf> Based on information from 100 countries, we found no examples of high-income countries referencing low-income countries as defined by the World Bank. On the basis of this finding, low prices offered by pharmaceutical companies to low-income countries would not result in reduced prices in high-income countries as a consequence of current, formal ERP practices. Moreover, the practical difficulties of identifying prices in low-income countries, especially actual prices (net of discounts, rebates, etc.) as opposed to official prices, makes the possibility of high-income countries referencing prices in low-income countries very unlikely**. A key secondary finding of this study is that ERP is not a “simple” system to operate and requires substantial human and institutional resources, and accurate information, to implement effectively**. Low-income countries which do not at present use ERP should consider these substantial resource requirements before they decide to attempt to implement such a system. [↑](#footnote-ref-120)
125. #### NPR

     Hensley, Scott. “Why Didn't Your Doctor Prescribe A Generic? Look In The Mirror.” NPR, NPR, 7 Jan. 2013, www.npr.org/sections/health-shots/2013/01/07/168810473/why-didnt-your-doctor-prescribe-a-generic-look- in-the-mirror.

     The generics are usually inexpensive. Think $4 for a month's supply of the depression drug fluoxetine (or Prozac) at Wal-Mart. If you have insurance that covers pharmaceuticals, your copay will be lower with a generic than a brand-name drug, too. So when there's a generic available, why do doctors still write prescriptions for the brand? One reason: You asked for it. Some 37 percent of **doctors surveyed say they sometimes go ahead and prescribe a brand-name drug upon request, even when there's a generic available. The researchers found that doctors' willingness to prescribe a brand was associated with their acceptance of free food from drugmakers. They were also more likely to accept samples of brand-name drugs to hand out to their patients, too.** The findings were just published online by JAMA Internal Medicine. The researchers figure their estimates of doctors' willingness to prescribe a brand are at the low end of what happens in reality. Doctors surveyed (about 1,900 in this study) may not be inclined to fess up about going along with patients' requests. One limitation of this study is that the researchers can't be sure exactly which drugs patients got. Pharmacists in many states can substitute a generic, when it's available, to fill a doctor's prescription for a brand. An accompanying editorial calls for direct action to overcome prescriptions driven by "irrational cultural practices." Some health systems override physicians' prescriptions choices when there's a generic option. And the editorial says that measures like that "have immense potential to increase value in prescription medication use." [↑](#footnote-ref-121)
126. #### Harvard Medical School

     Harvard Health Publishing. “Do Generic Drugs Compromise on Quality?” *Harvard Health*, Harvard Medical School , Jan. 2018, [www.health.harvard.edu/staying-healthy/do-generic-drugs](http://www.health.harvard.edu/staying-healthy/do-generic-drugs) compromise-on-quality.

     This brings us to the Canadian study that seems to show differences between generic and brand-name medications. While it didn't examine how well these medications performed when it came to reducing blood pressure, it did raise the question of whether patients experienced more serious side effects from the generic medications than the original versions of the blood pressure drugs researchers looked at. The researchers looked at the numbers of emergency room visits and hospitalizations for 136,177 individuals ages 66 and over (60% of them women) who used any of three blood pressure medications: losartan (U.S. brand name Cozaar), valsartan (Diovan), and candesartan (Atacand). They examined data for the periods 24 months before and 12 months after the generic versions of these medications went on the market. **They found that before the generic versions became available, about one in 10 people taking the blood pressure drugs had to go to the emergency room or be hospitalized each month. In the month after each of the generics went into use, the rates of these adverse events went up: 8% for losartan, almost 12% for valsartan, and 14% for candesartan**. But the question is, did this increase result from problems with the generic versions of these medications? Or were there other factors that occurred in this time frame? "It is always possible, in fairness, that strange things happen," says Dr. Choudhry. Maybe **the generic form was manufactured with a different inactive ingredient that caused patients to have more side effects. Or maybe a slight variation in the chemical formula made people react differently.** But the increase in medication-associated events could have also been a result of problems with the study and the patient population researchers followed. [↑](#footnote-ref-122)
127. #### Harvard Business Review

     Fox, Erin “How Pharma Companies Game the System to Keep Drugs Expensive”, Harvard Business Review, 6 April 2017, https://hbr.org/2017/04/how-pharma- companies-game-the-system-to-keep-drugs-expensive

     “Although makers of a branded drug are using a variety of tactics to create barriers to healthy competition, generic drug companies are often not helping their own case. **In 2015, there were 267 recalls of generic drug products—more than one every other day. These recalls are for quality issues such as products not dissolving properly, becoming contaminated, or even being outright counterfeits**. A few high-profile recalls have shaken the belief that generic drugs are truly the same. In 2014, the FDA withdrew approval of Budeprion XL 300 — Teva’s generic version of GlaxoSmithKline’s Wellbutrin XL. Testing showed the drug did not properly release its key ingredient, substantiating consumers’ claims that the generic was not equivalent. In addition, concerns about contaminated generic Lipitor caused the FDA to launch a $20 million initiative to test generic products to ensure they are truly therapeutically equivalent.” [↑](#footnote-ref-123)
128. Stanford

     Marina Kutyavina, June 1, 2010, " The Effect of Price Control Threats on Pharmaceutical R&D Investments," Harvard Economics, https://economics.stanford.edu/sites/default/files/publications/kutyavina\_hthesis2010.pdf

     The authors focus on decisions by pharmaceutical firms to expand an R&D project into Phase I clinical development. Using contemporary economic information available to the firms, the authors estimate the project's net present value and evaluate whether or not the firms would choose to expand the project. **Their results suggest that if U.S. prices of pharmaceuticals were decreased by 40 to 50%, which could occur if reimportation of prescription drugs from Canada were legalized, the number of early-stage R&D projects will decline by 30 to 60%.**

     Although **the results of this study do not definitively answer the question of whether the threats of increased regulation reduce R&D efforts of pharmaceutical firms**, the study presents an approach to measuring firm response that has not been previously applied to this question. Comparing pharmaceutical firms on the basis of their vulnerability to price control threats provides a valuable alternative to modeling firm behavior. However, an improvement upon the standard difference-in-differences analysis is needed in order to measure potential changes in R&D between groups of firms more accurately. [↑](#footnote-ref-124)
129. Harris

     Richard Harris (NPR) “R&amp;D Costs For Cancer Drugs Are Likely Much Less Than Industry Claims, Study Finds” September 11, 2017 https://www.npr.org/sections/health-shots/2017/09/11/550135932/r-d-costs-for-cancer-drugs- are-likely-much-less-than-industry-claims-study-finds

     The analysis, published in the current issue of JAMA Internal Medicine, concludes that it costs, on average, $650 million to develop a new cancer drug. The authors add in another $100 million or so to account for income those companies could have had if that money had been invested in the stock market instead of in new products. That total is far lower than the $2.7 billion figure that the drug industry frequently points to when it justifies the soaring cost of medicine. (It&#39;s far higher than $320 million — an inflation-adjusted figure from a 2001 study by the consumer group Public Citizen). To arrive at this new figure, cancer physicians Vinay Prasad, at Oregon Health and Science University, and Sham Mailankody, at the Memorial Sloan Kettering Cancer Center, took a novel approach. They identified 10 companies that each had a single cancer drug on the market. They looked up the companies&#39; research and development costs, as reported in their federal stock reporting paperwork, to come up with the average figure of $650 million. The companies reaped substantial rewards. On average, the study found each product produced seven times as much revenue as it cost in research and development — and the drugs will yield profits for years to come. &quot;I think these results would suggest that pharmaceutical drug development is extremely lucrative and the current drug prices are not necessarily justified by the R &amp; D [research and development] spending on these drugs,&quot; Mailankody says. It&#39;s hard to compare their findings directly with the industry&#39;s benchmark figure of$2.7 billion ($2.6 billion in 2015 dollars). **That figure comes from an analysis by the Tufts University Center for the Study of Drug Development Research**. The analysis is based on about 100 new drugs; not just those used to treat cancer. **The center,** which receives industry funding, **doesn’t disclose which drugs it uses in its analysis and isn’t transparent about its methods**, Mailankody says. [↑](#footnote-ref-125)
130. Vivian

     Ho, Vivian. [Reporter for US News]. “The Harm of High Drug Prices”. US News, 2016.<https://www.usnews.com/opinion/policy-dose/articles/2016-12-12/the-harm-of-highdrug-prices-to-americans-a-continuing-saga>

     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. [↑](#footnote-ref-126)
131. Scherer, F.M. [Professor emeritus of public policy and corporate management at the John F. Kennedy School of Government, Harvard University, in Cambridge, Massachuses]. “Price Controls And Global Pharmaceutical Progress”. Health Aﬀairs, 2009. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaﬀ.28.1.w161

     This Perspective reviews critically the work on price control impacts by Darius Lakdawalla and colleagues. It argues that **the innovation elasticity of 3.0 emphasized by the authors is too high, exaggerating the long-run costs of price controls**. It argues, too, that **the drugs chosen for the authors’ analysis are neither the most therapeutically innovative candidates nor those whose development is most likely to be discouraged by price controls.** [↑](#footnote-ref-127)