# Isidore Newman A2 PRO

## A2- Access

### A2- Prices High Uniqueness

1. **Howard ‘15[[1]](#footnote-1)** explains that direct drug spending accounts for just 10% of total U.S health care spending. Which is why ***Lakdawalla* ‘15** finds that cutting the price of drugs by 20% would only save 2% of the average person's total healthcare bill
2. **IQVIA[[2]](#footnote-2)** reports in ‘18 that although the pharmacy prices for drugs have increased in the last five years, final-out-of pocket costs for drugs has declined by 17% because consumers don't directly buy from manufacturers, they go through middlemen like insurance that has decreased cost
3. **Winegarden ‘17[[3]](#footnote-3)** explain that 90% of drugs dispensed in the U.S are cheap, unpatented generic medicines, which price controls wouldn’t touch because they’re inexpensive.
4. **Easton ‘18 of Harvard[[4]](#footnote-4)** finds that by 2032 drug prices will be approximately half of what they are today because every drug on the market today will lose its patent protection and become a generic, increasing competition and lowering costs

### A2 – Affordability

#### Delink

1. Prefer competition over price controls because **Lakwadalla** **of USC[[5]](#footnote-5)** finds that
	1. drug spending has been growing no faster than overall health care spending over the past decade
	2. A 20% price control would knock only 2% off our healthcare bill over the next decade,
	3. can only be used once, whereas competition solves in the long term over and over.

#### Mitigate

1. No impact-**Wright of the CAGW[[6]](#footnote-6)** writes that after the implementation of price controls measures such as Medicaid rebates, these have distorted the market and caused price shifting. Basically, the balloon effect would just take place meaning that high prices would just be shifted to another sector, meaning consumers will always pay the price

#### Turns

1. **Wright ‘13 of Cleveland State[[7]](#footnote-7)** explains that because new successful drugs decrease overall healthcare costs, by reducing hospital stays and physician visits, every $1 spent on innovation reduces total healthcare spending by $7.20.
2. **Pagani ‘18[[8]](#footnote-8)** explains that because innovation creates new drugs, which increases competition driving down prices in the market, it decreases drug prices by 26%.
3. TURN- **Sullivan[[9]](#footnote-9)** explains that Price controls incentivize pharmaceutical companies to leave the market of generic drugs in search of profit elsewhere, meaning that even less people have access to medicines.
4. Turn. **Wright from Citizens Against Government Waste[[10]](#footnote-10)** impacts in 2016 that price controls would make pharmaceuticals more expensive in the long-run by shifting costs and reducing the efficiency of innovation.
5. (iF you have time read ev about how prices increase in the developing world)

### A2- Black Market

1. Gut-Check. They’re trying to paint this picture that the black market is this huge big deal, but literally in order to get access to a black market you need certain connections and be well versed in the criminal underground, normal people can’t just find a black market
2. Turn- Price controls would force shortages. **Reisman[[11]](#footnote-11)** explains that price controls would uniquely cause shortages as there would be too much demand and not enough supply for drugs. This is problematic as **Coyne[[12]](#footnote-12)** concludes that price controls would incentivize a shift to the black market as there would be enough drugs available in the general market
3. **Spiegal 15 of The Hill[[13]](#footnote-13)** – Price controls = companies have to engage in a long drawn out negotiating process before being able to sell; **TCCRI[[14]](#footnote-14) 🡪** in this time a black market would form; 1/4th of Mexico’s pharmaceuticals are counterfeit because of price controls

### A2- Reference Based Pricing

1. First, there’s no actual probability that reference pricing will be the model; [**Oxford University**](http://economics.oxfordre.com/view/10.1093/acrefore/9780190625979.001.0001/acrefore-9780190625979-e-278) 🡪 there are 5 different forms of pricing; while 36 countries implement price controls, only 9 actually use reference pricing, they can’t just come up here and assert reference pricing will be the way.
2. [**Towse**](https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045747) **of the OHE**[[15]](#footnote-15) 🡪 reference pricing still leads to shortages of supply, no effective availability, unaffordable prices, and marketing delays; **spiegel of the Hill[[16]](#footnote-16)** = kills 600k every
3. **De-link** - reference pricing has only been implemented in socialized healthcare systems because it is a control on the reimbursement level between insurance companies and manufacturers, not manufacturers and consumers. This only works in socialized healthcare systems because insurance companies virtually pay for ALL drugs, while free market systems, i.e the U.S, does not
4. Historically ineffective, **Bardey ‘18[[17]](#footnote-17)** explains in an analysis of every single reference priced nation, reference pricing generates a net decline in health, explaining why **Trident ‘18[[18]](#footnote-18)** explains that reference pricing had a net negative impact on the German pharmaceutical industry, causing the government to disband the program in 1996

## A2- Different Drugs

### A2- EpiPen

1. Non-unique: **The FDA[[19]](#footnote-19)** on August 16 of 2018 reports that they just approved the first cheaper generic version of EpiPens. They further that this new drug from Teva Pharmaceuticals will provide a lower-cost option for those with allergies
2. **Rice[[20]](#footnote-20)** explains that Prescriptions have risen for EpiPen alternatives by 500% in the last year, meaning more people are getting access to cheaper medicines and are moving away from epipens.

### A2- Hepatitis C

1. Delink- Realize that they don’t tell you that Hepatitis C medication and the research involved with it is not exactly an easy and cheap process. **Ornstein[[21]](#footnote-21)** in 2015 points out that Medicare's spending on drugs to treat hepatitis C soared more than 15 fold from 2013 to 2014 as Medicare spent $4.5 billion last year on new, pricey medications that cure the liver disease hepatitis C — more than 15 times what it spent the year before on older treatments for the disease, previously undisclosed federal data shows.
2. Nonunique- hepatitis C problem is already being solved in the Status Quo. The US is following the same approach to Hepatitis C that worked out to be so effective for Egypt which is negotiating with the companies that make the medication directly. **ManagedCare in July of 2018[[22]](#footnote-22)** finds that Merck will drop the price of its Hepatitis C drug Zepatier by 60%, In addition, it plans to cut the price of “several other” drugs by 10%. Trump administration officials say that the president’s tough talk on drug prices helped precipitate this development. **Health and Human Services Secretary Alex Azar[[23]](#footnote-23)** has explained that The new blueprint for lower drug prices is working, drug prices are coming down, and American patients are going to see the savings in their pocketbook.
3. **Winegarden[[24]](#footnote-24)** explains that the FDA approved two new, cheap medications to treat Hepatitis C

### A2- Cancer Drug Prices

1. **Cohen ‘18[[25]](#footnote-25)** explains that without price controls, the pro-innovation market creates extraordinary levels of investment in cancer research. **Sikora ‘17[[26]](#footnote-26)** furthers that a cure for all cancer is expected to be as low as 5 years away. Unfortunately, because of decreased incentive for R&D with lower prices, **Lichtenburg ‘16[[27]](#footnote-27)** finds that every 10% decrease in drug prices decreases cancer research by 6%.

### A2- Naxalone

1. Naloxone literally costs $20
2. **Meyer ‘17[[28]](#footnote-28)** explains that anyone with commercial insurance can get nalaxone for free, and even without insurance the federal government subsidies donations if household income is below $100,000
3. **Meyer ‘17[[29]](#footnote-29)** furthers hat Naloxone companies are donating doses in the hundreds of thousands to first responders, but when you affirm you decrease pharmaceutical company revenue, forcing them to cut back donations

### A2- Opiods

1. The issue is being solved right now in 4 ways
	1. Federal Legislation- **Sotomayor of NBC[[30]](#footnote-30)** 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[[31]](#footnote-31)** 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[[32]](#footnote-32)** highlights that in the following year, the DEA will enforce a 10% reduction in the production in the most abused opioids.
2. Turn- price controls would limit research needed to reduce the opioid epidemic. **Compton of the STM[[33]](#footnote-33)** explains that while there are new medications coming out to combat opioid addiction, new research is needed in the pharmaceutical industry to both determine how to make opioids less addictive and to find new treatments to solve addiction. However, as **Vernon of the Southern Economic Journal[[34]](#footnote-34)** finds, research and development would fall by 38% as a result of less profits being made because of price controls, meaning less drugs would be put out into the market.

#### Buprenorphine

1. Non-unique- **The Moran company[[35]](#footnote-35)** explains that 83% of hospitals charge patients more than double the cost of medicine, the nationwide average markup for drugs is 83%. Hospitals are for profit and won’t charge patients less even if the price of drugs decrease**. Blau[[36]](#footnote-36)** furthers Buprenorphine injections are expensive because of hospital mark ups and because they are done in person. There is no harm as **Naabt[[37]](#footnote-37)** explains that there is no downside of taking the pill, rather that is cheaper.

### A2- Birth Control

1. They need to prove a brightline to show how low birth control prices have to be in order for them to trigger their impacts. We would contend that
	1. birth control doesn’t get as cheap as they say for poor people bc they inherently cant afford it
	2. [**the current administration**](https://www.vox.com/policy-and-politics/2018/11/12/18076120/trump-birth-control-2018) which they cite as being anti-birth control and reproductive rights would just prevent prices from getting lower to the point where their impacts would trigger. It doesn’t make sense that they would lower prices on a product that they’re literally getting rid of laws for.
2. **Donaldson of the NCBI[[38]](#footnote-38)** explains that The lack of price control makes the United States an attractive country for the introduction of new contraceptive products. She furthers, that any attempt to regulate prices through price controls would prevent even more research into more effective birth control both in the US and europe. This is critical as **ScienceDaily[[39]](#footnote-39)** writes that there is a a new hormone-free women's contraceptive with no side effects being developed. Affirming reverses this trend which would benefit women

## A2- Monopolies

### A2- Pay to Delay

1. Main impetus for Pay-for-Delay in the first place is lower revenue Only then companies feel the need to artificially change the market and establish monopoly power
2. Consolidation increases two ways:
3. **Shepherd ‘17[[40]](#footnote-40)** explains that lower profit margins reduce supplier entry into the generic market, because there is less potential reward
4. **Shepherd ‘17[[41]](#footnote-41)** furthers that lower profit margins for pharmaceutical companies to merge to offset losses in market share and achieve cost savings from greater economies of scale, thus increasing consolidation

### A2- Patent Monopolies

1. **Non-unique: Amin of CNBC[[42]](#footnote-42)** finds 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. This is an inherent loophole in US law, which is really important because price controls can’t solve that
2. The reason why loopholes for patents are allowed is found by **the Global CCS Institute[[43]](#footnote-43)** who writes that Patents are necessary for pharmaceutical companies, both in terms of spurring innovation and getting new products onto the market.
3. Price controls wouldn’t change anything that the pharmaceutical industry is doing. **Lamattina of forbes[[44]](#footnote-44)** writes that the profit margin that pharmaceutical companies make are relatively low compared to other industries at 16%. Price controls would just harm the availability of drugs if companies can make less profit.

### A2- Increased Guaranteed Competition

1. Product Hopping: **Jones of the NCBI[[45]](#footnote-45)** explains that large corporations engage in product hopping which involves switching the market for a drug, prior to its patent expiration date, to a reformulated version that has a later-expiring patent, but which offers little or no therapeutic advantages. This prevents generics from even reaching the market.
2. Regardless, **Fox[[46]](#footnote-46)** concludes that the recall of generic medicines is very common, finding that in just one year, almost more than one drug was pulled from the market every other day. This means that despite the control that pharmaceutical companies have, generic drug makers wont even make the market due to their low quality.

### A2- Mergers and Acquisitions

They are trying to create a false narrative when they say that mergers decimate competition. They would be correct if they were implying that big companies are eating up small companies – but that’s not the reality on the ground. Indeed, Donovan 17 from UPenn writes that empirically mergers and acquisitions within the pharmaceutical industry are almost always between 2 financially struggling firms rather than financially successful firms. With that set, there are 2 reasons why these types of mergers are actually really good.

1. Donovan writes that when 2 pharma companies merge they get new resources such as money and workers to pursue pathways to innovation that wasn’t there for them before, leading [**Li from the University of british Columbia**](http://www.fdsm.fudan.edu.cn/UserWebEditorUploadImage/JoU-ppX3X0A/bena_li_innovation_and_ma_20101202final.pdf)**[[47]](#footnote-47)** to conclude that mergers greatly enhance technological development and innovation.

## A2: Hospitals

### A2- Decreasing Hospital Costs for patients

1. **Non-Unique -** [**Thomas 18 of NYU**](https://www.nytimes.com/2018/01/18/health/drug-prices-hospitals.html)**[[48]](#footnote-48)** finds that hospitals have begun to manufacture and produce their own drugs intending to be a more affordable alternative to big pharma.
2. **The US Health Department[[49]](#footnote-49)** explains that Hospitals are reimbursed at super high rates by medical care, with rates up to 106% of the price being reimbursed.
3. no link- **Langwell of the HCFR[[50]](#footnote-50)** explains that Insurance companies insulate consumers from high costs, meaning that they hide high prices from consumers until it is time to pay. This is because **Belk[[51]](#footnote-51)** explains that most hospitals overcharge insurance companies, often times charging up to 10 times the normal cost for treatments and medicines. Price controls don’t solve as ultimately, hospitals are able to make more profits, but consumers never see a decrease in price
4. Non-unique- **the Moran Company[[52]](#footnote-52)** writes that 83% of hospitals charge patients more than double the cost of medicine, the nationwide average markup for drugs is 83%. Hospitals are for profit and won’t charge patients less even if the price of drugs decrease.

### A2- Rural Hospital Closure

1. Alt. cause for closures. **NRHA[[53]](#footnote-53)** reports in 2016 that there are only 39 rural doctors for every 100,000 patients. And Rabinowitz furthers that only 2% of med school grads plan to practice in rural areas
2. Delink- **Graban in 2011[[54]](#footnote-54)** finds that almost 50% of all spending done by hospitals is wasteful with no real impact to the people. So more money for hospitals doesn’t mean a better quality of life.
3. Turn- **Brownlee from the Huffington Post[[55]](#footnote-55)** in 2017 corroboratse that currently hospitals and pharmaceutical companies are driven by a growing desire for more and more profit.

## A2: Other Nations

### AT: Europe

1. **Lakdawalla of Health Affairs[[56]](#footnote-56)** explains in 2009 that a comparison simply cannot be made since the American market is exponentially larger and we run under a free market system.
2. Delink: **Lowe in 2010[[57]](#footnote-57)** from Science Medicine finds that the United States from 1998 to 2007 discovered 118 out of the 252 new drugs. He furthers that the United States is also an outlier in drugs that are actually innovative compared to simply extensions of already existing drugs, finding that while almost all major drug discovering countries in the world were tilted towards less innovative drugs, the U.S. was very much an exception. He also finds that Germany, Japan, and the rest of Europe overwhelmingly produce follow-on and me-too drugs compared to actual innovations. This is really problematic for them, because insofar as price controls are supposed to incentivize innovation, and Europe has price controls, what they’re telling you isn’t true.

### A2: Canada

* + - 1. **The Fraser Institute[[58]](#footnote-58)** quantifies in 2015 that Canada loses 5 billion dollars annually by not switching to a free market system.

### A2: India

* + - 1. **Lo[[59]](#footnote-59)** explains that India is currently backing off of reform plans. This is primarily due to pressure from the domestic pharmaceutical industry, at least pushing any new draft of the reform to 2019.
			2. **Lazarov from Erasmus University[[60]](#footnote-60)** conducted a statistical analysis and found that many pharmaceutical companies in India often collude together to avoid the price regulations established by the government. This means that many innovations are occurring because of the blatant disregard for price controls.

### A2: Britain

Britain’s policies take way to long losing lives in the process. **According to Lo[[61]](#footnote-61)** NICE negotiated lower prices for two life-extending branded drugs for the treatment of metastatic breast cancer – palbociclib and ribociclib, developed by Pfizer and Novartis/Astex respectively – allowing them to be used by the NHS, but by that time the drugs had already been available to patients in the US for nearly two years.

### A2: South Africa

Nothing can be taken from South Africa. **Bangalee and Fatima Suleman of the University of KwaZulu-Natal[[62]](#footnote-62)** in a 2016 study published in the South African Health Review further explain this by saying “Despite efforts to increase transparency in the supply chain, prices reflected in South African medicine price registries may not be a true reflection of prices negotiated between manufacturers and distributors/wholesalers,” “Initiatives to conduct larger, in-depth pharmaco-economics evaluations are required for a deeper understanding of market trends.”

## A2- Government/ Politics

### A2- Harming State Budgets

### A2- Too much government spending

* + - 1. Mitigate- **Paul Howard of the Manhattan institute[[63]](#footnote-63)** explains that we don’t overly spend on drugs and we actually spend most of our healthcare funding on hospital visits at 30%, while we only spend 10% on drugs.

### A2- Subsidies

1. Turn- The money from subsidies adds to our national debt. If the impacts of subsidies can happen in both the world of the pro and con, adding to the debt is an unnecessary strain on our economy. **JD Foster in 2013[[64]](#footnote-64)** explains that slow economic growth and higher interest rates are the result of adding to our debt.
2. T. Lobbying by big pharma companies means that subsidies go to big companies while small businesses are left in the dust. Ultimately, subsidies feed into our impact of hurting small businesses
3. T. **The World Bank in 2014[[65]](#footnote-65)** reports that subsidies are a root cause of corruption. By using subsidies, we allow government intervention to ruin the free-market competition and favor big pharma companies while disadvantaging small companies

### A2- Marketing

1. Squo solves **- Northwestern Journal of International Law & Business[[66]](#footnote-66)** ‘15 finds that federal and state laws restrict the use of marketing and have already discouraged doctor bribing through prosecution.

### A2- Advertising

1. **Pew Research[[67]](#footnote-67)** explains in 2013 that advertising generated the highest return on investment for pharmaceutical companies - they will pursue them regardless if it’s what makes profit
2. **Pew Research[[68]](#footnote-68)** furthers in 2013 that the FDA has ramped up regulations on ads, and are actively seeking ads to shut down

### A2- PBM’s

* + - 1. Turn- Health Affairs**[[69]](#footnote-69)** reports that PBM’s have been extremely effective in driving competition for drugs as well as negotiating cheaper prices for a variety of drugs, which is why the article concludes that PBM’s save an average person $941 per year.
			2. Even if PBM’s were that bad, The Washington Post**[[70]](#footnote-70)** reports that the status quo is already solving for them in a couple of ways
				1. Blocking Gag Clauses- a bill is already in the process of being passed that would allow consumers to pick from a variety of different treatment methods then just going with what their doctor prescribed them
				2. States are already requiring PBMs to have specific licenses to operate legitimately, which are not handed out like candy
				3. States are already setting limits to how much these companies are allowed to sell the drugs are, meaning states are already solving for the problem they provide
				4. Policies are being processed where PBM’s would be forced to report how much money they profit when reselling the drugs to the consumers, disincentivizing PBM’s to markup prices high
				5. The government has already vowed to take action if they do find that PBM’s are making too much profit off reselling drugs, there is no reason to vote for them

## A2- Healthcare

### A2- Premiums

* + - 1. Delink- **Time Magazine in 2018[[71]](#footnote-71)** analyzes the way in which price controls would affect insurance costs. Ultimately, they conclude that insurance costs would be unaffected by price controls because drug prices don’t factor in to how premiums are calculated.
			2. Turn- **miller of RCH[[72]](#footnote-72)** writes that Price controls will increase the cost of insurance as it is simply impossible for companies to make profits by selling premiums at the same price to everyone.
1. Times News reports**[[73]](#footnote-73)** that even if drug prices were cut, insurers take a long time to change their prices because
	1. They want to retain their high profit margins and
	2. New drug prices are only usually set at the beginning of each new year.
2. Turn-. **The Foundation for Economic Education[[74]](#footnote-74)** in 2017 reports that price controls significantly increase insurance premiums because of a phenomenon dubbed the death spiral. Insurance companies have to overcharge the young and healthy to keep prices low for older people who are higher risk for disease. This leads to younger adults opting out of insurance all together, which results in insurance companies jacking up rates to make up lost revenue. In the world of the pro, insurance becomes more expensive, not cheaper.
3. No impact- **kaick[[75]](#footnote-75)** writes that premiums being high are a result of monopolization, not because of drug prices. Affirming the resolution doesn’t do anything.

### A2- Tradeoff in Healthcare

* + - 1. **Don’t let them** tell you drug prices are the biggest factor that go into health costs. **In fact, CNBC News[[76]](#footnote-76) reports** that specialists, nurses, and doctors can earn up to 800% more compared to other countries, making their salaries have significant impact on healthcare costs.

### A2: Improving healthcare quality

**The Heritage Foundation[[77]](#footnote-77) reports** that price-setting in health care systems has consistently failed to produce saving and only devastates the quality and access people have towards these policies. There is no reason why would price controls would solve for this.

**Barrons[[78]](#footnote-78) reports** that government medical programs historically don’t yield any benefits. In fact, they find that beneficiaries of the Medicaid program pay 40% more than what they would pay through private insurance. There is no such thing as free money.,

## A2- Innovation

### A2- European Countries

1. **Lowe ‘10[[79]](#footnote-79)** explains that European innovation overwhelmingly produces “me-too” duplicative drugs that provide no benefit to the consumer
2. Alt causal, drug R&D and innovation has increased substantially around the globe for the past 40 years, they don’t do the comparative analysis of what European innovation “would-be” if they didn’t have price controls
3. Can’t compare markets, European healthcare is highly socialized with insurance companies reimbursing more for drugs, the U.S is free market

### A2- Canada

1. **The Fraser Institute[[80]](#footnote-80)** report in 2018 that Canada would save 2 billion annually if they didn’t have price controls because it cost the price of generic drugs to rise by around 76%

### A2- Me- Too Drugs

**1. Wetheimer of Temple University School of Pharmacy** crucially finds that Me-Too drugs are beneficial for several reasons

 a. Me-Too drugs are based on incremental improvements which represent advancement in safety and efficacy. **National Research Council[[81]](#footnote-81)** has observed, “the cumulative effect of numerous minor incremental innovations can sometimes be more transforming and have more economic impact than a few radical innovations or ‘technological breakthroughs’.” The net effect of increasing the number of drugs through innovation leads to advances in safety, efficacy, selectivity, and utility of drugs within a specific class.

 b. They also provide new formulations and dosing options that significantly increase patient compliance—both of which lead to improved health outcomes

 c. Markets with many me too drugs incentivize competition and are a lot cheaper.

 d. Additionally, pharmaceutical companies depend on incremental innovations to provide the revenue that will support development of the riskier, capital- and research-intensive blockbuster drugs. This is why **Atlas of CNN** finds that the next breakthrough treatment is 4 times more likely to be found in the United States

1. Howard, Paul. senior fellow and director of health policy at the Manhattan Institute, “Should the Government Impose Drug Price Controls?” The New York Times, The New York Times, 23 Sept. 2015, www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate.

Research shows that price controls in the United Sates would powerfully dampen innovation. "Cutting prices by 40 to 50 percent in the U.S. will lead to between 30 to 60 percent fewer R&D projects being undertaken," one study found. A 2008 RAND study exploring the effect of U.S. price controls on those aged 55 to 59 in the United States and Europe similarly found that, on net, pharmaceutical price controls would hurt patients. The idea that we “overspend” on drugs is also misleading. In 2014, **drug spending accounted for just 10 percent of U.S. health care spending,** and according to government actuaries, spending will increase by only 0.4 percentage points over the next decade. Hospitals, for comparison, account for more than 30 percent of total health care spending. Countries that use price controls advocated by industry critics actually spend a larger share on drugs and use fewer cost-saving generics than the United States does. Absent price controls, however, private negotiation works. A report from the Government Accountability Office concluded that the Medicare Part D drug program (where private insurers negotiate with drug manufacturers) obtained lower (pre-rebate) prices than the defense department or Medicaid. For generic drugs, where competition is the greatest, Part D's prices were essentially no different than Medicaid's. [↑](#footnote-ref-1)
2. https://olis.leg.state.or.us/liz/2017I1/Downloads/CommitteeMeetingDocument/151076

 List prices at pharmacies rose by 58% over the past five years, while final out-of-pocket costs declined by 17%. These divergent trends reflect the complex dynamics determining how much patients pay for their medicines and the influence those costs have on whether they fill their prescriptions. [↑](#footnote-ref-2)
3. https://www.forbes.com/sites/econostats/2017/10/12/price-controls-will-reduce-innovation-and-health-outcomes/#1bdc2b63a683

To start, the price controls would be irrelevant for most patients. Nearly [90 percent](http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021#form) of all drugs dispensed in the U.S. in 2016 were generic medicines, according to IMS Health. Therefore, any price control scheme would not apply to the majority of patients who are using inexpensive generics, not more expensive patented products. [↑](#footnote-ref-3)
4. <https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/>

Squeezing pharmaceutical R&D spending down to one-fifth of what it is today would also have an enormous impact on the problems that drug developers often choose to address. Orphan diseases would be deprioritized, as the returns under price controls would not warrant the investment. Complex diseases would also be deselected. While Alzheimer’s disease and diabetes have huge patient populations, the extremely high cost of conducting the difficult research and the need for huge and complex clinical trials would dissuade all but the largest companies from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today’s treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief.

**The upshot is simple. Forcing drug prices down would surely shave a few percentage points off what we spend on health care today. By 2032, drug prices could be half of what they are today, as every drug would be a generic**. But our ability to treat or cure the many serious diseases that still afflict us will have been crippled and squandered. In my view that is terrible policy. [↑](#footnote-ref-4)
5. ####  Lakwadalla

<https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-end-up-costing-patients-their-health>

On the other side of the ledger, drug price controls would not save that much money. According to federal government data, prescription drug spending makes up roughly one-tenth of America’s total bill for health care. **Lopping 20 percent off drug prices by negotiating prices would thus shave all of 2 percent off our total health care bill. What’s more, we will enjoy only a one-time cost reduction, because drug spending has been growing no faster than overall health care spending over the past 10 years.** [↑](#footnote-ref-5)
6. Elizabeth Wright. “Pharmaceutical Price Controls: A Prescription for Disaster”,
Citizens Against Government Waste, October 2016, https://www.cagw.org/sites/default/files/pdf/Pharmaceutical%20Price%20Contr ols%20-%20A%20Prescription%20for%20Disaster.pdf

“**Price control measures** such as Medicaid rebates, the 340B program, and the VA pricing structures **have distorted the pharmaceutical market and caused price shifting**. In a November 4, 2010, letter to then-House Budget Committee Ranking Member Paul Ryan (R-Wisc.), the CBO confirmed that Obamacare’s increased Medicaid discounts and mandated new Medicare Part D **discounts** in the cover gap (more commonly referred to as the “donut hole” between the end of initial coverage and the start of catastrophic coverage), **would likely cause manufacturers to raise prices to offset the costs of new discounts.[50] Markets respond to pricing pressure as if it were an inflated balloon: push down on one side and the other expands. It should come as no surprise that some drug costs are being shifted to the private sector because of government price controls**.” [↑](#footnote-ref-6)
7. <https://www.lifescienceleader.com/doc/how-important-is-medical-innovation-economy-0001>

From 1900 – 2010, the United States has witnessed a 96% decrease in deaths, and a 62% increase in life expectancy. By the year 2040, average U.S. life expectancy is anticipated at being 85 years of age, while the rest of the world is estimated to be at 72 years of age. According to Frank Lichtenberg, Ph.D., new therapies are the greatest contributor to increased life expectancy. A business professor at Columbia University, Lichtenberg assessed the contribution of pharmaceutical R&D to longevity and the economic growth which results. You may find some of his insights startling. First, the pharmaceutical industry is the most R&D-intensive sector of the economy, not technology. Second, the rate of return on investment in pharmaceutical R&D is 18%. Third, using **newer drugs actually decreases overall healthcare costs, with much of the savings being due to reduced hospital stays and physician office visits. For $1 spent on innovative medicines, healthcare spending is reduced by approximately $7.20**. So let me ask you — what type of financial impact does living longer have economically [↑](#footnote-ref-7)
8. Pietro Pagani (The Washington Examiner) “The real prescription for lower drug prices: Get Europe to drop its price controls” June 29, 2018

<https://www.washingtonexaminer.com/opinion/op-eds/the-real-prescription-for-lower-drug-prices-get-europe-to-drop-its-price-controls>

Ironically, these market-distorting interventions actually help prop up drug prices in the long term, by stifling the only reliable means of lowering them through real economic forces: innovation and competition. A number of studies have shown that pharmaceutical R&D results in lower drug prices by spurring competition. Since patents cover specific molecules but not the natural biological processes they interact with, following the discovery of a new drug rival companies have every incentive to develop drugs which exploit the same process — often offering additional benefits, such as greater efficacy or tolerability — thereby forcing down the price of the first drug, even while it remains under patent protection. **One study of twenty new “follow-on” drugs found that 80 percent launched at a discount relative to the first drug, with an average discount of 26 percent.** Another study identified discounts of 21 percent to 61 percent for seven major “follow-on” drugs launched in recent years. Regulators from the European Medicines Agency confirmed that in some cases “availability of these products can drive down prices almost as much as the availability of generics,” citing the example of follow-on drugs for hepatitis C, with eight new competitors forcing price reductions of 40 to 65 percent in just a few years. This process happens very quickly. The time needed for competitors to develop a “follow-on” drug plunged from 10.2 years in the 1970s to 1.2 years in the 1990s, while the period of “marketing exclusivity” fell from 8.2 years to 1.8, yielding price reductions with remarkable speed, and without the need for price controls or tampering with patents protections. [↑](#footnote-ref-8)
9. Sullivan, Thomas. “Increasing Generic Drug Shortages Linked to Government Price Controls”, Policy & Medicine, 6 May 2018, http://hinj.org/government-price- controls-on-prescription-drugs-may-be-more-than-patients-bargain-for/

**“First, the number of suppliers of generic drugs has dwindled**. There were 26 U.S. vaccine makers in 1967; today there are only six. Supply disruptions are common, including the possibility that a facility completely shuts down for a protracted time because of quality or safety problems. Second, unlike in most consumer-goods industries, many pharmaceutical manufacturers have failed to invest in the technology and quality-control improvements that would reduce the risks of partial or complete facility shutdowns—and this despite the FDA’s regularly issued current guidelines for good manufacturing practices. **Behind both problems are the government’s tight price controls for generic drugs**, especially when purchased by Medicare and Medicaid. **Low prices induce drug makers to exit various markets, or at least to reallocate their manufacturing capacity toward more profitable, patented pharmaceuticals**. Low prices also tend to eliminate the rationale for investments in better manufacturing technologies and processes, as shown in a 2009 study conducted by the author and published in the Journal of Management Science.” [↑](#footnote-ref-9)
10. Elizabeth Wright. “Pharmaceutical Price Controls: A Prescription for Disaster”, Citizens Against Government Waste, October 2016, https://www.cagw.org/sites/default/files/pdf/Pharmaceutical%20Price%20Contr ols%20-%20A%20Prescription%20for%20Disaster.pdf

“**Price control measures** such as Medicaid rebates, the 340B program, and the VA pricing structures **have distorted the pharmaceutical market and caused price shifting. In** a November 4, 2010, letter to then-House Budget Committee Ranking Member Paul Ryan (R-Wisc.), the CBO confirmed that Obamacare’s increased Medicaid discounts and mandated new Medicare Part D discounts in the cover gap (more commonly referred to as the “donut hole” between the end of initial coverage and the start of catastrophic coverage), would likely cause manufacturers to raise prices to offset the costs of new discounts.[50] **Markets respond to pricing pressure as if it were an inflated balloon: push down on one side and the other expands. It should come as no surprise that some drug costs are being shifted to the private sector because of government price controls.”**  [↑](#footnote-ref-10)
11. Reisman, George. “Price Controls and Shortages | George Reisman.” FEE, Foundation for Economic Education, 1 Feb. 1980, <fee.org/articles/price-controls-and- shortages/.>

“**The one consequence of price controls that is the most central and the most fundamental and important from the point of view of explaining all of the others is the fact that price controls cause shortages**. **A shortage is an excess of the quantity of a good buyers are seeking to buy over the quantity sellers are willing and able to sell. In a shortage, there are people willing and able to pay the controlled price of a good, but they cannot obtain it. The good is simply not available to them.** Experience of the gasoline shortage of the winter of 1974 should make the concept real to everyone. The drivers of the long lines of cars all had the money that was being asked for gasoline and were willing, indeed, eager, to spend it for gasoline. Their problem was that they simply could not obtain the gasoline. They were trying to buy more gasoline than was available. The concept of a shortage is not the same thing as the concept of a scarcity. An item can be extremely scarce, like diamonds, Rembrandt paintings, and so on, and yet no shortage exist. In a free market the effect of such a scarcity is a high price. At the high price, the quantity of the good demanded is levelled down to equality with the supply available, and no shortage exists. Anyone willing and able to pay the free-market price can buy whatever part of the supply he wishes; the height of the market price guarantees it, because it eliminates his competitors. **It follows that however scarce a good may be, the only thing that can explain a shortage of it is a price control, not a scarcity. It is a price control that prevents the price of a scarce good from being raised by the self-interest of the buyers and sellers to its free-market level and thus reducing the quantity of the good demanded to equality with the supply of the good available. Of course, if a price control on something exists, and a scarcity of it develops or grows worse, the effect will be a shortage, or a worsening of the shortage. Scarcities can cause shortages, or worsen them, but only in the context of price controls.** If no price [↑](#footnote-ref-11)
12. Coyne, Christopher, and Rachel Coyne. “Price Controls and the Damage They Cause.” IEA, Institute of Economic Affairs, 2015, <iea.org.uk/wp- content/uploads/2016/07/Coyne-Interactive.pdf.>

**“The emergence of crime and black markets are another indirect negative effect of price controls. Unable to adjust prices legally, producers and buyers may move into the extralegal market to engage in exchange. Others, desperate to obtain goods for which there is a shortage, may engage in theft to obtain goods.** To provide one illustration of black market activities, consider the case of farmers in the UK in World War II. Facing wartime meat rationing, many farmers under-reported animal births to the Ministry of Food and then sold the additional meat in the black market.**”**  [↑](#footnote-ref-12)
13. <https://thehill.com/blogs/pundits-blog/healthcare/332145-the-tragic-toll-of-drug-price-controls>

And the price control process significantly degrades patient well-being. Pharmaceutical firms have to undergo a long, drawn-out negotiating process every time they want to sell a new medication in a controlled market. All the while, sick people aren't getting the medicines they need. [↑](#footnote-ref-13)
14. http://www.txccri.org/content/RR000717.pdf

In addition to shortages, price controls on prescription drugs could cause, black markets to spring up and could also increase the potential for counterfeit medications. This is seen now in Mexico, where it is estimated that one-fourth of drugs sold is counterfeit. [↑](#footnote-ref-14)
15. This is highlighted by EU Commission Access to Medicine initiative, which investigated problems related to pharmaceutical supply in small markets:

From the countries’ perspective, the main problems cited were: lack of marketing authorisation, shortages of supply, no effective availability, unaffordable prices and marketing delays. Economic operators cited the following key factors: low profitability at allowed prices/margins, local language requirements, price spillovers through international reference pricing, and/or risk of parallel trade. (European Commission, [2014](https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045747)European Commission. 2014. *Project Group on Facilitating Supply in Small Markets - Position Paper and Recommendations*. European Commission Position Paper and Recommendations.<http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/smallmarkets_positionpaper_en.pdf>. [[Google Scholar]](http://scholar.google.com/scholar_lookup?hl=en&publication_year=2014&author=European+Commission&title=Project+Group+on+Facilitating+Supply+in+Small+Markets+-+Position+Paper+and+Recommendations)) [↑](#footnote-ref-15)
16. CHECK THE CASE [↑](#footnote-ref-16)
17. Bardey 2018, D , Et Al., xx-xx-xxxx, "Retail price regulation and innovation: reference pricing in the pharmaceutical industry.," No Publication, <https://www.ncbi.nlm.nih.gov/pubmed/20053474>

**Our results suggest that reference pricing typically generates a decline in health**, whereas discounted expenditures may decrease or increase, depending on the degree of deterrence of cost reducing innovations.

Bardey 2018, D , Et Al., xx-xx-xxxx, "Retail price regulation and innovation: reference pricing in the pharmaceutical industry.," No Publication, <https://www.ncbi.nlm.nih.gov/pubmed/20053474>

**Our results suggest that reference pricing typically generates a decline in health**, whereas discounted expenditures may decrease or increase, depending on the degree of deterrence of cost reducing innovations. [↑](#footnote-ref-17)
18. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3829766/#FN3

The number of countries with therapeutic reference pricing is smaller and stayed between two and three for the period 1992–2002. After this it increased, to five in 2003 and six in 2004. Australia adopted therapeutic reference pricing in 1998; Hungary and Italy moved from generic reference pricing to therapeutic reference pricing in 2003. Germany abandoned therapeutic reference pricing in 1996 (for new drugs), but then reintroduced it in 2004[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3829766/#FN3) [↑](#footnote-ref-18)
19. Food and Drug Administration, 8-16-2018, "Press Announcements > FDA approves first generic version of EpiPen," No Publication, <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm617173.htm>

The U.S. Food and Drug Administration today approved the first generic version of EpiPen and EpiPen Jr (epinephrine) auto-injector for the emergency treatment of allergic reactions, including those that are life-threatening (anaphylaxis), in adults and pediatric patients who weigh more than 33 pounds. Teva Pharmaceuticals USA gained approval to market its generic epinephrine auto-injector in 0.3 mg and 0.15 mg strengths.

“Today’s approval of the first generic version of the most-widely prescribed epinephrine auto-injector in the U.S. is part of our longstanding commitment to advance access to lower cost, safe and effective generic alternatives once patents and other exclusivities no longer prevent approval,” said FDA Commissioner Scott Gottlieb, M.D. “This approval means patients living with severe allergies who require constant access to life-saving epinephrine should have a lower-cost option, as well as another approved product to help protect against potential drug shortages. The path to developing generic drug-device combination products like this one is challenging. We remain committed to doing our part to provide scientific and regulatory clarity for sponsors seeking to develop complex generics, as well as prioritize the approval of medicines with little or no generic competition as part of our overarching effort to remove barriers to generic development and market entry of critically important medicines. Many of these steps were outlined in our Drug Competition Action Plan, announced last year. We’re especially committed to the development of generic copies of complex products. [↑](#footnote-ref-19)
20. https://www.athenahealth.com/insight/prescriptions-jump-epipen-alternatives [↑](#footnote-ref-20)
21. Ornstein 15

<https://www.propublica.org/article/cost-of-a-cure-medicare-spent-4.5-billion-on-hepatitis-c-drugs-last-year>

**Medicare's spending on drugs to treat hepatitis C soared more than 15 fold from 2013 to 2014 as new breakthroughs came to the market, according to previously undisclosed federal data. Medicare spent $4.5 billion last year on new, pricey medications that cure the liver disease hepatitis C — more than 15 times what it spent the year before on older treatments for the disease, previously undisclosed federal data shows.** [↑](#footnote-ref-21)
22. Managed Care article

<https://www.managedcaremag.com/dailynews/20180720/merck-steeply-cut-price-hepatitis-c-drug-zepatier>

Merck will drop the price of its Hepatitis C drug Zepatier by 60%, the company announced yesterday. In addition, it plans to cut the price of “several other” drugs by 10%. In doing so, Merck went further than two competitors—Pfizer and Novartis—who said that they would not increase drug prices for the rest of 2018. [↑](#footnote-ref-22)
23. Alex Azar

<https://www.hhs.gov/about/news/2018/08/20/100-days-of-action-on-the-presidents-american-patients-first-blueprint.html>

*The President’s blueprint for lower drug prices is working, drug prices are coming down, and American patients are going to see the savings in their pocketbook.”* — Secretary Alex Azar

Tomorrow, August 21, marks 100 days since the release of President Trump’s [American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs - PDF](https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf). In this short period of time, an unprecedented number of actions have been taken toward structurally rebuilding this entire segment of the economy to lead to enduring lower prices that are sustainable, support innovation, and put American patients first. [↑](#footnote-ref-23)
24. Winegarden https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm551407.htm [↑](#footnote-ref-24)
25. Cohen

<https://www.forbes.com/sites/joshuacohen/2018/08/09/better-u-s-patient-access-to-cancer-drugs-comes-at-a-price/#2a95f0584a9a>

In the U.S., some experts deem cancer prices too high in relation to their benefit. Policymakers are considering ways to bring down cancer drug prices. An important policy question is whether greater access may in part be **due to a lack of price controls. The U.S. pricing and reimbursement environment has been conducive towards extraordinary levels of investment in cancer drug research. This is because such investment is a function of anticipated market conditions for the products being invested in.** In effect, favorable pricing and reimbursement conditions indirectly impact the numbers of approvals and speed to approval. [↑](#footnote-ref-25)
26. Sikora

<https://www.independent.co.uk/life-style/health-and-families/health-news/world-cancer-day-2017-effective-cure-will-happen-five-to-10-years-expert-karol-sikora-a7558846.html>

**An effective cure for all types of cancer could be just five to 10 years away, according to one of the world’s leading experts on the disease.**

Survival rates have dramatically increased over the last five decades from an average of 24 per cent the early 1970s to about 50 per cent.

But some forms of the disease have remained extremely hard to treat – just one per cent of pancreatic cancer patients and five per cent of those with lung cancer are still alive 10 years after diagnosis.

Speaking to The Independent ahead of World Cancer Day on 4 February, **Professor Karol Sikora, former head of the World Health Organisation’s cancer programme, said advances in genetics meant doctors would soon be able to prescribe drugs specifically targeted at each individual’s cancer.** [↑](#footnote-ref-26)
27. Lichtenburg

<https://www.iedm.org/sites/default/files/pub_files/cahier0216_en.pdf>

The elasticity of PubMed drug cites with respect to cancer incidence throughout the world was 0.60. This suggested that in the long run, **a 10% decline in drug prices would be likely to cause at least a 5% to 6% decline in** two measures of pharmaceutical innovation: **the number of chemotherapy regimens, and the number of scientific articles about cancer.**40 This estimate is very consistent with Giaccotto et al.’s estimate (0.583) of the elasticity of pharmaceutical industry R&D with respect to the real price of pharmaceuticals. That study employed time series econometric techniques to explain R&D growth rates using industry-level data from 1952 to 2001. [↑](#footnote-ref-27)
28. Zlati Meyer (USA Today) “Another astronomical drug hike: Price of opioid antidote leaps 600%” February 13, 2017 [https://www.usatoday.com/story/money/nation-now/2017/02/13/naloxone-opioid-antidote- price-hike/97842830/](https://www.usatoday.com/story/money/nation-now/2017/02/13/naloxone-opioid-antidote-%20price-hike/97842830/)

**People with commercial insurance can get Evzio [(Nalaxone)] for free** whether or not they have high-deductible plans or if Evzio isn’t covered by their insurance companies, **as can patients without insurance who have a household income below $100,000,** according to the Spencer Williamson, chief executive of the Richmond, Va.-based drugmaker Kaléo. It&#39;s $360 for patients paying cash. Though the company is privately held, public company PDL BioPharma loaned Kaléo $150 million in April 2014 to support what the company called commercialization of the drug that the FDA approved April 3, 2014. &quot;In February 2016, the list price of Evzio increased so that we could launch this access program for patients,&quot; Williamson said in a written statement. &quot;Because of this patient-access program for Evzio, more Americans are able to obtain naloxone for $0 out-of-pocket than any time in history.&quot;

The listed wholesale price, which is for distributors selling to pharmacies, is $4,100, Williamson said. But **that’s “not a true net price to anyone, including the distributors or pharmacies, due to numerous discounts and rebates that are negotiated in the supply chain that make up our health-care system.”; He added that Kaléo has donated nearly 200,000 doses to “public health departments, first responders and nonprofits serving patients in need**.” Naloxone is an important lifesaving medication for those with opioid overdoses, FDA officials said. The agency doesn&#39;t have the authority to review or approve drug prices, which manufacturers and distributors set. &quot;The agency recognizes that emergency treatment of known or suspected opioid overdose is an urgent public-health priority, and there is still a need to improve access to naloxone to save lives from overdoses. Identifying ways to make naloxone more accessible is an important component of the FDA’s opioid action plan,&quot; spokesman Michael Felberbaum said in an e-mail. [↑](#footnote-ref-28)
29. Zlati Meyer (USA Today) “Another astronomical drug hike: Price of opioid antidote leaps 600%” February 13, 2017 [https://www.usatoday.com/story/money/nation-now/2017/02/13/naloxone-opioid-antidote- price-hike/97842830/](https://www.usatoday.com/story/money/nation-now/2017/02/13/naloxone-opioid-antidote-%20price-hike/97842830/)

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30. 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-30)
31. <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-31)
32. 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-32)
33. http://stm.sciencemag.org/content/10/434/eaan2595

 <https://sci-hub.tw/10.1126/scitranslmed.aan2595>

**We are thus faced with three urgent chal- lenges: determining how much reduction in drug use is clinically relevant, finding reliable and practical ways to measure such changes in drug use, and developing biomarkers pre- dicting and indicative of response to new agents. To meet these challenges, we need studies of how to better measure quantity and frequency of drug consumption as well as clinical or epidemiological studies to deter- mine how much of a change in quantity or frequency of opioid consumption is associated with meaningful health and functional out- comes. This will entail research on biomarkers of drug exposure, development of better self- report measures of quantity and frequency of drug use, and studies on the relationship**

of changes in quantity and frequency to mean- ingful health outcomes.

Accepting that meaningful reductions in quantity and frequency of drug use may be associated with improvements in health is part of a broader recognition that empirically new approaches are needed to address the opioid crisis. For instance, FDA Commissioner Scott Gottlieb’s recent testimony before the U.S. House Committee on Energy and Commerce about federal efforts to combat the opioid crisis reiterated the FDA’s commitment to the de- velopment and use of new non–abstinence- based end points as part of product development (*9*). He also stated that the FDA will facilitate the development of new products that address a fuller range of the symptoms of addiction, including craving. Measures of social func- tioning (for example, employment and avoid- ance of incarceration) could also be explored as end points for benefits of reduction in use. In addition, the identification of outcomes that are meaningful to patients with an opioid- use disorder could inform the FDA about patient-focused drug development guide- lines for opioid-use disorder medications. If these alternative end points could be used in drug development trials, this could attract pharmaceutical-sector investment because of enhanced trial feasibility, which could ulti- mately result in a wider range of effective medications to treat opioid-use disorders. It is important to emphasize, however, that seek- ing alternative efficacy outcomes is not an attempt to lower the standard of approval for medications to treat opioid-use disorders. Clearly, accepting alternative end points will be based on reliable and rigorous data that such outcomes provide meaningful benefits to patients and their families.

The opioid crisis and overdose epidemic gripping the United States make it imperative that we develop additional treatment options for opioid-use disorders in particular and substance-use disorders generally. Achieving a more nuanced understanding of how to achieve therapeutic benefit short of periods of absti- nence will facilitate the development of new treatments. **To achieve these transformative goals, the National Institutes of Health and the FDA are looking to actively support and partner with the academic community, with the pharmaceutical industr**y, and with patients

and their families (*10*). Together, we can de- velop the tools needed to bring effective ad- diction treatments to the growing population of patients who desperately need them. [↑](#footnote-ref-33)
34. Santerre, Rexford E. and John A. Vernon. "Assessing Consumer Gains From A Drug Price Control Policy In The United States," Southern Economic Journal, 2006, v73(1,Jul), 233-245.

However, over this same time period, Giaccotto, Santerre, and Vernon (2005) estimated that this same **price control regime would have caused firms to reduce pharmaceutical R&D expenditures (in $2000) by between $264.5 and $293.1 billion, because of lower profit expectations and possibly reduced levels of internal funds** (which are the primary source of R&D finance) 10 . **This reduced investment in R&D would have led to approximately 38 percent fewer new drugs being brought to market in the global economy.** If this 38 percent figure is applied to the total number of new chemical entities approved for marketing during this period in the U.S., we can use our simulation results to calculate the average social opportunity cost per new drug. [↑](#footnote-ref-34)
35. **The Moran Company 18** The Moran Company, 2018, “Hospital Charges and Reimbursement for Medicines: Analysis of Cost-to Charge Ratios” The Pharmaceutical Research and Manufacturers of America

 <http://www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf>

**We found that, on average, hospitals charge 479% of their cost for drugs nationwide**.7 This matches closely with the findings from our prior analysis. **Most hospitals (83%) charge patients and insurers more than double their acquisition cost for medicine, marking-up the medicines 200% or more.** **The majority of hospitals (53%) markup medicines between 200-400%, on average.** **A small share of hospitals - one in six (17%) - charge seven times the price of the medicine.** On a medicine with an ASP of $150, a 700% mark-up would result in a charge of $1050. One out of every twelve hospitals (8%) has average charge markups greater than 1000% - meaning they are charging at least 10 times their acquisition cost for medicines, on average. These data are presented in Chart one and Table one. [↑](#footnote-ref-35)
36. **Blau 17 of** statnews Max Blau, 11-30-2017, "FDA approves Indivior’s monthly injection to treat opioid addiction," STAT, <https://www.statnews.com/2017/11/30/fda-indivior-opioid-treatment/>

**Patients who get Sublocade will receive an abdominal injection administered by a health professional after starting a daily regimen of sublingual buprenorphine tablets for at least seven days.**If approved, Braeburn’s long-acting product, CAM 2038, would be available as either a weekly or a monthly shot, and would not require these stabilizing doses of daily buprenorphine.  [↑](#footnote-ref-36)
37. **Naabt** Naabt The National Alliance of Advocates for Buprenorphine Treatment , "Is buprenorphine addictive?," No Publication, https://www.naabt.org/faq\_answers.cfm?ID=33

**Amazingly despite 100% of people being treated for addiction with buprenorphine have demonstrated that they have a greater vulnerability to opioid addiction than the average person, very few become addicted to the buprenorphine,** meaning very few lose control of their medication intake, nor experience uncontrollable compulsions and cravings toward the buprenorphine.  [↑](#footnote-ref-37)
38. https://www.ncbi.nlm.nih.gov/books/NBK235205/

The lack of price control makes the United States an attractive country for the introduction of new contraceptive products. In Europe, the prices of contraceptives are normally controlled by governments, and companies claim that low profit margins barely allow recovery of R&D costs. Because of the size of the U.S. market, as well as its potential for higher profits than Europe, regulatory changes in the United States may affect contraceptive development activities in Europe as well as in the United States. [↑](#footnote-ref-38)
39. <https://www.sciencedaily.com/releases/2018/03/180328224232.htm>

A hormone-free women's contraceptive with no side effects is one promising use for a new technique developed by researchers in Sweden to tighten up the mucous membrane – the body’s first line of defense in protecting its inner lining.

The approach consists of cross-linking the mucus gel with chitosan, a type of polysaccharide derived from chitin, the substance that develops in the hard outer shells of crustaceans such as shrimp and crayfish. The material tightens the mucin polymer mesh barrier which lines the mucosal epithelium of our body’s cavities, says Thomas Crouzier, a researcher at KTH Royal Institute of Technology in Stockholm. [↑](#footnote-ref-39)
40. Case Western Reserve University Joanna Shepherd 2017 <https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1609&context=healthmatrix>

Finally, **lower profitability will likely reduce competition in the pharmaceutical industry. Generic entry, like the market entry of suppliers in any industry, depends on potential profits.** Indeed, several examples illustrate the relationship between profits and generic entry. First, the substantial profit potential under the Hatch-Waxman 180-day exclusivity period has led to a significant increase in generic challenges.157 Second, generics race to enter the market upon brand-patent expiry to claim a share of brand drugs’ market share and profits before the market is saturated with generic competitors.158 **Conversely, in periods when few patents are expiring, the existing profits available in the market are much lower and fewer generics enter.159** Finally, **foreign countries that utilize price controls to control drug prices have significantly less generic competition; without the profit potential, fewer generics enter the international markets.160** Currently, **the U.S. market has more generic competition than any other market, largely because of the significant profit potential for these firms.161** However, **additional price controls will lead to reductions in generic entry. This reduction in generic competition will reduce consumers’ choices of drugs and increase drug prices.** Although price controls will require set discounts from average prices, without generic competition, these average prices will be much higher than they would be with more competition. Similarly, **intensely competitive markets spur innovation as firms innovate to gain market share and outdo competitors. If price controls lead to a less-competitive market, incentives to innovate will also decline**. [↑](#footnote-ref-40)
41. Case Western Reserve University Joanna Shepherd 2017 <https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1609&context=healthmatrix>

**As of 2005, over twenty percent of drugs sold in the U.S. were sold under government programs that mandate price controls, such as Medicaid, the 340B Program, the Department of Defense and Veterans Affairs programs, and spending in the coverage gap of Medicare Part D.**18 Some programs even require drugs to be sold for a penny.19 Further price controls will create incentives for manufacturers to charge higher prices to non-covered patients to offset the discounted prices. If manufacturers are not able to offset discounts by increasing prices for non-covered consumers, all consumers may ultimately suffer. **Empirical data suggest that price controls contribute to drug shortages, slow innovation, and curtail generic competition.20 Ultimately, price controls meant to lower drug spending for some consumers could end up harming all consumers**

With the intensifying competition from generics, expanding power from PBMs, increasing costs of R&D, and growing risk of commercial failure, the pharmaceutical industry has undergone significant structural change. **Several large pharmaceutical companies have merged to offset losses in market share and achieve cost savings from greater economies of scale.84 Indeed, the number of pharmaceutical companies earning more than five billion dollars in annual profits has shrunk in the last two decades**.85 This consolidation has achieved some efficiencies and increased short-term earnings.86 Similarly, the generic industry has experienced recent consolidation in response to the reduction in patent expirations and exclusivity periods. **Many generic companies have merged, while others have acquired brand companies to diversify their risk and reliance on generic drugs.87** [↑](#footnote-ref-41)
42. 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-42)
43. Global CCS Institute. “How patents encourage innovation in technological development and deployment”, June 2013,

https://hub.globalccsinstitute.com/publications/intellectual-property-rights- role-patents-renewable-energy-technology-innovation/1-how-patents- encourage-innovation-technological-development-and-deployment

**“**Advocates of patenting argue that patents act as a strong incentive for innovation, while others are concerned that they restrain innovation. To some extent the role and impact of patents depend on the specific technology involved. **While some patents may temporarily limit the use of specific technologies to the patent's owner and licensees in some jurisdictions, such innovations often spur the development of competing technologies. For technologies requiring considerable financial and technical resources, and a long period to develop marketable products that are then relatively inexpensive to reproduce, patent protection is** critical. For pharmaceuticals, for example, patents are important both in terms of spurring innovation of new medicines and ensuring access to new medical technologies. **National and regional patent offices, such as the United States Patent and Trademark Office** (USPTO), the Japan Patent Office (JPO), EPO, the Korean Intellectual Property Office (KIPO) and the State Intellectual Property Office of the People's Republic of China (SIPO) **play a critical role in ensuring that patents are granted only to inventions that are genuine contributions** to the state of the art and comply with procedural, as well as substantive requirements prescribed under the applicable patent law of the country or region in question..**”**  [↑](#footnote-ref-43)
44. John Lamattina. “About Those Soaring Pharma Profits”, Forbes, 23 Jan 2018, https://www.forbes.com/sites/johnlamattina/2018/01/23/about-those-soaring- pharma-profits/#299331d53f9d

“It’s a critique often heard as pundits attack the costs of new drugs: the high price of drugs is fueling unseemly Big Pharma profits. Typical is the headline, “Drug prices rise as pharma profit soars”. **There is no doubt that the high cost of new drugs is an important issue, although arguments can be made that the prices charged for life-saving medicines** such as the cures for hepatitis C , childhood leukemia, and ALL **can be more than justified. However, pharma profits are not greatly increasing as a result.** This issue was hit hard by Pfizer CEO Ian Read at the recent Forbes Healthcare Summit. Is this industry obscenely profitable? There is no evidence of that. If you look at our return on investment, our return on capital, if you look at our P/E, if you look at anything inside this industry – looking at the Bloomberg indices – we are in the middle. So **I don’t see an industry that you can say is profiteering. I see an industry that is taking its resources and investing into a high risk business called ‘innovation’ and making modest returns on the capital at risk**. So, I think the societal issue is **how do you afford access to medicines that create great value, but require capital and risk to produce - the medicines that may represent 12 – 14% of the total costs and have automatic price adjustments in the form of loss of exclusivity**? 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 [↑](#footnote-ref-44)
45. Jones, Gregory “Strategies that delay or prevent the timely availability of affordable generic drugs in the United States”, NCBI, 27 Jan 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/

**“Product hopping, also called “forced switching” or “evergreening,” involves a brand- name company switching the market for a drug, prior to its patent expiration date, to a reformulated version that has a later-expiring patent, but which offers little or no therapeutic advantages.** The newer version, for example, could have a slightly different tablet or capsule dose or a slow-release formulation (given once a day rather than twice daily). In conjunction with this change, the company spends heavily to convince doctors and/or patients to switch to the new drug and may even withdraw the (often profitable) older drug from the market before its patent expiration date. **When the generic version of the drug becomes available, pharmacists cannot substitute it for the new (branded) version because state laws allow drug substitution only if the dosage strength and other characteristics remain the same.”**  [↑](#footnote-ref-45)
46. 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-46)
47. Using a large patent-merger dataset over the period 1984-2006, we examine the motives and outcomes of acquisitions from the perspective of property rights theory of the firm. Our measures of corporate innovation capture not only quantity, quality, but also more importantly, asset complementarity that stem from technological overlaps of merger partners. We first show that more innovative companies, as measured by both patent quantity and quality, are more likely to engage in acquisition activities. Further, technological overlaps between the bidder’s and the target firm’s innovation activities as captured by patent cross-citations and common knowledge base have positive and significant impact on merger pairing. Finally, we show that innovationdriven acquisitions achieve better long-term new outcomes: more and significant innovation output as well as improved operating and stock market performance. Overall, our evidence provides strong support for the property rights theory of the firm. [↑](#footnote-ref-47)
48. For years, hospital executives have expressed frustration when essential drugs like heart medicines have become scarce, or when prices have skyrocketed because investors manipulated the market.

Now, some of the country’s largest hospital systems are taking an aggressive step to combat the problem: They plan to go into the drug business themselves, in a move that appears to be the first on this scale.

“This is a shot across the bow of the bad guys,” said Dr. Marc Harrison, the chief executive of Intermountain Healthcare, the nonprofit Salt Lake City hospital group that is spearheading the effort. “We are not going to lay down. We are going to go ahead and try and fix it.” [↑](#footnote-ref-48)
49. ####  Hospitals are reimbursed at super high rates by medical care

The U.S. Department of Health & Human Services, May 2018, American Patients First, https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

Drugs more typically administered to patients by healthcare practitioners, however, are covered and paid under Medicare Part B, which is part of the fee-for-service traditional Medicare benefit.2 Under Part B, providers and suppliers “buy and bill” these types of drugs. Since 2005 for physicians, and 2006 for hospital outpatient departments, Medicare has paid suppliers and providers based upon the Average Sales Price (ASP) for each product, as reported by manufacturers to the Centers for Medicare & Medicaid Services (CMS). 3 Physician offices that buy and bill Part B drugs are paid 106% of the drug’s ASP. Depending on a hospital outpatient department’s participation in a safety net drug pricing program, hospitals are reimbursed either 106 or 77.5 percent of ASP.4 [↑](#footnote-ref-49)
50. Langwell, Kathryn. “Price Controls: On the One Hand... And on the Other.” Health Care Financing Review, vol. 14, no. 3, 1993, pp. 5–10.

Cost containment using mechanisms that affect prices could be achieved through several differing policy approaches. Although direct regulation of prices through government intervention has most often been the focus of policy deliberations, market- oriented health reform proposals also would, if successful, affect prices charged by providers. For example, under managed competition, which involves considerable government intervention in the health insurance and health care markets, insurers would have greater market power to negotiate with providers over price and quantity. Those who favor market-based approaches argue that relying on the market to determine fees would allow for greater flexibility in pricing and provide for variations in quality of care. **Proponents of direct price controls believe that the market for health services is irretrievably flawed. The presence of extensive health insurance renders consumers insensitive to the price of services. And the inability of consumers, under many circumstances, to make informed decisions leads to delegation of decisionmaking to providers who have little incentive to consider costs.**  [↑](#footnote-ref-50)
51. Belk, David. “Hospital Billing.” True Cost of Heathcare, 2017,

http://truecostofhealthcare.org/hospitalization/.

**Hospitals see no problem in sending bills to insurance companies for five to ten times the amount that they actually expect, because they are simply playing the game that the insurance companies fashioned.** But remember, they only produce one kind of bill, and it’s designed to send to someone who holds all the cards (an insurance company), and so can just refuse to pay anything they didn’t already agree to pay. That’s their game. But what happens when you have to play the game with the hospital alone (if you don’t have insurance, or if your insurance doesn’t cover that stay for some reason). Then you’re on the hook for the entire amount. Most hospitals have a policy that allows people to negotiate for a lower amount, but most people don’t know this. And don’t expect the hospital to tell you about it, let alone help out. So even if you can remember to negotiate while you’re convalescing from a long hospital stay, good luck trying to get the deal the insurance company gets. [↑](#footnote-ref-51)
52. **The Moran Company 18** The Moran Company, 2018, “Hospital Charges and Reimbursement for Medicines: Analysis of Cost-to Charge Ratios” The Pharmaceutical Research and Manufacturers of America <http://www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf>

**We found that, on average, hospitals charge 479% of their cost for drugs nationwide.**7 This matches closely with the findings from our prior analysis. **Most hospitals (83%) charge patients and insurers more than double their acquisition cost for medicine, marking-up the medicines 200% or more. The majority of hospitals (53%) markup medicines between 200-400%, on average. A small share of hospitals - one in six (17%) - charge seven times the price of the medicine**. On a medicine with an ASP of $150, a 700% mark-up would result in a charge of $1050. One out of every twelve hospitals (8%) has average charge markups greater than 1000% - meaning they are charging at least 10 times their acquisition cost for medicines, on average. These data are presented in Chart one and Table one. [↑](#footnote-ref-52)
53. NRHA

“NRHA.” NRHA, National Rural Health Association, 2016, www.ruralhealthweb.org/about-nrha/about-rural-health-care.

Ease of access to a physician is greater in urban areas. **The patient-to primary care physician ratio in rural areas is only 39.8 physicians per 100,000 people,** compared to 53.3 physicians per 100,000 in urban areas. This uneven distribution of physicians has an impact on the health of the population.[2]

There are 30 generalist dentists per 100,000 residents in urban areas versus 22 per 100,000 in rural areas.[3] [↑](#footnote-ref-53)
54. Graban 2011

<https://www.hhnmag.com/articles/4753-cut-costs-by-reducing-redundant-or-inefficient-activity>

**Many hospital CEOs, including John Toussaint, M.D., the former CEO of ThedaCare, and thought leaders, including Donald Berwick, M.D., M.P.P., administrator for the Centers for Medicare & Medicaid Services, estimate that 30 to 50 percent of all health care spending can be described as waste** — activity that provides no benefit to patients. This adds up to more than $1 trillion a year in the United States. Instead of merely slashing reimbursements or providing less care, there is a clear opportunity to do more — and provide the right care — with less waste and less spending. [↑](#footnote-ref-54)
55. Brownlee 2017

<https://www.huffingtonpost.com/entry/corrupt-health-care-practices-drive-up-costs-and-fail-patients_us_59286dd9e4b053f2d2ac51f0>

Because our increasingly corporatized health care system is driven by an insatiable appetite for profit. Our healthcare system is no longer about relieving the suffering of patients or the intrinsic value of maintaining the health of our population. **It’s about making money: for pharmaceutical companies, device manufacturers, hospitals, insurance companies, and increasingly, for doctors. And all of these players are gaming the system and hurting patients in the process.** [↑](#footnote-ref-55)
56. Lakdawalla, Darius N., Dana P. Goldman, Pierre-Carl Michaud, Neeraj Sood, Robert J. Lempert, Ze Cong, Han de Vries, and Italo A. Gutierrez, U.S. Pharmaceutical Policy in a Global Marketplace. Santa Monica, CA: RAND Corporation, 2009. <https://www.rand.org/pubs/reprints/RP1380.html>. *Health Affairs*, Vol. 28, No. 1, January/February 2009.

Implementing price controls in the United States would have adverse effects on European consumers, by depressing rates of innovation. These global linkages create major policy problems in an international marketplace, because a given country does not fully realize the benefits (or costs) of its own policies. European price controls, for example, have smaller effects on innovation, because of the presence of a large U.S. market, which acts as a counterweight to policies that reduce European revenues. Moreover, some of the costs that do accrue end up being borne by U.S. consumers, further dampening Europe's incentives for higher prices. [↑](#footnote-ref-56)
57. Lowe, Derek, 11-9-10-“Where Drugs Come From: By: Country” <http://blogs.sciencemag.org/pipeline/archives/2010/11/09/where_drugs_come_from_by_country> Science Translational Medicine

The same paper I was summarizing the other day has some interesting data on the 1998-2007 drug approvals, broken down by country and region of origin. The first thing to note is that the distribution by country tracks, quite closely, the corresponding share of the worldwide drug market. The US discovered nearly half the drugs approved during that period, and accounts for roughly that amount of the market, for example. But there are two big exceptions: the UK and Switzerland, which both outperform for their size. In case you’re wondering, the league tables look like this: the US leads in the discovery of approved drugs, by a wide margin (118 out of the 252 drugs). Then Japan, the UK and Germany are about equal, in the low 20s each. Switzerland is in next at 13, France at 12, and then the rest of Europe put together adds up to 29. Canada and Australia put together add up to nearly 7, and the entire rest of the world (including China and India) is about 6.5, with most of that being Israel. But **while the US may be producing the number of drugs you’d expect, a closer look shows that it’s still a real outlier in several respects. The biggest one, to my mind, comes when you use that criterion for innovative structures or mechanisms versus extensions of what’s already been worked on**, as mentioned in the last post. **Looking at it that way, almost all the major drug-discovering countries in the world were tilted towards less innovative medicines**. The only exceptions are Switzerland, Canada and Australia, **and (very much so) the US.** The UK comes close, running nearly 50/50. **Germany and Japan, though, especially stand out as the kings of follow-ons and me-toos, and the combined rest-of-Europe category is nearly as unbalanced**. What about that unmet-medical-need categorization? Looking at which drugs were submitted here in the US for priority review by the FDA (the proxy used across this whole analysis), again, the US-based drugs are outliers, with more priority reviews than not. Only in the smaller contributions from Australia and Canada do you see that, although Switzerland is nearly even. But in both these breakdowns (structure/mechanism and medical need) it’s the biotech companies that appear to have taken the lead. And here’s the last outlier that appears to tie all these together: in almost every country that discovered new drugs during that ten-year period, the great majority came from pharma companies. **The only exception is the US: 60% of our drugs have the fingerprints of biotech companies on them, either alone or from university-derived drug candidates**. In very few other countries do biotech-derived drugs make much of a showing at all. These trends show up in sales as well. Only in the US, UK, Switzerland, and Australia did the per-year-sales of novel therapies exceed the sales of the follow-ons. Germany and Japan tend to discover drugs with higher sales than average, but (as mentioned above) these are almost entirely followers of some sort. Taken together, it appears that the US biotech industry has been the main driver of innovative drugs over the past ten years. I don’t want to belittle the follow-on compounds, because they are useful. (As pointed out here before, it’s hard for one of those compounds to be successful unless it really represents some sort of improvement over what’s already available). At the same time, though, we can’t run the whole industry by making better and better versions of what we already know. And the contributions of universities – especially those in the US – has been strong, too. While university-derived drugs are a minority, they tend to be more innovative, probably because of their origins in basic research. There’s no academic magic involved: very few, if any, universities try deliberately to run a profitable drug-discovery business – and if any start to, I confidently predict that we’ll see more follow-on drugs from them as well. [↑](#footnote-ref-57)
58. https://www.fraserinstitute.org/sites/default/files/CanadasDrugPriceParadox.pdf

Governments in Canada defend their interference in pharmaceutical markets by claiming such policies reduce prescription drug costs for Canadians. Yet, this study shows that **Canadians pay much more than they should for generic drugs and that this is because of the very government policies that were supposed to make prescription medicines cheaper in the ﬁrst place**. This study also ﬁnds that **price controls on patented drugs are unnecessary because market prices in Canada would often be nearly the same as government-imposed prices anyway**. Even worse, price controls distort the pharmaceutical market in ways that harm Canadian consumers. In sum, government pharmaceutical policy is failing to provide better outcomes than competitive markets could. The cost of this government failure is signiﬁcant: **Canadians spent at least $2 billion more in 2003 than they would have if there were a competitive market for prescription drugs in Canada.** In fact, if consumers’ opportunity costs are included in the analysis, the losses could reach nearly $5 billion annually. These conclusions are drawn from some basic facts established by this study. [↑](#footnote-ref-58)
59. Lo, Chris. “Cost Control: Drug Pricing Policies around the World.” *Pharmaceutical Technology*, 12 Feb. 2018, [www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/](http://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/).

Branded generics represented around 80% of the Indian pharma industry’s $30bn in revenues for 2017. Generic drugs would instead have to be marketed using their standard generic names. **However, in January this year the government appeared to back off from its reform plans, primarily due to pressure from the domestic pharmaceutical industry, which cited quality issues and damage to the industry. According to Bloomberg, a new draft of the policy is not expected before the end of the government’s current term in 2019.** “It appears to be a hurriedly prepared document with several flaws,” said Indian Pharmaceutical Alliance secretary general DG Shah. “It is more a product of perceptions than evidence.” [↑](#footnote-ref-59)
60. Plamen Lazarov THE EFFECT OF REGULATIONS SUCH AS PRICE CONTROLS ON MEDICINE PRICES THE CASE OF INDIA. Erasmus University. https://www.google.com/search?safe=active&source=hp&ei=Qm\_aW9fVDMOZ0gKq0pboBQ&q=This+paper+examines+the+effect+of+price+control+regulations+on+medicine+prices+in+India+and+how+different+socio-economic+factors+influence+the+coordination+between+pharmaceutical+companies+in+the+country+from+March+2007+until+June+2015.&btnK=Google+Search&oq=This+paper+examines+the+effect+of+price+control+regulations+on+medicine+prices+in+India+and+how+different+socio-economic+factors+influence+the+coordination+between+pharmaceutical+companies+in+the+country+from+March+2007+until+June+2015.&gs\_l=psy-ab.3...1823.1823..2381...0.0..1.683.775.1j5-1......1....1j2..gws-wiz.....0.bvxBYTPpCfs

In general, price controls regulation are used to stabilize the market and normalize the inflation. However, the analyses that have been conducted indicate the ambiguity effect the measure has on economy. The policy has its supporters who strongly defend it along with many opponents who claim against the necessity of government interventions in the free market economy that result in welfare losses and anti-competitive practices among the economic agents in the market. Interesting example of the effects from price control regulation is Indian pharmaceutical market, which is the focus of this study. The **research analyzes the effect of socio-economic factors in India on medicine prices** of Paracetamol in the Indian pharmaceutical industry in the period March 2007 until June 2015. Its main goal is to determine how these factors influence coordination between pharmaceutical companies cross-regionally. The paper contributes to the existing literature by investigating the effect of these determinants on price difference between the regulated and unregulated formulations of Paracetamol in the Indian pharmaceutical market**. As there are evidence in the existing literature in support of the presence of collusion between pharmaceutical companies on medicine market in India**, including evidence in support of collusion on Paracetamol in particular (Bhaskarabahatla et. al.a (2016), a research on factors causing the collusion has not been conducted until now. However, different limitations that constrain the analysis raise a concern on the validity of its results. Nevertheless, the results contribute to the better understanding of arising coordination between pharmaceutical companies and shed a light on the conditions that favor the presence of collusion practices among companies operating in this sphere. The research could also help policy makers to utilize, based on the results received, a better improved regulatory framework for more effective imposition of price control regulation. In their paper, Bhaskarabahatla et. al.b (2016) conclude that to improve regulation and to understand the behavior of pharmaceutical firms it is important to understand the strategies that companies use to avoid regulation. Thus, the current paper is focused more on the side factors that allow companies to avoid regulation and further widen the scope of knowledge in the field. Another policy implication that could help in decreasing the level of collusion between pharmaceutical companies is if price control regulation is imposed over all formulations of essential drugs. Hence**, companies would not have a reason to coordinate prices, at least not for regulated medicine.** Furthermore, better law enforcement along with independent judicial system can to great extend terminate the corruption and collusion practices in the economy. [↑](#footnote-ref-60)
61. Lo, Chris. “Cost Control: Drug Pricing Policies around the World.” *Pharmaceutical Technology*, 12 Feb. 2018, [www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/](http://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/)

In April last year, the UK Government implemented a budget impact test, which stipulates that any treatment that would cost the NHS more than £20m in any of its first three years of use would trigger additional negotiations with the health service to mitigate the financial burden on the public health system. This was criticised by some health charities and many companies in the industry as a step too far, and the ABPI applied for a judicial review of the test, arguing that many drugs that have been deemed cost-effective by NICE would be affected by the new measure. This legal tussle is emblematic of the downside of the UK’s strict value-based approach to drug pricing, which some argue does not support innovation and leaves patients waiting longer for innovative new treatments. Last year, **NICE negotiated lower prices for two life-extending branded drugs for the treatment of metastatic breast cancer – palbociclib and ribociclib, developed by Pfizer and Novartis/Astex respectively – allowing them to be used by the NHS, but by that time the drugs had already been available to patients in the US for nearly two years.** [↑](#footnote-ref-61)
62. Lo, Chris. “Cost Control: Drug Pricing Policies around the World.” *Pharmaceutical Technology*, 12 Feb. 2018, [www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/](http://www.pharmaceutical-technology.com/features/cost-control-drug-pricing-policies-around-world/).

In 2004, South Africa introduced transparent drug pricing mechanisms, including a Single Exit Price (SEP). The SEP sets a price at which a prescription drug maker must sell to all pharmacies. The policy was designed to discourage the unnecessary prescribing of expensive drugs where alternatives are available, as pharmacies and doctors are able to add a small logistics fee, avoiding the informal arrangement of bonuses, incentives and rebates that can drive prices up for patients. Studies have shown that the SEP had an immediate effect on the price of medicines in South Africa, with a 22% reduction on prescription medicine prices in the first year after its introduction. But there remains a dearth of data on the long-term effectiveness of transparent pricing in the country. **“Despite efforts to increase transparency in the supply chain, prices reflected in South African medicine price registries may not be a true reflection of prices negotiated between manufacturers and distributors/wholesalers,” wrote V Bangalee and Fatima Suleman of the University of KwaZulu-Natal in a 2016 study published in the South African Health Review. “Initiatives to conduct larger, in-depth pharmaco-economics evaluations are required for a deeper understanding of market trends.”** [↑](#footnote-ref-62)
63. **Howard of the Manhattan Institute** Howard, Paul. “To Lower Drug Prices, Innovate, Don't Regulate.” Manhattan Institute, 8 Dec. 2015, www.manhattan-institute.org/html/lower-drug-prices-innovate-don%E2%80%99t-regulate-8229.html.

[Research](https://economics.stanford.edu/files/Kutyavina_HThesis2010.pdf) shows that price controls in the United Sates would powerfully dampen innovation. "Cutting prices by 40 to 50 percent in the U.S. will lead to between 30 to 60 percent fewer R&D projects being undertaken," one [study](http://www.nber.org/papers/w11114) found. A 2008 RAND study exploring the effect of U.S. price controls on those aged 55 to 59 in the United States and Europe similarly found that, on net, pharmaceutical price controls would hurt patients. **The idea that we “overspend” on drugs is also misleading. In 2014, drug spending accounted for just 10 percent of U.S. health care spending, and according to government actuaries, spending will increase by only 0.4 percentage points over the next decade. Hospitals, for comparison, account for more than 30 percent of total health care spending.** Countries that use price controls advocated by industry critics actually spend a larger share on drugs and use fewer cost-saving generics than the United States does**.** Absent price controls, however, private negotiation works. A [report](http://www.gao.gov/products/GAO-14-578) from the Government Accountability Office concluded that the Medicare Part D drug program (where private insurers negotiate with drug manufacturers) obtained lower (pre-rebate) prices than the defense department or Medicaid. For generic drugs, where competition is the greatest, Part D's prices were essentially no different than Medicaid's. Better prices can be enjoyed today without compromising tomorrow’s cures. But instead of exercising greater control over the industry, reformers should opt for less — focusing instead on efficiency, innovation and competition. [↑](#footnote-ref-63)
64. J. D. Foster, June 18,2013. "The Many Real Dangers of Soaring National Debt," Heritage Foundation, https://www.heritage.org/budget-and-spending/report/the-many-real-dangers-soaring-national-debt

Further, while both the Administration and the Congressional Budget Office forecast interest rates eventually returning to more normal levels as the economy returns to full employment, the forecasts appear to ignore the interest rate consequences of the recent and projected substantial increases in the ratio of U.S. government debt to the size of the economy. The higher interest rates the literature suggests are likely to follow from a high debt ratio are curiously missing from the government’s economic forecasts, meaning the government’s projected future annual interest expense is likely substantially understated. Even greater interest expenses and even slower economic growth and consequent slower government revenue growth is a deeply troubling combination. [↑](#footnote-ref-64)
65. Augusto Lopez-Claros On, 5-14-2014, "Six Strategies to Fight Corruption," Future Development, http://blogs.worldbank.org/futuredevelopment/six-strategies-fight-corruption

Replacing regressive and distorting subsidies with targeted cash transfers. Subsidies are another example of how government policy can distort incentives and create opportunities for corruption. According to an IMF study ([2013](http://www.imf.org/external/np/pp/eng/2013/012813.pdf)), consumer subsidies for energy products amount to some $1.9 trillion per year, equivalent to about 2.5 percent of global GDP or 8 percent of government revenues. These subsidies are very regressively distributed, with over 60 percent of total benefits accruing to the richest 20 percent of households, in the case of gasoline. Removing them could result in a significant reduction in CO2 emissions and generate other positive spillover effects. Subsidies often lead to smuggling, to shortages, and to the emergence of black markets. Putting aside the issue of the opportunity costs (how many schools could be built with the cost of one year’s energy subsidy?), and the environmental implications associated with artificially low prices, subsidies can often put the government at the center of corruption-generating schemes. Much better to replace expensive, regressive subsidies with targeted cash transfers. [↑](#footnote-ref-65)
66. <https://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1785&context=njilb>

“In recent years, federal and state laws have restricted the use of marketing (and, through prosecution, attempted to discourage less open tactics like bribes)” [↑](#footnote-ref-66)
67. **Pew, ‘13 "Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients," No Publication,** [**https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients**](https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients)

**Journal and Web Advertisements:** These advertisements are standard promotional techniques that provide an important source of revenue for medical journals. The accuracy of statements in such ads is regulated by the U.S. Food and Drug Administration, or FDA. According to one study, journal advertising generated the highest return on investment of all promotional strategies employed by pharmaceutical companies, with returns ranging from $2.22 to $6.86 per advertising dollar spent between 1995 and 1999.11 In April 2009, FDA warned 14 major drugmakers for running search ads for many of their products that highlighted the products' effectiveness without noting any of their risks.12 [↑](#footnote-ref-67)
68. **Pew, ‘13 "Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients," No Publication,** [**https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients**](https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients)

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69. https://www.healthaffairs.org/do/10.1377/hblog20181009.878948/full/
Patent monopolies, and the high prices that they empower drug makers to maintain, have been a problem for decades and only have gotten worse over time. PBMs were developed several decades ago as a private-market solution to this very problem. Since their creation, PBMs have negotiated directly with drug makers to lower prescription drug prices, drive competition for more generic drugs, and secure savings through rebates and discounts for employers, unions, and other customers, including hardworking families. Contrary to the article’s claims, PBMs save payers and patients 40–50 percent on their annual prescription drug and related medical costs compared to what they would have spent without PBMs. That’s an average of $941 per person per year, according to an analysis prepared for Pharmaceutical Care Management Association. In fact, an overwhelming body of independent research shows that, thanks to their ability to negotiate, PBMs are part of the solution to lowering health care costs: This includes research from the Federal Trade Commission (FTC), the Congressional Budget Office, and the Government Accountability Office. [↑](#footnote-ref-69)
70. https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2018/05/21/the-health-202-states-are-targeting-a-key-middleman-in-the-drug-pricing-chain/5aff300430fb0425887995b4/
1. Blocking gag clauses, which are included in PBMs's contracts and prevent pharmacists from telling patients about cheaper drug options. Such a bill would allow pharmacists to tell consumers, for example, when paying cash would cost less than using their insurance. 2. Requiring PBMs to obtain a specific license from the state to operate legitimately. 3. Regulating PBMs’s use of maximum allowable cost lists, which they generate specifying the maximum price an insurance plan will pay for drugs when there is a generic or competitor available. Some states want PBMs to be transparent about how they came up with this list and provide the pharmacy the ability to appeal the maximum reimbursement rate. 4. Requiring the intermediaries to post information about what they earn in rebates from drug manufacturers. This is in the bill Connecticut just passed. “With a simple calculator, every consumer in Connecticut is going to be able to know exactly how much money was passed on to them or what percentage was passed on to them versus how much was pocketed,” Scanlon said about his bill, which is now awaiting Gov. Dannel Malloy’s (D) signature. In Alaska, another bill targeting PBMs passed the legislature two weeks ago and is headed to the governor’s desk. The bill looks to create more transparency in the appeals process for when pharmacies dispute the reimbursement they receive from PBMs for medication, and also restricts the gag clauses in contracts between PBMs and pharmacies, according to local radio station KFSK. [↑](#footnote-ref-70)
71. O’brian, Elizabeth. “Several of the Biggest Pharma Giants Are Freezing Drug Prices. Here’s How It Will Affect You.” Money, 25 July 2018, http://time.com/money/5347360/drug-prices-freezes-costs-big-pharma/.

Even if the recently announced drug price freezes or cuts translate into some savings for insurers, it’s not at all a given that insurers will pass along those savings directly to patients taking that particular drug, Purvis cautions. For starters, many health plans don’t make changes to their formulary — that’s their list of covered drugs and pricing schemes — mid-year. And even if your drug is getting a price cut, insurers could choose to pass savings along more broadly next year, by limiting price hikes for all covered consumers, Purvis says. That’s because insurers usually pass high drug costs on to customers in the form of higher copayments, coinsurance, premiums and deductibles. So while more modest price increases for your medications could benefit everyone on your plan, they won’t necessarily mean a huge change for you, Purvis notes. Experts argue that — rather than relying on one-off actions by manufacturers — the health care system actually needs structural changes to meaningfully lower drug prices. [↑](#footnote-ref-71)
72. Miller, Tracy. Obamacare Repeal Can’t Ignore Price Controls | RealClearHealth. 2 May 2017,

https://www.realclearhealth.com/articles/2017/05/02/obamacare\_repeal\_cant\_ ignore\_price\_controls\_110574.html.

**But requiring insurance companies to charge the same premium to everyone has made selling coverage through the exchanges unprofitable for many of them. Healthy people have little incentive to buy coverage that costs them much more than it should, and the penalties for being uninsured are relatively small. This creates a cycle in which, without those healthy participants, the average health of the insured population declines. Costs go up, making it harder for insurance companies to keep premiums affordable and still make a profit.** Instead of requiring insurance companies to charge the same premium on the individual market for people with pre-existing conditions as everyone else, the federal government could fund reinsurance to keep premiums down for those who have maintained continuous coverage. Doing this— while also allowing insurance companies to lower prices for healthier people—would require another source of revenue. It might be necessary to maintain one or more of the types of taxes within the ACA, such as the Cadillac tax, which gradually reduces the tax deduction for employer-sponsored insurance plans. [↑](#footnote-ref-72)
73. http://time.com/money/5347360/drug-prices-freezes-costs-big-pharma/.
Even if the recently announced drug price freezes or cuts translate into some savings for insurers, it’s not at all a given that insurers will pass along those savings directly to patients taking that particular drug, Purvis cautions. For starters, many health plans don’t make changes to their formulary — that’s their list of covered drugs and pricing schemes — mid-year. And even if your drug is getting a price cut, insurers could choose to pass savings along more broadly next year, by limiting price hikes for all covered consumers, Purvis says. That’s because insurers usually pass high drug costs on to customers in the form of higher copayments, coinsurance, premiums and deductibles. So while more modest price increases for your medications could benefit everyone on your plan, they won’t necessarily mean a huge change for you, Purvis notes. Experts argue that — rather than relying on one-off actions by manufacturers — the health care system actually needs structural changes to meaningfully lower drug prices. [↑](#footnote-ref-73)
74. Daniel J., 7-14-2017, "Health Costs Are Rising Because of Price Controls," Foundation for Economic Education, https://fee.org/articles/health-costs-are-rising-because-of-price-controls/

Set aside that the entire purpose of insurance is to guard against risk. Instead, let’s focus on what happens when these types of price controls are imposed. For all intents and purposes, insurance companies are in a position where they have to over-charge young and healthy people in order to subsidize the premiums of old and sick people. That’s sounds great if you’re old and sick, but young and healthy people respond by choosing not to purchase insurance. And as fewer and fewer young and healthy people are in the system, that forces premiums ever higher. This is what is meant by a “[death spiral](https://danieljmitchell.wordpress.com/2016/01/12/more-perverse-but-predictable-economic-consequences-of-obamacare/).” The pro-intervention crowd has a supposed solution to this problem. Just impose a mandate that requires the young and healthy people to buy insurance. [↑](#footnote-ref-74)
75. Alex, Kacik. “Monopolized Healthcare Market Reduces Quality, Increases Costs.” Modern Healthcare, 13 Apr. 2017, http://www.modernhealthcare.com/article/20170413/NEWS/170419935.

**Consolidation will continue to drive up healthcare costs and reduce quality of care unless lawmakers and regulators push policy reforms and rules aimed at increasing competition, according to new research.** As providers increasingly look to consolidate in order to lower operating costs and create economies of scale, the Center for Health Policy at the Brookings Institution and Carnegie Mellon University's Heinz College on Thursday said the trend has led to a dearth of competition. **That's why the healthcare industry sees rising prices, price variation and uneven quality of care, according to the groups' white paper. The past 15 years have seen significant consolidation in hospital, physician and insurance markets, and that trend is expected to continue.**  [↑](#footnote-ref-75)
76. www.cnbc.com/2018/03/22/the-real-reasonmedical-care-costs-so-much-more-in-the-us.html.
The real difference between the American health care system and systems abroad is pricing. Specialists, nurses and primary care doctors all earn significantly more in the U.S. compared to other countries. General physicians in America made an average of $218,173 in 2016, the report notes, which was double the average of generalists in the other countries, where pay ranged from $86,607 in Sweden to $154,126 in Germany. Administrative costs, meanwhile, accounted for 8 percent of total national health expenditures in the U.S. For the other countries, they ranged from 1 percent to 3 percent. Health care professionals in America also reported a higher level of "administrative burden." A survey showed that a significant portion of doctors call the time they lose to issues surrounding insurance claims and reporting clinical data a major problem. [↑](#footnote-ref-76)
77. /health-carereform/report/government-price-controls-health-care-deficit-reductionstrategy-avoid.
The federal government sets prices for services paid for by Medicare, Medicaid, and the Veterans Administration (VA) employing a variety of mechanisms, with a variety of consequences. Medicare’s complex fee schedules overpay providers for some services, underpay them for others, and therefore do not reflect the value of medical goods and services accurately. As a result, providers who treat Medicare beneficiaries are encouraged by perverse financial incentives to offer inefficient, less-effective care. Seniors receive unnecessary tests and treatments, have less time with their physicians, and face mounting barriers to access to physicians’ services. Price controls for drug coverage have been just as damaging. Low payment for prescription drug coverage by Medicaid and the VA increases costs for other purchasers and bars access to effective treatments using restrictive formularies. Across the board, price-setting in health care has failed to produce expected savings, meanwhile devastating the quality of, as well as access to, health care. The only way to undo the damage wrought by decades of government price controls is to address the true causes of the problems of America’s health care system with market-oriented reforms. [↑](#footnote-ref-77)
78. http://www.barrons.com/articles/a-funding-mess-in-the-medicaid-program1458363194.
Medicaid is also inefficient: Even though it pays less for a given procedure than the average for private health insurance, the providers make it up on volume. Medicaid spending per beneficiary is 40% greater than spending per beneficiary of private insurance. After several major expansions of eligibility, the Medicaid program now has more than 70 million beneficiaries, which is more than 20% of the U.S. population. About a quarter of all states’ spending goes to their Medicaid programs, although every state’s program is different, and most states cover more people and services than the federal mandatory minimums. Free money from the feds looks like the most likely reason that states are so generous. [↑](#footnote-ref-78)
79. [1] Lowe, Derek, 11-9-10-“Where Drugs Come From: By: Country”<http://blogs.sciencemag.org/pipeline/archives/2010/11/09/where_drugs_come_from_by_country> Science Translational Medicine

The same paper I was summarizing the other day has some interesting data on the 1998-2007 drug approvals, broken down by country and region of origin. The first thing to note is that the distribution by country tracks, quite closely, the corresponding share of the worldwide drug market. The US discovered nearly half the drugs approved during that period, and accounts for roughly that amount of the market, for example. But there are two big exceptions: the UK and Switzerland, which both outperform for their size. In case you’re wondering, the league tables look like this: the US leads in the discovery of approved drugs, by a wide margin (118 out of the 252 drugs). Then Japan, the UK and Germany are about equal, in the low 20s each. Switzerland is in next at 13, France at 12, and then the rest of Europe put together adds up to 29. Canada and Australia put together add up to nearly 7, and the entire rest of the world (including China and India) is about 6.5, with most of that being Israel. But **while the US may be producing the number of drugs you’d expect, a closer look shows that it’s still a real outlier in several respects. The biggest one, to my mind, comes when you use that criterion for innovative structures or mechanisms versus extensions of what’s already been worked on**, as mentioned in the last post. **Looking at it that way, almost all the major drug-discovering countries in the world were tilted towards less innovative medicines**. The only exceptions are Switzerland, Canada and Australia, **and (very much so) the US.** The UK comes close, running nearly 50/50. **Germany and Japan, though, especially stand out as the kings of follow-ons and me-toos, and the combined rest-of-Europe category is nearly as unbalanced**. What about that unmet-medical-need categorization? Looking at which drugs were submitted here in the US for priority review by the FDA (the proxy used across this whole analysis), again, the US-based drugs are outliers, with more priority reviews than not. Only in the smaller contributions from Australia and Canada do you see that, although Switzerland is nearly even. But in both these breakdowns (structure/mechanism and medical need) it’s the biotech companies that appear to have taken the lead. And here’s the last outlier that appears to tie all these together: in almost every country that discovered new drugs during that ten-year period, the great majority came from pharma companies. **The only exception is the US: 60% of our drugs have the fingerprints of biotech companies on them, either alone or from university-derived drug candidates**. In very few other countries do biotech-derived drugs make much of a showing at all. These trends show up in sales as well. Only in the US, UK, Switzerland, and Australia did the per-year-sales of novel therapies exceed the sales of the follow-ons. Germany and Japan tend to discover drugs with higher sales than average, but (as mentioned above) these are almost entirely followers of some sort. Taken together, it appears that the US biotech industry has been the main driver of innovative drugs over the past ten years. I don’t want to belittle the follow-on compounds, because they are useful. (As pointed out here before, it’s hard for one of those compounds to be successful unless it really represents some sort of improvement over what’s already available). At the same time, though, we can’t run the whole industry by making better and better versions of what we already know. And the contributions of universities – especially those in the US – has been strong, too. While university-derived drugs are a minority, they tend to be more innovative, probably because of their origins in basic research. There’s no academic magic involved: very few, if any, universities try deliberately to run a profitable drug-discovery business – and if any start to, I confidently predict that we’ll see more follow-on drugs from them as well. [↑](#footnote-ref-79)
80. https://www.fraserinstitute.org/sites/default/files/CanadasDrugPriceParadox.pdf

Governments in Canada defend their interference in pharmaceutical markets by claiming such policies reduce prescription drug costs for Canadians. Yet, this study shows that **Canadians pay much more than they should for generic drugs and that this is because of the very government policies that were supposed to make prescription medicines cheaper in the ﬁrst place**. This study also ﬁnds that **price controls on patented drugs are unnecessary because market prices in Canada would often be nearly the same as government-imposed prices anyway**. Even worse, price controls distort the pharmaceutical market in ways that harm Canadian consumers. In sum, government pharmaceutical policy is failing to provide better outcomes than competitive markets could. The cost of this government failure is signiﬁcant: **Canadians spent at least $2 billion more in 2003 than they would have if there were a competitive market for prescription drugs in Canada.** In fact, if consumers’ opportunity costs are included in the analysis, the losses could reach nearly $5 billion annually. These conclusions are drawn from some basic facts established by this study. [↑](#footnote-ref-80)
81. ####  Me-Too drugs are essential for effective and affordable healthcare and R&D.

**Albert Wertheimer of the Temple University School of Pharmacy in Philadelphia in 2009 writes:**(Albert I. Wertheimer, Ph.D., MBA, is a professor of pharmacoeconomics and the director of the Center for Pharmaceutical Health Services Research at the Temple University School of Pharmacy in Philadelphia, and Thomas M. Santella is an assistant to the President and CEO at Lannett Company, a manufacturer and distributor of generic pharmaceuticals. He previously served as the research coordinator for the Center for Pharmaceutical Health Services Research at the Temple University School of Pharmacy in Philadelphia, “Pharmaceutical Evolution: The Advantages of Incremental Innovation in Drug Development,” April 2009, <https://cei.org/sites/default/files/Wertheimer%20and%20Santella%20-%20Pharmaceutical%20Evolution.pdf>)

Innovation is the lifeblood of the pharmaceutical industry. Over the last century, that industry has been responsible for thousands of new drugs, based on hundreds of thousands of smaller incremental innovations. **The breakthrough “blockbuster” drugs taken by millions of patients today were not produced from thin air. Most represent the combined weight of seemingly small improvements achieved over time.**The advantages of incremental improvements on existing drugs are paramount to overall increases in the quality of health care. As the pharmaceutical industry developed, classes of drugs—those with similar chemical composition and which treat similar conditions—have grown to provide physicians with the tools they need to treat diverse patient groups. **Still, critics have been highly condescending about what they call “Me-too” drugs—drugs within the same chemical class as one or more others already on the market—which they claim add little or no therapeutic value and are nothing more than an opportunity for pharmaceutical companies to fleece unsuspecting consumers. While some claim that there are too many similar drugs, and that pharmaceutical industry research and development could be more profitably directed toward developing entirely new classes of medicines, drugs based on incremental improvements generally represent advances in safety and efficacy. They also provide new formulations and dosing options that significantly increase patient compliance—both of which lead to improved health outcomes. From an economic standpoint, adding new drugs to a class of medicines also offers the possibility of lower drug prices as competition between manufacturers increases. Additionally, pharmaceutical companies depend on incremental innovations to provide the revenue that will support development of the riskier, capital- and research-intensive blockbuster drugs.** When critics refer to Me-too drugs, they do not mean exact generic copies of already existing drugs, or illegal counterfeits. Instead, Me-toos have a similar chemical composition to one or more others on the market, and have similar biological effects. **But, in order to be approved, Me-too drugs must undergo the same extensive clinical testing as other new drugs to determine their safety and efficacy because they are chemically different. In addition, these differences, even if small, typically must represent a medical advancement—such as fewer side effects or improved efficacy for patient sub-populations—in order to attract a portion of the market away from the first approved drug in the class.**Nevertheless, many drug industry critics have called for federal policies to inhibit the development and marketing of such incrementally improved medicines. But policies that curb incremental innovation will ultimately lead to a reduction in the overall quality of existing drug classes and could arrest the creation of truly novel drugs. Research in any industry is a building process. Few scientists develop groundbreaking drugs from no prior research. Most work within, and respond to, existing knowledge—reading the same medical literature, and reacting to new technological breakthroughs at the same time. It is not hard to imagine, therefore, that many different companies would be working on similar drugs. In fact, it is often the case that the only reason why one drug is called novel and another a Me-too analogue is the speed at which each moves through the regulatory process. **Like other technological and value-added industries, the pharmaceutical industry depends on small steps for the creation of blockbuster drugs, which often result from a long series of small innovations. It also depends on these steps for the creation of drugs that provide slight, incremental improvements on existing drugs— thereby adding to a drug class, increasing competition among drugs, and incentivizing further innovation. As the National Research Council has observed, “the cumulative effect of numerous minor incremental innovations can sometimes be more transforming and have more economic impact than a few radical innovations or ‘technological breakthroughs’.” The net effect of increasing the number of drugs through innovation leads to advances in safety, efficacy, selectivity, and utility of drugs within a specific class.** Importantly, providing physicians with a variety of prescription options within a given therapeutic class is paramount to the provision of optimal health care. This is especially true for some drug classes, such as those relating to the central nervous system, for which overall response rates can be as low as 50 percent. For unknown reasons, certain patients respond differently to different drugs within a single class. If physicians have many options at their disposal, they can calibrate their prescribing patterns to better address the needs of specifi c patients. The existence of multiple similar molecular agents also provides backup in situations where the novel drug in a class is found to have unacceptable side effects and is thus removed from the market. As patients come to depend on a particular class of drugs, it is essential to make sure that they do not lose access to needed medication as a result of regulatory action. One of the most vehement criticisms made against Me-too drugs is that they siphon money away from research that could be devoted to the creation of novel breakthrough drugs. **This assumption is incorrect for a host of reasons, the most important of which is the fact that the pharmaceutical industry depends on selling the products of incremental innovations to provide the revenue for research and development of breakthrough drugs. Additionally, while it is unrealistic to presume that every incremental innovation leads to cost savings, the sum of all drug innovations can result in cost savings by reducing overall treatment costs, shortening or obviating hospital stays, increasing worker productivity and reducing absenteeism, and lowering drug costs through increased competition among manufacturers.** Ideally, every new drug would represent an unprecedented breakthrough and lead to the creation of a completely novel treatment. This, however, is not the reality of the pharmaceutical industry, or of any other development-based industry. **Creating drugs based on incremental innovations provides pharmaceutical companies with a secure stream of revenue, which can be directed to higher-risk, potential blockbuster-yielding research.** Policies aimed at reducing the industry’s ability to obtain revenues from incremental innovations could be self-defeating, as those industries will then have less revenue to reinvest in R&D for new drugs. **Put simply, limiting incremental drug innovation is analogous to limiting competition. The ultimate result could have devastating consequences for the future of the pharmaceutical industry and for the millions of patients who depend on it.** [↑](#footnote-ref-81)